BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

WRIT PETITION (C) NO. 8448 OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. …PETITIONER(S)

VERSUS

UNION OF INDIA . …RESPONDENT

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Filed by:

New Delhi
Date 25.05.2022

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NOTICE OF MOTION

To,

UNION OF INDIA

[redacted]

...RESPONDENT NO. 1

Sir(s),

The enclosed writ petition in the aforesaid matter is being filed on behalf of the Petitioner and is likely to be listed on 22.11.2021 or any date thereafter. Please take notice accordingly.

Filed by:

[redacted]

New Delhi
Date 25.05.2022

Aditya Samaddar,
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URGENCY APPLICATION

To

The Registrar
High Court of Delhi
New Delhi-110003

Sir,

Kindly treat the accompanying petition on an urgent basis as per the High Court Rules and list the matter on 26.05.2022. The urgency in the present matter is that Petitioner is challenging the vires of the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021). Hence the urgency.

Filed by:

[redacted]

New Delhi
Date 25.05.2022

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BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

WRIT PETITION (C) NO. 8448 OF 2022

MEMO OF PARTES

KARAN BALRAJ MEHTA

...PETITIONER NO.1

DR. PANKHURI CHANDRA

…PETITIONER NO.2

VERSUS

UNION OF INDIA

...RESPONDENT NO. 1

[redacted]

Filed by:

[redacted]

New Delhi
Date 25.05.2022

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Ph. No. 9910013921

BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

WRIT PETITION (C) NO. 8448 OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. …PETITIONER(S)

VERSUS

UNION OF INDIA . …RESPONDENT

SYNOPSIS AND LIST OF DATES

The present Petitioners have been constrained to file the present petition seeking the declaration that certain provisions of the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) be declared ultra vires the Constitution of India as the said provisions are discriminatory against a single man desirous of being a father through surrogacy and a married woman who already has a child and is desirous of expanding her family through the means of surrogacy. As such the impugned Acts are ultra vires Article 14 and 21 of the Constitution of India.

The choice(s) of reproduction has been held to be a part of the right to life under Article 21 by the Hon'ble Supreme Court of India and the said choices also fall within the right to privacy also under Article 21 of the

Constitution of India. The Impugned Acts severely regulate these rights, so much so, that both the fundamental rights stand defeated for the Petitioners.

Petitioner No. 1 is arbitrarily ousted from any benefit under the impugned Acts at all whereas, Petitioner No. 2, not being able to find and obtain consent from an eligible surrogate mother cannot avail of surrogacy as a reproductive choice and is also barred under the Acts as she does not have medical indication necessitating surrogacy.

The Petitioners beseech this Hon'ble Court to intervene in the matter and allow the Petitioners the dignity to firstly, keep private their reproductive choices and secondly, to exercise their reproductive choices to their satisfaction and desire of having a family (wrt Petitioner No. 1) and or a family of a size they decide (Petitioner No. 2).

LIST OF DATES

10.12.1948	The General Assembly of the United Nations adopted the '*Universal Declaration of Human Rights*' (UDHR). India was one of the 48 countries that voted for its adoption.
16.12.1966	The General Assembly of the United Nations adopted the *'International Covenant on Civil and Political Rights'* (ICCPR)
25.06.1978[1]	The world's first '*test tube baby*', i.e., a baby born through

[1] Preface, National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005

'*In Vitro Fertilization*' ("IVF"), Ms. Louise Joy Brown was delivered in the United Kingdom.

03.10.1978 Ms. Kanupriya Agarwal @Durga was born in Kolkata, India and is widely regarded as the world's second test tube baby.

10.07.1979 The ratification of the *'International Covenant on Civil and Political Rights'* (ICCPR) by India on 10.04.1979 came into force.

18.12.1979 The General Assembly of the United Nations adopted the '*Convention on the Elimination of all Forms of Discrimination Against Women'* (CEDAW)

09.07.1993 India ratified the '*Convention on the Elimination of all Forms of Discrimination Against Women'* (CEDAW).

06.08.1986 India's first scientifically documented IVF baby, Harsha, was born in Mumbai, through the collaborative efforts of the Institute for Research in Reproduction of the Indian Council for Medical Research ('ICMR') and the King Edward's Memorial Hospital (KEM), Mumbai.

2005 The ICMR and NAMS issued the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics

in India. Bereft of any other guidelines or statute governing the field of surrogacy and or Assisted Reproductive Technology ('ART'), the said guidelines became the *de facto* rules in the said sphere. Needless to say, not being *de jure* rules framed under an appropriate statute, the said rules were in applicable in legal disputes before the Courts.

29.09.2008 The Hon'ble Supreme Court of India pronounced its judgement in *Baby Manji Yamada* v. *Union of India & Anr.,* (2008) 13 SCC 518. The Hon'ble Supreme Court of India recognised the practice of commercial and altruistic surrogacy and pertinently acknowledged that intended parents may include single males, or women who are fertile yet unwilling to undergo pregnancy.

2008 The ICMR prepared a draft ART (Regulation) Bill, 2008. It envisioned single parents to have children through surrogacy.

11.11.2009 The Hon'ble High Court of Gujrat pronounced its judgment in LPA 2151/2009 titled *Jan Balaz* v. *Anand Municipality and Ors*.[2]. The Hon'ble High Court in the

[2] 2009 SCC OnLine Guj 10446 : AIR 2010 Guj 21 : (2010) 2 AIR Kant R (NOC 139) 56 : (2010) 51 (2) GLR 1309 : 2010 AIHC (NOC 407) 123

said case had to adjudicate an unprecedented situation of whether babies born in India to a gestational surrogate are citizens of this country and therefore, entitled to get passports. The Hon'ble High Court held such babies to be citizens of India while observing that a comprehensive legislation dealing with the issues involved in surrogacy and ART is very imminent to meet the situation created by the reproductive science and technology which have no clear answers in the then existing legal system in the country.

05.08.2009 The Law Commission of India submitted the 228th report on Assisted Reproductive Technology procedures discussing the importance and need for surrogacy, and also the steps taken to control surrogacy arrangements. The Report *inter alia* stated the ART industry was at the time worth about Rs. 25,000 crores, Anand, Gujarat had grown a reputation for commercial surrogacy and that the draft bill prepared by the ICMR was full of lacunae. The Report went on to suggest as under:

- Surrogacy arrangement ought to continue to be governed by contract amongst parties, which would

contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement ought not be for commercial purposes.

- A surrogacy arrangement should provide for financial support for surrogate child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.
- A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.
- One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of

adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

- Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.
- The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.
- Right to privacy of donor as well as surrogate mother should be protected.
- Sex-selective surrogacy should be prohibited.
- Cases of abortion should be governed by the Medical Termination of Pregnancy Act 1971 only.

21.11.2016 The Surrogacy (Regulation) Bill, 2016 was introduced in the Lok Sabha.

12.01.2017 The Surrogacy (Regulation) Bill, 2016 was referred to the

Department Related Parliamentary Standing Committee on Health and Family Welfare.

10.08.2017 The Department Related Parliamentary Standing Committee on Health and Family Welfare presented its report on the Surrogacy (Regulation) Bill, 2016 before both the houses of Parliament.

19.12.2018 The Lok Sabha passed the Surrogacy (Regulation) Bill, 2016. However, the Bill thereafter lapsed before the Rajya Sabha.

15.07.2019 The Hon'ble Minister for Health and Family Welfare, Government of India, Dr Harsh Vardhan, introduced the Surrogacy (Regulation) Bill, 2019 in the Lok Sabha.

05.08.2019 The Surrogacy (Regulation) Bill, 2019 was passed by the Lok Sabha.

21.11.2019 The Surrogacy (Regulation) Bill, 2019 was referred to the Select Committee.

05.02.2020 The Select Committee on the Surrogacy (Regulation) Bill, 2019 presented its report to the Rajya Sabha.

08.12.2021 The Rajya Sabha passed the Assisted Reproductive Technology (Regulation) Bill, 2020 and the Surrogacy

(Regulation) Bill, 2019 as the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) respectively.

25.05.2022 Hence this petition.

[redacted]
Karan Balraj Mehta
[Petitioner No.1]

[redacted]
Dr. Pankhuri Chandra
[Petitioner No.2]

Filed by:

[redacted]

New Delhi
Date 25.05.2022

Aditya Samaddar,
Advocate for the Petitioner,
Off: B-7, Lower Ground Floor, Hazrat Nizamuddin (East), New Delhi, 110013; Email: aditya.samaddar@gmail.com;
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BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

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WRIT PETITION (C) NO. 8448 OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. …PETITIONER(S)

VERSUS

UNION OF INDIA . …RESPONDENT

WRIT PETITION UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA PRAYING FOR THE DECLARATION THAT SECTIONS 2(E), 14(2), 21, 27(3) AND 31(1) OF THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021 AND SECTIONS 2(H), 2(S), 2(R), 2(ZD), 2(ZG), 4(II)(A), 4(II)(B), 4(II)(C), 4(III), 8 AND 38(1)(A) OF THE SURROGACY (REGULATION) ACT, 2021 BE DECLARED AS ULTRA VIRES ARTICLE(S) 14 AND 21 OF THE CONSTITUTION OF INDIA .

TO

THE HON'BLE CHIEF JUSTICE
AND HIS COMPANION
JUSTICES OF THE HON'BLE
HIGH COURT OF DELHI

THE HUMBLE PETITION
OF THE PETITIONER
ABOVENAMED

MOST RESPECTFULLY SHEWETH

1. That the present petition seeks the declaration that certain provisions of the Assisted Reproductive Technology (Regulation) Act, 2021

(Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) be declared ultra vires the Constitution of India as the said provisions are discriminatory against a single man desirous of being a father through surrogacy and a married woman who already has a child and is desirous of expanding her family through the means of surrogacy. As such the impugned Acts are ultra vires Article 14 and 21 of the Constitution of India. A true copy of the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) published in the Gazette of India on 25.12.2021 is annexed herewith and marked as **ANNEXURE P-1**. A true copy of the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) published in the Gazette of India on 25.12.2021 is annexed herewith and marked as **ANNEXURE P-2**.

PARTIES

2. That Petitioner No. 1, Karan Balraj Mehta is a single unmarried man. He is an advocate by profession, regularly practicing before this Hon'ble Court and other forums in Delhi and specializes in civil and matrimonial disputes. He is desirous of being a father by means of surrogacy.

3. That Petitioner No. 2, Dr. Pankhuri Chandra is a married woman. She is a PhD and works as a Teacher (Psychology) teaching classes 11th and 12th in a private school in Noida. Her marriage has subsisted

since 08.12.2014. She became a mother on 01.09.2021. She is desirous of having another child but only through surrogacy.

4. That Respondent No. 1 is the Union of India, through the Secretary, Legislative Department of the Ministry of Law and Justice, Government of India and is responsible, inter alia for drafting, scrutiny and vetting of Principal Legislations. It falls within the definition of 'State' under Article 12 of the Constitution of India.

FACTS

5. That on 10.12.1948, the General Assembly of the United Nations adopted the '*Universal Declaration of Human Rights'* (UDHR). India was one of the 48 countries that voted for its adoption. The relevant articles of the UDHR are reproduced hereinunder:

> *"Article 1: All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood."*
>
> *....*
>
> *"Article 7: All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination."*
>
> *...*
>
> *"Article 16:*
>
> *(1) Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to*

found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.

(2) Marriage shall be entered into only with the free and full consent of the intending spouses.

(3) The family is the natural and fundamental group unit of society and is entitled to protection by society and the State."

A true copy of the Universal Declaration of Human Rights adopted by the United Nations General Assembly on 10.12.1948 is annexed herewith and marked as **ANNEXURE P-3**.

6. That on 16.12.1966, the General Assembly of the United Nations adopted the '*International Covenant on Civil and Political Rights' (ICCPR).* The relevant articles of the ICCPR are reproduced hereinbelow:

"Article 1.1: All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development."

...

"Article 17.1: No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation."

...

"Article 23.1: The family is the natural and fundamental group unit of society and is entitled to protection by society and the State."

A true copy of the International Covenant on Civil and Political Rights adopted by the United Nations General Assembly on 19.12.1966 is annexed herewith and marked as **ANNEXURE P-4**.

7. That on 25.06.1978, the world's first 'test tube baby', i.e., a baby born through 'In Vitro Fertilization' ("IVF"), Ms. Louise Joy Brown was delivered in the United Kingdom.

8. That on 03.10.1978, Ms. Kanupriya Agarwal @Durga was born in Kolkata, India and is widely regarded as the world's second test tube baby.

9. That on 10.07.1979, the ratification of the 'International Covenant on Civil and Political Rights' (ICCPR) by India on 10.04.1979 came into force.

10. That on 18.12.1979, the General Assembly of the United Nations adopted the 'Convention on the Elimination of all Forms of Discrimination Against Women' (CEDAW). The relevant articles of the CEDAW are reproduced as hereinunder:

> *"Article 12:*
>
> *1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.*
>
> *2. Notwithstanding the provisions of paragraph 1 of this article, States Parties shall ensure to women appropriate services in connexion with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation."*
>
> ...

"Article 16 (1)(d): The same rights and responsibilities as parents, irrespective of their marital status, in matters relating to their children; in all cases the interests of the children shall be paramount;"

A true copy of the Convention on the Elimination of all Forms of Discrimination Against Women adopted by the United Nations General Assembly on 18.12.1979 is annexed herewith and marked as **ANNEXURE P-5**.

11. That on 09.07.1993, India ratified the 'Convention on the Elimination of all Forms of Discrimination Against Women' (CEDAW).

12. That on 06.08.1986, India's first scientifically documented IVF baby, Harsha, was born in Mumbai, through the collaborative efforts of the Institute for Research in Reproduction of the Indian Council for Medical Research ('ICMR') and the King Edward's Memorial Hospital (KEM), Mumbai.

13. That in 2005, the ICMR and NAMS issued the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. Bereft of any other guidelines or statute governing the field of surrogacy and or Assisted Reproductive Technology ('ART'), the said guidelines became the de facto rules in the said sphere. Needless to say, not being de jure rules framed under an appropriate statute, the said rules were in applicable in legal disputes before the Courts.

The said Guidelines specifically stated that single women could use Artificial Reproductive Techniques and that no ART clinic could refuse its services to such women[3]. A true copy of National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005 is annexed herewith and marked as **ANNEXURE P-6.**

14. That on 29.09.2008, the Hon'ble Supreme Court of India pronounced its judgement in Baby Manji Yamada v. Union of India & Anr., (2008) 13 SCC 518. The Hon'ble Supreme Court of India recognised the practice of commercial and altruistic surrogacy and pertinently acknowledged that intended parents may include single males, or women who are fertile yet unwilling to undergo pregnancy. The relevant extract of the said judgement is reproduced hereinbelow:

> *"5. Stand of Respondent 3 was that there is no law governing surrogation in India and in the name of surrogation a lot of irregularities are being committed. According to it, in the name of surrogacy a money-making racket is being perpetuated. It is also the stand of the said respondent that the Union of India should enforce stringent laws relating to surrogacy. The present petitioner has questioned the locus standi of Respondent 3 to file a habeas corpus petition. It is pointed out that though custody of the child was being asked for but there was not even an indication as to in whose alleged illegal custody the child was. It is stated that though the petition before the High Court was styled as a "public interest litigation" there was no element of public interest involved.*

[3] Guideline 3.5.2

8. Surrogacy is a well-known method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to a contracted party. She may be the childs genetic mother (the more traditional form for surrogacy) or she may be, as a gestational carrier, carry the pregnancy to delivery after having been implanted with an embryo. In some cases surrogacy is the only available option for parents who wish to have a child that is biologically related to them.

9. The word "surrogate", from Latin "subrogare", means "appointed to act in the place of". The intended parent(s) is the individual or couple who intends to rear the child after its birth.

10. In traditional surrogacy (also known as the Straight method) the surrogate is pregnant with her own biological child, but this child was conceived with the intention of relinquishing the child to be raised by others; by the biological father and possibly his spouse or partner, either male or female. The child may be conceived via home artificial insemination using fresh or frozen sperm or impregnated via IUI (intrauterine insemination), or ICI (intracervical insemination) which is performed at a fertility clinic.

11. In gestational surrogacy (also known as the Host method) the surrogate becomes pregnant via embryo transfer with a child of which she is not the biological mother. She may have made an arrangement to relinquish it to the biological mother or father to raise, or to a parent who is themselves unrelated to the child (e.g. because the child was conceived using egg donation, germ donation or is the result of a donated embryo). The surrogate mother may be called the gestational carrier.

12.Altruistic surrogacy is a situation where the surrogate receives no financial reward for her pregnancy or the relinquishment of the child (although usually all expenses related to the pregnancy and birth are paid by the intended parents such as medical expenses, maternity clothing, and other related expenses).

13.Commercial surrogacy is a form of surrogacy in which a gestational carrier is paid to carry a child to maturity in her womb and is usually resorted to by well-off infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. This medical procedure is legal in several countries including in India where due to excellent medical infrastructure, high international demand and ready availability of poor surrogates it is reaching industry proportions. Commercial surrogacy is sometimes referred to by the emotionally charged and potentially offensive terms "wombs for rent", "outsourced pregnancies" or "baby farms".

14. Intended parents may arrange a surrogate pregnancy because a woman who intends to parent is infertile in such a way that she cannot carry a pregnancy to term. Examples include a woman who has had a hysterectomy, has a uterine malformation, has had recurrent pregnancy loss or has a health condition that makes it dangerous for her to be pregnant. A female intending parent may also be fertile and healthy, but unwilling to undergo pregnancy.

15. Alternatively, the intended parent may be a single male or a male homosexual couple.

16. Surrogates may be relatives, friends, or previous strangers. Many surrogate arrangements are made through agencies that help match up intended parents with women who want to be surrogates for a fee. The agencies often help manage the complex medical and legal aspects involved. Surrogacy arrangements can also be made independently. In compensated surrogacies the amount a surrogate receives varies widely from almost nothing above expenses to over $30,000. Careful screening is needed to assure their health as the gestational carrier incurs potential obstetrical risks."

A true copy of *Baby Manji Yamada* v. *Union of India & Anr*., (2008) 13 SCC 518 dated 29.09.2008 is annexed herewith and marked as **ANNEXURE P-7**.

15. That in 2008, The ICMR prepared a draft ART (Regulation) Bill, 2008.

16. That on 11.11.2009, the Hon'ble High Court of its judgment in LPA No.2151/2009 titled Jan Balaz v. Anand Municipality and Ors.[4]. The Hon'ble High Court in the said case had to adjudicate an unprecedented situation of whether babies born in India to a gestational surrogate are citizens of this country and therefore, entitled to get passports. The Hon'ble High Court held such babies to be citizens of India while observing that a comprehensive legislation dealing with the issues involved in surrogacy and ART is very imminent to meet the situation created by the reproductive science and technology which have no clear answers in the then existing legal system in the country. The pertinent observations of the Hon'ble High Court as hereinunder:

> *"9. We may at the outset point out that lot of legal, moral and ethical issues arise for our consideration in this case, which have no precedents in this country. We are primarily concerned with the rights of two new born innocent babies, much more than the rights of the biological parents, surrogate mother, or the donor of the ova. Emotional and legal relationship of the babies with the surrogate mother and the donor of the ova is also of vital importance. Surrogate mother is not the genetic mother or biologically related to the baby, but, is she merely a host of an embryo or a gestational carrier? What is the status of the ova (egg) donor, which in this case an Indian national but anonymous. Is the ova donor is the real mother or the gestational surrogate? Are the babies*

[4] 2009 SCC OnLine Guj 10446 : AIR 2010 Guj 21 : (2010) 2 AIR Kant R (NOC 139) 56 : (2010) 51 (2) GLR 1309 : 2010 AIHC (NOC 407) 123

motherless, can we brand them as legal orphans or Stateless babies? So many ethical and legal questions have come up for consideration in this case for which there are no clear answers, so far, at least, in this country. True, babies conceived through surrogacy, encounter a lot of legal complications on parentage issues, this case reveals. Legitimacy of the babies is therefore a live issue. Can we brand them as illegitimate babies disowned by the world. Further, a host of scientific materials are made available to us to explain what is traditional surrogacy, gestational surrogacy, altruistise surrogacy, commercial surrogacy etc. and also the response of various countries with regard to the surrogacy, especially commercial surrogacy.

10. Commercial surrogacy is never considered to be illegal in India and few of the countries like Ukrain, California in the United States. Law Commission of India in it's 220th Report on 'Need for Legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parents to a surrogacy' has opined that surrogacy agreement will continue to be governed by contract among parties, which will contain all terms requiring consent of surrogate mother to bear the child, agreement of a husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying the child to full term, willingness to hand over a child to a commissioning parents etc. Law Commission has also recommended that legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parents without there being any need for adoption or even declaration of guardian. Further it was also suggested that birth certificate of surrogate child should contain names of the commissioning parents only and that the right to privacy of the donor as well as surrogate mother should be protected. Exploitation of women through surrogacy was also a worrying factor, which is to be taken care of through legislation. Law Commission has expressed its desire that Assisted Reproductive Technology Bill with all safeguards would be passed in the near future.

...

(III) We are in this case primarily concerned with the relationship of the child with the gestational surrogate mother, and with the donor of the ova. In the absence of any legislation to the contrary, we are more

inclined to recognize the gestational surrogate who has given birth to the child as the natural mother, a view prevailing in Japan. Anonymous Indian woman, the egg donor, in our view, is not the natural mother. She has of course a right to privacy that forms part of right to life and liberty guaranteed under Article 21 of the Constitution of India. Nobody can compel her to disclose her identity. Babies born are not in a position to know who is the egg donor and they only know their surrogate mother who is real. Wife, of the biological father, who has neither donated the ova, nor conceived or delivered the babies cannot in the absence of legislation be treated as a legal mother and she can never be a natural mother. In our view, by providing ova, a woman will not become a natural mother. Life takes place not in her womb, nor she receives the sperm for fertilization. Human fertilization is the union of a human sperm and egg usually occurring in the ampulla of the urine tube. Process involves development of an embryo. Process in this case followed is In Vitro Fertilization, a process by which egg cells were fertilized by sperm outside the womb in vitro. Resultantly, the only conclusion that is possible is that a gestational mother who has blood relations with the child is more deserving to be called as the natural mother. She has carried the embryo for full 10 months in her womb, nurtured the babies through the umbilical cord. Even if we assume that the egg donor is the real natural mother, even then she is an Indian national so revealed before the learned Single Judge, we are told. Both the egg donor as well as the gestational surrogate are Indian nationals, and hence the babies are born to an Indian national.

...

19. A comprehensive legislation dealing with all these issues is very imminent to meet the present situation created by the reproductive science and technology which have no clear answers in the existing legal system in this country. Views expressed by us, we hope, in the present fact settings, will

pave way for a sound and secure legislation to deal with a situation created by the reproductive science and technology. Legislature has to address lot of issues like rights of the children born out of the surrogate mother, legal, moral, ethical. Rights, duties and obligations of the donor, gestational surrogate and host of other issues.

20. Further, under the Indian Evidence Act, no presumption can be drawn that child born out of a surrogate mother, is the legitimate child of the commissioning parents, so as to have a legal right to parental support, inheritance and other privileges of a child born to a couple through their sexual intercourse. The only remedy is a proper Legislation drawing such a presumption including adoption. Further the question as to whether the babies born out of a surrogate mother have any right of residence in or citizenship by birth or mere State orphanage and whether they acquire only the nationality or the biological father has to be addressed by the legislature.

21. Indian Council of Medical Research (ICMR) has issued certain guidelines on surrogacy and Assisted Reproductive Technology (ART) in 2005. The new Bill ART (Regulation) Bill and Rules, 2008 is yet to become law, and there is extreme urgency to push through the legislation answering all these issues.

22. We, in the present legal frame-work, have no other go but to hold that the babies born in India to the gestational surrogate are citizens of this country and therefore, entitled to get the Passports and therefore direct the Passport Authorities to release the Passports withdrawn from them forthwith."

A true copy of judgement and final order dated 11.11.2009 passed in LPA No. 2151/2009 by the High Court of Gujrat, reported as 2009 SCC Online Guj 10446 is annexed herewith and marked as **ANNEXURE P-8**.

17. That on 05.08.2009, the Law Commission of India submitted the 228th report on Assisted Reproductive Technology procedures

discussing the importance and need for surrogacy, and also the steps taken to control surrogacy arrangements. The Report inter alia stated the ART industry was at the time worth about Rs. 25,000 crores, Anand, Gujarat had grown a reputation for commercial surrogacy and that the draft bill prepared by the ICMR was full of lacunae. The report, pertinently stated that the prohibition of surrogacy on vague moral grounds without a proper assessment of social ends and purposes which surrogacy can serve would be irrational[5]. The Report went on to suggest as under:

> • Surrogacy arrangement ought to continue to be governed by contract amongst parties, which would contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement ought not be for commercial purposes.
>
> • A surrogacy arrangement should provide for financial support for surrogate child in the event of death of the commissioning couple or individual before delivery of the

[5] Report No. 228, Law Commission of India, paragraph 4.1

child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.

• A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.

• One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

• Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

• The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

• Right to privacy of donor as well as surrogate mother should be protected.

• Sex-selective surrogacy should be prohibited.

• Cases of abortion should be governed by the Medical Termination of Pregnancy Act 1971 only.

A true copy of Report No. 228 of the Law Commission of India dated 05.08.2009 is annexed herewith and marked as **ANNEXURE P-9**.

18. That in 2010, the Indian Council of Medical Research, New Delhi circulated its draft of the Assisted Reproductive Technologies (Regulation) Bill, 2010. The said draft Bill specifically provided that

b. Assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples[6].

c. In case of a single woman the child will be the legitimate child of the woman, and in the case of a single man the child will be the legitimate child of the man[7]

A true copy of the Assisted Reproductive Technologies (Regulation) Bill, 2010 circulated by the Indian Council of Medical Research, New Delhi is annexed herewith and marked as **ANNEXURE P-10**.

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[6] S. 32, Draft Assisted Reproductive Technologies (Regulation) Bill, 2010, ICMR

[7] S. 35(3) Draft Assisted Reproductive Technologies (Regulation) Bill, 2010, ICMR

19. That on 21.11.2016, The Surrogacy (Regulation) Bill, 2016 was introduced in the Lok Sabha. A true copy of the Surrogacy (Regulation) Bill, 2016 (Bill No. 257 of 2016) is annexed herewith and marked as **ANNEXURE P-11**.

20. That on 12.01.2017, The Surrogacy (Regulation) Bill, 2016 was referred to the Department Related Parliamentary Standing Committee on Health and Family Welfare.

21. That on 10.08.2017, the Department Related Parliamentary Standing Committee on Health and Family Welfare presented its report on the Surrogacy (Regulation) Bill, 2016 before both the houses of Parliament. The said report, *inter alia* observed the opinion of certain stakeholders as hereinunder:

    a. *"4.1 During their deposition before the Committee, Shri Chetan B. Sanghi, Joint Secretary, Ministry of Women and Child Development informed the Committee that though the Ministry of Health and Family Welfare consulted them on 'Assisted Reproductive Technology' Bill, 2014, no specific consultation took place on the 'Surrogacy (Regulation)' Bill, 2016 per se. Their views and comments on the ART Bill have, however, been incorporated in the Surrogacy Bill. He inter-alia suggested that option of surrogacy should be made available to every lawfully married infertile couple and also to every Indian woman whether married or single including not married; separated; widowed irrespective of their ability to bear the child…"*

b. *"4.7 Smt. Jayshree Wad, Supreme Court Lawyer, suggested that a provision of surrogacy agreement should be added in the Bill to have a binding effect on intending couple to take the delivery of the child born out of surrogacy irrespective of any abnormalities. Such agreement would also act as proof of willingness of surrogate mother for the procedure. She also suggested that the word 'legal' should be added before 'parents' to have a binding effect on the intending couple. She further highlighted changes required in the definitions of 'surrogate mother' and 'surrogacy'. She mentioned that the Bill is silent with regard to live-in relationship, same sex marriages, single parents (divorcee/ widow/ unmarried). She suggested a provision for depositing the amount in the Court which will take care of the required expenses of the surrogate regarding her health problem during pregnancy period."*

c. *"5.31 Various other stakeholders were in support to allow the individuals who are single including unmarried, separated, widows, transgenders, single parents to exercise their right to parenthood. They argued that if single individuals are financially capable of taking care of their children and if they have family support, they should be fully entitled to have children through surrogacy. They felt that restricting the people to commission surrogacy on the basis of their marital status, would be violation of human rights."*

A true copy of the Report on The Surrogacy (Regulation) Bill, 2016 by the Department-Related Parliamentary Standing Committee on Health And Family Welfare dated 10.08.2017 is annexed herewith and marked as **ANNEXURE P-12**.

22. That on 19.12.2018, the Lok Sabha passed the Surrogacy (Regulation) Bill, 2016. However, the Bill thereafter lapsed before the Rajya Sabha.

23. That on 15.07.2019, the Hon'ble Minister for Health and Family Welfare, Government of India, Dr Harsh Vardhan, introduced the Surrogacy (Regulation) Bill, 2019 in the Lok Sabha. A true copy of the Surrogacy (Regulation) Bill, 2019 dated 15.07.2019 is annexed herewith and marked as **ANNEXURE P-13**.

24. That on 05.08.2019, The Surrogacy (Regulation) Bill, 2019 was passed by the Lok Sabha.

25. That on 21.11.2019, The Surrogacy (Regulation) Bill, 2019 was referred to the Select Committee.

26. That on 05.02.2020, the Select Committee presented its report to on the Surrogacy (Regulation) Bill, 2019 the Rajya Sabha. The conclusions arrived at by the Committee are on pertinent issues are unjust and illogical and or without any stated reasons. The most grievous instances are:

    a. The Report observes that *"4.31 Some Members/stakeholders also desired that debarring single man, single woman – divorcee or widow, live-in couples and gay*

couples from availing surrogacy is violative of their reproductive autonomy. They, therefore, demanded that the people of above categories may also be permitted to avail surrogacy". Thereafter, without alluding to any concrete reasoning, the Committee arrives at the conclusion that *"4.35 The Committee extensively debated both the issues and came to a conclusion that keeping in view the interest of the child, only single woman (divorcee or widow) between the age of 35 to 45 years and persons of Indian origin may be permitted to avail surrogacy, provided they obtain a certificate of recommendations from the National Surrogacy Board on an application made by the above said persons in such manner and such format as may be prescribed. The format may contain No Objection Certificate for the Indian origin couple, country status regarding surrogacy, details of surrogate mother, parental order for the child to be born and*

clearance from Ministry of External Affairs and satisfying all provision of the Bill.".

b. The Report observes that "*5.28 The Committee was given to understand by many witnesses/stakeholders that the right to avail surrogacy services has been limited to Indian married couples only which is not justified. Restricting it to only Indian married couples is discriminatory and violative of the right to life, personal liberty, reproductive autonomy and right to equality guaranteed to all persons under the Constitution of India. 5.29 It was also pointed out that the Hon'ble Supreme Court has recognized the status of live-in partners as a "relationship in the nature of marriage" and the proposed Bill in an unreasonable and discriminatory manner fails to recognize the rights of live-in partners to surrogacy. Therefore, a mechanism should be established which can incorporate everyone in the ambit of*

surrogacy regulatory framework. 5.30 Ministry of Women and Child Development has informed that they are in favour of allowing the option of surrogacy to foreigners, every lawfully married infertile heterosexual couples, every Indian woman whether married or single (which include not married/separated/widow etc.) irrespective of their ability to bear child or not. However, they favored putting restrictions on single men commissioning surrogacy to make it on par with Juvenile Justice (Care and Prevention of Children) Act, 2015 which prohibits adoption of girls by single men. Some other stakeholders were also in favor of extending the option of surrogacy to foreigners, NRIs, PIOs, OCI cardholders, stating that surrogacy should not be restricted to Indian nationals only. 5.31 Various other stakeholders were in support to allow the individuals who are single including unmarried, separated, widows, transgenders, single parents to

exercise their right to parenthood. They argued that if single individuals are financially capable of taking care of their children and if they have family support, they should be fully entitled to have children through surrogacy. They felt that restricting the people to commission surrogacy on the basis of their marital status, would be violation of human rights. 5.32 Some concerns have been raised with respect to the condition of childlessness as one of the eligibility criteria to commission surrogacy as proposed n the Bill. It has been argued that there is no one child policy in our country and therefore, this condition of childlessness may be removed from the Surrogacy Bill. 5.33 As regards the definition of 'infertility', the World Health Organization terms infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse".

The earlier draft Assisted Reproductive Technologies (ART) Bill 2010 and 2014 also defined Infertility as "the inability to conceive after at least one year of unprotected coitus". Majority of the experts/stakeholders have contended that the proposed Bill imposing the extended time period of five years before commissioning surrogacy seems irrational and arbitrary in many aspects. They have cited judicial pronouncements in cases like B.K. Parthasarthi vs. Government of Andhra Pradesh and in Govind vs. State of MP to buttress their argument that the five year waiting Clause was violative of the right of reproductive autonomy. 5.34 Though the definition of infertility is limited to failure to conceive only, there are other medical conditions for which surrogacy is availed. For example, TB destroys thousands of uteruses irreversibly. A large number of girls are born without a uterus or a very under developed uterus. A

large number of women have repeated miscarriages. There are many women who have their uterus removed because of cancer or because of many tumors. The Bill also ignores medical condition of a woman where she conceives but is not able to carry the child to the full term. 5.35 The Bill discriminates against medically infertile couples as this condition of five years is applicable for infertile couples only whereas it is not applicable to other couples who are healthy and free from medical complications and are free to attain parenthood any time before five years of their wedlock or without observing the waiting time period of five years. The Committee understands that in the present context of late marriage (late 30's), further delay of five years would adversely affect the quality of gametes of couples or render the couple's gametes less viable. 5.36 The National Commission for Women has supported the definition of infertility as

proposed in the Bill justifying that in today's time, due to a gross imbalance of work life ratio, it is essential to give a couple enough time to try and conceive a child themselves before engaging in external aid. Few other stakeholders also agree with psychologists that after marriage, it takes one to two years to understand each other. After that, there is one year of unprotected sex and then, there has to be one year of continuous trying through fertility clinics.". Thereafter, on the issue of limiting the benefit of the legislation to only Indian married couples, the Committee cites '*sentiment and sensibility*' to oust other sections of society by stating that *"5.40 The Committee notes that the Bill limits the option of surrogacy to legally married Indian couples. The Committee observes that limiting the option to avail surrogacy facilities to an Indian heterosexual married couple to have their own biological child has*

overlooked a large section of the society. Given our sentiments and sensibility, the social status of a woman in our society is judged by her reproductive life and there is a lot of pressure on her for child bearing. The Department of Health Research by imposing prohibition on widows and divorced women seems to have closed its eyes to the ground reality. Besides, the decision to keep live-in partners out of the purview of the Bill is indicative of the fact that the Bill is not in consonance with the present day modern social milieu that we live in and is "too narrow" in its understanding. Even the Supreme Court has given legal sanctity to live-in relationships. Surrogacy is one of the least used options by childless Indians. If all these categories are to be banned then why have surrogacy at all. The Committee, therefore, recommends that the Department should broadbase the eligibility criteria in this regard and widen

the ambit of persons who can avail surrogacy services by including live-in couples, divorced women and widows. Appropriate alterations accordingly be made in Clause 2(g) and 4(iii)(c) of the Bill.". Further, the Committee does not even give a view on the issue of the legislation giving benefit only to infertile married couples and not fertile married couples who may not want a natural birth.

A true copy of the Report of the Select Committee on the Surrogacy (Regulation) Bill, 2019 dated 05.02.2020 is annexed herewith and marked as **ANNEXURE P-14**.

27. That the Assisted Reproductive Technology (Regulation) Bill, 2020 was introduced in Lok Sabha on 14.07.2020.

28. That the Department Related Parliamentary Standing Committee on Health and Family Welfare presented its report on the Assisted Reproductive Technology (Regulation) Bill, 2020 before both houses of the Parliament on 19.03.2021. A true copy of the Report of the Department Related Parliamentary Standing Committee on Health and Family Welfare on the Assisted Reproductive Technology

(Regulation) Bill, 2020 dated 19.03.2021 is annexed herewith and marked as **ANNEXURE P-15**.

29. That on 08.12.2021, The Rajya Sabha passed the Assisted Reproductive Technology (Regulation) Bill, 2020 and the Surrogacy (Regulation) Bill, 2019 as the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) respectively.

30. In view of the aforesaid facts and circumstances of the case, the Petitioner is preferring the instant petition *inter alia* on the following amongst other grounds:

GROUNDS

THE LEGISLATIONS ARE ULTRA VIRES ARTICLE 14 OF THE CONSTITUTION OF INDIA

A. Because the Section 2(e) of the Assisted Reproductive Technology (Regulation) Act, 2021 defines "*commissioning couple*" as *"an infertile married couple who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorised of the said clinic or bank"*.

B. Because Section 2(j) of the Assisted Reproductive Technology (Regulation) Act, 2021 defines "*infertility*" as "*the inability to*

conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception".

C. Because Section 2 (zd) of the Surrogacy (Regulation) Act, 2021 defines "*surrogacy*" as *"a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth"*.

D. Because Section 2 (zg) of the Surrogacy (Regulation) Act, 2021 defines "*surrogate mother*" as a *"woman who agrees to bear a child (who is genetically related to the intending couple or intending woman) through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause (b) of clause (iii) of section 4;"*

E. Because by means of the aforesaid sections and all the others under challenge, the fundamental rights of the petitioners are being violated and they are being discriminated against, hence the said provisions ought to be stuck as being ultra vires to the Articles of the Constitution of India.

BAN ON COMMERCIAL SURROGACY ROBS THE PETITIONERS OF THE OPTION OF SURROGACY

F. Because Section 4(ii)(b) of the Surrogacy (Regulation) Act, 2021 prohibits all forms of commercial surrogacy and allows only altruistic surrogacy.

G. Because commercial surrogacy is the only option available to the Petitioners as they are unable to obtain consent from a woman who fulfils the rigours of the eligibility of a surrogate mother.

H. Because the ban on commercial surrogacy, seemingly enacted to protect impoverished women, de-nudes such women from their right over their bodies and denies them the opportunity to exercise agency over their divine right of giving birth.

I. Because the issue of surrogacy ought to be governed by the Indian Contract Act, 1872.

J. Because S. 38(1)(A) of the Surrogacy (Regulation) Act, 2021 makes commercial surrogacy an offence.

THE PRESCRIBED ELIGIBILITY OF SURROGATE MOTHERS IMPOSSIBLY LIMITS THE NUMBER OF ELIGIBLE WOMEN TO BECOME SURROGATE MOTHERS

K. Because Section 4 (iii)(b)(I) of the Surrogacy (Regulation) Act, 2021 permits only married women between 25 and 35 years of age who have at least one biological child to be surrogates.

L. Because Section 2 (zg) read with Section 4 (iii)(b)(I) of the Surrogacy (Regulation) Act, 2021 has the effect that only a woman who fulfils the following criteria can become a surrogate mother:

a. Is married; and

b. between 25 and 35 years of age; and

c. has at least one biological child; and

d. is genetically related to the 'intending couple' or 'intending woman'

M. Because Section 2 (zg) read with Section 4 (iii)(b)(I) of the Surrogacy (Regulation) Act, 2021 does not let the following classes of women become surrogate mothers which is violative of Article 14 of the Constitution of India:

a. Unmarried

b. Above 18 but below 25 of age

c. Above 35 years of age but with a healthy reproductive system.

d. Not already a mother

N. Because the limitations imposed on who can be a surrogate mother in terms of Section 2 (zg) read with Section 4 (iii)(b)(I) of the Surrogacy (Regulation) Act, 2021, limit the options available to an *'intending couple' or 'intending woman'* and diminish their chances of finding a consenting surrogate mother. The best eligibility criteria to maximise the chances of finding the best surrogate mother, in the interests of both the '*intending couple*'/ '*intending woman*' or the surrogate baby, would be any healthy woman above the age of majority. The needless conditions of being genetically related, of a particular age, married and already having at least one child only constrict the universe of available candidates who may otherwise become healthy surrogate mothers.

ELIGIBILITY UNDER THE LEGISLATIONS, OF WHO CAN AVAIL OF SURROGACY DOES NOT ALLOW THE PETITIONERS TO OPT FOR IT

O. Because Section 2 (s) of the Surrogacy (Regulation) Act, 2021 defines "*intending woman*" as *"an Indian woman who is a*

widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy".

P. Because Petitioner No. 1, a single man cannot avail of surrogacy to become a father under the provisions of the Surrogacy (Regulation) Act, 2021.

Q. Because Petitioner No. 2, a married woman cannot elect for surrogacy under the provisions of the Surrogacy (Regulation) Act, 2021 as she is not having any medical indications necessitating surrogacy as per the act and is not a widow or a divorcee between the ages of 35 to 45 years.

R. Because a woman who may choose not to marry cannot elect for surrogacy under the provisions of the Surrogacy (Regulation) Act, 2021.

S. Because even a divorcee or widow who is above 18 years old but less than 35 and a woman who is above 45 years of age cannot elect for surrogacy under the provisions of the Surrogacy (Regulation) Act, 2021.

MARRIED COUPLE

T. Because Section 2 (h) of the Surrogacy (Regulation) Act, 2021 defines "*couple*" as "*the legally married Indian man and woman above the age of 21 years and 18 years respectively"*.

U. Because Section 2 (r) of the Surrogacy (Regulation) Act, 2021 defines "*intending couple*" as "*a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy*".

V. Because Section 4(ii)(a) of the Surrogacy (Regulation) Act, 2021 reads as hereinunder:

> *"4. On and from the date of commencement of this Act,—(ii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:— (a) when an intending couple has a medical indication necessitating gestational surrogacy:".*

W. Because Section 4(iii) of the Surrogacy (Regulation) Act, 2021 reads as hereinunder:

> *"(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—*
>
> > *(a) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—*

(I) a certificate of a medical indication in favour of either or both members of the intending couple or intending woman necessitating gestational surrogacy from a District Medical Board."

X. Because a married couple cannot elect for surrogacy under the provisions of the Surrogacy (Regulation) Act, 2021 unless there is a '*medical indication*' in favour of either or both partners that surrogacy is necessary and they are in possession of such a certificate.

Y. Because '*medical indication*' has not been defined in the Surrogacy (Regulation) Act, 2021 or Assisted Reproductive Technology (Regulation) Act, 2021 and such lacunae is manifestly arbitrary.

Z. Because Section 4(iii)(c) of the Surrogacy (Regulation) Act, 2021 reads as hereinunder:

"(c) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(III) (I) the intending couple are married and between the age of 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(II) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or

physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(III) such other conditions as may be specified by the regulations"

AA. Because a married couple cannot elect for surrogacy under the provisions of the Surrogacy (Regulation) Act, 2021 unless they are not parents to a surviving child and the intending father is between the ages of 23-50 years and the intending mother is between the ages of 26-55 years.

BB. Because the Assisted Reproductive Technology (Regulation) Act, 2021 is discriminatory towards all single men and women inasmuch as Ss. 2(e), 14(2), 21, 27(3) and 31(1) as these sections only recognise 'commissioning couple'.

CC. Because the conclusions of the Select Committee report dated 05.02.2020 on the Surrogacy (Regulation) Bill, 2019 submitted to the Rajya Sabha on pertinent issues are unjust and illogical and or without any stated reasons.

DD. Because the Law Commis[si]on of India's 228th report on "NEED FOR LEGISLATION TO REGULATE ASSISTED" stated the ART industry was at the time worth about Rs. 25,000 crores, Anand, Gujarat had grown a reputation for

commercial surrogacy and that the draft bill prepared by the ICMR was full of lacunae. The report, pertinently stated that the prohibition of surrogacy on vague moral grounds without a proper assessment of social ends and purposes which surrogacy can serve would be irrational[8]. The Report went on to suggest as under:

• Surrogacy arrangement ought to continue to be governed by contract amongst parties, which would contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement ought not be for commercial purposes.

• A surrogacy arrangement should provide for financial support for surrogate child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and

[8] Report No. 228, Law Commission of India, paragraph 4.1

subsequent willingness of none to take delivery of the child.

• A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.

• One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

• Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

• The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

• Right to privacy of donor as well as surrogate mother should be protected.

• Sex-selective surrogacy should be prohibited.

• Cases of abortion should be governed by the Medical Termination of Pregnancy Act 1971 only.

THE LEGISLATIONS ARE ULTRA VIRES ARTICLE 21 OF THE CONSTITUTION OF INDIA

EE. Because reproductive choices are a part of the individual's inalienable right of personal liberty. The very narrow and arbitrary zone of eligibility for both surrogates and intended parents strips the Petitioners of reproductive autonomy.

FF. Because the 102nd Report by the Department Related Parliamentary Standing Committee on Health and Family Welfare dated 10.08.2017 unequivocally observed that as under

> *"5.22 Based on the analysis of the facts in the preceding paras, the Committee is convinced that the altruistic surrogacy model as proposed in the Bill is based more on moralistic assumptions than on any scientific criteria and all kinds of value judgments have been injected into it in a paternalistic manner. Altruistic surrogacy across the world means compensated surrogacy and a range of monetary payments to surrogate mothers are permitted as reasonable compensation. Even the Law Commission Report No. 228 of 2009 recommends reimbursement of*

all reasonable expenses to the surrogate mother. The Committee, therefore, recommends that the word "altruistic" in Clause 2 (b) of the Bill be replaced with the word "compensated" and appropriate modifications be incorporated in the said Clause and other relevant Clauses of the Bill with a view to harmonizing the Bill with the compensated surrogacy model."

GG. Because the personal decision of a single person about the birth of a baby through surrogacy, i.e., the right of reproductive autonomy is a facet of the right to privacy guaranteed under Article 21 of the Constitution. Thus, the right of privacy of every citizen or person to be free from unwarranted governmental intrusion into matters fundamentally affecting a decision to bear or beget a child through surrogacy cannot be taken away. In the simplest of terms, the right to commission surrogacy, to found a family, to procreate is a personal decision which cannot and should not have government intrusion in a democratic society.

THE LEGISLATIONS ARE IN THE TEETH OF INTERNATIONAL COVENANTS

HH. Because the UDHR, the International Covenant on Civil and Political Rights and the Convention on the Elimination of Discrimination against Women are pertinent international treaties ratified by the Indian Parliament. Article 1 of the UDHR guarantees equal rights to all human beings, while

Article 7 mandates State parties to ensure equal protection of the law to all human beings without any discrimination. Similarly, the ICCPR commands State parties to refrain from discriminating against any persons on any grounds. Further, the CEDAW expects signatory nations to ensure equality between men and women in deciding freely on the number and spacing of their children. The Acts impugned herein arbitrarily excludes certain classes of citizens as it necessitates that intended parents have no surviving offspring; and it specifies unequivocally that women can act as surrogates only once in their lifetime.

CASE LAW

II. The Hon'ble Supreme Court of India in *Suchita Srivastava v. Chandigarh Admn.*, (2009) 9 SCC 1 [3 Judges], inter alia held that:

> ***"22.*** *There is no doubt that a woman's right to make reproductive choices is also a dimension of "personal liberty" as understood under Article 21 of the Constitution of India. It is important to recognise that reproductive choices can be exercised to procreate as well as to abstain from procreating. The crucial consideration is that a woman's right to privacy, dignity and bodily integrity should be respected. This means that there should be no restriction whatsoever on the exercise of reproductive choices such as a woman's right to refuse participation in sexual activity or alternatively the insistence on use of contraceptive methods. Furthermore, women are also free to choose*

birth control methods such as undergoing sterilisation procedures. Taken to their logical conclusion, reproductive rights include a woman's entitlement to carry a pregnancy to its full term, to give birth and to subsequently raise children. However, in the case of pregnant women there is also a "compelling State interest" in protecting the life of the prospective child. Therefore, the termination of a pregnancy is only permitted when the conditions specified in the applicable statute have been fulfilled. Hence, the provisions of the MTP Act, 1971 can also be viewed as reasonable restrictions that have been placed on the exercise of reproductive choices."

JURISDICTION

31. That the Petitioners are residents and permanent residents of New Delhi whose residential address are as given in the memo of parties and Petitioner No. 1 also works within the territorial jurisdiction of this Hon'ble Court. Further, offices of the Respondent are in New Delhi. Further still, the present petition seeks the enforcement of the Petitioners' Constitutional Fundamental right to equality under Article 14 and 21as such this Hon'ble Court has jurisdiction to adjudicate the present writ petition.

DELAY AND LACHES

32. That the impugned legislation came into effect on 25.12.2021 and as the present petition has been filed on 31.03.2022, it does not suffer from any delay or latches. Further, it is stated that as a consequence of Office Order dated 23.03.2020 and subsequent office orders on the issue of the functioning of this Hon'ble Court during the Covid 19

pandemic, only matters of extreme urgency were listed and heard before this Hon'ble Court. This system of listing and its remnant system of listing by way of urgent mentioning through the weblink was done away with only in terms of this Hon'ble Court's Office Order dated 11.03.2022. In view of these circumstances, it is stated that the present petition does not suffer from any delay and latches and has been filed within reasonable time.

33. That no similar petition or application has been preferred by the Petitioners herein seeking similar relief before this Hon'ble Court or any other Court.

34. That the present petition is bona fide and in the interest of justice and equity.

PRAYER

In view of the above facts and circumstances, it is most respectfully prayed that this Hon'ble Court:

A. Declare Sections 2(e), 14(2), 21, 27(3) and 31(1) of the Assisted Reproductive Technology (Regulation) Act, 2021 as ultra vires Articles 14 and 21 of the Constitution of India

B. Declare Sections 2(h), 2(s), 2(r), 2(zd),2(zg), 4(ii)(a), 4(ii)(b) and 4(iii), 4(II)(C),8 and Section 38(1)(a) of the Surrogacy

(Regulation) Act, 2021 as ultra vires Article(s) 14 and 21 of the Constitution of India.

C. Pass such other order/orders as the court may deem fit and proper in the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE PETITIONERS DUTY BOUND SHALL EVER PRAY

Karan Balraj Mehta
[Petitioner No.1]

Dr. Pankhuri Chandra
[Petitioner No.2]

Filed by:

New Delhi
Date 25.05.2022

Aditya Samaddar,
Advocate for the Petitioner,
Off: B-7, Lower Ground Floor, Hazrat Nizamuddin (East), New Delhi, 110013; Email: aditya.samaddar@gmail.com;
Ph. No. 9910013921

BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

WRIT PETITION (C) NO. _____OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. ...PETITIONER(S)

VERSUS

UNION OF INDIA . ...RESPONDENT

AFFIDAVIT

I, Karan Balraj Mehta, son [redacted], hereby solemnly affirm as hereinunder:

1. That I am the Petitioner No. 1 in the present matter. I am well conversant with the facts and circumstances of the case and as such am competent to swear the present affidavit.

2. That I have read the contents of the accompanying Writ Petition at paragraph numbers 1 to 31 and pages number 1 to 10. Having understood the same I state that the contents thereof have been drafted on my instructions by my Counsel and the same are true and correct to the best of my knowledge.

3. That the annexures to the present writ petition are true or true typed or translated copies, as the case may be, of the original documents.

[redacted]

DEPONENT

25 MAY 2022

VERIFICATION

Verified at New Delhi on this the 25th day of May, 2022 that the contents of paragraph numbers 1-3 hereinabove are true and correct to the best of my knowledge and records available and nothing material has been concealed therefrom.

I identified the deponent who has signed in my presence.

NOTARY
ALAKA NAYAK
Advocate
Reg. No. 10639
Period 27/06/2019
to 27/06/2024
GOVT. OF INDIA

25 MAY 2022

[redacted]

DEPONENT

CERTIFIED THAT THE DEPONENT
S/Smt/Km. Shri Ram
S/o, W/o, D/o Late Shri
R/o
Identified by Sh./Smt.
has Solemnly affirmed before me at
New Delhi on as Sl. No.
That the contents of the affidavit which have
been read & explained to him are true and
Correct to the knowledge.

Notary Public

BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

WRIT PETITION (C) NO. _____OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. ...PETITIONER(S)

VERSUS

UNION OF INDIA . ...RESPONDENT

AFFIDAVIT

I, Dr. Pankhuri Chandra, w[redacted], New Delhi, India 110048, hereby solemnly affirm as hereinunder:

1. That I am the Petitioner No. 2 in the present matter. I am well conversant with the facts and circumstances of the case and as such am competent to swear the present affidavit.

NOTARY ALAKA NAYAK Advocate Reg No. 17539 Valid upto 21/03/2022 GOVT. OF INDIA

2. That I have read the contents of the accompanying writ petition at paragraph numbers 1 to 34 and pages number 1 to 60. Having understood the same I state that the contents thereof have been drafted on my instructions by my Counsel and the same are true and correct to the best of my knowledge.

3. That the annexures to the present writ petition are true or true typed or translated copies, as the case may be, of the original documents.

[redacted]

DEPONENT

25 MAY 2022

VERIFICATION

Verified at New Delhi on this the 25th day of May, 2022 that the contents of paragraph numbers 1-3 hereinabove are true and correct to the best of my knowledge and records available and nothing material has been concealed therefrom.

[redacted]

DEPONENT

Delhi

I identified deponent who has signed in my presence.

CERTIFIED THAT THE DEPONENT
Sri/Smt/Km.....
S/o, W/o, D/o.....
R/o.....
Identified by.....
has Solemnly affirmed before me at
New Delhi No.....
That the contents of which have been read & explained to him are true and
Correct to this knowledge.

Notary Public

25 MAY 2022

NOTARY
ALAKA NAYAK
Advocate
Regd.No. 10639
Period 27/05/2019
to 27/05/2024
GOVT. OF INDIA

रजिस्ट्री सं० डी० एल०—(एन)04/0007/2003—21 REGISTERED NO. DL—(N)04/0007/2003—21

भारत का राजपत्र
The Gazette of India

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असाधारण
EXTRAORDINARY
भाग II — खण्ड 1
PART II — Section 1
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PUBLISHED BY AUTHORITY

सं० 59] नई दिल्ली, सोमवार, दिसम्बर 20, 2021/अग्रहायण 29, 1943 (शक)
No. 59] NEW DELHI, MONDAY, DECEMBER 20, 2021/AGRAHAYANA 29, 1943 (SAKA)

इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 20th December, 2021/*Agrahayana* 29, 1943 (*Saka*)

The following Act of Parliament received the assent of the President on the 18th December, 2021 and is hereby published for general information:—

THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) ACT, 2021

(No. 42 of 2021)

[18*th December*, 2021]

An Act for the regulation and supervision of the assisted reproductive technology clinics and the assisted reproductive technology banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services for addressing the issues of reproductive health where assisted reproductive technlogy is required for becoming a parent or for freezing gametes, embryos, embryonic tissues for further use due to infertility, disease or social or medical concerns and for regulation and supervision of research and development and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Seventy-second Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. (*1*) This Act may be called the Assisted Reproductive Technology (Regulation) Act, 2021. Short title and commencement.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions.

2. (*1*) In this Act, unless the context otherwise requires,—

(*a*) "assisted reproductive technology" with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive system of a woman;

(*b*) "assisted reproductive technology bank" means an organisation which shall be responsible for collection of gametes, storage of gametes and embryos and supply of gametes to the assisted reproductive technology clinics or their patients;

(*c*) "assisted reproductive technology clinic" means any premises equipped with requisite facilities and medical practitioners registered with the National Medical Commission for carrying out the procedures related to the assisted reproductive technology;

(*d*) "child" means any individual born through the use of the assisted reproductive technology;

(*e*) "commissioning couple" means an infertile married couple who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorised of the said clinic or bank;

(*f*) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days from the day of fertilisation;

(*g*) "gamete" means sperm and oocyte;

(*h*) "gamete donor" means a person who provides sperm or oocyte with the objective of enabling an infertile couple or woman to have a child;

(*i*) "gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*j*) "infertility" means the inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception;

(*k*) "National Board" means the National Assisted Reproductive Technology and Surrogacy Board to be constituted under sub-section (*1*) of section 15 of the Surrogacy Act;

(*l*) "National Registry" means the National Assisted Reproductive Technology and Surrogacy Registry established under section 9;

(*m*) "notification" means a notification published in the Official Gazette;

(*n*) "patients" means an individual or couple who comes to any registered assisted reproductive technology clinic for management of infertility;

(*o*) "prescribed" means prescribed by rules made under this Act;

(*p*) "appropriate authority" means the authority appointed under section 12;

(*q*) "regulations" means the regulations made by the National Board under this Act;

(*r*) "sperm" means the mature male gamete;

(*s*) "State Board" means a State Assisted Reproductive Technology and Surrogacy Board to be constituted under sub-section (*1*) of section 24 of the Surrogacy Act;

(*t*) "Surrogacy Act" means the Surrogacy (Regulation) Act, 2021; and

(*u*) "woman" means any woman above the age of twenty-one years who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the authorised services of the clinic or bank.

(*2*) The expressions "clinics" and "banks" occurring in this Act shall be construed as "assisted reproductive technology clinics" and "assisted reproductive technology banks".

(*3*) Words and expressions used herein and not defined in this Act but defined in the Surrogacy (Regulation) Act shall have the meanings respectively assigned to them in that Act.

CHAPTER II

AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY

A. THE NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARD

National Assisted Reproductive Technology and Surrogacy Board.

3. The National Assisted Reproductive Technology and Surrogacy Board to be constituted under sub-section (*1*) of section 15 of the Surrogacy Act shall be the National Board for the purposes of this Act.

Application of provisions of Surrogacy Act with respect to National Board.

4. Subject to the provisions of this Act and the rules made thereunder, the provisions of the Surrogacy Act relating to—

(*i*) constitution of the National Assisted Reproductive Technology and Surrogacy Board;

(*ii*) term of office of Members of the National Board;

(*iii*) meetings of the National Board;

(*iv*) vacancies, etc., not to invalidate proceedings of the National Board;

(*v*) disqualifications for appointment as Member of the National Board;

(*vi*) temporary association of persons with the National Board for particular purposes;

(*vii*) authentication of orders and other instruments of the National Board; and

(*viii*) eligibility of Members of the National Board for re-appointment,

shall, *mutatis mutandis,* apply, so far as may be, in relation to assisted reproductive technology as they apply in relation to surrogacy, as if they are enacted under this Act.

Powers and functions of National Board.

5. The National Board shall exercise and discharge the following powers and functions, namely:—

(*a*) to advise the Central Government on policy matters relating to the assisted reproductive technology;

(*b*) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, any suitable changes therein;

(*c*) to lay down code of conduct to be observed by persons working at clinics and banks, to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by clinics and banks;

(*d*) to oversee the performance of various bodies constituted under this Act and take appropriate steps to ensure their effective performance;

(*e*) to supervise the functioning of the National Registry and liaison with the State Boards;

(*f*) to pass orders as per the provisions made under this Act; and

(*g*) such other powers and functions as may be prescribed.

B. STATE ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARD

State Assisted Reproductive Technology and Surrogacy Board.

6. The State Assisted Reproductive Technology and Surrogacy Board to be constituted under sub-section (*1*) of section 24 of the Surrogacy Act shall be the State Board for the purposes of this Act.

Application of provisions of Surrogacy Act with respect to State Board.

7. Subject to the provisions of this Act and the rules made thereunder, the provisions of the Surrogacy Act relating to—

(*i*) constitution of the State Assisted Reproductive Technology and Surrogacy Board;

(*ii*) composition of the State Board;

(*iii*) term of office of members of the State Board;

(*iv*) meetings of the State Board;

(*v*) vacancies, etc., not to invalidate proceedings of the State Board;

(*vi*) disqualifications for appointment as member of the State Board;

(*vii*) temporary association of persons with the State Board for particular purposes;

(*viii*) authentication of orders and other instruments of the State Board; and

(*ix*) eligibility of member of the State Board for re-appointment,

shall, *mutatis mutandis,* apply, so far as may be, in relation to assisted reproductive technology as they apply in relation to surrogacy, as if they are enacted under this Act.

Powers and functions of State Board.

8. (*1*) Subject to the provisions of this Act and the rules and regulations made thereunder, the State Board shall have the responsibility to follow the policies and plans laid by the National Board for clinics and banks in the State.

(*2*) Without prejudice to the generality of the provisions contained in sub-section (*1*), the State Board, taking into account the recommendations, policies and regulations of the National Board, shall—

(*a*) co-ordinate the enforcement and implementation of the policies and guidelines for assisted reproduction; and

(*b*) such other powers and functions as may be prescribed.

(*3*) In the exercise of its functions under this Act, the State Board shall give such directions or pass such orders as directed by the National Board.

C. THE NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY REGISTRY AND THE APPROPRIATE ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY AUTHORITY

Establishment of National Registry of clinics and banks.

9. The Central Government may, within a period of ninety days from the date of commencement of this Act, by notification, establish for the purposes of this Act and Surrogacy Act, a Registry to be called the National Assisted Reproductive Technology and Surrogacy Registry.

Composition of National Registry.

10. The National Registry referred to in section 9 shall consist of such scientific, technical, administrative and supportive staff and the terms and conditions of their service shall be such as may be prescribed.

Functions of National Registry.

11. The National Registry shall discharge the following functions, namely:—

(*a*) it shall act as a central database in the country through which the details of all the clinics and banks of the country including nature and types of services provided by them, outcome of the services and other relevant information shall be obtained on regular basis;

(*b*) it shall assist the National Board in its functioning by providing the data generated from the central database of the Registry;

(*c*) the data generated from the National Registry shall be utilised by the National Board for making policies, guidelines and shall help in identifying new research areas and conducting research in the area of assisted reproduction and other related fields in the country; and

(*d*) such other functions as may be prescribed.

Appointment of appropriate authority.

12. (*1*) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate assisted reproductive technology and surrogacy authorities for each of the Union territories for the purposes of this Act and the Surrogacy Act.

(*2*) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate assisted reproductive technology and surrogacy authorities for the whole or any part of the State for the purposes of this Act and the Surrogacy Act.

(*3*) The appropriate authority, under sub-section (*1*) or sub-section (*2*), shall,—

(*a*) when appointed for the whole of the State or the Union territory, consist of—

(*i*) an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department—Chairperson, *ex officio;*

(*ii*) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department — Vice Chairperson, *ex officio;*

(*iii*) an eminent woman representing women's organisation—member;

(*iv*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—member, *ex officio;* and

(*v*) an eminent registered medical practitioner—member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(*b*) when appointed for any part of the State or the Union territory, the officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

(*4*) The members of appropriate authority, other than *ex officio* members, shall receive only compensatory travelling expenses for attending the meetings of such Authority.

Functions of appropriate authority.

13. The appropriate authority shall discharge the following functions, namely:—

(*a*) to grant, suspend or cancel registration of a clinic or bank;

(*b*) to enforce the standards to be fulfilled by the clinic or bank;

(*c*) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provisions of this Act;

(*d*) to take appropriate legal action against the misuse of assisted reproductive technology by any person and also to initiate independent investigations in such matter;

(*e*) to supervise the implementation of the provisions of this Act and the rules and regulations made thereunder;

(*f*) to recommend to the National Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(*g*) to take action after investigation of complaints received by it against the assisted reproductive technology clinics or banks; and

(*h*) such other functions as may be prescribed.

Powers of appropriate authority.

14. (*1*) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act and the rules and regulations made thereunder;

(*b*) production of any document or material object relating to clause (*a*);

(*c*) searching of any place suspected to be violating the provisions of this Act and the rules and regulations made thereunder; and

(*d*) such other powers as may be prescribed.

(*2*) The appropriate authority shall maintain the details of registration of assisted reproductive technology clinics and banks, cancellation of registration, renewal of registration, grant of certificates to the commissioning couple and woman or any other matter pertaining to grant of licence and the like of the clinic or bank in such format as may be prescribed and submit the same to the National Board.

CHAPTER III

PROCEDURES FOR REGISTRATION

Registration of assisted reproductive technology clinic or assisted reproductive technology bank.

15. (*1*) No person shall establish any clinic or bank for undertaking assisted reproductive technology or to render assisted reproductive technology procedures in any form unless such clinic or bank is duly registered under this Act.

(*2*) Every application for registration under sub-section (*1*) shall be made to the National Registry through the appropriate assisted reproductive technology and surrogacy authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(*3*) Every clinic or bank which is conducting assisted reproductive technology, partly or exclusively shall, within a period of sixty days from the date of establishment of the National Registry, apply for registration:

Provided that such clinics and banks shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinics and banks have applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(*4*) No clinics or banks shall be registered under this Act, unless the appropriate authority is satisfied that such clinics and banks are in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

Grant of registration.

16. (*1*) On receipt of the application under sub-section (*1*) of section 15, the appropriate authority shall within a period of thirty days—

(*i*) grant registration subject to the provisions of this Act and the rules and regulations made thereunder, and provide a registration number to the applicant; or

(*ii*) reject the application for reasons to be recorded in writing, if such application does not conform to the provisions of this Act or the rules or regulations made thereunder:

Provided that no application shall be rejected unless the applicant has been given an opportunity of being heard in the matter.

(*2*) If the appropriate authority fails to grant the registration or reject the application, as the case may be, as provided under sub-section (*1*), the appropriate authority shall, within a period of seven days from the expiry of the said period of thirty days specified under sub-section (*1*), provide a reason for the failure to process the application.

(*3*) The appropriate authority shall, within a period of one month of registration being granted under this section, intimate such registration to the State Board.

(*4*) The State Board shall maintain a record of all registrations applied for and granted under this section.

(*5*) No registration shall be granted unless the State Board has inspected the premises of the applicant.

(*6*) The registration granted under this section shall be valid for a period of five years from the date of registration granted by the appropriate authority.

(*7*) The certificate of registration shall be displayed by the clinic or bank at a conspicuous place and such certificate shall contain the duration of validity of such registration.

Renewal of registration.

17. The registration granted under section 16, may be renewed for a further period of five years by the appropriate authority, on an application made by the applicant, under such conditions, in such form and on payment of such fee as may be prescribed:

Provided that no application for renewal of registration shall be rejected without giving an opportunity of being heard to the applicant.

Suspension or cancellation of registration.

18. (*1*) The appropriate authority may on receipt of a complaint, issue a notice to the clinic or bank to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(*2*) If after giving a reasonable opportunity of being heard to the clinic or bank, the appropriate authority is satisfied that there has been a breach of the provision of this Act or the rules or regulations made thereunder or if the data obtained from them periodically do not satisfy the provisions of this Act, the rules and regulations made thereunder, it may, without prejudice to any criminal action, suspend its registration for such period as it may deem fit or cancel its registration.

(*3*) On cancellation of registration, a copy of the cancellation letter shall be sent to the respective State Board and accordingly the State Board shall cancel the registration of such clinics and banks.

Appeal.

19. The clinic or bank or the commissioning couple or the woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section 16 or section 18, prefer an appeal against such order to—

(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;

(*b*) the Central Government, where the appeal is against the order of the appropriated authority of a Union territory,

in such manner as may be prescribed.

Power to inspect premises, etc.

20. The National Board, the National Registry and the State Board shall have the power to,—

(*i*) inspect, any premises relating to assisted reproductive technology; or

(*ii*) call for any document or material,

in exercise of their powers and discharge of their functions.

CHAPTER IV

DUTIES OF ASSISTED REPRODUCTIVE TECHNOLOGY CLINIC AND ASSISTED REPRODUCTIVE TECHNOLOGY BANK

General duties of assisted reproductive technology clinics and banks.

21. The clinics and banks shall perform the following duties, namely:—

(*a*) the clinics and banks shall ensure that commissioning couple, woman and donors of gametes are eligible to avail the assisted reproductive technology procedures subject to such criteria as may be prescribed;

(*b*) the clinics shall obtain donor gametes from the banks and such banks shall ensure that the donor has been medically tested for such diseases as may be prescribed;

(*c*) the clinics shall—

(*i*) provide professional counselling to commissioning couple and woman about all the implications and chances of success of assisted reproductive technology procedures in the clinic;

(*ii*) inform the commissioning couple and woman of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy; and

(*iii*) help the commissioning couple or woman to arrive at an informed decision on such matters that would most likely be the best for the commissioning couple;

(*d*) the clinics shall make commissioning couple or woman, aware of the rights of a child born through the use of assisted reproductive technology;

(*e*) the clinics and banks shall ensure that information about the commissioning couple, woman and donor shall be kept confidential and the information about treatment shall not be disclosed to anyone except to the database to be maintained by the National Registry, in a medical emergency at the request of the commissioning couple to whom the information relates, or by an order of a court of competent jurisdiction;

(*f*) every clinic and every bank shall maintain a grievance cell in respect of matters relating to such clinics and banks and the manner of making a compliant before such grievance cell shall be such as may be prescribed;

(*g*) the clinics shall apply the assisted reproductive technology services,—

(*i*) to a woman above the age of twenty-one years and below the age of fifty years;

(*ii*) to a man above the age of twenty-one years and below the age of fifty-five years;

(*h*) the clinics shall issue to the commissioning couple or woman a discharge certificate stating details of the assisted reproductive technology procedure performed on the commissioning couple or woman;

(*i*) all clinics and banks shall co-operate and make available their premises for physical inspection by the National Board, National Registry and State Boards;

(*j*) all clinics and banks shall provide all information related to—

(*i*) enrolment of the commissioning couple, woman and gamete donors;

(*ii*) the procedure being undertaken; and

(*iii*) outcome of the procedure, complications, if any, to the National Registry periodically, in such manner as may be prescribed.

Written informed consent.

22. (*1*) The clinic shall not perform any treatment or procedure without—

(*a*) the written informed consent of all the parties seeking assisted reproductive technology;

(*b*) an insurance coverage of such amount as may be prescribed for a period of twelve months in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999. 41 of 1999.

(*2*) The clinics and banks shall not cryo-preserve any human embryos or gamete, without specific instructions and consent in writing from all the parties seeking assisted reproductive technology, in case of death or incapacity of any of the parties.

(*3*) The clinic shall not use any human reproductive material, except in accordance with the provisions of this Act to create a human embryo or use an *in-vitro* human embryo for any purpose without the specific consent in writing of all the concerned persons to whom the assisted reproductive technology relates.

(*4*) Any of the commissioning couple may withdraw his or her consent under sub-section (*1*), any time before the human embryos or the gametes are transferred to the concerned woman's uterus.

Explanation.—For the purposes of this section, the expressions—

(*i*) "cryo-preserve" means the freezing and storing of gametes, zygotes, embryos, ovarian and testicular tissues;

(*ii*) "insurance" means an arrangement by which a company, individual or commissioning couple undertake to provide a guarantee of compensation for specified loss, damage, complication or death of oocyte donor during the process of oocyte retrieval; and

(*iii*) "parties" includes the commissioning couple or woman and the donor.

Duties of assisted reproductive technology clinics and banks to keep accurate records.

23. The duties of clinics and banks while keeping the records relating to such clinics and banks are as under:—

(*a*) all clinics and banks shall maintain detailed records of all donor's oocytes, sperm or embryos used or unused, the manner and technique of their use in such manner as may be prescribed;

(*b*) all clinics and banks shall, as and when the National Registry is established, submit by online,—

(*i*) all information available with them in regard to progress of the commissioning couple or woman; and

(*ii*) information about number of donors (sperm and oocyte), screened, maintained and supplied and the like to the National Registry within a period of one month from the date of receipt of such information;

(*c*) the records maintained under clause (*a*) shall be maintained for at least a period of ten years, upon the expiry of which the clinic and bank shall transfer the records to a central database of the National Registry:

Provided that if any criminal or other proceedings are instituted against any clinics or banks, the records and all other documents of such clinics and banks shall be preserved till the final disposal of such proceedings;

(*d*) in the event of the closure of any clinic or bank before the expiry of the period of ten years under clause (*c*), such clinic or bank shall immediately transfer the records to the central database of the National Registry; and

(*e*) all such records shall, at all reasonable times, be made available for inspection to the National Board or the National Registry or the State Board or to any other person authorised by the National Board in this behalf.

Duties of assisted reproductive technology clinics using human gametes and embryos.

24. While using human gametes and embryos, the duties to be performed by the clinics and banks shall be as under:—

(*a*) the clinics shall retrieve oocytes in such manner as may be specified by regulations;

(*b*) not more than three oocytes or embryos may be placed in the uterus of a woman during the treatment cycle in such manner as may be specified by regulations;

(*c*) a woman shall not be treated with gametes or embryos derived from more than one man or woman during any one treatment cycle;

(*d*) a clinic shall never mix semen from two individuals for the procedures specified under this Act;

(*e*) the embryos shall not be split and used for twinning to increase the number of available embryos;

(*f*) the collection of gametes posthumously shall be done only if prior consent of the commissioning couple is available in such manner as may be prescribed;

(*g*) the clinic shall not use ovum that are derived from a foetus, in any process of *in-vitro* fertilisation; and

(*h*) such other duties as may be prescribed.

Explanation.—For the purposes of this section, the expression—

(*i*) "fertilisation" means the penetration of the ovum by the spermatozoon and fusion of genetic materials resulting in the development of a zygote; and

(*ii*) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation and ending at birth or abortion.

Pre-implantation Genetic Diagnosis.

25. (*1*) The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases only.

(*2*) The donation of an embryo after Pre-implantation Genetic Diagnosis to an approved research laboratory for research purposes shall be done only-—

(*a*) with the approval of the commissioning couple or woman; and

(*b*) when the embryo suffers from pre-existing, heritable, life-threatening or genetic diseases.

(*3*) The National Board may lay down such other conditions as it deems fit in the interests of the Pre-implantation Genetic testing.

Explanation.—For the purposes of this section, the expression—

(*i*) "Pre-implantation Genetic Diagnosis" means the genetic diagnosis when one or both genetic parents has a known genetic abnormality and testing is performed on an embryo to determine if it also carries a genetic abnormality; and

(*ii*) "Pre-implantation Genetic testing" means a technique used to identify genetic defects in embryos created through *in-vitro* fertilisation before pregnancy.

Sex selection.

26. (*1*) Subject to the provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, the clinic shall not offer to provide a couple or woman with a child of a pre-determined sex. 57 of 1994.

(*2*) It is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology to separate, or yield fractions enriched in sperm of X or Y variations.

(*3*) A person shall not knowingly provide, prescribe or administer anything that shall ensure or increase the probability that an embryo shall be of a particular sex, or that shall identify the sex of an *in-vitro* embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.

Sourcing of gametes by assisted reproductive technology banks.

27. (*1*) The screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done only by a bank registered as an independent entity under the provisions of this Act.

(*2*) The banks shall—

(*a*) obtain semen from males between twenty-one years of age and fifty-five years of age, both inclusive;

(*b*) obtain oocytes from females between twenty-three years of age and thirty-five years of age; and

(*c*) examine the donors for such diseases, as may be prescribed.

(*3*) A bank shall not supply the sperm or oocyte of a single donor to more than one commissioning couple.

(*4*) An oocyte donor shall donate oocytes only once in her life and not more than seven oocyte shall be retrieved from the oocyte donor.

(*5*) All unused oocytes shall be preserved by the banks for use on the same recipient, or given for research to an organisation registered under this Act after seeking written consent from the commissioning couple.

(*6*) A bank shall obtain all necessary information in respect of a sperm or oocyte donor, including the name, Aadhaar number as defined in clause (*a*) of section 2 of the Aadhaar (Targeted Delivery of Financial and other Subsidies, Benefits and Services) Act, 2016, address and any other details of such donor, in such manner as may be prescribed, and shall undertake in writing from such donor about the confidentiality of such information.

18 of 2016.

Explanation.—For the purposes of this section, the expressions—

(*i*) "retrieval" means a procedure of removing oocytes from the ovaries of a woman;

(*ii*) "screening" means the genetic test performed on embryos produced through *in-vitro* fertilisation.

Storage and handling of human gametes and embryos.

28. (*1*) The standards for the storage and handling of gametes, gonadal tissues and human embryos in respect of their security, recording and identification shall be such as may be prescribed.

(*2*) The gamete of a donor or embryo shall be stored for a period of not more than ten years and at the end of such period such gamete or embryo shall be allowed to perish or be donated to a research organisations registered under this Act for research purposes with the consent of the commissioning couple or individual, in such manner as may be prescribed.

Restriction on sale, etc., of human gametes, zygotes and embryos.

29. The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within or outside India shall be prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board.

Explanation.—For the purposes of this section, the expression "zygote" means the fertilised oocyte prior to the first cell division.

Research on human gametes and embryos.

30. (*1*) The use of any human gametes and embryos or their transfer to any country outside India for research shall be absolutely prohibited.

(*2*) The research on human gamete or embryo within India shall be performed in such manner as may be prescribed.

Rights of child born through assisted reproductive technology.

31. (*1*) The child born through assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to a natural child only from the commissioning couple under any law for the time being in force.

(*2*) A donor shall relinquish all parental rights over the child or children which may be born from his or her gamete.

CHAPTER V

OFFENCES AND PENALTIES

Sex selective assisted reproductive technology.

32. (*1*) The clinic, or bank or agent thereof, shall not issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner including internet, regarding facilities of sex selective assisted reproductive technology.

(*2*) Whoever contravenes the provisions of sub-section (*1*) shall be punishable with imprisonment for a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both.

Offences and penalties.

33. (*1*) Any medical geneticist, gynaecologist, registered medical practitioner or any person shall not—

(*a*) abandon, disown or exploit or cause to be abandoned, disowned or exploited in any form the child or children born through assisted reproductive technology;

(*b*) sell human embryos or gametes, run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes;

(*c*) import or help in getting imported in whatsoever manner, the human embryos or human gametes;

(*d*) exploit the commissioning couple, woman or the gamete donor in any form;

(*e*) transfer human embryo into a male person or an animal;

(*f*) sell any human embryo or gamete for the purpose of research; or

(*g*) use any intermediates to obtain gamete donors or purchase gamete donors.

(*2*) Whoever contravenes the provisions of clauses (*a*) to (*g*) of sub-section (*1*), shall be punishable with a fine which shall not be less than five lakh rupees but may extend to ten lakh rupees for the first contravention and for subsequent contravention, shall be punishable with imprisonment for a term which shall not be less than three years but may extend to eight years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees.

Punishment for contravention of provisions of Act or rules for which no specific punishment is provided.

34. Whoever contravenes any of the provisions of this Act or any rules made thereunder, for which no penalty has been provided in this Act shall be punishable as per sub-section (*2*) of section 33.

Cognizance of offences.

35. (*1*) No court shall take cognizance of any offence punishable under this Act, save on a complaint made by the National Board or the State Board or by an officer authorised by it.

(*2*) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Offences to be cognizable and bailable.

36. Notwithstanding anything contained in the Code of Crimincal Procedure, 1973, all the offences under this Act shall be cognizable and bailable. 2 of 1974.

Offences by clinics or banks.

37. (*1*) Where an offence under this Act has been committed by any clinic or bank, the executive head of such clinic or bank shall be deemed to be guilty of an offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(*2*) Notwithstanding anything contained in sub-section (*1*), where an offence under this Act has been committed by any clinic or bank and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of any officer, other than the executive head of the clinic or bank, such officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

CHAPTER VI

MISCELLANEOUS

Power of Central Government to issue directions to National Board, National Registry and appropriate authority.

38. (*1*) The Central Government may, from time to time issue to the National Board, the National Registry and the appropriate authority with respect to the Union territory, such directions as it may think necessary in the interest of the sovereignty and integrity of India, security of the State, friendly relation with foreign States, public order, decency or morality.

(*2*) Without prejudice to the foregoing provisions of this Act, the National Board, the National Registry and the appropriate authority shall, in exercise of its powers or the performance of its functions under this Act, be bound by such directions on questions of policy as the Central Government or the State Government, as the case may be, may give in writing to it from time to time:

Provided that the National Board shall, as far as practicable, be given an opportunity to express its views before any direction is given under sub-section (*1*).

(*3*) If any dispute arises between the Central Government and the National Board as to whether a question is or is not a question of policy, the decision of the Central Government shall be final.

Power of State Government to issue directions to State Board, etc.

39. (*1*) The State Government may, from time to time issue to the State Board and to the appropriate authority with respect to the State Government such directions as it may think necessary in the interest of the sovereignty and integrity of India, security of the State, friendly relation with foreign States, public order, decency or morality.

(*2*) Without prejudice to the foregoing provisions of this Act, the State Board and the appropriate authority shall, in exercise of its powers or the performance of its functions under this Act, be bound by such directions on questions of policy as the State Government may give in writing to it from time to time:

Provided that the State Board and the appropriate authority shall, as far as practicable, be given an opportunity to express its views before any direction is given under sub-section (*1*).

(*3*) If any dispute arises between the State Government and the State Board as to whether a question is or is not a question of policy, the decision of the State Government shall be final.

Power to search and seize records, etc.

40. (*1*) If the National Board, the National Registry or the State Board has reason to believe that an offence under this Act has been or is being committed at any facility using assisted reproductive technology, such Board or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such Board or officer considers necessary, such facility using assisted reproductive technology and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize the same, if the said Board has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

2 of 1974.

(*2*) The provisions of the Code of Criminal Procedure, 1973, relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

Protection of action taken in good faith.

41. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the National Board or the National Registry or the State Board or the appropriate authority or any other officer authorised by the Central

Government or the State Government or the National Board or the National Registry or the State Board or the appropriate authority for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or the rules or regulations made thereunder.

Power to make rules.

42. (*1*) The Central Government may by notification make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(*a*) the other powers and functions of the National Board under clause (*g*) of section 5;

(*b*) the other powers and functions of the State Board under clause (*b*) of sub-section (*2*) of section 8;

(*c*) the terms of office and other conditions of service of scientific, technical and other employees of the National Registry under section 10;

(*d*) the other functions of the National Registry under clause (*d*) of section 11;

(*e*) the other functions of the appropriate authority under clause (*h*) of section 13;

(*f*) the other powers to be exercised by the appropriate authority under clause (*d*) of sub-section (*1*) of section 14;

(*g*) the format for granting of licences to the clinic or bank by the appropriate authority under sub-section (*2*) of section 14;

(*h*) the form and manner in which an application shall be made for registration and fee payable thereof under sub-section (*2*) of section 15;

(*i*) the facilities and equipments to be provided and maintained by the clinics and banks under sub-section (*4*) of section 15;

(*j*) the conditions, form and fee for application of renewal of the registration of clinic or bank under section 17;

(*k*) the manner in which an appeal may be preferred to the State Government or the Central Government under section 19;

(*l*) the criteria for availing the assisted reproductive technology procedures under clause (*a*) of section 21;

(*m*) the medical examination of the diseases with respect to which the donor shall be tested under clause (*b*) of section 21;

(*n*) the manner of making a complaint before a grievance cell and the mechanism adopted by the clinic under clause (*f*) of section 21;

(*o*) the manner of providing information by the clinics and banks to the National Registry under clause (*j*) of section 21;

(*p*) the amount of insurance coverage for oocyte donor under clause (*b*) of sub-section (*1*) of section 22;

(*q*) the manner of maintaining the records by the clinics and banks under clause (*a*) of section 23;

(*r*) the manner of collection of gametes posthumously under clause (*f*) of section 24;

(*s*) the other duties of clinics under clause (*h*) of section 24;

(*t*) the examination of the donors by the assisted reproductive technology banks for diseases under clause (*c*) of sub-section (*2*) of section 27;

(*u*) the manner of obtaining information in respect of a sperm or oocyte donor by a bank under sub-section (*6*) of section 27;

(*v*) the standards for the storage and handling of gametes, human embryos in respect of their security, recording and identification under sub-section (*1*) of section 28;

(*w*) the manner of obtaining the consent of the commissioning couple or individual for perishing or donating the gametes of a donor or embryo under sub-section (*2*) of section 28;

(*x*) the manner of performing research on human gametes or embryo within India under sub-section (*2*) of section 30;

(*y*) the manner of entry and search by the National Board, the National Registry or the State Board or any officer authorised by it under sub-section (*1*) of section 40;

(*z*) any other matter which is to be, or may be prescribed, or in respect of which provision is to be made by rules.

Power to make regulations.

43. (*1*) The National Board may, with the prior approval of the Central Government, by notification make regulations consistent with this Act and the rules made thereunder to carry out the provisions of the Act;

(*2*) In particular, and without prejudice to the generality of the foregoing power, such regulations may provide for—

(*a*) the manner of retrieving the oocytes under clause (*a*) of section 24;

(*b*) the manner of placing the oocytes or embryos in the uterus of a woman under clause (*b*) of section 24; and

(*c*) any other matter which is required to be, specified by regulations or in respect of which provision is to be made by regulations.

Laying of rules, regulations and notifications.

44. Every rule or regulation made and notification issued under this Act shall be laid, as soon as may be after it is made or issued, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rules or regulations or notifications, as the case may be or both Houses agree that the rules or regulations or notifications, as the case may be, should not be made or issued, such rules or regulations or notifications, as the case may be, shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification, as the case may be.

Application of other laws not barred.

45. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 and the Clinical Establishment (Registration and Regulation) Act, 2010 or of any other law for the time being in force.

57 of 1994.
23 of 2010.

Power to remove difficulties.

46. (*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to it to be necessary or expedient for removing the difficulty:

Provided that no such order shall be made after the expiry of a period of three years from the date of commencement of this Act.

(2) Every order made under this section shall, as soon as may be made, be laid before each House of Parliament.

———

DR. REETA VASISHTA,
Secretary to the Govt. of India.

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 25th December, 2021/Pausa 4, 1943 (Saka)

The following Act of Parliament received the assent of the President on the 25th December, 2021 and is hereby published for general information:—

THE SURROGACY (REGULATION) ACT, 2021

(No. 47 OF 2021)

[*25th December*, 2021.]

An Act to constitute National Assisted Reproductive Technology and Surrogacy Board, State Assisted Reproductive Technology and Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

BE it enacted by Parliament in the Seventy-second Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. (*1*) This Act may be called the Surrogacy (Regulation) Act, 2021. Short title and commencement.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. (*1*) In this Act, unless the context otherwise requires,— Definitions.

(*a*) "abandoned child" means a child born out of surrogacy procedure who has been deserted by his intending parents or guardians and declared as abandoned by the appropriate authority after due enquiry;

(*b*) "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses and such other prescribed expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

(*c*) "appropriate authority" means the appropriate authority appointed under section 35;

(*d*) "Assisted Reproductive Technology Act" means the Assisted Reproductive Technology (Regulation) Act, 2021;

(*e*) "Board" means the National Assisted Reproductive Technology and Surrogacy Board constituted under section 17;

(*f*) "clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010; 23 of 2010.

(*g*) "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses and such other prescribed expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

(*h*) "couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;

(*i*) "egg" includes the female gamete;

(*j*) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;

(*k*) "embryologist" means a person who possesses any post-graduate medical qualification or doctoral degree in the field of embryology or clinical embryology from a recognised university with not less than two years of clinical experience;

(*l*) "fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;

(*m*) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;

(*n*) "gamete" means sperm and oocyte;

(*o*) "gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*p*) "implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;

(*q*) "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for medical expenses, health issues, specified loss, damage, illness or death of surrogate mother and such other prescribed expenses incurred on such surrogate mother during the process of surrogacy;

(*r*) "intending couple" means a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy;

(*s*) "intending woman" means an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy;

(*t*) "Member" means a Member of the National Assisted Reproductive Technology and Surrogacy Board or a State Assisted Reproductive Technology and Surrogacy Board, as the case may be;

(*u*) "notification" means a notification published in the Official Gazette;

(*v*) "oocyte" means naturally ovulating oocyte in the female genetic tract;

(*w*) "Paediatrician" means a person who possesses a post-graduate qualification in paediatrics as recognised under the Indian Medical Council Act, 1956; 102 of 1956.

(*x*) "prescribed" means prescribed by rules made under this Act;

(*y*) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register; 102 of 1956.

(*z*) "regulation" means regulations made by the Board under this Act;

(*za*) "sex selection" shall have the same meaning as assigned to it in clause (*o*) of section 2 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*zb*) "State Board" means the State Assisted Reproductive Technology and Surrogacy Board constituted under section 26;

(*zc*) "State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under article 239 of the Constitution;

(*zd*) "surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;

(*ze*) "surrogacy clinic" means surrogacy clinic, centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called, conducting surrogacy procedures in any form;

(*zf*) "surrogacy procedures" means all gynaecological, obstetrical or medical procedures, techniques, tests, practices or services involving handling of human gametes and human embryo in surrogacy;

(*zg*) "surrogate mother" means a woman who agrees to bear a child (who is genetically related to the intending couple or intending woman) through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause (*b*) of clause (*iii*) of section 4;

(*zh*) "zygote" means the fertilised oocyte prior to the first cell division.

(*2*) Words and expressions used herein and not defined in this Act but defined in the Assisted Reproductive Technology Act shall have the meanings respectively assigned to them in that Act.

CHAPTER II

REGULATION OF SURROGACY CLINICS

Prohibition and regulation of surrogacy clinics.

3. On and from the date of commencement of this Act,—

(*i*) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;

(*ii*) no surrogacy clinic, paediatrician, gynaecologist, embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;

(*iii*) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment, who does not possess such qualifications as may be prescribed;

(*iv*) no registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;

(*v*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(*a*) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(*b*) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(*c*) seeks or aimed at seeking a woman to act as a surrogate mother;

(*d*) states or implies that a woman is willing to become a surrogate mother; or

(*e*) advertises commercial surrogacy in print or electronic media or in any other form;

(*vi*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:

Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971; 34 of 1971.

(*vii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:

Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed;

(*viii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall in any form conduct or cause to be conducted sex selection for surrogacy.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

Regulation of surrogacy and surrogacy procedures.

4. On and from the date of commencement of this Act,—

(*i*) no place including a surrogacy clinic shall be used or cause to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause (*ii*) and after satisfying all the conditions specified in clause (*iii*);

(*ii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(*a*) when an intending couple has a medical indication necessitating gestational surrogacy:

Provided that a couple of Indian origin or an intending woman who intends to avail surrogacy, shall obtain a certificate of recommendation from the Board on an application made by the said persons in such form and manner as may be prescribed.

Explanation.—For the purposes of this sub-clause and item (*I*) of sub-clause (*a*) of clause (*iii*) the expression "gestational surrogacy" means a practice whereby a surrogate mother carries a child for the intending couple through implantation of embryo in her womb and the child is not genetically related to the surrogate mother;

(*b*) when it is only for altruistic surrogacy purposes;

(*c*) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(*d*) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(*e*) any other condition or disease as may be specified by regulations made by the Board;

(*iii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(*a*) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(*I*) a certificate of a medical indication in favour of either or both members of the intending couple or intending woman necessitating gestational surrogacy from a District Medical Board.

Explanation.—For the purposes of this item, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, has been passed by a court of the Magistrate

of the first class or above on an application made by the intending couple or the intending woman and the surrogate mother, which shall be the birth affidavit after the surrogate child is born; and

(*III*) an insurance coverage of such amount and in such manner as may be prescribed in favour of the surrogate mother for a period of thirty-six months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999; 41 of 1999.

(*b*) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(*II*) a willing woman shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act:

Provided that the intending couple or the intending woman shall approach the appropriate authority with a willing woman who agrees to act as a surrogate mother;

(*III*) no woman shall act as a surrogate mother by providing her own gametes;

(*IV*) no woman shall act as a surrogate mother more than once in her lifetime:

Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed; and

(*V*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(*c*) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) the intending couple are married and between the age of 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(*II*) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(*III*) such other conditions as may be specified by the regulations.

Prohibition of conducting surrogacy.

5. No person including a relative or husband of a surrogate mother or intending couple or intending woman shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause (*ii*) of section 4.

6. (*1*) No person shall seek or conduct surrogacy procedures unless he has— Written informed consent of surrogate mother.

(*i*) explained all known side effects and after effects of such procedures to the surrogate mother concerned; and

(*ii*) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

(*2*) Notwithstanding anything contained in sub-section (*1*), the surrogate mother shall have an option to withdraw her consent for surrogacy before the implantation of human embryo in her womb.

7. The intending couple or intending woman shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like. Prohibition to abandon child born through surrogacy.

8. A child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple or intending woman and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force. Rights of surrogate child.

9. The number of oocytes or human embryos to be implanted in the uterus of the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed. Number of oocytes or human embryos to be implanted.

10. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed. Prohibition of abortion.

CHAPTER IV

REGISTRATION OF SURROGACY CLINICS

11. (*1*) No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act. Registration of surrogacy clinics.

(*2*) Every application for registration under sub-section (*1*) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(*3*) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in clause (*ii*) of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:

Provided that such clinic shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(*4*) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

12. (*1*) The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed. Certificate of registration.

(*2*) Where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(*3*) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

(*4*) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Cancellation or suspension of registration.

13. (*1*) The appropriate authority may, *suo motu* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(*2*) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provisions of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(*3*) Notwithstanding anything contained in sub-sections (*1*) and (*2*), if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (*1*).

Appeal.

14. The surrogacy clinic or the intending couple or the intending woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section 13 and communication relating to rejection of the certificates under section 4, prefer an appeal against such order to—

(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;

(*b*) the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,

in such manner as may be prescribed.

Establishment of National Assisted Reproductive Technology and Surrogacy Registry.

15. There shall be established a Registry to be called the National Assisted Reproductive Technology and Surrogacy Registry for the purposes of registration of surrogacy clinics under this Act.

Application of provisions of Assisted Reproductive Technology Act with respect to National Registry.

16. The National Assisted Reproductive Technology and Surrogacy Registry referred to in section 15 and to be established under section 9 of the Assisted Reproductive Technology Act shall be the National Registry for the purposes of this Act and the functions to be discharged by the said Registry under the Assisted Reproductive Technology Act shall, *mutatis mutandis,* apply.

CHAPTER V

NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARD AND STATE ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARDS

Constitution of National Assisted Reproductive Technology and Surrogacy Board.

17. (*1*) The Central Government shall, by notification, constitute a Board to be known as the National Assisted Reproductive Technology and Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(*2*) The Board shall consist of—

(*a*) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*;

(*b*) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;

(*c*) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio*;

(*d*) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, *ex officio*;

(*e*) the Director General of Health Services of the Central Government, Member, *ex officio*;

(*f*) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experience as may be prescribed;

(*g*) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*; and

(*h*) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio.*

Term of office of Members.

18. (*1*) The term of office of a Member, other than an *ex officio* Member, shall be—

(*a*) in case of nomination under clause (*c*) of sub-section (*2*) of section 14, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of sub-section (*2*) of section 17, three years:

Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of Board.

19. (*1*) The Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the Board shall meet at least once in six months.

(*2*) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

(*3*) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the Board.

Vacancies, etc., not to invalidate proceedings of Board.

20. No act or proceeding of the Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Board; or

(*b*) any defect in the appointment of a person acting as a Member of the Board; or

(*c*) any irregularity in the procedure of the Board not affecting the merits of the case.

Disqualifications for appointment as Member.

21. (*1*) A person shall be disqualified for being appointed and continued as a Member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a Member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office-bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(*g*) is an office-bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The Members referred to in clause (*f*) of section 17 shall not be removed from their office except by an order of the Central Government on the ground of their proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

(*3*) The Central Government may suspend any Member against whom an inquiry under sub-section (*2*) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with Board for particular purposes.

22. (*1*) The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with the Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of Board.

23. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Eligibility of Member for re-appointment.

24. Subject to other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Functions of Board.

25. The Board shall discharge the following functions, namely:—

(*a*) to advise the Central Government on policy matters relating to surrogacy;

(*b*) to review and monitor the implementation of the Act, and the rules and regulations made thereunder and recommend to the Central Government, changes therein;

(*c*) to lay down the code of conduct to be observed by persons working at surrogacy clinics;

(*d*) to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(*e*) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(*f*) to supervise the functioning of State Assisted Reproductive Technology and Surrogacy Boards; and

(*g*) such other functions as may be prescribed.

Constitution of State Assisted Reproductive Technology and Surrogacy Board.

26. Each State and Union territory having Legislature shall constitute a Board to be known as the State Assisted Reproductive Technology and Surrogacy Board or the Union territory Assisted Reproductive Technology and Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(*i*) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them;

(*ii*) to monitor the implementation of the provisions of the Act, and the rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(*iii*) to send such consolidated reports as may be prescribed, in respect of the various activities undertaken in the State under the Act, to the Board and the Central Government; and

(*iv*) such other functions as may be prescribed.

Composition of State Board.

27. The State Board shall consist of—

(*a*) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;

(*b*) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;

(*c*) Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, *ex officio*;

(*d*) Director-General of Health and Family Welfare of the State Government, member, *ex officio*;

(*e*) three women members of the State Legislative Assembly or Union territory Legislative Council, members, *ex officio*;

(*f*) ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experiences as may be prescribed;

(*g*) an officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of members.

28. (*1*) The term of office of a member, other than an *ex officio* member, shall be—

(*a*) in case of nomination under clause (*e*) of section 27, three years:

Provided that the term of such member shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of section 27, three years:

Provided that the person to be appointed as member under this clause shall be of such age, as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of State Board.

29. (*1*) The State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be specified by the regulations:

Provided that the State Board shall meet at least once in four months.

(*2*) The Chairperson shall preside at the meetings of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

(*3*) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The members, other than *ex officio* members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Vacancies, etc., not to invalidate proceedings of State Board.

30. No act or proceeding of the State Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the State Board; or

(*b*) any defect in the appointment of a person acting as a member of the State Board; or

(*c*) any irregularity in the procedure of the State Board not affecting the merits of the case.

Disqualifications for appointment as member.

31. (*1*) A person shall be disqualified for being appointed and continued as a member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office-bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his functions as a member; or

(*g*) is an office-bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The members referred to in clause (*f*) of section 27 shall not be removed from their office except by an order of the State Government on the ground of their proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the member ought on any such ground to be removed.

(*3*) The State Government may suspend any member against whom an inquiry under sub-section (*2*) is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with State Board for particular purposes.

32. (*1*) The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with it by the State Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a member for any other purpose.

Authentication of orders and other instruments of State Board.

33. All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Eligibility of member for re-appointment.

34. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for re-appointment as such member:

Provided that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.

CHAPTER VI

APPROPRIATE AUTHORITY

Appointment of appropriate authority.

35. (*1*) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act and the Assisted Reproductive Technology Act.

(*2*) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or any part of the State for the purposes of this Act and the Assisted Reproductive Technology Act.

(*3*) The appropriate authority, under sub-section (*1*) or sub-section (*2*), shall,—

(*a*) when appointed for the whole of the State or the Union territory, consist of—

(*i*) an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department—Chairperson, *ex officio*;

(*ii*) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department—Vice Chairperson, *ex officio*;

(*iii*) an eminent woman representing women's organisation—member;

(*iv*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—member; and

(*v*) an eminent registered medical practitioner—member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(*b*) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Functions of appropriate authority.

36. The appropriate authority shall discharge the following functions, namely:—

(*a*) to grant, suspend or cancel registration of a surrogacy clinic;

(*b*) to enforce the standards to be fulfilled by the surrogacy clinics;

(*c*) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act;

(*d*) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter;

(*e*) to supervise the implementation of the provisions of this Act and rules and regulations made thereunder;

(*f*) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(*g*) to take action after investigation of complaints received by it against the surrogacy clinics; and

(*h*) to consider and grant or reject any application under clause (*vi*) of section 3 and sub-clauses (*a*) to (*c*) of clause (*iii*) of section 4 within a period of ninety days.

Powers of appropriate authorities.

37. (*1*) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, and rules and regulations made thereunder;

(*b*) production of any document or material object relating to clause (*a*);

(*c*) search any place suspected to be violating the provisions of this Act, and the rules and regulations made thereunder; and

(*d*) such other powers as may be prescribed.

(*2*) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of license, etc., of the surrogacy clinics in such format as may be prescribed and submit the same to the National Assisted Reproductive Technology and Surrogacy Board.

CHAPTER VII

OFFENCES AND PENALTIES

Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

38. (*1*) No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(*a*) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(*b*) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated, any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(*c*) abandon or disown or exploit or cause to be abandoned, disowned or exploited in any form, the child or children born through surrogacy;

(*d*) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(*e*) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(*f*) import or shall help in getting imported in, whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures; and

(*g*) conduct sex selection in any form for surrogacy.

45 of 1860.

(*2*) Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of clauses (*a*) to (*g*) of sub-section (*1*) by any person shall be an offence punishable with imprisonment for a term which may extend to ten years and with fine which may extend to ten lakh rupees.

(*3*) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Punishment for contravention of provisions of Act.

39. (*1*) Any registered medical practitioner, gynaecologists, paediatrician, embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any

of the provisions of this Act (other than the provisions referred to in section 38) and rules and regulations made thereunder shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(*2*) In case of subsequent or continuation of the offence referred to in sub-section (*1*), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Punishment for not following altruistic surrogacy.

40. Any intending couple or intending woman or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person for not following the altruistic surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

41. Whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been provided in this Act, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Presumption in the case of surrogacy.

42. Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause (*ii*) of section 4 and such person shall be liable for abetment of such offence under section 40 and shall be punishable for the offence specified under that section. 1 of 1872.

Offence to be cognizable, non-baliable and non-compoundable.

43. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable. 2 of 1974.

Cognizance of offences.

44. (*1*) No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—

(*a*) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or

(*b*) a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

(*2*) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Certain provisions of Code of Criminal Procedure, 1973 not to apply.

45. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea bargaining shall not apply to the offences under this Act. 2 of 1974.

CHAPTER VIII

MISCELLANEOUS

Maintenance of records.

46. (*1*) The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed:

Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

(*2*) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Power to search and seize records, etc.

47. (*1*) If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

2 of 1974.

(*2*) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act.

Protection of action taken in good faith.

48. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

Application of other laws not barred.

49. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Power to make rules.

50. (*1*) The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(*a*) the prescribed expenses under clauses (*b*), (*f*) and (*q*) of sub-section (*1*) of section 2;

(*b*) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3;

(*c*) the period and manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3;

(*d*) the form and manner of application for obtaining certificate of recommendation from the Board under proviso to sub-clause (*a*) of clause (*ii*) of section 4;

(*e*) the insurance coverage in favour of the surrogate mother from an insurance company and the manner of such coverage under item (*III*) of sub-clause (*a*) of clause (*iii*) of section 4;

(*f*) the number of attempts of surrogacy or providing of gametes under the proviso to item (*III*) of sub-clause (*b*) of clause (*iii*) of section 4;

(*g*) the form in which consent of a surrogate mother has to be obtained under clause (*ii*) of section 6;

(*h*) the number of oocytes or embryos to be implanted in the uterus of the surrogate mother under section 9;

(*i*) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 10;

(*j*) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (*2*) of section 11;

(*k*) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (*4*) of section 11;

(*l*) the period, manner and form in which a certificate of registration shall be issued under sub-section (*1*) of section 12;

(*m*) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (*3*) of section 12;

(*n*) the manner in which an appeal may be preferred under section 14;

(*o*) the qualifications and experiences of the Members as admissible under clause (*f*) of sub-section (*2*) of section 17;

(*p*) the procedures for conducting an inquiry against the Members under sub-section (*2*) of section 21;

(*q*) the conditions under which a Member of the Board eligible for re-appointment under section 24;

(*r*) the other functions of the Board under clause (*g*) of section 25;

(*s*) the manner in which reports shall be furnished by the State Assisted Reproductive Technology and Surrogacy Board and the Union territory Assisted Reproductive Technology and Surrogacy Board to the Board and the Central Government under clause (*iii*) of section 26;

(*t*) the other functions of the State Board under clause (*iv*) of section 26;

(*u*) the qualifications and experiences of the members as admissible under clause (*f*) of section 27;

(*v*) the age of the person to be appointed as a member, referred to in clause (*f*) of section 27, under the proviso to clause (*b*) of sub-section (*1*) of section 28;

(*w*) the procedures for conducting an inquiry against the members under sub-section (*2*) of section 31;

(*x*) the conditions under which the members of State Board eligible for re-appointment under section 34;

(*y*) empowering the appropriate authority in any other matter under clause (*d*) of section 36;

(*z*) the other powers of appropriate authority under clause (*d*) of sub-section (*1*) of section 37;

(*za*) the particulars of the details of registration of surrogacy clinics, cancellation of registration, etc., in such format under sub-section (*2*) of section 37;

(*zb*) the manner of giving notice by a person under clause (*b*) of sub-section (*1*) of section 44;

(*zc*) the period up to which records, charts, etc., shall be preserved under sub-section (*1*) of section 46;

(*zd*) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (*1*) of section 47; and

(*ze*) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

Power to make regulations.

51. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—

(*a*) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under sub-clause (*d*) of clause (*v*) of section 4;

(*b*) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 19;

(*c*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 22;

(*d*) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (*1*) of section 29;

(*e*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 32; and

(*f*) any other matter which is required to be, or may be, specified by regulations.

Rules and regulations to be laid before Parliament.

52. Every rule made by the Central Government and every regulation made by the Board under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

Transitional provision.

53. Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Power to remove difficulties.

54. (*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

———

DR. REETA VASISHTA,
Secretary to the Govt. of India.

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इस भाग में भिन्न पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Separate paging is given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the 25th December, 2021/Pausa 4, 1943 (Saka)

The following Act of Parliament received the assent of the President on the 25th December, 2021 and is hereby published for general information:—

THE SURROGACY (REGULATION) ACT, 2021

(No. 47 OF 2021)

[*25th December*, 2021.]

An Act to constitute National Assisted Reproductive Technology and Surrogacy Board, State Assisted Reproductive Technology and Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

BE it enacted by Parliament in the Seventy-second Year of the Republic of India as follows:—

CHAPTER I
PRELIMINARY

1. (*1*) This Act may be called the Surrogacy (Regulation) Act, 2021. Short title and commencement.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

2. (*1*) In this Act, unless the context otherwise requires,— Definitions.

(*a*) "abandoned child" means a child born out of surrogacy procedure who has been deserted by his intending parents or guardians and declared as abandoned by the appropriate authority after due enquiry;

(*b*) "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses and such other prescribed expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

(*c*) "appropriate authority" means the appropriate authority appointed under section 35;

(*d*) "Assisted Reproductive Technology Act" means the Assisted Reproductive Technology (Regulation) Act, 2021;

(*e*) "Board" means the National Assisted Reproductive Technology and Surrogacy Board constituted under section 17;

(*f*) "clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010; 23 of 2010.

(*g*) "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses and such other prescribed expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

(*h*) "couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;

(*i*) "egg" includes the female gamete;

(*j*) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;

(*k*) "embryologist" means a person who possesses any post-graduate medical qualification or doctoral degree in the field of embryology or clinical embryology from a recognised university with not less than two years of clinical experience;

(*l*) "fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;

(*m*) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;

(*n*) "gamete" means sperm and oocyte;

(*o*) "gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*p*) "implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;

(*q*) "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for medical expenses, health issues, specified loss, damage, illness or death of surrogate mother and such other prescribed expenses incurred on such surrogate mother during the process of surrogacy;

(*r*) "intending couple" means a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy;

(*s*) "intending woman" means an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy;

(*t*) "Member" means a Member of the National Assisted Reproductive Technology and Surrogacy Board or a State Assisted Reproductive Technology and Surrogacy Board, as the case may be;

(*u*) "notification" means a notification published in the Official Gazette;

(*v*) "oocyte" means naturally ovulating oocyte in the female genetic tract;

(*w*) "Paediatrician" means a person who possesses a post-graduate qualification in paediatrics as recognised under the Indian Medical Council Act, 1956; 102 of 1956.

(*x*) "prescribed" means prescribed by rules made under this Act;

(*y*) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register; 102 of 1956.

(*z*) "regulation" means regulations made by the Board under this Act;

(*za*) "sex selection" shall have the same meaning as assigned to it in clause (*o*) of section 2 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*zb*) "State Board" means the State Assisted Reproductive Technology and Surrogacy Board constituted under section 26;

(*zc*) "State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under article 239 of the Constitution;

(*zd*) "surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;

(*ze*) "surrogacy clinic" means surrogacy clinic, centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called, conducting surrogacy procedures in any form;

(*zf*) "surrogacy procedures" means all gynaecological, obstetrical or medical procedures, techniques, tests, practices or services involving handling of human gametes and human embryo in surrogacy;

(*zg*) "surrogate mother" means a woman who agrees to bear a child (who is genetically related to the intending couple or intending woman) through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause (*b*) of clause (*iii*) of section 4;

(*zh*) "zygote" means the fertilised oocyte prior to the first cell division.

(*2*) Words and expressions used herein and not defined in this Act but defined in the Assisted Reproductive Technology Act shall have the meanings respectively assigned to them in that Act.

CHAPTER II

REGULATION OF SURROGACY CLINICS

Prohibition and regulation of surrogacy clinics.

3. On and from the date of commencement of this Act,—

(*i*) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;

(*ii*) no surrogacy clinic, paediatrician, gynaecologist, embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;

(*iii*) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment, who does not possess such qualifications as may be prescribed;

(*iv*) no registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;

(*v*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(*a*) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(*b*) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(*c*) seeks or aimed at seeking a woman to act as a surrogate mother;

(*d*) states or implies that a woman is willing to become a surrogate mother; or

(*e*) advertises commercial surrogacy in print or electronic media or in any other form;

(*vi*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:

Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971; 34 of 1971.

(*vii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:

Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed;

(*viii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall in any form conduct or cause to be conducted sex selection for surrogacy.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

Regulation of surrogacy and surrogacy procedures.

4. On and from the date of commencement of this Act,—

(*i*) no place including a surrogacy clinic shall be used or cause to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause (*ii*) and after satisfying all the conditions specified in clause (*iii*);

(*ii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(*a*) when an intending couple has a medical indication necessitating gestational surrogacy:

Provided that a couple of Indian origin or an intending woman who intends to avail surrogacy, shall obtain a certificate of recommendation from the Board on an application made by the said persons in such form and manner as may be prescribed.

Explanation.—For the purposes of this sub-clause and item (*I*) of sub-clause (*a*) of clause (*iii*) the expression "gestational surrogacy" means a practice whereby a surrogate mother carries a child for the intending couple through implantation of embryo in her womb and the child is not genetically related to the surrogate mother;

(*b*) when it is only for altruistic surrogacy purposes;

(*c*) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(*d*) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(*e*) any other condition or disease as may be specified by regulations made by the Board;

(*iii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(*a*) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(*I*) a certificate of a medical indication in favour of either or both members of the intending couple or intending woman necessitating gestational surrogacy from a District Medical Board.

Explanation.—For the purposes of this item, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, has been passed by a court of the Magistrate

of the first class or above on an application made by the intending couple or the intending woman and the surrogate mother, which shall be the birth affidavit after the surrogate child is born; and

(*III*) an insurance coverage of such amount and in such manner as may be prescribed in favour of the surrogate mother for a period of thirty-six months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999; 41 of 1999.

(*b*) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(*II*) a willing woman shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act:

Provided that the intending couple or the intending woman shall approach the appropriate authority with a willing woman who agrees to act as a surrogate mother;

(*III*) no woman shall act as a surrogate mother by providing her own gametes;

(*IV*) no woman shall act as a surrogate mother more than once in her lifetime:

Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed; and

(*V*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(*c*) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) the intending couple are married and between the age of 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(*II*) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(*III*) such other conditions as may be specified by the regulations.

Prohibition of conducting surrogacy.

5. No person including a relative or husband of a surrogate mother or intending couple or intending woman shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause (*ii*) of section 4.

6. (*1*) No person shall seek or conduct surrogacy procedures unless he has— Written informed consent of surrogate mother.

(*i*) explained all known side effects and after effects of such procedures to the surrogate mother concerned; and

(*ii*) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

(*2*) Notwithstanding anything contained in sub-section (*1*), the surrogate mother shall have an option to withdraw her consent for surrogacy before the implantation of human embryo in her womb.

7. The intending couple or intending woman shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like. Prohibition to abandon child born through surrogacy.

8. A child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple or intending woman and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force. Rights of surrogate child.

9. The number of oocytes or human embryos to be implanted in the uterus of the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed. Number of oocytes or human embryos to be implanted.

10. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed. Prohibition of abortion.

CHAPTER IV

REGISTRATION OF SURROGACY CLINICS

11. (*1*) No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act. Registration of surrogacy clinics.

(*2*) Every application for registration under sub-section (*1*) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(*3*) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in clause (*ii*) of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:

Provided that such clinic shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(*4*) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

12. (*1*) The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed. Certificate of registration.

(*2*) Where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(*3*) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

(*4*) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Cancellation or suspension of registration.

13. (*1*) The appropriate authority may, *suo motu* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(*2*) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provisions of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(*3*) Notwithstanding anything contained in sub-sections (*1*) and (*2*), if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (*1*).

Appeal.

14. The surrogacy clinic or the intending couple or the intending woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section 13 and communication relating to rejection of the certificates under section 4, prefer an appeal against such order to—

(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;

(*b*) the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,

in such manner as may be prescribed.

Establishment of National Assisted Reproductive Technology and Surrogacy Registry.

15. There shall be established a Registry to be called the National Assisted Reproductive Technology and Surrogacy Registry for the purposes of registration of surrogacy clinics under this Act.

Application of provisions of Assisted Reproductive Technology Act with respect to National Registry.

16. The National Assisted Reproductive Technology and Surrogacy Registry referred to in section 15 and to be established under section 9 of the Assisted Reproductive Technology Act shall be the National Registry for the purposes of this Act and the functions to be discharged by the said Registry under the Assisted Reproductive Technology Act shall, *mutatis mutandis,* apply.

CHAPTER V

NATIONAL ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARD AND STATE ASSISTED REPRODUCTIVE TECHNOLOGY AND SURROGACY BOARDS

Constitution of National Assisted Reproductive Technology and Surrogacy Board.

17. (*1*) The Central Government shall, by notification, constitute a Board to be known as the National Assisted Reproductive Technology and Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(*2*) The Board shall consist of—

(*a*) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*;

(*b*) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;

(*c*) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio*;

(*d*) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, *ex officio*;

(*e*) the Director General of Health Services of the Central Government, Member, *ex officio*;

(*f*) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experience as may be prescribed;

(*g*) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*; and

(*h*) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of Members.

18. (*1*) The term of office of a Member, other than an *ex officio* Member, shall be—

(*a*) in case of nomination under clause (*c*) of sub-section (*2*) of section 14, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of sub-section (*2*) of section 17, three years:

Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of Board.

19. (*1*) The Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the Board shall meet at least once in six months.

(*2*) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

(*3*) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the Board.

Vacancies, etc., not to invalidate proceedings of Board.

20. No act or proceeding of the Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Board; or

(*b*) any defect in the appointment of a person acting as a Member of the Board; or

(*c*) any irregularity in the procedure of the Board not affecting the merits of the case.

Disqualifications for appointment as Member.

21. (*1*) A person shall be disqualified for being appointed and continued as a Member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a Member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office-bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(*g*) is an office-bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The Members referred to in clause (*f*) of section 17 shall not be removed from their office except by an order of the Central Government on the ground of their proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

(*3*) The Central Government may suspend any Member against whom an inquiry under sub-section (*2*) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with Board for particular purposes.

22. (*1*) The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with the Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of Board.

23. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Eligibility of Member for re-appointment.

24. Subject to other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Functions of Board.

25. The Board shall discharge the following functions, namely:—

(*a*) to advise the Central Government on policy matters relating to surrogacy;

(*b*) to review and monitor the implementation of the Act, and the rules and regulations made thereunder and recommend to the Central Government, changes therein;

(*c*) to lay down the code of conduct to be observed by persons working at surrogacy clinics;

(*d*) to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(*e*) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(*f*) to supervise the functioning of State Assisted Reproductive Technology and Surrogacy Boards; and

(*g*) such other functions as may be prescribed.

Constitution of State Assisted Reproductive Technology and Surrogacy Board.

26. Each State and Union territory having Legislature shall constitute a Board to be known as the State Assisted Reproductive Technology and Surrogacy Board or the Union territory Assisted Reproductive Technology and Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(*i*) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them;

(*ii*) to monitor the implementation of the provisions of the Act, and the rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(*iii*) to send such consolidated reports as may be prescribed, in respect of the various activities undertaken in the State under the Act, to the Board and the Central Government; and

(*iv*) such other functions as may be prescribed.

Composition of State Board.

27. The State Board shall consist of—

(*a*) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;

(*b*) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;

(*c*) Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, *ex officio*;

(*d*) Director-General of Health and Family Welfare of the State Government, member, *ex officio*;

(*e*) three women members of the State Legislative Assembly or Union territory Legislative Council, members, *ex officio*;

(*f*) ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experiences as may be prescribed;

(*g*) an officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of members.

28. (*1*) The term of office of a member, other than an *ex officio* member, shall be—

(*a*) in case of nomination under clause (*e*) of section 27, three years:

Provided that the term of such member shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of section 27, three years:

Provided that the person to be appointed as member under this clause shall be of such age, as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of State Board.

29. (*1*) The State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be specified by the regulations:

Provided that the State Board shall meet at least once in four months.

(*2*) The Chairperson shall preside at the meetings of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

(*3*) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The members, other than *ex officio* members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Vacancies, etc., not to invalidate proceedings of State Board.

30. No act or proceeding of the State Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the State Board; or

(*b*) any defect in the appointment of a person acting as a member of the State Board; or

(*c*) any irregularity in the procedure of the State Board not affecting the merits of the case.

Disqualifications for appointment as member.

31. (*1*) A person shall be disqualified for being appointed and continued as a member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office-bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his functions as a member; or

(*g*) is an office-bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The members referred to in clause (*f*) of section 27 shall not be removed from their office except by an order of the State Government on the ground of their proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the member ought on any such ground to be removed.

(*3*) The State Government may suspend any member against whom an inquiry under sub-section (*2*) is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with State Board for particular purposes.

32. (*1*) The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with it by the State Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a member for any other purpose.

Authentication of orders and other instruments of State Board.

33. All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Eligibility of member for re-appointment.

34. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for re-appointment as such member:

Provided that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.

CHAPTER VI

APPROPRIATE AUTHORITY

Appointment of appropriate authority.

35. (*1*) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act and the Assisted Reproductive Technology Act.

(*2*) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or any part of the State for the purposes of this Act and the Assisted Reproductive Technology Act.

(*3*) The appropriate authority, under sub-section (*1*) or sub-section (*2*), shall,—

(*a*) when appointed for the whole of the State or the Union territory, consist of—

(*i*) an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department—Chairperson, *ex officio*;

(*ii*) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department—Vice Chairperson, *ex officio*;

(*iii*) an eminent woman representing women's organisation—member;

(*iv*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—member; and

(*v*) an eminent registered medical practitioner—member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(*b*) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Functions of appropriate authority.

36. The appropriate authority shall discharge the following functions, namely:—

(*a*) to grant, suspend or cancel registration of a surrogacy clinic;

(*b*) to enforce the standards to be fulfilled by the surrogacy clinics;

(*c*) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act;

(*d*) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter;

(*e*) to supervise the implementation of the provisions of this Act and rules and regulations made thereunder;

(*f*) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(*g*) to take action after investigation of complaints received by it against the surrogacy clinics; and

(*h*) to consider and grant or reject any application under clause (*vi*) of section 3 and sub-clauses (*a*) to (*c*) of clause (*iii*) of section 4 within a period of ninety days.

Powers of appropriate authorities.

37. (*1*) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, and rules and regulations made thereunder;

(*b*) production of any document or material object relating to clause (*a*);

(*c*) search any place suspected to be violating the provisions of this Act, and the rules and regulations made thereunder; and

(*d*) such other powers as may be prescribed.

(*2*) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of license, etc., of the surrogacy clinics in such format as may be prescribed and submit the same to the National Assisted Reproductive Technology and Surrogacy Board.

CHAPTER VII

OFFENCES AND PENALTIES

Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

38. (*1*) No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(*a*) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(*b*) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated, any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(*c*) abandon or disown or exploit or cause to be abandoned, disowned or exploited in any form, the child or children born through surrogacy;

(*d*) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(*e*) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(*f*) import or shall help in getting imported in, whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures; and

(*g*) conduct sex selection in any form for surrogacy.

45 of 1860.

(*2*) Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of clauses (*a*) to (*g*) of sub-section (*1*) by any person shall be an offence punishable with imprisonment for a term which may extend to ten years and with fine which may extend to ten lakh rupees.

(*3*) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Punishment for contravention of provisions of Act.

39. (*1*) Any registered medical practitioner, gynaecologists, paediatrician, embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any

of the provisions of this Act (other than the provisions referred to in section 38) and rules and regulations made thereunder shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(*2*) In case of subsequent or continuation of the offence referred to in sub-section (*1*), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Punishment for not following altruistic surrogacy.

40. Any intending couple or intending woman or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person for not following the altruistic surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

41. Whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been provided in this Act, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Presumption in the case of surrogacy.

42. Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause (*ii*) of section 4 and such person shall be liable for abetment of such offence under section 40 and shall be punishable for the offence specified under that section. 1 of 1872.

Offence to be cognizable, non-baliable and non-compoundable.

43. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable. 2 of 1974.

Cognizance of offences.

44. (*1*) No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—

(*a*) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or

(*b*) a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

(*2*) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Certain provisions of Code of Criminal Procedure, 1973 not to apply.

45. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea bargaining shall not apply to the offences under this Act. 2 of 1974.

CHAPTER VIII

MISCELLANEOUS

Maintenance of records.

46. (*1*) The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed:

Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

(*2*) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Power to search and seize records, etc.

47. (*1*) If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

2 of 1974.

(*2*) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act.

Protection of action taken in good faith.

48. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

Application of other laws not barred.

49. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Power to make rules.

50. (*1*) The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(*a*) the prescribed expenses under clauses (*b*), (*f*) and (*q*) of sub-section (*1*) of section 2;

(*b*) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3;

(*c*) the period and manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3;

(*d*) the form and manner of application for obtaining certificate of recommendation from the Board under proviso to sub-clause (*a*) of clause (*ii*) of section 4;

(*e*) the insurance coverage in favour of the surrogate mother from an insurance company and the manner of such coverage under item (*III*) of sub-clause (*a*) of clause (*iii*) of section 4;

(*f*) the number of attempts of surrogacy or providing of gametes under the proviso to item (*III*) of sub-clause (*b*) of clause (*iii*) of section 4;

(*g*) the form in which consent of a surrogate mother has to be obtained under clause (*ii*) of section 6;

(*h*) the number of oocytes or embryos to be implanted in the uterus of the surrogate mother under section 9;

(*i*) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 10;

(*j*) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (*2*) of section 11;

(*k*) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (*4*) of section 11;

(*l*) the period, manner and form in which a certificate of registration shall be issued under sub-section (*1*) of section 12;

(*m*) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (*3*) of section 12;

(*n*) the manner in which an appeal may be preferred under section 14;

(*o*) the qualifications and experiences of the Members as admissible under clause (*f*) of sub-section (*2*) of section 17;

(*p*) the procedures for conducting an inquiry against the Members under sub-section (*2*) of section 21;

(*q*) the conditions under which a Member of the Board eligible for re-appointment under section 24;

(*r*) the other functions of the Board under clause (*g*) of section 25;

(*s*) the manner in which reports shall be furnished by the State Assisted Reproductive Technology and Surrogacy Board and the Union territory Assisted Reproductive Technology and Surrogacy Board to the Board and the Central Government under clause (*iii*) of section 26;

(*t*) the other functions of the State Board under clause (*iv*) of section 26;

(*u*) the qualifications and experiences of the members as admissible under clause (*f*) of section 27;

(*v*) the age of the person to be appointed as a member, referred to in clause (*f*) of section 27, under the proviso to clause (*b*) of sub-section (*1*) of section 28;

(*w*) the procedures for conducting an inquiry against the members under sub-section (*2*) of section 31;

(*x*) the conditions under which the members of State Board eligible for re-appointment under section 34;

(*y*) empowering the appropriate authority in any other matter under clause (*d*) of section 36;

(*z*) the other powers of appropriate authority under clause (*d*) of sub-section (*1*) of section 37;

(*za*) the particulars of the details of registration of surrogacy clinics, cancellation of registration, etc., in such format under sub-section (*2*) of section 37;

(*zb*) the manner of giving notice by a person under clause (*b*) of sub-section (*1*) of section 44;

(*zc*) the period up to which records, charts, etc., shall be preserved under sub-section (*1*) of section 46;

(*zd*) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (*1*) of section 47; and

(*ze*) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

Power to make regulations.

51. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—

(*a*) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under sub-clause (*d*) of clause (*v*) of section 4;

(*b*) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 19;

(*c*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 22;

(*d*) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (*1*) of section 29;

(*e*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 32; and

(*f*) any other matter which is required to be, or may be, specified by regulations.

Rules and regulations to be laid before Parliament.

52. Every rule made by the Central Government and every regulation made by the Board under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

Transitional provision.

53. Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Power to remove difficulties.

54. (*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

———

DR. REETA VASISHTA,
Secretary to the Govt. of India.

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[TRUE COPY]

Universal Declaration of Human Rights

Preamble

Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Whereas disregard and contempt for human rights have resulted in barbarous acts which have outraged the conscience of mankind, and the advent of a world in which human beings shall enjoy freedom of speech and belief and freedom from fear and want has been proclaimed as the highest aspiration of the common people,

Whereas it is essential, if man is not to be compelled to have recourse, as a last resort, to rebellion against tyranny and oppression, that human rights should be protected by the rule of law,

Whereas it is essential to promote the development of friendly relations between nations,

Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom,

Whereas Member States have pledged themselves to achieve, in cooperation with the United Nations, the promotion of universal respect for and observance of human rights and fundamental freedoms,

Whereas a common understanding of these rights and freedoms is of the greatest importance for the full realization of this pledge,

Now, therefore,

The General Assembly,

Proclaims this Universal Declaration of Human Rights as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by

teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction.

Article I

All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

Article 2

Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty.

Article 3

Everyone has the right to life, liberty and the security of person.

Article 4

No one shall be held in slavery or servitude; slavery and the slave trade shall be prohibited in all their forms.

Article 5

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.

Article 6

Everyone has the right to recognition everywhere as a person before the law.

Article 7

All are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination.

Article 8

Everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law.

Article 9

No one shall be subjected to arbitrary arrest, detention or exile.

Article 10

Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights and obligations and of any criminal charge against him.

Article 11

1. Everyone charged with a penal offence has the right to be presumed innocent until proved guilty according to law in a public trial at which he has had all the guarantees necessary for his defence.
2. No one shall be held guilty of any penal offence on account of any act or omission which did not constitute a penal offence, under national or international law, at the time when it was committed. Nor shall a heavier

penalty be imposed than the one that was applicable at the time the penal offence was committed.

Article 12

No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

Article 13

1. Everyone has the right to freedom of movement and residence within the borders of each State.
2. Everyone has the right to leave any country, including his own, and to return to his country.

Article 14

1. Everyone has the right to seek and to enjoy in other countries asylum from persecution.
2. This right may not be invoked in the case of prosecutions genuinely arising from non-political crimes or from acts contrary to the purposes and principles of the United Nations.

Article 15

1. Everyone has the right to a nationality.
2. No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality.

Article 16

1. Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and to found a family. They are entitled to equal rights as to marriage, during marriage and at its dissolution.
2. Marriage shall be entered into only with the free and full consent of the intending spouses.
3. The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

Article 17

1. Everyone has the right to own property alone as well as in association with others.
2. No one shall be arbitrarily deprived of his property.

Article 18

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance.

Article 19

Everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive and impart information and ideas through any media and regardless of frontiers.

Article 20

1. Everyone has the right to freedom of peaceful assembly and association.
2. No one may be compelled to belong to an association.

Article 21

1. Everyone has the right to take part in the government of his country, directly or through freely chosen representatives.
2. Everyone has the right to equal access to public service in his country.
3. The will of the people shall be the basis of the authority of government; this will shall be expressed in periodic and genuine elections which shall be by universal and equal suffrage and shall be held by secret vote or by equivalent free voting procedures.

Article 22

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.

Article 23

1. Everyone has the right to work, to free choice of employment, to just and favourable conditions of work and to protection against unemployment.
2. Everyone, without any discrimination, has the right to equal pay for equal work.
3. Everyone who works has the right to just and favourable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.
4. Everyone has the right to form and to join trade unions for the protection of his interests.

Article 24

Everyone has the right to rest and leisure, including reasonable limitation of working hours and periodic holidays with pay.

Article 25

1. Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
2. Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Article 26

1. Everyone has the right to education. Education shall be free, at least in the elementary and fundamental stages. Elementary education shall be compulsory. Technical and professional education shall be made generally available and higher education shall be equally accessible to all on the basis of merit.
2. Education shall be directed to the full development of the human personality and to the strengthening of respect for human rights and fundamental freedoms. It shall promote understanding, tolerance and friendship among all nations, racial or religious groups, and shall further the activities of the United Nations for the maintenance of peace.
3. Parents have a prior right to choose the kind of education that shall be given to their children.

Article 27

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 28

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.

Article 29

1. Everyone has duties to the community in which alone the free and full development of his personality is possible.
2. In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.
3. These rights and freedoms may in no case be exercised contrary to the purposes and principles of the United Nations.

Article 30

Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.

[TRUE TYPED COPY]

International Covenant on Civil and Political Rights

Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 23 March 1976, in accordance with Article 49

Preamble

The States Parties to the present Covenant,

Considering that, in accordance with the principles proclaimed in the Charter of the United Nations, recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world,

Recognizing that these rights derive from the inherent dignity of the human person,

Recognizing that, in accordance with the Universal Declaration of Human Rights, the ideal of free human beings enjoying civil and political freedom and freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his civil and political rights, as well as his economic, social and cultural rights,

Considering the obligation of States under the Charter of the United Nations to promote universal respect for, and observance of, human rights and freedoms,

Realizing that the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant,

Agree upon the following articles:

PART I

Article 1

1. All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.

2. All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.

3. The States Parties to the present Covenant, including those having responsibility for the administration of Non-Self-Governing and Trust Territories, shall promote the realization of the right of self-determination, and shall respect that right, in conformity with the provisions of the Charter of the United Nations.

PART II

Article 2

1. Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

2. Where not already provided for by existing legislative or other measures, each State Party to the present Covenant undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such laws or other measures as may be necessary to give effect to the rights recognized in the present Covenant.

3. Each State Party to the present Covenant undertakes:

(a) To ensure that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy, notwithstanding that the violation has been committed by persons acting in an official capacity;

(b) To ensure that any person claiming such a remedy shall have his right thereto determined by competent judicial, administrative or legislative authorities, or by any other competent authority provided for by the legal system of the State, and to develop the possibilities of judicial remedy;

(c) To ensure that the competent authorities shall enforce such remedies when granted.

Article 3

The States Parties to the present Covenant undertake to ensure the equal right of men and women to the enjoyment of all civil and political rights set forth in the present Covenant.

Article 4

1 . In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin.

2. No derogation from articles 6, 7, 8 (paragraphs I and 2), 11, 15, 16 and 18 may be made under this provision.

3. Any State Party to the present Covenant availing itself of the right of derogation shall immediately inform the other States Parties to the present Covenant, through the intermediary of the Secretary-General of the United Nations, of the provisions from which it has derogated and of the reasons by which it was actuated. A further communication shall be made, through the same intermediary, on the date on which it terminates such derogation.

Article 5

1. Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein or at their limitation to a greater extent than is provided for in the present Covenant.

2. There shall be no restriction upon or derogation from any of the fundamental human rights recognized or existing in any State Party to the present Covenant pursuant to law, conventions, regulations or custom on the pretext that the present Covenant does not recognize such rights or that it recognizes them to a lesser extent.

PART III

Article 6

1. Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.

2. In countries which have not abolished the death penalty, sentence of death may be imposed only for the most serious crimes in accordance with the law in force at the time of the commission of the crime and not contrary to the provisions of the present Covenant and to the Convention on the Prevention and Punishment of the Crime of Genocide. This penalty can only be carried out pursuant to a final judgement rendered by a competent court.

3. When deprivation of life constitutes the crime of genocide, it is understood that nothing in this article shall authorize any State Party to the present Covenant to derogate in any way from any obligation assumed under the provisions of the Convention on the Prevention and Punishment of the Crime of Genocide.

4. Anyone sentenced to death shall have the right to seek pardon or commutation of the sentence. Amnesty, pardon or commutation of the sentence of death may be granted in all cases.

5. Sentence of death shall not be imposed for crimes committed by persons below eighteen years of age and shall not be carried out on pregnant women.

6. Nothing in this article shall be invoked to delay or to prevent the abolition of capital punishment by any State Party to the present Covenant.

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

Article 8

1. No one shall be held in slavery; slavery and the slave-trade in all their forms shall be prohibited.

2. No one shall be held in servitude.

3.

(a) No one shall be required to perform forced or compulsory labour;

(b) Paragraph 3 (a) shall not be held to preclude, in countries where imprisonment with hard labour may be imposed as a punishment for a crime, the performance of hard labour in pursuance of a sentence to such punishment by a competent court;

(c) For the purpose of this paragraph the term "forced or compulsory labour" shall not include:

(i) Any work or service, not referred to in subparagraph (b), normally required of a person who is under detention in consequence of a lawful order of a court, or of a person during conditional release from such detention;

(ii) Any service of a military character and, in countries where conscientious objection is recognized, any national service required by law of conscientious objectors;

(iii) Any service exacted in cases of emergency or calamity threatening the life or well-being of the community;

(iv) Any work or service which forms part of normal civil obligations.

Article 9

1. Everyone has the right to liberty and security of person. No one shall be subjected to arbitrary arrest or detention. No one shall be deprived of his liberty except on such grounds and in accordance with such procedure as are established by law.

2. Anyone who is arrested shall be informed, at the time of arrest, of the reasons for his arrest and shall be promptly informed of any charges against him.

3. Anyone arrested or detained on a criminal charge shall be brought promptly before a judge or other officer authorized by law to exercise judicial power and shall be entitled to trial within a reasonable time or to release. It shall not be the general rule that persons awaiting trial shall be detained in custody, but release may be subject to guarantees to appear for trial, at any other stage of the judicial proceedings, and, should occasion arise, for execution of the judgement.

4. Anyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings before a court, in order that that court may decide without delay on the lawfulness of his detention and order his release if the detention is not lawful.

5. Anyone who has been the victim of unlawful arrest or detention shall have an enforceable right to compensation.

Article 10

1. All persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person.

2.

(a) Accused persons shall, save in exceptional circumstances, be segregated from convicted persons and shall be subject to separate treatment appropriate to their status as unconvicted persons;

(b) Accused juvenile persons shall be separated from adults and brought as speedily as possible for adjudication.

3. The penitentiary system shall comprise treatment of prisoners the essential aim of which shall be their reformation and social rehabilitation. Juvenile offenders shall be segregated from adults and be accorded treatment appropriate to their age and legal status.

Article 11

No one shall be imprisoned merely on the ground of inability to fulfil a contractual obligation. Article 12

1. Everyone lawfully within the territory of a State shall, within that territory, have the right to liberty of movement and freedom to choose his residence.

2. Everyone shall be free to leave any country, including his own.

3. The above-mentioned rights shall not be subject to any restrictions except those which are provided by law, are necessary to protect national security, public order (ordre public), public health or morals or the rights and freedoms of others, and are consistent with the other rights recognized in the present Covenant.

4. No one shall be arbitrarily deprived of the right to enter his own country.

Article 13

An alien lawfully in the territory of a State Party to the present Covenant may be expelled therefrom only in pursuance of a decision reached in accordance with law and shall, except where compelling reasons of national security otherwise require, be allowed to submit the reasons against his expulsion and to have his case reviewed by, and be represented for the purpose before, the competent authority or a person or persons especially designated by the competent authority.

Article 14

1. All persons shall be equal before the courts and tribunals. In the determination of any criminal charge against him, or of his rights and obligations in a suit at law, everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. The press and the public may be excluded from all or part of a trial for reasons of morals, public order (ordre public) or national security in a democratic society, or when the interest of the private lives of the parties so requires, or to the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice; but any judgement rendered in a criminal case or in a suit at law shall be made public except where the interest of juvenile persons otherwise requires or the proceedings concern matrimonial disputes or the guardianship of children.

2. Everyone charged with a criminal offence shall have the right to be presumed innocent until proved guilty according to law.

3. In the determination of any criminal charge against him, everyone shall be entitled to the following minimum guarantees, in full equality: (a) To be informed promptly and in detail in a language which he understands of the nature and cause of the charge against him;

(b) To have adequate time and facilities for the preparation of his defence and to communicate with counsel of his own choosing;

(c) To be tried without undue delay;

(d) To be tried in his presence, and to defend himself in person or through legal assistance of his own choosing; to be informed, if he does not have legal assistance, of this right; and to have legal assistance assigned to him, in any case where the interests of justice so require, and without payment by him in any such case if he does not have sufficient means to pay for it;

(e) To examine, or have examined, the witnesses against him and to obtain the attendance and examination of witnesses on his behalf under the same conditions as witnesses against him;

(f) To have the free assistance of an interpreter if he cannot understand or speak the language used in court;

(g) Not to be compelled to testify against himself or to confess guilt.

4. In the case of juvenile persons, the procedure shall be such as will take account of their age and the desirability of promoting their rehabilitation. 5. Everyone convicted of a crime shall have the right to his conviction and sentence being reviewed by a higher tribunal according to law.

6. When a person has by a final decision been convicted of a criminal offence and when subsequently his conviction has been reversed or he has been pardoned on the ground that a new or newly discovered fact shows conclusively that there has been a miscarriage of justice, the person who has suffered punishment as a result of such conviction shall be compensated according to law, unless it is proved that the non-disclosure of the unknown fact in time is wholly or partly attributable to him.

7. No one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country.

Article 15

1 . No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence, under national or international law, at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time when the criminal offence was committed. If, subsequent to the commission of the offence, provision is made by law for the imposition of the lighter penalty, the offender shall benefit thereby.

2. Nothing in this article shall prejudice the trial and punishment of any person for any act or omission which, at the time when it was committed, was criminal according to the general principles of law recognized by the community of nations.

Article 16

Everyone shall have the right to recognition everywhere as a person before the law.

Article 17

1. No one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.

2. Everyone has the right to the protection of the law against such interference or attacks.

Article 18

1. Everyone shall have the right to freedom of thought, conscience and religion. This right shall include freedom to have or to adopt a religion or belief of his choice, and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in worship, observance, practice and teaching.

2. No one shall be subject to coercion which would impair his freedom to have or to adopt a religion or belief of his choice.

3. Freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others.

4. The States Parties to the present Covenant undertake to have respect for the liberty of parents and, when applicable, legal guardians to ensure the religious and moral education of their children in conformity with their own convictions.

Article 19

1. Everyone shall have the right to hold opinions without interference.

2. Everyone shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of his choice.

3. The exercise of the rights provided for in paragraph 2 of this article carries with it special duties and responsibilities. It may therefore be subject to certain restrictions, but these shall only be such as are provided by law and are necessary:

(a) For respect of the rights or reputations of others;

(b) For the protection of national security or of public order (ordre public), or of public health or morals.

Article 20

1. Any propaganda for war shall be prohibited by law.

2. Any advocacy of national, racial or religious hatred that constitutes incitement to discrimination, hostility or violence shall be prohibited by law.

Article 21

The right of peaceful assembly shall be recognized. No restrictions may be placed on the exercise of this right other than those imposed in conformity with the law and which are necessary in a democratic society in the interests of national security or public safety, public order (ordre public), the protection of public health or morals or the protection of the rights and freedoms of others.

Article 22

1. Everyone shall have the right to freedom of association with others, including the right to form and join trade unions for the protection of his interests.

2. No restrictions may be placed on the exercise of this right other than those which are prescribed by law and which are necessary in a democratic society in the interests of national security or public safety, public order (ordre public), the protection of public health or morals or the protection of the rights and freedoms of others. This article shall not prevent the imposition of lawful restrictions on members of the armed forces and of the police in their exercise of this right.

3. Nothing in this article shall authorize States Parties to the International Labour Organisation Convention of 1948 concerning Freedom of Association and Protection of the Right to Organize to take legislative measures which would prejudice, or to apply the law in such a manner as to prejudice, the guarantees provided for in that Convention.

Article 23

1. The family is the natural and fundamental group unit of society and is entitled to protection by society and the State.

2. The right of men and women of marriageable age to marry and to found a family shall be recognized.

3. No marriage shall be entered into without the free and full consent of the intending spouses.

4. States Parties to the present Covenant shall take appropriate steps to ensure equality of rights and responsibilities of spouses as to marriage, during marriage and at its dissolution. In the case of dissolution, provision shall be made for the necessary protection of any children.

Article 24

1. Every child shall have, without any discrimination as to race, colour, sex, language, religion, national or social origin, property or birth, the right to such measures of protection as are required by his status as a minor, on the part of his family, society and the State.

2. Every child shall be registered immediately after birth and shall have a name.

3. Every child has the right to acquire a nationality.

Article 25

Every citizen shall have the right and the opportunity, without any of the distinctions mentioned in article 2 and without unreasonable restrictions:

(a) To take part in the conduct of public affairs, directly or through freely chosen representatives;

(b) To vote and to be elected at genuine periodic elections which shall be by universal and equal suffrage and shall be held by secret ballot, guaranteeing the free expression of the will of the electors;

(c) To have access, on general terms of equality, to public service in his country.

Article 26

All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all

persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Article 27

In those States in which ethnic, religious or linguistic minorities exist, persons belonging to such minorities shall not be denied the right, in community with the other members of their group, to enjoy their own culture, to profess and practise their own religion, or to use their own language.

PART IV

Article 28

1. There shall be established a Human Rights Committee (hereafter referred to in the present Covenant as the Committee). It shall consist of eighteen members and shall carry out the functions hereinafter provided.

2. The Committee shall be composed of nationals of the States Parties to the present Covenant who shall be persons of high moral character and recognized competence in the field of human rights, consideration being given to the usefulness of the participation of some persons having legal experience.

3. The members of the Committee shall be elected and shall serve in their personal capacity.

Article 29

1. The members of the Committee shall be elected by secret ballot from a list of persons possessing the qualifications prescribed in article 28 and nominated for the purpose by the States Parties to the present Covenant.

2. Each State Party to the present Covenant may nominate not more than two persons. These persons shall be nationals of the nominating State.

3. A person shall be eligible for renomination.

Article 30

1. The initial election shall be held no later than six months after the date of the entry into force of the present Covenant.

2. At least four months before the date of each election to the Committee, other than an election to fill a vacancy declared in accordance with article 34, the Secretary-General of the United Nations shall address a written invitation to the States Parties to the present Covenant to submit their nominations for membership of the Committee within three months.

3. The Secretary-General of the United Nations shall prepare a list in alphabetical order of all the persons thus nominated, with an indication of the States Parties which have nominated them, and shall submit it to the States Parties to the present Covenant no later than one month before the date of each election.

4. Elections of the members of the Committee shall be held at a meeting of the States Parties to the present Covenant convened by the Secretary General of the United Nations at the Headquarters of the United Nations. At that meeting, for which two thirds of the States Parties to the present Covenant shall constitute a quorum, the persons elected to the Committee shall be those nominees who obtain the largest number of votes and an absolute majority of the votes of the representatives of States Parties present and voting.

Article 31

1. The Committee may not include more than one national of the same State.

2. In the election of the Committee, consideration shall be given to equitable geographical distribution of membership and to the representation of the different forms of civilization and of the principal legal systems.

Article 32

1. The members of the Committee shall be elected for a term of four years. They shall be eligible for re-election if renominated. However, the terms of nine of the members elected at the first election shall expire at the end of two years; immediately after the first election, the names of these nine members shall be chosen by lot by the Chairman of the meeting referred to in article 30, paragraph 4. 2. Elections at the expiry of office shall be held in accordance with the preceding articles of this part of the present Covenant.

Article 33

1. If, in the unanimous opinion of the other members, a member of the Committee has ceased to carry out his functions for any cause other than absence of a temporary character, the Chairman of the Committee shall notify the Secretary-General of the United Nations, who shall then declare the seat of that member to be vacant.

2. In the event of the death or the resignation of a member of the Committee, the Chairman shall immediately notify the Secretary-General of the United Nations, who shall declare the seat vacant from the date of death or the date on which the resignation takes effect.

Article 34

1. When a vacancy is declared in accordance with article 33 and if the term of office of the member to be replaced does not expire within six months of the declaration of the vacancy, the Secretary-General of the United Nations shall notify each of the States Parties to the present Covenant, which may within two months submit nominations in accordance with article 29 for the purpose of filling the vacancy.

2. The Secretary-General of the United Nations shall prepare a list in alphabetical order of the persons thus nominated and shall submit it to the States Parties to the present Covenant. The

election to fill the vacancy shall then take place in accordance with the relevant provisions of this part of the present Covenant.

3. A member of the Committee elected to fill a vacancy declared in accordance with article 33 shall hold office for the remainder of the term of the member who vacated the seat on the Committee under the provisions of that article.

Article 35

The members of the Committee shall, with the approval of the General Assembly of the United Nations, receive emoluments from United Nations resources on such terms and conditions as the General Assembly may decide, having regard to the importance of the Committee's responsibilities.

Article 36

The Secretary-General of the United Nations shall provide the necessary staff and facilities for the effective performance of the functions of the Committee under the present Covenant.

Article 37

1. The Secretary-General of the United Nations shall convene the initial meeting of the Committee at the Headquarters of the United Nations.

2. After its initial meeting, the Committee shall meet at such times as shall be provided in its rules of procedure.

3. The Committee shall normally meet at the Headquarters of the United Nations or at the United Nations Office at Geneva.

Article 38

Every member of the Committee shall, before taking up his duties, make a solemn declaration in open committee that he will perform his functions impartially and conscientiously.

Article 39

1. The Committee shall elect its officers for a term of two years. They may be re-elected.

2. The Committee shall establish its own rules of procedure, but these rules shall provide, inter alia, that:

(a) Twelve members shall constitute a quorum;

(b) Decisions of the Committee shall be made by a majority vote of the members present.

Article 40

1. The States Parties to the present Covenant undertake to submit reports on the measures they have adopted which give effect to the rights recognized herein and on the progress made in the enjoyment of those rights: (a) Within one year of the entry into force of the present Covenant for the States Parties concerned;

(b) Thereafter whenever the Committee so requests.

2. All reports shall be submitted to the Secretary-General of the United Nations, who shall transmit them to the Committee for consideration. Reports shall indicate the factors and difficulties, if any, affecting the implementation of the present Covenant.

3. The Secretary-General of the United Nations may, after consultation with the Committee, transmit to the specialized agencies concerned copies of such parts of the reports as may fall within their field of competence.

4. The Committee shall study the reports submitted by the States Parties to the present Covenant. It shall transmit its reports, and such general comments as it may consider appropriate, to the States Parties. The Committee may also transmit to the Economic and Social Council these comments along with the copies of the reports it has received from States Parties to the present Covenant.

5. The States Parties to the present Covenant may submit to the Committee observations on any comments that may be made in accordance with paragraph 4 of this article.

Article 41

1. A State Party to the present Covenant may at any time declare under this article that it recognizes the competence of the Committee to receive and consider communications to the effect that a State Party claims that another State Party is not fulfilling its obligations under the present Covenant. Communications under this article may be received and considered only if submitted by a State Party which has made a declaration recognizing in regard to itself the competence of the Committee. No communication shall be received by the Committee if it concerns a State Party which has not made such a declaration. Communications received under this article shall be dealt with in accordance with the following procedure:

(a) If a State Party to the present Covenant considers that another State Party is not giving effect to the provisions of the present Covenant, it may, by written communication, bring the matter to the attention of that State Party. Within three months after the receipt of the communication the receiving State shall afford the State which sent the communication an explanation, or any other statement in writing clarifying the matter which should include, to the extent possible and pertinent, reference to domestic procedures and remedies taken, pending, or available in the matter;

(b) If the matter is not adjusted to the satisfaction of both States Parties concerned within six months after the receipt by the receiving State of the initial communication, either State shall have the right to refer the matter to the Committee, by notice given to the Committee and to the other State;

(c) The Committee shall deal with a matter referred to it only after it has ascertained that all available domestic remedies have been invoked and exhausted in the matter, in conformity with the generally recognized principles of international law. This shall not be the rule where the application of the remedies is unreasonably prolonged;

(d) The Committee shall hold closed meetings when examining communications under this article;

(e) Subject to the provisions of subparagraph (c), the Committee shall make available its good offices to the States Parties concerned with a view to a friendly solution of the matter on the basis of respect for human rights and fundamental freedoms as recognized in the present Covenant;

(f) In any matter referred to it, the Committee may call upon the States Parties concerned, referred to in subparagraph (b), to supply any relevant information;

(g) The States Parties concerned, referred to in subparagraph (b), shall have the right to be represented when the matter is being considered in the Committee and to make submissions orally and/or in writing;

(h) The Committee shall, within twelve months after the date of receipt of notice under subparagraph (b), submit a report:

(i) If a solution within the terms of subparagraph (e) is reached, the Committee shall confine its report to a brief statement of the facts and of the solution reached;

(ii) If a solution within the terms of subparagraph (e) is not reached, the Committee shall confine its report to a brief statement of the facts; the written submissions and record of the oral submissions made by the States Parties concerned shall be attached to the report. In every matter, the report shall be communicated to the States Parties concerned.

2. The provisions of this article shall come into force when ten States Parties to the present Covenant have made declarations under paragraph I of this article. Such declarations shall be deposited by the States Parties with the Secretary-General of the United Nations, who shall transmit copies thereof to the other States Parties. A declaration may be withdrawn at any time by notification to the Secretary-General. Such a withdrawal shall not prejudice the consideration of any matter which is the subject of a communication already transmitted under this article; no further communication by any State Party shall be received after the notification of withdrawal of the declaration has been received by the Secretary-General, unless the State Party concerned has made a new declaration.

Article 42

1.

(a) If a matter referred to the Committee in accordance with article 41 is not resolved to the satisfaction of the States Parties concerned, the Committee may, with the prior consent of the States Parties concerned, appoint an ad hoc Conciliation Commission (hereinafter referred to as the Commission). The good offices of the Commission shall be made available to the States Parties concerned with a view to an amicable solution of the matter on the basis of respect for the present Covenant;

(b) The Commission shall consist of five persons acceptable to the States Parties concerned. If the States Parties concerned fail to reach agreement within three months on all or part of the composition of the Commission, the members of the Commission concerning whom no agreement has been reached shall be elected by secret ballot by a two-thirds majority vote of the Committee from among its members.

2. The members of the Commission shall serve in their personal capacity. They shall not be nationals of the States Parties concerned, or of a State not Party to the present Covenant, or of a State Party which has not made a declaration under article 41.

3. The Commission shall elect its own Chairman and adopt its own rules of procedure.

4. The meetings of the Commission shall normally be held at the Headquarters of the United Nations or at the United Nations Office at Geneva. However, they may be held at such other convenient places as the Commission may determine in consultation with the Secretary-General of the United Nations and the States Parties concerned.

5. The secretariat provided in accordance with article 36 shall also service the commissions appointed under this article.

6. The information received and collated by the Committee shall be made available to the Commission and the Commission may call upon the States Parties concerned to supply any other relevant information.

7. When the Commission has fully considered the matter, but in any event not later than twelve months after having been seized of the matter, it shall submit to the Chairman of the Committee a report for communication to the States Parties concerned:

(a) If the Commission is unable to complete its consideration of the matter within twelve months, it shall confine its report to a brief statement of the status of its consideration of the matter;

(b) If an amicable solution to the matter on tie basis of respect for human rights as recognized in the present Covenant is reached, the Commission shall confine its report to a brief statement of the facts and of the solution reached;

(c) If a solution within the terms of subparagraph (b) is not reached, the Commission's report shall embody its findings on all questions of fact relevant to the issues between the States Parties concerned, and its views on the possibilities of an amicable solution of the matter. This report shall also contain the written submissions and a record of the oral submissions made by the States Parties concerned;

(d) If the Commission's report is submitted under subparagraph (c), the States Parties concerned shall, within three months of the receipt of the report, notify the Chairman of the Committee whether or not they accept the contents of the report of the Commission.

8. The provisions of this article are without prejudice to the responsibilities of the Committee under article 41.

9. The States Parties concerned shall share equally all the expenses of the members of the Commission in accordance with estimates to be provided by the Secretary-General of the United Nations.

10. The Secretary-General of the United Nations shall be empowered to pay the expenses of the members of the Commission, if necessary, before reimbursement by the States Parties concerned, in accordance with paragraph 9 of this article.

Article 43

The members of the Committee, and of the ad hoc conciliation commissions which may be appointed under article 42, shall be entitled to the facilities, privileges and immunities of experts on mission for the United Nations as laid down in the relevant sections of the Convention on the Privileges and Immunities of the United Nations.

Article 44

The provisions for the implementation of the present Covenant shall apply without prejudice to the procedures prescribed in the field of human rights by or under the constituent instruments and the conventions of the United Nations and of the specialized agencies and shall not prevent the States Parties to the present Covenant from having recourse to other procedures for settling a dispute in accordance with general or special international agreements in force between them.

Article 45

The Committee shall submit to the General Assembly of the United Nations, through the Economic and Social Council, an annual report on its activities.

PART V

Article 46

Nothing in the present Covenant shall be interpreted as impairing the provisions of the Charter of the United Nations and of the constitutions of the specialized agencies which define the respective responsibilities of the various organs of the United Nations and of the specialized agencies in regard to the matters dealt with in the present Covenant.

Article 47

Nothing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources.

PART VI

Article 48

1. The present Covenant is open for signature by any State Member of the United Nations or member of any of its specialized agencies, by any State Party to the Statute of the International Court of Justice, and by any other State which has been invited by the General Assembly of the United Nations to become a Party to the present Covenant.

2. The present Covenant is subject to ratification. Instruments of ratification shall be deposited with the Secretary-General of the United Nations.

3. The present Covenant shall be open to accession by any State referred to in paragraph 1 of this article.

4. Accession shall be effected by the deposit of an instrument of accession with the Secretary-General of the United Nations.

5. The Secretary-General of the United Nations shall inform all States which have signed this Covenant or acceded to it of the deposit of each instrument of ratification or accession.

Article 49

1. The present Covenant shall enter into force three months after the date of the deposit with the Secretary-General of the United Nations of the thirty-fifth instrument of ratification or instrument of accession.

2. For each State ratifying the present Covenant or acceding to it after the deposit of the thirty-fifth instrument of ratification or instrument of accession, the present Covenant shall enter into force three months after the date of the deposit of its own instrument of ratification or instrument of accession.

Article 50

The provisions of the present Covenant shall extend to all parts of federal States without any limitations or exceptions.

Article 51

1. Any State Party to the present Covenant may propose an amendment and file it with the Secretary-General of the United Nations. The Secretary-General of the United Nations shall thereupon communicate any proposed amendments to the States Parties to the present Covenant with a request that they notify him whether they favour a conference of States Parties for the purpose of considering and voting upon the proposals. In the event that at least one third of the States Parties favours such a conference, the Secretary-General shall convene the conference under the auspices of the United Nations. Any amendment adopted by a majority of the States Parties present and voting at the conference shall be submitted to the General Assembly of the United Nations for approval.

2. Amendments shall come into force when they have been approved by the General Assembly of the United Nations and accepted by a two-thirds majority of the States Parties to the present Covenant in accordance with their respective constitutional processes. 3. When amendments come into force, they shall be binding on those States Parties which have accepted them, other States Parties still being bound by the provisions of the present Covenant and any earlier amendment which they have accepted.

Article 52

1. Irrespective of the notifications made under article 48, paragraph 5, the Secretary-General of the United Nations shall inform all States referred to in paragraph I of the same article of the following particulars:

(a) Signatures, ratifications and accessions under article 48;

(b) The date of the entry into force of the present Covenant under article 49 and the date of the entry into force of any amendments under article 51.

Article 53

1. The present Covenant, of which the Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited in the archives of the United Nations.

2. The Secretary-General of the United Nations shall transmit certified copies of the present Covenant to all States referred to in article 48.

[TRUE TYPED COPY]

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Convention on the Elimination of All Forms of Discrimination against Women

Full text of the Convention in English

"...the full and complete development of a country, the welfare of the world and the cause of peace require the maximum participation of women on equal terms with men in all fields "

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PART VI

INTRODUCTION

On 18 December 1979, the Convention on the Elimination of All Forms of Discrimination against Women was adopted by the United Nations General Assembly. It entered into force as an international treaty on 3 September 1981 after the twentieth country had ratified it. By the tenth anniversary of the Convention in 1989, almost one hundred nations have agreed to be bound by its provisions.

The Convention was the culmination of more than thirty years of work by the United Nations Commission on the Status of Women, a body established in 1946 to monitor the situation of women and to promote women's rights. The Commission's work has been instrumental in bringing to light all the areas in which women are denied equality with men. These efforts for the advancement of women have resulted in several declarations and conventions, of which the Convention on the Elimination of All Forms of Discrimination against Women is the central and most comprehensive document.

Among the international human rights treaties, the Convention takes an important place in bringing the female half of humanity into the focus of human rights concerns. The spirit of the Convention is rooted in the goals of the United Nations: to reaffirm faith in fundamental human rights, in the dignity,v and worth of the human person, in the equal rights of men and women. The present document spells out the meaning of equality and how it can be achieved. In so doing, the Convention establishes not only an international bill of rights for women, but also an agenda for action by countries to guarantee the enjoyment of those rights.

In its preamble, the Convention explicitly acknowledges that "extensive discrimination against women continues to exist", and emphasizes that such discrimination "violates the principles of equality of rights and respect for human dignity". As defined in article 1, discrimination is understood as "any distinction, exclusion or restriction made o.1 the basis of sex...in the political, economic, social, cultural, civil or any other field". The Convention gives positive affirmation to the principle of equality by requiring States parties to take "all appropriate measures, including legislation, to ensure the full development and advancement of women, for the purpose of guaranteeing them the exercise and enjoyment of human rights and fundamental freedoms on a basis of equality with men"(article 3).

The agenda for equality is specified in fourteen subsequent articles. In its approach, the Convention covers three dimensions of the situation of women. Civil rights and the legal status of women are dealt with in great detail. In addition, and unlike other human rights treaties, the Convention is also concerned with the dimension of human reproduction as well as with the impact of cultural factors on gender relations.

The legal status of women receives the broadest attention. Concern over the basic rights of political participation has not diminished since the adoption of the Convention on the Political Rights of Women in 1952. Its provisions, therefore, are restated in article 7 of the present document, whereby women are guaranteed the rights to vote, to hold public office and to exercise public functions. This includes equal rights for women to represent their countries at the international level (article 8). The Convention on the Nationality of Married Women - adopted in 1957 - is integrated under article 9 providing for the statehood of women, irrespective of their marital status. The Convention, thereby, draws attention to the fact that often women's legal status has been linked to marriage, making them dependent on their husband's nationality rather than individuals in their own right. Articles 10, 11 and 13, respectively, affirm women's rights to non-discrimination in education, employment and economic and social activities. These demands are given special emphasis with regard to the situation of rural women, whose particular struggles and vital economic contributions, as noted in article 14, warrant more attention in policy planning. Article 15 asserts the full equality of women in civil and business matters, demanding that all instruments directed at restricting women's legal capacity "shall be deemed null and void". Finally, in article 16, the Convention returns to the issue of marriage and family relations, asserting the equal rights and obligations of women and men with regard to choice of spouse, parenthood, personal rights and command over property.

Aside from civil rights issues, the Convention also devotes major attention to a most vital concern of women, namely their reproductive rights. The preamble sets the tone by stating that "the role of women in procreation should not be a basis for discrimination". The link between discrimination and women's reproductive role is a matter of recurrent concern in the Convention. For example, it advocates, in article 5, "a proper understanding of maternity as a social function", demanding fully shared responsibility for child-rearing by both sexes. Accordingly, provisions for maternity protection and child-care are proclaimed as essential rights and are incorporated into all areas of the Convention, whether dealing with employment, family law, health core or education. Society's obligation extends to offering social services, especially child-care facilities, that allow individuals to combine family responsibilities with work and participation in public life. Special measures for maternity protection are recommended and "shall not be considered discriminatory". (article 4). "The Convention also affirms women's right to reproductive choice. Notably, it is the only human rights treaty to mention family planning. States parties are obliged to include advice on family planning in the education process (article l O.h) and to develop family codes that guarantee women's rights "to decide freely and responsibly on the number and spacing of their children and to hove access to the information, education and means to enable them to exercise these rights" (article 16.e).

The third general thrust of the Convention aims at enlarging our understanding of the concept of human rights, as it gives formal recognition to the influence of culture and tradition on restricting women's enjoyment of their fundamental rights. These forces take shape in stereotypes, customs and norms which give rise to the multitude of legal, political and economic constraints on the advancement of women. Noting this interrelationship, the preamble of the Convention stresses "that a change in the traditional role of men as well as the role of women in society and in the family is needed to achieve full equality of men and women". States parties are therefore obliged to work towards the modification of social and cultural patterns of individual conduct in order to eliminate "prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes or on stereotyped roles for men and women" (article 5). And Article 1O.c. mandates the revision of textbooks, school programmes and teaching methods with a view to eliminating stereotyped concepts in the field of education. Finally, cultural patterns which define the public realm as a man's world and the domestic sphere as women's domain are strongly targeted in all of the Convention's provisions that affirm the equal responsibilities of both sexes in family life and their equal rights with regard to education and employment. Altogether, the Convention provides a comprehensive framework for challenging the various forces that have created and sustained discrimination based upon sex.

The implementation of the Convention is monitored by the Committee on the Elimination of Discrimination against Women (CEDAW). The Committee's mandate and the administration of the treaty are defined in the Articles 17 to 30 of the Convention. The Committee is composed of 23 experts nominated by their Governments and elected by the States parties as individuals "of high moral standing and competence in the field covered by the Convention".

At least every four years, the States parties are expected to submit a national report to the Committee, indicating the measures they have adopted to give effect to the provisions of the Convention. During its annual session, the Committee members discuss these reports with the Government representatives and explore with them areas for further action by the specific country. The Committee also makes general recommendations to the States parties on matters concerning the elimination of discrimination against women.

The full text of the Convention is set out herein

CONVENTION ON THE ELIMINATION OF ALL FORMS OF DISCRIMINATION AGAINST WOMEN

The States Parties to the present Convention,

> Noting that the Charter of the United Nations reaffirms faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women,

Noting that the Universal Declaration of Human Rights affirms the principle of the inadmissibility of discrimination and proclaims that all human beings are born free and equal in dignity and rights and that everyone is entitled to all the rights and freedoms set forth therein, without distinction of any kind, including distinction based on sex,

Noting that the States Parties to the International Covenants on Human Rights have the obligation to ensure the equal rights of men and women to enjoy all economic, social, cultural, civil and political rights,

Considering the international conventions concluded under the auspices of the United Nations and the specialized agencies promoting equality of rights of men and women,

Noting also the resolutions, declarations and recommendations adopted by the United Nations and the specialized agencies promoting equality of rights of men and women,

Concerned, however, that despite these various instruments extensive discrimination against women continues to exist,

Recalling that discrimination against women violates the principles of equality of rights and respect for human dignity, is an obstacle to the participation of women, on equal terms with men, in the political, social, economic and cultural life of their countries, hampers the growth of the prosperity of society and the family and makes more difficult the full development of the potentialities of women in the service of their countries and of humanity,

Concerned that in situations of poverty women have the least access to food, health, education, training and opportunities for employment and other needs,

Convinced that the establishment of the new international economic order based on equity and justice will contribute significantly towards the promotion of equality between men and women,

Emphasizing that the eradication of apartheid, all forms of racism, racial discrimination, colonialism, neo-colonialism, aggression, foreign occupation and domination and interference in the internal affairs of States is essential to the full enjoyment of the rights of men and women,

Affirming that the strengthening of international peace and security, the relaxation of international tension, mutual co-operation among all States irrespective of their social and economic systems, general and complete disarmament, in particular nuclear disarmament under strict and effective international control, the affirmation of the principles of justice, equality and mutual benefit in relations among countries and the realization of the right of peoples under alien and colonial domination and foreign occupation to self-determination and independence, as well as respect for national sovereignty and territorial integrity, will promote social progress and development and as a consequence will contribute to the attainment of full equality between men and women,

Convinced that the full and complete development of a country, the welfare of the world and the cause of peace require the maximum participation of women on equal terms with men in all fields,

Bearing in mind the great contribution of women to the welfare of the family and to the development of society, so far not fully recognized, the social significance of maternity and the role of both parents in the family and in the upbringing of children, and aware that the role of women in procreation should not be a basis for discrimination but that the upbringing of children requires a sharing of responsibility between men and women and society as a whole,

Aware that a change in the traditional role of men as well as the role of women in society and in the family is needed to achieve full equality between men and women,

Determined to implement the principles set forth in the Declaration on the Elimination of Discrimination against Women and, for that purpose, to adopt the measures required for the elimination of such discrimination in all its forms and manifestations,

Have agreed on the following:

PART I

Article I

For the purposes of the present Convention, the term "discrimination against women" shall mean any distinction, exclusion or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by women, irrespective of their marital status, on a basis of equality of men and women, of human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field.

Article 2

States Parties condemn discrimination against women in all its forms, agree to pursue by all appropriate means and without delay a policy of eliminating discrimination against women and, to this end, undertake:

(a) To embody the principle of the equality of men and women in their national constitutions or other appropriate legislation if not yet incorporated therein and to ensure, through law and other appropriate means, the practical realization of this principle;

(b) To adopt appropriate legislative and other measures, including sanctions where appropriate, prohibiting all discrimination against women;

(c) To establish legal protection of the rights of women on an equal basis with men and to ensure through competent national tribunals and other public institutions the effective protection of women against any act of discrimination;

(d) To refrain from engaging in any act or practice of discrimination against women and to ensure that public authorities and institutions shall act in conformity with this obligation;

(e) To take all appropriate measures to eliminate discrimination against women by any person, organization or enterprise;

(f) To take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices which constitute discrimination against women;

(g) To repeal all national penal provisions which constitute discrimination against women.

Article 3

States Parties shall take in all fields, in particular in the political, social, economic and cultural fields, all appropriate measures, including legislation, to en sure the full development and advancement of women , for the purpose of guaranteeing them the exercise and enjoyment of human rights and fundamental freedoms on a basis of equality with men.

Article 4

1. Adoption by States Parties of temporary special measures aimed at accelerating de facto equality between men and women shall not be considered discrimination as defined in the present Convention, but shall in no way entail as a consequence the maintenance of unequal or separate standards; these measures shall be discontinued when the objectives of equality of opportunity and treatment have been achieved.

2. Adoption by States Parties of special measures, including those measures contained in the present Convention, aimed at protecting maternity shall not be considered discriminatory.

Article 5

States Parties shall take all appropriate measures:

(a) To modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices which are based on the idea of the inferiority or the superiority of either of the sexes or on stereotyped roles for men and women;

(b) To ensure that family education includes a proper understanding of maternity as a social function and the recognition of the common responsibility of men and women in the upbringing and development of their children, it being understood that the interest of the children is the primordial consideration in all cases.

Article 6

States Parties shall take all appropriate measures, including legislation, to suppress all forms of traffic in women and exploitation of prostitution of women.

PART II

Article 7

States Parties shall take all appropriate measures to eliminate discrimination against women in the political and public life of the country and, in particular, shall ensure to women, on equal terms with men, the right:

(a) To vote in all elections and public referenda and to be eligible for election to all publicly elected bodies;

(b) To participate in the formulation of government policy and the implementation thereof and to hold public office and perform all public functions at all levels of government;

(c) To participate in non-governmental organizations and associations concerned with the public and political life of the country.

Article 8

States Parties shall take all appropriate measures to ensure to women, on equal terms with men and without any discrimination, the opportunity to represent their Governments at the international level and to participate in the work of international organizations.

Article 9

1. States Parties shall grant women equal rights with men to acquire, change or retain their nationality. They shall ensure in particular that neither marriage to an alien nor change of nationality by the husband during marriage shall automatically change the nationality of the wife, render her stateless or force upon her the nationality of the husband.

2. States Parties shall grant women equal rights with men with respect to the nationality of their children.

PART III

Article 10

States Parties shall take all appropriate measures to eliminate discrimination against women in order to ensure to them equal rights with men in the field of education and in particular to ensure, on a basis of equality of men and women:

(a) The same conditions for career and vocational guidance, for access to studies and for the achievement of diplomas in educational establishments of all categories in rural as well as in urban areas; this equality shall be ensured in pre-school, general, technical, professional and higher technical education, as well as in all types of vocational training;

(b) Access to the same curricula, the same examinations, teaching staff with qualifications of the same standard and school premises and equipment of the same quality;

(c) The elimination of any stereotyped concept of the roles of men and women at all levels and in all forms of education by encouraging coeducation and other types of education which will help to achieve this aim and, in particular, by the revision of textbooks and school programmes and the adaptation of teaching methods;

(d) The same opportunities to benefit from scholarships and other study grants;

(e) The same opportunities for access to programmes of continuing education, including adult and functional literacy programmes, particulary those aimed at reducing, at the earliest possible time, any gap in education existing between men and women;

(f) The reduction of female student drop-out rates and the organization of programmes for girls and women who have left school prematurely;

(g) The same Opportunities to participate actively in sports and physical education;

(h) Access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning.

Article 11

1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of employment in order to ensure, on a basis of equality of men and women, the same rights, in particular:

(a) The right to work as an inalienable right of all human beings;

(b) The right to the same employment opportunities, including the application of the same criteria for selection in matters of employment;

(c) The right to free choice of profession and employment, the right to promotion, job security and all benefits and conditions of service and the right to receive vocational training and retraining, including apprenticeships, advanced vocational training and recurrent training;

(d) The right to equal remuneration, including benefits, and to equal treatment in respect of work of equal value, as well as equality of treatment in the evaluation of the quality of work;

(e) The right to social security, particularly in cases of retirement, unemployment, sickness, invalidity and old age and other incapacity to work, as well as the right to paid leave;

(f) The right to protection of health and to safety in working conditions, including the safeguarding of the function of reproduction.

2. In order to prevent discrimination against women on the grounds of marriage or maternity and to ensure their effective right to work, States Parties shall take appropriate measures:

(a) To prohibit, subject to the imposition of sanctions, dismissal on the grounds of pregnancy or of maternity leave and discrimination in dismissals on the basis of marital status;

(b) To introduce maternity leave with pay or with comparable social benefits without loss of former employment, seniority or social allowances;

(c) To encourage the provision of the necessary supporting social services to enable parents to combine family obligations with work responsibilities and participation in public life, in particular through promoting the establishment and development of a network of child-care facilities;

(d) To provide special protection to women during pregnancy in types of work proved to be harmful to them.

3. Protective legislation relating to matters covered in this article shall be reviewed periodically in the light of scientific and technological knowledge and shall be revised, repealed or extended as necessary.

Article 12

1. States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.

2. Notwithstanding the provisions of paragraph I of this article, States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.

Article 13

States Parties shall take all appropriate measures to eliminate discrimination against women in other areas of economic and social life in order to ensure, on a basis of equality of men and women, the same rights, in particular:

(a) The right to family benefits;

(b) The right to bank loans, mortgages and other forms of financial credit;

(c) The right to participate in recreational activities, sports and all aspects of cultural life.

Article 14

1. States Parties shall take into account the particular problems faced by rural women and the significant roles which rural women

play in the economic survival of their families, including their work in the non-monetized sectors of the economy, and shall take all appropriate measures to ensure the application of the provisions of the present Convention to women in rural areas.

2. States Parties shall take all appropriate measures to eliminate discrimination against women in rural areas in order to ensure, on a basis of equality of men and women, that they participate in and benefit from rural development and, in particular, shall ensure to such women the right:

(a) To participate in the elaboration and implementation of development planning at all levels;

(b) To have access to adequate health care facilities, including information, counselling and services in family planning;

(c) To benefit directly from social security programmes;

(d) To obtain all types of training and education, formal and non-formal, including that relating to functional literacy, as well as, inter alia, the benefit of all community and extension services, in order to increase their technical proficiency;

(e) To organize self-help groups and co-operatives in order to obtain equal access to economic opportunities through employment or self employment;

(f) To participate in all community activities;

(g) To have access to agricultural credit and loans, marketing facilities, appropriate technology and equal treatment in land and agrarian reform as well as in land resettlement schemes;

(h) To enjoy adequate living conditions, particularly in relation to housing, sanitation, electricity and water supply, transport and communications.

PART IV

Article 15

1. States Parties shall accord to women equality with men before the law.

2. States Parties shall accord to women, in civil matters, a legal capacity identical to that of men and the same opportunities to exercise that capacity. In particular, they shall give women equal rights to conclude contracts and to administer property and shall treat them equally in all stages of procedure in courts and tribunals.

3. States Parties agree that all contracts and all other private instruments of any kind with a legal effect which is directed at restricting the legal capacity of women shall be deemed null and void.

4. States Parties shall accord to men and women the same rights with regard to the law relating to the movement of persons and the freedom to choose their residence and domicile.

Article 16

1. States Parties shall take all appropriate measures to eliminate discrimination against women in all matters relating to marriage and family relations and in particular shall ensure, on a basis of equality of men and women:

(a) The same right to enter into marriage;

(b) The same right freely to choose a spouse and to enter into marriage only with their free and full consent;

(c) The same rights and responsibilities during marriage and at its dissolution;

(d) The same rights and responsibilities as parents, irrespective of their marital status, in matters relating to their children; in all cases the interests of the children shall be paramount;

(e) The same rights to decide freely and responsibly on the number and spacing of their children and to have access to the information, education and means to enable them to exercise these rights;

(f) The same rights and responsibilities with regard to guardianship, wardship, trusteeship and adoption of children, or similar institutions where these concepts exist in national legislation; in all cases the interests of the children shall be paramount;

(g) The same personal rights as husband and wife, including the right to choose a family name, a profession and an occupation;

(h) The same rights for both spouses in respect of the ownership, acquisition, management, administration, enjoyment and disposition of property, whether free of charge or for a valuable consideration.

2. The betrothal and the marriage of a child shall have no legal effect, and all necessary action, including legislation, shall be taken to specify a minimum age for marriage and to make the registration of marriages in an official registry compulsory.

PART V

Article 17

1. For the purpose of considering the progress made in the implementation of the present Convention, there shall be established a Committee on the Elimination of Discrimination against Women (hereinafter referred to as the Committee) consisting, at the time of entry into force of the Convention, of eighteen and, after ratification of or accession to the Convention by the thirty-fifth State Party, of twenty-three experts of high moral standing and competence in the field covered by the Convention. The experts shall be elected by States Parties from among their nationals and shall serve in their personal capacity, consideration being given to equitable geographical distribution and to the representation of the different forms of civilization as well as the principal legal systems.

2. The members of the Committee shall be elected by secret ballot from a list of persons nominated by States Parties. Each State Party may nominate one person from among its own nationals.

3. The initial election shall be held six months after the date of the entry into force of the present Convention. At least three months before the date of each election the Secretary-General of the United Nations shall address a letter to the States Parties inviting them to submit their nominations within two months. The Secretary-General shall prepare a list in alphabetical order of all persons thus nominated, indicating the States Parties which have nominated them, and shall submit it to the States Parties.

4. Elections of the members of the Committee shall be held at a meeting of States Parties convened by the Secretary-General at United Nations Headquarters. At that meeting, for which two thirds of the States Parties shall constitute a quorum, the persons

elected to the Committee shall be those nominees who obtain the largest number of votes and an absolute majority of the votes of the representatives of States Parties present and voting.

5. The members of the Committee shall be elected for a term of four years. However, the terms of nine of the members elected at the first election shall expire at the end of two years; immediately after the first election the names of these nine members shall be chosen by lot by the Chairman of the Committee.

6. The election of the five additional members of the Committee shall be held in accordance with the provisions of paragraphs 2, 3 and 4 of this article, following the thirty-fifth ratification or accession. The terms of two of the additional members elected on this occasion shall expire at the end of two years, the names of these two members having been chosen by lot by the Chairman of the Committee.

7. For the filling of casual vacancies, the State Party whose expert has ceased to function as a member of the Committee shall appoint another expert from among its nationals, subject to the approval of the Committee.

8. The members of the Committee shall, with the approval of the General Assembly, receive emoluments from United Nations resources on such terms and conditions as the Assembly may decide, having regard to the importance of the Committee's responsibilities.

9. The Secretary-General of the United Nations shall provide the necessary staff and facilities for the effective performance of the functions of the Committee under the present Convention.

Article 18

1. States Parties undertake to submit to the Secretary-General of the United Nations, for consideration by the Committee, a report on the legislative, judicial, administrative or other measures which they have adopted to give effect to the provisions of the present Convention and on the progress made in this respect:

(a) Within one year after the entry into force for the State concerned;

(b) Thereafter at least every four years and further whenever the Committee so requests.

2. Reports may indicate factors and difficulties affecting the degree of fulfilment of obligations under the present Convention.

Article 19

1. The Committee shall adopt its own rules of procedure.

2. The Committee shall elect its officers for a term of two years.

Article 20

1. The Committee shall normally meet for a period of not more than two weeks annually in order to consider the reports submitted in accordance with article 18 of the present Convention.

2. The meetings of the Committee shall normally be held at United Nations Headquarters or at any other convenient place as determined by the Committee. (amendment, status of ratification)

Article 21

1. The Committee shall, through the Economic and Social Council, report annually to the General Assembly of the United Nations on its activities and may make suggestions and general recommendations based on the examination of reports and information received from the States Parties. Such suggestions and general recommendations shall be included in the report of

the Committee together with comments, if any, from States Parties.

2. The Secretary-General of the United Nations shall transmit the reports of the Committee to the Commission on the Status of Women for its information.

Article 22

The specialized agencies shall be entitled to be represented at the consideration of the implementation of such provisions of the present Convention as fall within the scope of their activities. The Committee may invite the specialized agencies to submit reports on the implementation of the Convention in areas falling within the scope of their activities.

PART VI

Article 23

Nothing in the present Convention shall affect any provisions that are more conducive to the achievement of equality between men and women which may be contained:

(a) In the legislation of a State Party; or

(b) In any other international convention, treaty or agreement in force for that State.

Article 24

States Parties undertake to adopt all necessary measures at the national level aimed at achieving the full realization of the rights recognized in the present Convention.

Article 25

1. The present Convention shall be open for signature by all States.

2. The Secretary-General of the United Nations is designated as the depositary of the present Convention.

3. The present Convention is subject to ratification. Instruments of ratification shall be deposited with the Secretary-General of the United Nations.

4. The present Convention shall be open to accession by all States. Accession shall be effected by the deposit of an instrument of accession with the Secretary-General of the United Nations.

Article 26

1. A request for the revision of the present Convention may be made at any time by any State Party by means of a notification in writing addressed to the Secretary-General of the United Nations.

2. The General Assembly of the United Nations shall decide upon the steps, if any, to be taken in respect of such a request.

Article 27

1. The present Convention shall enter into force on the thirtieth day after the date of deposit with the Secretary-General of the United Nations of the twentieth instrument of ratification or accession.

2. For each State ratifying the present Convention or acceding to it after the deposit of the twentieth instrument of ratification or accession, the Convention shall enter into force on the thirtieth day after the date of the deposit of its own instrument of ratification or accession.

Article 28

1. The Secretary-General of the United Nations shall receive and circulate to all States the text of reservations made by States at the time of ratification or accession.

2. A reservation incompatible with the object and purpose of the present Convention shall not be permitted.

3. Reservations may be withdrawn at any time by notification to this effect addressed to the Secretary-General of the United Nations, who shall then inform all States thereof. Such notification shall take effect on the date on which it is received.

Article 29

1. Any dispute between two or more States Parties concerning the interpretation or application of the present Convention which is not settled by negotiation shall, at the request of one of them, be submitted to arbitration. If within six months from the date of the request for arbitration the parties are unable to agree on the organization of the arbitration, any one of those parties may refer the dispute to the International Court of Justice by request in conformity with the Statute of the Court.

2. Each State Party may at the time of signature or ratification of the present Convention or accession thereto declare that it does not consider itself bound by paragraph I of this article. The other States Parties shall not be bound by that paragraph with respect to any State Party which has made such a reservation.

3. Any State Party which has made a reservation in accordance with paragraph 2 of this article may at any time withdraw that reservation by notification to the Secretary-General of the United Nations.

Article 30

The present Convention, the Arabic, Chinese, English, French, Russian and Spanish texts of which are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, duly authorized, have signed the present Convention.

[TRUE COPY]

National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India

Ministry of Health and Family Welfare
Government of India

Indian Council of Medical Research
National Academy of Medical Sciences (India), New Delhi - 110029
2005

National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India

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Foreword

Shri Prasanna Hota
Secretary
Ministry of Health and Family Welfare
Government of India

Infertility, though not life threatening, can cause intense agony and trauma to the infertile couples. No data on the extent of infertility prevalent in India is available; but the multinational study carried out by WHO (Diagnosis and Treatment of Infertility, ed. P. Rowe and E.N. Vikhlyaeva, 1988) that included India, places the incidence of infertility between 10 and 15%. Out of the population of 1020 million Indians, an estimated 25% (about 250 million individuals) may be conservatively estimated to be attempting parenthood at any given time. By extrapolating the WHO estimates, approximately 13 to 19 million couples are likely to be infertile in the country at any given time. These couples approach ART Clinics.

The increasing demand for ART has resulted in mushrooming of infertility clinics in India. The Assisted Reproductive Technology (ART) in India is being provided by private sector only. Many of these technologies require enormous technical expertise and infrastructure. However, the success rate is below 30% under the best of circumstances. Moreover, it taxes the couple's endurance physically, emotionally and monetarily. Many of these clinics do not have adequate trained manpower and infrastructure facilities to deliver these highly sophisticated technologies and even services provided by some of these clinics are highly questionable. In some cases, the infertile couple are being cheated by providing relatively simple procedure and charged for complicated and expensive procedures. The procedures, wherein Round Spermatid Nuclear Injection and Pre-implantation

Genetic Diagnosis in gender selection of the embryo are used, have not been universally accepted. These issues are of great concern to the society.

In order to regulate and supervise the ART clinics, the Indian Council of Medical Research (ICMR) and National Academy of Medical Sciences (NAMS) have come out with National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. These Guidelines have been evolved after detailed discussion and debate by experts, practitioners of ART and public.

I take immense pleasure in presenting these Guidelines, which I strongly feel, would be very useful in regulating and supervising the functioning of ART Clinics and would be helping the ART Clinics in providing safe and ethical services to the needy infertile couples. I also place on record our appreciation of the efforts of the experts of ICMR & NAMS in bringing out these Guidelines.

(Prasanna Hota)
Secretary
Ministry of Health and Family Welfare
Government of India
New Delhi-110011

Preface

Prof. N. K. Ganguly
Director General
Indian Council of Medical Research

The successful birth of the world's first baby conceived by *in vitro* fertilization (IVF) and embryo transfer occurred on July 25, 1978, in the UK. The world's second IVF baby was born 67 days later on October 3, 1978 in Kolkata. India's first scientifically documented IVF baby was, however, born on August 6, 1986 in Mumbai through the support of the Indian Council of Medical Research. Since then, over one and half million babies conceived by Assisted Reproductive Technologies (ART) have reportedly been born throughout the world.

The advent of any new technology that affects mankind raises several technical and moral dilemmas and poses many ethical and technical challenges. ART is no exception. In the Indian context where barrenness is looked down upon, infertile patients look up to ART as the last resort to parenthood. Some of them are prepared to go to any extent to achieve their life's ambition. Unfortunately, ART has not reached a stage where all forms of infertility can be treated, nor can any clinic offer a 100% success if the couples were to undergo any of the assisted reproductive technologies. The ART practitioner is often faced with a technical challenge of trying to select the right treatment for a particular type of infertility, knowing fully well that none of the available techniques offer 100% success. The practitioner also faces moral responsibility of trying to convince the infertile couple of this fact and let them know the chances of success and failure by the particular treatment that is being offered.

The increasing demand for ART has resulted in mushrooming of infertility clinics in India. There is no reliable information on the number of ART clinics in India in the absence of a national registry of ART clinics. There is no information on the follow-up of babies born after the use of ART to know the incidence of congenital malformation in them. There have been reports in the press of malpractices carried out by some ART clinics.

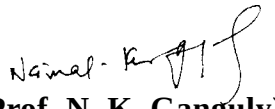
Such malpractices are not unique to India but are a global phenomenon. Many countries have taken steps to prevent such aberrant occurrences. Austria, Australia, Brazil, Canada, the Czech Republic, Denmark, France, Germany, Greece, Hungary, Iceland, Israel, Italy, Japan, Korea, Mexico, the Netherlands, Norway, Saudi Arabia, Singapore, South Africa, Spain, Sweden, Switzerland, Taiwan and Turkey have legislations for the practice of ART. Scientific societies in Finland, Poland, Portugal and the USA have drawn up guidelines for the practices of ART. Argentina, Egypt and the UK have both guidelines and legislation. Guidelines and/or legislation in these countries have been shown to improve the process of patient care and procedure outcomes.

There are no guidelines for the practice of ART, accreditation of infertility clinics and supervision of their performance in India. This document aims to fill this lacuna and also provide a means of maintaining a national registry of ART clinics in India. The document has been widely publicized, discussed and debated by expert groups of the ICMR and the National Academy of Medical Sciences and then by practitioners of ART and the public in Chennai, Jodhpur, Kolkata, Bangalore, Hyderabad and Mumbai. These discussions involved over 4000 participants including doctors, scientists, bureaucrats, legal experts, infertile couples and the general public. This document was also put on the Council's website and elicited many comments and responses.

All attempts have been diligently made to encompass all points of view and bring out a document that conveys the views of the vast majority of participants in the above mentioned discussions and debates.

This document should be useful to the infertility clinics as well as to those who seek the services of such clinics. However, as ART is an evolving field, this

document will need to be periodically reviewed. This will be a challenging task both for the practitioners of ART and the regulatory authority that is yet to be established.



(Prof. N. K. Ganguly)
Director General
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Acknowledgements

The Council gratefully acknowledges the valuable contribution of all the members of the Expert Committee responsible for formulating these guidelines, for providing continued guidance in drafting and finalizing the guidelines. We are extremely grateful to the Chairpersons of the subcommittees of the Expert Committee for conducting regional discussions and preparing the draft document on the respective topics assigned to them.

This document is a concerted effort made possible by the advice, assistance and co-operation of many individuals, institutions and government and non-governmental organizations, specially the National Academy of Medical Sciences (NAMS), The Medically Aware and Responsible Citizens of Hyderabad (The MARCH), Indian Society for the Study of Reproduction and Fertility (ISSRF) and Federation of Obstetrics and Gynaecology Society of India (FOGSI).

The suggestions and advice emerging from the workshop sponsored by the National Academy of Medical Sciences held on 16th September 2001 at Bangalore were of great significance. Therefore, the Council is particularly grateful to the participants of the NAMS workshop (i.e. Manohar, Aruna Sivakami, J Mehta, S. Narang, M. S. Sreenivas, M. Gourie Devi, B. Kalyan, N. Krishnan, N. Pandiyan, K. S. Jayaraman, P. B. Seshagiri, R. H. Mehta, Seema Singh, P. V. Kulkarni, Lalitha, P. Sarkar, M. Sarkar, M. Priya, K. Nath, M. Nirad, D. Raghunath, Gopinathan, R. S. Sharma, N. C. Saxena, V. Muthuswamy, B. N. Chakravarthy, C. S. Bhaskaran, M. Rajalakshmi and T. C. Anand Kumar).

Special thanks are due to Dr. P. M. Bhargava not only for his initiative, professional and editorial inputs and consistent interest in and enthusiasm for the guidelines, but also doing everything in good humour, inspite of continual office interruptions and information overload on the various topics of the guidelines.

We are also grateful to the National Commission for Women and the National Human Rights Commission for their valuable advise.

Secretarial assistance provided by Mr. Mahesh Kumar is gratefully acknowledged.

Abbreviations

AIDS	-	Acquired Immune Deficiency Syndrome
ASRM	-	American Society for Reproductive Medicine
AI	-	Artificial Insemination
AID	-	Artificial Insemination with Donor Semen
AIH	-	Artificial Insemination with Husband's Semen
ART	-	Assisted Reproductive Technology
BBT	-	Basal Body Temperature
CO_2	-	Carbon Dioxide
CC	-	Clomiphene Citrate
CASA	-	Computer-Aided Sperm Analysis
CBAVD	-	Congenital Bilateral Absence of Vas Deferens
CMV	-	Cytomegalo Virus
DHEA	-	Dehydro-epiandrostendione
DNA	-	Deoxyribonucleic Acid
DMSO	-	Dimethylsulfoxide
ED	-	Embryo Donation
ELSNI	-	Elongated Spermatid Nuclear injection
ESHRE	-	European Society for Human Reproduction and Embryology
FISH	-	Fluorescent *in situ* Hybridization

FSH - Follicle Stimulating Hormone

GIFT - Gamete Intrafallopian Transfer

GnRH - Gonadotropin Releasing Hormone

GLP - Good Laboratory Practices

HBV - Hepatitis B Virus

HCV - Hepatitis C Virus

hCG - Human Chorionic Gonadotropin

hMG - Human Menopausal Gonadotropin

HIV - Human Immunodeficiency Virus

HOST - Hypo-Osmotic Swelling Test

ICMR - Indian Council of Medical Research

ICPD - International Conference for Population and Development

IFFS - International Federation of Fertility Societies

ICSI - Intracytoplasmic Sperm Injection

IUI - Intra-uterine Insemination

IRR - Institute for Research in Reproduction, (now National Institute for Research in Reproductive Health, NIRRH)

IVF-ET - *In vitro* Fertilization–Embryo Transfer

IVMTS - *In vitro* Maturation of Testicular Sperm

LH - Luteinizing Hormone

OD	-	Oocyte Donation
OT	-	Operation Theatre
OHS	-	Ovarian Hyperstimulation Syndrome
PESA	-	Percutaneous Epididymal Sperm Aspiration
PGD	-	Pre–implantation Genetic Diagnosis
PCOS	-	Polycystic Ovarian Syndrome
PCR	-	Polymerase Chain Reaction
RNA	-	Ribonucleic Acid
SCMPT	-	Sperm Cervical Mucous Penetration Test
SOP	-	Standard Operating Procedure
TESA	-	Testicular Sperm Aspiration
TESE	-	Testicular Sperm Extraction
TSH	-	Thyroid Stimulating Hormone
TVS	-	Transvaginal Sonography
UPS	-	Uninterrupted Power Supply
WHO	-	World Health Organization
WMA	-	World Medical Assembly

Corrigendum

(1) 1.2.1 Artificial Insemination (AI)

AI is the procedure of artificially transferring semen into reproductive system of a woman. This technique comprises artificial insemination with husband's (AIH) or with donor sperm (AID). (Page No. 5)

(2) 1.5.5 Programme co-ordinator/director

This should be a senior person who has had considerable experience in handling all aspects of ART. (Page No. 23)

(3) 1.6 ART Procedure

"National Accreditation Committee" appearing in para 1.6 may be read as "National Advisory Committee". (Page No. 24)

(4) 1.6.10 The future ART technologies

"National Accreditation Committee" appearing in para 1.6.10 may be read as "National Advisory Committee". (Page No. 32)

(5) 3.14.7 The State Government would close down any unregulated clinics not satisfying the above criteria. (Page No. 73)

(6) 3.15 Responsibilities of the Accreditation Authority

The para 3.15 may be read as follows:

3.15 Responsibilities of the Accreditation/Appropriate Authority

3.15.1 State Accreditation Authority :

A State Accreditation Authority will be set up by the State /UT Governments through their Department of Health and /or Family Welfare to oversee all matters relating to accreditation, supervision and regulation of ART Clinics in the States/UTs in accordance with the Guidelines. The functions of the Accreditation Authority, inter-alia, include-

i) to review the activities of Appropriate Authorities functioning in the State and take appropriate action against them;
ii) to monitor the implementation of the provision of the Guidelines by ART clinics;
iii) to order closure of an ART Clinic if the ethical Guidelines and operative procedures laid down in the Guidelines are not followed.

3.15.2 Appropriate Authority.

The State Government may also set up one or more Appropriate Authorities for implementation of the Guidelines for the whole or a part of the State having regard to the number of ART Clinics. Functions of the Appropriate Authority are:

- to grant or suspend registration of an ART Clinic;
- to enforce the provisions of the Guidelines by ART Clinics;
- to investigate complaints of breach of the Guidelines;
- to visit any ART Clinic/Centre accredited or not accredited, once a year with or without prior information

to the clinic/centre, to determine if the ethical guidelines and operative procedures are being followed. If not, the Authority will point out lapses to the clinic/centre in writing. If these lapses continued for a maximum period of six months (during which period that clinic shall not engage in any activity related to the lapses), the Appropriate Authority would recommend to the State Accreditation Authority that the clinic/centre may be ordered to be closed;

- to impose a fine or a penalty on the clinic/centre for violation of any provisions of Guidelines as per delegation of powers by the State Accreditation Authority;
- to visit and regulate semen banks in the manner mentioned above;
- any other function as directed by Accreditation Authority

3.15.3 Complaints Redressal Mechanism

A client of an ART Clinic or any other person can file a complaint against an ART Clinic for breach of any provisions of the Guidelines or in respect of any related matter to the Appropriate Authority. The Appropriate Authority shall investigate such complaints and take appropriate action under intimation to the complainant.

3.15.4 Central Advisory Committee

Ministry of Health and Family Welfare, Government of India will set up a National Advisory Committee under the Chairmanship of Secretary, Health & Family Welfare and Director General, ICMR as Co-chairman. The composition of the Committee is given in Chapter 9. The National Advisory Committee will review and monitor the implementation of the

Guidelines and advise the Central Government on all policy matters relating to regulation of ART Clinics.

(7) 3.16.4 Rights of an unmarried woman to AID

Para 3.16.4 is to be deleted. (Page No. 75)

(8) 5.0 Training

The last three lines of page 101 may be read as: Such conference must be encouraged through organization such as the Indian Council of Medical Research (ICMR), Department of Science and Technology (DST), Department of Biotechnology (DBT), Council of Scientific and Industrial Research (CSIR) and the various science academies in India. (Page 101)

(9) 9.0 Composition of the National Advisory Committee.

Executive Secretary: A Officer not below the rank of Joint Secretary in the Ministry of Health and Family Welfare, Govt. of India. (Page 117)

Chapter 1

Introduction, Brief History of ART and Requirements of ART Clinics

1 Introduction

Infertility, though not life threatening, causes intense mental agony and trauma that can only be best described by infertile couples themselves. There are no detailed figures of the extent of infertility prevalent in India but a multinational study carried out by WHO (Diagnosis and treatment of infertility, ed. P. Rowe and E. M. Vikhlyaeva, 1988) that included India, places the incidence of infertility between 10 and 15%. Out of a population of 1000 million Indians, an estimated 25% (250 million individuals) may be conservatively estimated to be attempting parenthood at any given time; by extrapolating the WHO estimate, approximately 13 to 19 million couples are likely to be infertile in the country at any given time.

Prevention and appropriate treatment of infertility has been included in the ICPD (International Conference on Population and Development) Programme of Action; it follows that alleviation of infertility should be included as a component of the primary health care system. Most types of infertility such as reproductive tract infections (RTI) and genital tuberculosis, are preventable and amenable to treatment. About 8% of infertile couples, however, need serious medical intervention involving the use of advanced ART (Assisted Reproductive Technologies) procedures such as IVF (*In virto* Fertilization) or ICSI (Intracytoplasmic Sperm Injection). Such advanced treatment is expensive and not easily affordable to the majority of Indians. Further, the successful practice of ART requires considerable technical expertise and expensive infrastructure. Moreover, the success rate of any ART procedure is below 30% under the best of circumstances. Infertility, specially in our country, also has far-reaching societal implications. Therefore, with the rapidly increasing use of ART in our country, it has become imperative to ensure their safety and have safeguards against their possible misuse.

Scientific societies around the world, such as the ASRM, ESHRE and IFFS, have drawn up guidelines for the safe and ethical practice of ART. The European Union and the Governments of several countries such as Australia, the UK and the USA have taken steps to accredit and supervise the performance of infertility clinics.

At present here are neither guidelines nor a legislation in regard to the practice of ART in India. This document aims to fill this lacuna. It has been prepared after extensive consultations held at both the ICMR and other national institutions, with scientists, medical practitioners, lawyers, social scientists and activists.

The present guidelines are meant to ensure that ART clinics in India are accredited, regulated and supervised to assure the patients as well as the public that our ART clinics offer services that are at par with those available anywhere in the world. Medical malpractice now comes under the purview of the legal redressal machinery of the country; this makes it all the more necessary to have national guidelines for the practice of ART.

1.1 Brief History of IVF in India

The world's first IVF baby, Louise Brown, was born on July 25, 1978, in the UK through the efforts of Dr. Robert G Edwards and Dr. Patrick Steptoe. The world's second and India's first IVF baby, Kanupriya, alias Durga, was born 67 days later on October 3, 1978, through the efforts of Dr. Subhas Mukherjee and his two colleagues in Kolkata.

Dr. Mukherjee and his colleagues published a short note on their above work, in the Indian Journal of Cryogenics (Vol. 3: page 80, 1978). The techniques used by Mukherjee were markedly different from those used by Edwards and Steptoe. Mukherjee was the first person in the world to use

(a) gonadotropins for ovarian stimulation prior to ovum pick-up in an IVF treatment cycle;

(b) the transvaginal route by colpotomy for harvesting oocytes; and

(c) freezing and thawing of human embryos before transferring them into the uterus that led to the successful birth of Durga.

India's first scientifically documented IVF baby, Harsha, was born on August 6, 1986, in Mumbai, through the collaborative efforts of the ICMR's Institute for Research in Reproduction and the King Edward's Memorial Hospital (KEM). This work was executed after being approved by the

Scientific Advisory Committee of the ICMR's Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of the KEM Hospital. Full details of this and other studies in this area were published in the ICMR Bulletin (1986: No. 16) and in peer reviewed national (Natl. Med. J. India 1:10, 1988) and international journals (J. *In vitro* Fertilization & ET 5:376, 1988). Births of IVF babies were reported subsequently during the same year by two other clinics in India. There are an estimated 250 IVF clinics in India today.

1.1.1 ART - an alternative to reversal of Sterilization

Infertility, consequent to use of terminal methods of contraception under the Family Planning Programme, may sometimes need to be reversed for personal reasons such as having lost a child/children born prior to sterilization. IVF is one of the options for women in whom fallopian tubes have been surgically severed and where recanalisation for correction of infertility has failed.

1.2 Definitions

1.2.1 Artificial Insemination (AI)

AI is the procedure of transferring semen into the reproductive system of a woman. This technique comprises artificial insemination with husband's (AIH) or with donor sperm (AID).

1.2.2 Aspiration cycle

Initiated ART cycle in which one or more follicles are punctured and aspirated irrespective of whether or not oocytes are retrieved.

1.2.3 Assisted Hatching

Assisted hatching allows easier release of the embryo from its shell (zona pellucida), helping implantation and increasing the pregnancy rate.

1.2.4 Assisted Reproductive Technology (ART)

For the purpose of these guidelines, ART would be taken to encompass all techniques that attempt to obtain a pregnancy by manipulating the sperm or/ and oocyte outside the body, and transferring the gamete or embryo into the uterus.

1.2.5 Blastocyst

An embryo with a fluid-filled blastocele cavity (usually developing by five or six days after fertilization).

1.2.6 Controlled ovarian hyperstimulation (COH)

Medical treatment to induce the development of multiple ovarian follicles to obtain multiple oocytes at follicular aspiration.

1.2.7 Cryopreservation

Freezing and storage of gametes, zygotes or embryos

1.2.8 Donation of Gametes

Donation of gametes is a process by which a person voluntarily offers his or her gametes for the process of procreation.

1.2.9 Ectopic pregnancy

A pregnancy in which implantation takes place outside the uterine cavity

1.2.10 Embryo

Embryo is defined as the fertilized ovum that has begun cellular division and continued development up to the blastocyst stage till the end of eight weeks.

1.2.11 Embryo donation

The transfer of an embryo resulting from gametes that did not originate from the recipient and/or her partner.

1.2.12 Embryo transfer (ET)

Procedure in which embryo(s) are placed in the uterus or fallopian tube.

1.2.13 Fertilization

The penetration of the ovum by the spermatozoon and fusion of genetic materials resulting in the development of a zygote.

1.2.14 Foetus

The product of conception starting from completion of embryonic development (at eight completed weeks after fertilization) until birth or abortion.

1.2.15 Foetal Reduction

Foetal reduction is an invasive/interventional process by which a higher order multiple pregnancy is reduced to a single or twin pregnancy in order to improve the perinatal outcome.

1.2.16 Gamete

Oocytes and sperm are called gametes.

1.2.17 Hatching

It is the process that precedes implantation by which an embryo at the blastocyst stage separates from the zona pellucida.

1.2.18 ICSI (Intracytoplasmic Sperm Injection)

In ICSI, a single sperm is injected into the cytoplasm of the ovum to effect fertilization, before the fertilized ovum is transferred to the uterus of the woman.

1.2.19 Implantation

The attachment and subsequent penetration by the zona-free blastocyst (usually in the endometrium) which starts five to seven days following fertilization.

1.2.20 Infertility

Failure to conceive after at least one year of unprotected *coitus*

1.2.21 Intrauterine Insemination (IUI)

Intrauterine Insemination involves the introduction of sperm into the uterus of the woman. In IUI, specially prepared sperm are injected into the uterine cavity via a fine cannula passed through the cervix. At this site, the sperm are near the uterine entrance of each of the two fallopian tubes and thus have a shorter distance to swim in order to reach the oocyte(s) released at the time of ovulation.

1.2.22 IVF-ET (*In vitro* Fertilization-Embryo Transfer)

In vitro Fertilization-Embryo Transfer (IVF-ET) is the fertilization of an ovum outside the body and the transfer of the fertilized ovum to the uterus of a woman.

1.2.23 IVMTS & IVMO (*In vitro* Maturation of Testicular Sperm and *In vitro* Maturation of Oocytes)

In vitro Maturation of Testicular Sperm (IVMTS) involves keeping the testicular sperm in a culture medium under optimal conditions where they can attain physiological maturity and acquire motility.

In vitro maturation of immature oocytes involves keeping the immature oocytes in an appropriate culture medium under optimal conditions where they can attain physiological maturity.

1.2.24 Oocyte donation

An ART procedure performed with third-party oocytes

1.2.25 Ovum/Oocyte

Ovum/oocyte is the female gamete produced in the ovary.

1.2.26 PESA (Percutaneous Epididymal Sperm Aspiration) and TESA/TESE (Testicular Sperm Aspiration/ Extraction)

Percutaneous Epididymal Sperm Aspiration (PESA) and Testicular Sperm Aspiration (TESA) are simplified, minimally invasive outpatient procedures that allow the physician to recover the sperm for fertilization in patients with obstructive azoospermia (lack of sperm in semen).

PESA requires a needle to be introduced into the epididymis and the contents aspirated. The aspirate is observed under the microscope to determine if motile sperm are present.

In TESA, the needle is introduced into the testicle itself.

1.2.27 Pre–implantation Genetic Diagnosis (PGD)

Pre–implantation Genetic Diagnosis is a technique in which an embryo formed through IVF is tested for specific genetic disorders (e.g. cystic fibrosis) or other characteristics prior to implantation.

1.2.28 Preterm Birth

A birth which takes place after at least 20, but less than 37, completed weeks of gestation. This includes both live births and stillbirths. Births are

counted as birth events (e.g. a twin or triplet live birth is counted as one birth event).

1.2.29 Semen

A thick, whitish fluid discharged through the penis during ejaculation containing spermatozoa, secretions from the testes, seminal vesicles, prostate gland, bulbo-uretheral and other glands associated with the male reproductive system.

1.2.30 Semen Donor

Semen obtained from third party for purpose of inseminating the wife in cases where husband is unable to produce healthy semen.

1.2.31 Sperm

Sperm are the male gametes produced in the testicles.

1.2.32 Spontaneous abortion

Spontaneous loss of a clinical pregnancy before 20 completed weeks of gestation or, if gestational age is unknown, a weight of 500 g or less.

1.2.33 Surrogacy

Surrogacy is an arrangement in which a woman agrees to carry a pregnancy that is genetically unrelated to her and her husband, with the intention to carry it to term and hand over the child to the genetic parents for whom she is acting as a surrogate.

1.2.34 Surrogacy with Oocyte Donation

Surrogacy with oocyte donation is a process in which a woman allows insemination by the sperm/semen of the male partner of a couple with a view to carry the pregnancy to term and hand over the child to the couple.

1.2.35 Zygote

Fertilized oocyte prior to first cell division is called zygote

1.3 Minimal Physical Requirements for an ART Clinic

A well designed ART clinic of Level 2 or Level 3 (Sections 2.5.3 and 2.5.4) should have a non-sterile and a strictly sterile area as detailed below. Some of the spaces mentioned below could be combined (that is, the same space may be used for more than one purpose) as long as such a step does not compromise the quality of service. However, the space provision for the sterile area cannot be combined with those for the non-sterile area and vice-versa. For level 1B infertility care units (section 2.5.2), a strictly sterile area will not be required. The space requirement, however, will include, a reception area, a waiting room for the patients, a consulting room for the gynaecologist, and requirements mentioned under 1.3.1.8, 1.3.1.9 and 1.3.1.10.

1.3.1 The non-sterile area

The non-sterile area must include what is listed under 1.3.1.1 to 1.3.1.9 below.

1.3.1.1 A reception and waiting room for patients

1.3.1.2 A room with privacy*:* A room with privacy for interviewing and examining male and female partners independently is essential. Evaluation of infertility necessitates history taking of the most intimate sexual practices between the couples. This is followed by close examination of the reproductive tract and sexual organs. Adequate measures must be taken to ensure that history taking and examination are carried out in strict privacy, maintaining the dignity of the patients. In case a male doctor examines a female patient, there must always be a female attendant present. The room must be

equipped with an examination table and gynecological instruments for examining the female per vaginum, an appropriate ultrasonographic machine with a probe for transvaginal examination of the female and examination of the testes and excurrent male reproductive tract. A colour Doppler would be useful but not essential.

1.3.1.3 A general-purpose clinical laboratory

1.3.1.4 Store room: A well-stocked store for keeping essential stock of especially those items that have to be imported, precluding the need to be caught short in the middle of treatment. Facilities must be available for storing sterile (media, needles, catheters, petri dishes and such-like items) and non-sterile material under refrigerated and non-refrigerated conditions as appropriate.

1.3.1.5 Record room: Record keeping must be computerized as far as possible so that data is accessible retrospectively for analysis or when called upon by the supervisory agency. There are many software programmes for this purpose, which are commercially available today. A user-friendly one should be chosen that could be used widely. Besides containing essential details of the patient's records, it must contain history of the cause of infertility as diagnosed earlier, results of new diagnosis if relevant, the treatment option best suited for the particular patient, the treatment carried out and the outcome of treatment, and follow-up if any. Any other noteworthy point such as possible adverse reaction to drugs, must be recorded. ICMR should make an effort to devise a form for basic data recording, which would be suitable for India.

1.3.1.6 Autoclave room: A separate facility must be available for sterilizing and autoclaving all surgical items as well as some of those to be used in the *in vitro* culture laboratory.

1.3.1.7 Steps for vermin proofing: Adequate steps should be taken to make the whole clinic vermin proof, with suitable traps for preventing insects and other forms of unwanted creatures entering the clinic.

This essential detail should be planned at an early stage because no pesticide can be used in a fully functional IVF clinic, as it could be toxic to the gametes and embryos.

1.3.1.8 Semen collection room: This must be a well-appointed room with privacy and an appropriate environment; it should be located in a secluded area close to the laboratory. Such a facility must be available in-house rather than having the patient collect the sample and bring it to the laboratory for analysis as, in the latter case, semen quality and identity is likely to be compromised. Procedures for collection of semen as described in the WHO Semen Analysis Manual must be followed with special reference to the type of container used; these containers must be sterile, maintained at body temperature and non-toxic. This room must have a washbasin with availability of soap and clean towels. The room must also have a toilet and must not be used for any other purpose.

1.3.1.9 Semen processing laboratory: There must be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room. This laboratory must also have facilities for microscopic examination of post-coital test smears. Good Laboratory Practice (GLP) guidelines as defined internationally must be followed. Care must be taken for the safe disposal of biological waste and other materials (syringes, glass slides, etc.). Laboratory workers should be immunized against hepatitis B and tetanus.

1.3.1.10 Clean room for IUI: There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).

1.3.2 The sterile area

The sterile area shall house the operation theatre, a room for intrauterine transfer of sperm or embryos and an adjoining embryology laboratory. Entry to the sterile area must be strictly controlled by an anteroom for changing footwear, area for changing into sterile garments and a scrub-station. The sterile area must be

air-conditioned where fresh air filtered through an approved and appropriate filter system is circulated at an ambient temperature (22-25^0 C).

1.3.2.1 The operation theatre: This must be well equipped with facilities for carrying out surgical endoscopy and transvaginal ovum pick-up. The operation theatre must be equipped for emergency resuscitative procedures.

1.3.2.2 Room for intrauterine transfer of embryo: This room must be a sterile area having an examination table on which the patient can be placed for carrying out the procedure and rest undisturbed for a period of time.

1.3.2.3 The embryology laboratory complex: The embryology laboratory must have facilities for the control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour. Walls and floors must be composed of materials that can be easily washed and disinfected; use of carpeting must be strictly avoided. The embryology laboratory must have the following:

- a laminar flow bench with a thermostatically controlled heating plate
- a stereo microscope
- a routine high-powered binocular light microscope
- a 'high resolution' inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording
- a micromanipulator (if ICSI is done)
- a CO_2 incubator, preferably with a back up
- a hot air oven
- a laboratory centrifuge
- equipment for freezing embryos in a programmed manner
- liquid nitrogen cans

- a refrigerator

Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups. All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm should be kept together on the same tray and double-checked. Pipettes used should be disposed off immediately after use. The embryology laboratory must have a daily logbook in which all the day's activities are recorded, including the performance of the equipment.

1.3.3 Ancillary laboratory facilities

The infertility clinic need not have in-house facilities to perform all the procedures necessary to diagnose infertility, such as those mentioned below. They can be farmed out to speciality laboratories specializing in delivering such services, as long as they are located in the neighborhood.

1.3.3.1 Hormone and other assays: The infertility clinic must have ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, hCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It is also necessary to estimate blood estradiol in samples taken from a woman undergoing controlled ovarian hyperstimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyperstimulation.

1.3.3.2 Microbiology and histopathology: Another important facility in an ART clinic (or easily accessible to it) would be that of a microbiology laboratory that can carry out rapid tests for any infection,

and a clinical chemistry laboratory. Facilities for carrying out histopathological studies on specimens obtained from the operation theatre would also be desirable.

1.3.3.3 Maintenance of the laboratories: Each laboratory should maintain in writing, standard-operating manuals for the different procedures carried out in the laboratory. It should be ensured that there is no "mix up" of gametes or embryos. The patient's name should be clearly labeled on all the tubes, dishes and pipettes containing the gametes and embryos. All pipettes should be immediately discarded after use.

Laminar flowhoods, laboratory tables, incubators and other areas where sterility is required must be periodically checked for microbial contamination using standard techniques, and a record of such checks must be kept.

A logbook should be maintained which records the temperature, carbon dioxide content and humidity of the incubators and the manometer readings of the laminar air flow.

All instruments must be calibrated periodically (at least once every year) and a record of such calibration maintained.

1.3.3.4 Quality of consumables used in the laboratory: All disposable plasticware must be procured from reliable sources after ensuring that they are not toxic to the embryo. Culture media used for processing gametes or growing embryos *in vitro* should be preferably procured from reliable manufacturers. Each batch of culture medium needs to be tested for sterility, endotoxins, osmolality and pH. The embryologist should know the composition of the media that are being used. Most media are supplemented with serum; they should, therefore, be tested for antibodies to HIV 1 and 2, Hepatitis B Surface Antigen and Hepatitis C RNA.

1.4 Back-up Power Supply

There should be no interruption in power supply to the incubator and to other essential services in the clinic. Given the power supply situation in India, it is, therefore, imperative that a power back up in the form of UPS systems and/or a captive power generation system is available in infertility clinics offering ART services.

1.5 Essential Qualifications of the ART Team

The practice of ART requires a well-orchestrated teamwork between the **gynaecologist, the andrologist and the clinical embryologist** supported by a **counsellor** and a **programme coordinator/director**. The staff requirements given below would be mandatory for Level 2 and Level 3 clinics (see Section 2.5.3 and 2.5.4). In the case of small Level 2 and Level 3 clinics, the services of the andrologist, the clinical embryologist and/or the counsellor could be shared.

1.5.1 Gynaecologist

The minimal qualification for a gynaecologist in a Level 1B, Level 2 or Level 3 clinic (see Sections 2.5.2, 2.5.3 and 2.5.4) is a post-graduate diploma or degree in gynaecology. Additional experience should include:

- © Understanding the causative factors of male and female infertility.
- © Acquiring knowledge of the practice and use of diagnostic methods for determining the cause of infertility.
- © Acquiring knowledge of the clinical aspects of reproductive endocrinology and the reproductive defects caused by endocrine factors, and an understanding of the limitations of the currently used hormone assay methods, and of the techniques available for medically or surgically correcting endocrine disorders.
- © Acquiring competence/skills in gynecological ultrasonography to diagnose reproductive tract anomalies, monitoring ovarian and uterine response to ovarian stimulation, picking up oocytes at the most appropriate time, and transferring embryos by any one of the several methods currently available to handle embryo transfer in

'difficult cases'.

© The gynaecologist must be well versed, particularly in the pharmacology of hormone action, and know how to avoid situations such as Ovarian Hyperstimulation Syndrome that can pose a great health hazard.

The responsibilities of the gynaecologist would include the following:

- Interviewing of the infertile couple initially.
- History taking.
- Physical examination of the female.
- Recommending appropriate tests to be carried out, interpreting them and treating medical disorders (infections, endocrine anomalies).
- Carrying out laparoscopy or sonohysterosalpingography for determining the status of the uterus and the fallopian tube.
- Advising the couple on planned relationship in simple cases.
- Carrying out AIH, AID, IUI, IVF or ICSI as the case may warrant, based on diagnostic evidence.

In case of male factor infertility, if the gynaecologist is confident and competent, he/she can treat such cases or refer them to the andrologist. The treating doctor must be responsible for maintaining all records of diagnosis, treatment given and consent forms. Before any treatment is given, it is advisable that the couple is referred to the counsellor, with all the details of the case, for proper advise and counselling. It would be the gynaecologist's responsibility to see that all equipment and instruments in the operation theatre are properly functional and in order, and that a logbook is maintained of their use and operation.

1.5.2 Andrologist

Fifty percent of infertility cases are related to male factors, many of which can be treated by specific ART procedures or other less invasive procedures. Andrology, a subject related to male reproduction, does not constitute a formal course in the medical curriculum in India, although several journals in andrology are published from different parts of the world including China. There is also an International Andrological Society with branches or affiliated societies all over the world. In India it is the urologist with a post-graduate degree in urology that often takes on the task of treating male infertility. Such individuals must receive additional training in diagnosis of various types of male infertility covering psychogenic impotence, anatomical anomalies of the penis which disable normal intercourse, endocrine factors that cause poor semen characteristics and/or impotence, infections, and causes of erectile dysfunction.

- The andrologist must have knowledge of the occupational hazards, infections and fever that cause reversible or irreversible forms of infertility, and knowledge of ultrasonographic or vasographic studies of the reproductive excurrent ducts to detect partial occlusion that can be surgically corrected.
- He/she must understand the principles of semen analysis and their value and limitation in diagnosis of male fertility status. The person should also be able to interpret the fertility status of the male from the result of semen analysis. The andrologist must be able to collect semen by prostatic massage for microbial culture in cases where infection may lie in the upper regions (prostate, seminal vesicles) of the reproductive tract. He/she should also be able to collect spermatozoa from the excurrent ducts or testis for use in ICSI and must also be knowledgeable about the genetic implications of using poor-quality sperm for ICSI as this technique can vertically transfer the genetic defects of the father to the child. He/she should be familiar with the surgical procedures available for correcting an anatomical defect in the reproductive system such as epididymo-vasal re-anastmosis and varicocoelectomy.

© An individual may act as an andrologist for more than one clinic but each clinic where the andrologist works must own responsibility for the andrologist and ensure that the andrologist is able to take care of the entire work load of the clinic without compromising on the quality of service.

The responsibilities of the andrologist would include the following:

- Recording case histories.
- Prescribing appropriate diagnosis and treatment based on the diagnosis.
- Carrying out such surgical procedures as warranted by the diagnosis.
- Maintaining all the records, from the case history to the treatment given, and the patient consent forms.
- Referring the couple to the gynaecologist for carrying out the appropriate ART procedure if necessary, after the male factor has been duly investigated.
- Referring the couple to the counsellor if necessary.
- In cases of surgical intervention, making sure that the operation theatre is fully functional and all supplies are available before the start of any surgical procedure.
- Entering any deficiency that needs attention in the operation theatre logbook.

1.5.3 Clinical Embryologist

The **clinical embryologist** must be knowledgeable in mammalian embryology, reproductive endocrinology, genetics, molecular biology, biochemistry, microbiology and *in vitro* culture techniques. The biologist must also be familiar with ART. He/she must be either a medical graduate or have a post-graduate degree or a doctorate in an appropriate area of life sciences. (In the case of a clinic in existence for at least one year before the promulgation

of these guidelines, a person with a B Sc or BV Sc degree but with at least five years of first-hand, hands-on experience of the techniques mentioned below and of discharging the responsibilities listed below, would be acceptable for functioning as a clinical embryologist in the particular clinic. Such persons would also be eligible to take a test to be designed and conducted by an appropriate designated authority, to qualify for a position of a clinical embryologist in a new clinic.) He/she must be familiar with the following:

- © Principles and practice of semen analysis and cryopreservation of semen.
- © Cytology of mammalian and human oocyte to identify stages of oocyte maturation accurately.
- © All aspects of embryology including developmental biology.
- © Cell biological techniques used in cell and tissue culture.
- © Molecular biology and genetics of human reproduction.
- © Micromanipulation of sperm and oocytes for carrying out ICSI and single-cell biopsies of embryos for preimplantation genetic diagnosis.
- © Principles and functioning of all the equipment used in the laboratory.
- © In vitro fertilization of oocytes after processing the gametes.
- © Principles and practice of embryo freezing.

The responsibilities of the clinical embryologist would be:

- To ensure that all the necessary equipments are present in the laboratory and are functional.
- To perform all the procedures pertaining to processing, handling and culturing of gametes and embryos in the laboratory and hand over the embryo to the gynaecologist.
- To maintain records of all the procedures carried out in the laboratory.
- In case of shortage of adequately trained clinical embryologists, an

individual may act as a clinical embryologist for more than one clinic but each clinic where the person works must own responsibility for the embryologist and ensure that the embryologist is able to take care of the entire work load of the clinic without compromising on the quality of service. An embryologist must not be associated with more than two centers at any given time.

1.5.4 Counsellors

Counsellors are an important adjunct to any infertility clinic. Indeed, in the UK, counsellors are appointed by the clinic but they report to an independent body. This ensures that there is fair play by the clinic and the patients are adequately informed of what and what not to expect from the treatment offered to them. Counselling for ART is not taught as a separate subject anywhere. A person who has at least a degree (prefarably a postgraduate degree) in Social Sciences, Psychology, Life Sciences or Medicine, and a good knowledge of the various causes of infertility and its social and gender implications, and the possibilities offered by the various treatment modalities, should be considered as qualified to occupy this position. The person should have a working knowledge of the psychological stress that would be experienced by potential patients, and should be able to counsel them to assuage their fears and anxiety and not to have unreasonable expectations from ART. A member of the staff of an ART clinic who is not engaged in any other full-time activity in the clinic can act as a counsellor.

The counsellor must invariably appraise the couple of the advantages of adoption as against resorting to ART involving a donor. An individual may act as a counsellor for more than one clinic but each clinic where the counsellor works must own responsibility for the counsellor and ensure that the counsellor is able to take care of the entire counselling load of the clinic without compromising on the quality of the counselling service.

1.5.5 Programme co-ordinator/director

This should be a senior person who has had considerable experience in all aspects of ART. The programme co-ordinator/director should be able to co-

ordinate the activities of the rest of the team and take care of staff administrative matters, stock keeping, finance, maintenance of patient records, statutory requirements, and public relations. He/she should ensure that the staff are keeping up with the latest developments in their subject, by providing them with information from the literature, making available to them access to the latest journals, and encouraging them to participate in conferences and meetings and present their data. The programme co-ordinator/director should have a post-graduate degree in an appropriate medical or biological science. In addition, he/she must have a reasonable experience of ART.

1.6 ART Procedures

A variety of ART procedures have been described in the literature. Only those procedures that have been widely tested and proven to be satisfactory as of writing this document are listed here. It would be the responsibility of the National Accreditation Committee (Chapter 9) to ensure that the list given in this document is enlarged in real time as progress occurs in the field. It is hoped that the practitioners of ART in the country will bring to the notice of the Committee on a continuing basis, any new procedure for the practice of which there would appear to be a sound scientific case. The National Accreditation Committee or a body appointed by it will approve or disapprove the new procedure within six months of its having been made aware of in writing: if this is not done, the clinic could continue to use the procedure until the above body has taken a decision on it. No new procedure that has not been approved as above should be permitted to be used by an infertility clinic for more than the period mentioned above.

One of the primary concerns of all ART treatments is the safety of the patients and of their gametes and embryos which constitute the very beginning of a new individual's life. The basic tenets of any medical treatment mentioned in the Helsinki Declaration of 1964 and reiterated in October 2000 in Scotland (information available on the Internet) clearly spell out the ethical concerns of treating patients. These basic tenets are also applicable to ART. The clinic must ensure that a particular ART being offered is fully in consonance with the diagnosis made of the cause of infertility. More particularly, the clinic must make sure that patients are well informed about the treatment being offered to them, the reasons

of suggesting a particular form of treatment, and alternative therapies available if any.

If a clinic is offering an ART that is not listed in these guidelines now or as modified in the future (vide para 1 of this Section), the procedure must be approved by the clinics ethics committee (constituted as recommended by the ICMR ethical guidelines, 2000), justifying the need for the procedure and explaining why alternatives are not suitable. [Only clinics of Level 2 or Level 3 (Sections 2.5.3 and 2.5.4) would be required to have an ethics committee.] Informed consent from the patients would be mandatory in such cases as well. As mentioned in para one of this section, the clinic must also bring the new procedure to the notice of the National Accreditation Committee for its approval; if such an approval is not granted, all further use of the procedure must stop.

1.6.1 Artificial insemination with husband's semen (AIH)

The technique consists in placing in the interior of the vagina a sample of the unprocessed semen.

1.6.2 Artificial insemination with donor semen (AID)

The indications for AID are when there is (a) non-obstructive azoospermia; (b) the husband has a hereditary genetic defect; or (c) when the couples have Rh incompatibility.

The main advantage of AID is that it enables a couple to achieve pregnancy even though the husband is not the biological father. However, the possible transmission of diseases from the donor to the future child and the risk of consanguinity, constitute some drawbacks that must be brought to the notice of the patients. It is necessary to get the informed consent of both the partners after they are counselled about the possible psychological conflict they may face later in their life with the knowledge that one of them is not the biological parent of their child.

AID is an ethically acceptable procedure provided there is a medical indication and psychological confirmation for its use. Also, the normal

conditions of anonymity and screening of the donor must be met and only frozen sperm samples that have passed appropriate quarantining for infectious diseases such as HIV, hepatitis B and C, and syphilis should be used (for details see Chapter 3). AID involves the placing of a donor's semen into the interior of the vagina.

Common indications:

- © Husband has non-obstructive azoospermia.
- © Husband has a hereditary genetic defect.
- © The couple has Rh incompatibility.
- © The women is iso-immunized and has lost previous pregnancies and intrauterine transfusion is not possible.
- © Husband has severe oligozoospermia and the couple does not wish to undergo any of the sophisticated ART such as ICSI.

1.6.3 Intrauterine insemination with either husband's or donor semen (IUI-H or IUI-D)

IUI involves the processing of semen in the laboratory so as to yield pure, activated sperm, devoid of seminal plasma, which are then directly placed into the uterus.

Common indications:

- © Hostile uterine cervix that does not respond to medication. (Cervical hostility can readily be determined by carrying out proper tests such as the sperm-mucous interaction test or post-coital tests. Technical skills constitute an important factor in carrying out these tests correctly and reading the results.)
- © In cases where husband's sperm cannot be used for reasons as described above for AID.

1.6.4 *In vitro* fertilization and embryo transfer (IVF-ET)

The technique of IVF consists of bringing about the fertilization of the oocyte and the spermatozoa in the laboratory instead of in the woman's fallopian tube. IVF involves induction of ovulation in order to obtain multiple oocytes, thus making available more embryos with which higher pregnancy rates can be achieved. Serial determination of plasma estradiol levels and daily monitoring of ovarian follicular growth by ultrasonography would indicate the response to ovarian stimulation. At the appropriate moment of follicular growth, the follicles are aspirated to obtain the oocytes. The oocytes are mixed with appropriately capacitated spermatozoa from the husband (or the donor, if the medical condition indicates the use of donor sperm) and kept in an incubator for fertilization which is observed microscopically after 16 to 18 hours. Embryos are transferred into the uterine cavity between days 2 and 6 after oocyte aspiration. If implantation ensues, pregnancy can be confirmed by 14 to 16 days after embryo transfer by determining the presence of hCG in a blood or urine sample. Such a test is reliable only when progesterone is used for luteal supplementation instead of hCG.

The success rate of IVF is approximately one in every 4-5 women. IVF is the therapeutic option of reproductive medicine with the highest yield per attempt, coming close on many occasions to that achieved by fertile couples conceiving naturally.

Common indications:

© The original indication for IVF was irreversible pathology of the fallopian tubes, resulting from an inflammatory process or from previous surgery. However, in recent years the indications for IVF include infertility due to a subnormal male factor.

Other indications include:

© Idiopathic infertility.

© Endometriosis.

© Infertility of immunological origin.

1.6.5 IVF-associated techniques

Gamete Intrafallopian Tube Transfer (GIFT) or Tubal Embryo Transfer (TET) has been recommended for patients with undamaged fallopian tubes. Access to the tube is gained by laparoscopy or by retrograde catheterization through the uterine cervix. GIFT is associated with higher levels of pregnancy than IVF but it has the drawback that it is unable to demonstrate the fertilizing capacity of the gametes.

1.6.6 Intracytoplasmic sperm injection (ICSI) with ejaculated, epididymal or testicular spermatozoa

It is well known that the incidence of fertilization with sub-optimal semen is much lower in contrast to normal semen samples. It has been argued that since a sizeable number of couples are not suitable for IVF because their sperm count is far below 10 million/ml with less then 30% sperm being motile and more than 30% having abnormal morphology, alternate methods must be found to facilitate fertilization. Several approaches have been developed to circumvent the barriers (the zona pellucida and the ooplasmic membrane) that prevent the sperm reaching the ooplasm. Notable amongst these are: partial zona dissection (PZD), subzonal insemination (SUZI), and intracytoplasmic sperm injection (ICSI).

Live births have been reported using all these methods. The use of PZD or SUZI must be discouraged, as they do not offer any distinct advantage. ICSI is the most widely accepted choice of treatment for male factor infertility. ICSI can be carried out with fresh or frozen-thawed ejaculated or epididymal/ testicular motile or live spermatozoa.

1.6.6.1 Indications of ICSI with ejaculated spermatozoa

- Severe male-factor infertility.
- Fertilization failure after standard IVF treatment.

- Number of spermatozoa in the ejaculate too low for IVF.

1.6.6.2 Indications of ICSI with epididymal spermatozoa obtained by microsurgical epididymal sperm aspiration (MESA/PESA)

- Congenital bilateral absence of the vas deferens (CBAVD).
- Failed vasoepididymal anastomosis.
- Failed vasovasal anastomosis.
- Obstruction of both ejaculatory ducts.
- Anejaculation because of spinal cord injury.
- Retrograde ejaculation.

1.6.6.3 Indications of ICSI with testicular spermatozoa (TESA)

- Extensive scarring, rendering MESA/PESA impossible.
- Germ-cell hypoplasia (hypospermatogenesis).
- Germ-cell aplasia with focal spermatogenesis.
- Sertoli cell-only syndrome with focal spermatogenesis.

1.6.6.4 Indications of ICSI with *in vitro* matured oocytes

- Polycystic ovary.
- History of ovarian hyperstimulation.

1.6.7 Oocyte donation (OD) or embryo donation (ED)

Oocyte donation would necessitate using the husband's semen for fertilization and transferring the resultant embryo to the infertile female partner. Embryo donation would obviate the necessity of using the husband's semen. The choice of oocytes and embryos for oocyte or embryo donation would depend entirely on the circumstances prevalent at the time the infertile couple comes for treatment, and the access of the infertility clinic to frozen oocytes or embryos.

1.6.7.1 Indications for oocyte or embryo donation

- Gonadal dysgenesis.
- Premature ovarian failure.
- Iatrogenic (due to ovarian surgery or radiation, or chemical castration) ovarian failure.
- Women who have resistant ovary syndrome, or who are poor responders to ovulation induction.
- Women who are carriers of recessive autosomal disorders.
- Women who have attained menopause.

Donors should be healthy (as determined by medical and psychological examination, screening for STDs, and absence of HIV antibodies) women in the age group of 18-35 years. Oocytes may be obtained for donation, mostly by surgical intervention from women participating in an IVF program, or those undergoing elective sterilization or surgery.

The recipient should be a healthy woman (determined by medical and psychological examination) having normal genitalia (as determined by physical examination) and uterine cavity (as determined by hystero-salpingography). In case of OD, the semen characteristics of the husband must be determined to see if they are in conformity with those associated with normal fertility. The blood group of the donor should be noted; the donor should also be tested for antibodies to rubella, HIV, hepatitis, CMV, gonorrhea, syphilis, chlamydia, mycoplasma and trichomonas.

Ovum/embryo donation can be carried out in menopausal women with no surviving child and desiring to have a child. The endometrium of menopausal women has the ability to respond to sex hormones and provide a receptive environment for the implantation of an embryo.

Various protocols are now available to prepare the endometrium of the recipient for OD or ED with estrogens and progestogens until the placenta takes over the function of maintaining the gestation.

1.6.8 Cryopreservation

Facilities for cryopreservation are an essential component of an ART clinic as they are to be used under a variety of conditions such as those described below.

1.6.8.1 Freezing semen

Men, who are likely to suffer from psychological stress at the time of ovum pick-up or those who cannot be present at the time of ovum pick-up, are recommended to have their semen frozen for use at the appropriate time. One of the important reasons for freezing semen from donors is that any donor semen has to be quarantined for six months. The safety of using frozen sperm has been abundantly proven, both by experimental work and the actual results in humans. Matters of concern are the donor's health and the necessity to avoid donors who are infected with venereal diseases, hepatitis B or C, or HIV. One of the drawbacks of sperm freezing is an approximate 20 % loss in motility after thawing. Donors whose semen is frozen for future use are required to report to the semen bank six months after donation to be checked for HIV, HBV or HCV infection/disease status.

1.6.8.2 Freezing embryos

Embryos are routinely cryopreserved to enable storage of supernumerary embryos, as upto a maximum of only three embryos is allowed for transfer to avoid the risk of multiple pregnancies. Embryo freezing is a widespread routine procedure to increase cumulative pregnancy rates.

Human embryos can be successfully cryopreserved at any stage from zygote to blastocyst, using 1, 2 propanediol (PROH) or dimethylsulfoxide (DMSO) for zygotes and cleaved embryos and glycerol for blastocysts. The formation of ice crystals is of concern during embryo freezing. Using programmed, slow freezers reduces this problem considerably, and slow cooling is the most widely employed method. Human embryos are known to survive a simple ultra-rapid procedure of fast cooling but there is not much data on the efficacy of these techniques when used routinely. Straws or ampoules used for freezing embryos should be carefully and permanently labeled for identification purpose.

Patients should be fully informed before the treatment cycle on the procedure of cryopreservation, the risks and, particularly, what is to be done with their embryos if they do not use them. They should sign a consent form concerning the agreement for embryo freezing as well as for the future use of the embryos (also see Section 3.11).

When a serum supplementation is used in the preparation of freezing and thawing solutions, one must carefully avoid any risk of viral transmission to the embryo through the serum.

1.6.8.3 Oocyte cryopreservation

This procedure has been successfully used in cases where a large number of immature oocytes have been retrieved during ovum-pick-up. The oocyte can be thawed at a later date, matured *in vitro* and used for oocyte donation or similar procedures either on the person from whom the oocytes were retrieved or on other prospective recipients. However, the success rates in terms of fertilization, pregnancy and live births with the use of cryopreserved oocytes are not very encouraging. Much remains to be learnt on identifying the optimal stage of oocyte development when cryopreservation would be of value.

1.6.9 *In vitro* culture media

There has been a spurt of new media introduced for *in vitro* culture of gametes and embryos. If one takes a close look at these media, they are products that have evolved over the years. However, some manufacturers do not give the exact composition of their media but merely state that for reasons of patent protection or as trade secret they are constrained to give full details of the composition of their media (J D Biggers, Reproductive Biomedicine Online Vol. 1, No 3, 2000; also available on the world-wide web: rbmonline. com).

This is an undesirable situation. Infertility clinics that deal with human embryos and the future life of the products they create in the laboratory must be privy to the knowledge about the media they use, if need be by signing an

appropriate confidentiality agreement which would prohibit the clinic from using or passing on the proprietary information provided by the manufactures of the media to any other organisation that may commercially exploit this information.

When a serum supplementation has to be used in the preparation of media, one must carefully avoid the risk of viral transmission to the embryo through the serum.

1.6.10 The future ART technologies

Assisted reproductive technologies represent a rapidly progressing area in modern biology. It would be the responsibility of the National Accreditation Committee (Chapter 9) to ensure that this list of techniques is kept updated in real time.

1.6.11 Caution, precautions and concerns about ART practice

1.6.11.1 Ovarian stimulation

It is important that ART procedures aimed to facilitate the bringing together of oocytes and spermatozoa should occur when the oocyte is ready to fertilize. Under normal conditions it is very difficult to predict when ovulation will occur and whether the oocytes released will be fertilizable. It is, therefore, a common practice to induce follicular development by administering clomiphene citrate (CC) and or human menopausal gonadotropin (hMG) prepared from menopausal urine, followed by human chorionic gonadotropin (hCG) for the induction of ovulation just when the ovarian follicle has ripened and grown to its optimal size as determined by ultrasonography. Insemination can be carried out *in vivo*, or the oocyte aspirated and subjected to *in vitro* fertilization or ICSI. The time of oocyte maturation can be predicted by this method to facilitate carrying out the rest of the ART procedure.

Ovarian stimulation should be carried out with the utmost caution to avoid Ovarian Hyperstimulation Syndrome (OHSS). Basal blood levels of FSH and LH should be estimated on day 1 or 2 of the menstrual cycle. LH

levels twice as high as FSH are indicative of the woman having polycystic ovaries; such women are prone to develop multiple follicles when stimulated and also undergo OHSS. Oocytes aspirated from such ovaries usually fail to fertilize. If such women are subjected to mild ovarian stimulation with CC, it is important to carefully monitor their ovarian response ultrasonographically.

1.6.11.2 Indiscriminate use of ICSI

ICSI, one of the latest entrants to the field of ART, has been claimed to be a panacea for severe male infertility. This technique has never undergone critical evaluation in animal models before introducing it to treat human infertility. There are, therefore, some genuine concerns in regard to the use of ICSI; some of the fears underlying these concerns have come true (S. Oehninger and R. G. Gasolen: Should ICSI be the treatment of choice for all cases of *in vitro* conception ? No, not in light of the scientific data. Human Reproduction 17: 2337, 2002).

Although, ICSI has revolutionized the treatment for male infertility, its widespread use has raised medical concerns about the transfer of genetic defects to future generations. There is a higher than normal frequency of sex chromosome abnormalities in children born of ICSI procedures compared with the normal population (Science 281:651-652, 1988; Human Reproduction 13: 781-782,1998; Human Reproduction 16:115-120,2001; British Medical Journal 327: 852, 2003; Fertility and Sterility 80: 851, 2003). Besides, infertile men carrying Y chromosome microdeletions pass this defect to ICSI-born sons (Fertility and Sterility 74:909-915, 2000). During ICSI, the process of fertilization is dramatically changed. For example, there is no fertilization occurring *in vivo,* and the physiological maturation of sperm, its selection and penetration through oocyte investments, and its influence on embryonic spatial patterning (Nature 409: 517-521,2001), are bypassed. Because ICSI bypasses a part of the process of natural selection and certain early developmental mechanisms, concerns are expressed on the possible reproductive health risk(s) to the offspring.

In India, it is estimated that about 15% of married couples are sub-

fertile or infertile. Treatment of male-factor infertility in the country has improved dramatically with the introduction of ICSI, which is currently being practiced rather extensively in various major ART clinics in the country. It is, however, extremely important that this approach to treating male-factor infertility is carried out with caution, in view of the possible risk of vertically transmitting defective (spermatogenetic) fertility gene(s) to the male progeny, when the etiology of infertility is genetic in origin (Human Reproduction 13:219-227,1998). Thus, ICSI may fall below the general expectations of the Helsinki Declaration (WMA 1964 and 2000). ART clinics accredited under the present programme must therefore take due note of the above before resorting to ICSI, and counsel the couple for whom ICSI is being recommended, appropriately. Inspite of what has been said above, in some case, ICSI may still be the preferred choice of treatment for infertility.

1.6.11.3 Possible misuse of ART – sale of embryos and stem cells

There is a growing interest in embryonic stem cells because of their potential use for developing spare organs or replacing defective tissues such as parts of the brain destroyed due to Alzheimer's disease, or pancreatic cells in diabetic patients. The range of their potential use is limited only by one's imagination.

ART clinics are the only source of embryonic stem cells. Spare embryos are either frozen or returned to the infertile couple for replacement during a later cycle, or donated to another infertile couple, or discarded after five years using a suitable protocol (Section 3.11).

Recently, the USA banned all federal support for embryonic stem cell researches unless the laboratories could demonstrate that they had developed embryonic stem lines before August 10, 2001. However, private funding is allowed which encourages scientists in the USA to procure stem cells from abroad. Germany has banned all research on embryos produced in that country but permits the use of embryos brought from abroad.

The stand taken by the foreign governments on embryo research opens up the possibility of embryos from developing countries that do not have

appropriate national guidelines in this area, being commercially exploited and sold to foreign countries. Therefore sale or transfer of human embryos or any part thereof, or of gametes in any form and in any way – that is, directly or indirectly – to any party outside the country must be prohibited. Within the country, such embryos or gametes could be made available to bonafide researchers only as a gift, with both parties (the donor and the donee) having no commercial transaction, interest or intent.

Chapter 2

Screening of Patients for ART: Selection Criteria and Possible Complications

2.1 Patient Selection

During last two decades, there has been a marked increase in patient population in all infertility clinics the world over, but all infertility clinics may not be sufficiently equipped with the latest technology and expertise essential to offer the best possible help. Hence there is a need for patient selection, in order to categorise them in specific groups and then refer them to different levels of infertility care units for step-wise investigation and treatment.

Patient selection for referral and, finally, for ART should be based on the findings of basic investigations on the cause of infertility. These investigations should consist of the following.

2.1.1 Husband

- © Physical examination, both systemic and local, to detect any problem that might be the cause of infertility or that may modify the management of infertility.
- © Semen analysis including both morphological and functional tests; if any abnormality is detected, repeat tests should be done after suitable intervals. An abnormal finding on a repeat semen examination warrants full-scale investigation by an appropriate specialist to ascertain the cause and then institute the necessary treatment.
- © Screening for infections including syphilis, HBV, HCV and HIV, and their appropriate management.
- © If needed, appropriate endocrinological investigations and therapy.

2.1.2 Wife

- © Physical examination, both systemic and local, to detect any problem that might be the cause of infertility or that may modify the management of infertility.
- © Detection and timing of ovulation by basal body temperature (BBT), cervical mucus studies, ultrasonography, premenstrual endometrial biopsy, histopathological examination and serum progesterone estimation in the mid-luteal phase.

- © Assessment of tubal patency by appropriate investigations including hysterosalpingography, sonosalpingography, or laparoscopy if required, to find out/rule out specific problems and to select the appropriate therapy.
- © Screening for local factors including cervical mucus-related problems and lower genital tract infections, and instituting appropriate therapy.
- © Assessment of uterine cavity by hysteroscopy.
- © Screening for reproductive tract infections including syphilis, chlamydia, tuberculosis, HBV, HCV and HIV, and appropriate management.
- © If needed, appropriate endocrinological investigations and therapy.

Any gynaecologist not specifically trained in the subspeciality of infertility care can also complete these investigations.

Based on the results of these investigations, couples should be selected for treatment at different levels of infertility care units. Depending on the personnel competence and availability of facilities for investigation and treatment, there should be three levels of infertility care units: (a) primary infertility care units, (b) secondary infertility care units, and (c) tertiary infertility care units. These care units should work in a tier system.

2.2 Patient Selection for Treatment in Different Infertility Care Units

In general, infertile couples can be categorized broadly into three groups: (1) those with single defect in one of the partners; (2) those with multiple defects in one or both the partners; (3) no apparent defect in either partner (unexplained infertility).

2.2.1 Single defect in one of the partner

The fault may exist either in the male or in the female partner. The defect may be either treatable or untreatable. For example, in the female partner, a treatable defect could be tough or imperforate hymen, or oligo- or anovulation due to polycystic ovary syndrome or a sub-mucous fibroid. The untreatable female partner defects would include premature ovarian failure,

absence of uterus, dense pelvic adhesions due to endometriosis, tuberculosis, and pelvic inflammatory disease as a sequel to pelvic surgery.

Unlike female factor infertility, male factor infertility is seldom easily correctable. Except oligozoospermia without asthenospermia, and sexual dysfunction due to phimosis, no other male factor infertility is amenable to simple medical or surgical therapy.

If a single defect in one of the partners is correctable, approximately half of the patients will respond to conventional medical or surgical therapy and the other half will not. Further treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART – failing which, adoption may be the only alternative.

For an uncorrectable single defect, either in the male or in the female partner, the choice would be between ART and adoption. The alternative to be chosen should be suggested by the counsellor after evaluation of the age, financial capabilities and psychological attitude of the couple.

2.2.2 Multiple defects in one or both partners

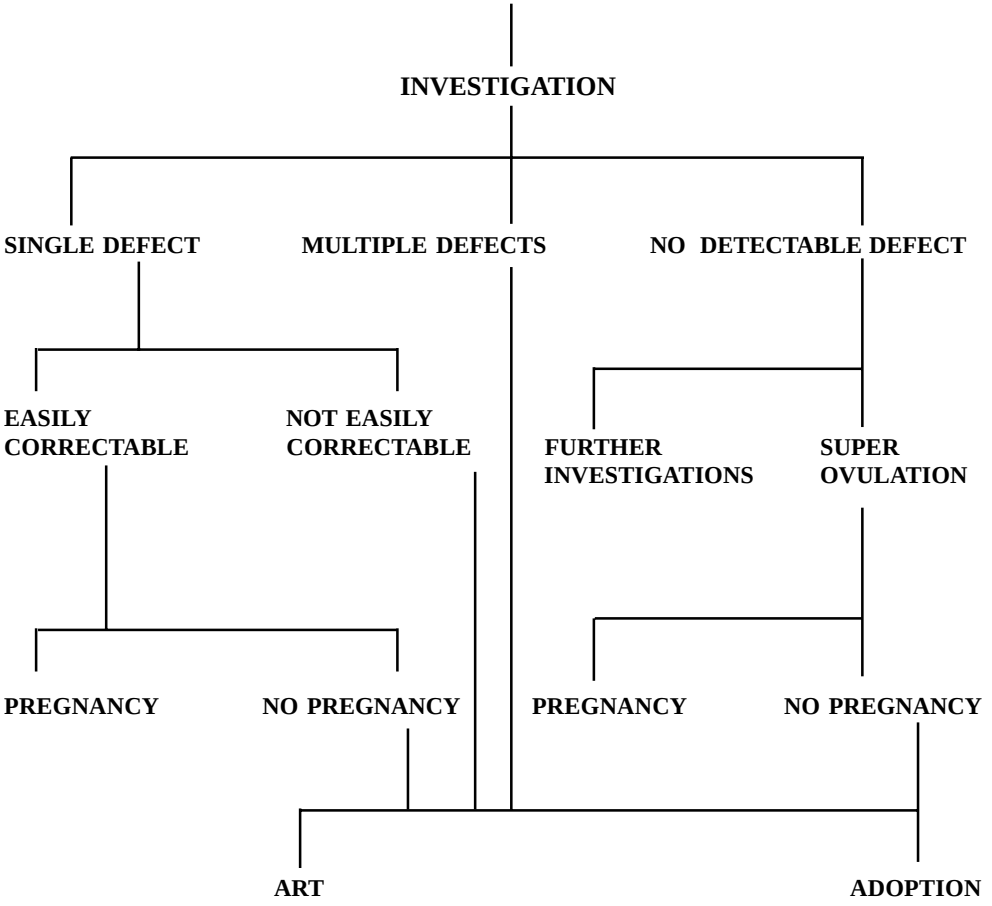
When multiple defects involve either one or both partners, attempt to correct these defects and hoping to achieve a pregnancy in the natural way is almost always unrewarding. This should be explained by the consulting gynaecologist/physician to the couple to prevent unnecessary expenditure by the couple. Judicious and effective counselling plays a very vital role under such circumstances; at least some couples will accept that at this point their treatment ends. A few will opt for adoption while others might wish to try the challenges of ART procedures.

2.2.3 No detectable defect in either partner (unexplained or idiopathic infertility)

This is a group most difficult to deal with as, they would have a right to ask that, in spite of everything being normal, what is standing in their way to achieve conception.

The approach to management protocol of infertile couples with regard to nature of defects may be summarized as follows:

OUTLINE OF MANAGEMENT PROTOCOL OF INFERTILE COUPLE:



2.3 Selection Criteria for ART

The choice of the procedure used, e.g. IVF-ET, GIFT, ZIFT, or ICSI, is made depending upon the needs, resources and circumstances of the couple, availability of the facilities, and experience and expertise of the gynaecologist/ embryologist. This section should be read in conjunction with Section 1.6.

2.3.1 Selection criteria for *in vitro* fertilization and embryo transfer (IVF-ET)

2.3.1.1 Tubal disease

IVF-ET can be offered where microsurgical techniques for tubal and peritoneal disease have failed or are unlikely to benefit the patient. The presence of peritubal adhesions, condition of the tubal wall, condition of the ciliary epithelium and degree of fimbrial damage would dictate the choice between IVF and microsurgery. Patients who have already undergone tuboplasty and those with inaccessible ovaries would be more suitable for IVF. In cases of history of ectopic pregnancy, IVF would be a better option.

2.3.1.2 Endometriosis

IVF is a suitable option for (a) women with moderate to severe endometriosis; (b) those in whom medical or surgical therapy has failed; and (c) sometimes in cases of mild to moderate endometriosis in the presence of other factors contributing to infertility.

2.3.1.3 Unexplained infertility

Couples who have prolonged unexplained infertility would benefit from IVF, as many factors such as subtle ovulation defects, defects in ovum pick-up, gamete transport, tubal environment, sperm abnormality, or oocyte abnormality may come to light when IVF is used.

2.3.1.4 Immunological factor

IVF can be used when there are antisperm antibodies either in the male or the female and when other techniques such as immunosuppression, use of condoms, intrauterine insemination and other therapeutic measures have failed.

2.3.1.5 Cervical factor

IVF can be offered for cervical factor only if repeated attempts (6 to 8 cycles) of intrauterine insemination have failed and other therapies have not resulted in pregnancy.

2.3.1.6 Male factor

IVF-ET is the logical therapy in cases of low concentrations of sperm (say, less than 10 million/ml), low motility (less than 30%), and/or abnormal sperm morphology (presence of > 60% abnormal forms). No universally accepted minimal sperm concentration for success in IVF exists. In cases of severe male factor infertility, assisted fertilization by means of micromanipulation and sperm injection (ICSI) can be offered even in obstructive and non-obstructive cases. In severe oligozoospermia, teratozoospermia, cryptozoospermia and azoospermia (obstructive/ nonobstructive), ICSI can be employed using either ejaculated or epididiymal sperm.

2.3.1.7 Ovarian disorders

IVF-ET can benefit patients with hypogonadotropic anovulation, oligoovulation, and luteal phase deficiency, although IVF is rarely indicated when these disorders exist as isolated conditions. IVF-ET can be used for women with luteinized unruptured follicle syndrome in polycystic ovarian disease.

2.3.1.8 Uterine disorders

Patients with Mullerian agenesis or congenital uterine anomalies, women with severe intrauterine adhesion refractory to surgical lysis of the adhesions, and hysterectomized patients can, through IVF, transfer their embryos to a surrogate mother.

2.3.1.9 In association with donor oocytes and donor embryos

Women who have undergone premature or timely menopause and women in the perimenopausal age group who do not show proper recruitment of follicles and who have other existing causes of infertility, can avail of the option of donor oocytes and donor embryos. Women with genetic disorders, those who have undergone radiation therapy, and those with ovaries that are not accessible by ultrasound due to severe adhesions, can also be advised to avail of donor oocytes for IVF-ET.

2.3.2 Selection criteria for gamete intra-fallopian transfer (GIFT)

The experimental background for GIFT is the ability of the fallopian tube to serve as the site for capacitation and fertilization in human beings. Earlier experiments using GIFT were carried out on monkeys that had undergone tubal resection and ligation. In 1979, Shettles reported pregnancy after intratubal transfer of freshly aspirated oocytes at the time of tubal re-anastomosis combined with cervical insemination. Asch and colleagues (1987) reported the first pregnancy and birth using laparoscopic GIFT. The indications for GIFT are almost similar to that for IVF-ET, except that GIFT cannot be performed on those who have both the fallopian tubes blocked.

2.3.3 Choosing between IVF-ET and GIFT

Decision in regard to which of these techniques should be utilized, must be individualized for each patient. The advantages of IVF over GIFT are documentation of fertilization, less trauma and relatively lower anaesthetic risk. There is no exposure to excess quantities of carbon dioxide in IVF as happens during laparoscopic insufflation with GIFT. On the other hand, GIFT is more

natural as fertilization occurs in the tubal ampulla, the gametes are minimally exposed *in vitro*, and early embryo development occurs in a natural environment.

2.3.4 Micro-assisted fertilization (SUZI and ICSI)

Subzonal insemination (SUZI), intracytoplasmic sperm injection (ICSI) and assisted hatching need micromanupulation of gametes. SUZI involves sperm injection in *in vitro*, in-to the sub zonal space of oocytes. This technique has now been virtually totally replaced by ICSI, which involves injection of sperm into the cytoplasm of the oocyte and which is useful in a variety of cases such as aging ova, elderly women, repeated failure of implantation in IVF, and in certain cases of male factor infertility. Assisted hatching of embryo by drilling a hole in the zona pellucida is resorted prior to embryo transfer for improving implantation rates.

2.4 Complications

ART procedures carry a small risk both to the mother and the offspring. These risks must be explained to the couple and appropriate counselling done. ART procedures are to be initiated only after patients understand these risks and still want to undergo ART. Some of the most commonly encountered risks are mentioned below (this list is not exhaustive).

2.4.1 Multiple gestation

The reported incidence of multiple gestation ranges from 20 to 30%. Incidence of twin pregnancies in the range of 10-20% may have to be accepted as inevitable, but specific efforts must be made to reduce the incidence of triplets and multiple births of higher order. Therefore, not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality; also see Section 3.5.13) which should be recorded; the remaining embryos, if any, may be cryopreserved and, if required, transferred at a later cycle.

2.4.2 Ectopic pregnancy

Ectopic pregnancy rates could be as high as up to 8% for ART procedures. The choice of an appropriate procedure as per guidelines mentioned earlier, especially in persons with tubal disease, may reduce the chances of an ectopic pregnancy.

2.4.3 Spontaneous abortion

Spontaneous abortion rates range from 20 to 35%. Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more foetuses. In cases where more than two foetuses are present, selective embryo reduction should be advised. It is essential that the advantages of embryo reduction (better chances of the survival of other foetuses and the fact that they are likely to be born nearer term and with better birth weight) and disadvantages (the possibility that there might be an increased risk of abortion following the procedure) must be explained to the couple, and their informed consent taken before embryo reduction is attempted.

2.4.4 Preterm birth

There is a higher risk of premature/low birth weight delivery following ART, especially in the presence of multiple foetuses.

2.4.5 Ovarian hyperstimulation syndrome

The use of superovulation for ART entails a risk of hyperstimulation in some women, in the range of 0.2 to 8.0%. The extent of this risk is determined by the hormonal profile of the woman, the estradiol values (greater than 2500 pg/ml), the dose required for triggering ovulation, the ability to aspirate all the follicles at the time of oocyte retrieval, and several other factors. The programme director should be fully aware of the means to avoid hyperstimulation and also its treatment. Careful monitoring and management will reduce this risk as well as the morbidity associated with it.

In addition to these specific complications of ART, couples undergoing various ART procedures incur the risks associated with the operative and anaesthetic procedures involved in ART.

2.5 Categories of Infertility Care Units

The severity in the cause of infertility varies between couples. Sometimes, simple counselling or minor intervention will be all that is necessary. Others may require more aggressive treatment; such cases should be referred to speciality clinics. It is, therefore, recommended that infertility treatment should be offered at four levels. The infertility care units should be categorized into the four levels and authorized to offer treatments as described below. Patients should be referred by their gynaecologist or physician to whom they go first, if necessary, to the specific level of infertility care unit where appropriate facilities for investigation and treatment for that patient would be available. Level 1B, Level 2 and level 3 infertility clinics may encourage appropriately qualified gynaecologists of Level 1A clinics to use their facilities, provided the clinic thus being used by a gynaecologist takes the responsibility of ensuring that all norms stated in this document - including the maintenance of records - are followed.

2.5.1 Primary (Level 1A) infertility care units

These would be clinics where preliminary investigations are carried out and type and cause of infertility diagnosed. Primary infertility care unit or clinic could be a doctor's consulting room, such as a gynaecologist's or a physician's consulting room, or even a general hospital. Depending on the severity of infertility, the couple could be treated at the Level 1A clinic or referred to a speciality (Level 1B, Level 2 or Level 3) clinic.

Investigations into the cause of infertility by diligent history taking, physical examination and a simple semen analysis that can detect cases of azoospermia, can determine if the cause of infertility is related to the female or the male or to both the partners. Multifactorial or unexplainable cases should be referred to speciality secondary (Level 2) or tertiary (Level 3) infertility care units.

The gynaecologist or the physician in charge of a Level 1A infertility care unit should have an appropriate post-graduate degree and be capable of taking care of the above responsibilities.

The responsibilities of a Level 1A primary infertility care unit would be

1. Completion of the basic investigations mentioned above.
2. Treatment of minor anatomical defects like tough imperforate hymen. (Surgical perforation of hymen can be carried out after ensuring that the husband does not have erectile dysfunction. Extreme care must be taken in performing hymenectomy).
3. Treatment of mild endometriosis after confirming its presence by diagnostic laparoscopy carried out by a competent surgeon with adequate endoscopic experience.
4. Introduction of ovulation in non-ovulatory women (especially PCOS) with clomiphene citrate, with or without adjuncts like bromocriptine, eltroxin, dexamethasone or spironolactone. (Gonadotropin should not be used at a primary infertility care unit level).
5. Correcting minor endocrine disorders such as thyroid disorders or hyperprolactinemia, by prescribing appropriate corrective medications.
6. Treatment of oligozoospermia without asthenozoospermia.
7. Detecting infection of the reproductive tract using appropriate diagnostic tests, followed by normal health-care steps after carrying out appropriate antibiotic sensitivity tests. (Particular care must be taken to treat the couple and not the female or the male patient alone).
8. Ability to carry out AIH.
9. Ability to carry out IUI using processed semen of husband or donor obtained from an accredited laboratory or semen bank which must maintain a record (as in section 3.3.7) of complete details including the name, qualification and complete address of the gynaecologist/ clinic requesting the processed semen and carrying out the IUI.
10. Referral of the couple to Level 1B, Level 2 or Level 3 infertility care unit as appropriate, specially when the woman's age is more than 35, or when the couple has a multifactorial defect, or when

patients with single treatable defect have not responded to conventional therapy.

The gynaecologist or the physician in charge of a Level 1A infertility care unit should have an appropriate post-graduate degree or diploma, and be capable of taking care of the above responsibility. In case a Level 1A clinic is engaged in AIH and IUI it must maintain records (as in section 3.3.7) of the use of the requisitioned semen and of all AIH & IUI done, appropriately and confidentially; these records will be liable to inspection by an appropriate Review Committee (section 3.15). A Level 1A infertility care unit will not require an accreditation under these guidelines.

2.5.2 Primary (Level 1B) infertility care units engaging in IUI

These units would be required to have, in addition to what has been stated in Section 2.5.1, the facilities mentioned in the following two sub-sections (2.5.2.1 and 2.5.2.2). Infertility clinics falling into this category [like those of Level 2 and Level 3 (see the following sections)] shall need accreditation. The IUI in such clinics must be done under the supervision of a gynaecologist with a post-graduate degree.

2.5.2.1 Facilities for investigations:

i. Immunological tests for infertility, sperm cervical mucous penetration test (SCMPT), sperm cervical mucous test (SCMT), and test for antibodies (IgG, IgA) against sperm antigen in cervical mucous.
ii. Sperm function tests like hypo-osmotic swelling test (HOST), and assessment for improvement of sperm motility potential with pentoxifyllene co-culture.
iii. Assessment of follicular growth and ovulation by serial transvaginal sonography (TVS).
iv. Hysteroscopy, laparoscopy and transvaginal sonography.

2.5.2.2 Treatment facilities:

i. Facilities for semen preparation and certification and for intrauterine insemination (IUI), including an appropriate sterile area for IUI. (The facilities for investigation and for sperm preparation mentioned above could be shared with another accredited infertility clinic or semen bank).

2.5.3 Secondary (Level 2) infertility care units

These units must have infrastructure for further in-depth investigation and extended treatment of infertility except where oocytes are handled outside the body. Some of the investigations and treatment facilities required for Level 2 care units are detailed below:

2.5.3.1 Facilities for investigations:

i. Immunological tests for infertility, sperm cervical mucous penetration test (SCMPT), sperm cervical mucous test (SCMT), and tests for antibodies (IgG, IgA) against sperm antigen in cervical mucous.
ii. Sperm function tests like hypo-osmotic swelling test (HOST), and assessment of the improvement of sperm motility potential with pentoxifyllene co-culture.
iii. Assessment of follicular growth and ovulation by serial transvaginal sonography (TVS).
iv. Hysteroscopy, laparoscopy and transvaginal sonography.

2.5.3.2 Treatment facilities:

i. Facilities for semen preparation and intrauterine insemination (IUI).
ii. Provision for semen collection in men with a vibrator or an electroejaculator in functional erectile and ejaculatory problems.
iii. Conservative surgery either through a laparoscope, hysteroscope or via laparotomy. It should be possible to perform hysteroscopic cannulation of blocked tubes, and resection of submucous myoma or uterine septum.

iv. Combined medical-surgical therapy by a co-ordinated team as in endometriosis or in some cases of polycystic ovaries (ovarian drilling).
v. Provision for extended treatment of infertility except for oocyte pick up and IVF, ICSI etc.

2.5.4 Tertiary (Level 3) infertility care units

Such units will have three functions to perform, viz. diagnostic and therapeutic at the highest level of specialization and with the best of facilities, and research. Some examples of the first two functions are given below in Sections 2.5.4.1 to 2.5.4.3. If any of the facilities mentioned below does not exist in the clinic, the clinic should have access to such a facility in another appropriately accredited clinic, semen bank, or laboratory.

2.5.4.1 Diagnostic procedures for male infertility

i. Endocrine assay.
ii. Further tests for sperm function and integrity such as acrosome reaction and sperm-oocyte interaction *in vitro*.
iii. Assessment of cell contaminants, debris and infection.
iv. Karyotyping when sperm density, morphology and motility are abnormal.
v. Assessment of seminal plasma for viscosity, thinness, blood contamination and biochemical constituents.

2.5.4.2 Diagnostic procedures for female infertility

i. Endocrine assay.
ii. Karyotyping in premature ovarian failure in Kallman's syndrome.
iii. Colour Doppler for checking growing follicles, functional integrity of corpus luteum, and developing endometrium in stimulated or unstimulated cycle.
iv. GnRH challenge test in non-ovulation due to hypothalamic pituitary failure.
v. Clomiphene challenge tests to ascertain ovarian reserves before

ovulation induction or controlled ovarian hyperstimulation.

2.5.4.3 Therapeutic procedures

i. Induction of ovulation in refractory non-ovulation due to PCO-down regulation with a GnRH-agonist followed by induction with gonadotropin.
ii. All varieties of assisted reproductive technologies, including ICSI, mentioned earlier.
iii. Procedures for IUI using split ejaculate, pooled ejaculate or sperm recovered from post-coital specimen of urine in retrograde ejaculation.
iv. Embryo freezing.

Chapter 3

Code of Practice, Ethical Considerations and Legal Issues

3.1 Clinics which should be Registered

Clinics involved in any one of the following activities should be regulated, registered and supervised by the State Accreditation Authority/State Appropriate Authorities (Section 3.15).

1. Any treatment involving the use of gametes which have been donated or collected or processed *in vitro*, *except for* AIH, and for IUI by level 1A clinics who will not process the gametes themselves.
2. Any infertility treatment that involves the use and creation of embryos outside the body.
3. The processing or /and storage of gametes or embryos.
4. Research on human embryos.

The term ART clinic used in this document refers to a clinic involved in any one of the first three of the above activities.

3.2 Code of Practice

This Code of Practice deals with all aspects of the treatment provided and the research done at registered clinics. Those areas which most affect the doctors, scientists and patients and are a part of this code are summarized below.

3.2.1 Staff: A 'person responsible' shall take full responsibility for ensuring that the staff of the registered unit is sufficiently qualified, that proper equipment is used, that genetic material is kept and disposed off properly, and that the center complies with the conditions of its registeration. ***Guidelines for minimum standards*** and qualifications of clinical, scientific and counselling staffs are laid down in Chapter 1. Failure of the 'person responsible' to comply with the ***mandatory code of practice*** can lead to his/her removal or prosecution, or to the suspension of the clinic's registration.

3.2.2 Facilities: These must cover the standards expected in respect of provision of clinical, laboratory and counselling care mentioned in Chapters 1 and 2. Proper systems for monitoring and assessing practices and procedures are required to be in place (for example in the form of Standard Operating Procedures) in order to optimize the outcome of ART.

3.2.3 Confidentiality: Any information about clients and donors must be kept confidential. No information about the treatment of couples provided under a treatment agreement may be disclosed to anyone other than the accreditation authority or persons covered by the registration, except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a court order. It is the above person's right to decide what information will be passed on and to whom, except in the case of a court order.

3.2.4 Information to patient: All relevant information must be given to the patient before a treatment is given. Thus, before starting treatment, information should be given to the patient on the limitations and results of the proposed treatment, possible side-effects, the techniques involved, comparison with other available treatments, the availability of counselling, the cost of the treatment, the rights of the child born through ART, and the need for the clinic to keep a register of the outcome of a treatment.

3.2.5 Consent: No treatment should be given without the written consent of the couple to all the possible stages of that treatment, including the possible freezing of supernumerary embryos. A standard consent form recommended by the accreditation authority should be used by all ART clinics. Specific consent must be obtained from couples who have their gametes or embryos frozen, in regard to what should be done with them if he/she dies, or becomes incapable of varying or revoking his or her consent.

3.2.6 Counselling: People seeking registered treatment must be given a suitable opportunity to receive proper counselling about the various implications of the treatment. No one is obliged to accept counselling but it is generally recognized as being beneficial, and couples should be encouraged to go

through it. The provision of facilities for counselling in an ART clinic (of Levels 1B, 2 or 3) is, therefore, mandatory. Couples should be referred for support or therapeutic counselling as appropriate.

3.2.7 Use of gametes and embryos: No more than three oocytes or embryos may be placed in a woman in any one cycle, regardless of the procedure/s used, excepting under exceptional circumstances (such as elderly women, poor implantation, adenomiosis, or poor embryo quality) which should be recorded. No woman should be treated with gametes or with embryos derived from the gametes of more than one man or woman during any one-treatment cycle.

3.2.8 Storage and handling of gametes and embryos: The 'highest possible standards' in the storage and handling of gametes and embryos in respect of their security, and in regard to their recording and identification, should be followed.

3.2.9 Research: The accreditation authority must approve all research that involves embryos created *in vitro*. A separate registration should be issued for each research project involving human embryos. The accreditation authority must not give a registation certificate unless it is satisfied that the use of human embryos is essential for the purposes of the proposed research and the research is in public interest.

Additionally:

(i) No human embryo may be placed in a non-human animal

(ii) All research projects must be approved by the Institutional Ethics Committee before submission to the accreditation authority.

3.2.10 Complaints: All registered ART clinics are required to have procedures for acknowledging and investigating complaints, and to have a nominated person to deal properly with such complaints. The accreditation authority must be informed of the number of complaints made in any year and those that are outstanding.

3.3 Responsibilities of the Clinic

3.3.1 To give adequate information to the patients (detailed in Section 3.4).

3.3.2 To explain to the patient the rationale of choosing a particular treatment (see Chapter 2) and indicate the choices the patient has (including the cheapest possible course of treatment), with advantages and disadvantages of each choice.

3.3.3 To help the patient exercise a choice, which may be best for him/her, taking into account the individual's circumstances.

3.3.4 To maintain records in an appropriate proforma (to be prescribed by the authority) to enable collation by a national body.

3.3.5 When commercial DNA fingerprinting becomes available, to keep on its record, if the ART clinic desires and couple agrees, DNA fingerprints of the donor, the child, the couple and the surrogate mother should be done.

3.3.6 To keep all information about donors, recipients and couples confidential and secure. The information about the donor (including a copy of the donor's DNA fingerprint if available, but excluding information on the name and address – that is, the individual's personal identity) should be released by the ART clinic after appropriate identification, only to the offspring and only if asked by him/her after he/she reaches the age of 18 years, or as and when specified and required for legal purposes, and never to the parents (excepting when directed by a court of law).

3.3.7 To maintain appropriate, detailed record of all donor oocytes, sperm or embryos used, the manner of their use (e.g. the technique in which they are used, and the individual/couple/surrogate mother on whom they are used). These records must be maintained for at least ten years after which the records must be transferred to a central depository to be maintained by the ICMR. If the ART clinic/centre is wound up during this period, the records must be transferred to the central repository in the ICMR.

3.3.8 To have the schedule of all its charges suitably displayed in the clinic and made known to the patient at the beginning of the treatment. There must be no extra charges beyond what was intimated to the patient at the beginning of the treatment.

3.3.9 To ensure that no technique is used on a patient for which demonstrated expertise does not exist with the staff of the clinic.

3.3.10 To be totally transparent in all its operations. The ART clinics must, therefore, let the patient know what the success rates of the clinic are in regard to the procedures intended to be used on the patient.

3.3.11 To have all consent forms available in English and local language(s).

3.4 Information and Counselling to be given to Patients

Information must be given to couples seeking treatment, on the following points:

3.4.1. The basis, limitations and possible outcome of the treatment proposed, variations in its effectiveness over time, including the success rates with the recommended treatments obtained in the clinic as well as around the world (this data should be available as a document with references, and updated every 6 – 12 months).

3.4.2. The possible side-effects (e.g. of the drug used) and the risks of treatment to the women and the resulting child, including (where relevant) the risks associated with multiple pregnancy.

3.4.3 The need to reduce the number of viable foetuses, in order to ensure the survival of at least two foetuses.

3.4.4. Possible disruption of the patient's domestic life which the treatment may cause.

3.4.5 The techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort.

3.4.6 The cost (with suitable break-up) to the patient of the treatment proposed and of an alternative treatment, if any (there must be no other "hidden costs").

3.4.7 The importance of informing the clinic of the result of the pregnancy in a pre-paid envelope.

3.4.8 To make the couple aware, if relevant, that a child born through ART has a right to seek information (including a copy of the DNA fingerprint, if available) about his genetic parent/surrogate mother on reaching 18 years, excepting information on the name and address – that is, the individual's personal identity – of the gamete donor or the surrogate mother. The couple is not obliged to provide the information to which the child has a right, on their own to the child when he/ she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child should an occasion arise when this issue becomes important for the child.

3.4.9 The advantages and disadvantages of continuing treatment after a certain number of attempts.

Pamphlets (one-page on each technique in all local languages and English) which give clear, precise and honest information about the procedure recommended to be used will help the couple make an informed choice.

3.5 Desirable Practices/Prohibited Scenarios

3.5.1 A third party donor of sperm or oocytes must be informed that the offspring will not know his/her identity. He/She must also be informed of the provisions in Section 3.4.8.

3.5.2 There would be no bar to the use of ART by a single women who wishes to have a child, and no ART clinic may refuse to offer its services to the above, provided other criteria mentioned in this document are satisfied. The child thus born will have all the legal rights on the woman or the man.

3.5.3 The ART clinic must not be a party to any commercial element in donor programmes or in gestational surrogacy.

3.5.4 A surrogate mother carrying a child biologically unrelated to her must register as a patient in her own name. While registering she must mention that she is a surrogate mother and provide all the necessary information about the genetic parents such as names, addresses, etc. She must not use/register in the name of the person for whom she is carrying the child, as this would pose legal issues, particularly in the untoward event of maternal death (in whose names will the hospital certify this death?). The birth certificate shall be in the name of the genetic parents. The clinic, however, must also provide a certificate to the genetic parents giving the name and address of the surrogate mother. All the expenses of the surrogate mother during the period of pregnancy and post-natal care relating to pregnancy should be borne by the couple seeking surrogacy. The surrogate mother would also be entitled to a monetary compensation from the couple for agreeing to act as a surrogate; the exact value of this compensation should be decided by discussion between the couple and the proposed surrogate mother. An oocyte donor can not act as a surrogate mother for the couple to whom the ooctye is being donated.

3.5.5 A third-party donor and a surrogate mother must relinquish in writing all parental rights concerning the offspring and vice versa.

3.5.6 No ART procedure shall be done without the spouse's consent.

3.5.7 The provision or otherwise of AIH or ART to an HIV-positive woman would be governed by the implications of the decision of the Supreme Court in the case of X – vs – Hospital 2 (1998) 8 Sec. 269 or any other relevant judgement of the Supreme Court, or law of the country, whichever is the latest.

3.5.8 Gametes produced by a person under the age of 21 shall not be used. The accepted age for a sperm donor shall be between 21 and 45 years and for the donor woman between 18 and 35 years.

3.5.9 Sex selection at any stage after fertilization, or abortion of foetus of any particular sex should not be permitted, except to avoid the risk of transmission of a genetic abnormality assessed through genetic testing of biological parents or through preimplantation genetic diagnosis (PGD).

3.5.10 No ART clinic shall offer to provide a couple with a child of the desired sex.

3.5.11 Collection of gametes from a dying person will only be permitted if the widow wishes to have a child.

3.5.12 No more than three eggs or embryos should be placed in a woman during any one treatment cycle, regardless of the procedure used, excepting under exceptional circumstances {such as elderly women (above 37 years), poor implantation (more than three previous failures), advanced endometriosis, or poor embryo quality} which should be recorded.

3.5.13 Use of sperm donated by a relative or a known friend of either the wife or the husband shall not be permitted. It will be the responsibility of the ART clinic to obtain sperm from appropriate banks; neither the clinic nor the couple shall have the right to know the donor identity and address, but both the clinic and the couple, however, shall have the right to have the fullest possible information from the semen bank on the donor such as height, weight, skin colour, educational qualification, profession, family background, freedom from any known diseases or carrier status (such as hepatitis B or AIDS), ethnic origin, and the DNA fingerprint (if possible), before accepting the donor semen. It will be the responsibility of the semen bank and the clinic to ensure that the couple does not come to know the identity of the donor. The ART clinic will be authorized to appropriately charge the couple for the semen provided and the tests done on the donor semen.

3.5.14 What has been said above under 3.5.13 also would be true of oocyte donation.

3.5.15 When DNA fingerprinting technology becomes commercially available, the ART clinic may offer to the couple, a DNA fingerprint of the donor

without revealing his/her identity, against appropriate payment towards the cost of the DNA fingerprint. An ART clinic will then have DNA fingerprinting done of the couple and keep the DNA fingerprints on its records.

3.5.16 Trans-species fertilization involving gametes of two species is prohibited.

3.5.17 Ova derived from foetuses cannot be used for IVF but may be used for research.

3.5.18 Semen from two individuals must never be mixed before use, under any circumstance.

3.5.19 Transfer of human embryo into a human male or into any animal belonging to any other species, must never be done and is prohibited.

3.5.20 The data of every accredited ART clinic must be accessible to an appropriate authority of the ICMR for collation at the national level.

3.5.21 Any publication or report resulting out of analysis of such data by the ICMR will have the concerned members of the staff of the ART clinic as co-authors.

3.5.22 The consent on the consent form must be a true informed consent witnessed by a person who is in no way associated with the clinic.

3.6 Requirements for a Sperm Donor

3.6.1 The individual must be free of HIV and hepatitis B and C infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia.

3.6.2 The age of the donor must not be below 21 or above 45 years.

3.6.3 An analysis must be carried out on the semen of the individual, preferably using a semen analyzer, and the semen must be found to be normal according to WHO method manual for semen analysis, if intended to be used for ART.

3.6.4 The blood group and the Rh status of the individual must be determined and placed on record.

3.6.5 Other relevant information in respect of the donor, such as height, weight, age, educational qualifications, profession, colour of the skin and the eyes, record of major diseases including any psychiatric disorder, and the family background in respect of history of any familial disorder, must be recorded in an appropriate proforma.

3.7 Requirements for an Oocyte Donor

3.7.1 The individual must be free of HIV and hepatitis B and C infections, hypertension, diabetes, sexually transmitted diseases, and identifiable and common genetic disorders such as thalassemia.

3.7.2 The blood group and the Rh status of the individual must be determined and placed on record.

3.7.3 Other relevant information in respect of the donor, such as height, weight, age, educational qualifications, profession, colour of the skin and the eyes, and the family background in respect of history of any familial disorder, must be recorded in an appropriate proforma.

3.7.4 The age of the donor must not be less than 21 or more than 35 years.

3.8 Requirements for a Surrogate Mother

See Section 3.10.

3.9 How may Sperm and Oocyte Donors and Surrogate Mothers be Sourced?

3.9.1 Semen banks

3.9.1.1 Either an ART clinic or a law firm or any other suitable independent organization may set up a semen bank. If set up by an ART clinic it must operate as a separate identity.

3.9.1.2 The bank will ensure that all criteria mentioned in Section 3.6 (Requirements for a sperm donor) are met and a suitable record of all donors is kept for 10 years after which, or if the bank is wound up during this period, the records shall be transferred to an ICMR repository.

3.9.1.3 A bank may advertise suitably for semen donors who may be appropriately compensated financially.

3.9.1.4 On request for semen by an ART clinic, the bank will provide the clinic with a list of donors (without the name or the address but with a code number) giving all relevant details such as those mentioned in Section 3.6. The semen bank shall not supply semen of one donor for more than ten successful pregnancies. It will be the responsibility of the ART clinic or the patient, as appropriate, to inform the bank about a successful pregnancy. The bank shall keep a record of all semen received, stored and supplied, and details of the use of the semen of each donor. This record will be liable to be reviewed by the accreditation authority.

3.9.1.5 The bank must be run professionally and must have facilities for cryopreservation of semen, following internationally accepted protocols. Each bank will prepare its own SOP (Standard Operating Procedures) for cryopreservation.

3.9.1.6 Semen samples must be cryopreserved for at least six months before first use, at which time the semen donor must be tested for HIV and hepatitis B and C.

3.9.1.7 The bank must ensure confidentiality in regard to the identity of the semen donor.

3.9.1.8 A semen bank may store a semen preparation for exclusive use on the donor's wife or on any other woman designated by the donor. An appropriate charge may be levied by the bank for the storage. In the case of non-payment of the charges when the donor is alive, the bank would have the right to destroy the semen sample or give it to a bonafide organisation to be used only for research purposes. In the case of the death of the donor, the semen would become the property of the legal

heir or the nominee of the donor at the time the donor gives the sample for storage to the bank. All other conditions that apply to the donor would now apply to the legal heir, excepting that he cannot use it for having a woman of his choice inseminated by it. If after the death of the donor, there are no claimants, the bank would have the right to destroy the semen or give it to a bonafide research organisation to be used only for research purposes.

3.9.1.9 All semen banks will require accreditation.

3.9.2. Sourcing of oocytes and surrogate mothers

Law firms and semen banks will be encouraged to obtain (for example, through appropriate advertisement) and maintain information on possible oocyte donors and surrogate mothers as per details mentioned elsewhere in this document. The above organizations may appropriately charge the couple for providing an oocyte or a surrogate mother. The oocyte donor may be compensated suitably (e.g. financially) by the law firm or semen bank when the oocyte is donated. However, negotiations between a couple and the surrogate mother must be conducted independently between them.

3.9.3. Oocyte sharing

The system of oocyte sharing in which an indigent infertile couple that needs to raise resources for ART agrees to donate oocytes to an affluent infertile couple wherein the wife can carry a pregnancy through but cannot produce her own oocyte, for in-vitro fertilization with the sperm of the male partner of the affluent couple, for a monitory compensation that would take care of the expenses of an ART procedure on the indigent couple, must be encouraged.

3.10 Surrogacy: General Considerations

3.10.1 A child born through surrogacy must be adopted by the genetic (biological) parents unless they can establish through genetic (DNA) fingerprinting (of which the records will be maintained in the clinic) that the child is theirs.

3.10.2 Surrogacy by assisted conception should normally be considered only for patients for whom it would be physically or medically impossible/ undesirable to carry a baby to term.

3.10.3 Payments to surrogate mothers should cover all genuine expenses associated with the pregnancy. Documentary evidence of the financial arrangement for surrogacy must be available. The ART centre should not be involved in this monetary aspect.

3.10.4 Advertisements regarding surrogacy should not be made by the ART clinic. The responsibility of finding a surrogate mother, through advertisement or otherwise, should rest with the couple, or a semen bank (see 3.9.1.1; 3.9.2).

3.10.5 A surrogate mother should not be over 45 years of age. Before accepting a woman as a possible surrogate for a particular couple's child, the ART clinic must ensure (and put on record) that the woman satisfies all the testable criteria to go through a successful full-term pregnancy.

3.10.6 A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.

3.10.7 A prospective surrogate mother must be tested for HIV and shown to be seronegative for this virus just before embryo transfer. She must also provide a written certificate that (a) she has not had a drug intravenously administered into her through a shared syringe, (b) she has not undergone blood transfusion; and (c) she and her husband (to the best of her/his knowledge) has had no extramarital relationship in the last six months. (This is to ensure that the person would not come up with symptoms of HIV infection during the period of surrogacy.) The prospective surrogate mother must also declare that she will not use drugs intravenously, and not undergo blood transfusion excepting of blood obtained through a certified blood bank.

3.10.8 No woman may act as a surrogate more then thrice in her lifetime.

3.11 Preservation, Utilization & Destruction of Embryos

3.11.1 Couples must give specific consent to storage and use of their embryos. The Human Fertilization & Embryology Act, UK (1990), allows a 5-year storage period which India would also follow.

3.11.2 Consent shall need to be taken from the couple for the use of their stored embryos by other couples or for research, in the event of their embryos not being used by themselves. This consent will not be required if the couple defaults in payment of maintenance charges after two reminders sent by registered post.

3.11.3 Research on embryos shall be restricted to the first fourteen days only and will be conducted only with the permission of the owner of the embryos.

3.11.4 No commercial transaction will be allowed for the use of embryos for research.

3.12 Rights of a Child Born through various ART Technologies

3.12.1 A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses. Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to a couple through sexual intercourse.

3.12.2 Children born through the use of donor gametes, and their "adopted" parents shall have a right to available medical or genetic information about the genetic parents that may be relevant to the child's health.

3.12.3 Children born through the use of donor gametes shall not have any right whatsoever to know the identity (such as name, address, parentage, etc.) of their genetic parent(s). A child thus born will, however, be provided all other information (including that mentioned in Section 3.4.8)

about the donor as and when desired by the child, when the child becomes an adult. While the couple will not be obliged to provide the above "other" information to the child on their own, no deliberate attempt will be made by the couple or others concerned to hide this information from the child as and when asked for by the child.

3.12.4 In the case of a divorce during the gestation period, if the offspring is of a donor programme – be it sperm or ova – the law of the land as pertaining to a normal conception would apply.

3.13 Responsibilities of the Drug Industry

3.13.1 Drug companies must not make exaggerated claims for infertility drugs and market them only to qualified specialists. All available information on the drug must be provided to the specialist.

3.13.2 Infertility drugs must be sold only on prescription by a qualified doctor/ ART specialist.

3.13.3 There has been a spurt of new media introduced for *in vitro* culture of gametes and embryos. Companies dealing with culture media do not give full details of the composition because they wish to retain this as a trade secret. This poses problems for those dealing with human embryos. The future life of the products created in the laboratory is dependant, to a certain extent, on the culture media used. ART centers should not encourage companies that do not give details of the full composition of the culture media. This will also make it possible to take legal action against a company supplying something different from what it is stated to be.

3.14 General Considerations

3.14.1 Minimum age for ART:

For a woman between 20 and 30 years, two years of cohabitation/ marriage without the use of a contraceptive, excepting in cases where the man is infertile or the woman cannot physiologically conceive. For a

woman over 30 years, one year of cohabitation/marriage without use of contraceptives. Normally, no ART procedure shall be used on a woman below 20 years.

3.14.2 Advertisements of an infertility centre:

False claims via hoardings and paper advertisements are a cheap way of attracting a clientele that is vulnerable and, therefore, easily swayed. Such advertisements shall be banned. An honest display at appropriate places or publicity of statistics, fee structure, quality of service and of service provided, will be encouraged, provided the guidelines laid down by the Medical Council of India in this regard, are not violated.

3.14.3 As already mentioned, sperm banks where a complete assessment of the donor has been done, medical and other vital information stored, quality of preservation ensured, confidentiality assured, and strict control exercised by a regulatory body, must be set up. Donor sperm would be made available only through such specialized banks/centers.

3.14.4 In the light of a recent technological breakthrough where a fertilized ovum containing ooplasm (including mitochondria) from a donor ovum has been successfully cultured, the embryo or the future child may now have three genetic parents. In such cases, the ooplasm donor must sign a waiver relinquishing all rights on the child, and must be screened for and declared free of known mitochondrial genetic abnormalities.

3.14.5 No new ART clinic may start operating unless it has obtained a temporary registration to do so. This registration would be confirmed only if the clinic obtains accreditation (permanent registration) from the Center or State's appropriate accreditation authority within two years of obtaining the temporary registration. The registration must be renewed every seven years.

3.14.6 Existing ART clinics must obtain a temporary registration within six months of the notification of the accreditation authority, and appropriate accreditation (permanent registration) within two years of the notification.

3.14.7 The Center/State Government would close down any unregistered clinic not satisfying the above criteria.

3.14.8 If the ART clinic that has applied for a temporary registration to the appropriate accreditation authority, does not receive the registration (or a reply) within two months of the receipt of the application from the concerned office of the authority, the ART clinic would be deemed to have received the registration. The same would apply for the permanent registration after the above-prescribed period.

3.14.9 As pointed out in section 1.6.12.2, the technique of ICSI has never undergone critical testing in animal models, but was introduced into the human situation directly. Defects in spermatogenesis and sperm production can be often traced to genetic defects. Such individuals are normally prevented from transmitting these defects to their offspring because of their natural infertility. ICSI by–passes this barrier and may help in transmitting such defects to the offspring, which sometimes may be exaggerated in the offspring. In view of this, the ART clinic must point out to the prospective parents that their child born through ICSI may have a slightly higher risk over and above the normal risk, of suffering from a genetic disorder.

3.14.10 Human cloning for delivering replicas must be banned.

3.14.11 Stem cell cloning and research on embryos (less than 15 days old) needs to be encouraged.

3.14.12 All the equipments/machines should be calibrated regularly.

3.15 Responsibilities of the Accreditation Authority

A State Accreditation Authority will be set up by the State Governments through its Department of Health and/or Family Welfare to oversee all policy matters relating to Accreditation, Supervision and Regulation of ART Clinics in the States in accordance with the National Guidelines. The State Government may also set up appropriate authorities for implementation of the Guidelines for the whole or a part of State having regard to the number of the ART Clinics. The

appropriate authority would have right to visit individually or collectively, any ART Clinic/Centre(s) accredited or not accredited, once a year with or without prior information to the clinic/center, to determine if the ethical guidelines and operative procedures mentioned here are being followed. If not, the appropriate authority will point out the lapses to the clinic/center in writing. If these lapses continued for a maximum period of six months (during which period the clinic shall not engage in any activity related to the lapses), the appropriate authority would recommend to the State Accreditation Authority that the clinic/center may be ordered to be closed. The State Accreditation Authority will have the powers to order the closing of such a clinic or a center. The appropriate authority may be delegated powers to impose a fine or a penalty on the center/clinic. The above-mentioned appropriate authority would consist of appropriately qualified scientists, technologists and sociologists. The appropriate authority will also be authorized to visit and regulate semen banks in the manner mentioned above. In addition to the above, the Ministry of Health and Family Welfare, Govt. of India, will set up a National Advisory Committee. The National Advisory Committee may be headed by the Secretary, Health and Family Welfare as chairman and the Director General of ICMR as co-chairman. The National Advisory Committee will advise the Central Government on policy matters relating to regulation of ART Clinics. Composition of the Committee is given in Chapter 9.

The State Accreditation Authority will have the rights and the responsibility of fixing the upper limit of charges for gamete donation and surrogacy and of revising these charges from time to time.

3.16 Legal Issues

3.16.1 Legitimacy of the child born through ART

A child born through ART shall be presumed to be the legitimate child of the couple, born within wedlock, with consent of both the spouses, and with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donors shall have no parental right or duties in relation to the child, and their anonymity shall be protected except in regard to what is mentioned under item 3.12.3.

3.16.2 Adultery in the case of ART

ART used for married woman with the consent of the husband does not amount to adultery on part of the wife or the donor. AID without the husband's consent can, however, be a ground for divorce or judicial separation.

3.16.3 Consummation of marriage in case of AIH

Conception of the wife through AIH does not necessarily amount to consummation of marriage and a decree of nullity may still be granted in favor of the wife on the ground of impotency of the husband or his willful refusal to consummate the marriage. However, such a decree could be excluded on the grounds of approbation.

3.16.4 Rights of an unmarried woman to AID

There is no legal bar on an unmarried woman going for AID. A child born to a single woman through AID would be deemed to be legitimate. However, AID should normally be performed only on a married woman and that, too, with the written consent of her husband, as a two-parent family would be always better for the child than a single parent one, and the child's interests must outweigh all other interests.

3.16.5 Posthumous AIH through a sperm bank

Though the Indian Evidence Act, 1872, says that a child born within 280 days after dissolution of marriage (by death or divorce) is a legitimate child since that is considered to be the gestation period, it is pertinent to note that this Act was enacted as far back as 1872 when one could not even visualize ART. The law needs to take note of the scientific advancements since that time. Thus a child born to a woman artificially inseminated with the stored sperms of her deceased husband must be considered to be a legitimate child notwithstanding the existing law of presumptions under our Evidence Act. The law needs to move alongwith medical advancements and suitably amended so that it does not give rise to dilemma or unwarranted harsh situations.

3.17 Institutional Ethics Committees

Each ART clinic of Levels 1B, 2 and Level 3 must have its own ethics committee constituted according to ICMR Guidelines, comprising reputed ART practitioners, scientists who are knowledgeable in developmental biology or in clinical embryology, a social scientist, a member of the judiciary and a person who is well-versed in comparative theology. Should the local ART clinic have difficulty in establishing such a body, the state accreditation authority should constitute such a body, co-opting a representative of the ART clinic.

Chapter 4

Sample Consent Forms

4.1 Consent Form to be signed by the Couple

We have requested the Centre (named above) to provide us with treatment services to help us bear a child.

We understand and accept (as applicable) that:

1. The drugs that are used to stimulate the ovaries to raise oocytes have temporary side effects like nausea, headaches and abdominal bloating. Only in a small proportion of cases, a condition called ovarian hyper-stimulation occurs, where there is an exaggerated ovarian response. Such cases can be identified ahead of time but only to a limited extent. Further, at times the ovarian response is poor or absent, in spite of using a high dose of drugs. Under these circumstances, the treatment cycle will be cancelled.

2. There is no guarantee that:

   a. The oocytes will be retrieved in all cases.

   b. The oocytes will be fertilized.

   c. Even if there were fertilization, the resulting embryos would be of suitable quality to be transferred.

   All these unforeseen situations will result in the cancellation of any treatment.

3. There is no certainty that a pregnancy will result from these procedures even in cases where good quality embryos are replaced.

4. Medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal living child.

5. **Endorsement by the ART clinic**

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

6. This consent would hold good for all the cycles performed at the clinic.

Name and Signature of the Husband

Name and Signature of the Wife

Name, Address and Signature of the Witness from the clinic

Name and Signature of the Doctor

Dated:

4.2 Consent for Artificial Insemination with Husband's Semen

_____and_____
_____, being husband and wife and both of legal age, authorize Dr._____ to inseminate the wife artificially with the semen of the husband for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

The procedure(s) carried out does (do) not ensure a positive result, nor do they guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART clinic

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Name, Address and Signature of the Witness from the clinic

Signed: _____ (Husband)
_____ (Wife)

Name and Signature of the Doctor

Dated:

4.3 Consent for Artificial Insemination with Donor Semen

We, _____ and _____, being husband and wife and both of legal age, authorize Dr._____ to inseminate the wife artificially with semen of a donor (registration no._____; obtained from _____ semen bank) for achieving conception.

We understand that even though the insemination may be repeated as often as recommended by the doctor, there is no guarantee or assurance that pregnancy or a live birth will result.

We have also been told that the outcome of pregnancy may not be the same as those of the general pregnant population, for example in respect of abortion, multiple pregnancies, anomalies or complications of pregnancy or delivery.

We declare that we shall not attempt to find out the identity of the donor.

I, the husband, also declare that should my wife bear any child or children as a result of such insemination (s), such child or children shall be as my own and shall be my legal heir (s).

The procedure(s) carried out does (do) not ensure a positive result, nor do they guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART clinic

I/we have personally explained to _____and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Name, Address and Signature
of the Witness from the clinic

Signed: _____
(Husband)
(Wife) _____

Name and Signature of the Doctor

Dated:

4.4 Consent for Freezing of Embryos

We _____ and _____ consent to freezing of the embryos that have resulted out of IVF/ICSI with our gametes. We understand that the embryos would be normally kept frozen for five years. If we wish to extend this period, we would let you (the ART clinic) know at least six months ahead of time. If you do not hear from us before that time, you will be free to (a) use the embryos for a third party; (b) use them for research purposes; or (c) dispose them off. We also understand that some of the embryos may not survive the subsequent thaw and that frozen embryo-replaced cycles have a lower pregnancy rate than when fresh embryos are transferred.

*Husband

In the unforeseen event of my death, I would like

The embryos to perish	☐
To be donated to my wife	☐
To be donated to a third party	☐
Used for research purposes	☐

Signed: Dated:

***Wife**

In the unforeseen event of my death, I would like

The embryos to perish	☐
To be donated to my husband	☐
To be donated to a third party	☐
Used for research purposes	☐

Signed Dated :

Endorsement by the ART clinic

I/we have personally explained to _____ and _____the details and implication of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Name, Address and Signature of the Witness from the clinic

Name and Signature of the Doctor Dated

* The appropriate option may be ticked

4.5 Consent for the Procedure of PESA and TESA

Name of female partner
Name of male partner

We hereby request and give consent to the procedure of PESA and TESA for ICSI, to be performed on the male partner.

We understand that

a) There is no guarantee that the sperm will be successfully removed or that sperm will necessarily fertilise our oocytes.

b) Should the sperm retrieval fail, the following options will be available for the retrieved oocytes.

i) Insemination of all or some oocytes using donor sperm ☐

ii) Donation of oocytes to another infertile couple ☐

iii) Disposal of oocytes according to the ethical guidelines ☐

(Tick the appropriate option)

Each of the above points has been explained to us by _____

The procedure(s) carried out does (do) not ensure a positive result, nor do they guarantee a mentally and physically normal body. This consent holds good for all the cycles performed at the clinic.

Endorsement by the ART clinic

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Signature of Male Partner

Signature of Female Partner

Name, Address and Signature of the Witness from the clinic

Name and Signature of the Doctor

Dated

4.6 Consent for Oocyte Retrieval/Embryo Transfer

Woman's Name:

Woman's Address:
Name of the Clinic:

I have asked the Clinic named above to provide me with treatment services to help me bear a child. I consent to:

a) Being prepared for oocyte retrieval by the administration of hormones and other drugs

b) The removal of oocytes from my ovaries under ultrasound guidance/ laparoscopy

c) The mixing of the following:

☐ My oocytes ☐ the sperm of my husband

☐ Anonymous donor oocyte ☐ anonymous donor sperm

(Tick the appropriate and strike off the others)

d) the placing in my _____ of

e) 1. _____ (no) of the oocytes mixed with the sperm

f) 2. _____ (no) of the resulting embryos

g) 3. _____ (no) of our cryo-preserved embryos

h) 4. _____ (no) of embryo (s) obtained anonymously

I had a full discussion with _____ about the above procedures and I have been given oral and written information about them.

I have been given a suitable opportunity to take part in counselling about the implications of the proposed treatment.

The type of anaesthetic proposed (general/regional/sedation) has been discussed in terms which I have understood.

Endorsement by the ART clinic

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Signature of Female Partner

Name, Address and Signature
of the Witness from the clinic

Name and Signature of the Doctor

Dated

4.6.1 Consent of Husband

As the husband, I consent to the course of the treatment outlined above. I understand that I will become the legal father of any resulting child, and that the child will have all the normal legal rights on me.

Name, Address & Signature : _____
(Husband)

Name, Address and Signature
of the witness from the clinic: _____

Name and Signature of the Doctor: _____

Dated

4.7 Agreement for Surrogacy

I, _____ (the woman), with the consent of my husband (name), of _____ (address) have agreed to act as a host mother for the couple, _____ _____ (wife) and _____ (husband), both of whom are unable (or do not wish to) to have a child by any other means.

I had a full discussion with _____of the clinic on _____ in regard to the matter of my acting as a surrogate mother for the child of the above couple.

I understand that the methods of treatment may include:

1. Stimulation of the genetic mother for follicular recruitment
2. The recovery of one or more oocytes from the genetic mother by ultrasound-guided oocyte recovery or by laparoscopy.
3. The fertilisation of the oocytes from the genetic mother with the sperm of her husband or an anonymous donor.
4. The fertilisation of a donor oocyte by the sperm of the husband.
5. The maintenance and storage by cryopreservation of the embryo resulting from such fertilisation until, in the view of the medical and scientific staff, it is ready for transfer.
6. Implantation of the embryo obtained through any of the above possibilities into my uterus, after the necessary treatment if any.

I have been assured that the genetic mother and the genetic father have been screened for HIV and hepatitis B and C before oocyte recovery and found to be seronegative for all these diseases. I have, however, been also informed that there is a small risk of the mother or/and the father becoming seropositive for HIV during the window period.

I consent to the above procedures and to the administration of such drugs that may be necessary to assist in preparing my uterus for embryos transfer, and for support in the luteal phase.

I understand and accept that there is no certainty that a pregnancy will result from these procedures.

I understand and accept that the medical and scientific staff can give no assurance that any pregnancy will result in the delivery of a normal and living child.

I am unrelated/related (relation) _____ to the couple (the would be genetic parents).

I have worked out the financial terms and conditions of the surrogacy with the couple in writing and an appropriately authenticated copy of the agreement has been filed with the clinic, which the clinic will keep confidential.

I agree to hand over the child to _____ and _____ , the couple (to _____ in case of their separation during my pregnancy, or to the survivor in case of the death of one of them during pregnancy) as soon as I am permitted to do so by the Hospital/Clinic/Nursing home where the child is delivered.

I undertake to inform the ART clinic, _____, of the result of the pregnancy.

I take no responsibility that the child delivered by me will be normal in all respects. I understand that the biological parents of the child have a legal obligation to accept their child that I deliver and that the child would have all the inheritance rights of a child of the biological parents as per the prevailing law.

I will not be asked to go through sex determination tests for the child during the pregnancy and that I have the full right to refuse such tests.

I understand that I would have the right to terminate the pregnancy at my will; I will then refund all certified and documented expenses incurred on the pregnancy by the biological parents or their representative. If, however, the pregnancy has to be terminated on expert medical advice, these expenses will not be refunded.

I have been tested for HIV, hepatitis B and C and shown to be seronegative for these viruses just before embryo transfer.

I certify that (a) I have not had any drug intravenously administered into me through a shared syringe; (b) I have not undergone blood transfusion; and (c) I and my husband have had no extramarital relationship in the last six months.

I also declare that I will not use drugs intravenously, undergo blood transfusion excepting of blood obtained through a certified blood bank, and avoid sexual intercourse during the pregnancy.

I undertake not to disclose the identity of the couple.

In the case of the death of both the husband and wife (the couple) during my pregnancy, I will deliver the child to _____ or _____ in this order; I will be provided, before the embryo transfer into me, a written agreement of the above persons to accept the child in the case of the above-mentioned eventuality.

Endorsement by the ART clinic

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Signed:
(Surrogate Mother)

Name, Address and Signature
of the Witness from the clinic

Name and Signature of the Doctor

Dated

4.8 Consent Form for the Donor of Eggs

I Ms. _____ consent to donate my eggs to couples who are unable to have a child by other means.

I have had a full discussion with Dr. _____ (name and address of the clinician) on _____.

I have been counselled by _____ (name and address of independent counsellor) on _____.

I understand that there will be no direct or indirect contact between me and the recipient, and my personal identity will not be disclosed to the recipient or to the child born through the use of my gamete.

I understand that I shall have no rights whatsoever on the resulting offspring and vice versa.

I understand that the method of treatment may include:

- Stimulating my ovaries for multifollicular development.
- The recovery of one or more of my eggs under ultrasound-guidance or by laparoscopy under sedation or general anesthesia.
- The fertilization of my oocytes with recipient's husband's or donor sperm and transferring the resulting embryo into the recipient.

Endorsement by the ART clinic/oocyte bank

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Signed: _____

Name, Address and Signature of the Witness from the clinic

Name and Signature of the Doctor

Dated

4.9 Consent Form for the Donor of Sperm

I Mr. _____ consent to donate my sperm to couples who are unable to have a child by other means.

I have had a full discussion with Dr. _____ (name and address of the clinician) on _____.

I have been counselled by _____ (name and address of independent counsellor) on _____.

I understand that there will be no direct or indirect contact between the recipient, and me and my personal identity will not be disclosed to the recipient or to the child born through the use of my gamete.

I understand that I shall have no rights whatsoever on the resulting offspring and vice versa.

Endorsement by the ART clinic/semen bank

I/we have personally explained to _____ and _____ the details and implications of his/her/their signing this consent/approval form, and made sure to the extent humanly possible that he/she/they understand these details and implications.

Signed: _____

Name, Address and Signature
of the Witness from the clinic

Name and Signature of the Doctor Dated

Chapter 5

Training

5 Training

ART necessitates that the laboratory staff must have basic knowledge of mammalian embryology, reproductive endocrinology, genetics, biochemistry, molecular biology, microbiology, and *in vitro* culture techniques. The laboratory staff must also be knowledgeable in the subjects practiced by the clinician. The clinical staff must be well-versed in reproductive endocrinology, pathology, endoscopy, ultrasonography, gynaecology and/or andrology. The clinician must be knowledgeable about the importance of the procedures used in the embryology laboratory. It is only through an understanding of the basic principles of the several disciplines involved that an integrated team can be put in place to make a successful ART clinic.

ART does not form a part of the medical curriculum anywhere in India although the number (10 – 15% of the adult population in the reproductive age group) of infertile couples needing ART is quite large. There is, therefore, a need to institute training programes in ART. Such training can best be imparted in a teaching institution, which has all the branches of the basic life sciences as distinct disciplines, so that the trainees are exposed to the diverse disciplines involved in ART. Alternatively, universities or other institutions having the appropriate basic science departments can offer training for the laboratory staff, and medical institutions can offer training in the clinical aspects of ART. Nevertheless, there must be a nodal point where the staff trained in the above two types of institutions can come and work together to acquire capabilities of practicing ART. Speciality ART clinics, either in the public or the private sector, can act as such nodal points and play a major role in establishing such training programmes.

Scientific discoveries and advances, especially in modern biological sciences, are occurring at a very rapid pace. There is concomitant development of new reproductive technologies. Training in ART should, therefore, be a continuous and an ongoing process. The only way in which already trained staff could keep up with the new advances is to take part in workshops and conferences organized by scientific societies. The Government of India must encourage such conferences through organizations such as the ICMR, Department of Science and Technology, Department of Biotechnology, CSIR, and the various science academies in India.

Chapter 6

Future Research Prospects

6 Future Research Prospects

Progress in any field can only occur through research. There have hardly been any publications by Indian scientists in the area of ART in peer reviewed, internationally reputed, scientific journals, except for a few that appeared from the Institute for Research in Reproduction in the late 1980's. Consequently, much of ART practice that is used in India is based on papers published outside India, and there is hardly any information either on the basic profile of the infertile couples in India or even on the clinical experience in respect of the ART technologies developed elsewhere but used in India as per the Western protocols.

ART offers a unique situation to study the biology of reproduction in human subjects without compromising ethical issues. For example, it is perfectly legitimate and ethical to take tissue and body fluid samples from an infertile couple to study the cause of infertility. This is an area that has not been exploited in India. Another line of research that is extremely important is to study early embryonic development – subject that has remained in darkness for quite a long time. What kinds of genes are turned on and off at different stages of pre-implantation embryos? This would aid in developing methods for implanting only the appropriate embryos in individuals who are known carriers of inheritable genetic disorders. Can embryos be used for developing tissues or organs (kidneys, pancreas etc.) for replacement? Stem cells obtained from developing embryos hold much promise in this field of biotechnology. There is hardly any serious research going on in such areas in the country. It must be borne in mind that one important area of future medical advances, is gene therapy, and such therapy may require *in vitro* fertilization and development.

What is urgently required is the identification of projects that are of value to advance our knowledge of human reproduction and develop better methods for treating infertility, or even identify better contraceptives because infertility is the kind of situation that we intend to create in a fertile couple desirous of limiting their family size. Following such identification, research in reproduction, with special reference to infertility treatment, must be

identified as a priority area for research for funding by the national scientific agencies.

6.1 Pre-implantation Genetic Diagnosis and Chromosomal and Single-Gene Defects

There is a growing volume of information that is now available showing that many forms of infertility are caused by genetically transmittable disorders. The genetic disorders include trisomy, translocations, inversions, deletions and microdeletions. All this new information suggests that great care must be exercised with ART because infertile couple may be carriers of such disorders; when one tries to force fertilization, the question arises whether one is transmitting genetic disorders to the offspring. This raises many moral and ethical issues.

One way to get around this problem is to institute top-class genetic diagnostic facilities that will be able to carry out diagnosis of genetic defects in single cells obtained from embryos. This is a very expensive and labor-intensive project and therefore there is a need to establish just a few well-equipped centers in the country and later expand them if there is a need. These centers could serve as referral centers and should be used judiciously. The establishment of such centers will go a long way in placing ART practice in India on a firm, healthy and ethical footing.

Chapter 7

Providing ART services to the Economically Weaker Sections of the Society

7.0 Providing ART services to the Economically Weaker Sections of the Society

7.1 The setting up of a modern ART clinic and running it satisfactorily is an expensive affair, requiring a dedicated staff that would render long-term service. The setting up of ART clinics in the public sector, which do not exist as of now, must be explored.

7.2 *Reduction of drug costs:* The concerned Ministries must take a look at the reason for the high cost of ovarian stimulation hormones, and encourage and support local pharmaceutical industries to start manufacture of human menopausal gonadotropins indigenously so that the treatment of our infertility patients is not dictated by the commercial motives of the multinational pharmaceutical companies but by national needs.

Chapter 8

Establishing a National Database for Human Infertility

8 Establishing a National Database for Human Infertility

It is important to realize that diagnostic and therapeutic approaches in reproductive medicine have to keep pace with rapidly developing molecular knowledge of human reproduction. It is now possible to detect the incidence of chromosomal abnormalities using a variety of high-powered PCR techniques (Human Reproduction 13: 3032-3038, 1998.) and multicolour fluorescent *in situ* hybridization (FISH) analysis (Chromosome 6:481-486,1998; Human Reproduction 16:115-120,2001). FISH studies on sperm are becoming necessary to understand whether there is a genetic cause for male infertility, before patients can be subjected to ICSI. New spermatogenesis genes are bound to be discovered (Endocrinological Investigations 23: 584-591, 2000); testing their mutation will become easier with DNA chips and microarray technology.

Unfortunately, there is no documented database available in our country that would cover data on all aspects of infertility, and there is an urgent need for the same. It is worrisome to see that, with the primary aim of providing a child to the infertile couple, a variety of sophisticated ART are being used to overcome male factor infertility without understanding the underlying cellular and molecular etiology. In the process of curing infertility in the patient, there is a high iatrogenic risk of transmitting an abnormal paternal geno-(pheno-)type to the ART-born child. An appropriate database would allow the quantification of such risks.

Chapter 9

Composition of the National Advisory Committee

9 Composition of the National Advisory Committee

Chairman: Secretary, Ministry of Health and Family Welfare, Govt. of India.

Co-chairman: Director General, Indian Council of Medical Research, New Delhi.

Executive Secretary: A officer below the rank of Joint Secretary in Ministry of Health and Family Welfare, Govt. of India.

Members:

- Representative of the Indian Council of Medical Research.
- Representative of the National Academy of Medical Sciences.
- Representative from the Ministry of Health & Family Welfare, Govt. of India.
- Representative of a scientific society that deals with ART. Care must be taken to ensure that such a representative should be from a society that has democratically elected office bearers and is governed by reasonable rules and regulations. The representative must have a proven track record of having contributed significantly to ART. The nature of the person's association with commercial companies must be made known publicly.
- A social scientist of repute.
- The Chairman of the National Bioethics Committee.
- A gynaecological endocrinologist.
- A gynaecological sonographist.
- An operative gynaecologist.
- A mammalian reproductive biologist.
- An andrologist.
- A representative of NGOs.

- A counsellor.
- A representative of patients.
- A medico-legal expert.
- A representative of FOGSI.
- A representative of ISSRF.

Notes: 1. A meeting of the National Advisory Committee may be chaired either by the Chairman or Co-chairman.

2. The Advisory Committee should meet at least once in six months.

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[TRUE COPY]

(2008) 13 Supreme Court Cases 518

(BEFORE DR. ARIJIT PASAYAT AND DR. M.K. SHARMA, JJ.)

BABY MANJI YAMADA .. Petitioner;

Versus

UNION OF INDIA AND ANOTHER .. Respondents.

Writ Petition (C) No. 369 of 2008†, decided on September 29, 2008

A. **Constitution of India — Art. 32 — Maintainability — Alternative remedy — Petitioner (Japanese grandmother) of a surrogate child (by Indian mother) aggrieved with the Central Government in matters concerning issuance of visa and passport for the child and herself — Action/Remedy relating to offences against children or of violation of child rights and for matters connected therewith or incidental thereto are available under the provisions of Commissions for Protection of Child Rights Act, 2005 — Therefore, if the petitioner has any grievance against the Central Government relating to passport, visa, movement, etc., held, such remedy, as is available in law may be availed — Human and Civil Rights — Commissions for Protection of Child Rights Act, 2005 — S. 13 and Ch. III — Indian Medical Council Act, 1956, S. 20-A**

B. **Constitution of India — Arts. 226 and 32 — Maintainability — Locus standi — No complaint in Supreme Court relating to child/writ petitioner concerned — High Court in a PIL by an NGO passing some orders relating to custody of a Indian surrogate child — The child, writ petitioner under Art. 32 of Constitution, questioning the locus standi of Respondent 3 (NGO) to file PIL under Art. 226 — In the absence of any complaint in relation to the child, held, there is no need to go into the locus standi of Respondent 3 and/or bona fides involved**

C. **Human and Civil Rights — Commissions for Protection of Child Rights Act, 2005 — Ch. III and S. 13 — Powers and functions of Commission, discussed**

A baby girl, *M* was born on 25-7-2008, under a surrogacy agreement executed between Japanese biological/genetic parents (father, *I* and mother, *Y*) and an Indian surrogate mother. On 3-8-2008, the child was moved to Arya Hospital in Jaipur following a law and order situation in Gujarat and was provided with much needed care including being breastfed by a woman. By the impugned order, the High Court, in a habeas corpus petition, styled as a PIL, filed by M/s SATYA (an NGO), passed certain directions on issues relating to custody/production of baby girl *M*. The writ jurisdiction of the Supreme Court under Article 32 of the Constitution of India was invoked thereagainst.

As per *E* (the grandmother of *M*), *I*, the genetic father, had to return to Japan due to expiration of his visa. *E* also claimed that the municipality concerned in Gujarat, India has issued a birth certificate indicating the name of the genetic father. The grievance of the writ petitioner related to matters concerning issuance of visa and passport for the child and the grandmother. The Solicitor General, on instructions, stated that if a comprehensive application, as required under law, is filed within a week, the same would be disposed of expeditiously and not later than four weeks from the date of receipt of such application.

† Under Article 32 of the Constitution of India

Disposing of the writ petition, the Supreme Court

Held :

If the petitioner has any grievance in relation to the order to be passed by the Central Government, such remedy, as is available in law may be availed. It is to be noted that the Commissions for Protection of Child Rights Act, 2005 (the Act) has been enacted for the constitution of a National Commission and the State Commissions for protection of child rights and children's courts for providing speedy trial of offences against children or of violation of child rights and for matters connected therewith or incidental thereto. In the present case, if any action is to be taken that has to be taken by the Commission. Section 13 which appears in Chapter III of the Act is of considerable importance. (Paras 20, 7 and 17)

There is no need to go into the locus standi of Respondent 3 and/or whether bona fides are involved or not. No complaint has been made in the Supreme Court, by anybody relating to the child, the petitioner. Therefore, the writ petition was disposed of with a direction that if any person has any grievance, the same can be ventilated before the Commission constituted under the Act. It needs no emphasis that the Commission has to take into account various aspects necessary to be taken note of. (Paras 7 and 18)

The Commissions concerned for Protection of Child Rights have a right to inquire into complaints and even to take suo motu notice of matters relating to: (*i*) deprivation and violation of child rights, (*ii*) non-implementation of laws providing for protection and development of children, and (*iii*) non-compliance with policy decisions, guidelines or instructions aimed at mitigating hardships to and ensuring welfare of the children and to provide relief to such children, or take up the issues arising out of such matters with the appropriate authorities. (Para 17)

D. **Family Law — Surrogacy — Meaning, scope, origin and types, discussed, explained and stated**

The word "surrogate", is derived from Latin "subrogare", which means "appointed to act in the place of". The intended parent(s) is the individual or couple who intends to rear the child after its birth. Surrogacy is a well-known method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to the contracted party. Intended parents may arrange a surrogate pregnancy because a woman who intends to parent is infertile or is unwilling to undergo pregnancy. Alternatively, the intended parent may be a single male or a male homosexual couple. Examples include a woman who has had a hysterectomy, has a uterine malformation, has had recurrent pregnancy loss or has a health condition that makes it dangerous for her to be pregnant. (Paras 9, 8, 14 and 15)

In *traditional surrogacy* (also known as the *Straight* method) the surrogate is pregnant with her own biological child, but this child is conceived with the intention of relinquishing the child to be raised by others; by the biological father and possibly his spouse or partner, either male or female. The child may be conceived via home artificial insemination using fresh or frozen sperm or impregnated via IUI (intrauterine insemination), or ICI (intracervical insemination) which is performed at a fertility clinic. In *gestational surrogacy* (also know as the *Host* method) the surrogate becomes pregnant via embryo transfer with a child of which she is not the biological mother. She may have

made an arrangement to relinquish it to the biological mother or father to raise, or to a parent who is themselves unrelated to the child (e.g. because the child was conceived using egg donation, germ donation or is the result of a donated embryo). The surrogate mother may be called the gestational carrier. *Altruistic surrogacy* is a situation where the surrogate receives no financial reward for her pregnancy or the relinquishment of the child (although usually all expenses related to the pregnancy and birth are paid by the intended parents such as medical expenses, maternity clothing, and other related expenses). *Commercial surrogacy* is a form of surrogacy in which a gestational carrier is paid to carry a child to maturity in her womb and is usually resorted to by well-off infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. Surrogates may be relatives, friends, or previous strangers. Many surrogate arrangements are made through agencies that help match up intended parents with women who want to be surrogates for a fee. The agencies often help manage the complex medical and legal aspects involved. Surrogacy arrangements can also be made independently. In compensated surrogacies, the amount a surrogate receives, varies widely from almost nothing to over $30,000. Careful screening is needed to assure their health as the gestational carrier incurs potential obstetrical risks. This medical procedure is legal in several countries including in India where due to excellent medical infrastructure, high international demand and ready availability of poor surrogates it is reaching industry proportions. Commercial surrogacy is sometimes referred to by the emotionally charged and potentially offensive terms "wombs for rent", "outsourced pregnancies" or "baby farms".

(Paras 8, 10 to 13 and 16)

SS-M/39275/S

Advocates who appeared in this case :

Ms Indira Jaising, Senior Advocate (Ms Lalit Mohini Bhat, Ms Hetu Arora and Naveen R. Nath, Advocates) for the Petitioner;

G.E. Vahanvati, Solicitor General (Abhinav Sharma, R.K. Singh, Narender Tripathi, Debasis Misra, Devadatt Kamat, Ms Sushma Suri, Saket Sikri, V.K. Rao and Ms Madhu Sikri, Advocates) for the Respondents.

The Judgment of the Court was delivered by

DR. ARIJIT PASAYAT, J.— This petition under Article 32 of the Constitution of India (hereinafter for short "the Constitution") raises some important questions.

2. Essentially, challenge is to certain directions given by a Division Bench of the Rajasthan High Court relating to production/custody of a child, Manji Yamada. Emiko Yamada, claiming to be the grandmother of the child, has filed this petition. The writ petition before the Rajasthan High Court was filed by M/s SATYA, stated to be an NGO, Opposite Party No. 3 in this petition.

3. The DB Habeas Corpus Writ Petition No. 7829 of 2008 was filed by M/s SATYA wherein the Union of India through the Ministry of Home Affairs, State of Rajasthan through the Principal Secretary, the Director General of Police, Government of Rajasthan and the Superintendent of Police, Jaipur City (East), Jaipur were made the parties.

4. There is no dispute about Baby Manji Yamada having been given birth to by a surrogate mother. It is stated that the biological parents Dr. Yuki Yamada and Dr. Ikufumi Yamada came to India in 2007 and had chosen a surrogate mother in Anand, Gujarat and a surrogacy agreement was entered into between the biological father and biological mother on one side and the surrogate mother on the other side. It appears from some of the statements made that there were matrimonial discords between the biological parents. The child was born on 25-7-2008. On 3-8-2008 the child was moved to Arya Hospital in Jaipur following a law and order situation in Gujarat and she was being provided with much needed care including being breastfed by a woman. It is stated by the petitioner that the genetic father Dr. Ikufumi Yamada had to return to Japan due to expiration of his visa. It is also stated that the municipality at Anand has issued a birth certificate indicating the name of the genetic father.

5. Stand of Respondent 3 was that there is no law governing surrogation in India and in the name of surrogation a lot of irregularities are being committed. According to it, in the name of surrogacy a money-making racket is being perpetuated. It is also the stand of the said respondent that the Union of India should enforce stringent laws relating to surrogacy. The present petitioner has questioned the locus standi of Respondent 3 to file a habeas corpus petition. It is pointed out that though custody of the child was being asked for but there was not even an indication as to in whose alleged illegal custody the child was. It is stated that though the petition before the High Court was styled as a "public interest litigation" there was no element of public interest involved.

6. The learned counsel for Respondent 3 with reference to the counter-affidavit filed in this Court had highlighted certain aspects relating to surrogacy. The learned Solicitor General has taken exception to certain statements made in the said counter-affidavit and has submitted that the petition before the High Court was not in good faith and was certainly not in public interest.

7. We need not go into the locus standi of Respondent 3 and/or whether bona fides are involved or not. It is to be noted that the Commissions for Protection of Child Rights Act, 2005 (hereinafter for short "the Act") has been enacted for the constitution of a National Commission and the State Commissions for protection of child rights and children's courts for providing speedy trial of offences against children or of violation of child rights and for matters connected therewith or incidental thereto. Section 13 which appears in Chapter III of the Act is of considerable importance. The same reads as follows:

> "13. *Functions of Commission.*—(1) The Commission shall perform all or any of the following functions, namely:
>
> (*a*) examine and review the safeguards provided by or under any law for the time being in force for the protection of child rights and recommend measures for their effective implementation;

(*b*) present to the Central Government, annually and at such other intervals, as the Commission may deem fit, reports upon the working of those safeguards;

(*c*) inquire into violation of child rights and recommend initiation of proceedings in such cases;

(*d*) examine all factors that inhibit the enjoyment of rights of children affected by terrorism, communal violence, riots, natural disaster, domestic violence, HIV/AIDS, trafficking, maltreatment, torture and exploitation, pornography and prostitution and recommend appropriate remedial measures;

(*e*) look into the matters relating to children in need of special care and protection including children in distress, marginalised and disadvantaged children, children in conflict with law, juveniles, children without family and children of prisoners and recommend appropriate remedial measures;

(*f*) study treaties and other international instruments and undertake periodical review of existing policies, programmes and other activities on child rights and make recommendations for their effective implementation in the best interest of children;

(*g*) undertake and promote research in the field of child rights;

(*h*) spread child rights literacy among various sections of the society and promote awareness of the safeguards available for protection of these rights through publications, the media, seminars and other available means;

(*i*) inspect or cause to be inspected any juvenile custodial home, or any other place of residence or institution meant for children, under the control of the Central Government or any State Government or any other authority, including any institution run by a social organisation; where children are detained or lodged for the purpose of treatment, reformation or protection and take up with these authorities for remedial action, if found necessary;

(*j*) inquire into complaints and take suo motu notice of matters relating to,—

(*i*) deprivation and violation of child rights;

(*ii*) non-implementation of laws providing for protection and development of children;

(*iii*) non-compliance of policy decisions, guidelines or instructions aimed at mitigating hardships to and ensuring welfare of the children and to provide relief to such children,

or take up the issues arising out of such matters with appropriate authorities; and

(*k*) such other functions as it may consider necessary for the promotion of child rights and any other matter incidental to the above functions.

(2) The Commission shall not inquire into any matter which is pending before a State Commission or any other commission duly constituted under any law for the time being in force."

8. Surrogacy is a well-known method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to a contracted party. She may be the child's genetic mother (the more traditional form for surrogacy) or she may be, as a gestational carrier, carry the pregnancy to delivery after having been implanted with an embryo. In some cases surrogacy is the only available option for parents who wish to have a child that is biologically related to them.

9. The word "surrogate", from Latin "subrogare", means "appointed to act in the place of". The intended parent(s) is the individual or couple who intends to rear the child after its birth.

10. In *traditional surrogacy* (also known as the *Straight* method) the surrogate is pregnant with her own biological child, but this child was conceived with the intention of relinquishing the child to be raised by others; by the biological father and possibly his spouse or partner, either male or female. The child may be conceived via home artificial insemination using fresh or frozen sperm or impregnated via IUI (intrauterine insemination), or ICI (intracervical insemination) which is performed at a fertility clinic.

11. In *gestational surrogacy* (also known as the *Host* method) the surrogate becomes pregnant via embryo transfer with a child of which she is not the biological mother. She may have made an arrangement to relinquish it to the biological mother or father to raise, or to a parent who is themselves unrelated to the child (e.g. because the child was conceived using egg donation, germ donation or is the result of a donated embryo). The surrogate mother may be called the gestational carrier.

12. *Altruistic surrogacy* is a situation where the surrogate receives no financial reward for her pregnancy or the relinquishment of the child (although usually all expenses related to the pregnancy and birth are paid by the intended parents such as medical expenses, maternity clothing, and other related expenses).

13. *Commercial surrogacy* is a form of surrogacy in which a gestational carrier is paid to carry a child to maturity in her womb and is usually resorted to by well-off infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. This medical procedure is legal in several countries including in India where due to excellent medical infrastructure, high international demand and ready availability of poor surrogates it is reaching industry proportions. Commercial surrogacy is sometimes referred to by the emotionally charged and potentially offensive terms "wombs for rent", "outsourced pregnancies" or "baby farms".

14. Intended parents may arrange a surrogate pregnancy because a woman who intends to parent is infertile in such a way that she cannot carry a pregnancy to term. Examples include a woman who has had a hysterectomy, has a uterine malformation, has had recurrent pregnancy loss or has a health condition that makes it dangerous for her to be pregnant. A

female intending parent may also be fertile and healthy, but unwilling to undergo pregnancy.

15. Alternatively, the intended parent may be a single male or a male homosexual couple.

16. Surrogates may be relatives, friends, or previous strangers. Many surrogate arrangements are made through agencies that help match up intended parents with women who want to be surrogates for a fee. The agencies often help manage the complex medical and legal aspects involved. Surrogacy arrangements can also be made independently. In compensated surrogacies the amount a surrogate receives varies widely from almost nothing above expenses to over $30,000. Careful screening is needed to assure their health as the gestational carrier incurs potential obstetrical risks.

17. In the present case, if any action is to be taken that has to be taken by the Commission. It has a right to inquire into complaints and even to take suo motu notice of matters relating to: (*i*) deprivation and violation of child rights, (*ii*) non-implementation of laws providing for protection and development of children, and (*iii*) non-compliance with policy decisions, guidelines or instructions aimed at mitigating hardships to and ensuring welfare of the children and to provide relief to such children, or take up the issues arising out of such matters with the appropriate authorities.

18. It appears that till now no complaint has been made by anybody relating to the child, the petitioner in this Court. We, therefore, dispose of this writ petition with a direction that if any person has any grievance, the same can be ventilated before the Commission constituted under the Act. It needs no emphasis that the Commission has to take into account various aspects necessary to be taken note of.

19. Another grievance of the petitioner is that the permission to travel so far as the child is concerned including issuance of a passport is under consideration of the Central Government; but no orders have been passed in that regard. The other prayer in the petition is with regard to an extension of the visa of the grandmother of the child requesting for such an order.

20. The learned Solicitor General, on instructions, stated that if a comprehensive application, as required under law, is filed within a week, the same shall be disposed of expeditiously and not later than four weeks from the date of receipt of such application. If the petitioner has any grievance in relation to the order to be passed by the Central Government, such remedy, as is available in law may be availed.

21. The writ petition is accordingly disposed of without any order as to costs. All proceedings pending in any High Court relating to the matter which we have dealt with in this petition shall stand disposed of because of this order.

Letters Patent Appeal No. 2151 of 2009; Special Civil Application No. 3020 of 2009; and Civil Application No. 11364 of 2009

Jan Balaz v. Anand Municipality

2009 SCC OnLine Guj 10446 : AIR 2010 Guj 21 : (2010) 2 AIR Kant R (NOC 139) 56 : (2010) 51 (2) GLR 1309 : 2010 AIHC (NOC 407) 123

(BEFORE K.S. RADHAKRISHNAN, C.J. AND ANANT S. DAVE, J.)

Jan Balaz ..... Appellant(s)

v.

Anand Municipality & 6 ..... Respondent(s)

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None for Respondent(s): 1 - 2, 4 - 7.

Mr. Anshin H Desai for Respondent(s): 3,

Letters Patent Appeal No. 2151 of 2009

In

Special Civil Application No. 3020 of 2008

With

Civil Application No. 11364 of 2009

In

Letters Patent Appeal No. 2151 of 2009

With

Special Civil Application No. 3020 of 2009

Decided on November 11, 2009

CAV JUDGMENT

(Per: HONOURABLE THE CHIEF JUSTICE MR. K.S. RADHAKRISHNAN)

The question whether a child born in India to a surrogate mother, an Indian national, whose biological father is a foreign national, would get citizenship in India, by birth, is a momentous question which has no precedent in this country.

2. Petitioner is a German national and is a biological father of two babies given birth by a surrogate mother by name - Marthaben Immanuel Khristi - a citizen of India. Petitioner's wife Susanne Anna Lohle is a German national. Due to biological reasons, the wife of the petitioner was not in a position to conceive a child. Desiring to have a child of their own, they opted for In Vitro Fertilization (IVF). Assisted Reproductive Technology Infertility Clinic at Anand came to their help. Investigation revealed that wife of the petitioner would not be in a position to reproduce ova (eggs) as a result of which it would not be possible to conceive a child even with the help of a surrogate mother by using the sperm of the petitioner. An Indian citizen keeping anonymity volunteered to donate ova, and through a scientific process the petitioner's sperm was fertilized with the donor's ova and the fertilized embryo was implanted to the uterus of the surrogate mother. Petitioner and his wife had entered into a surrogacy agreement with the second respondent - surrogate mother. After full discussion with Dr. Nayanaben Patel of the Clinic, surrogate mother was made known about the method of treatment. She had also agreed to hand over the child to the petitioner and his wife on delivery. Further surrogate mother had also agreed that she would not take any

responsibility about the well being of the child and the biological parents would have legal obligation to accept their child and that surrogate mother would deliver and the child would have all inheritance facts of a child of biological parents as per the prevailing law.

3. Surrogate mother gave birth to two baby boys on 4.1.2008. Petitioner then applied for registration of the birth of the children in the prescribed form to Anand Nagar Palika. Anand Nagar Palika issued a certificate of birth to the children as per the provisions of Registration of Birth and Deaths Act, 1969. Earlier date of birth was shown as 14.1.2008, which was later corrected as 4.1.2008 and the name of the petitioner's wife who was shown as the mother of the babies, was replaced with the name of Marthaben Immanuel Khristi.

4. Petitioner and his wife, though German nationals, are working in United Kingdom, stated that they are desirous of settling down in U.K. and for the said purpose they have to obtain VISA from the Consulate of the United Kingdom in India. Since babies were born in India and are Indian citizens, petitioner applied for their Passport in India showing their names as 'Balaz Nikolas' and 'Balaz Leonard'. Petitioner's name was shown as the father and surrogate mother's name was shown as the mother. Applications were entertained by the Passport Authorities and Passport No. G-8229646 and Passport No. G-8229647 respectively were issued in the name of above mentioned babies. Later, petitioner received an intimation-cum-notice issued by the Government of India, Ministry of External Affairs, Regional Passport Office, vide letter dated 6.5.2008 stating as follows:-

"On process it revealed that as usual procedure Passport is already issued under Tatkaal Scheme to both. Still the matter is pending in Hon'ble High Court of Gujarat and this is the citizenship related issue and also the endorsement regarding your surrogacy is to be taken in the Passport of your sons. Kindly let this office know in whose possession at present the passport is lying? One such identical case Passport application is also received in which the name of the Mother who did not conceive the birth is given in the Birth Certificate, which is also violation of Scheme 2(1)a and 2(1)(d) of the Birth and Death Registration Act 1969 therefore making endorsement of Hon'ble High Court's order is to be done in Passports.

You are also hereby informed to surrender both the passport to this office immediately, it will be returned to you after the final decision received from Hon'ble High Court."

5. Petitioner, on the basis of the direction of this Court on 13.5.2008, surrendered both the Passports on 14.5.2009 before the Passport Authority at Ahmedabad. Petitioner now seeks a direction to the Regional Passport Officer to return those Passports so that he can take the babies to Germany and then make an application in Germany so as to acquire German Citizenship. Petitioner submits that surrogacy is not recognized in Germany. Even the Immigration Office at Siberia is also insisting production of the Passport and not Certificates of Identity issued by the Passport Office, Ahmedabad. Petitioner submits that since babies are born in India and are citizens of India, Germany would not recognize them as its citizens. Denial of Passports, according to the petitioner, is illegal and violative of Article 21 of the Constitution of India.

6. Detailed counter affidavit has been filed on behalf of the Regional Passport Officer at Ahmedabad on 25.3.2008 and 4.11.2009, stating that surrogate mother cannot be treated as mother of the babies, and children born out of surrogacy, though in India, cannot be treated as Indian citizens within the meaning of Section 3 of the Citizenship Act, 1955. Further it is also stated that parents of the children are not Indian citizens

and therefore, children are also not Indian citizens as per Section 3(1)(b) of Citizenship Act, 1955. Further it is also stated that as per Passport Act, 1967, only Indian citizens can apply for Indian Passport and as per Section 6(2)(a) of the Act, Passport cannot be issued to non-citizens. Further it is also stated that as per direction of the Government of India, Ministry of External Affairs, Passport Authority can issue identity certificate, showing name of surrogate mother, which does not entail citizenship to the children but would enable him to take his children out of India. Further, it was also pointed out that the Central Government is yet to legalize surrogacy and hence, children born out of surrogacy, though in India, cannot be treated as Indian citizens.

7. Learned counsel appearing for the petitioner Mr. Dhaval C. Dave submitted that since both the children are born in India, they are Indian citizens by birth as per Section 3 of the Citizenship Act, 1955 and therefore, entitled to have all the rights of Indian citizens and the Passport Authorities are legally obliged to issue Passports to them under the Indian Passports Act, 1967. Learned counsel submitted that surrogacy is not prohibited in India and admittedly, children are born in India to a surrogate mother who herself is an Indian citizen. Learned counsel submitted that petitioner and his wife are German citizens but as the children are not born in Germany, they would not get German citizenship, especially when German law does not recognize surrogacy. Learned counsel submitted that for the purpose of obtaining VISA from the Consulate of United Kingdom, it is necessary that children should have an Indian Passport since they are born in India and not in Germany.

8. Learned counsel Mr. Anshin Desai appearing for the Passport Authority submitted that children are not Indian citizens and therefore, not entitled to get Passport under the Indian Passport Act. Learned counsel submitted that petitioner's intention is to acquire German citizenship and in order to facilitate that he is seeking Indian citizenship for the children. Learned counsel submitted that in exceptional cases Passport Authorities can issue certificate of identity as was done in the case case of one Baby Manju Yamada. Learned Counsel also referred to the judgment of the Apex Court in *Baby Manju Yamada* v. *Union of India* - (2008) 13 SCC 518 where the Passport Authorities have issued only certificate for permission to travel out of India.

9. We may at the outset point out that lot of legal, moral and ethical issues arise for our consideration in this case, which have no precedents in this country. We are primarily concerned with the rights of two new born innocent babies, much more than the rights of the biological parents, surrogate mother, or the donor of the ova. Emotional and legal relationship of the babies with the surrogate mother and the donor of the ova is also of vital importance. Surrogate mother is not the genetic mother or biologically related to the baby, but, is she merely a host of an embryo or a gestational carrier? What is the status of the ova (egg) donor, which in this case an Indian national but anonymous. Is the ova donor is the real mother or the gestational surrogate? Are the babies motherless, can we brand them as legal orphans or Stateless babies? So many ethical and legal questions have come up for consideration in this case for which there are no clear answers, so far, at least, in this country. True, babies conceived through surrogacy, encounter a lot of legal complications on parentage issues, this case reveals. Legitimacy of the babies is therefore a live issue. Can we brand them as illegitimate babies disowned by the world. Further, a host of scientific materials are made available to us to explain what is traditional surrogacy, gestational surrogacy, altruistise surrogacy, commercial surrogacy etc. and also the response of various countries with regard to the surrogacy, especially commercial surrogacy.

10. Commercial surrogacy is never considered to be illegal in India and few of the countries like Ukrain, California in the United States. Law Commission of India in it's 220th Report on 'Need for Legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parents to a surrogacy' has opined that surrogacy agreement will continue to be governed by contract among parties, which will contain all terms requiring consent of surrogate mother to bear the child, agreement of a husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying the child to full term, willingness to hand over a child to a commissioning parents etc. Law Commission has also recommended that legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parents without there being any need for adoption or even declaration of guardian. Further it was also suggested that birth certificate of surrogate child should contain names of the commissioning parents only and that the right to privacy of the donor as well as surrogate mother should be protected. Exploitation of women through surrogacy was also a worrying factor, which is to be taken care of through legislation. Law Commission has expressed its desire that Assisted Reproductive Technology Bill with all safeguards would be passed in the near future.

11. Ukraine Surrogacy Laws are very favourable and fully support the individuals reproductive rights. Clause 123 of the Family Code of Ukraine and Order 771 of the Health Ministry of Ukraine regulate surrogacy. Ukraine laws permit commissioned parents to choose the gestational surrogacy, ova, or sperm donation embryo, adoption, programmes for which no permission is required. Legislation also provides for a commercial surrogacy agreement between the parties. Child born legally belongs to the commissioned parents and the surrogate mother cannot keep the child to herself. California is also accepting the surrogacy agreements, which has no statute directly dealing with surrogacy. Courts generally rely on Uniform Parentage Act to deal with various surrogacy agreements. California Supreme Court in *Johnson* v. *Calvert* (1993) 5 CAL 4th 484 held that gestational surrogate has no parental rights to a child born to her since a gestational surrogacy contract is legal and enforceable and the intended mother is the natural mother under the Californian law. In the above case the intended mother donated the egg and a surrogate mother gave birth, in such a case the Court held that the person who intended to procreate should be considered as the natural mother. In another case decided by the U.S Court in the year 1998 - *Buzzanca* v. *Buzzanca* - 1961 CAL. Appl.4th 1410 (1998), the Court considered the issue of traditional surrogacy agreements. That was a case where the surrogate mother has been artificially inseminated i.e. a surrogate mother was impregnated by using her ova and anonymous sperm, meaning thereby the intended parents had a genetic link to the child. Court held that when a married couple uses non-genetically related embryo and sperm implanted into a surrogate intended to procreate a child, they are lawful parents of the child. In another U.S case decided in 1998, In Re *Marrijo Moschetta* awarded legal parent rights to the intended father and surrogate mother. In another U.S case considered by the New Jersy Supreme Court, In Re *Baby* 537 A.2d 1227 (NJ.02/03/1988), gave custody to the natural father of the child, but rights of the adopted mother was denied. Surrogate mother who conceived the child via artificial insemination was granted visitation rights.

12. Japan has taken a different legal stand in respect of surrogacy. Supreme Court of Japan, on March 23, 2007, denied parenthood to genetic parents since the twin babies were born to a surrogate mother at United States. Interpreting the Civil Code of Japan, the Supreme Court, held a mother who physically gives birth to a child is the legal mother. There is no provision in the Code to recognize the genetic mother as the legal

mother. There exists no specific laws in Japan concerning parent-child relationship for artificial insemination, and the mother - and - child relationship will be based on the fact of delivery. The issue of Citizenship status of such an infant is also a burning problem in Japan. The Japan Supreme Court rejected the Japanese commissioning parents bid to register their twins born to a U.S surrogate mother in Japan, on the ground that the law presumes the woman, who gives birth to a child as its mother.

13. Germany, as law stands today, does not recognize surrogacy agreements. Law also prohibits egg donation and advocates for embryo procreation. Medical practitioners are also prevented from performing artificial insemination or embryo donation, which are all criminal offences. Same seems to be the situation in Sweden, Norway, Italy and so on. But countries like Belgium, Netherlands and Great Britain are little more liberal. Reference may be made to the decisions of the High Court of Justice, Family Division, Rex & Y (Foreign Surrogacy) 2008 EWHC 3030 (Fam) U.K.

14. We have indicated, in India there is no law prohibiting artificial insemination, egg donation, lending a womb or surrogacy agreements. No civil or criminal penalties are also imposed. Public pressure, for a comprehensive legislation defining the rights of a child born out of surrogacy agreement, rights and responsibilities of a surrogate mother, egg donor, commissioning parties, legal validity of the surrogacy agreement, the parent child relationship, responsibilities of Infertility Clinic etc. are gaining momentum. Legislature will have to address a lot of emotional, legal and ethical issues. Question as to whether surrogacy can be seen as a ray of hope to otherwise a childless couple, so as to build up a family of their own, necessary for human happiness and social stability also calls for attention. Few are the case laws and precedents defining the rights of those who have a vital role to play in this reproductive technology. One case law worth mentioning in India is *Baby Manje's* case decided by the apex Court of India (2008) 13 SCC 518. Various issues which we have highlighted in this case were not discussed or answered in that case. That was a case where the Japanese Embassy in India refused to grant the child, born to surrogate Indian mother, VISA or Passport on the ground that the Japanese Civil Code recognizes a mother only to be a woman who gives birth to a baby. Attempts made to adopt Manji also did not fructify since Guardian Wards Act, 1890 did not allow single man to adopt those babies. Efforts were made to obtain Indian Passport, which also required a birth certificate. Question arose as to who was the real mother whether it was anonymous egg donor or the surrogate mother. Birth certificate was then issued by the local Municipality, by showing the father's name. Later the Regional Passport Office, Rajasthan issued a certificate of identity as part of a transit document and not the Passport. Certificate did not contain nationality, mother's name or religion of the baby.

15. Mother - child relationship is fraught with various problems, emotional, moral, ethical, legal, social etc. Study conducted by some organizations reveal that surrogate mothers have little difficulty in relinquishing their rights over a surrogate child to the intending parents and that the majority of surrogates are satisfied with their surrogacy experience and do not bother upon their bonding with the child they gave birth. Few other studies state that the surrogate mothers at time depict deep emotional attachment to the babies they give birth. Conflicting views have also been highlighted. Further elaboration on these ethical, psychological or moral issues are not necessary for our purpose.

16. We are in this case primarily concerned with the relationship of the child with the gestational surrogate mother, and with the donor of the ova. In the absence of any legislation to the contrary, we are more inclined to recognize the gestational surrogate

who has given birth to the child as the natural mother, a view prevailing in Japan. Anonymous Indian woman, the egg donor, in our view, is not the natural mother. She has of course a right to privacy that forms part of right to life and liberty guaranteed under Article 21 of the Constitution of India. Nobody can compel her to disclose her identity. Babies born are not in a position to know who is the egg donor and they only know their surrogate mother who is real. Wife, of the biological father, who has neither donated the ova, nor conceived or delivered the babies cannot in the absence of legislation be treated as a legal mother and she can never be a natural mother. In our view, by providing ova, a woman will not become a natural mother. Life takes place not in her womb, nor she receives the sperm for fertilization. Human fertilization is the union of a human sperm and egg usually occurring in the ampulla of the urine tube. Process involves development of an embryo. Process in this case followed is In Vitro Fertilization, a process by which egg cells were fertilized by sperm outside the womb in vitro. Resultantly, the only conclusion that is possible is that a gestational mother who has blood relations with the child is more deserving to be called as the natural mother. She has carried the embryo for full 10 months in her womb, nurtured the babies through the umbilical cord. Even if we assume that the egg donor is the real natural mother, even then she is an Indian national so revealed before the learned Single Judge, we are told. Both the egg donor as well as the gestational surrogate are Indian nationals, and hence the babies are born to an Indian national.

17. The Registrar, Birth and Deaths functioning under the Registration of Births and Deaths Act, 1969 has already issued certificate of birth to the children stating that they are born within the local area of Anand Nagar Palika, and showing mother's name as Marthaben Immanuel Khristi and father's name as the petitioner. Be that as it may, for the purpose of issuance of the Birth Certificate. Factum of birth of the babies has been established and that too in India to an Indian mother, whether to a gestational surrogate or donor of an ova. In the application for Passport, we have already indicated that petitioner has shown “Khristi Marthaben Immanuel” as mother gestational surrogate who is admittedly an Indian national. Egg donor is also reported to be an Indian woman, of course her identity is not disclosed. Either way the mother of the babies is an Indian national. Petitioner, it is true, has not married Khristi Marthaben Immanuel, surrogate mother of the children or the egg donor. Children are born not out of a subsisting marriage. Even if the children are described as illegitimate children, even then they are born in this country to an Indian national and hence, they are entitled to get Citizenship by birth as per Section 3(1)(c)(ii) of the Citizenship Act, 1955, since one of their parent is an Indian citizen. Relevant portion of Sec.3 is extracted hereunder for easy reference.

“3. Citizenship by birth - (1) Except as provided in sub-section (2), every person born in India, --

(a) …….. ……

(b) …….

(c) on or after the commencement of the

Citizenship (Amendment) Act, 2003, where --

(i) ……

(ii) one of whose parents is a citizen of India and the other is not an illegal migrant at the time of his birth, shall be a citizen of India by birth.”

Section 3 uses the expression 'every person born' and the emphasis is on the expressions 'person' and 'born'. 'Person' means a natural person. In *Webster* v. *Reproduction Health Services*__ (1989) 492 U.S 490, the Court held the word 'personal' within 14th Amendment means a human being after birth and not a foetus. Black's Legal Dictionary, Sixth Edition defines the word 'born' as an act of being delivered or expelled from mother's body whether or not placenta has been separated or cord cut. Both the babies in this case are persons born in India, indisputedly one of their parents is an Indian citizen, a surrogate mother. The two babies have therefore satisfied the ingredients of Section 3(1)(c)(ii) and hence they are Indian citizens by birth. Passport to travel abroad therefore, cannot be denied to those babies, who are Indian citizens, which would otherwise be violative of Article 21 of the Constitution of India. Section 6 of the Passport Act refers to the grounds for refusal of Passport. Section 6(2)(a) says that Passport can be denied if the applicant is not a citizen of India. In the instant case, we have already found that two babies born to the surrogate mother are Indian citizens by birth and hence entitled to get Passports.

18. Passport Authorities are willing to issue a certificate of identity under Section 4(2)(b) of the Passports Act, which is issued only for the purpose of establishing the identity of a person. In the instant case, the identity of the two babies has already been established, they are born in this country to a surrogate mother, an Indian national, and hence citizens of India within the meaning of Section 3(1)(c)(ii) of the Citizenship Act.

19. A comprehensive legislation dealing with all these issues is very imminent to meet the present situation created by the reproductive science and technology which have no clear answers in the existing legal system in this country. Views expressed by us, we hope, in the present fact settings, will pave way for a sound and secure legislation to deal with a situation created by the reproductive science and technology. Legislature has to address lot of issues like rights of the children born out of the surrogate mother, legal, moral, ethical. Rights, duties and obligations of the donor, gestational surrogate and host of other issues.

20. Further, under the Indian Evidence Act, no presumption can be drawn that child born out of a surrogate mother, is the legitimate child of the commissioning parents, so as to have a legal right to parental support, inheritance and other privileges of a child born to a couple through their sexual intercourse. The only remedy is a proper Legislation drawing such a presumption including adoption. Further the question as to whether the babies born out of a surrogate mother have any right of residence in or citizenship by birth or mere State orphanage and whether they acquire only the nationality or the biological father has to be addressed by the legislature.

21. Indian Council of Medical Research (ICMR) has issued certain guidelines on surrogacy and Assisted Reproductive Technology (ART) in 2005. The new Bill ART (Regulation) Bill and Rules, 2008 is yet to become law, and there is extreme urgency to push through the legislation answering all these issues.

22. We, in the present legal frame-work, have no other go but to hold that the babies born in India to the gestational surrogate are citizens of this country and therefore, entitled to get the Passports and therefore direct the Passport Authorities to release the Passports withdrawn from them forthwith.

23. Special Civil Application is accordingly allowed. Appeal and the Civil Application stand disposed of accordingly. Interim orders stand vacated.

Learned counsel appearing for the Union of India sought for stay of the judgment. Request is rejected.

[TRUE COPY]

LAW COMMISSION OF INDIA
(REPORT NO. 228)

NEED FOR LEGISLATION TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS AS WELL AS RIGHTS AND OBLIGATIONS OF PARTIES TO A SURROGACY

Submitted to the Union Minister of Law and Justice, Ministry of Law and Justice, Government of India by Dr. Justice AR. Lakshmanan, Chairman, Law Commission of India, on the 5th day of August, 2009.

The 18th Law Commission was constituted for a period of three years from 1st September, 2006 by Order No. A.45012/1/2006-Admn.III (LA) dated the 16th October, 2006, issued by the Government of India, Ministry of Law and Justice, Department of Legal Affairs, New Delhi.

The Law Commission consists of the Chairman, the Member-Secretary, one full-time Member and seven part-time Members.

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D.O. No. 6(3)/157/2009-LC (LS) 5 August, 2009

Dear Dr Veerappa Moily ji,

Subject: Need for Legislation to regulate Assisted Reproductive Technology Clinics as well as Rights and Obligations of Parties to a Surrogacy

I am forwarding herewith the 228th Report of the Law Commission of India on the above subject.

2. The world's second and India's first IVF (in vitro fertilization) baby, Kanupriya alias Durga was born in Kolkata on October 3, 1978 about two months after the world's first IVF boy, Louise Joy Brown born in Great Britain on July 25, 1978. Since then the field of assisted reproductive technology (ART) has developed rapidly.

3. The growth in the ART methods is recognition of the fact that infertility as a medical condition is a huge impediment in the overall well-being of couples and cannot be overlooked especially in a patriarchal society like India. A woman is respected as a wife only if she is mother of a child, so that her husband's masculinity and sexual potency is proved and the lineage continues. Some authors put it as follows: *The parents construct the child biologically, while the child constructs the parents socially.* The problem however arises when the parents are unable to construct the child through the conventional biological means. Infertility is seen as a major problem as kinship and family ties are dependent on progeny. Herein surrogacy comes as a supreme saviour.

4. The legal issues related with surrogacy are very complex and need to be addressed by a comprehensive legislation. Surrogacy involves conflict of various interests and has inscrutable impact on the primary unit

of society viz. family. Non-intervention of law in this knotty issue will not be proper at a time when law is to act as ardent defender of human liberty and an instrument of distribution of positive entitlements. At the same time, prohibition on vague moral grounds without a proper assessment of social ends and purposes which surrogacy can serve would be irrational. Active legislative intervention is required to facilitate correct uses of the new technology i.e. ART and relinquish the cocooned approach to legalization of surrogacy adopted hitherto. The need of the hour is to adopt a pragmatic approach by legalizing altruistic surrogacy arrangements and prohibit commercial ones.

5. The subject was *suo motu* taken up for study. Most important points in regard to the rights and obligations of the parties to a surrogacy and rights of the surrogate child the proposed legislation should include have been given in this Report.

With warm regards,

Yours sincerely,

(Dr AR. Lakshmanan)

Dr M. Veerappa Moily,
Union Minister of Law and Justice,
Government of India,
Shastri Bhawan,
New Delhi – 110 001.

NEED FOR LEGISLATION TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY CLINICS AS WELL AS RIGHTS AND OBLIGATIONS OF PARTIES TO A SURROGACY

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I. INTRODUCTION

1.1 The world's second and India's first IVF (in vitro fertilization) baby, Kanupriya alias Durga was born in Kolkata on October 3, 1978 about two

months after the world's first IVF boy, Louise Joy Brown born in Great Britain on July 25, 1978. Since then the field of assisted reproductive technology (ART) has developed rapidly.

1.2 The growth in the ART methods is recognition of the fact that infertility as a medical condition is a huge impediment in the overall well-being of couples and cannot be overlooked especially in a patriarchal society like India. A woman is respected as a wife only if she is mother of a child, so that her husband's masculinity and sexual potency is proved and the lineage continues. Some authors put it as follows: *The parents construct the child biologically, while the child constructs the parents socially.* The problem however arises when the parents are unable to construct the child through the conventional biological means. Infertility is seen as a major problem as kinship and family ties are dependent on progeny. Herein surrogacy comes as a supreme saviour.

Surrogacy - meaning

1.3 The word 'surrogate' has its origin in Latin '*surrogatus*', past participle of '*surrogare*', meaning a substitute, that is, a person appointed to act in the place of another. Thus a surrogate mother is a woman who bears a child on behalf of another woman, either from her own egg or from the implantation in her womb of a fertilized egg from other woman. According to the Black's Law Dictionary, surrogacy means the process of carrying and delivering a child for another person. The New Encyclopaedia Britannica defines 'surrogate motherhood' as the practice in which a woman bears a child for a couple unable to produce children in the usual

way. The Report of the Committee of Inquiry into Human Fertilization and Embryology or the Warnock Report (1984) defines surrogacy as the practice whereby one woman carries a child for another with the intention that the child should be handed over after birth.

1.4 The Black' Law Dictionary categorizes surrogacy into two classes: 'gestational surrogacy' and 'traditional surrogacy'. They are defined as follows:

> *Gestational surrogacy*. A pregnancy in which one woman (the genetic mother) provides the egg, which is fertilized, and another woman (the surrogate mother) carries the fetus and gives birth to the child.
>
> *Traditional surrogacy*. A pregnancy in which a woman provides her own egg, which is fertilized by artificial insemination, and carries the fetus and gives birth to a child for another person.

1.5 'Gestational surrogacy' is total in the sense that an embryo created by the process of IVF is implanted into the surrogate mother. 'Traditional surrogacy' may be called partial or genetically contracted motherhood because the surrogate mother is impregnated with the sperm of the intended father making her both the genetic and the gestational mother; the child shares make-up of the commissioning father and the surrogate mother.

1.6 Surrogacy is commercial or altruistic depending on whether the surrogate receives financial reward for her pregnancy or the relinquishment of the child, or not.

India – a reproductive tourism destination

1.7 In commercial surrogacy agreements, the surrogate mother enters into an agreement with the commissioning couple or a single parent to bear the burden of pregnancy. In return of her agreeing to carry the term of the pregnancy, she is paid by the commissioning agent for that. The usual fee is around $25,000 to $30,000 in India which is around 1/3rd of that in developed countries like the USA. This has made India a favourable destination for foreign couples who look for a cost-effective treatment for infertility and a whole branch of medical tourism has flourished on the surrogate practice. ART industry is now a 25,000 crore rupee pot of gold. Anand, a small town in Gujarat, has acquired a distinct reputation as a place for outsourcing commercial surrogacy. It seems that wombs in India are on rent which translates into babies for foreigners and dollars for Indian surrogate mothers.

Legal and moral issues

1.8 The moral issues associated with surrogacy are pretty obvious, yet of an eye-opening nature. This includes the criticism that surrogacy leads to commoditization of the child, breaks the bond between the mother and the child, interferes with nature and leads to exploitation of poor women in underdeveloped countries who sell their bodies for money. Sometimes, psychological considerations may come in the way of a successful surrogacy arrangement.

1.9 As far as the legality of the concept of surrogacy is concerned it would be worthwhile to mention that Article 16.1 of the *Universal*

Declaration of Human Rights 1948 says, *inter alia*, that "men and women of full age without any limitation due to race, nationality or religion have the right to marry and found a family". The Judiciary in India too has recognized the reproductive right of humans as a basic right. For instance, in *B. K. Parthasarthi v. Government of Andhra Pradesh*[1], the Andhra Pradesh High Court upheld "the right of reproductive autonomy" of an individual as a facet of his "right to privacy" and agreed with the decision of the US Supreme Court in *Jack T. Skinner v. State of Oklahoma*[2], which characterised the right to reproduce as "one of the basic civil rights of man". Even in *Javed v. State of Haryana*[3], though the Supreme Court upheld the two living children norm to debar a person from contesting a *Panchayati Raj* election it refrained from stating that the right to procreation is not a basic human right.

1.10 Now, if reproductive right gets constitutional protection, surrogacy which allows an infertile couple to exercise that right also gets the same constitutional protection. However, jurisdictions in various countries have held different views regarding the legalization of surrogacy. In England, surrogacy arrangements are legal and the Surrogacy Arrangements Act 1985 prohibits advertising and other aspects of commercial surrogacy. In the US also, commercial surrogacy seems prohibited in many states. In the famous *Baby M case*[4], the New Jersey Supreme Court, though allowed custody to commissioning parents in the "best interest of the child", came to the conclusion that surrogacy contract is against public policy. It must

[1] AIR 2000 A. P. 156
[2] 316 US 535
[3] (2003) 8 SCC 369
[4] 537 A.2d 1227

be noted that in the US, surrogacy laws are different in different states.

1.11 If the 1988 *Baby M case* in the US forced many to put on legal thinking caps, then that year also saw Australia battling with societal eruptions over the *Kirkman sisters' case* in Victoria. Linda Kirkman agreed to gestate the genetic child of her older sister Maggie. The baby girl, called Alice, was handed over to Maggie and her husband at birth. This sparked much community and legal debate and soon Australian states attempted to settle the legal complications in surrogacy. Now in Australia, commercial surrogacy is illegal, contracts in relation to surrogacy arrangement unenforceable and any payment for soliciting a surrogacy arrangement is illegal.

Motherhood – an enigma

1.12 How surrogacy can lead to an array of legal complexities regarding motherhood was shown by *Jaycee B. v. Superior Court*[5]. A child was born to a surrogate mother using sperm and eggs from anonymous donors because the infertile couple was unable to create their own embryo using the in vitro fertilization techniques. The couple chose to use anonymous donors rather than asking the surrogate to use her own eggs because of the *Baby M case* in New Jersey in which the surrogate had eventually refused to hand over the baby saying that she was its biological mother and her right to raise the child pre-empted the commissioning parents'. The child thus had five people who could lay claim to parenthood – a genetic mother, a commissioning mother, a surrogate mother, a genetic father and a

[5] 42 Cal.App.4Th 718 (1996)

commissioning father. One month prior to the birth of the baby Jaycee the intended parents John and Luanne separated and John sought to rescind his obligations under the surrogacy contract so as to avoid having to pay child-support for Jaycee. Luanne sought both custody and support from her ex-husband. The court battle continued and for three years Jaycee did not have a legal parent. A Californian court granted temporary custody of the baby Jaycee to Luanne and ordered John to pay for child-support.

1.13 Different countries have taken different stands to address this issue. In UK, the surrogate mother is the legal mother, *vide* section 27(1) of the Human Fertilisation and Embryology Act 1990. Section 30 of the said Act at the same time provides that if the surrogate mother consents to the child to be treated as the child of the commissioning parents the court may make a parental order to that effect. This section also prohibits giving or taking of money or other benefit (other than expenses reasonably incurred) in consideration of the making of the order or handing over of the child.

1.14 In India, according to the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics, evolved in 2005 by the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS), the surrogate mother is not considered to be the legal mother. The birth certificate is made in the name of the genetic parents. The US position as per the Gestational Surrogacy Act 2004 is pretty similar to that of India.

Indian Baby M case

1.15 *Baby Manji Yamada v. Union of India*[6] concerned production/custody of a child Manji Yamada given birth by a surrogate mother in Anand, Gujarat under a surrogacy agreement with her entered into by Dr Yuki Yamada and Dr Ikufumi Yamada of Japan. The sperm had come from Dr Ikufumi Yamada, but egg from a donor, not from Dr Yuki Yamada. There were matrimonial discords between the commissioning parents. The genetic father Dr Ikufumi Yamada desired to take custody of the child, but he had to return to Japan due to expiration of his visa. The Municipality at Anand issued a birth certificate indicating the name of the genetic father. The child was born on 25.07 2008 and moved on 03.08.2008 to Arya Hospital in Jaipur following a law and order situation in Gujarat. The baby was provided with much needed care including being breastfed by a woman.

1.16 The grandmother of the baby Manji, Ms Emiko Yamada flew from Japan to take care of the child and filed a petition in the Supreme Court under article 32 of the Constitution. The Court relegated her to the National Commission for Protection of Child Rights constituted under the Commissions for Protection of Child Rights Act 2005. Ultimately, baby Manji left for Japan in the care of her genetic father and grandmother.

Israeli gay couple's case

[6] JT 2008 (11) SC 150

1.17 Thereafter was in the news the Israeli gay couple's case[7]. The gay couple Yonathan and Omer could not in Israel adopt or have a surrogate mother. They came to Mumbai. Yonathan donated his sperm. They selected a surrogate. Baby Evyatar was born. The gay couple took son Evyatar to Israel. Israeli government had required them to do a DNA test to prove their paternity before the baby's passport and other documents were prepared.

II. THE DRAFT ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) BILL AND RULES 2008

2.1 The legal issues related with surrogacy, as we have seen, are very complex and need to be addressed by a comprehensive legislation. After

[7] The Times of India, Mumbai, 18.11.2008

a long wait for so many years, the Indian Council of Medical Research (ICMR) has come out with a draft Assisted Reproductive Technology (Regulation) Bill and Rules 2008. The draft Bill contains 50 clauses under nine chapters.

2.2 The Bill acknowledges surrogacy agreements and their legal enforceability**.** This will ensure that surrogacy agreements are treated on par with other contracts and the principles of the Indian Contract Act 1872 and other laws will be applicable to these kinds of agreements. The Bill provides that single persons may also go for surrogacy arrangements.

2.3 The Bill provides that a foreigner or foreign couple not resident in India or a non-resident Indian individual or couple, seeking surrogacy in India, shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after pregnancy till the child is delivered to the foreigner or foreign couple or the local guardian. It is further provided that the commissioning parents or parent shall be legally bound to accept the custody of the child irrespective of any abnormality that the child may have, and the refusal to do so shall constitute an offence. A surrogate mother shall relinquish all parental rights over the child. The birth certificate in respect of a baby born through surrogacy shall bear the name(s) of genetic parents/parent of the baby.

2.4 The Bill also provides that a child born to a married couple or a single person through the use of ART shall be presumed to be the

legitimate child of the couple or the single person, as the case may be. If the commissioning couple separates or gets divorced after going for surrogacy but before the child is born, then also the child shall be considered to be the legitimate child of the couple.

2.5 The Bill further provides that a couple or an individual shall not have the service of more than one surrogate at any given time. A couple shall also not have simultaneous transfer of embryos in the woman and in a surrogate.

2.6 Chapter I of the Bill contains definitions. Chapter II provides for constitution of a National Advisory Board for ART and State Boards for ART for laying down policies, regulations and guidelines, and Registration Authorities for registering ART clinics. Chapter III lays down procedure for registration of ART clinics. Chapter IV prescribes duties of ART clinics. One of the duties is to make couples or individuals, as the case may be, aware of the rights of a child born through the use of ART. The duties also include the obligation not to offer to provide a couple with a child of a pre-determined sex. Chapter V provides for sourcing, storage, handling and record-keeping for gametes, embryos and surrogates. Chapter VI regulates research on embryos. Chapter VII discusses rights and duties of patients, donors, surrogates and children. Chapter VIII deals with offences and penalties therefor. Chapter IX is titled 'Miscellaneous' and includes power to search and seize records etc. and the power to make rules and regulations. This legislation is intended to be in addition to, and not in derogation of, other

relevant laws in force.

III. SEMINAR ON 'SURROGACY – BANE OR BOON'

3.1 A seminar on "Surrogacy – Bane or Boon" was held at the India International Centre on 13.02.2009. The discussion focused on the aforesaid draft Bill and Rules. Certain lacunae were noted in the Bill.

3.2 The Bill neither creates, nor designates or authorizes any court or quasi-judicial forum for adjudication of disputes arising out of surrogacy, ART and surrogacy agreements. Disputes may, *inter alia*, relate to parentage, nationality, issuance of passport, grant of visa. There is already a conflict on adoption and guardianship as non-Hindus cannot adopt in India. Such disputes need to be resolved before a child is removed from India to a foreign country.

3.3 A suggestion at the above Seminar emerged that if a specialized court called "Surrogacy Court" is created, it could comprehensively look at all the above problems for adjudicating disputes.

3.4 The points highlighted in the discussion at the Seminar included:

(i) what would be the remedy available to biological parents to obtain exclusive legal custody of surrogate children,

(ii) how can the rights of the surrogate mother be waived completely,

(iii) how can the rights of the ovum or sperm donor be restricted,

(iv) how can the genetic constitution of the surrogate baby be established and recorded with authenticity,

(v) whether a single or a gay parent can be considered to be the custodial parent of a surrogate child,

(vi) what would be the status of divorced biological parents in respect of the custody of a surrogate child, and

(vii) would a biological parent/s be considered the legal parent of the surrogate child?

3.5 The answers discussed at the Seminar were:

a) Surrogacy in India is legitimate because no Indian law prohibits surrogacy. To determine the legality of surrogacy agreements, the Indian Contract Act would apply and thereafter the enforceability of any such agreement would be within the domain of section 9 of the Code of Civil Procedure (CPC). Alternatively, the biological parent/s can also move an application under the Guardians and Wards Act 1890 for seeking an order of appointment or a declaration as the guardian of the surrogate child.

b) In the absence of any law to govern surrogacy, the 2005 Guidelines[8] apply. But, being non-statutory, they are not enforceable or justiciable in a court of law. Under paragraph 3.10.1 of the Guidelines a child born through surrogacy must be adopted by the genetic

[8] *Supra* paragraph 1.14

(biological) parents. However, this may not be possible in case of those parents who cannot adopt in India.

c) Under Section 10 of the Contract Act, all agreements are contracts, if they are made by free consent of parties competent to contract, for a lawful consideration and with a lawful object, and are not expressly declared to be void. Therefore, if any surrogacy agreement satisfies these conditions, it is an enforceable contract. Thereafter, under section 9, CPC, it can be the subject of a civil suit before a civil court for adjudication of all disputes relating to the surrogacy agreement and for a declaration/injunction as to the relief prayed for.

d) As of today, it may be stated that a single or a gay parent can be considered to be the custodial parent by virtue of being the genetic or biological parent of the child born out of a surrogacy arrangement. Japanese baby Manji Yamada's case and the Israel gay couple's case who fathered the child in India are clear examples to establish that this is possible. Under paragraph 3.16.1 of the Guidelines dealing with legitimacy of children born through ART (which was the basis of the claim in the Japanese baby's case in the Supreme Court), this claim can be made. However, only in a

petition for guardianship under the Guardians and Wards Act and/or in a suit for declaration in a civil court, the exclusive custodial rights can be adjudicated by a court of competent jurisdiction upon appreciation of evidence and considering all claims made in this regard.

e) Essentially, this is a question which will require determination in accordance with the surrogacy agreement between the parties. There would apparently be no bar to either of the divorced parents claiming custody of a surrogate child if the other parent does not claim the same. However, if the custody is contested, it may require adjudication by a court of competent jurisdiction.

f) In answer to this question it can be stated that the biological parents would be considered to be the legal parents of the child by virtue of the surrogacy agreement executed between them and the surrogate mother. Under paragraph 3.16.1 of the Guidelines dealing with legitimacy of the child born through ART, it is stated that "a child born through ART shall be presumed to be the legitimate child of the couple, born within wedlock, with consent of both the spouses, and with all the attendant rights of parentage, support and inheritance". Even in the 2008 draft Bill and

Rules, a child born to a married couple, an unmarried couple, a single parent or a single man or woman, shall be the legitimate child of the couple, man or woman, as the case may be.

g) However, the moot question which may arise for determination is as to whether a judicial verdict determining rights of parties in a surrogacy arrangement is essential in respect of a foreign biological parent who wishes to take the surrogate child to his/her country of origin or permanent residence. It can be said that either a declaration from a civil court and/or a guardianship order ought to be a must to conclusively establish the rights of all parties and to prevent any future discrepancies arising in respect of any claims thereto.

IV. CONCLUSION AND RECOMMENDATION

4.1 Surrogacy involves conflict of various interests and has inscrutable impact on the primary unit of society viz. family. Non-intervention of law in this knotty issue will not be proper at a time when law is to act as ardent defender of human liberty and an instrument of distribution of

positive entitlements. At the same time, prohibition on vague moral grounds without a proper assessment of social ends and purposes which surrogacy can serve would be irrational. Active legislative intervention is required to facilitate correct uses of the new technology i.e. ART and relinquish the cocooned approach to legalization of surrogacy adopted hitherto. The need of the hour is to adopt a pragmatic approach by legalizing altruistic surrogacy arrangements and prohibit commercial ones.

4.2 The draft Bill prepared by the ICMR is full of lacunae, nay, it is incomplete. However, it is a beacon to move forward in the direction of preparing legislation to regulate not only ART clinics but rights and obligations of all the parties to a surrogacy including rights of the surrogate child. Most important points in regard to the rights and obligations of the parties to a surrogacy and rights of the surrogate child the proposed legislation should include may be stated as under:

[1] Surrogacy arrangement will continue to be governed by contract amongst parties, which will contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement should not be for commercial purposes.

[2] A surrogacy arrangement should provide for financial support for surrogate child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.

[3] A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.

[4] One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

[5] Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

[6] The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

[7] Right to privacy of donor as well as surrogate mother should be protected.

[8] Sex-selective surrogacy should be prohibited.

[9] Cases of abortions should be governed by the Medical Termination of Pregnancy Act 1971 only.

4.3 We recommend accordingly.

(Dr Justice AR. Lakshmanan)
Chairman

(Prof. Dr Tahir Mahmood)
Member

(Dr Brahm A. Agrawal)
Member-Secretary

[TRUE COPY]

Draft

THE ASSISTED REPRODUCTIVE TECHNOLOGIES (REGULATION) BILL - 2010

MINISTRY OF HEALTH & FAMILY WELFARE
GOVT. OF INDIA, NEW DELHI

INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI

THE
ASSISTED REPRODUCTIVE TECHNOLOGY
(REGULATION) BILL - 2010

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PREAMBLE

It is estimated that 15 percent of couples around the world are infertile. This implies that infertility is one of the most highly prevalent medical problems. The magnitude of the infertility problem also has enormous social implications. Besides the fact that every couple has the right to have a child, in India infertility widely carries with it a social stigma. In the Indian social context specially, children are also a kind of old-age insurance.

With the enormous advances in medicine and medical technologies, today 85 percent of the cases of infertility can be taken care of through medicines, surgery and/or the new medical technologies such as *in vitro* fertilization (IVF) or intracytoplasmic sperm injection (ICSI). It may be recalled that the birth of the first child, Louise Brown in 1978, through the technique of in vitro fertilization by Robert G Edwards and Patrick Steptoe, was a path-breaking step in control of infertility; it is, in retrospect, considered as one of the most important medical advances of the last century.

Most of the new technologies aimed at taking care of infertility, involve handling of the gamete – spermatozoa or the ooctye – outside the body; they also often involve the donation of spermatozoa or oocyte, or the use of a surrogate mother who would be carrying a child with whom she has no biological relationship. These technologies not only require expertise but also open up many avenues for unethical practices which can affect adversely the recipient of the treatment, medically, socially and legally.

The last nearly 20 years have seen an exponential growth of infertility clinics that use techniques requiring handling of spermatozoa or the oocyte outside the body, or the use of a surrogate mother. As of today, anyone can open infertility or assisted reproductive technology (ART) clinic; no permission is required to do so. There has been, consequently a mushrooming of such clinics around the country.

In view of the above, in public interest, it has become important to regulate the functioning of such clinics to ensure that the services provided are ethical and that the medical, social and legal rights of all those concerned are protected.

The bill details procedures for accreditation and supervision of infertility clinics (and related organizations such as semen banks) handling spermatozoa or oocytes outside of the body, or dealing with gamete donors and surrogacy, ensuring that the legitimate rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice.

STATEMENT OF OBJECTS AND REASONS

An act to provide for a national framework for the accreditations, regulation and supervision of assisted reproductive technology clinics, for prevention of misuse of assisted reproductive technology, for safe and ethical practice of assisted reproductive technology services and for matters connected therewith or incidental thereto.

BE IT ENACTED by the Parliament in the 60th year of the Republic of India as follows:

CHAPTER - I

PRELIMINARY

1. Short title, extent and commencement –

(1) This Act may be called the Assisted Reproductive Technology (Regulation) Act, 2010

(2) It applies, in the first instance, to the whole States of …….. and …….. and the Union Territories; and it shall apply to such other States which adopt this Act by resolution passed in that behalf under Clause (1) of Article 252 of the Constitution.

(3) It shall come into force at once in the States of …… and …….. and the Union Territories, on such dates as the Central Government may, by notification appoint, and in any other States which adopt this Act under Clause (1) of Article 252 of the Constitution, on the date of such adoption; and any reference in this Act to the commencement of this Act shall, in relation to any State or Union Territory, mean the date on which this Act comes into force in such a State or Union Territory.

2. Definitions — In this Act, and in any rules and regulations framed hereunder, unless the context otherwise requires –

a. "ART bank", means an organisation that is set up to supply sperm / semen, oocytes / oocyte donors and surrogate mothers to assisted reproductive technology clinics or their patients;

b. "artificial insemination", means the procedure of artificially transferring semen into the reproductive system of a woman and includes insemination with the husband's semen or with donor semen;

c. "assisted reproductive technology" (ART), with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the

oocyte outside the human body, and transferring the gamete or the embryo into the reproductive tract;

d. “assisted reproductive technology clinic”, means any premises used for procedures related to assisted reproductive technology;

e. “biological parent(s)”, means genetic parent(s);

f. “child”, means any individual born through the use of assisted reproductive technology;

g. “Commissioning parents/couples/individuals”, means parents, couples or individuals, respectively, who approach an ART clinics or ART bank for providing a service that the ART Clinic or the ART bank is authorized to provide.

h. “couple”, means two persons living together and having a sexual relationship that is legal in India;

i. “cryo-preservation”, means the freezing and storing of gametes, zygotes and embryos;

j. “Department of Health Research”, means Department of Health Research, Ministry of Health and Family Welfare, Government of India;

k. “donor”, means the donor of a gamete or gametes but does not include the husband who provides the sperm or the wife who provides the oocyte to be used in the process of assisted reproduction for their own use;

l. “egg”, means the female gamete (that is, oocyte)

m. “embryo”, means the fertilized ovum that has begun cellular division and continued development up to eight weeks;

n. “fertilization”, means the penetration of the ovum by the spermatozoon and fusion of genetic materials resulting in the development of a zygote;

o. “foetal reduction”, means reduction in the number of foetuses in the case of multiple pregnancies;

p. “foetus”, means the product of conception, starting from completion of embryonic development until birth or abortion;

q. “gamete", means sperm and oocyte (that is egg);

r. “gamete donor”, means a person who provides sperm or oocyte with the objective of enabling an infertile couple or individual to have a child;

s. “Indian Council of Medical Research”, means the Indian Council of Medical Research (ICMR) as registered under the Societies Registration Act, 1860;

t. “implantation”, means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilization;

u. “infertility”, means the inability to conceive after at least one year of unprotected coitus; or an anatomical / physiological condition that would prevent an individual from having a child;

v. “married couple”, means two persons whose marriage is legal in the country / countries of which they are citizens;

w. “oocyte” and “ovum”, mean, respectively, the female gamete (that is, egg) present in the ovary, and an ovulated oocyte in which the first polar body has been released;

x. “patient(s)”, means an individual / couple who comes to an infertility clinic and is under treatment for infertility;

y. “Pre-implantation Genetic Diagnosis”, includes the technique in which an embryo formed through in-vitro fertilisation is tested for specific disorders prior to the transfer;

z. “sperm”, means the male gametes produced in the testicles and contained in semen;

aa. “surrogacy”, means an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belong to her or her husband, with the intention to carry it and hand over the child to the person or persons for whom she is acting as a surrogate;

bb. “surrogate mother”, means a woman who is a citizen of India and is resident in India, who agrees to have an embryo generated from the sperm of a man who is not her husband and the oocyte of another woman, implanted in her to carry the pregnancy to viability and deliver the child to the couple / individual that had asked for surrogacy;

cc. “surrogacy agreement”, means a contract between the person(s) availing of assisted reproductive technology and the surrogate mother;

dd. “unmarried couple”, means two persons, both of marriageable age, living together with mutual consent but without getting married, in a relationship that is legal in the country / countries of which they are citizens;

ee. “zygote”, means the fertilized oocyte prior to the first cell division.

CHAPTER - II

CONSTITUTION OF AUTHORITIES TO REGULATE ASSISTED REPRODUCTIVE TECHNOLOGY

3. Establishment of National Advisory Board –

(1) With effect from such date as the Central Government may, by notification, appoint, there shall be established a Board to be known as the National Advisory Board for Assisted Reproductive Technology, hereafter referred to as the National Board, to exercise the jurisdiction and powers and discharge the functions and duties conferred or imposed on the Board by or under this Act.

(2) The National Board shall consist of such number of members, not exceeding twenty one, as may be prescribed by the Central Government and, unless the rules otherwise provide, the National Board shall consist of the following –

(a) Secretary, Department of Health Research, Government of India, who shall be the Chairman of the Board;

(b) A senior scientist having knowledge of assisted reproductive technology, from the Department of Health Research or the Indian Council of Medical Research, who shall be the Member-Secretary of the Board;

(c) A representative, not below the rank of Joint Secretary, from the Ministry of Health and Family Welfare;

(d) The nominee of an Indian professional society concerned primarily with assisted reproduction;

(e) Up to sixteen other experts – of whom one each shall be a nominee of the Ministry of Health and Family Welfare and Indian Council of Medical Research, and at least six of whom shall be women – in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the Central Government.

(3) The Chairman of National Board shall nominate a Vice Chairman from among its members.

4. Meetings of National Advisory Board –

(1) The National Board shall meet as and when necessary, not less than two times a year, and at such time and place in the country as the Chairperson of the National Board may think fit.

(2) The Chairperson of the National Board shall preside over the meetings of the National Board.

(3) If, for any reason, the Chairperson of the National Board is unable to attend any meeting of the National Board, the Vice-Chairperson of the National Board shall preside over the meeting.

5. Functions of National Advisory Board –

(1) The National Board may recommend modification from time to time in the attached rules and schedules where relevant in regard to the following, and perform any other functions and tasks assigned to it by the Central Government:

(a) minimum requirements related to staff and physical infrastructure for the various categories of assisted reproductive technology clinics;

(b) regulations in respect of permissible assisted reproductive technology procedures;

(c) regulations in respect of selection of patients for assisted reproductive technology procedures;

(d) encouragement and promotion of training and research in the field of assisted reproduction;

(e) encouragement of the establishment and maintenance of a national database in respect of infertility;

(f) guidelines for counselling and providing patients with all necessary information and advice on various aspects of assisted reproductive technology procedures;

(g) ways and means of disseminating information related to infertility and assisted reproductive technologies to various sections of the society;

(h) regulations in respect of research on human embryos;

(i) proformae for obtaining information from donors of gametes and surrogate mothers, consent forms for various procedures, and contracts and / or agreements between the various parties involved, in all of the languages listed in the Eighth Schedule of the Constitution;

(j) policies from time to time on assisted reproduction;

6. Establishment of State Boards –

(1) Every State Government shall, within 180 days of the issue of the notification under sub-section (1) of section 3, by notification in the Official Gazette, establish a State Board for Assisted Reproductive Technology to exercise the jurisdiction and powers and discharge the functions and duties conferred or imposed on the State Boards by or under this Act.

(2) The State Boards shall consist of such number of members, not exceeding twelve, as may be prescribed by the State Government and, unless the rules otherwise provide, the State Boards shall consist of the following members, namely –

(a) The Secretary of the Department of Health and Family Welfare, who shall be Chairperson, *ex officio;*

(b) The nominee of an Indian professional society concerned primarily with assisted reproduction who shall be the Vice Chairperson, ex officio;

(c) An officer not below the rank of a Joint Secretary, who shall be the Member-Secretary of the Board;

(d) Up to nine other members – of whom at least four shall be women – who shall be experts in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the State Government.

(3) The Chairman of the State Board shall nominate a Vice Chairman from among its members.

7. Meetings of State Boards –

(1) The State Board shall meet as and when necessary, but not less than three times a year, and at such time and place as the Chairperson of the State Board may think fit.

(2) The Chairperson of the State Board shall preside over the meetings of the State Board.

(3) If for any reason the Chairperson of the State Board is unable to attend any meeting of the State Board, the Vice Chairperson of the State Board shall preside over the meeting.

8. Powers and functions of State Boards –

(1) Subject to the provisions of this Act and the rules and regulations adopted thereunder, the State Board shall have the responsibility for

laying down the policies and plans for assisted reproduction in the State.

(2) Without prejudice to the generality of the provisions contained in sub-section (1) of this section, the State Board, taking into account the recommendations, policies and regulations of the National Board, may –

(a) advise the State Government to constitute a Registration Authority or Authorities as required, at least of six experts in assisted reproduction technology or a related field, for the use of assisted reproductive technology in the State;

(b) monitor the functioning of the Registration Authority subject, in particular, to the guidelines laid down by the National Advisory Board;

(c) coordinate the enforcement and implementation of the policies and guidelines for assisted reproduction;

(d) constitute advisory committees consisting of experts in the field of assisted reproduction and related fields at the State or district level, to make recommendations on different aspects of assisted reproduction;

(e) perform such other functions prescribed under this Act;

(3) Notwithstanding anything contained in section 12 of this Act, the State Board may, *suo moto*, whether on the basis of a complaint or otherwise, examine and review any decision of the Registration Authority.

(4) In the exercise of its functions under this Act, the State Board shall give such directions or pass such orders as are necessary, with reasons to be recorded in writing.

9. Term of office, conditions of service, etc., of Chairperson and other members of State Boards –

(1) Before appointing any person as the Chairperson or other member, the appropriate Government shall satisfy itself that the person's integrity is such that his / her professional interest shall not affect prejudicially his functions as such member.

(2) The Chairperson and every other Member shall hold office for such period, not exceeding five years, as may be specified by the appropriate government in the order of his appointment, but shall be eligible for re-appointment.

(3) Notwithstanding anything contained in sub-section (1) of this section, a member may by writing under his / her hand and addressed to the appropriate Government resign his / her office at any time;

(4) A vacancy caused by the resignation or removal of the Chairperson or any other member shall be filled by fresh appointment.

(5) In the event of the occurrence of a vacancy in the office of the Chairperson by reason of his / her death, resignation or otherwise, such one of the members as the appropriate Government may, by notification, authorise in this behalf, shall act as the Chairperson till the date on which a new Chairperson, appointed in accordance with the provisions of this Act to fill such vacancy, takes charge of the office.

(6) When the Chairperson is unable to discharge his / her functions owing to absence, illness or any other cause, the Vice Chairperson shall discharge the function of the Chairpersons, till the date on which the Chairperson resumes his duties.

(7) The salaries and allowances payable to and the other terms and conditions of service of the Chairperson and other members shall be such as may be prescribed: provided that neither the salary and allowances nor the other terms and conditions of service of the Chairperson or any other member shall be varied to his disadvantage after his appointment.

(8) The Chairperson and every other member shall, before entering upon his / her office make a declaration of fidelity and secrecy in the form set out in the Schedule.

(9) The Chairperson ceasing to hold office as such shall not hold any appointment or be connected with the management or administration in any company, hospital, clinic, society, trust or other undertaking in relation to which any matter has been the subject matter of consideration before the State Board, for a period of three years from the date on which he ceases to hold such office.

10. Procedure of State Boards –

(1) Subject to the provisions of this Act, the State Board shall have powers to –

(a) regulate the procedure and conduct of the business;

(b) delegate its powers or functions to such persons or authorities as prescribed in the rules or regulations made under this Act.

(2) The State Boards shall, for the purposes of any inquiry or for any other purpose under this Act, have the powers to –

(a) summon and enforce the attendance of any witness and examine him / her on oath;

(b) order the discovery and production of document or other material objects producible as evidence;

(c) receive evidence on affidavit;

(d) requisition any public record from any court or office;

(e) issue any order for the examination of witnesses;

(f) any other matter which may be prescribed.

11. Constitution and functions of the Registration Authority –

(1) The State Government shall constitute the Registration Authority as per the advise of the State Board, within a period of three months of the advise.

(2) The Registration Authority shall have a full-time Chairman of the level of a Secretary to the State Government, who shall be a recognised expert in assisted reproductive technology or a related field.

(3) The other members of the Registration Authority shall be part-time members, and shall be adequately compensated for their services.

(4) Before appointing any member of the Registration Authority, the Government shall satisfy itself that his / her integrity is such that his / her professional interest shall not affect prejudicially his / her functions as a member.

(5) The Registration Authority shall be provided by the State Government with adequate supporting staff and secretarial assistance, and suitable accommodation.

(6) The Registration Authority shall issue an appropriate letter granting or rejecting registration to an assisted reproductive technology clinic.

12. Proceedings before State Boards to be judicial proceedings –

(1) Every State Board shall be deemed to be a civil court and when any offence as is described in this Act is committed in the view or presence of the State Board, the State Board may, after recording the facts constituting the offence and the statement of the accused as provided for in the Code of Criminal Procedure, 1973, forward the case to a Magistrate having jurisdiction to try the same, and the Magistrate to whom any such case is forwarded shall proceed to hear the complaint against the accused as if the case has been forwarded to him under section 346 of the Code of Criminal Procedure, 1973.

(2) Every proceeding before a State Board shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228, and for the purposes of section 196 of the Indian Penal Code, and the Board shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

CHAPTER - III

PROCEDURES FOR REGISTRATIONS AND COMPLAINTS

13. Registration and accreditation of clinics –

(1) All assisted reproductive technology clinics shall, within such period and in such form and manner as may be prescribed, register themselves with the Registration Authority.

(2) An application for registration by an assisted reproductive technology clinic under sub-section (1) of this section shall contain the particulars of the applicant including all details of techniques and procedures of assisted reproductive technology practiced at such clinic.

(3) The State Board may, subject to such terms and conditions as may be prescribed, register any assisted reproductive technology clinic on the basis of the techniques and procedures of assisted reproductive technology practiced at such clinic, such as –

(a) infertility treatment, including Intra-Uterine Insemination (IUI), Artificial Insemination with Husband's semen (AIH), and Artificial Insemination using Donor Semen (AID), involving the use of donated or collected gametes;

(b) infertility treatment involving the use and creation of embryos outside the human body;

(c) processing or storage of embryos;

(d) research.

(4) Notwithstanding anything contained in this Act or any of the Rules made thereunder, no assisted reproductive technology clinic performing any of the functions under sub-section (3) of this section, or any other advanced diagnostic, therapeutic or research functions, shall practice any aspect of such diagnosis, therapy or research without a certificate of accreditation issued by the State Board.

(5) The practice of any aspect of assisted reproductive technology in contravention of the provisions of this section shall constitute an offence under this Act.

(6) Assisted reproductive technology clinics registered under this Act shall be deemed to have satisfied the provisions of the PC & PNDT Act, 1994 [amended in 2002], and shall not be required to seek a separate registration under the said Act.

14. Who may apply for registration –

(1) Assisted reproductive technology clinics, ART banks and research organizations using human embryos, operative on the date of notification of this Act, shall obtain a temporary registration within six months of the notification of the State Registration Authority by the State Board, and regular registration within 18 months of the above notification. If an assisted reproductive technology clinic that has applied for temporary registration under this clause to the State Registration Authority does not receive the registration or hear from the above Authority within 60 days of the receipt of the application by the Authority, the clinic would be deemed to have received the temporary registration.

(2) No assisted reproductive technology clinic, ART bank or research organisation using human embryos, other than the ones specified above, shall practice any aspect of assisted reproductive technology, or carry out any research on or using human embryos, or use any premises for such purposes, without a registration under this Act.

(3) Any assisted reproductive technology clinic or ART bank or research organisation using human embryos, by whatsoever name called, may apply to the Registration Authority for registration to operate the clinic, ART bank or research organisation in accordance with the procedure and criteria laid down in this Act.

(4) Every application under sub-section (2) of this section shall be in such form and shall be accompanied by such fee and such documents as may be prescribed by the State Government.

15. Grant of registration –

(1) The Registration Authority may, if it is satisfied that the criteria specified in the Rules have been met, grant registration to the applicant for a term of three years under such terms and conditions as it thinks fit.

(2) The Registration Authority shall, within one month of a registration being granted under this section, report such registration to the State Board.

(3) The State Board shall maintain a record of all registrations applied for and granted under this section.

(4) No registration shall be granted unless the Registration Authority, or such authorised person or persons acting on its behalf, have inspected the premises of the applicant.

16. Renewal, suspension or revocation of registration –

(1) The Registration Authority may, on an application made to it in such form and manner as may be prescribed, renew a registration granted under the provisions of this Act with effect from the date of its expiry if it is satisfied that the criteria prescribed in the Schedule continue to be met.

(2) The Registration Authority may at any time suspend the operation of a registration and call upon the holder of the registration to produce such documents or furnish such evidence as may be required if it has reasonable grounds to believe that the terms and conditions of the registration have not been met.

(3) When acting under sub-section (2) of this section, the Registration Authority shall either revoke the registration or continue the registration, as the case may be, after giving the holder of the registration adequate opportunity to be heard.

(4) The Registration Authority shall inform the concerned State Board of every assisted reproductive technology clinic in respect of which it has granted, renewed, revoked or denied a registration under this Act within one month of such an action being taken.

(5) The Registration Authority shall be deemed to have granted renewal for three years to the applicant if the applicant does not receive a definitive communication from the Registration Authority regarding the renewal application within sixty days of the receipt of the application in the office of the Registration Authority.

17. Registration Authority to inspect premises – In the exercise of its powers under this Act, the Registration Authority shall have the power to inspect, with or without prior notice on a working day during working hours, any premises or call for any document or material in the discharge of its powers and functions.

18. Applicability to ART banks and research organisations – The provisions of sections 13 to 16, as relevant, shall apply also to ART banks and research organisations using human embryos.

19. Appeal to the State Board –

(1) Any person aggrieved by the decision of the Registration Authority made under this Act may, within such period and in such manner and form as may be prescribed, prefer an appeal to the State Board.

(2) On receipt of an appeal under sub-section (1) of this section, the State Board may, after giving an opportunity to the appellant to be heard, and after making such further inquiry as it thinks fit, confirm, modify or set aside the decision of the Registration Authority, within three months of the receipt of the appeal.

CHAPTER - IV

DUTIES OF AN ASSISTED REPRODUCTIVE TECHNOLOGY CLINIC

20. General duties of assisted reproductive technology clinics –

(1) Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers are eligible to avail of assisted reproductive technology procedures under the criteria prescribed by the rules under this Act and that they have been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

(2) It shall be the responsibility of an assisted reproductive technology clinic to obtain, from ART bank(s), all relevant information, other than the name, personal identity and address, of possible gamete donors, and assist the couple or individual desirous of the donation, to choose the donor.

(3) When an ART bank receives a request from an assisted reproductive technology clinic for a donor oocyte, a responsible member of the staff of the ART bank will accompany the particular donor to the assisted reproductive technology clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made aware of the fact that any step leading to disclosure of the identify (i.e., name and address) to the recipient couple or individual or to anyone else, shall amount to an offence punishable under this Act.

(4) Either of the parties seeking assisted reproductive technology treatment or procedures shall be entitled to specific information in respect of donor of gametes including, but not restricted to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not made known.

(5) Assisted reproductive technology clinics shall obtain donor gametes from ART banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

(6) Assisted reproductive technology clinics shall provide professional counselling to patients or individuals about all the implications and chances of success of assisted reproductive technology procedures in the clinic and in India and internationally, and shall also inform patients

and individuals of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple or individual arrive at a decision that would be most likely to be the best for the couple or individual.

(7) Assisted reproductive technology clinics shall make couples or individuals, as the case may be, aware of the rights of a child born through the use of assisted reproductive technology.

(8) Assisted reproductive technology clinics shall explain to couples or individuals, as the case may be, the choice or choices of treatment available to them and the reason or reasons of the clinic for recommending a particular treatment, and shall clearly explain the advantages, disadvantages, limitations and cost of any recommended or explained treatment or procedure.

(9) Assisted reproductive technology clinics shall ensure that information about clients, donors and surrogate mothers is kept confidential and that information about assisted reproductive technology treatment shall not be disclosed to anyone other than a central database to be maintained by the Department of Health Research, except with the consent of the person or persons to whom the information relates, or in a medical emergency at the request of the person or persons or the closest available relative of such person or persons to whom the information relates, or by an order of a court of competent jurisdiction.

(10) No assisted reproductive technology clinic shall consider conception by surrogacy for patients for whom it would normally be possible to carry a baby to term. Provided that where it is determined that unsafe or undesirable medical implications of such conception may arise, the use of surrogacy may be permitted.

(11) Assisted reproductive technology clinics shall provide to couples or individuals, as the case may be, a pre-stamped self-addressed envelop to inform the clinic of the results of the assisted reproductive technology procedure performed for the couple or the individual.

(12) No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the parties seeking assisted reproductive technology treatment or procedures.

(13) Every assisted reproductive technology clinic shall establish a mechanism to look into complaints in such manner as may be prescribed.

(14) No assisted reproductive technology procedure shall be performed on a woman below 21 years of age, and any contravention of this stipulation shall amount to an offence punishable under this Act.

(15) All assisted reproductive technology clinics shall issue to the infertile couple / individual a discharge certificate stating details of the assisted reproductive technology procedure(s) performed on the couple / individual.

(16) Only a registered ART bank (and no other organization) shall be authorised to advertise for, procure or provide semen, oocyte donor or surrogate mother.

21. Duty of the assisted reproductive technology clinic to obtain written consent –

(1) No assisted reproductive technology clinic shall perform any treatment or procedure of assisted reproductive technology without the consent in writing of all the parties seeking assisted reproductive technology to all possible stages of such treatment or procedures including the freezing of embryos.

(2) No assisted reproductive technology clinic shall freeze any human embryos without specific instructions and consent in writing from all the parties seeking assisted reproductive technology in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties.

(3) No assisted reproductive technology clinic shall use any human reproductive material to create an embryo or use an in vitro embryo for any purpose without the specific consent in writing of all the parties to whom the assisted reproductive technology relates.

(4) The consent of any of the parties obtained under this section may be withdrawn at any time before the embryos or the gametes are transferred to the concerned woman's uterus.

22. Duty of the assisted reproductive technology clinic to keep accurate records –

(1) All assisted reproductive technology clinics shall maintain detailed records, in such manner as may be prescribed, of all donor oocytes, sperm or embryos used, the manner and technique of their use, and the individual or couple or surrogate mother, in respect of whom it was used.

(2) All assisted reproductive technology clinics will, as and when such central facilities are established, put on line all information available to them in regard to progress of the patient (such as biochemical and clinical pregnancy) within seven days of the information being available, withholding the identity of the patient.

(3) Records maintained under sub-section (1) of this section shall be maintained for at least a period of ten years, upon the expiry of which

the assisted reproductive technology clinic shall transfer the records to a central database of a, national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR.

(4) In the event of the closure of any assisted reproductive technology before the expiry of the period of ten years under sub-section (2) of this section, the assisted reproductive technology clinic or ART bank shall immediately transfer the records to a central database of a, national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR

23. Duties of assisted reproductive technology clinics using gametes and embryos –

(1) Assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations of the National Board or concerned State Board or any rule as may be prescribed under this Act.

(2) The number of oocytes or embryos that may be placed in a woman in any one cycle shall be according to the rules and regulations provided under this Act.

(3) No woman should be treated with gametes or embryos derived from the gametes of more than one man or woman during any one treatment cycle.

(4) An assisted reproductive technology clinic shall never mix semen from two individuals before use.

(5) Where a multiple pregnancy occurs as a result of assisted reproductive technology, the concerned assisted reproductive technology clinic shall inform the patient immediately of the multiple pregnancy and its medical implications and may carry out foetal reduction after appropriate counselling.

(6) The collection of gametes from a person whose death is imminent shall only be permissible if such person’s spouse intends to avail assisted reproductive technology to have a child.

(7) No assisted reproductive technology clinic shall use ova that are derived from a foetus, in any process of in vitro fertilisation.

(8) No assisted reproductive technology clinic shall utilise any semen, whether from an ART bank or otherwise, for any aspect of assisted reproductive technology unless such semen is medically analysed in such manner as may be prescribed.

(9) Any contravention of stipulation under sub-section 3, 4, 7 and 8 of this section shall amount to an offence under this Act.

24. Pre-implantation Genetic Diagnosis –

(1) Pre-implantation Genetic Diagnosis shall be used only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority.

(2) Destruction or donation (with the approval of the patient) to an approved research laboratory for research purposes, of an embryo after Pre-implantation Genetic Diagnosis, shall be done only when the embryo suffers from pre-existing, heritable, life-threatening or genetic diseases

(3) The State Board may lay down such other conditions as it deems fit in the interests of Pre-implantation Genetic Diagnosis.

25. Sex selection –

(1) No assisted reproductive technology clinic shall offer to provide a couple with a child of a pre-determined sex.

(2) It shall be a criminal offence and it is prohibited for anyone to do any act, at any stage, to determine the sex of the child to be born through the process of assisted reproductive technology.

(3) No person shall knowingly provide, prescribe or administer any thing that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.

(4) No assisted reproductive technology clinic will carry out any assisted reproductive technology procedure to separate, or yield fractions enriched in sperm of X or Y variations.

(5) Any contravention of stipulation under sub-section 1, 2, 3 and 4 of this section shall amount to an offence under this Act.

CHAPTER - V

SOURCING, STORAGE, HANDLING AND RECORD KEEPING FOR GAMETES, EMBRYOS AND SURROGATES

26. Sourcing of gametes –

(1) The screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates, shall be done by an ART bank registered as an independent entity under the provisions of this Act.

(2) An ART bank shall operate independently of any assisted reproductive technology clinic.

(3) ART banks shall obtain semen from males between twenty one years of age and forty five years of age, both inclusive, and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, both inclusive, and examine the donors for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

(4) All ART banks shall have standard, scientifically established facilities and defined standard operating procedures for all its scientific and technical activities.

(5) All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period, the ART bank shall not supply the sperm to any assisted reproductive technology clinic unless the sperm donor is tested for such diseases, sexually transmitted or otherwise, as may be prescribed.

(6) An ART bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank.

(7) An ART bank shall not supply the sperm of a single donor for use more than seventy five times.

(8) No woman shall donate oocytes more than six times in her life, with not less than a three-month interval between the oocyte pick-ups.

(9) Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient.

(10) All unused oocytes would be either appropriately preserved by the assisted reproductive technology clinic for use on the same recipient(s), or given for research to a bonafide organisation.

(11) One sample of semen supplied by an ART bank shall be used by the assisted reproductive technology clinic only once on only one recipient.

(12) An ART bank shall obtain all necessary information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate, in such manner as may be prescribed, and shall undertake in writing to the donor to keep such information confidential.

(13) No ART bank shall divulge the name, identity or address of any sperm or oocyte donor to any person or assisted reproductive technology clinic except in pursuance of an order or decree of a court of competent jurisdiction.

(14) Any person or ART bank who divulges the name, identity or address of a sperm donor in contravention of subsections 11 and 12 of this section shall be guilty of an offence under this Act.

(15) An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

27. Storage and handling of gametes and embryos –

(1) The highest possible standards should be followed in the storage and handling of gametes and embryos in respect of their security, and with regard to their recording and identification.

(2) No donor gamete shall be stored for a period of more than five years.

(3) An embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of five years and at the end of such period such embryo shall be allowed to perish or donated to an approved research organization for research purposes with the consent of the patients. If during the period of five years, one of the commissioning partners dies, the surviving partner can use the embryo for herself or for her partner, provided an appropriate consent was taken earlier.

Provided that where the persons to whom such embryo relates fails to pay the fee, or both the commissioning persons die, the assisted reproductive technology clinic may, subject to such regulations as may be prescribed, destroy the embryo or transfer the embryo to any accredited research organisation under section 18 of this Act.

28. Records to be maintained by the ART bank –

(1) The ART bank shall keep a record of all the gametes received, stored and supplied, and details of the use of the gametes of each donor.

(2) The records shall be maintained for at least ten years, after which the records shall be transferred to a central database of the Department of Health Research, Government of India.

(3) Where an ART bank closes before the expiry of the ten year period, the records shall be immediately transferred to the central database of the Department of Health Research, Government of India.

(4) If not otherwise ordered by a court of competent jurisdiction, all ART banks shall ensure that all information about clients and donors is kept confidential and that information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research.

29. Restriction on sale of gametes, zygotes and embryos –

(1) The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India is prohibited and shall be deemed to be an offence under this Act except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board.

(2) The sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India, is prohibited and shall be deemed to be an offence under this Act.

CHAPTER - VI

REGULATION OF RESEARCH ON EMBRYOS

30. Permission of the Department of Health Research for research –

(1) The sale of any gametes and embryos or their transfer to any country outside India, for research is absolutely prohibited and shall constitute a criminal offence under this Act.

(2) Research shall only be conducted on such gametes and embryos that have been donated for such purpose.

(3) No research shall be conducted using embryos except with the permission of the Department of Health Research.

(4) Any person or organisation, by whatsoever name called, may apply to the Department of Health Research for registration as a research institution permitted to conduct research on embryos.

(5) While granting permission on an application for registration made under sub-section 4 of this section, the Department of Health Research may prescribe, and the applicant shall be bound by such terms and conditions as it thinks fit.

(6) The Department of Health Research may, if it has reasonable grounds to believe that any of the terms and conditions prescribed under sub-section 5 of this section have not been met, –

(a) call for the production of such documents or the furnishing of such evidence as may be required;

(b) inspect, or order any officer authorised in this behalf to inspect, any premises related to the grant of registration;

(c) suspend the registration of the research institution, after giving all concerned parties adequate opportunity to be heard.

(7) The Department of Health Research may make such regulations as it thinks fit to provide for research on embryos.

(8) Any act or thing done or omitted to be done in contravention of the provisions of this Chapter shall be deemed to be an offence under this Act.

31. Regulation of research –

(1) In exercising its powers under this Chapter, the Department of Health Research shall ensure that –

(a) no research is conducted on any human embryo unless such research is necessary in public interest;

(b) no research is conducted on any human embryo created *in vitro* unless such research is necessary in public interest to acquire further scientific knowledge;

(c) no research is conducted on any human embryo, other than embryos given for storage to an ART bank under sub-section (3) of section 27, unless full and informed consent in writing is obtained from the persons from whom such embryo was created;

(d) no advertisement is issued, and no purchase, sale or transfer is made, of any human embryo created *in vitro* or any part thereof, except in accordance with this Act;

(e) no human embryo *created in vitro* is maintained for a period exceeding fourteen days or such other period as recommended by the National Advisory Board;

(f) no work is done leading to human reproductive cloning;

(g) such other terms and conditions that may be prescribed by the ICMR, are adhered to.

(2) Any assisted reproductive technology clinic or other research institution or person conducting any research in contravention of the provisions of this Act or any rules or regulations prescribed hereunder shall be an offence under this Act.

CHAPTER - VII

RIGHTS AND DUTIES OF PATIENTS, DONORS, SURROGATES AND CHILDREN

32. Rights and duties of patients –

(1) Subject to the provisions of this Act and the rules and regulations made thereunder, assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples.

(2) In case assisted reproductive technology is used by a married or unmarried couple, there must be informed consent from both the parties.

(3) The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate mother, when and to the extent necessary for the welfare of the child.

(4) All information about the patients shall be kept confidential and information about assisted reproductive technology procedures done on them shall not be disclosed to anyone other than the central depository of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by a court order.

33. Rights and duties of donors –

(1) Subject to the other provisions of this Act, all information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by an order of a court of competent jurisdiction.

(2) Subject to the other provisions of this Act, the donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.

(3) A donor shall relinquish all parental rights over the child which may be conceived from his or her gamete.

(4) No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained the consent in writing of his or her spouse, if there, to such procedure.

(5) The identity of the recipient shall not be made known to the donor.

34. Rights and duties in relation to surrogacy –

(1) Both the couple or individual seeking surrogacy through the use of assisted reproductive technology, and the surrogate mother, shall enter into a surrogacy agreement which shall be legally enforceable.

(2) All expenses, including those related to insurance if available, of the surrogate related to a pregnancy achieved in furtherance of assisted reproductive technology shall, during the period of pregnancy and after delivery as per medical advice, and till the child is ready to be delivered as per medical advice, to the biological parent or parents, shall be borne by the couple or individual seeking surrogacy.

(3) Notwithstanding anything contained in sub-section (2) of this section and subject to the surrogacy agreement, the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.

(4) A surrogate mother shall relinquish all parental rights over the child.

(5) No woman less than twenty one years of age and over thirty five years of age shall be eligible to act as a surrogate mother under this Act.

Provided that no woman shall act as a surrogate for more than five successful live births in her life, including her own children.

(6) Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and must declare in writing that she has not received a blood transfusion or a blood product in the last six months.

(7) Individuals or couples may obtain the service of a surrogate through an ART bank, which may advertise to seek surrogacy provided that no such advertisement shall contain any details relating to the caste, ethnic identity or descent of any of the parties involved in such surrogacy. No assisted reproductive technology clinic shall advertise to seek surrogacy for its clients.

(8) A surrogate mother shall, in respect of all medical treatments or procedures in relation to the concerned child, register at the hospital or such medical facility in her own name, clearly declare herself to be a surrogate mother, and provide the name or names and addresses of the person or persons, as the case may be, for whom she is acting as a surrogate, along with a copy of the certificate mentioned in clause 17 below.

(9) If the first embryo transfer has failed in a surrogate mother, she may, if she wishes, decide to accept on mutually agreed financial terms, at

most two more successful embryo transfers for the same couple that had engaged her services in the first instance. No surrogate mother shall undergo embryo transfer more than three times for the same couple.

(10) The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of individual / individuals who commissioned the surrogacy, as parents.

(11) The person or persons who have availed of the services of a surrogate mother shall be legally bound to accept the custody of the child / children irrespective of any abnormality that the child / children may have, and the refusal to do so shall constitute an offence under this Act.

(12) Subject to the provisions of this Act, all information about the surrogate shall be kept confidential and information about the surrogacy shall not be disclosed to anyone other than the central database of the Department of Health Research, except by an order of a court of competent jurisdiction.

(13) A surrogate mother shall not act as an oocyte donor for the couple or individual, as the case may be, seeking surrogacy.

(14) No assisted reproductive technology clinic shall provide information on or about surrogate mothers or potential surrogate mothers to any person.

(15) Any assisted reproductive technology clinic acting in contravention of sub-section 14 of this section shall be deemed to have committed an offence under this Act.

(16) In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate.

(17) A surrogate mother shall be given a certificate by the person or persons who have availed of her services, stating unambiguously that she has acted as a surrogate for them.

(18) A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple/ individual. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.

(19) A foreigner or foreign couple not resident in India, or a non-resident Indian individual or couple, seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child / children are delivered to the foreigner or foreign couple or the

local guardian. Further, the party seeking the surrogacy must ensure and establish to the assisted reproductive technology clinic through proper documentation (a letter from either the embassy of the Country in India or from the foreign ministry of the Country, clearly and unambiguously stating that (a) the country permits surrogacy, and (b) the child born through surrogacy in India, will be permitted entry in the Country as a biological child of the commissioning couple/individual) that the party would be able to take the child / children born through surrogacy, including where the embryo was a consequence of donation of an oocyte or sperm, outside of India to the country of the party's origin or residence as the case may be. If the foreign party seeking surrogacy fails to take delivery of the child born to the surrogate mother commissioned by the foreign party, the local guardian shall be legally obliged to take delivery of the child and be free to hand the child over to an adoption agency, if the commissioned party or their legal representative fails to claim the child within one months of the birth of the child. During the transition period, the local guardian shall be responsible for the well-being of the child. In case of adoption or the legal guardian having to bring up the child, the child will be given Indian citizenship.

(20) A couple or an individual shall not have the service of more than one surrogate at any given time.

(21) A couple shall not have simultaneous transfer of embryos in the woman and in a surrogate.

(22) Only Indian citizens shall have a right to act as a surrogate, and no ART bank/ART clinics shall receive or send an Indian for surrogacy abroad.

(23) Any woman agreeing to act as a surrogate shall be duty-bound not to engage in any act that would harm the foetus during pregnancy and the child after birth, until the time the child is handed over to the designated person(s).

(24) The commissioning parent(s) shall ensure that the surrogate mother and the child she deliver are appropriately insured until the time the child is handed over to the commissioning parent(s) or any other person as per the agreement and till the surrogate mother is free of all health complications arising out of surrogacy.

35. Determination of status of the child –

(1) A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse.

(2) A child born to an unmarried couple through the use of assisted reproductive technology, with the consent of both the parties, shall be the legitimate child of both parties.

(3) In the case of a single woman the child will be the legitimate child of the woman, and in the case of a single man the child will be the legitimate child of the man.

(4) In case a married or unmarried couple separates or gets divorced, as the case may be, after both parties consented to the assisted reproductive technology treatment but before the child is born, the child shall be the legitimate child of the couple.

(5) A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.

(6) If a donated ovum contains ooplasm from another donor ovum, both the donors shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and the donor of both the ooplasm and the ovum shall relinquish all parental rights in relation to such child.

(7) The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.

(8) If a foreigner or a foreign couple seeks sperm or egg donation, or surrogacy, in India, and a child is born as a consequence, the child, even though born in India, shall not be an Indian citizen.

36. Right of the child to information about donors or surrogates –

(1) A child may, upon reaching the age of 18, ask for any information, excluding personal identification, relating to the donor or surrogate mother.

(2) The legal guardian of a minor child may apply for any information, excluding personal identification, about his / her genetic parent or parents or surrogate mother when required, and to the extent necessary, for the welfare of the child.

(3) Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother.

Provided that such personal identification will not be released without the prior informed consent of the genetic parent or parents or surrogate mother.

CHAPTER - VIII

OFFENCES AND PENALTIES

37. Prohibition of advertisement relating to pre-natal determination of sex and punishment for contravention –

(1) No assisted reproductive technology clinic shall issue or cause to be issued any advertisement in any manner regarding facilities of pre-natal determination of sex.

(2) No assisted reproductive technology clinic, or agent thereof, shall publish or distribute or cause to be published or distributed any advertisement in any manner regarding facilities of pre-natal determination of sex.

(3) Any person who contravenes the provisions of this section shall be punishable with imprisonment for a term which may extend to five years and with fine which may be specified.

Explanation - For the purposes of this section, “advertisement” includes any notice, circular, label wrapper or other document and also includes any visible representation made by means of any light, sound, smoke or gas.

38. Offences and penalties –

(1) Any medical geneticist, gynaecologist, registered medical practitioner or any person who owns or operates any assisted reproductive technology clinic, or is employed in such a facility and renders his professional or technical services to such facility, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act or rules made thereunder, shall be punishable with imprisonment for a term which may extend to three years and / or with fine which may be specified, and on any subsequent conviction, with imprisonment which may extend to five years and / or fine which may be specified.

(2) The name of the registered medical practitioner who has been convicted by the court under sub-section 1 of this section shall be reported by the State Board to the respective State Medical Council for taking necessary action including the removal of his name from the register or the Council for a period of two years for the first offence and permanently for any subsequent offence.

(3) Any person who seeks the aid of assisted reproductive technology or of a medical geneticist, gynaecologist or registered medical practitioner for conducting pre-natal diagnostic techniques on any pregnant woman for purposes other than those specified in clause (2) of section 4 of the Pre-natal Diagnostic Techniques (Regulation and Prevention of

Misuse) Act, 1994 [Act 57 of 1994], shall be punishable with imprisonment for a term which may extend to three years and with fine which may be specified, and on any subsequent conviction with imprisonment which may extend to five years and with fine which may be specified.

(4) The transfer of a human embryo into a male person or into an animal that is not of the human species shall be an offence under this Act and shall be punishable with imprisonment for a term which may extend to three years and with fine which may be specified.

(5) The sale of any embryo for research is absolutely prohibited and shall be an offence under this Act punishable by imprisonment for a term which may extend to three years and with fine which may be specified.

(6) Use of individual brokers or paid intermediaries to obtain gamete donors or surrogates shall be an offence under this Act, punishable by imprisonment for a term which may extend to three years and fine which may be specified.

39. Presumption in the case of conduct of pre-natal diagnostic techniques – Notwithstanding anything in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the pregnant woman has been compelled by her husband or the relative to undergo pre-natal diagnostic technique.

40. Penalty for contravention of the provisions of the Act or rules for which no specific punishment is provided – Whoever contravenes any of the provisions of this Act or any rules made thereunder, for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may be specified, or with both, and in the case of continuing contravention, with an additional fine which may be specified.

41. Offences by companies –

(1) Where any offence, punishable under this Act has been proven to be committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment, if he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1) of this section, where any offence punishable under this Act has been committed by a

company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation – For the purposes of this section,

(a) "company" means any body corporate and includes a firm or other association of individuals, and

(b) "director", in relation to a firm, means a partner in the firm.

42. Offence to be cognizable – Every offence under this Act shall be cognizable.

CHAPTER - IX

MISCELLANEOUS

43. Maintenance of records –

(1) All records, charts, forms, reports, consent letters and all other documents required to be maintained under this Act and the rules shall be preserved for a period of ten years or for such period as may be prescribed

Provided that, if any criminal or other proceedings are instituted against any facility using assisted reproductive technology, the records and all other documents of such facility shall be preserved till the final disposal of such proceedings.

(2) All such records shall, at all reasonable times, be made available for inspection to the concerned State Board or to any other person authorised by the concerned State Board in this behalf.

44. Power to search and seize records etc. –

(1) If the State Board has reason to believe that an offence under this Act has been or is being committed at any facility using assisted reproductive technology, such Board or any officer authorised thereof in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officer considers necessary, such facility, and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize the same if the State Board or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(2) The provisions of the Code of Criminal Procedure, 1973, relating to searches and seizures shall, so far as may be, apply to every search or seizure made under this Act.

45. Power to remove difficulties –

(1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of this Act as may appear to be necessary for removing the difficulty:

Provided that no order shall be made under this section after the expiry of three years from the commencement of this Act.

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

46. **Protection of action taken in good faith –** No suit, prosecution or other legal proceeding shall lie against the Central or the State Government or the National Board or State Boards or Registration Authority or any officer authorised by any of them, for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

47. **Power to make regulations –** The National Advisory Board may, with the previous sanction of the Central Government, by notification in the Official Gazette, make regulations not inconsistent with the provisions of this Act and the rules made thereunder, to provide for –

(a) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings, and the number of members which shall form the quorum;

(b) the conditions for the transfer of embryos and gametes to research institutions;

(c) regulation of Pre-implantation Genetic Diagnosis;

(d) research on embryos;

(e) the efficient conduct of the affairs of the Board;

(f) any other purpose that may be prescribed.

48. **Power of the Central Government to make rules –**

(1) The Central Government may make rules for carrying out the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for –

(a) categories of assisted reproductive technology clinics;

(b) the minimum requirements regarding staff in assisted reproductive technology clinics;

(c) the minimum physical infrastructure requirements for an assisted reproductive technology clinic;

(d) the various assisted reproductive technology procedures to be adopted by an assisted reproductive technology clinic;

(e) the criteria for selecting patients for an assisted reproductive technology procedure;

(f) the criteria for selecting an assisted reproductive technology procedure for a patient;

(g) information and advise to, and counselling of patient;

(h) the eligibility of couples and individuals to use assisted reproductive technology;

(i) the eligibility of donors;

(j) the eligibility of surrogate mothers;

(k) the number of embryos that can be implanted in a woman;

(l) the number of times that a patient can be given a procedure;

(m) the maintenance of records;

(n) procedure to search and seize;

(o) the criteria to be fulfilled for a license;

(p) the effective implementation of the Act.

(3) Every rule made by the Central Government under sub-section (1) of this section shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation.

49. Power of State Government to make rules – Subject to the provisions of this Act and the rules and regulations made thereunder, the State Government may make rules to carry out the purposes of this Act.

50. Act to have effect in addition to other Acts – The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law, for the time being in force, except for the following:

a) Provision made in Section 13(6) of this Act;

b) Inapplicability of the provision of the Right to Information Act in regard to provision made in Section 20(9) and 26(13) of this Act.

[TRUE COPY]

As introduced in Lok Sabha

Bill No. 257 of 2016

THE SURROGACY (REGULATION) BILL, 2016

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As introduced in Lok Sabha

Bill No. 257 of 2016

THE SURROGACY (REGULATION) BILL, 2016

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Sixty-seventh Year of the Republic of India as follows:—

CHAPTER I

Preliminary

Short title, extent and commencement.

1. (*1*) This Act may be called the Surrogacy (Regulation) Act, 2016.

(*2*) It extends to the whole of India except the State of Jammu and Kashmir.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions.

2. In this Act, unless the context otherwise requires,—

(*a*) "abandoned child" means a child—

(*i*) born out of surrogacy procedure;

(*ii*) deserted by his intending parents or guardians; and

(*iii*) who has been declared as abandoned by the appropriate authority after due enquiry;

(*b*) “altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

(*c*) “appropriate authority" means the appropriate authority appointed under section 32;

(*d*) “Board" means the National Surrogacy Board constituted under section 14;

(*e*) “clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010; 23 of 2010.

(*f*) “commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

(*g*) “couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;

(*h*) “egg" includes the female gamete;

(*i*) “embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;

(*j*) “fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;

(*k*) “foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;

(*l*) “gamete" means sperm and oocyte;

(*m*) “gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*n*) “human embryologist" means a person who possesses any post-graduate medical qualification in the field of human embryology recognised under the Indian Medical Council Act, 1956 or who possesses a post-graduate degree in human embryology from a recognised university with not less than two years of clinical experience; 102 of 1956.

(*o*) “implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;

(*p*) “infertility" means the inability to conceive after five years of unprotected coitus or other proven medical condition preventing a couple from conception;

(*q*) “insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for specified loss, damage, illness or death of surrogate mother during the process of surrogacy;

(*r*) “intending couple" means a couple who have been medically certified to be an infertile couple and who intend to become parents through surrogacy;

(*s*) “Member" means a Member of the National Surrogacy Board or a State Surrogacy Board, as the case may be;

(*t*) “notification" means a notification published in the Official Gazette;

(*u*) “oocyte" means naturally ovulating oocyte in the female genetic tract;

(*v*) “Paediatrician" means a person who possess a post-graduate qualification in paediatrics as recognised under the Indian Medical Council Act, 1956; 102 of 1956.

(*w*) "prescribed" means prescribed by rules made under this Act;

(*x*) “registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register; 102 of 1956.

(*y*) “regulation" means regulations made by the Board under this Act;

(*z*) “State Board" means the State Surrogacy Board constituted under section 23;

(*za*) “State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under article 239 of the Constitution;

(*zb*) “surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;

(*zc*) “surrogacy clinic" means surrogacy clinic or centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called conducting surrogacy procedures in any form;

(*zd*) “surrogacy procedures" means all gynaecological or obstetrical or medical procedures, techniques, tests, practices or services involving handling of human gametes and human embryo in surrogacy;

(*ze*) “surrogate mother" means a woman bearing a child who is genectically related to the intending couple, through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause (*b*) of clause (*iii*) of section 4;

(*zf*) “zygote" means the fertilised oocyte prior to the first cell division.

CHAPTER II

REGULATION OF SURROGACY CLINICS

Prohibition and regulation of surrogacy clinics.

3. On and from the date of commencement of this Act,—

(*i*) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;

(*ii*) no surrogacy clinic, paediatrician, gynaecologist, human embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;

(*iii*) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess such qualifications as may be prescribed;

(*iv*) no registered medical practitioner, gynaecologist, paediatrician, human

embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;

(*v*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(*a*) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(*b*) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(*c*) seeks or aimed at seeking a woman to act as a surrogate mother;

(*d*) states or implies that a woman is willing to become a surrogate mother; or

(*e*) advertises commercial surrogacy in print or electronic media or in any other form;

(*vi*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:

Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971; 34 of 1971.

(*vii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:

Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

Regulation of surrogacy and surrogacy procedures.

4. On and from the date of commencement of this Act,—

(*i*) no place including a surrogacy clinic shall be used or caused to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause (*ii*) and after satisfying all the conditions specified in clause (*iii*);

(*ii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(*a*) when either or both members of the couple is suffering from proven infertility;

(*b*) when it is only for altruistic surrogacy purposes;

(*c*) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(*d*) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(*e*) any other condition or disease as may be specified by regulations made by the Board;

(*iii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(*a*) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying for itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(*I*) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board.

Explanation.—For the purposes of this item, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, have been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and surrogate mother;

(*III*) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;

41 of 1999.

(*b*) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(*II*) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;

(*III*) no women shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime:

Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed;

(*IV*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(*c*) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(*II*) the intending couple are married for at least five years and are Indian citizens;

(*III*) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent

cure and approved by the appropriate authority with due medical certificate from a District Medical Board;

(*IV*) such other conditions as may be specified by the regulations.

Prohibition of conducting surrogacy.

5. No person including a relative or husband of a surrogate mother or intending couple shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause (*ii*) of section 4.

Written informed consent of surrogate mother.

6. No person shall seek or conduct surrogacy procedures unless he has—

(*i*) explained all known side effects and after effects of such procedures to the surrogate mother concerned;

(*ii*) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

Prohibition to abandon child born through surrogacy.

7. The intending couple shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like:

Provided that any child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple and the said child shall be entitled to all the rights and privileges available to a natural child under any law for the time being in force.

Number of oocytes or embryos to be implanted.

8. The number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.

Prohibition of abortion.

9. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.

CHAPTER IV

REGISTRATION OF SURROGACY CLINICS

Registration of surrogacy clinics.

10. (*1*) No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.

(*2*) Every application for registration under sub-section (*1*) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(*3*) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in clause (*ii*) of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:

Provided that such clinic shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(*4*) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

Certificate of registration.

11. (*1*) The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act, rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic,

within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.

(*2*) Where, after the enquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(*3*) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

(*4*) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Cancellation or suspension of registration.

12. (*1*) The appropriate authority may, *suo motu*, or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(*2*) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provision of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(*3*) Notwithstanding anything contained in sub-sections (*1*) and (*2*), if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (*1*).

Appeal.

13. The surrogacy clinic may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section 12, prefer an appeal against such order to—

(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;

(*b*) to the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,

in such manner as may be prescribed.

CHAPTER V

National Surrogacy Board

Constitution of National Surrogacy Board.

14. (*1*) The Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(*2*) The Board shall consist of—

(*a*) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*;

(*b*) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;

(*c*) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio*;

(*d*) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs not below the rank of Joint Secretary, Members, *ex officio*;

(*e*) the Director-General of Health Services of the Central Government, Member, *ex officio*;

(*f*) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(*i*) eminent medical geneticists or human embryologists;

(*ii*) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra;*

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing of such qualifications and experience as may be prescribed;

(*g*) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*;

(*h*) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of Members.

15. (*1*) The term of office of a Member, other than an *ex officio* Member, shall be—

(*a*) in case of nomination under clause (*c*) of sub-section (*2*) of section 14, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of sub-section (*2*) of section 14, one year:

Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of Board.

16. (*1*) The Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the Board shall meet at least once in six months.

(*2*) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

(*3*) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality

of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

(*4*) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meeting of the Board.

Vacancies, etc., not to invalidate proceedings of Board.

17. No act or proceeding of the Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Board; or

(*b*) any defect in the appointment of a person acting as a Member of the Board; or

(*c*) any irregularity in the procedure of the Board not affecting the merits of the case.

Disqualifications for appointment as Member.

18. (*1*) A person shall be disqualified for being appointed and continued as a Member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a Member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(*g*) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The Members referred to in clause (*f*) of section 14 shall not be removed from his office except by an order of the Central Government on the ground of his proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

(*3*) The Central Government may suspend any Member in respect of whom an inquiry under sub-section (*2*) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with Board for particular purposes.

19. (*1*) The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with the Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of Board.

20. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Eligibility of Member for re-appointment.

21. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Functions of Board.

22. The Board shall discharge the following functions, namely:—

(*a*) to advise the Central Government on policy matters relating to surrogacy;

(*b*) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein;

(*c*) to lay down code of conduct to be observed by persons working at surrogacy clinics; to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(*d*) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(*e*) to supervise the functioning of State Surrogacy Boards; and

(*f*) such other functions as may be prescribed.

Constitution of State Surrogacy Board.

23. Each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(*i*) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them;

(*ii*) to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(*iii*) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and

(*iv*) such other functions as may be prescribed.

Composition of State Board.

24. The State Board shall consist of—

(*a*) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;

(*b*) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;

(*c*) Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, Members, *ex officio*;

(*d*) the Director-General of Health and Family Welfare of the State Government, Member, *ex officio*;

(*e*) three women Members of the State Legislative Assembly or Union territory Legislative Council, Members, *ex officio*;

(*f*) ten expert Members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(*i*) eminent medical geneticists or human embryologists;

(*ii*) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra;*

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing of such qualifications and experiences as may be prescribed;

(*g*) an officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of Members.

25. (*1*) The term of office of a Member, other than an *ex officio* Member, shall be—

(*a*) in case of nomination under clause (*e*) of section 24, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a Member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of section 24, one year:

Provided that the person to be appointed as Member under this clause shall be of such age, as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of State Board.

26. (*1*) The State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the State Board shall meet at least once in four months.

(*2*) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

(*3*) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

(*4*) The Members, other than, *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Vacancies, etc., not to invalidate proceedings of State Board.

27. No act or proceeding of the State Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the State Board; or

(*b*) any defect in the appointment of a person acting as a Member of the State Board; or

(*c*) any irregularity in the procedure of the State Board not affecting the merits of the case.

Disqualifications for appointment as Member.

28. (*1*) A person shall be disqualified for being appointed and continued as a Member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(*g*) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The Members referred to in clause (*f*) of section 24 shall not be removed from his office except by an order of the State Government on the ground of his proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the Member ought on any such ground to be removed.

(*3*) The State Government may suspend any Member in respect of whom an inquiry under sub-section (*2*) is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with State Board for particular purposes.

29. (*1*) The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with it by the State Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of State Board.

30. All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Eligibility of Member for re-appointment.

31. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

CHAPTER VI

APPROPRIATE AUTHORITY

Appointment of appropriate authority.

32. (*1*) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act.

(*2*) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or part of the State for the purposes of this Act.

(*3*) The appropriate authority, under sub-section (*1*) or sub-section (*2*), shall,—

(*a*) when appointed for the whole of the State or the Union territory, consist of—

(*i*) an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson;

(*ii*) an eminent woman representing women's organisation—Member;

(*iii*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—Member; and

(*iv*) an eminent registered medical practitioner—Member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(*b*) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Functions of appropriate authority.

33. The appropriate authority shall discharge the following functions, namely:—

(*a*) to grant, suspend or cancel registration of a surrogacy clinic;

(*b*) to enforce the standards to be fulfilled by the surrogacy clinics;

(*c*) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act;

(*d*) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter;

(*e*) to supervise the implementation of the provisions of this Act, rules and regulations made thereunder;

(*f*) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(*g*) to take action after investigation of complaints received by it against the surrogacy clinics; and

(*h*) to consider and grant or reject any application under clause (*vi*) of section 3 and sub-clauses (*a*) to (*c*) of clause (*iii*) of section 4.

Powers of appropriate authority.

34. (*1*) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, rules and regulations made thereunder;

(*b*) production of any document or material object relating to clause (*a*);

(*c*) search any place suspected to be violating the provisions of this Act, rules and regulations made thereunder; and

(*d*) such other powers as may be prescribed.

(*2*) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of licence, etc., of the surrogacy clinics in such format as may be prescribed.

CHAPTER VII

OFFENCES AND PENALTIES

Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

35. (*1*) No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(*a*) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(*b*) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(*c*) abandon or disown or exploit or cause to be abandoned, exploited or disowned in any form the child or children born through surrogacy;

(*d*) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(*e*) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(*f*) import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures.

(*2*) Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of clauses (*a*) to (*f*) of sub-section (*1*) by any person shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees. 45 of 1860.

(*3*) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Punishment for contravention of provisions of Act.

36. (*1*) Any registered medical practitioner, gynaecologists, paediatrician, human embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in section 35), rules and regulations made thereunder shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to ten lakh rupees.

(*2*) In case of subsequent or continuation of the offence referred to in sub-section (*1*), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Punishment for initiation of commercial surrogacy.

37. Any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person for commercial surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

38. Whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which shall not be less than three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Presumption in case of surrogacy.

39. Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the woman or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause (*ii*) of section 4 and such person shall be liable for abetment of such offence under section 37 and shall be punishable for the offence specified under that section. 1 of 1872.

2 of 1974.

40. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable.

Offence to be cognizable, non-bailable and non-compoundable.

41. (*1*) No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—

Cognizance of offences.

(*a*) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or

(*b*) a person including a social organisation who has given notice of not less than fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

(*2*) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

2 of 1974.

42. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXIA of the said Code relating to plea of bargaining shall not apply to the offences under this Act.

Certain provisions of the Code of Criminal Procedure, 1973 not to apply.

CHAPTER VIII

MISCELLANEOUS

43. (*1*) The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed:

Maintenance of records.

Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

(*2*) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

44. (*1*) If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

Power to search and seize records, etc.

2 of 1974.

(*2*) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act.

45. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provision of this Act.

Protection of action taken in good faith.

46. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Application of other laws not barred.

Power to make rules.

47. (*1*) The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(*a*) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3;

(*b*) the manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3;

(*c*) the insurance coverage in favour of the surrogate mother from an insurance company under item (iii) of sub-clause (*a*) of clause (*iii*) of section 4;

(*d*) the number of attempts of surrogacy or providing of gametes under the proviso to item (iii) of sub-clause (*b*) of clause (*iii*) of section 4;

(*e*) the form in which consent of a surrogate mother has to be obtained under clause (*ii*) of section 6;

(*f*) the number of oocytes or embryos to be implanted in the surrogate mother under section 8;

(*g*) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 9;

(*h*) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (*2*) of section 10;

(*i*) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (*4*) of section 10;

(*j*) the period, manner and form in which a certificate of registration shall be issued under sub-section (*1*) of section 11;

(*k*) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (*3*) of section 11;

(*l*) the manner in which an appeal may be preferred under section 13;

(*m*) the qualifications and experiences to the Members as admissible under clause (*f*) of sub-section (*2*) of section 14;

(*n*) the procedures for conducting an inquiry against the Members under sub-section (*2*) of section 18;

(*o*) the conditions under which a Member of the Board eligible for re-appointment under section 21;

(*p*) the other functions of the Board under clause (*e*) of section 22;

(*q*) the manner in which reports shall be furnished by the State and Union territory Boards to the Board and the Central Government under clause (*iii*) of section 23;

(*r*) the other functions of the State Board under clause (*iv*) of section 23;

(*s*) the qualifications and experiences to the Members as admissible under clause (*f*) of section 24;

(*t*) the age of the person to be appointed as a Member, referred to in clause (*f*) of section 24, under the proviso to clause (*b*) of sub-section (*1*) of section 25;

(*u*) the procedures for conducting an inquiry against the members under sub-section (*2*) of section 28;

(*v*) the conditions under which the members of the State Board eligible for re-appointment under section 31;

(*w*) empowering the appropriate authority in any other matter under clause (*d*) of section 33;

(*x*) the other powers of appropriate authority under clause (*d*) of sub-section (*1*) of section 34;

(*y*) the particulars of the details of registration of surrogacy clinics, cancellation of registration, etc., in such format under sub-section (*2*) of section 34;

(*z*) the manner of giving notice by a person under clause (*b*) of sub-section (*1*) of section 41;

(*za*) the period up to which records, charts, etc., shall be preserved under sub-section (*1*) of section 43;

(*zb*) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (*1*) of section 44; and

(*zc*) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

Power to make regulations.

48. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—

(*a*) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under Item (IV) of sub-clause (*c*) of clause (*iii*) of section 4;

(*b*) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 16;

(*c*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 19;

(*d*) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 26;

(*e*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 29;

(*f*) any other matter which is required to be, or may be, specified by regulations.

Rules and regulations to be laid before Parliament.

49. Every rules and every regulations made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

Transitional provision.

50. Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Power to remove difficulties.

51. (*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

STATEMENT OF OBJECTS AND REASONS

India has emerged as a surrogacy hub for couples from different countries for past few years. There have been reported incidents of unethical practices, exploitation of surrogate mothers, abandonment of children born out of surrogacy and import of human embryos and gametes. Widespread condemnation of commercial surrogacy in India has been regularly reflected in different print and electronic media for last few years. The Law Commission of India has, in its 228th Report, also recommended for prohibition of commercial surrogacy by enacting a suitable legislation. Due to lack of legislation to regulate surrogacy, the practice of surrogacy has been misused by the surrogacy clinics, which leads to rampant of commercial surrogacy and unethical practices in the said area of surrogacy.

2. In the light of above, it had become necessary to enact a legislation to regulate surrogacy services in the country, to prohibit the potential exploitation of surrogate mothers and to protect the rights of children born through surrogacy.

3. The Surrogacy (Regulation) Bill, 2016, *inter alia*, provides for the following, namely:—

(*a*) to constitute the Surrogacy Boards at National and State level;

(*b*) to allow ethical altruistic surrogacy to the intending infertile Indian married couple between the age of 23-50 years and 26-55 years for female and male respectively;

(*c*) the intending couples should be legally married for at least five years and should be Indian citizens to undertake surrogacy or surrogacy procedures;

(*d*) to provide that the intending couples shall not abandon the child, born out of a surrogacy procedure, under any condition and the child born out of surrogacy procedure shall have the same rights and privileges as are available to the biological child;

(*e*) the surrogate mother should be a close relative of the intending couple and should be an ever married woman having a child of her own and between the age of 25-35 years;

(*f*) to provide that the surrogate mother shall be allowed to act as surrogate mother only once;

(*g*) to constitute the Surrogacy Board at National level which shall exercise and perform functions conferred on it under the Act. It is also proposed to constitute Surrogacy Boards at the State and Union territory level to perform similar functions in respective States and Union territories;

(*h*) to appoint one or more appropriate authorities at State and Union territory level which shall be the executive bodies for implementing the provisions of the Act;

(*i*) to provide that the surrogacy clinics shall be registered only after the appropriate authority is satisfied that such clinics are in a position to provide facilities and can maintain equipments and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be provided in the rules and regulations;

(*j*) to provide that no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall undertake commercial surrogacy, issue advertisements regarding commercial surrogacy, abandon the child born through surrogacy, exploit the surrogate mother, sell human embryo or import human embryo for the purpose of surrogacy and contravention of the said provisions shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

4. The Notes on Clauses explain in detail the various provisions contained in the Surrogacy (Regulation) Bill, 2016.

5. The Bill seeks to achieve the above objectives.

NEW DELHI;
The 28*th October*, 2016.

JAGAT PRAKASH NADDA

Notes on clauses

Clause 1.—This clause relates to Short title, Extent and Commencement of the proposed legislation.

Clause 2.—This clause contains the definitions of various expressions used in the proposed legislation.

Clause 3.—This clause relates to prohibition and regulation of surrogacy clinics.

Sub-clause (*i*) of this clause provides that no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures.

Sub-clause (*ii*) of this clause provides that no surrogacy clinic, paediatrician, gynaecologist, human embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form.

Sub-clause (*iii*) of this clause provides that no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess such qualifications as may be prescribed.

Sub-clause (*iv*) of this clause provides that no registered medical practitioner, gynecologist, pediatrician, human embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act.

Sub-clause (*v*) of this clause provides that no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, human embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(*a*) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(*b*) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(*c*) seeks or aimed at seeking a woman to act as a surrogate mother;

(*d*) states or implies that a woman is willing to become a surrogate mother; or

(*e*) advertises commercial surrogacy in print or electronic media or in any other form.

Sub-clause (*vi*) of this clause provides that no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, human embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned. However, that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971.

Sub-clause (*vii*) of this clause provides that no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, human embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy. However, that nothing contained in this sub-clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed.

Clause 4.—This clause relates to regulation of surrogacy and surrogacy procedures.

Sub-clause (*i*) of this clause provides that no place including a surrogacy clinic shall be used or caused to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in sub-clause (*ii*) and after satisfying all the conditions specified in sub-clause (*iii*).

Sub-clause (*ii*) of this clause provides that no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—(*a*) when either or both members of the couple is suffering from proven infertility; (*b*) when it is only for altruistic surrogacy purposes; (*c*) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures; (*d*) when it is not for producing children for sale, prostitution or any other form of exploitation; and (*e*) any other condition or disease as may be specified by regulations made by the Board.

Sub-clause (*iii*) of this clause provides that no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(*a*) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying for itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(*I*) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board;

(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, have been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and surrogate mother;

(*III*) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;

(*b*) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(*II*) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;

(*III*) no women shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime. However, that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed;

(*IV*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(*c*) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(*II*) the intending couple are married for at least five years and are Indian citizens;

(*III*) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier. However, that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(*IV*) such other conditions as may be specified by the regulations.

Clause 5.—This clause relates to prohibition of conducting surrogacy.

This clause provides that no person including a relative or husband of a surrogate mother or intending couple shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in sub-clause (*ii*) of clause 4.

Clause 6.—This clause relates to written informed consent of surrogate mother.

This clause provides that no person shall seek or conduct surrogacy procedures unless he has —(*i*) explained all known side effects and after effects of such procedures to the surrogate mother concerned; (*ii*) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

Clause 7.—This clause relates to prohibition to abandon child born through surrogacy.

This clause provides that the intending couple shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like. However, that any child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force.

Clause 8.—This clause relates to number of oocytes or embryos to be implanted.

This clause provides that the number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.

Clause 9.—This clause relates to prohibition of abortion.

This clause provides that no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.

Clause 10.—This clause relates to registration of surrogacy clinics.

Sub-clause (1) of this clause provides that no person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.

Sub-clause (2) of this clause provides that every application for registration under sub-clause (1) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

Sub-clause (3) of this clause provides that every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in sub-clause (ii) of clause 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration. However, that such clinic shall cease to conduct any such counseling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

Sub-clause (4) of this clause provides that no surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to

provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

Clause 11.—This clause relates to certificate of registration.

Sub-clause (1) of this clause provides that the appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act, rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.

Sub-clause (2) of this clause provides that where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

Sub-clause (3) of this clause provides that every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

Sub-clause (4) of this clause provides that the certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Clause 12.—This clause relates to cancellation or suspension of registration.

Sub-clause (1) of this clause provides that the appropriate authority may, *suo motu* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

Sub-clause (2) of this clause provides that if after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provision of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

Sub-clause (3) of this clause provides that notwithstanding anything contained in the sub-clauses (1) and (2) of clause 12, if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (1) of clause 12.

Clause 13.—This clause relates to appeal.

This clause provides that the surrogacy clinic may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under clause 12, prefer an appeal against such order to—(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State; (*b*) to the Central Government, where the appeal is against the order of the appropriate authority of a Union territory, in such manner as may be prescribed.

Clause 14.—This clause relates to constitution of National Surrogacy Board.

Sub-clause (1) of this clause provides that the Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

Sub-clause (2) of this clause provides that the Board shall consist of—(*a*) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*; (*b*) the Secretary to the Government of India in- charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*; (*c*) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members,

ex officio; (*d*) three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs not below the rank of Joint Secretary, Members, *ex officio*; (*e*) the Director General of Health Services of the Central Government, Member, *ex officio*; (*f*) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—(*i*) eminent medical geneticists or human embryologists; (*ii*) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra*; (*iii*) eminent social scientists; (*iv*) representatives of women welfare organisations; and (*v*) representatives from civil society working on womens' health and child issues, possessing of such qualifications and experience as may be prescribed; (*g*) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*; (*h*) an officer, not below the rank of a Joint Secretary to the Central Government, in charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio*.

Clause 15.—This clause relates to term of office of Members.

Sub-clause (1) of this clause provides that the term of office of a Member, other than an *ex officio* Member, shall be—(*a*) in case of nomination of three women Members of Parliament, three years. However, that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; (*b*) in case of appointment of ten expert Members, one year. However, that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

Sub-clause (2) of this clause provides that any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

Sub-clause (3) of this clause provides that the Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Clause 16.—This clause relates to meetings of Board.

Sub-clause (1) of this clause provides that the Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations. However, that the Board shall meet at least once in six months.

Sub-clause (2) of this clause provides that the Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

Sub-clause (3) of this clause provides that all questions which come up before any meeting of the Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

Sub-clause (4) of this clause provides that the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meeting of the Board.

Clause 17.—This clause relates to vacancies, etc., not to invalidate proceedings of Board.

This clause provides that no act or proceeding of the Board shall be invalid merely by reason of—(*a*) any vacancy in, or any defect in the constitution of the Board; or (*b*) any

defect in the appointment of a person acting as a Member of the Board; or (c) any irregularity in the procedure of the Board not affecting the merits of the case.

Clause 18.—This clause relates to disqualifications for appointment as Member.

Sub-clause (1) of this clause provides that a person shall be disqualified for being appointed and continued as a Member if, he—(*a*) has been adjudged as an insolvent; or (*b*) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or (*c*) has become physically or mentally incapable of acting as a Member; or (*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or (*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or (*f*) is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or (*g*) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

Sub-clause (2) of this clause provides that the Members referred to in item (*f*) of sub-clause (2) of clause 14 shall not be removed from his office except by an order of the Central Government on the ground of his proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

Sub-clause (3) of this clause provides that the Central Government may suspend any Member in respect of whom an inquiry under sub-clause (2) of clause 18 is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Clause 19.—This clause relates to temporary association of persons with Board for particular purposes.

Sub-clause (1) of this clause provides that the Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

Sub-clause (2) of this clause provides that a person associated with the Board under sub-clause (1) of clause 19 shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Clause 20.—This clause relates to authentication of orders and other instruments of Board.

This clause provides that all orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Clause 21.—This clause relates to eligibility of Member for reappointment.

This clause provides that subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for reappointment as such Member. However, that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Clause 22.—This clause relates to functions of Board.

This clause provides that the Board shall discharge the following functions, namely:—(*a*) to advise the Central Government on policy matters relating to surrogacy; (*b*) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein; (*c*) to lay down code of conduct to be observed by persons working at surrogacy clinics; to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be

employed by the surrogacy clinics; (*d*) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance; (*e*) to supervise the functioning of State Surrogacy Boards; and (*f*) such other functions as may be prescribed.

Clause 23.—This clause relates to Constitution of State Surrogacy Board.

Sub-clause (1) of this clause provides that the each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—(*i*) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them; (*ii*) to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board; (*iii*) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and (*iv*) such other functions as may be prescribed.

Clause 24.—This clause relates to composition of State Board.

This clause provides that the State Board shall consist of— (*a*) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*; (*b*) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*; (*c*) Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, Members, *ex officio*; (*d*) Director General of Health and Family Welfare of the State Government, Member, *ex officio*; (*e*) three women Members of the State Legislative Assembly or Union territory Legislative Council, Members, *ex officio*; (*f*) ten expert Members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—(*i*) eminent medical geneticists or human embryologists; (*ii*) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra*; (*iii*) eminent social scientists; (*iv*) representatives of women welfare organisations; and (*v*) representatives from civil society working on womens' health and child issues, possessing of such qualifications and experiences as may be prescribed; (*g*) an officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Clause 25.—This clause relates to term of office of Members.

Sub-clause (1) of this clause provides that the term of office of a Member, other than an *ex officio* Member, shall be—(*a*) in case of nomination of three women Members of the State Legislative Assembly or Union territory Legislative Council, Members, *ex officio*, three years. However, that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a Member of the House from which she was elected; (*b*) in case of appointment of ten expert Members, one year. However, that the person to be appointed as Member under this clause shall be of such age, as may be prescribed.

Sub-clause (2) of this clause provides that any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

Sub-clause (3) of this clause provides that the Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Clause 26.—This clause relates to meetings of State Board.

Sub-clause (1) of this clause provides that the State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations. However, that the State Board shall meet at least once in four months.

Sub-clause (2) of this clause provides that the Chairperson shall preside at the meeting of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

Sub-clause (3) of this clause provides that the all questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

Sub-clause (4) of this clause provides that the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Clause 27.—This clause relates to vacancies, etc., not to invalidate proceedings of State Board.

This clause provides that no act or proceeding of the State Board shall be invalid merely by reason of—(*a*) any vacancy in, or any defect in the constitution of the State Board; or (*b*) any defect in the appointment of a person acting as a Member of the State Board; or (*c*) any irregularity in the procedure of the State Board not affecting the merits of the case.

Clause 28.—This clause relates to disqualifications for appointment as Member.

Sub-clause (1) of this clause provides that the a person shall be disqualified for being appointed and continued as a Member if, he—(*a*) has been adjudged as an insolvent; or (*b*) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or (c) has become physically or mentally incapable of acting as a Member; or (*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or (*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or (*f*) is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or (*g*) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

Sub-clause (2) of this clause provides that the Members referred to in sub-clause (*f*) of clause 24 shall not be removed from his office except by an order of the State Government on the ground of his proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the Member ought on any such ground to be removed.

Sub-clause (3) of this clause provides that the State Government may suspend any Member in respect of whom an inquiry under sub-clause (2) of clause 28 is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Clause 29.—This clause relates to temporary association of persons with State Board for particular purposes.

Sub-clause (1) of this clause provides that the State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

Sub-clause (2) of this clause provides that a person associated with it by the State Board under sub-clause (1) of clause 29 shall have a right to take part in the discussions

relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a Member for any other purpose.

Clause 30.—This clause relates to authentication of orders and other instruments of State Board.

This clause provides that all orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Clause 31.—This clause relates to eligibility of Member for reappointment.

This clause provides that subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for reappointment as such Member. However, that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Clause 32.—This clause relates to appointment of appropriate authority.

Sub-clause (1) of this clause provides that the Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act.

Sub-clause (2) of this clause provides that the State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or part of the State for the purposes of this Act.

Sub-clause (3) of this clause provides that the appropriate authority, under sub-clause (1) or sub-clause (2) of clause 32, shall,—(*a*) when appointed for the whole of the State or the Union territory, consist of— (*i*) an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson; (*ii*) an eminent woman representing womens' organisation—Member; and (*iii*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—Member; (*iv*) an eminent registered medical practitioner — Member. However, that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy; (*b*) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Clause 33.—This clause relates to functions of appropriate authority.

This clause provides that the appropriate authority shall discharge the following functions, namely:—(*a*) to grant, suspend or cancel registration of a surrogacy clinic; (*b*) to enforce the standards to be fulfilled by the surrogacy clinics; (*c*) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act; (*d*) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter; (*e*) to supervise the implementation of the provisions of this Act, rules and regulations made thereunder; (*f*) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions; (*g*) to take action after investigation of complaints received by it against the surrogacy clinics; and (*h*) to consider and grant or reject any application under the provisions of this Act.

Clause 34.—This clause relates to powers of appropriate authorities.

Sub-clause (1) of this clause provides that the appropriate authority shall exercise the powers in respect of the following matters, namely:—(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, rules and regulations made thereunder; (*b*) production of any document or material object relating to

sub-clause (*a*); (*c*) search any place suspected to be violating the provisions of this Act, rules and regulations made thereunder; and (*d*) such other powers as may be prescribed.

Sub-clause (2) of this clause provides that the appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of licence, etc., of the surrogacy clinics in such format as may be prescribed.

Clause 35.—This clause relates to prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

Sub-clause (1) of this clause provides that the no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—(*a*) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place; (*b*) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise; (*c*) abandon or disown or exploit or cause to be abandoned, exploited or disowned in any form the child or children born through surrogacy; (*d*) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever; (*e*) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy; (*f*) import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures.

Sub-clause (2) of this clause provides that the notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of sub-clause (1) of clause 35 by any person shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

Sub-clause (3) of this clause provides that the for the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Clause 36.—This clause relates to punishment for contravention of provisions of Act.

Sub-clause (1) of this clause provides that the any registered medical practitioner, gynaecologists, pediatrician, human embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in clause 35), rules and regulations made thereunder shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to ten lakh rupees.

Sub-clause (2) of this clause provides that the in case of subsequent or continuation of the offence referred to in sub-clause (1) of clause 36, the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Clause 37.—This clause relates to punishment for initiation of commercial surrogacy.

This clause provides that any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynecologist, pediatrician, human embryologist or any other person for commercial surrogacy or for conducting

surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Clause 38.—This clause relates to penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

This clause provides that whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which shall not be less than three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Clause 39.—This clause relates to presumption in the case of surrogacy.

This clause provides that notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in sub-clause (*ii*) of clause 4 and such person shall be liable for abetment of such offence under clause 37 and shall be punishable for the offence specified under that clause.

Clause 40.—This clause relates to offence to be cognizable, non-bailable and non-compoundable.

This clause provides that notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable.

Clause 41.—This clause relates to cognizance of offences.

Sub-clause (1) of this clause provides that the no court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—(*a*) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or (*b*) a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

Sub-clause (2) of this clause provides that the no court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Clause 42.—This clause relates to certain provisions of the Code of Criminal Procedure, 1973 not to apply.

This clause provides that notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea of bargaining shall not apply to the offences under this Act.

Clause 43.—This clause relates to maintenance of records.

Sub-clause (1) of this clause provides that the surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed: However, that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

Sub-clause (2) of this clause provides that all such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Clause 44.—This clause relates to power to search and seize records, etc.

Sub-clause (1) of this clause provides that if the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

Sub-clause (2) of this clause provides that the provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act.

Clause 45.—This clause relates to protection of action taken in good faith.

Sub-clause (1) of this clause provides that no suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provision of this Act.

Clause 46.—This clause relates to application of other laws not barred.

This clause provides that the provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Clause 47.—This clause relates to power to make rules.

This clause provides that the Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

Clause 48.—This clause relates to power to make regulations.

This clause provides that the Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder.

Clause 49.—This clause provides that every rule, regulation and notification made under the proposed legislation shall be laid, as soon as may be after it is made, before the House of Parliament.

Clause 50.—This clause relates to transitional provision.

This clause provides that subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Clause 51.—This clause relates to power to remove difficulties.

Sub-clause (1) of this clause provides that the if any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty. However, that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

Sub-clause (2) of this clause provides that the every order made under this clause shall be laid, as soon as may be after it is made, before each House of Parliament.

FINANCIAL MEMORANDUM

Clause (4) of section 16 and section 26 of the Surrogacy (Regulation) Bill, 2016 provides that for meetings of the National Surrogacy Board and State Surrogacy Board, the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of such Boards. There will not be any financial implications except for the meetings of the National, State Surrogacy Boards and appropriate authorities which will be met out of the regular budget of the Central Government and State Governments.

2. The Bill does not involve any other expenditure of recurring or non-recurring nature from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 47 of the Bill seeks to empower the Central Government, by notification and subject to the condition of pre-publication, to make rules for carrying out the provisions of this Act. In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—(*a*) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3; (*b*) the manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3; (*c*) the insurance coverage in favour of the surrogate mother from an insurance company under item (*III*) of sub-clause (*a*) of clause (*iii*) of section 4; (*d*) the number of attempts of surrogacy or providing of gametes under the proviso to item (*III*) of sub-clause (*b*) of clause (*iii*) of section 4; (*e*) the form in which consent of a surrogate mother has to be obtained under clause (*ii*) of section 6; (*f*) the number of oocytes or embryos to be implanted in the surrogate mother under section 8; (*g*) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 9; (*h*) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (2) of section 10; (*i*) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (*4*) of section 10; (*j*) the, manner and form in which a certificate of registration shall be issued under sub-section (*1*) of section 11; (*k*) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (*3*) of section 11; (*l*) the manner in which an appeal may be preferred under section 13; (*m*) the qualifications and experiences to the Members as admissible under clause (*f*) of sub-section (*2*) of section 14; (*n*) the procedures for conducting an inquiry against the Members under sub-section (*2*) of section 18; (*o*) the terms and conditions under which a Member of the Board eligible for re-appointment under section 21; (*p*) the other functions of the Board under clause (*f*) of section 22; (*q*) the reports to be sent by the State and Union territory Boards to the Board and the Central Government under clause (iii) of section 23; (*r*) the other functions of the State Board under clause (iv) of section 23; (*s*) the qualifications and experiences to the members and the manner of their appointment under clause (*f*) of section 24; (*t*) the age of the person to be appointed as a member, referred to in clause (*f*) of section 24, under the proviso to clause (*b*) of sub-section (*1*) of section 25; (u) the procedures for conducting an inquiry against the members under sub-section (*2*) of section 28; (*v*) the conditions under which the members of State Board eligible for re-appointment under section 31; (*w*) appropriate legal action by appropriate authority under clause (*d*) of section 33; (*x*) the other powers of appropriate authority under clause (*d*) of sub-section (*1*) of section 34; (*y*) the particulars of the details of registration of surrogacy clinics, cancellation of registration etc. in such format under sub-section (*2*) of section 34; (*z*) the manner of giving notice by a person under clause (*b*) of sub-section (*1*) of section 41; (*za*) the period up to which records, charts, etc., shall be preserved under sub-section (*1*) of section 43; (*zb*) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (*1*) of section 44; and (*zc*) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

2. *Clause* 48 of the Bill empowers the Board, with the prior approval of the Central Government, by notification, to make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—(*a*) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under Item (IV) sub-clause (*c*) of clause (*iii*) of section 4; (*b*) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 16; (*c*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 19; (*d*) the time and place of the meetings of the State Board and the procedure

to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (*1*) of section 26; (*e*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 29; and (*f*) any other matter which is required to be, or may be, specified by regulations.

3. The matters in respect of which the said rules and regulations may be made are matters of procedure and administrative detail, and as such, it is not practicable to provide for them in the proposed Bill itself. The delegation of legislative power is, therefore, of a normal character.

LOK SABHA

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

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(Shri Jagat Prakash Nadda, Minister of Health and Family Welfare)

GMGIPMRND—3014LS(S3)—11-11-2016.

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REPORT NO.
102

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

ONE HUNDRED SECOND REPORT

The Surrogacy (Regulation) Bill, 2016

(Presented to the Rajya Sabha on 10th August, 2017)
(Laid on the Table Lok Sabha on 10th August, 2017)

Rajya Sabha Secretariat, New Delhi
August, 2017/ Shravana, 1939 (Saka)

Hindi version of this publication is also available

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COMPOSITION OF THE COMMITTEE

(2016-17)

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Shri Rajkumar Dhoot
4. Dr. R. Lakshmanan
5. Dr. Vikas Mahatme
6. Shri Jairam Ramesh
7. Shri Ashok Siddharth
8. Shri Gopal Narayan Singh
9. Shri K. Somaprasad
10. Dr. C. P. Thakur

LOK SABHA

11. Shri Thangso Baite
[$]12. Shrimati Ranjanaben Bhatt
[%]13. Shri Gyan Singh
14. Shri Nandkumar Singh Chauhan
*15. Dr. Ratna De (Nag)
[^]16. Shri Dasrath Tirkey
17. Dr. (Smt.) Heena Vijay Gavit
18. Dr. Sanjay Jaiswal
19. Dr. K. Kamaraj
20. Shri Arjunlal Meena
21. Shri Anoop Mishra
22. Shri J. Jayasingh Thiyagaraj Natterjee
23. Shri Chirag Paswan

[$] ceased to be member of the Committee w.e.f 20th October, 2016
[%] nominated as a member of the Committee w.e.f. 02nd January, 2017
* ceased to be member of the Committee w.e.f 02nd January, 2017
[^] nominated as a member of the Committee w.e.f. 02nd January, 2017

24. Shri C. R. Patil
25. Shri M.K. Raghavan
26. Dr. Manoj Rajoria
27. Dr. Shrikant Eknath Shinde
28. Shri R.K. Singh (Arrah)
29. Shri Bharat Singh
30. Shri Kanwar Singh Tanwar
31. Shrimati Rita Tarai
32. Shri Manohar Untwal

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shri J. Sundriyal, *Joint Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Director*

Shri Dinesh Singh, *Additional Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

INTRODUCTION

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this One Hundred Second Report of the Committee on the Surrogacy (Regulation) Bill, 2016*.

2. In pursuance of Rule 270 of the Rules of Procedure and Conduct of Business in the Council of States relating to the Department-related Parliamentary Standing Committees, the Chairman, Rajya Sabha, referred** the Surrogacy (Regulation) Bill, 2016 (Annexure I) on the 12th January, 2017 as introduced in the Lok Sabha on the 21st November, 2016 for examination and report by 11 April, 2017. Subsequently, Hon'ble Chairman granted extension of time for presentation of Report on the Bill upto 11th July, 2017 and again till 11th September, 2017.

3. The Committee issued a Press Release inviting memoranda/views from individuals and other stakeholders. In response thereto, a number of Memoranda from individuals/organisations were received.

4. The Committee held ten sittings during the course of examination of the Bill, *i.e.*, on 2nd, 3rd, 17th and 30th March, 27th and 28th April, 24th and 25th May, 4th July and 8th August, 2017. The list of witnesses heard by the Committee is at Annexure-II.

5. The Committee considered the draft Report and adopted the same on 8th August, 2017.

6. The Committee has relied on the following documents in finalizing the Report:

(i) The Surrogacy (Regulation) Bill, 2016;

(ii) Background Note on the Bill received from the Department of Health Research;

(iii) Presentation, clarifications and Oral evidence of Secretary, Department of Health Research;

(iv) Memoranda received on the Bill from various institutes/bodies/associations/organizations/ experts and replies of the Ministry on the memoranda selected by the Committee for examination.

(v) Oral evidence and written submissions by various stakeholders/experts on the Bill; and

(vi) Replies received from the Department of Health Research to the questions/queries raised by Members during the meetings on the Bill.

7. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who deposed before the Committee and also those who gave their valuable suggestions to the Committee through their written submissions.

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* Published in Gazette of India Extraordinary Part II Section 2, dated 21st November, 2016.
** Rajya Sabha Parliamentary Bulletin Part II, No. 56225, dated 13th January, 2017.

8. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI;
8 *August*, 2017
Shravana, 17, 1939 *(Saka)*

PROF. RAM GOPAL YADAV,
Chairman,
Department-related Parliamentary Standing Committee on Family Welfare,
Rajya Sabha.

ACORNYMS

ART	:	Artificial Reproduction Technology
BVSc	:	Bachelor of Veterinary Sciences
CARA	:	Central Adoption Resource Authority
CPV	:	Consular, Passport and Visa
DNA	:	Deoxyribonucleic Acid
ET	:	Embryo Transfer
FOGSI	:	Federation of Obstetric and Gynaecological Societies of India
FRO	:	Foreigner's Registration Officers
HC	:	High Court
ICMR	:	Indian Council of Medical Research
INSTAR	:	Indian Society of Third Party Assisted Reproduction
IRDA	:	Insurance Regulatory and Development Authority
ISAR	:	Indian Society for Assisted Reproduction
IVF	:	In-vitro Fertilization
MCI	:	Medical Council of India
NCW	:	National Commission for Women
NGOs	:	Non-Government Organizations
NOC	:	No Objection Certificate
NRIs	:	Non-Resident Indian
OCI	:	Overseas Citizen of India
PGD	:	Pre-Genetic Diagnosis
PIO	:	Persons of Indian Origin
TB	:	Tuberculosis
UK	:	United Kingdom
WHO	:	World Health Organization

REPORT

I. BRIEF BACKGROUND

1.1 India is called the ‘ world capital of surrogacy’ . Surrogacy generates 2 billion dollars annually in India. Despite India being a hub of surrogacy, there are no laws to regulate it. However, commercial surrogacy has been held legal in India as witnessed in the case of Baby Manaji *Vs.* Union of India with the Supreme Court judgment. Similarly, in the case of Jan Balaz *vs.* Anand Municipality, the Gujarat High Court reiterated the apex court judgment legalizing commercial surrogacy in India and further elucidated that commercial surrogacy was held legal in India as there was no law prohibiting womb lending or surrogacy agreements. Both these judgments directed for the enactment of law on surrogacy in India. Consequent to this, the ICMR drafted the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India in 2005 as the first ever national guidelines for laying down standards of conduct for surrogacy in India. Later, the draft ART Bill was formulated in 2008, reviewed and redrafted in 2010 and 2014 but was never passed as law.

1.2 The Law Commission *suo-motu* took up the subject of the need for legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parties to a surrogacy. The Commission presented its 228th Report in 2009 which stated that the growth in the ART methods was recognition of the fact that the infertility as a medical condition is a huge impediment in the overall well-being of couples. Further, the Commission recognized the fact that India had become a favorable destination for foreign couples who look for a cost effective treatment of infertility leading to a flourishing medical tourism due to cheap surrogacy services in the country.

1.3 The Law Commission, however, recommended for legalizing altruistic surrogacy and to ban commercial surrogacy. It recommended measures for better protection of rights of surrogate mother, securing full informed consent from surrogate mother, insurance cover, life insurance cover, right to abortion or medical termination of surrogate pregnancy, right to privacy and other health safeguards. The Commission also recommended for financial support for surrogate child, legitimacy, parentage right to registration of birth certificate of the surrogate child among others. It further recognized the fact that the legal issues related with surrogacy were very complex and needed to be addressed by a comprehensive legislation.

1.4 The Ministry of Home Affairs has attempted to control the misuse of surrogacy services by foreign nationals through their Guidelines introduced in July, 2012. These guidelines imposed certain restrictions by redefining the eligibility criteria exclusively for the foreign couples commissioning surrogacy in India which intended to prohibit foreigners, homosexuals, and singles from commissioning surrogacy in India and permit only such heterosexual married couples with a marriage subsisting for two years or more to commission surrogacy in India. Medical visa for commissioning of surrogacy in India was stopped through the Notification No. 2502/74/2011-F-1 dated 9th July, 2012. The Punjab HC upheld the Home Ministry guidelines as a binding law.

1.5 Restrictions on surrogacy were also provided in the Ministry of Commerce, Notification No. 25/ 2015-2020 dated 26th October, 2015 prohibiting the import of human embryo except for the purpose

of research. Another Notification (No. 25022/74/2011-F-1) dated 3rd November, 2015 of the Ministry of Home Affairs prohibited foreign nationals, PIO and OCI card holders from commissioning surrogacy in India. The Department of Health Research notification (No. 250211/119/2015-HR) dated 4th November, 2015 validated the notification of the Home Ministry banning commercial surrogacy in India. State Governments were accordingly advised in this matter.

1.6 On a specific query about the number of IVF/ART Clinics in the country, the Department of Health Research apprised the Committee that 1035 clinics are registered with ICMR. However, the actual number of such clinics is likely to be more. 468 IVF/ART Clinics are not registered with ICMR. As per unconfirmed reports, the number of surrogacy births in the country in the last three years is approximately 2000. The Department also submitted that only 11 complaints of surrogacy clinics have been reported so far. However, a number of court cases relating to surrogacy can be seen in the list attached in **Annexure III.**

1.7 The developments narrated in the preceding paras laid the justifiable grounds for bringing forth a legislation to regulate surrogacy with a view to safeguard the interests of both surrogate mother and child and to put a check on the ART clinics running in the country.

II. THE SURROGACY (REGULATION) BILL, 2016- AN INTRODUCTION

2.1 The Surrogacy (Regulation) Bill, 2016 was introduced in Lok Sabha on 21st November, 2016 (hereinafter referred to as the Bill) and referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare by the Chairman, Rajya Sabha in consultation with the Speaker, Lok Sabha on the 12th January, 2017 for examination and report.

2.2 The Statement of Objects and Reasons to the Bill reads as follows:

> "India has emerged as a surrogacy hub for couples from different countries for past few years. There have been reported incidents of unethical practices, exploitation of surrogate mothers, abandonment of children born out of surrogacy and import of human embryos and gametes. Widespread condemnation of commercial surrogacy in India has been regularly reflected in different print and electronic media for last few years. The Law Commission of India has, in its 228th Report, also recommended for prohibition of commercial surrogacy by enacting a suitable legislation. Due to lack of legislation to regulate surrogacy, the practice of surrogacy has been misused by the surrogacy clinics, which leads to rampant commercial surrogacy and unethical practices in the said area of surrogacy. In the light of above, it had become necessary to enact a legislation to regulate surrogacy services in the country, to prohibit the potential exploitation of surrogate mothers and to protect the rights of children born through surrogacy."

2.3 As per information provided by the Department of Health Research, the major objectives of the Bill are:

(i) to regulate surrogacy services in the country;

(ii) to provide altruistic ethical surrogacy to the needy infertile Indian couples;

(iii) to prohibit commercial surrogacy including sale and purchase of human embryo and gametes;

(iv) to prevent commercialization of surrogacy;

(v) to prohibit potential exploitation of surrogate mothers and protect the rights of children born through surrogacy.

2.4 The Surrogacy (Regulation) Bill, 2016 proposes to regulate surrogacy in India by establishing National Surrogacy Board at Central Level, State Surrogacy Boards and Appropriate Authority in States and Union Territories. In a nutshell, the proposed legislation ensures effective regulation of surrogacy, prohibit commercial surrogacy and allow ethical surrogacy to the needy infertile Indian couples.

2.5 According to the Department of Health Research, surrogacy has been in practice in India for last few decades. However, there is no legislation to regulate it. This has resulted in malpractices ranging from commercialization of surrogacy, trade in human embryos, exploitation of surrogate mothers and abandonment of children born through surrogacy. The issue of surrogacy including the exploitation of surrogate mothers and need for regulation in surrogacy has been raised time and again in the Parliament since 2010. As on date, there are 11 such Parliament Assurances pending on the matter. The Law Commission of India has strongly recommended for prohibiting commercial surrogacy. Hon' ble Supreme Court has been intimated of the commitment of the Government to bring the legislation in this regard. As per the Affidavit filed in the Hon' ble Supreme Court of India, the Government intends to ban commercial surrogacy through a proper legislation.

2.6 As per the background note received from the Department of Health Research, the proposed Bill appears to have been conceived on the basis of following parameters laid to achieve the following objectives:-

- The Bill proposes to allow altruistic ethical surrogacy to intending infertile Indian married couple between the age of 23-50 years and 26-55 years for female and male respectively.
- The couples should be legally married for at least five years and should be Indian citizens.
- The couples should not have any surviving child biologically or through adoption or through surrogacy earlier except when they have a child and who is mentally or physically challenged or suffer from life threatening disorder with no permanent cure.
- The couples shall not abandon the child, born out of a surrogacy procedure under any condition.
- The child born through surrogacy will have the same rights as are available for the biological child.
- The surrogate mother should be a close relative of the intending couple and should be between the age of 25-35 years. She will carry a child which is genetically related to the intending couple and can act as surrogate mother only once.
- An order concerning the parentage and custody of the child to be born through surrogacy, is to be passed by a court of the Magistrate of the first class.
- An insurance coverage of reasonable and adequate amount shall be ensured in favour of the surrogate mother.

- The Bill provides for setting up of a National Surrogacy Board and State Surrogacy Boards which shall exercise the powers and shall perform functions conferred on the Board under this Act. The National Surrogacy Board shall consist of the Minister in-charge of the Ministry of Health and Family Welfare, as the Chairperson, Secretary to the Government of India in- charge of the Department dealing with the surrogacy matter, as Vice-Chairperson and three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of State as Members. The total number of members of National Surrogacy Board will be 24.
- The National Surrogacy Board and State Surrogacy Board shall be the policy making bodies and Appropriate Authority will be the implementation body for the Act. The total number of members of State Surrogacy board will be 24.
- The Appropriate Authority shall comprise of an officer of or above the rank of the Joint Director of Health and Family Welfare Department, as Chairperson and an eminent woman representing women' s organization, an officer of Law Department of the State or the Union Territory concerned not below the rank of a Deputy Secretary, and an eminent registered medical practitioner, as members.
- No person, organization, surrogacy clinic, laboratory or clinical establishment of any kind shall undertake commercial surrogacy, abandon the child born out of surrogacy, exploit the surrogate mother, sell human embryo or import embryo for the purpose of surrogacy. Violation to the said provision shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.
- The surrogacy clinics shall have to maintain all records for a period of 25 years.
- There will be Transitional provision under this Act providing a gestation period of ten months from the date of coming into force of this Act to protect the wellbeing of already existing surrogate mothers.

III. EXAMINATION OF THE BILL BY THE COMMITTEE

3.1 Keeping in view the objectives envisaged in the proposed legislation and their impact on the people, the Committee decided to elicit the views of various stakeholders and the general public on the Bill through a Press Release inviting suggestions/views from all concerned people. A good response to the Press Release from various organizations, stakeholders, individuals, associations was received by the Committee. The Committee also held extensive interactions with representatives of Associations/ Organizations/Councils/Institutes as well as renowned experts and professionals from the assisted reproductive industry and the benefactors. These included representatives from Ministry of Women and Child Development; Ministry of Home Affairs; Ministry of External Affairs; National Commission for Women; Federation of Obstetric and Gynaecological Societies of India (FOGSI), Indian Society of Assisted Reproduction (ISAR) and Indian Society of Third Party Assisted Reproduction (INSTAR). The Committee also interacted with professionals namely Ms. Sonali Kusum, Member, International Surrogacy Forum, Ms. Pinki Virani, Journalist and Human Rights Activist and Dr. Kamini Rao, Member, National

Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology. The Committee also got benefit of the views of Smt. Jayshree Wad, Supreme Court Lawyer, Shri Anurag Chawla, Advocate, Surrogacy Laws India, Ms. Petal Chandok, Advocate, Trust Legal, Advocates and Consultants, Ms. Aprajita Amar, Student, Amity Law School, surrogate mothers, a commissioning parent and Dr. Mrinal Satish, Associate Professor of Law, National Law University, Delhi.

IV. VIEWS OF STAKEHOLDERS/EXPERTS

Several important issues were deliberated extensively during interactions with the experts/ stakeholders which are mentioned briefly hereunder:

MINISTRY OF WOMEN AND CHILD DEVELOPMENT

4.1 During their deposition before the Committee, Shri Chetan B. Sanghi, Joint Secretary, Ministry of Women and Child Development informed the Committee that though the Ministry of Health and Family Welfare consulted them on ‘ Assisted Reproductive Technology’ Bill, 2014, no specific consultation took place on the ‘ Surrogacy (Regulation)’ Bill, 2016 per se. Their views and comments on the ART Bill have, however, been incorporated in the Surrogacy Bill. He *inter-alia* suggested that option of surrogacy should be made available to every lawfully married infertile couple and also to every Indian woman whether married or single including not married; separated; widowed irrespective of their ability to bear the child. According to him, surrogacy should be allowed only after strict screening of intending parents as done in the case of adoption procedure and a provision of mandatory counseling of intending couple should be made wherein an option of adoption should also be explored. As regards the ban on foreigners, he was of the view that all countries that do not allow full citizenship rights to children born out of surrogacy should be barred from availing the benefit of the Act. In context of the eligibility criteria for the surrogates, it was pointed out that relatives and friends of intending couple should not serve as surrogates as it may lead to conflict of interest in the future. He advocated for a system wherein surrogates are empanelled by the States and should have an option to withdraw their names if they choose to do so at any point of time after enrolment, before the commencement of the procedure. It was also suggested that a psychological counseling for such women must be provided before she gives consent for willingness to become a surrogate. A surrogate mother, if declared medically fit, should be provided the option of being surrogate twice in her lifetime with 3 years of interval period between two pregnancies. Reacting to a query on the nature of surrogacy, he clarified that a total ban on commercial surrogacy might lead to opening of unregulated market for this kind of service which in turn may adversely affect women offering services as surrogates. He suggested for a comprehensive legally binding agreement between the intending parent(s) and the surrogate mother providing for monetary compensation, its pre and post delivery disbursement and the follow up care for surrogates. Considering the health risk that surrogacy entails, a comprehensive health care should be made an integral part of the agreement providing coverage to surrogates for a period of 5 years starting from the date she undergoes the surrogacy procedure. In case of any health complications/ risks and death, provision of compensation to surrogate and her family should also be incorporated. Six months of breast feeding should be provided to the child or facilities of Breast Milk Banks may be utilized for the purpose.

NATIONAL COMMISSION FOR WOMEN (NCW)

4.2 During her deposition, Smt. Lalitha Kumaramagalam, Chairperson, National Commission for Women supported the Bill as it prohibits commercial surrogacy in the backdrop of exploitation of surrogate mother belonging to the poor strata of society. She was of the view that providing education, skill development training, and jobs to such poor women would empower them more instead of allowing them to rent out their wombs for money. She also suggested that the Bill should encourage adoption at first instance. She further cited that surrogate mother should be considered as skilled employee and not just as a womb on rent and a fair wage should be paid compulsorily along with a wide insurance coverage. In addition, provision of psychological counseling, post delivery care and related expenses preferably till three months after delivery should also be provided. She suggested that the object of the Bill needs to clearly mention that infertility is a medical condition and not a stigma.

MINISTRY OF HOME AFFAIRS

4.3 Shri Mukesh Mittal, Joint Secretary, Ministry of Home Affairs apprised the Committee that earlier foreigners coming to India to commission surrogacy were given tourist visa. Later in the year 2012, it was decided to give medical visa for the surrogacy purpose. After discussion with Ministry of Health and Family Welfare and Ministry of External Affairs, it was decided that no visa should be issued by Indian missions to foreign nationals intending to visit India for commissioning surrogacy. Also, no permission should be granted by the Foreigners Regional Registration Offices and FROs to Overseas Citizen of India cardholders to commission surrogacy in Indian and no exit permit to the child who is born of surrogacy would be issued.

MINISTRY OF EXTERNAL AFFAIRS

4.4 Shri Upender Singh Rawat, Joint Secretary (CPV), Ministry of External Affairs informed the Committee that foreigners had come to India for surrogacy in the past and to deal with the problems associated with it, the visa rules were changed during the year 2012. The mission posts abroad were also instructed to follow the revised instructions. Shri Rawat also clarified that Overseas Citizenship of India cardholders are foreigners and therefore, they are kept out of the purview of the Bill.

FEDERATION OF OBSTETRIC AND GYNECOLOGICAL SOCIETIES OF INDIA (FOGSI)

4.5 Dr. Rishma Pai, President, FOGSI informed the Committee that India is witnessing a high burden of infertility, with an estimated 22 to 33 million couples in the reproductive age suffering from infertility. It is well established that surrogacy cycles constitute approximately 1% of the total number of IVF Cycles. If 100000 cycles are the projected number of IVF cycles per year in India- the approximate number of surrogacy cycles in India is around 1000 per year. At a pregnancy rate of 40%, this would result in 400 pregnancies per year. At a take home baby rate of 32%, this would result in 320 babies being born from surrogacy a year. According to her, the Bill is biased and unfair to the surrogacy procedure, its benefits, its seekers, its providers and the women who become surrogates. She suggested that the Bill should be made more equitable and effective by providing a single window system for registration and reporting of surrogacy procedures. She wanted a provision of compensation towards expenses for medically indicated surrogacy.

INDIAN SOCIETY OF THIRD PARTY ASSISTED REPRODUCTION (INSTAR)

4.6 Dr. Rita Bakshi, Vice-President, INSTAR drew the Committee's attention to the concept of altruistic surrogacy and suggested that there should be some kind of minimum as well as maximum capping on compensation amount to be paid to a surrogate mother. She was of the view that focus should also be on rights of intending parents along with the rights of surrogates. She objected to some Clauses of the Bill relating to the ' close relative' and the surrogate being genetically related to the intending couple. She was in favour of allowing gestational surrogacy only. She pointed out that foreigners, OCI and PIO cardholders should be allowed to avail surrogacy. To her, the five years duration before commissioning surrogacy was irrational. Provision of life insurance for surrogate mother and her medical insurance for one year post-delivery was underlined. She expressed that a national registry of surrogate mother is a must to curb their exploitation.

4.7 Smt. Jayshree Wad, Supreme Court Lawyer, suggested that a provision of surrogacy agreement should be added in the Bill to have a binding effect on intending couple to take the delivery of the child born out of surrogacy irrespective of any abnormalities. Such agreement would also act as proof of willingness of surrogate mother for the procedure. She also suggested that the word ' legal' should be added before ' parents' to have a binding effect on the intending couple. She further highlighted changes required in the definitions of ' surrogate mother' and ' surrogacy' . She mentioned that the Bill is silent with regard to live-in relationship, same sex marriages, single parents (divorcee/ widow/ unmarried). She suggested a provision for depositing the amount in the Court which will take care of the required expenses of the surrogate regarding her health problem during pregnancy period.

4.8 Ms. Sonali Kusum, Member, International Surrogacy Forum was of the view that there should be a right based perspective in the Preamble of the Bill itself to ensure the protection of the best interest of the child born through surrogacy, reproductive health interest of the surrogate mothers and the intending mother. She advocated a scheme of compensation for surrogacy arrangement which should include reasonable expenses and the whole procedure should have a legal documentation in form of surrogacy agreement. The compensation should be fixed by the Government appointed committee instead of being a matter of bargain. She also suggested that a minimum and a maximum limit should be fixed in the compensated surrogacy. She pointed out that the Bill was silent on issues of birth certificate of the child born out of surrogacy, control of sex-selective surrogacy, trafficking, exploitation, inter country movement of the surrogate mother and child's right to be breastfed. In her opinion, the Bill fails to address the twibling cases wherein two surrogates are being hired by same couple, provision of local guardian appointed for child's social security, insurance for child and protection of privacy of the stakeholders of surrogacy arrangement. She suggested that instead of five years, a minimum period of one year should be specified to determine infertility. She was of the view that the issue of close relative, genetic connection of the surrogate mother, gamete donation, the quantum of punishment for violation of surrogacy laws etc. are provided appropriately in draft ART (Regulation) Bill, 2014 in comparison to the proposed Surrogacy Bill.

4.9 Ms. Pinki Virani, Journalist and Human Rights Activist informed that India is being constantly referred to as commercial surrogacy capital of the world which amounted to commodification of women

and children. She suggested that the Surrogacy Board should be entrusted with the authority to approve and evaluate surrogacy contracts in detail from home visits of intending couple to psychological evaluation of stakeholders within a legal framework. She further suggested that an insurance coverage for surrogate mother should be for six years duration for all purposes. She also expressed her views on issues such as exploitation of surrogate mothers, five year waiting period, donation of eggs, switching of embryos, pre-condition of close relative to be surrogate mother, etc.

4.10 Dr. Kamini Rao, Member, National Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology pointed out that none of the members of the drafting Committee (ART Bill) of the Government of India were invited for the drafting of the Surrogacy (Regulation) Bill. She was of the view that surrogacy cannot be done without ART procedures and therefore, the proposed Bill should not be passed in isolation. On the issue of a period of five years for declaring a couple as infertile, she submitted that the fundamental right to reproduce must be that of the couple. She was also not in favour of the Clause of the Bill limiting surrogacy to close relatives. As regards the safeguards to protect the interest of surrogate mother in the Bill, she referred to the provisions under ART Bill and suggested that regulation is the answer to all commercialization of these procedures. She, however, also favoured commercial surrogacy but within a legal structure and regulatory purview. She opined that unlike organ donation, surrogacy is a kind of service for which consideration should be given. She also suggested for a National Registry to keep a record of surrogate women which can be linked to their Aadhar Cards to record details of number of times they have provided such services.

4.11 Shri Anurag Chawla, Advocate, Surrogacy Laws India submitted that the Bill was restricted to Indian married couples only whereas the ambit of the Bill should be extended to foreigners to enable them to avail services of medical tourism in India. He felt that since the appropriate authorities are formed to scrutinize every applicant, the application to commission surrogacy would be rejected if any angle of commercialization or exploitation is found. He further submitted that the Bill is silent on the definition of ‘ donor’ who is also an essential party in the whole process.

4.12 Ms. Petal Chandok, Advocate, Trust Legal Advocates and Consultants, during her deposition highlighted certain aspects in the Bill relating to close relative, allowance of altruistic surrogacy arrangement and ban on commercial surrogacy that are violative of the rights of the surrogates, the rights of the couple and the rights of the child. She was of the view that although surrogate mothers and child are being exploited in the country, a complete ban on commercial surrogacy would lead to black market of this industry.

4.13 Ms. Aprajita Amar, Student, Amity Law School suggested that there should be provision of home study of intending couple in line with Central Adoption Resource Authority (CARA) guidelines, breastfeeding for the child and its awareness to ensure child rights. She also underlined the inclusion of provision for psychological counseling of surrogate mother’s first child to ensure his/her mental health and supported compensated surrogacy instead of altruistic or commercial surrogacy.

4.14 The Committee also heard the views of surrogate mothers and a parent who had commissioned surrogacy. The women who became surrogates informed the Committee that the reason they went ahead for surrogacy was the need of money as they were from economically weaker sections of the society.

From the money they earned out of surrogacy, they were able to send their children to better schools, provide them with good food and better standard of living. They also informed the Committee that there was an agency who contacted them and there was a surrogate home which took care of their delivery, nutritional and medical needs during the entire pregnancy period. They further informed the Committee that they willfully signed the contract with the consent of their families and were informed about the contract beforehand. They suggested that the surrogacy should be allowed only for needy couples and not for completion of an ideal family. For them, it was an honest means to earn and commercial surrogacy should not be banned rather they suggested that amount to be paid to them should be raised and a second chance to become surrogate should be given.

4.15 A commissioning parent submitted before the Committee that altruistic surrogacy does not exist in today's world. With reference to his personal experience, he shared the financial break-up of a successful surrogacy arrangement that amounted to ₹ 20 lakh. He was of the view that Government should not determine the method of procreation for an individual and number of children for an infertile couple. He also drew Committee's attention towards the fact that eggs of female celebrities were available at a price depending upon the socio-economic background of the lady in question.

4.16 Dr. Mrinal Satish, Associate Professor and Executive Director, Centre for Constitutional Law, Policy and Governance, National Law University, Delhi submitted that as of now there is no binding legal framework for the regulation of surrogacy in India and the ICMR Guidelines of 2005 governing surrogacy are not binding on any of the parties. There are no safeguards for the surrogate mothers and the contracts signed between the surrogate mother and the commissioning couples do not mention the risks associated with surrogacy. Prof. Satish suggested that compensated surrogacy should be permitted under stringent regulatory regime. He also suggested that the surrogates should be given guaranteed payment from the day they begin use of any medication and there should be limits on the number of embryos implanted. He underlined the need of a regulatory body for monitoring compliance with the provisions of this Act, banning of surrogate homes, etc.

V. CLAUSE BY CLAUSE EXAMINATION OF THE BILL

5.1 During the course of the examination of the Bill, the Committee took note of concerns, suggestions and amendments expressed by various experts/stakeholders on the Bill and duly communicated them to the Department of Health Research for its response. Committee's observations and recommendations contained in the Report reflect an extensive scrutiny of submissions and all the viewpoints put forth before it. Upon scrutiny of the replies received from the Ministry, the Committee is of the view that certain provisions of the Bill need to be recast to serve the intended purpose of the Bill better. Various amendments to the Bill have been suggested by the Committee which are discussed in the succeeding paragraphs.

Clause 2(a)-Definition of 'Abandoned Child'

5.2 Clause 2 (a) reads as under:

'In this Act, unless the context otherwise requires,—

(a) "abandoned child" means a child—

(i) born out of surrogacy procedure;

(ii) deserted by his intending parents or guardians; and

(iii) who has been declared as abandoned by the appropriate authority after due enquiry;'

Suggestions

5.3 Some stakeholders have sought to modify the definition of ' abandoned child' in the proposed Bill. They suggested that the explanation for the term ' abandoned child' should be given in one sentence as the three points mentioned in Clause 2 (a) (i),(ii)&(iii) are not mutually exclusive and have to be read together.

Department's Response

5.4 The Ministry while justifying the Clause has stated that the definition of the ' abandoned child' has been drafted in consultation with Ministry of law.

Recommendation

5.5 **The Committee is of the view that since the proposed Bill is an attempt to regulate the practice of surrogacy and protect the interest of the surrogate mother and child, it is essential to define the term 'abandoned child' appropriately. Protection of the interests and rights of the child born out of surrogacy is the essence of this proposed legislation. The definition of 'abandoned child' as given in the present form fails to explain the meaning clearly as the three sub Clauses of Clause 2 (a) in (i), (ii) & (iii) indicate three different conditions which are liable to misinterpretation. The Committee recommends that the three conditions have to be read together to make the definition of abandoned child proper and to ensure that there are no ambiguities in the proposed legislation. Therefore, this Clause should be reframed in the following manner after legislative vetting:-**

'abandoned child means a child born out of surrogacy procedure, deserted by his intending parents or guardian and who has been declared as abandoned by the appropriate authority after due enquiry'.

Clause 2 (b) and Clause 2 (f)- Definition of 'Altruistic Surrogacy' and 'Commercial Surrogacy'

5.6 Clause 2 (b) reads as under :

"altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

Clause 2 (f) reads as under :

"commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration

or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

Suggestions

5.7 Stakeholders have submitted that the Surrogacy (Regulation) Bill, 2016 allows altruistic surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature except the medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative. The Bill also warrants that the surrogate mother should be a close relative who is genetically related to the intending couple. The Bill imposes a "blanket ban on the commercial surrogacy" and imposes stringent "penal sanctions" including imprisonment upto 10 years and fine upto ₹ 10 lakhs for violating the provisions of the Bill.

5.8 Stakeholders have also pointed out that the Surrogacy (Regulation) Bill, 2016 through its altruistic model promotes ' forced labour' as non-payment of any compensation is against Article 23 of the Constitution of India. Pure altruistic drive for any substantial and meaningful contribution of someone else's life is unreasonable to expect in today's economic and social environment. Endorsing altruistic surrogacy will enforce emotional and social pressure on close female relatives without any compensation for immense emotional and bodily labour of gestation involved in surrogacy as well as loss of livelihood. A woman should not be expected to act as a surrogate and go through all the trial and tribulations of physical and emotional tolls of this arrangement free of cost and only out of compassion. A surrogate is indeed the most important stakeholder in this whole process who puts her life to risk and thus should be compensated for doing so. It has also been argued that one cannot guarantee that the altruistic surrogate who is a ' close relative' is not coerced into becoming a surrogate by just removing the commercial component of the practice. Not every member of a family has the ability to resist a demand that she be a surrogate for another family member. As such within family, surrogacy might become even more exploitative than compensated surrogacy.

5.9 Stakeholders in support of commercial surrogacy were of the view that the Bill proceeds on the incorrect premise that commercial surrogacy is synonymous with purported unethical practices and seeks to ban commercial surrogacy instead of preparing a positive legislative regime to protect the rights of surrogate mothers and prohibit any exploitation of such surrogate mothers. The money paid to the surrogate is a mere compensation for the loss of wages over the period of nine months when they cannot engage in strenuous occupation. The surrogates use the money they get from surrogacy for education of their children, construction of their home, treatment of child or spouse, starting a small business or buying an auto rickshaw or farm or small shop which can make them independent and empower her whole family.

5.10 It has also been stated that permitting uncompensated surrogacy but prohibiting compensated surrogacy assumes the women's inherent role to give birth but it denies women the capacity to earn wages for this work. By banning compensated surrogacy, there could be a black market in surrogacy services. The whole surrogacy service could go underground and would lead to increased exploitation with no mechanism for protection of any of the parties involved in the surrogacy arrangement. There

is also the likelihood of surrogacy being driven underground involving illicit inter-country movement of women to be surrogate mothers into foreign nations or safe surrogacy heavens globally for monetary returns. This may subject the surrogate to worst sufferings. Hence, a prohibition of commercial sector is likely to hurt the very people it seeks to protect.

5.11 It has also been pointed out that with small family norms and increase in number of working women, very few ‘ close relatives’ would be interested in helping out by being a surrogate. Also, the intending parents may not be comfortable sharing their infertility issue with their relatives as it is a private matter. In the present socio-cultural familial context where impotence and infertility is associated with social stigma and ridicule, such disclosure of medical incapacity of women to bear child before her in-laws and family members is breach of her privacy and confidentiality. This will rather put her at greater risk of domestic violence, abuse, name shaming, loss of respect, eviction of women from home and annulment of marriage.

5.12 Further, it has also been pointed out that some of the altruistic models across the world include certain expenses like food / nutrition, medical / legal /psychological counseling charges, reasonable out of pocket expenses, loss of earning, post delivery care including free health supplements and free diagnosis, child care support or crèche support for surrogate mother’s own children, maternity clothing etc.

5.13 It has been argued that instead of putting a blanket ban on commercial surrogacy, a compensated surrogacy should be permitted and should be viewed as a form of labour that requires adequate labour protection by granting minimum conditions of work.

5.14 Some stakeholders have argued that the urge for a child cannot be subject to the moral judgment of politics and society. It needs a safe, regulated and legally binding environment and framework in which individual choices may be made. It is a private right of an individual to choose a means of attaining parenthood and family formation. A stringent legal framework is, therefore, required to control the illegal practices under the ambit of assisted reproduction technology.

5.15 The Chairperson, NCW and few other stakeholders have, however, supported the Surrogacy (Regulation) Bill, 2016 as it has put a blanket ban on commercial surrogacy which exploits surrogate mothers. According to NCW, most of the surrogates are poverty stricken, hence they opt for surrogacy. It was suggested that focus should be on providing education, skill development / training so as to empower them.

Department’s Response

5.16 The Department of Health Research has not furnished any comments on the issues raised on the ‘ altruistic surrogacy’ . The Ministry informed that the Bill proposes to ban commercial surrogacy in the country after detailed deliberation with all Departments/Ministries and other stakeholders and as per existing legal provisions in most countries. They added that as per the Bill, the sale or purchase of gametes is also commercial surrogacy.

Recommendation

5.17 **The Committee has come across different views of various stakeholders with regard to altruistic surrogacy. The Committee notes that as of now except for the National Guidelines for**

Accreditation, Supervision and Regulation of ART Clinics in India 2005 of ICMR, there are no binding rules or legislation for the protection of surrogates. Since ICMR guidelines do not have the force of law, they provide little protection for surrogate mothers. The paramount objective of this Bill is to control the exploitation of poor surrogate mothers and safeguard their interests by banning commercial surrogacy because surrogate mothers mostly come from the lowest socio-economic *strata* who are doing surrogacy for money and are being exploited in the process. It has been argued before the Committee that poor women who become surrogates are not capable of exercising real autonomy since they are in such dire economic situations that they are coerced by their circumstances to engage in surrogacy. The Committee observes that there is no doubt that as of today there is a potential for exploitation and the surrogacy model that exists today can and does exploit surrogate women. But this potential for exploitation is linked to the lack of regulatory oversight and lack of legal protection to the surrogate and can be minimized through adequate legislative norm-setting and robust regulatory oversight.

5.18 **The Committee learnt from the surrogate mothers who appeared before the Committee that they engaged themselves in surrogacy out of economic necessity and saw surrogacy as a means of economically uplifting their families. Surprisingly, their other economic options were equally, if not more, exploitative and nowhere close to being as remunerative as surrogacy. The Committee is, therefore, of the view that economic opportunities available to surrogates through surrogacy services should not be dismissed in a paternalistic manner. Permitting women to provide reproductive labour for free to another person but preventing them from being paid for their reproductive labour is grossly unfair and arbitrary. The Committee would like to observe that if many impoverished women are able to provide their children with education, construct home, start a small business, etc. by resorting to surrogacy, there is no reason to take this away from them.**

5.19 **The Committee is of the view that altruistic surrogacy is another extreme and entails high expectations from a woman willing to become a surrogate without any compensation or reward but a decision based on noble intentions and kindness. Pregnancy is not a one minute job but a labour of nine months with far reaching implications regarding her health, her time and her family. In the altruistic arrangement, the commissioning couple gets a child; and doctors, lawyers and hospitals get paid. However, the surrogate mothers are expected to practice altruism without a single penny.**

5.20 **The Committee, therefore, finds merit in the argument that the proposed altruistic surrogacy is far removed from the ground realities. The Committee is, therefore, of the view that expecting a woman, that too, a close relative to be altruistic enough to become a surrogate and endure all hardships of the surrogacy procedure in the pregnancy period and post partum period is tantamount to a another form of exploitation.**

5.21 **The Bill limits the circle of choosing a surrogate mother from within close relatives. Given the patriarchal familial structure and power equations within families, not every member of a family has the ability to resist a demand that she be a surrogate for another family member.**

A close relative of the intending couple may be forced to become a surrogate which might become even more exploitative than commercial surrogacy. The Committee, therefore, firmly believes that altruistic surrogacy only by close relatives will always be because of compulsion and coercion and not because of altruism.

5.22 **Based on the analysis of the facts in the preceding paras, the Committee is convinced that the altruistic surrogacy model as proposed in the Bill is based more on moralistic assumptions than on any scientific criteria and all kinds of value judgments have been injected into it in a paternalistic manner. Altruistic surrogacy across the world means compensated surrogacy and a range of monetary payments to surrogate mothers are permitted as reasonable compensation. Even the Law Commission Report No. 228 of 2009 recommends reimbursement of all reasonable expenses to the surrogate mother. The Committee, therefore, recommends that the word "altruistic" in Clause 2 (b) of the Bill be replaced with the word "compensated" and appropriate modifications be incorporated in the said Clause and other relevant Clauses of the Bill with a view to harmonizing the Bill with the compensated surrogacy model.**

5.23 **The Committee takes note of the view of the Department of Health Research that surrogacy is a privilege and should be resorted to in exceptional circumstances only and that adoption should be the first preference for family formation. The Committee is also aware of Central Adoption Resource Agency (CARA) study of March, 2016 to the extent that only 1600 odd children were available for adoption while 7700 applications from prospective parents for adoption were received. Out of the 1600 children available for adoption, 770 were normal and the rest were those with special needs. Also, the waiting time for adoption in India is one to three years. The Committee is, therefore, unable to comprehend as to how the adoption route would be an answer to infertility which is growing in India. The Committee also observes that adoption is a benevolent choice available to the community at large and the Government cannot force adoption *in lieu* of surrogacy. Surrogacy and adoption have to be an equal choice and in the name of adoption, the Government cannot take away the reproductive rights of couples to have a biologically related child through surrogacy.**

5.24 **The proposed Bill has confined the expenses to "medical" and insurance coverage to surrogate mother during the process of surrogacy which has narrowed down the expenses incurred on the surrogate mother only. There is no scope for the other reasonable expenses. The Committee is of the view that medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother are not the only expenses incurred during the surrogacy pregnancy. For any woman who is going through surrogacy, there is a certain cost and certain loss of health involved. Not only will she be absent from her work, but will also be away from her husband and would not be able to look after her own children. The Committee, therefore, recommends that surrogate mother should be adequately and reasonably compensated. The quantum of compensation should be fixed keeping in mind the surrogacy procedures and other necessary expenses related to and arising out of surrogacy process. The compensation should be commensurate with the lost wages for the duration of pregnancy, medical screening and psychological counseling of surrogate;**

child care support or psychological counseling for surrogate mother's own child/children, dietary supplements and medication, maternity clothing and post delivery care. The Committee also recommends that in case the surrogate mother dies in the course of surrogate pregnancy or while giving birth to the surrogate child, additional compensation should be given to the kin of the surrogate mother.

5.25 **The Committee observes that the surrogacy industry in India is currently governed by the private contract model which relies on the bargaining power of the parties in setting the terms of the contract and its enforcement. Since there are enormous inequalities in the bargaining power of surrogates *vis-à-vis* medical clinics and commissioning parents due to surrogate's illiteracy, socio-economic marginalization and lack of access to legal representation, the chances of exploitation of surrogate mothers are immense. The Committee, therefore, recommends that the amount of compensation should be fixed by relevant authorities and the compensation so fixed should not be the subject matter of bargain between the commissioning couple and the surrogate mother. The Committee further recommends that the compensation to surrogates should be guaranteed from the moment they begin any use of medication in connection with surrogacy procedures and the money should be deposited directly in their bank accounts, by the commissioning parents.**

5.26 **The Committee would simultaneously like to observe that surrogacy cannot be a way out for women opting for surrogacy due to poverty and should not be allowed as a profession. In fact, the Bill rightly provides that no woman can become a surrogate more than once. It is, indeed, sad that the burden of the whole poverty striken family falls on the woman who resorts to becoming a surrogate to earn quick money. As suggested by National Commission for Women, education and vocational training should be given to women so that they can be financially empowered. However, the Committee taking cognizance of the harsh realities of the poverty striken families cannot simply suggest to take away the opportunity surrogacy provides to a family to better their lives.**

Clause 2(g), Clause 2(p), and Clause 4 (iii) (c) - Definition of "couple", Infertility, and eligibility certificate for intending couple.

5.27 Clause 2 (g) of the Bill deals with the definition of couple and reads as under:

> *"couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;*

Clause 2 (p) of the Bill deals with the definition of "infertility" and reads as under:

> *"Infertility" means the inability to conceive after five years of unprotected coitus or other proven medical condition preventing a couple from conception;*

Clause 4(iii) (c) of the Bill deals with eligibility certificate for intending couple and reads as under:

> *(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are*

satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(c) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(I) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(II) the intending couple are married for at least five years and are Indian citizens;

(III) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board;

(IV) such other conditions as may be specified by the regulations.

Suggestions

5.28 The Committee was given to understand by many witnesses/stakeholders that the right to avail surrogacy services has been limited to Indian married couples only which is not justified. Restricting it to only Indian married couples is discriminatory and violative of the right to life, personal liberty, reproductive autonomy and right to equality guaranteed to all persons under the Constitution of India.

5.29 It was also pointed out that the Hon'ble Supreme Court has recognized the status of live-in partners as a "relationship in the nature of marriage" and the proposed Bill in an unreasonable and discriminatory manner fails to recognize the rights of live-in partners to surrogacy. Therefore, a mechanism should be established which can incorporate everyone in the ambit of surrogacy regulatory framework.

5.30 Ministry of Women and Child Development has informed that they are in favour of allowing the option of surrogacy to foreigners, every lawfully married infertile heterosexual couples, every Indian woman whether married or single (which include not married/separated/widow etc.) irrespective of their ability to bear child or not. However, they favored putting restrictions on single men commissioning surrogacy to make it on par with Juvenile Justice (Care and Prevention of Children) Act, 2015 which prohibits adoption of girls by single men. Some other stakeholders were also in favor of extending the option of surrogacy to foreigners, NRIs, PIOs, OCI cardholders, stating that surrogacy should not be restricted to Indian nationals only.

5.31 Various other stakeholders were in support to allow the individuals who are single including unmarried, separated, widows, transgenders, single parents to exercise their right to parenthood. They argued that if single individuals are financially capable of taking care of their children and if they have family support, they should be fully entitled to have children through surrogacy. They felt that restricting the people to commission surrogacy on the basis of their marital status, would be violation of human rights.

5.32 Some concerns have been raised with respect to the condition of childlessness as one of the eligibility criteria to commission surrogacy as proposed in the Bill. It has been argued that there is no one child policy in our country and therefore, this condition of childlessness may be removed from the Surrogacy Bill.

5.33 As regards the definition of ' infertility', the World Health Organization terms infertility as "a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse". The earlier draft Assisted Reproductive Technologies (ART) Bill 2010 and 2014 also defined Infertility as "the inability to conceive after at least one year of unprotected coitus". Majority of the experts/stakeholders have contended that the proposed Bill imposing the extended time period of five years before commissioning surrogacy seems irrational and arbitrary in many aspects. They have cited judicial pronouncements in cases like B.K. Parthasarthi *vs.* Government of Andhra Pradesh and in Govind *vs.* State of MP to buttress their argument that the five year waiting Clause was violative of the right of reproductive autonomy.

5.34 Though the definition of infertility is limited to failure to conceive only, there are other medical conditions for which surrogacy is availed. For example, TB destroys thousands of uteruses irreversibly. A large number of girls are born without a uterus or a very under developed uterus. A large number of women have repeated miscarriages. There are many women who have their uterus removed because of cancer or because of many tumors. The Bill also ignores medical condition of a woman where she conceives but is not able to carry the child to the full term.

5.35 The Bill discriminates against medically infertile couples as this condition of five years is applicable for infertile couples only whereas it is not applicable to other couples who are healthy and free from medical complications and are free to attain parenthood any time before five years of their wedlock or without observing the waiting time period of five years. The Committee understands that in the present context of late marriage (late 30's), further delay of five years would adversely affect the quality of gametes of couples or render the couple's gametes less viable.

5.36 The National Commission for Women has supported the definition of infertility as proposed in the Bill justifying that in today's time, due to a gross imbalance of work life ratio, it is essential to give a couple enough time to try and conceive a child themselves before engaging in external aid. Few other stakeholders also agree with psychologists that after marriage, it takes one to two years to understand each other. After that, there is one year of unprotected sex and then, there has to be one year of continuous trying through fertility clinics.

Department's Response

5.37 On being asked about the exclusion of homosexual couples, single parents, live-in couples from Surrogacy (Regulation) Bill, 2016, the Department clarified that inclusion of these sections of society would open the scope of misuse of such facilities and it would be difficult to ensure better future of the child born through surrogacy. Secondly, upbringing of a child is a big responsibility equally shared between a father and mother and is a lifelong commitment. A single parent might not be able to fulfil his/her responsibility completely. In Indian context, both parents, a mother and a father should be there

to raise a child. Since, there is no legal liability for gay couples and live-in couples as they can get separated or get married whenever they decide to. But complication arises when such decisions are taken in middle of surrogacy procedure.

5.38 The Department while justifying their stand on keeping a period of 5 year duration stated that the five year period is provided for the couple to avail all assisted reproductive techniques to have a child of their own. It has also been submitted that the conditions of infertility will be specified in rules and regulations.

5.39 The Department while justifying its stand on limiting the option of surrogacy to married Indian couples stated that the single woman or man is not allowed to avail surrogacy as the Bill intends to provide a complete family to the child born out of surrogacy. Moreover, the single parent needs a donor for oocytes and sperm from a third party which may lead to legal complications and custody issues at later stage. Also, the live-in partners are not bound by law and safety of the child born through surrogacy will be questionable.

Recommendation

5.40 **The Committee notes that the Bill limits the option of surrogacy to legally married Indian couples. The Committee observes that limiting the option to avail surrogacy facilities to an Indian heterosexual married couple to have their own biological child has overlooked a large section of the society. Given our sentiments and sensibility, the social status of a woman in our society is judged by her reproductive life and there is a lot of pressure on her for child bearing. The Department of Health Research by imposing prohibition on widows and divorced women seems to have closed its eyes to the ground reality. Besides, the decision to keep live-in partners out of the purview of the Bill is indicative of the fact that the Bill is not in consonance with the present day modern social milieu that we live in and is "too narrow" in its understanding. Even the Supreme Court has given legal sanctity to live-in relationships. Surrogacy is one of the least used options by childless Indians. If all these categories are to be banned then why have surrogacy at all. The Committee, therefore, recommends that the Department should broadbase the eligibility criteria in this regard and widen the ambit of persons who can avail surrogacy services by including live-in couples, divorced women and widows. Appropriate alterations accordingly be made in Clause 2(g) and 4(iii)(c) of the Bill.**

5.41 **The Committee would, however, observe that surrogacy is a privilege and cannot be extended to foreign nationals indiscriminately. Foreigners come to India for commissioning surrogacy because the procedure is much cheaper here. The Committee is, therefore, not in favour of extending the option of commissioning surrogacy to foreign nationals.**

5.42 **The Committee notes that the proposed Bill has excluded NRIs, PIOs and OCI card holders from the purview of the Bill. Based on the scrutiny of the facts put forth before the Committee, it feels that there are adequate provisions in the Bill for the Appropriate Authority to scrutinize all the documents submitted by the intending couple before commissioning surrogacy and to reject the application in case of any violation of rules and regulations. The Committee finds no**

point in restricting NRIs, PIOs and OCI card holders from availing surrogacy services in India. The Committee is of the view that since the NRIs, PIOs and OCIs cardholders are of Indian origin only, there should not be any prejudice and discrimination towards them when it comes to allowing them for opting surrogacy in the country of their origin. The Government has been extending several concessions to PIOs/OCIs to boost the ties of the Indian diaspora with the country of their origin. The Committee is of the view that PIOs/OCIs should not be classified along with other foreign nationals for the purpose of availing surrogacy in India. The Committee, therefore, recommends that an appropriate mechanism should be made for a complete background check of the NRIs, PIOs and OCIs cardholders who intend to commission surrogacy and they be permitted after a thorough scrutiny of their documents submitted to the appropriate authority designated for granting permission for availing surrogacy services in India. The Committee further recommends that the intending couple should provide a specific 'declaration' or a 'NOC' that the child born out of surrogacy would be getting the same citizenship rights as possessed by the intending couple. The Committee recommends that while foreign nationals be kept out of the ambit of surrogacy bill, Persons of Indian Origin (PIOs), Overseas Citizens of India (OCIs) and NRIs should be permitted to avail surrogacy services in the country.

5.43 **The Committee also takes note of the submission of the Department of Health Research that "the five year period has been provided for the couple to avail all assisted reproductive techniques to have a child of their own". Five year waiting period for surrogate parenthood appears to be based on the impression that surrogacy, which is third party reproduction, is being resorted to as a first choice of family formation which should be checked. However, from the information made available to the Committee, it notes that surrogacy is a rare practice among childless Indian couples who try various medical options before they choose surrogacy which costs them anywhere between Rs. 15 to 20 lakh. Since surrogacy is not well-regulated in the country, specific and reliable data on surrogacy is not available. However, as per Ernst and Young Study (Call For Action: expanding IVF treatment in India, July 2015), in India, around 27.5 million couples in the reproductive age group are infertile and about one percent *i.e.* about 2,70,000 infertile couples seek infertility evaluation as per the Annexure IV. As per the information made available to the Committee, of the people seeking remedy for infertility, 20-25% undergo IVF treatment and of that small group, one percent may require surrogacy. Ten to Twelve per cent of surrogacy is commissioned because of irreversible destruction of uterus due to TB, 8 per cent because of absence of uterus, 12 per cent because of multiple failed IVF cycles, 12 per cent because of multiple miscarriages, 10 per cent because of removal of uterus due to cancers, fibroids etc.**

5.44 **The Committee also notes that a lot of people are getting married in their 30's and 40's and the requirement of five year wait would adversely affect the quality of their gametes and thus impair their chances of attaining parenthood through surrogacy. Besides, this time bar of five years plausibly violates the right to reproductive autonomy, and an individual's right to exercise his choice.**

5.45 **Looking to all these facts there is no gainsaying that the definition of infertility as the inability to conceive after five years of unprotected coitus and the condition of subsistence of five years of wedlock as laid down in Clause 2(p) and Clause 4 (iii)(c)(II) of the Bill respectively have not been stipulated with due diligence and with due regard to the ground reality in society, well-indicated medical reasons for infertility, current scenario of late marriages and the need for safeguarding reproductive autonomy.**

5.46 **It is also worth mentioning that the definition of 'infertility' in the Surrogacy (Regulation) Bill, 2016 is inconsistent with the definition given by WHO and also as in the ART (Regulation) Bill, 2014 which describe infertility as the inability to conceive after at least "one year of unprotected coitus". The Committee is of the view that the fundamental right to reproduce to have a child is a part of a person's personal domain and fixing a period of five years will only cause breach of his/her reproductive rights and delayed or deferred parenthood. In India, infertility is considered a social stigma and the infertile couples go through a lot of agony and trauma due to infertility. Since conception has many interplay functions, a five year time bar would add to the misery of already distressed intending couples. The five year waiting period is therefore arbitrary, discriminatory and without any definable logic. The Committee, therefore, recommends that the definition of infertility should be made commensurate with the definition given by WHO. The words "five years" in Clause 2(p) and 4(iii)(c) II, be therefore, replaced with "one year" and consequential changes be made in other relevant Clauses of the Bill. The Committee further recommends that in circumstances where the need for surrogacy is absolute due to medical reasons like absence of uterus, destruction of uterus because of cancers, fibroids etc., even the prescribed one year period should be waived-off.**

5.47 **The Bill provides that for those intending couples who have their own child who is mentally or physically challenged or suffering from life threatening disorder or fatal illnesses with no permanent cure can commission surrogacy after the approval from the appropriate authority. The Committee also notes that the Bill provides prohibition to abandon child born through surrogacy for the reasons of any genetic defects, birth defects, any other medical conditions. However, as per provisions of the Bill, a couple who is commissioning surrogacy cannot go for surrogacy again to have a normal child even in the event of child born through surrogacy having genetic and birth defects or other life-threatening disorders. The Committee fails to understand rationale behind such contradictory provisions in the Bill. This appears discriminatory. The Committee is, accordingly, of the view that all intending couples should have the right to go for second chance at surrogacy in case of any abnormality in the previous child irrespective of the fact whether the abnormal child is born through surrogacy or by other means. The Committee, therefore, recommends that necessary amendment may, accordingly, be made in Clause 4 (iii)(c). Consequential changes in other relevant Clauses of the Bill may also be made.**

5.48 **The Committee also recommends that Clause 4(c) III should contain an unambiguous provision to an effect that the intending couple shall produce an affidavit declaring that they do not have any surviving child.**

Clause 2(n)-Definition of "Human Embryologist"

5.49 Clause 2 (n) of the Bill deals with the definition of "human embryologist" which reads as:

> *"human embryologist" means a person who possesses any post-graduate medical qualification in the field of human embryology recognized under the Indian Medical Council Act, 1956 or who possesses a post-graduate degree in human embryology from a recognized university with not less than two years of clinical experience;*

Suggestions

5.50 During the examination of the Bill, the Committee's attention was drawn to the fact that there is no degree given by the MCI designating as Human Embryologist. Therefore, it was suggested that the name may be termed as Clinical Embryologist. The Committee understands that a Clinical Embryologist means a person having either a medical graduate degree or a post graduate degree or a doctorate in an appropriate area of life science or degree in Bachelor of Veterinary Sciences (BVSc.) and having an experience in mammalian embryology, reproductive endocrinology, genetics, molecular biology, biochemistry, microbiology, in-vitro culture techniques and familiar with ART. There is no university in India which offers a post-graduate medical qualification in the field of human embryology.

Department's Response

5.51 In response to the concerns raised by the stakeholders on the definition of ' Human Embryologist', the Department of Health Research has stated that there are clinical embryologists working on human embryo.

Recommendation

5.52 **The Committee is surprised to observe the desultory approach of the Department while drafting the proposed Bill. Interestingly, there is no university offering medical courses across the country that confers the degree of human embryology. The Committee fails to understand how the Department would utilize the services of such specialty doctors in every corner of the country when these doctors do not exist. The Department does not have the data about number of clinical embryologists working in the country. The Committee feels that in the absence of a regulatory framework for assisted reproductive technology and surrogacy procedures, dearth of these specialty doctors would add to the plight of already suffering childless couples who would be prey to the physical, mental and financial exploitation in the name of these advanced reproductive medical science facilities. Therefore, the Committee would like the Department to get their facts correct and collect information regarding the same and rephrase the definition of Human Embryologist also entailing the qualification of specialty doctors performing surrogacy and related procedures to avoid any kind of negligent and violatory incidents. Clause 2 (n) and other relevant Clauses of the Bill may accordingly be modified.**

Clause 2(q)-Definition of "insurance"

5.53 Clause 2 (q) of the Bill deals with the definition of "insurance" and reads as under:

> *"insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for specified loss, damage, illness or death of surrogate mother during the process of surrogacy;*

Suggestions

5.54 The Committee has received various views on the definition of "insurance" as proposed in the Bill. Stakeholders have submitted that the definition of insurance needs to be more comprehensive and inclusive of other aspects as well like expenses during the process of surrogacy and after the process is complete.

5.55 An important suggestion put forth before the Committee was that the insurance coverage should be for a period of six years. Explaining the rationale behind the six year period, it was submitted that one year should be for the evaluation of surrogate on medical, psychological, her domestic and other evaluations and withdrawal if she so desires; and also to evaluate the intending parents. One year maximum should be for specified IVF cycles on the surrogate. If successful, one year should be for carrying and delivery, one year for post-delivery recuperation, breastfeeding, two years for health monitoring for after-effects, if any, of the aggressive-IVF and chemical-hormones. It was argued that the provision of insurance cover was necessary beyond the period of surrogacy to account for effects of health that may arise out of surrogacy but manifest thereafter. Substantial evidence exists that point to the possibilities of such long term health consequences during as well as beyond the period of surrogacy.

5.56 It was also submitted that since the insurance for the purpose of surrogacy pregnancy and related conditions is a new class of insurance and as of now, there are no insurance products specific to surrogacy, IRDA, should be involved in developing appropriate insurance product for surrogacy. Insurance cover must also be provided for the surrogate child/children till they attend the age of majority, so that in situations like death, disability, sickness of commissioning parents, his interests could be protected.

5.57 It has also been pointed out by witnesses/stakeholders that it is necessary to have more clarity on who would be responsible and accountable for such insurance. In case of death during pregnancy or during the time of childbirth, a separate compensation must be paid to her family.

5.58 Another issue that was raised was clarity on Maternity benefits wherein it was submitted that in case of surrogacy, there are two women – one, the surrogate mother who carries the pregnancy and two, the commissioning mother who has to rear the new born child. Both women must be entitled for appropriate part of leave and other maternity benefits.

Department's Response

5.59 The Department while giving clarification stated that the insurance period will cover post partum delivery. The insurance coverage will be as per the IRDA dispersal system monitored by the Government of India. As regards the clarity on maternity benefits the Department was of the view that the proposed suggestion can be considered while framing the rules.

Recommendation

5.60 **The Committee notes that the definition of insurance as given in the Clause 2(q) does not extend to the surrogate beyond the process of surrogacy. The Committee observes that surrogate pregnancy is not a disease. However, it is not risk-free and there are certain long-term health-risks arising out of surrogate pregnancy because surrogate's complete menstrual cycles have to**

be altered for an embryo to be transplanted inside her womb and large doses of hormonal treatment are given. Surrogacy has also resulted in deaths of surrogate mothers in many cases. The Committee, therefore, recommends a comprehensive insurance cover for the surrogate mother covering even the after effects of surrogacy. A period of six years of medical insurance cover along with life insurance of a certain sum of money for the surrogate mother needs to be determined to cover any health complications that may occur long after delivery. The Committee is of the view that insurance for surrogate mother should be in two steps. The first step would provide insurance cover for one year from the date the surrogacy procedure starts. The second step would provide insurance cover for six years from date of confirmation of pregnancy even if there is no take home baby. The Committee, therefore, recommends that the definition of insurance may be revised accordingly.

5.61 **The Committee finds that the Bill does not provide for the social security insurance for the surrogate child in the event of death of commissioning parents during the process of surrogacy. The earlier ART Bill 2014 provided the social security insurance for all the three stakeholders, *i.e.* the surrogate mother, the surrogate child and the egg donor. The Committee would, therefore, like the Department of Health Research to provide for insurance for the surrogate child in case of unforeseen contingencies like accidental death of the commissioning parents or divorce during the process of surrogacy. Accordingly, the definition of insurance for the surrogate child may also be incorporated in the Bill.**

5.62 **The Committee would also like to recommend to the Department to consider incorporating the provision of Maternity Benefits to the surrogate mother as well as the intending mother as both of them are involved in child birth and child rearing respectively. They both should be entitled to maternity benefits to ensure the continuity of their service and to cover loss of wages.**

Clause 2(r)-Definition of 'intending couple'

5.63 Clause 2 (r) of the Bill deals with the definition of "intending couple" which reads as under:

> *"intending couple" means a couple who have been medically certified to be an infertile couple and who intend to become parents through surrogacy;*

Suggestions

5.64 It has been suggested by a stakeholder that after the words, "who intend to become", the word "legal" should be added so that the provision may be read as follows:

> *"who intend to become legal parents through surrogacy by legally adopting the baby/babies born through surrogacy process and thereafter obtaining parental order from the District Surrogacy Board"*

5.65 There was a suggestion that the words "the intending couple", be replaced with "the intending parents" who wish to commission surrogacy to have a child of their own.

Department's Response

5.66 The Department of Health Research has not commented on this issue.

Recommendation

5.67 **The Committee is of the view that suggestion of the stakeholders can be considered on the justification that the word 'legal' before the parents in the definition of the 'intending couple' will have binding effect on the couple and it will reduce the scope of exploitation of surrogate mother or the child born out of surrogacy either directly or indirectly. The suggestion on inclusion of the word "legal" before the word "parents" in Clause 2(r) of the Bill may, therefore, be examined in consultation with the Legislative Department to explore its inclusion, if necessary.**

Clause 2(zb)-Definition of "surrogacy"

5.68 Clause 2 (zb) of the Bill deals with the definition of "surrogacy" and reads as under:

> *"Surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;"*

Suggestions

5.69 The Committee was given to understand that in the earlier ART Bill 2010 and 2014 "surrogacy" is defined as "an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of gametes belong to her or her husband, with the intention to carry it and hand over the child to the commissioning couple for whom she is acting as a surrogate". This definition of surrogacy provided under the ART Bill is more comprehensive as it enumerates all the salient features of surrogacy. Hence, it was suggested that the Surrogacy Bill may provide for definition of surrogacy as provided in the ART Bill 2010 and 2014.

Department's Response

5.70 The Department did not comment on these changes in definition of surrogacy.

Recommendation

5.71 **The Committee notes that the Clause 2(zb) is not clear and explicit in articulating the procedure of surrogacy holistically. The Clause does not refer to the manner of achieving surrogate pregnancy by a surrogate mother. It does not mention pregnancy through the assisted reproductive technology either which is essentially a medical procedure by way of "in-vitro fertilization or IVF". Also, there is no mention of origin of gamete either from the intending couples or gamete donors. The definition of surrogacy provided under the Bill does not specify whether gestational or traditional surrogacy is permissible, though the Department of Health Research in its written submissions has submitted that only gestational surrogacy is allowed under the Bill. The Committee observes that the definition of surrogacy should be precise, explicit and descriptive with no scope of arbitrary interpretation. The definition of surrogacy in the draft ART Bill is inclusive of all the relevant ingredients as required to understand the surrogacy in its entirety. The Committee recommends that the definition of surrogacy as provided in the ART Bill, 2014 be included in Clause 2(zb) of the Surrogacy Bill, with specific provision for Gestational Surrogacy.**

Clause 2(ze): Definition of "surrogate mother" and Clause 4: Regulation of surrogacy and surrogacy procedures

5.72 Clause 2 (ze) of the Bill deals with the definition of "surrogate mother" which reads as under:

> *"surrogate mother" means a woman bearing a child who is genetically related to the intending couple, through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-Clause (b) of Clause (iii) of section 4;*

Clause 4 (iii) (b) (I), (II), (III) & (IV) deals with the conditions to be fulfilled to be surrogate and reads as under:

4. On and from the date of commencement of this Act,—

(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

> *"(b) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—*
>
> *(i) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;*
>
> *(ii) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;*
>
> *(iii) no women shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime;*
>
> *Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed;*
>
> *(IV) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;"*

Suggestions

5.73 The Committee has received several perspectives on the definition of ' surrogate mother' and pre-conditions to be a surrogate mother. Most of the stakeholders have expressed concern over the term ' genetically related' to the intending couple as well as the condition of being a ' close relative' of the intending couple as one of the eligibility criteria of a surrogate mother. They sought deletion of the term ' genetically related' from the Bill. If a surrogate mother is a close relative of the male member of the intending couple (*e.g.*, his sister), and is allowed to donate her egg for the surrogacy, it may result in congenital anomalies for the surrogate child.

5.74 Majority of the stakeholders expressed objection to the provision relating to ' close relative' of the concerned couple as an eligibility to be a surrogate mother. According to them, this may result into

unavailability of women to act as surrogate mother. There are many socio- legal problematic issues with the "surrogate mother" being the "close relative" and genetically related to Intending couples which are as follows-

- In case of close family relative acting as surrogate mother, this may give scope for familial disputes concerning inheritance and property issues. There is also likelihood of custody disputes over the child.
- The surrogate and couples being close relatives sharing the same ancestry, familial or kinship ties, there is greater likelihood of surrogate mother developing emotional attachment to the surrogate child thereby causing emotional wrangles surrounding the custody and parentage of child.
- Altruistic surrogacy through a close relative has the potential of creating harsh psychological and emotional implications on child as well as on the parents and surrogate relative as the child shall grow up within the same family.
- Being a close relative is also no guarantee for non-commercial surrogacy. By limiting surrogate mothers to ' close relatives' , an attempt may be made to force women to become surrogate mother for their relatives.
- Asking or coercing a close relative to be a surrogate mother will make the relations more complex, shaking apart the very foundation of Indian family.

Department's Response

5.75 The Department while justifying this Clause stated that the Surrogacy Regulation Bill allows only Gestational surrogacy as the child has to be related to the intending couple. However, the definition of the surrogate mother has been drafted in consultation with Ministry of Law. The provision for the surrogate mother to be a close relative of the intending parents has been kept with a view to avoid commercialization of surrogacy. The Clause has been incorporated after detailed deliberation with stakeholders and Ministry of Law. On the definition of ' close relative' , the Department clarified that the same will be elaborated after deliberations with the National Surrogacy Board.

Recommendation

5.76 **The Committee notes that despite Department's clarification, the way Clause 2 (ze) is worded, it would make it appear that the surrogate mother should be genetically related to the intending couple. The Committee observes that such ambiguity in the Clause would lead to arbitrariness in interpretation of the law. The Committee, therefore, recommends that necessary drafting modifications be carried out in the said Clause to stipulate that the surrogate child and not the surrogate mother will be genetically related to the intending couple. It also needs to be clarified in the Clause that only Gestational surrogacy will be permissible. Other consequential changes in relevant Clauses of the Bill may also be made.**

5.77 **The Committee is also dismayed to observe that on the one hand the Department asserts that only Gestational surrogacy is permitted under the Bill, whereas Clause 4(iii)(b)(III) advocates the concept of Traditional Surrogacy. Thus, there is an apparent contradiction between the Department assertions and provisions of Clause 4(iii)(b)(III). The Committee, therefore, recommends that the infirmity in Clause 4(iii)(b)(III) be rectified and the Clause be amended suitably so as to spell out in unambiguous terms that the surrogate mother will not donate her eggs for the surrogacy.**

5.78 **The Committee notes that as per Clause 4 (iii) (b) (II), only a close relative of couples is permitted to act as a surrogate mother. According to the Department this provision has been proposed with a view to avoid commercialization and stop exploitation of surrogates. The Committee is, however, of the view that the proposition of a close relative becoming a surrogate mother overlooks the various social, legal, emotional and ethical dynamics of this issue and is fraught with numerous disruptive issues for several reasons.**

5.79 **Curbing exploitation of surrogates has been touted as the main objective of the proposed legislation. The Bill seeks to operate from the understanding that just by changing the nature of surrogacy from commercial to altruistic and confining the practice of surrogacy in the private domain of family would end the exploitation of surrogates. Such a proposition, however, ignores the ground reality that in Indian marital homes the decision making power rarely rests with women and not so privileged or financially weak relatives who can be coerced into becoming surrogate mothers and the chances of coercion and exploitation are even more in case of close relatives due to family pressures.**

5.80 **This Clause also disregards the social and cultural ethos of our country. The restriction that the surrogate mother must be a close relative of the intending couples may also result in the surrogate mother and the child developing an emotional bond given that the commissioning couple and the surrogate are accessible and related and the child is always in proximity. Such an attachment will not only have the detrimental psychological and emotional impact on the child who could feel divided between the two mothers, it may also lead to parentage and custody issues apart from inheritance and property disputes within the family.**

5.81 **Infertility is a real stigma in our society but undergoing surrogacy and IVF is a taboo even today in our country. For these reasons, surrogate pregnancy is a private affair and majority of the patients seeking parenthood through surrogacy want to keep their treatment private and confidential. This precondition of only close relatives to become surrogate mothers would tend to compromise their privacy by way of forcing them to declare their infertility within family. This is violative of the basic rights of privacy and reproductive autonomy of the medically infertile persons who whilst maintaining the privacy of their medical problems have the right to surrogacy from women who volunteer to be surrogate mothers.**

5.82 **In today's social order of nuclear families, it would be unrealistic to expect that all infertile persons will have a close relative between 25 and 35 years of age, having one child, satisfying all conditions as prescribed in the Bill and would voluntarily consent to be a surrogate mother**

altruistically for the infertile couples. This condition of close relative being surrogate mother will therefore cause acute dearth and unavailability of women to act as a surrogate mother and shut all options for the medically infertile for whom surrogacy is the only option to have their biological child.

5.83 **Keeping in view the facts as stated above, the Committee is convinced that limiting the practice of surrogacy to close relatives is not only non pragmatic and unworkable but also has no connect with the object to stop exploitation of surrogates envisaged in the proposed legislation. The Committee, therefore, recommends that this Clause of "close relative" should be removed to widen the scope of getting surrogate mothers from outside the close confines of the family of intending couple. In fact, both related and unrelated women should be permitted to become a surrogate. Appropriate modifications may be carried out in the provisions of Clause 4(iii)(b)(II) and other relevant Clauses of the Bill to address the concerns as pointed out in the preceding paras.**

Suggestions

5.84 Stakeholders have raised concerns over other requirements stipulated in Clause 4 (iii)(b), (I), (III) and (IV). The issues raised are as follows:

(i) The age limit of the surrogate mother is prescribed between 25-35 years of age. However, it has been suggested that it should be raised to 39 years as in today's life, there is increase in number of working women who reach the age of 35 years in planning their own family.

(ii) The terms "ever married women" are not defined in the Bill, and it is not clear if the terms 'ever married' women would include surrogate mother who may be a widower or a divorcee. The Bill also fails to mention "Indian nationality" of women to be surrogate mother.

(iii) The Bill does not clarify about egg donation by women for money.

(iv) There should be provision wherein surrogate mother or egg donor may be sourced from the surrogacy clinic provided under Bill which includes ART Bank within itself. Such surrogacy clinic may conduct necessary medical screening and record keeping on the same as provided under the earlier ART Bill, 2010 and 2014.

(v) The Bill proposes that no woman shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime. It has been suggested that since the procedure does not guarantee success in first attempt, the number of attempts for surrogacy procedures on the surrogate mother shall be three cycles of assisted/artificial reproduction techniques with a fourth, if necessary, as the last and final "closure" cycle. The ART Bill also allows maximum three cycles of medications for surrogate mother.

(vi) Other experts suggested that a woman should be allowed to be a surrogate mother only two times with a gap of at least 3 years between the two, whereas the ART allowed minimum

2 years of interval between two deliveries. According to Ministry of Women and Child Development, if surrogate is declared medically fit, then she should be provided with the option of being surrogate twice in her lifetime with a mandatory period of interval as prescribed between two pregnancies. It was also pointed out that in ART (Regulation) Bill, 2014, the Clause 60 (5) provided that a surrogate mother should have atleast one child of her own with minimum age of three years. There is, however, no such condition for the age requirement of the surrogate mother's own child in the proposed Bill that fails to define the time interval between two pregnancies of surrogate mother.

Department's Response

5.85 In response to various concerns and suggestions, the Department has stated that the procedures of surrogacy and the adjuvant hormonal therapy has some side effects which is why the number of times a woman can be a surrogate is kept only once in her life time. The number of attempts will be as per rules and regulations. The Clause (iii) b(I) of Section 4 has been incorporated after detailed deliberations with stakeholders and the Ministry of Law. The Department is, however, silent on the other issues raised with respect to the conditions mentioned in Clause 4 of the Bill.

Recommendation

5.86 **Provisio to Clause 4(iii)(b)(III) mandates that the number of attempts for surrogacy procedure shall be prescribed. The Committee also takes note of the suggestion that there should not be more than four cycles of surrogacy procedures on the surrogate mother. The Committee is aware that there are risks with IVF and fertility medications and the more the cycles, greater the risks. The Committee, therefore, expresses agreement with the suggestion that 'the number of attempts for surrogacy procedures on the surrogate mother should be three cycles of assisted/ artificial reproduction techniques with a 4th, if necessary, as the last cycle'.**

5.87 **The Committee would, however, like to emphasize in this regard that this is a procedural aspect of surrogacy which may require periodic revision depending on the various scientific advances and progress. The Committee would like this aspect to remain in the domain of delegated legislation to ensure that frequent amendments are not warranted in the governing statute.**

5.88 **Any pregnancy carries with it multiple risks and surrogate pregnancy also involves the same, even more risks due to potential reaction to fertility drugs. Taking this risk for someone else is a huge commitment. Taking all factors into account, the Committee is not in favour of providing the surrogate the option of being the surrogate more than once in her lifetime. The Committee is, however, inclined to accept the suggestion on raising the upper age limit of the surrogate mother from 35 years to 39 years.**

5.89 **The Committee understands that if the pregnancy of a woman, who has acted as a surrogate mother, does not mature due to abortion, she will be allowed to volunteer to be a surrogate mother again. However, there are no explicit provisions in the Bill to this effect. It is a cardinal principle of law that there should be no ambiguity in the law and therefore, suitable changes be**

made in the definition of the surrogate mother encompassing the above stated position to avoid any ambiguity on this aspect.

5.90 **The Committee notes that there is no mention of egg or sperm donor in the Bill. This suggests that both gametes should come from the couple. However, this cannot be possible in all cases of infertility. Clause 4(ii)(a) lays down that surrogacy can be availed "when either or both members of the couple is suffering from proven infertility". Needless to say that in case of one of the commissioning couple being infertile, the gamete will be required to be donated by somebody. Gamete donation also assumes significance in view of the fact that the option of surrogate parenthood should also be open to widows and divorced women. Since the lack of provision for gamete donation will greatly narrow down the category of people who can avail surrogacy, the Committee recommends that appropriate modifications be made and provision for gamete donation be incorporated in the Bill.**

Clause 2 (zc) : Definition of Surrogacy Clinic

5.91 Clause 2 (zc) of the Bill reads as under:

> *(zc) "surrogacy clinic" means surrogacy clinic or centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called conducting surrogacy procedures in any form;*

Suggestions

5.92 The Committee has been given to understand that this Clause is not applicable to IVF clinics not conducting surrogacy.

Department's Response

5.93 The Department has stated that the Bill clearly restricts to surrogacy and surrogacy procedures.

Recommendation

5.94 **The Committee would like to point out that there are no separate surrogacy clinics as such. Generally ART clinics offer surrogacy services as well. It would be difficult to monitor ART clinics as it would not be easy to distinguish between a surrogate pregnancy and other pregnancy through IVF. The other IVF clinics which are not involved in surrogacy are out of the purview of the Bill. The need of the hour, hence, is to regulate all ART clinics. The Committee learns that the Department would be bringing forth the draft ART Bill after the Surrogacy (Regulation) Bill, 2016 for regulation of ART Clinics. In this context, the Committee opines that bringing ART Bill before the Surrogacy (Regulation) Bill, 2016 would have been an ideal attempt for regulation of such clinics.**

Clause 3(vi): Abortion during the period of surrogacy.

5.95 Clause 3 (vi) provides as under:

On and from the date of commencement of this Act,—

> *(vi) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:*
>
> *Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971;*

Suggestions

5.96 The stakeholders have informed that the Medical Termination of Pregnancy Act and Indian Penal code sufficiently imposes restrictions to safeguard the interests of pregnant woman and child. Therefore, an additional requirement of approval from the appropriate authority was unreasonable. Further, the Bill has not provided the time period by which such authorisation for abortion has to be given. It has also ignored the stake of the intending couple in the event of an abortion. It was also pointed out that this is different from the provisions of the Medical Termination of Pregnancy Act, 1971 which allows abortion in such circumstances with the consent of the "pregnant woman". The complication in the case of surrogacy is that the surrogate mother (who is carrying the child) is different from the intending couple which has to bring up the child. Another concern expressed was that the "right to seek abortion or medical termination of pregnancy" is a statutory right of every Indian woman as per the Medical Termination of Pregnancy Act. It was therefore unreasonable to put a condition of authorization for same from appropriate authority before performing abortion. Also, in crucial life threatening cases requiring abortion to save the life of surrogate mother, obtaining authorisation from appropriate authority may not be pragmatic or workable; rather this may go against the interest of surrogate mother. Therefore, it was suggested that the condition seeking authorisation from the appropriate authority before conduct of abortion on surrogate mother should be removed. The written consent of surrogate mother herself subject to compliance with relevant provision of the Medical Termination of Pregnancy Act, 1971 is adequate safeguard of reproductive right of surrogate mother.

Department's Response

5.97 The Department has been silent on this issue.

Recommendation

5.98 **In view of the concerns raised by the stakeholders, the Committee would like the Department to review the requirement of approval of the appropriate authority for abortion. The time factor is crucial in such cases of medical emergencies where there would be no time left to ask for permission from an authority for performing abortion to save the life of the surrogate. Since Medical Termination of Pregnancy Act imposes restrictions to safeguard the interests of pregnant woman and child, the rationale behind seeking permission from appropriate authority is not clear. The role of appropriate authority can be envisaged where abnormalities of any kind have been detected in the unborn surrogate child. In such cases, it may be statutorily mandated upon the appropriate authority to state categorically the reasons for permitting abortion within**

a specified time-frame taking into account the consent of the intending couple and the physical well-being of the surrogate mother. The Committee, therefore, recommends that suitable modifications be made in Clause 3(vi) on the above lines. Consequential changes in other relevant Clauses of the Bill may also be incorporated.

Clause 3 (vii) : Prohibition of storage of human embryo or gametes

5.99 Clause 3 (vii) reads as under:

On and from the date of commencement of this Act,—

> *(vii) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:*
>
> *Provided that nothing contained in this Clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed.*

Suggestions

5.100 The stakeholders have informed that the prohibition of storage of embryos and gametes for the purpose of surrogacy is contrary to the ICMR guidelines which allow the storage of embryos for a period of five years. It was submitted that in order to initiate surrogacy arrangement, the eggs are extracted from the intending mother, which are then implanted in the surrogate mother's uterus. This requires multiple implantation attempts on the surrogate mother as the success rate of one implantation in one single attempt is below 30% under best of circumstances. Therefore, extra eggs are extracted in order to secure availability of eggs for repeat attempts for implantation in surrogate mother's uterus. The infertile intending mother needs to undergo extensive hormonal treatment for the extraction of eggs to be successful. This sometime requires repeated stimulation of woman's periodic cycle to extract eggs putting her to risk of other diseases. Further, in case of oocyte donor or sperm donor, it will not be possible to use the donated gametes in creation of embryos in-vitro immediately for surrogacy. Scientifically also, the donated sperm needs to be quarantined for certain period before use. It has been argued that human embryo is treated as life in itself and prohibiting its storage will force clinics to discard the remaining embryos without the consent of the parent, which is apparently unethical. In case the baby dies at early stages or is born still, parents would not have stored embryos to try again. The procedure would also become very expensive for the intending infertile couple. Hence, it was suggested that provision for storage and use as per the need should be made under provisions of law and the procedure should be on the basis of medical certificate by ART Clinic doctor. One of the stakeholders also pointed out that in fertility clinics, embryos are being switched to accommodate intending parents which is unethical.

Department's Response

5.101 The Department of Health Research, in reply to these suggestions informed that the storage of embryos will be as per rules and regulations.

Recommendation

5.102 **The Committee notes that Section 53 of the draft ART Bill, 2014 mandates highest possible standards in the storage and handling of human gametes and embryos for the duration of not more than five years on a prescribed fee after which such embryo shall be allowed to perish or donated to a research organization registered for research purposes. The Committee understands that generally three or more embryos are created during the process of surrogacy and in-vitro fertilization. Out of them either two or three embryos are transferred in the womb of the surrogate mother during one cycle and remaining embryos are cryo-preserved so that if the first cycle fails, then the remaining embryos can be used in subsequent cycles. The success rate of implantation of embryos in one singular attempt is around 30% under the best of circumstances. Gamete (either oocytes or sperm or both) also need to be cryo-preserved before creating the embryos as the timing of the creation of the embryos in-vitro has to be in line with the menstrual cycle of the surrogate mother. The Committee notes that repeated extraction of eggs and fertility medicines that stimulate egg production may lead to the risk of Ovarian Hyperstimulation for the intending mother or the donor. There may be several situations like the surrogate mother aborting on the way, the baby being born still or dying early or turning out to be congenitally abnormal, which may warrant storage of embryos.**

5.103 **Keeping in view the facts as stated above the Committee fails to comprehend the rationale behind such limitations on the storage of human gametes and embryos. The Committee feels that the infertile couple and the surrogate mother should not undergo same trauma repeatedly. This can be avoided with the storage facilities. The Committee, therefore, recommends that the storage of embryos should be permitted and Clause 3(vii) be amended appropriately permitting storage of embryos on the lines of ART Bill 2014.**

Clause 4 - Regulation of surrogacy and surrogacy procedures

5.104 Clause 4 (ii) deals with regulation of surrogacy and surrogacy procedures and reads as under:

On and from the date of commencement of this Act,—

(ii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(a) when either or both members of the couple is suffering from proven infertility;

(b) when it is only for altruistic surrogacy purposes;

(c) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(d) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(e) any other condition or disease as may be specified by regulations made by the Board;

Suggestions

5.105 The Committee was informed by the stakeholders that under Clause 4 (ii) (a), it is impossible to certify infertility as infertility is not an absolute condition. The Bill does not cover the cases where surrogacy can be commissioned for reasons other than infertility as there may be couples who may not be infertile but due to medical complications/other diseases, doctors may have advised them not to conceive or get pregnant.

5.106 The Committee has received a suggestion to include a provision in the Bill for mandatory screening of the intending couple on the lines of CARA guidelines. This would enable effective screening or assessment of the couple by qualified social worker, preparation of a home study report after such assessment before vesting custody of child. The screening would ensure better custody, care arrangement and effective parental responsibility of intending couples towards the child.

Department's response

5.107 The Department has submitted that infertility conditions will be elaborated in rules and regulations. The Department has not responded to the suggestion regarding home study.

Recommendation

5.108 **The Committee supports the compensated surrogacy and expects the Department to carry out necessary amendments to Clause 4(ii)(b) and (c) in consonance with the concept of compensated surrogacy. The Committee endorses the suggestion seeking a provision in the Bill mandating on the rights of the surrogate child and the interest of the child so that the child is not ill-treated, abused, sold or trafficked or exploited in any way. The Committee, therefore, recommends that the Surrogacy Bill must incorporate enabling provisions on screening of intending couple seeking medical assessment of their fitness to be parent, social economic background, criminal records in past, age, family information and related checks before they are permitted to commission surrogacy. There should be a provision to ensure that the intending parents have not been involved in any child trafficking or child abuse.**

5.109 **The Committee notes that Clause 4(ii)(e) has left certain conditions for surrogacy to be specified through regulations by the National Surrogacy Board and observes that this Clause is couched too much in ambiguities and generalities. The Committee is of the considered view that the substantive purposes for which surrogacy will be allowed should be enshrined in the statute itself and not left to be covered under regulations. If required, an exhaustive list of purposes for surrogacy may be provided by way of regulations. The Committee, therefore, recommends that Clause 4(ii)(e) may be amended suitably and the substantive purposes for surrogacy be clearly delineated therein.**

Clause 4(iii)(a): Conditions of surrogacy and surrogacy procedures

5.110 Clause 4 (iii) (a) deals with the conditions of surrogacy and surrogacy procedures and reads as under:

On and from the date of commencement of this Act,—

(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated,

unless the director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(a) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying for itself, for the reasons to be recorded in writing, about the fulfillment of the following conditions, namely:—

(i) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board.

Explanation.—For the purposes of this item, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(ii) an order concerning the parentage and custody of the child to be born through surrogacy, have been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and surrogate mother; and

(iii) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999.

Suggestions

5.111 Various stakeholders in their written comments furnished to the Committee, have stated that the Surrogacy Bill does not define ' certificate of essentiality' . The maximum time duration, the criteria or the grounds on which this certificate may be granted or denied, grievance redressal or recourse in case of rejection or refusal of such certificate is not provided. The purpose behind seeking such certificate from appropriate authority by couples is not clear and therefore, it was suggested that the certificate of essentiality may be removed.

5.112 It has also been submitted that the minimum and maximum time duration to be required by the Magistrate court in issuing an order on parentage and custody of the child born through surrogacy is not specified. Even the grounds for grant or denial of such order are not prescribed and the recourse in case of refusal of such order is also not provided in the Bill. Further, it does not mention about any appellate forum against the order of Magistrate same. These gaps give rise to legal issues in establishing parentage of child born of surrogacy. It has been suggested that the court order on parentage and custody may be in the nature of "pre birth court order" which may be applied by the intending couple after successful conception in surrogate mother before birth of child. Having a pre birth court order would mean that the couple may take immediate custody of child and there is registration of birth of child immediately after birth to avoid any legal complications or delay of parentage determination post birth of child ensuring stability and predictability of surrogacy arrangement.

Department's Response

5.113 The Ministry while justifying the provision stated that the appropriate authority will be the monitoring and implementing authority in the State and Union Territory. A parental order will be issued through the Magistrate of the first class or above before commissioning surrogacy.

Recommendation

5.114 **The Committee notes that certificate of essentiality is required to be obtained by the intending couple from the Appropriate authority after giving the reasons to commission surrogacy. This certificate of essentiality would include three conditions that need to be fulfilled *viz.* certificate of proven infertility, order on parentage and custody of child from court. This further requires an insurance coverage in favour of surrogate mother from an insurance company or an agent recognized by Insurance Regulatory and Development Authority (IRDA). The Committee observes that childless couples in India try various medical treatment options including assisted reproductive methods before they go for surrogacy as the last resort. Infertility is considered a taboo in our society and infertile couples go through a lot of mental agony and psychological trauma due to infertility. The couples who are already reeling under such emotional trauma of infertility and huge costs of the surrogacy treatment would be additionally burdened with the requirement of certificate of infertility from appropriate authority causing further distress and hardships. Besides, certificate of infertility has a negative impact psychologically and is considered derogatory for women in India. A certificate of infertility may also act as an evidence for filing divorce in case one partner is certified to be infertile. Hence, the Committee is of the view that once the couple has had all the procedures under assisted reproductive technology without any success, certificate of infertility from appropriate authority is unwarranted. The Committee, therefore, recommends that requirement of having certificate for infertility from an appropriate authority should be done away with and instead medical reports and prescription of the couple certifying repeated failures in conception or inability to carry the baby to full term should be allowed as a proof for their decision to commission surrogacy. Necessary modifications may accordingly be made in Clause 4(iii)(a)(I).**

5.115 **The Committee notes that neither any time limit has been prescribed for issuing an essentiality certificate by the District Medical Board nor there is any appeal or review procedure, in case the application for surrogacy is rejected. This confers huge discretionary powers to the District Medical Board for issuance of essentiality certificate. It would, therefore, be in the fitness of things if suitable safeguards are built in the Bill and it is mandated that the essentiality certificate will be issued within a specified time frame. Also, there is an imperative need for an appellate authority to be provided for in case of refusal of such an order. The Committee, therefore, recommends that suitable enabling amendments may accordingly be made in Clause 4 and other relevant Clauses of the Bill.**

Clause 6: Written informed consent of surrogate mother

5.116 Clause 6 provides that:-

No person shall seek or conduct surrogacy procedures unless he has—

(i) explained all known side effects and after effects of such procedures to the surrogate mother concerned;

(ii) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

Suggestions

5.117 The stakeholders have pointed out that the term ' written informed consent' is not defined in the Surrogacy Bill. The Bill only provides for written informed consent of the surrogate mother but exempts her husband and the intending couples from such consent. Secondly, there is no provision for securing consent under the Surrogacy Bill. There is no competent statutory authority responsible for obtaining such consent from surrogate mother and the intending couple. There is no mention of counselling to proceed first in order to provide information and subsequently obtaining consent following the counselling. The Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Subjects 2006 and Statement of specific principles of ART, under the principles of Informed Consent provide for prior counselling with explanation of various risk factors associated with ART procedures to be in simple language of understanding. There should be an obligation on the assisted reproductive technology clinics and banks for obtaining written consent from all the parties seeking assisted reproductive technology in all possible stages of such treatment or procedures as provided under the earlier ART Bill 2010 and 2014.

5.118 It was also suggested to the Committee that a surrogate mother should have a representative who can attest to the surrogate having informed consent without coercion or family pressure. Such representative should not be a relative of the intended parents but a relative of the surrogate mother.

5.119 The Ministry of Women and Child Development has suggested that a system should be developed wherein women willing to provide services are empanelled by the State.

Department's Response

5.120 The Department has been silent on this issue.

Recommendation

5.121 **The Committee observes that there is huge disparity in the bargaining power of surrogates *vis-à-vis* commissioning parents due to surrogates' impoverishment, illiteracy and the resultant lack of access to legal representation. Surrogate mothers are not informed of the effects of fertility medications and treatment protocols and as a result thereof, they are left completely unprotected and vulnerable in the matter. Therefore, mere explaining of all side effects of surrogacy procedure does not hold good in this context. The Committee, therefore, recommends an elaborate mechanism for obtaining full informed consent by a competent authority after comprehensive medical, social and psychological conselling and the risks associated with ART procedures, fertility medications and surrogate pregnancy. The competent authority should consist of independent functionaries including civil society members and NGOs working on women's health and rights. The Committee also feels that consent from the husband of surrogate mother**

is also important. The Committee accordingly recommends that suitable amendments be made in the Bill, incorporating the provisions for mandatory appointment of a competent authority to obtain full informed consent of surrogate mothers.

5.122 **The Committee is also of the view that a mandatory consent from intending couple would be legally binding on all the stakeholders of the surrogacy arrangement. The Committee endorses the suggestion of the Ministry of Women and Child Development that a surrogate mother should have an option to withdraw from the surrogacy arrangement if she chooses to do so before the start of the procedure. Empanelment of women wanting to be a surrogate by the State is a good suggestion of the Ministry as the surrogates can be identified, traced and counselled before giving their consent. The Committee, therefore, recommends to the department to incorporate the changes in the proposed Bill on the above lines.**

Clause 8: Number of oocytes or embryos to be implanted.

5.123 Clause 8 reads as under:

> *The number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.*

Suggestions

5.124 The Committee has received various suggestions regarding the number of embryos to be implanted in the uterus of surrogate mother. It has been pointed out that it is only the embryo that are transferred and not the oocytes as provided in the present Bill. More than one embryo are implanted into uterus of surrogate which increases success rate in IVF/surrogacy avoiding thereby the repetition of IVF cycle further due to failure. Another viewpoint was that no more than two embryos should be transferred to the surrogate mother. The risks with embryo transfer (ET) should be explained in detail beforehand. The process of foetal reduction should not be permitted. The Committee understands that that most countries have restricted this to two or maximum three.

Department's Response

5.125 In response to the suggestions related to number of embryos transfer in surrogate mother's uterus, the department stated that the number of embryo to be implanted will be as per rules and regulations and suggestions would be considered while framing the rules.

Recommendation

5.126 **The Committee notes that the proposed Bill does not specify the number of embryo transfer with respect to the number of attempts or number of cycles or number of embryos that are implanted in the surrogate's body. The Committee is of the view that considering the complexities of the procedures and scope of exploitation of a woman's body, there should be a prescribed limit to number of embryo implants. However, the Committee is not in favour of including the number of embryos to be implanted in the main statute. Since the department has assured to consider the suggestion while framing rules, the Committee recommends that the requisite safeguard limiting the number of embryos to be implanted be provided in the Rules.**

Clause 14: Constitution of National Surrogacy Board

5.127 Clause 14 reads as under:

14. (1) The Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(2) The Board shall consist of—

(a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, ex officio;

(b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, ex officio;

(b) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, ex officio;

(c) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs not below the rank of Joint Secretary, Members, ex officio;

(e) the Director-General of Health Services of the Central Government, Member, ex officio;

(f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(i) eminent medical geneticists or human embryologists;

(ii) eminent gynaecologists and obstetricians or experts of stri-roga or prasuti-tantra;

(iii) eminent social scientists;

(iv) representatives of women welfare organisations; and

(v) representatives from civil society working on women's health and child issues, possessing of such qualifications and experience as may be prescribed;

(g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union Territories, two in the alphabetical order and two in the reverse alphabetical order, Member, ex officio; and

(h) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, ex officio.

Suggestions

5.128 The stakeholders have suggested that the members who have the knowledge and experience in the field of law or human rights, bioethics and assisted reproduction should be in the National Surrogacy Board. It has also been pointed out that surrogacy is part of super specialized field and there should be adequate representation from related professional associations.

5.129 There was another suggestion that an independent Registrar having a law degree be appointed in the Board to explain the implications of the surrogacy agreement to the parties after obtaining their consent. He should register the surrogacy agreement in the Register to be kept separately by the State Boards.

Department's Response

5.130 The Department has clarified that the Bill already incorporates the members from specialized fields in the National Surrogacy Board and the Appropriate Authority will be the monitoring and implementing body in the State and Union Territory.

Recommendation

5.131 **The Committee notes that there are twenty four members in the Board representing various Government bodies and specialized fields. They may be from amongst medical geneticists, human embryologist, gynaecologist, obstetrician, experts from stri-rog, prasuti-tantra, social science, women welfare organization, and representatives from the civil society working on women's health and child issues possessing requisite prescribed qualifications and experience. The Committee also notes that the National Board of Assisted Reproductive Technology in the draft ART Bill, 2014 is represented by experts from the field of assisted reproduction, andrology, mammalian reproduction, biomedical sciences, embryology, bioethics, gynaecology, social science, law or human rights, public health and civil society representatives apart from the officials from Government bodies. Since the National Surrogacy Board is a critical instrument for advising the Government on policy matters relating to surrogacy and supervising various bodies constituted under the Act, it is important that there should be appropriate mix of different categories of professionals in the Board who could help the Board play its designated role effectively. The Committee, therefore, recommends that the composition of the National Surrogacy Board may be modelled on that of the National Board of Assisted Reproductive Technology in the ART Bill, 2014. The Committee also sees logic in having a Registrar at the national level Board having in-depth legal knowledge of the concerned subject. The Committee, accordingly, recommends to the Department to include a Registrar in the Board who would facilitate the surrogacy procedure informing the legal implications of the surrogacy agreement to the concerned parties.**

Clause 22: Functions of Board.

5.132 Clause 22 deals with functions of Board and reads as under :

22. The Board shall discharge the following functions, namely:—

(a) to advise the Central Government on policy matters relating to surrogacy;

(b) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein;

(c) to lay down code of conduct to be observed by persons working at surrogacy clinics; to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(d) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(e) to supervise the functioning of State Surrogacy Boards; and

(f) such other functions as may be prescribed.

Suggestions

5.133 It has been suggested that the regulatory authority should also maintain a Registry for surrogates, ART banks and fertility clinics.

Department's Response

5.134 The Department is silent on the matter.

Recommendation

5.135 **Keeping in mind the complexities and ambit of the surrogacy procedures and to effectively regulate and monitor the entire spectrum of this field, the Committee appreciates the need to keep a record of all the cases of surrogacy from the beginning of the process till its end. Having a centralized database at the National level would be a step in right direction so as to monitor the surrogates, surrogacy clinics and the commissioning parents. All State Surrogacy Boards should be required to submit to the National Surrogacy Board, data on the surrogacy services and arrangements. Therefore, the Committee is in unison with the suggestion of keeping a registry at the national level having details of the registration and conduct of every surrogacy clinic, surrogacy arrangements, including its stakeholders, taking place across the country. Such a registry will also help in tracking the surrogate mothers who will act as surrogate only once in their lifetime. The Committee, therefore, recommends the Department that a National Registry should be maintained on similar lines as in the ART Bill, 2014 which contains details of all the ART clinics and ART banks, nature and type of services provided, outcome of the services etc.**

Clause 23: Constitution of State Surrogacy Board

5.136 Clause 23 deals with Constitution of State Surrogacy Board and reads as under:

23. Each State and Union Territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union Territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(i) to review the activities of the appropriate authorities functioning in the State or Union Territory and recommend appropriate action against them;

(ii) to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(iii) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and

(iv) such other functions as may be prescribed.

Suggestions

5.137 It has been pointed out by stakeholders that the State Board is given under Chapter-V titled National Surrogacy Board whereas the State Board should have been under a separate chapter. The State Surrogacy Board should have members who have the knowledge and experience in the field of law or human rights, bioethics and assisted reproduction. It has also been suggested that every State Surrogacy Board or Union Territory Board shall constitute District Surrogacy Boards for smooth implementation of the provisions of the Act at the grassroots level. This District Surrogacy Board should consist of an officer not below the rank of a Joint Secretary to the Central Government or the State Government, in-charge of the Surrogacy Division in the Ministry of Health and Family Welfare. There should also be a Registrar of the Board in each District Surrogacy Board to explain the implications of the surrogacy agreement to the parties, obtaining their consent and register the surrogacy agreement in the Register.

5.138 Stakeholders have informed that there is no mention of the reporting mechanism of the Appropriate Authority. They suggested that the Appropriate Authority should be made responsible to report its activity to the National and State Surrogacy Board regularly. Furthermore, Board' s accountability to report should also be specified in the Bill.

Department's Response

5.139 The Department is silent on these issues.

Recommendation

5.140 **The Committee recommends that the State/ Union Territory Surrogacy Board may be structured on the lines of the Committee's recommendation made in respect of the National Surrogacy Board.**

Clause 32 : Appointment of appropriate authority.

5.141 Clause 32 reads as under :

32. (1) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union Territories for the purposes of this Act.

(2) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or part of the State for the purposes of this Act.

(3) The appropriate authority, under sub-section (1) or sub-section (2), shall,—

(a) when appointed for the whole of the State or the Union Territory, consist of—

(i) an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson;

(ii) an eminent woman representing women's organisation—Member;

(iii) an officer of Law Department of the State or the Union Territory concerned not below the rank of a Deputy Secretary—Member; and

(iv) an eminent registered medical practitioner—Member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(b) when appointed for any part of the State or the Union Territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Suggestions

5.142 The stakeholders have suggested that the Appropriate Authority should consist of members who have the knowledge and experience in the field of bioethics and assisted reproduction.

5.143 They mentioned that the Bill provides for only one civil society member in Appropriate Authority. According to them, more civil society members should be included in the Appropriate Authority, the National Board and also in State Boards in order to bring transparency in implementation. Moreover, the medical practitioner should be from Government Sector, so that s/he has less or no business interest out of the surrogacy arrangements.

Department's response

5.144 According to the Department the provision as suggested has already been incorporated in the Bill.

Recommendation

5.145 **The Committee agrees with the suggestion of having a wide representation of members from surrogacy related fields. The Committee recommends to the Department to include experts having knowledge and experience of bioethics and assisted reproduction and also have more than one civil society member as the whole arrangement of surrogacy has social, psychological, physical and emotional implications for all involved in the procedures. The Committee also recommends that a single window system should be set up for registration and reporting of surrogacy clinics so that it is easier for the clinics to follow the law.**

Clause 35: Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

5.146 Clause 35 provides as under :

35. (1) No person, organization, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(a) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organized group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(b) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(c) abandon or disown or exploit or cause to be abandoned, exploited or disowned in any form the child or children born through surrogacy;

(d) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(e) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(f) import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures.

Suggestions

5.147 The Committee has received various suggestions for and against commercial surrogacy practices, which have been dealt with under Clause 2(f) in earlier part of this Report. On some other issues like exploitation of the surrogate mother, the surrogate child, sex-selective surrogacy, sale of gametes, etc., the following suggestions/submissions were received by the Committee:

(a) The Surrogacy Bill prohibits and penalizes "exploitation of surrogate mother" but the term "exploitation of surrogate mother" is not defined in the Surrogacy Bill. There is no prohibition, no offense of "human trafficking, abduction or inter country movement of surrogate mother for bodily exploitation for gestation, extracting oocytes (eggs)/gametes" without their consent under force or coercion or threat or under deception, for commercial purposes or vested interest. Therefore, it is suggested that the Surrogacy Bill may include all such possible means of exploitation and be declared a punishable offense under Surrogacy Bill.

(b) As regards exploitation of surrogate child, it has been pointed out that there is no prohibition, no offense of "human trafficking, abduction or inter-country movement of child born out of surrogacy in the proposed Bill." Though the Surrogacy Bill prohibits "exploitation of surrogate child," the term "exploitation of surrogate child" is not described or defined in the Bill. Considering the illicit practices of child trafficking under the garb of surrogacy at national and at international level, it has been suggested that the term "exploitation of surrogate child under surrogacy" should provide for abduction, trafficking or sale, auction and inter-country movement of child conducted in the guise of surrogacy.

(c) It has also been pointed out that the Surrogacy Bill is silent on incorporating relevant provisions on the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994. There is no prohibition, no offense of "sex selective surrogacy" or surrogacy to have child of a pre-determined sex" or no prohibition on conduct of sex selective techniques (pre-natal, post-natal) in guise of surrogacy to have child of desired

sex, no prohibition on "use of pre genetic diagnosis (PGD) for detection of sex-linked genetic disorders" by screening for carriers of X-linked, Y-linked genetic diseases thereby causing sex selective surrogacy. It has been suggested that a strict prohibition on such practices and penalization on the "sex selective surrogacy" needs to be in place.

(d) Another issue that has been raised is that there is no offense, no punishment, no penalization on the practice of Twiblings *i.e* "using of two surrogate mothers" for successive embryo transfers at the same time or simultaneously by the same intending couples. This Twibling is associated with multiple embryo transfers or multiple pregnancies among surrogate mothers which is highly dangerous to the health of surrogate mothers and is a grave misuse of surrogacy. Therefore, it has been suggested that there should be strict prohibition and penalization on couples who use more than one surrogate at any given time.

(e) Stakeholders have pointed out that prohibition on sale of gametes *i.e.,* human sperm and egg will also prohibit the availability of human sperm and egg to infertile couples for in-vitro fertilization and surrogacy.

Department's Response

5.148 The Department has not addressed the concerns raised in the above suggestions.

Recommendation

5.149 **The Committee in the earlier part of this Report has recommended that compensated surrogacy be permitted. The Committee recommends that the spirit of the Committee's recommendation in this regard be captured and Clause 35 be modified accordingly. As regards the exploitation of surrogate mothers and children born through surrogacy, the Committee notes that the Bill lacks clarity about certain specific offences like human trafficking, abduction or inter-country movement of surrogate mother or child for surrogacy purposes. Therefore, the Committee recommends that the Bill should have explicit provisions prohibiting inter-country movement of surrogate mother or child.**

5.150 **The Committee has noticed that although Clause 7 provides for prohibition to abandon the child born through surrogacy on the reasons of the sex of the child; it nowhere prohibits sex selective surrogacy. It again does not prohibit conduct of sex selective techniques (pre-natal, post-natal) in the name of surrogacy to have a child of desired sex and on use of pre-genetic diagnosis for detection of sex-linked genetic disorder. In view of the above, the Committee feels that the whole purpose of the Bill would get defeated if there is no provision on sex selective techniques/surrogacy which may lead to exploitation of surrogate mother and child. Therefore, the Committee recommends that the provisions of the Bill may be harmonized with relevant provisions of Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and suitable drafting changes be made in the Bill.**

5.151 **The Committee treats the practice of twiblings as a grave offence which directly leads to exploitation of the surrogate mother. Considering the high chances of such misconduct and its**

associated risks for the well being of the surrogate mother, the Committee recommends that the Bill should have specific provisions for prohibition of such a practice and penalization of couples and clinics on utilizing two surrogates for same intending couple at same time.

5.152 **The Committee notes that selling and buying human gametes or embryos for surrogacy is prohibited as per the provisions of the Bill and involvement of a third party *i.e.* donors who would donate egg/sperm are nowhere mentioned in the Bill. The Committee has already dealt with this issue in the earlier part of this Report and therefore, recommends even at the cost of sounding repetitive that the Bill should include adequate provision of donors for gametes for the use of intending couple during surrogacy procedure.**

Clauses 35(2), 36, 37, 38 : Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy; Punishment for contravention of provisions of Act; Punishment for initiation of commercial surrogacy; Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

5.153 Clauses 35(2), 36, 37, 38 read as under :

> ***Clause 35(2):*** *Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of Clauses (a) to (f) of sub-section (1) (of Clause 35) by any person shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.*
>
> *36. (1) Any registered medical practitioner, gynaecologists, paediatrician, human embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in section 35), rules and regulations made thereunder shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to ten lakh rupees.*
>
> *(2) In case of subsequent or continuation of the offence referred to in sub-section (1), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.*
>
> *37. Any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person for commercial surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.*
>
> *38. Whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment*

for a term which shall not be less than three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Suggestions

5.154 The Surrogacy Bill enumerates a series of grounds for culpability for couples including commissioning commercial surrogacy. These provisions of Surrogacy Bill by imposing penal sanctions on intending parents cause criminalization for exercising reproductive rights, family making choices, privacy rights.

5.155 The nature and quantum of criminal sanctions on Intending Couples under Surrogacy Bill has been referred as unjustified and unreasonable. The quantum of punishment extends to ten years that is close to a life time imprisonment and the offences are non bailable. Considering the medical condition and background of the couples, it may be noted the couples, are not hardened criminals who need reform, repentance, correction. They neither cause law and order problem nor are they a threat to larger community if left in society. Hence, such stringent, excessive punishment for the same may not be justified. It is important to note that there is no element of criminality in a surrogacy arrangement, nor do the couples or individuals bear any malice or criminal intent. Therefore, making such innocent, bonafide couples or individuals suffer such severe imprisonment alongwith fine would serve no purpose of justice or reform, repentance or deterrence but only impose culpability penal sanctions on the innocent.

5.156 It has also been pointed out by stakeholders that the criminal provisions in the current Bill do not adhere to basic principles of criminal law and basic constitutional guarantees. For instance, Sections 35(2), 36, 37 and 38 provide for minimum punishments without stipulating the maximum punishment. This clearly violates Article 20 (1) of the Constitution.

5.157 It has been pointed out that imposing criminal sanctions would affect surrogate child's interest. Criminal actions on intending couples or individuals may gravely prejudice interest of child born through such surrogacy. The rights of child including right to parentage, custody, citizenship would be affected. Any such punishment would separate the child from its own biological parents, the child would be abandoned, denied of custody care arrangement which would make the child vulnerable to being declared parentless, stateless, state orphaned.

Department's response

5.158 The Department is silent on this issue.

Recommendation

5.159 **The Committee notes that Clause 36(1) deals with punishment for surrogacy professionals or any other person who owns a surrogacy clinic or is employed with such a clinic or centre etc. and renders his professional or technical services. This Clause stipulates imprisonment for minimum five years and fine upto ten lakh rupees. The Committee would like to emphasize that transgressions which are purely procedural or technical in nature should be viewed in a broader perspective and should not invite stringent provisions. On the other hand, the fraudulent practices**

and activities should be dealt with severely and in a deterrent fashion. The Committee would therefore, recommend that the gravity of punishment in Clause 36(1) be modified suitably.

5.160 **The Committee agrees with the contention of the stakeholders that surrogacy and its related procedures are not criminal activities. It is a procedure which is an advancement in the medical science in the field of assisted reproductive technology to have a biological child for infertile couple or for those who are unable to have their own child due to medical reasons. It is also true that the concerned parties are neither criminals nor are they threat to the society. Moreover, penal sanctions on the commissioning parents would have a definite impact on the surrogate child. The child would be separated from his/her own biological parents, and would be denied of custody care arrangement defeating the very purpose of the Bill.**

5.161 **In view of the above, the Committee is of the view that punishment should be commensurate with the level or degree of infraction committed. Minor infractions of law should be considered in mild manner and not carry any criminal liability. Also, if default is unintentional, the same should be taken into consideration without rigidly giving a harsh punishment. The Committee, accordingly, recommends that Clause 37 may be modified suitably, keeping in view the best interest of the surrogate child.**

5.162 **The Committee also notes that the criminal provisions as contained in Clauses 35, 36, 37 and 38 provide for a minimum punishment and no maximum punishment, which is unheard of in any criminal legislation. This is indicative of the fact that the Department has not exercised the required due diligence at the time of drafting the Bill. The Committee, therefore, recommends that the necessary modifications relating to the maximum punishment be incorporated in the Bill.**

VI. MISCELLANEOUS POINTS

6.1 The Committee has received many submissions containing issues and concerns that have been raised by the stakeholders with respect to the proposed Surrogacy (Regulation) Bill, 2016 that have not been considered in the said Bill or have not been given due importance. On examining these issues, the Committee found them relevant for surrogacy and related procedures and worth incorporating in the Bill. These are as follows:

(i) SURROGACY AGREEMENT

Suggestions

6.2 The Committee has received various suggestions regarding incorporating a provision of surrogacy agreement in the proposed Bill in the languages understood by all the stakeholders of the surrogacy arrangement. It has been suggested that surrogacy agreement should be a duly signed, notarised and registered written agreement made prior to the initiation of surrogacy procedure between the intending couple and the woman chosen to be the surrogate to have a binding effect on the intending couple to take the delivery of baby/babies born out of surrogacy, irrespective of any condition/abnormalities in the baby. This would also give protection to surrogate in case abnormal baby/babies is/are born.

6.3 It has been suggested that instead of two separate agreements first between commissioning parents and surrogate mother and second between IVF clinic and the surrogate mother, a tripartite agreement between the commissioning parents, the surrogate mother and the IVF Clinic should be provided for, because the rights and liabilities of all three parties are intertwined and interdependent on the performance of the parties.

6.4 Ministry of Women & Child Development is of the opinion that every surrogacy should be backed by a comprehensive legally binding agreement between the intending parent(s) and surrogate mother.

Department's Response

6.5 The Department in response to the suggestion of having a provision of surrogacy agreement has stated that the parental order will be equal to a surrogacy agreement passed by the court of the Magistrate of the first class or above.

Recommendation

6.6 **The Committee is of the view that mere parentage order issued by the first class magistrate will not suffice. If the intent of the Bill is to protect the surrogate mothers and children, it must provide a legal framework for a comprehensive surrogacy agreement containing all safeguards. The agreement should mandatorily provide insurance, monetary compensation to surrogates, the manner of its disbursement and pre/post delivery care of the surrogates. It should also contain a provision for nourishment of the surrogates not just during the pregnancy but also in the post partum period; comprehensive healthcare for a period of five years starting from the date any medication for surrogacy procedure is begun; legal, medical and psychological counselling etc. Since the surrogates are predominantly uneducated, the contract should be made available in the language they fully understand and should be explained properly to them. The surrogacy agreement should be registered also. The jurisdiction for registration should lie before the Registrar where surrogate mother resides or where the intending parents reside or where the agreement is executed. Since a surrogacy agreement is a legal document, it will act as bedrock of the surrogacy arrangement and shall have a legal binding on all the parties involved in the surrogacy and help in solidifying the rights and duties of both the participants to the arrangement. Therefore, the Committee recommends that an agreement of surrogacy among all the stakeholders of the facility *i.e* the intending parents, surrogate mother and the surrogacy clinic should be made a mandatory document for the surrogacy arrangement for them. Necessary amendments/alternate Clauses may accordingly be incorporated in the Bill.**

(ii) **CHILD RIGHTS**

Suggestions

6.7 It has been submitted that in the development of surrogacy in India the child in the womb is at the centre of whole surrogacy arrangement, and is as such entitled for legal protection against any acts of commission and omission by the other parties to the contract. Therefore, an Act for protection of unborn child is required to be enacted simultaneously. After all, the entire purpose is to complete the

family of the infertile couple and bring them joy and happiness. The proposed Bill does not incorporate sufficient safeguards for the protection of the rights of children born through surrogacy. In UK, Congenital Disabilities/Civil Liabilities Act 1976 provides for the protection of the rights of the unborn child.

6.8 The fact that the Surrogacy Bill fails to provide for insurance for the child born through surrogacy proves that it overlooks such situations where commissioning or intending parents may incur death, disability, sickness during the process of surrogacy leaving the child parentless at birth. It was suggested that the Bill requires commissioning couples to secure appropriate insurance for child or children the surrogate delivers, at the time of signing the agreement through an appropriate Insurance Policy like Jeevan Balya for maintenance of the child up till the age of twenty-one years.

6.9 It has also been suggested that a definition of "Surrogate child" should be added in the Bill which means: ' a human life which is conceived in womb of surrogate mother by process of surrogacy. A surrogate child, on conception till birth and thereafter shall be deemed to be a surrogate child of intended couple.

Department's Response

6.10 The Department has stated that rights of child born through surrogacy have already been incorporated in the Bill.

Recommendation

6.11 **The Committee strongly believes that the interest of the surrogate child needs to be secured in all situations including unforeseen contingencies. The Committee, therefore, recommends that the Bill should have a comprehensive provision entailing adequate insurance coverage for the unborn child. The Committee is of the view that mere insurance for the surrogate child would not suffice and recommends that the Bill should contain provisions for Bank guarantees/fixed deposits for taking care of the expenses of the surrogate child in any emergent situation. Such a cover would ensure financial support for the surrogate child in case of any eventuality. It would also ensure cover for a child born with any abnormality/disability. It would also be the responsibility of the State Government to take care of all abandoned children born out of surrogacy.**

6.12 **The Committee recommends that surrogate child is defined separately in the Bill so as to distinguish the surrogate child from a child born to a couple who have undergone ART procedures themselves.**

(iii) **PROVISION FOR BREAST MILK FOR SURROGATE CHILD**

Suggestions

6.13 Various stakeholders have suggested that the Bill should make provision for breastfeeding after the delivery of child or provide that the surrogacy agreement should have mandatory provision for the same. In this regard, the Ministry of Women and Child Development submitted that care should be taken to monitor that child/children born out of this arrangement are provided with six months of breastfeeding and for the purpose, facilities of Breast Milk Banks etc. may be utilized.

Department's Response

6.14 The Department has submitted that it would consider to incorporate the suggestions during framing of rules and regulations.

Recommendation

6.15 **The Committee observes that the provision of breastfeeding or making available breast milk for child born out of surrogacy finds no place in the proposed Bill. It is the right of the child to have mother's milk for adequate nutrition for his/her well being. As regards the way mother's milk is provided to the child, the Committee is of the view that the provision of breast milk should be allowed by way of Human Milk Bank services only and not by direct breastfeeding by surrogate mother as six months of breast feeding will establish an emotional attachment of surrogate child with the surrogate mother. It would be very difficult for the surrogate mother to give up the child leading to complications. Therefore, the Committee suggests that the surrogate child should get mother's milk for initial six months and recommends the Department to include a provision in the Bill for providing breast milk to the surrogate child through Human Milk Bank services only.**

(iv) **BIRTH CERTIFICATE**

Suggestions

6.16 It has also been given to note that The Birth Registration Act provides for recognition of birthing mother as "natural mother" or "natural parent". Accordingly, the name of birthing mother is registered in the birth certificate as mother for all legal purposes.

6.17 It has been pointed out by stakeholders that the Bill has no provision on "birth certificate" of child born of surrogacy. It is suggested that the Surrogacy Bill may provide for issue of birth certificate to child born of surrogacy, indicating the names of intending couple who commissioned surrogacy. Therefore, it has been suggested that the existing Birth Registration Act may be amended by making a provision in case of child born of surrogacy through assisted reproductive technology by allowing the name of women commissioning surrogacy to be placed in the birth certificate, not the birthing or surrogate mother as an exception.

Department's Response

6.18 The Department has stated that a parental order passed by the court of the Magistrate of the first class or above will be equal to a birth certificate.

Recommendation

6.19 **The Committee notes that there is no such provision regarding birth certificate in the Surrogacy Bill while such provision is there in the draft ART Bill, 2014. The Committee notes that the Bill provides for an intending couple to get a parentage order from Court to establish their parentage over the surrogate child. The Committee recommends that the Bill should also have the provision of birth certificate which is a legal document for the child born out of**

surrogacy with the names of the commissioning parents on it and for the requirement of date of birth of the surrogate child. Since in surrogacy arrangement, the birth mother is not genetically related to the child, logically her name should not be written on the birth certificate. Therefore, the Committee agrees with the suggestion of making an amendment in the Birth Registration Act for the cases of surrogacy arrangements in order to avoid legal complexities related to parentage of the child born out of surrogacy. Therefore, the Committee recommends to the Department to incorporate the provision of birth certificate of the surrogate child in the Surrogacy Bill and to take up the matter with relevant authorities to make necessary amendments in the existing rules of registration of birth.

(v) **DEFINITION OF GAMETE DONORS**

Suggestions

6.20 It has been pointed out by some stakeholders that the Surrogacy Bill has not defined the gamete donors and the process of seeking gamete donors (egg and sperm donors).

Department's Response

6.21 **The Department is silent on this issue.**

Recommendation

6.22 **The Committee notes that the Bill allows only Gestational surrogacy wherein the surrogate mother would only assist in carrying pregnancy and hand over the surrogate child to the intending couple. However, there is no definition of gamete donors in the Bill and no mention of process of seeking human gamete donors for the purpose of surrogacy. Since gamete donation is part of surrogacy procedure and may entail huge scope of exploitation associated with the related procedures, the Committee feels that it is important to specify the role of gamete donors in the Surrogacy Bill. Also, as recommended earlier, the national registry would have a database of such donors too. Therefore, the Committee recommends to the Department to include the definition of gamete donors in the Bill appropriately. The Committee also recommends that egg donation should not be allowed as a profession and a woman should be permitted to donate her eggs only once in her lifetime.**

(vi) **DISPUTE RESOLUTION SYSTEM**

Suggestions

6.23 Some stakeholders have raised concern over the absence of provision for dispute resolution in the proposed Bill. It has been suggested that a mandatory counselor at the Surrogacy Clinic should act as a mediator for any disputes that arises in the surrogacy arrangement.

Department's Response

6.24 The Department is silent on this issue.

Recommendation

6.25 The Committee notes that the Bill does not provide for any dispute resolution mechanism between the surrogate mother, intending parents and the clinic. In case of any conflict of interest or disagreement between the surrogate mother and the intending couple, the surrogate mother has no one to advocate her case. To handle such issues that can be dealt at the clinic level, there is a need to have an independent agency for resolution of disputes or redressal of any grievances of any of the parties involved in surrogacy process. The authority so created should have quasi-judicial powers to get its orders implemented. The Committee, accordingly, recommends to the Department to have an agency/body for the said purpose and incorporate enabling provisions to this effect in the Bill.

(vii) **PROVISION FOR DNA TESTING**

Suggestions

6.26 Some of the stakeholders raised concern over the lack of provision in the Bill to have a scientific proof of parentage of intending couple about the child born through surrogacy.

Recommendation

6.27 **The Committee notes that there is no provision in the proposed Bill to have a scientific proof to establish parentage of the intending couple over their child born through surrogacy. In order to avoid any kind of custody disputes between the surrogate mother and the intending couple or to confirm the genetic connection between the child and intending couple, there should be a scientific mechanism to establish the fact that the child born through surrogacy is the biological child of the intending couple which can be done through DNA Testing. The Committee also feels that DNA testing can help in determining parenthood of intending couple so that surrogacy clinics do not indulge in any kind of unethical practices. The Committee, therefore, recommends to the Department to incorporate the provision allowing DNA testing in the Bill in circumstances where there is need to have genetic determination of parenthood in any surrogacy arrangement so that surrogacy clinics do not indulge in any kind of fraud.**

(viii) **ASSISTED REPRODUCTIVE TECHNOLOGY (ART) (REGULATION) BILL**

6.28 The Committee has observed that the Assisted Reproductive Technologies (Regulation) Bill, drafted in 2008, was subjected to frequent reviews and redrafting once in the year 2010, then in the year 2014. The Bill aimed at proper regulation and supervision of Assisted Reproduction Technology (ART) clinics and banks in the country and for prevention of misuse of this technology including surrogacy and for safe and ethical practice of ART services. At present, the ART (Regulation) Bill is under consideration in the Department of Health Research, Ministry of Health & Family Welfare, Government of India.

6.29 The Committee has been given to understand by the stakeholders that the ART Bill has been pending before the Government for long and the Surrogacy (Regulation) Bill, 2016 has been brought by passing the ART Regulation Bill. On being asked about the reasons for suddenly introducing the Surrogacy (Regulation) Bill, the Department has stated that they would soon bring the ART Regulation Bill after the Surrogacy Bill.

6.30 One of the stakeholders submitted before the Committee that the very essence of the Surrogacy (Regulation) Bill, 2016 was explained in the ART Bill and hence there cannot be a Surrogacy Bill without ART Bill. She was of the view that Surrogacy Bill cannot be passed in isolation as the procedure of surrogacy cannot take place without Assisted Reproductive Technology. Surrogacy Bill was already included in ART Bill and by not passing the ART Bill along with the Surrogacy Bill, many problems could come to surface. She also pointed out while drafting the Surrogacy (Regulation) Bill, that no one from the Drafting Committee of Government of India were consulted.

6.31 It has also been pointed by stakeholders that the Surrogacy Bill does not touch various points related to ART like surrogacy agreement, gamete donor, ART banks and clinics, records, foetal reduction, provision of National Registry of ART Banks and clinics, duties of ART clinics etc. Further, many provisions of the ART Bill have been drafted with more clarity and precision when compared with the Surrogacy Bill like definitions of surrogacy, surrogate mother & infertility, organization structure, powers and functions of the regulatory bodies etc.

6.32 **The Committee observes that the Assisted Reproductive Technologies (Regulation) Bill, 2008 had been drafted in 2008 and revised in 2010 and 2014. Since then, it has been lying with the Government. Moreover, the draft ART Bill also included provisions on regulation of surrogacy facilities. The Committee takes note of the inordinate delay in bringing forth the draft ART Bill especially in view of the fact that there has been mushrooming of ART clinics across the country offering various services from IVF to surrogacy etc. The Committee fails to comprehend the reasons behind bringing a fresh Bill specifically on surrogacy, when a detailed, comprehensive and all en-compassing Bill on ART services had already been drafted by the Department. The Committee, therefore, would like to be apprised of the reasons behind such prompt decision to bring a separate legislation for surrogacy without the ART Bill.**

6.33 **The Committee strongly believes that with the rapid advancement of science and technology in all spheres of life, there is an urgent need to regulate the use of modern techniques especially w.r.t. assisted reproduction and use of ART for surrogacy. Hence, the Committee feels that along with surrogacy regulation, there is urgent need to regulate the ART clinics across the country. It is a fact that surrogacy procedures cannot be conducted without assisted reproduction techniques and therefore, mere enactment of the Surrogacy Bill would not serve the purpose of controlling commercialization of the surrogacy facilities across the country in the absence of regulation of assisted reproductive clinics and banks where surrogacy is being conducted as ART Clinics and Surrogacy Clinics are not separate. The Committee, therefore, strongly recommends that the ART Bill should be brought forth before the Surrogacy (Regulation), Bill, 2016.**

RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE

V CLAUSE BY CLAUSE EXAMINATION OF THE BILL

The Committee is of the view that since the proposed Bill is an attempt to regulate the practice of surrogacy and protect the interest of the surrogate mother and child, it is essential to define the term 'abandoned child' appropriately. Protection of the interests and rights of the child born out of surrogacy is the essence of this proposed legislation. The definition of 'abandoned child' as given in the present form fails to explain the meaning clearly as the three sub Clauses of Clause 2 (a) in (i), (ii) & (iii) indicate three different conditions which are liable to misinterpretation. The Committee recommends that the three conditions have to be read together to make the definition of abandoned child proper and to ensure that there are no ambiguities in the proposed legislation. Therefore, this Clause should be reframed in the following manner after legislative vetting:-

'abandoned child means a child born out of surrogacy procedure, deserted by his intending parents or guardian and who has been declared as abandoned by the appropriate authority after due enquiry'. (Para 5.5)

The Committee has come across different views of various stakeholders with regard to altruistic surrogacy. The Committee notes that as of now except for the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India 2005 of ICMR, there are no binding rules or legislation for the protection of surrogates. Since ICMR guidelines do not have the force of law, they provide little protection for surrogate mothers. The paramount objective of this Bill is to control the exploitation of poor surrogate mothers and safeguard their interests by banning commercial surrogacy because surrogate mothers mostly come from the lowest socio-economic strata who are doing surrogacy for money and are being exploited in the process. It has been argued before the Committee that poor women who become surrogates are not capable of exercising real autonomy since they are in such dire economic situations that they are coerced by their circumstances to engage in surrogacy. The Committee observes that there is no doubt that as of today there is a potential for exploitation and the surrogacy model that exists today can and does exploit surrogate women. But this potential for exploitation is linked to the lack of regulatory oversight and lack of legal protection to the surrogate and can be minimized through adequate legislative norm-setting and robust regulatory oversight. (Para 5.17)

The Committee learnt from the surrogate mothers who appeared before the Committee that they engaged themselves in surrogacy out of economic necessity and saw surrogacy as a means of economically uplifting their families. Surprisingly, their other economic options were equally, if not more, exploitative and nowhere close to being as remunerative as surrogacy. The Committee is, therefore, of the view that economic opportunities available to surrogates through surrogacy services should not be dismissed in a paternalistic manner. Permitting women to provide reproductive labour for free to another person but preventing them from being paid for

their reproductive labour is grossly unfair and arbitrary. The Committee would like to observe that if many impoverished women are able to provide their children with education, construct home, start a small business, etc. by resorting to surrogacy, there is no reason to take this away from them. (Para 5.18)

The Committee is of the view that altruistic surrogacy is another extreme and entails high expectations from a woman willing to become a surrogate without any compensation or reward but a decision based on noble intentions and kindness. Pregnancy is not a one minute job but a labour of nine months with far reaching implications regarding her health, her time and her family. In the altruistic arrangement, the commissioning couple gets a child; and doctors, lawyers and hospitals get paid. However, the surrogate mothers are expected to practice altruism without a single penny. (Para 5.19)

The Committee, therefore, finds merit in the argument that the proposed altruistic surrogacy is far removed from the ground realities. The Committee is, therefore, of the view that expecting a woman, that too, a close relative to be altruistic enough to become a surrogate and endure all hardships of the surrogacy procedure in the pregnancy period and post partum period is tantamount to a another form of exploitation. (Para 5.20)

The Bill limits the circle of choosing a surrogate mother from within close relatives. Given the patriarchal familial structure and power equations within families, not every member of a family has the ability to resist a demand that she be a surrogate for another family member. A close relative of the intending couple may be forced to become a surrogate which might become even more exploitative than commercial surrogacy. The Committee, therefore, firmly believes that altruistic surrogacy only by close relatives will always be because of compulsion and coercion and not because of altruism. (Para 5.21)

Based on the analysis of the facts in the preceding paras, the Committee is convinced that the altruistic surrogacy model as proposed in the Bill is based more on moralistic assumptions than on any scientific criteria and all kinds of value judgments have been injected into it in a paternalistic manner. Altruistic surrogacy across the world means compensated surrogacy and a range of monetary payments to surrogate mothers are permitted as reasonable compensation. Even the Law Commission Report No. 228 of 2009 recommends reimbursement of all reasonable expenses to the surrogate mother. The Committee, therefore, recommends that the word "altruistic" in Clause 2 (b) of the Bill be replaced with the word "compensated" and appropriate modifications be incorporated in the said Clause and other relevant Clauses of the Bill with a view to harmonizing the Bill with the compensated surrogacy model. (Para 5.22)

The Committee takes note of the view of the Department of Health Research that surrogacy is a privilege and should be resorted to in exceptional circumstances only and that adoption should be the first preference for family formation. The Committee is also aware of Central Adoption Resource Agency (CARA) study of March, 2016 to the extent that only 1600 odd children were available for adoption while 7700 applications from prospective parents for adoption were received. Out of the 1600 children available for adoption, 770 were normal and the rest were

those with special needs. Also, the waiting time for adoption in India is one to three years. The Committee is, therefore, unable to comprehend as to how the adoption route would be an answer to infertility which is growing in India. The Committee also observes that adoption is a benevolent choice available to the community at large and the Government cannot force adoption *in lieu* of surrogacy. Surrogacy and adoption have to be an equal choice and in the name of adoption, the Government cannot take away the reproductive rights of couples to have a biologically related child through surrogacy. (Para 5.23)

The proposed Bill has confined the expenses to "medical" and insurance coverage to surrogate mother during the process of surrogacy which has narrowed down the expenses incurred on the surrogate mother only. There is no scope for the other reasonable expenses. The Committee is of the view that medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother are not the only expenses incurred during the surrogacy pregnancy. For any woman who is going through surrogacy, there is a certain cost and certain loss of health involved. Not only will she be absent from her work, but will also be away from her husband and would not be able to look after her own children. The Committee, therefore, recommends that surrogate mother should be adequately and reasonably compensated. The quantum of compensation should be fixed keeping in mind the surrogacy procedures and other necessary expenses related to and arising out of surrogacy process. The compensation should be commensurate with the lost wages for the duration of pregnancy, medical screening and psychological counseling of surrogate; child care support or psychological counseling for surrogate mother's own child/ children, dietary supplements and medication, maternity clothing and post delivery care. The Committee also recommends that in case the surrogate mother dies in the course of surrogate pregnancy or while giving birth to the surrogate child, additional compensation should be given to the kin of the surrogate mother. (Para 5.24)

The Committee observes that the surrogacy industry in India is currently governed by the private contract model which relies on the bargaining power of the parties in setting the terms of the contract and its enforcement. Since there are enormous inequalities in the bargaining power of surrogates *vis-à-vis* medical clinics and commissioning parents due to surrogate's illiteracy, socio-economic marginalization and lack of access to legal representation, the chances of exploitation of surrogate mothers are immense. The Committee, therefore, recommends that the amount of compensation should be fixed by relevant authorities and the compensation so fixed should not be the subject matter of bargain between the commissioning couple and the surrogate mother. The Committee further recommends that the compensation to surrogates should be guaranteed from the moment they begin any use of medication in connection with surrogacy procedures and the money should be deposited directly in their bank accounts, by the commissioning parents. (Para 5.25)

The Committee would simultaneously like to observe that surrogacy cannot be a way out for women opting for surrogacy due to poverty and should not be allowed as a profession. In fact, the Bill rightly provides that no woman can become a surrogate more than once. It is, indeed, sad that the burden of the whole poverty striken family falls on the woman who resorts to

becoming a surrogate to earn quick money. As suggested by National Commission for Women, education and vocational training should be given to women so that they can be financially empowered. However, the Committee taking cognizance of the harsh realities of the poverty striken families cannot simply suggest to take away the opportunity surrogacy provides to a family to better their lives. (Para 5.26)

The Committee notes that the Bill limits the option of surrogacy to legally married Indian couples. The Committee observes that limiting the option to avail surrogacy facilities to an Indian heterosexual married couple to have their own biological child has overlooked a large section of the society. Given our sentiments and sensibility, the social status of a woman in our society is judged by her reproductive life and there is a lot of pressure on her for child bearing. The Department of Health Research by imposing prohibition on widows and divorced women seems to have closed its eyes to the ground reality. Besides, the decision to keep live-in partners out of the purview of the Bill is indicative of the fact that the Bill is not in consonance with the present day modern social milieu that we live in and is "too narrow" in its understanding. Even the Supreme Court has given legal sanctity to live-in relationships. Surrogacy is one of the least used options by childless Indians. If all these categories are to be banned then why have surrogacy at all. The Committee, therefore, recommends that the Department should broadbase the eligibility criteria in this regard and widen the ambit of persons who can avail surrogacy services by including live-in couples, divorced women and widows. Appropriate alterations accordingly be made in Clause 2(g) and 4 (iii) (c) of the Bill. (Para 5.40)

The Committee would, however, observe that surrogacy is a privilege and cannot be extended to foreign nationals indiscriminately. Foreigners come to India for commissioning surrogacy because the procedure is much cheaper here. The Committee is, therefore, not in favour of extending the option of commissioning surrogacy to foreign nationals. (Para 5.41)

The Committee notes that the proposed Bill has excluded NRIs, PIOs and OCI card holders from the purview of the Bill. Based on the scrutiny of the facts put forth before the Committee, it feels that there are adequate provisions in the Bill for the Appropriate Authority to scrutinize all the documents submitted by the intending couple before commissioning surrogacy and to reject the application in case of any violation of rules and regulations. The Committee finds no point in restricting NRIs, PIOs and OCI card holders from availing surrogacy services in India. The Committee is of the view that since the NRIs, PIOs and OCIs cardholders are of Indian origin only, there should not be any prejudice and discrimination towards them when it comes to allowing them for opting surrogacy in the country of their origin. The Government has been extending several concessions to PIOs/OCIs to boost the ties of the Indian diaspora with the country of their origin. The Committee is of the view that PIOs/OCIs should not be classified along with other foreign nationals for the purpose of availing surrogacy in India. The Committee, therefore, recommends that an appropriate mechanism should be made for a complete background check of the NRIs, PIOs and OCIs cardholders who intend to commission surrogacy and they be permitted after a thorough scrutiny of their documents submitted to the appropriate authority designated for granting permission for availing surrogacy services in India. The Committee

further recommends that the intending couple should provide a specific 'declaration ' or a 'NOC' that the child born out of surrogacy would be getting the same citizenship rights as possessed by the intending couple. The Committee recommends that while foreign nationals be kept out of the ambit of surrogacy bill, Persons of Indian Origin (PIOs), Overseas Citizens of India (OCIs) and NRIs should be permitted to avail surrogacy services in the country. (Para 5.42)

The Committee also takes note of the submission of the Department of Health Research that "the five year period has been provided for the couple to avail all assisted reproductive techniques to have a child of their own". Five year waiting period for surrogate parenthood appears to be based on the impression that surrogacy, which is third party reproduction, is being resorted to as a first choice of family formation which should be checked. However, from the information made available to the Committee, it notes that surrogacy is a rare practice among childless Indian couples who try various medical options before they choose surrogacy which costs them anywhere between ₹ 15 to 20 lakh. Since surrogacy is not well-regulated in the country, specific and reliable data on surrogacy is not available. However, as per Ernst and Young Study (Call For Action: expanding IVF treatment in India, July 2015), in India, around 27.5 million couples in the reproductive age group are infertile and about one percent *i.e.* about 270,000 infertile couples seek infertility evaluation as per the Annexure IV. As per the information made available to the Committee, of the people seeking remedy for infertility, 20-25% undergo IVF treatment and of that small group, one percent may require surrogacy. Ten to Twelve percent of surrogacy is commissioned because of irreversible destruction of uterus due to TB, 8 percent because of absence of uterus, 12 percent because of multiple failed IVF cycles, 12 percent because of multiple miscarriages, 10 percent because of removal of uterus due to cancers, fibroids etc. (Para 5.43)

The Committee also notes that a lot of people are getting married in their 30's and 40's and the requirement of five year wait would adversely affect the quality of their gametes and thus impair their chances of attaining parenthood through surrogacy. Besides, this time bar of five years plausibly violates the right to reproductive autonomy, and an individual's right to exercise his choice. (Para 5.44)

Looking to all these facts there is no gainsaying that the definition of infertility as the inability to conceive after five years of unprotected coitus and the condition of subsistence of five years of wedlock as laid down in Clause 2(p) and Clause 4 (iii)(c)(II) of the Bill respectively have not been stipulated with due diligence and with due regard to the ground reality in society, well-indicated medical reasons for infertility, current scenario of late marriages and the need for safeguarding reproductive autonomy. (Para 5.45)

It is also worth mentioning that the definition of 'infertility' in the Surrogacy (Regulation) Bill, 2016 is inconsistent with the definition given by WHO and also as in the ART (Regulation) Bill, 2014 which describe infertility as the inability to conceive after at least "one year of unprotected coitus". The Committee is of the view that the fundamental right to reproduce to have a child is a part of a person's personal domain and fixing a period of five years will only

cause breach of his/her reproductive rights and delayed or deferred parenthood. In India, infertility is considered a social stigma and the infertile couples go through a lot of agony and trauma due to infertility. Since conception has many interplay functions, a five year time bar would add to the misery of already distressed intending couples. The five year waiting period is therefore arbitrary, discriminatory and without any definable logic. The Committee, therefore, recommends that the definition of infertility should be made commensurate with the definition given by WHO. The words "five years" in Clause 2(p) and 4 (iii) (c) II, be therefore, replaced with "one year" and consequential changes be made in other relevant Clauses of the Bill. The Committee further recommends that in circumstances where the need for surrogacy is absolute due to medical reasons like absence of uterus, destruction of uterus because of cancers, fibroids etc., even the prescribed one year period should be waived off. (Para 5.46)

The Bill provides that for those intending couples who have their own child who is mentally or physically challenged or suffering from life threatening disorder or fatal illnesses with no permanent cure can commission surrogacy after the approval from the appropriate authority. The Committee also notes that the Bill provides prohibition to abandon child born through surrogacy for the reasons of any genetic defects, birth defects, any other medical conditions. However, as per provisions of the Bill, a couple who is commissioning surrogacy cannot go for surrogacy again to have a normal child even in the event of child born through surrogacy having genetic and birth defects or other life-threatening disorders. The Committee fails to understand rationale behind such contradictory provisions in the Bill. This appears discriminatory. The Committee is, accordingly, of the view that all intending couples should have the right to go for second chance at surrogacy in case of any abnormality in the previous child irrespective of the fact whether the abnormal child is born through surrogacy or by other means. The Committee, therefore, recommends that necessary amendment may, accordingly, be made in Clause 4 (iii) (c). Consequential changes in other relevant Clauses of the Bill may also be made. (Para 5.47)

The Committee also recommends that Clause 4(c) III should contain an unambiguous provision to an effect that the intending couple shall produce an affidavit declaring that they do not have any surviving child. (Para 5.48)

The Committee is surprised to observe the desultory approach of the Department while drafting the proposed Bill. Interestingly, there is no university offering medical courses across the country that confers the degree of human embryology. The Committee fails to understand how the Department would utilize the services of such specialty doctors in every corner of the country when these doctors do not exist. The Department does not have the data about number of clinical embryologists working in the country. The Committee feels that in the absence of a regulatory framework for assisted reproductive technology and surrogacy procedures, dearth of these specialty doctors would add to the plight of already suffering childless couples who would be prey to the physical, mental and financial exploitation in the name of these advanced reproductive medical science facilities. Therefore, the Committee would like the Department to get their facts correct and collect information regarding the same and rephrase the definition of Human Embryologist also entailing the qualification of specialty doctors performing surrogacy

and related procedures to avoid any kind of negligent and violatory incidents. Clause 2 (n) and other relevant Clauses of the Bill may accordingly be modified. (Para 5.52)

The Committee notes that the definition of insurance as given in the Clause 2(q) does not extend to the surrogate beyond the process of surrogacy. The Committee observes that surrogate pregnancy is not a disease. However, it is not risk-free and there are certain long-term health-risks arising out of surrogate pregnancy because surrogate's complete menstrual cycles have to be altered for an embryo to be transplanted inside her womb and large doses of hormonal treatment are given. Surrogacy has also resulted in deaths of surrogate mothers in many cases. The Committee, therefore, recommends a comprehensive insurance cover for the surrogate mother covering even the after effects of surrogacy. A period of six years of medical insurance cover along with life insurance of a certain sum of money for the surrogate mother needs to be determined to cover any health complications that may occur long after delivery. The Committee is of the view that insurance for surrogate mother should be in two steps. The first step would provide insurance cover for one year from the date the surrogacy procedure starts. The second step would provide insurance cover for six years from date of confirmation of pregnancy even if there is no take home baby. The Committee, therefore, recommends that the definition of insurance may be revised accordingly. (Para 5.60)

The Committee finds that the Bill does not provide for the social security insurance for the surrogate child in the event of death of commissioning parents during the process of surrogacy. The earlier ART Bill 2014 provided the social security insurance for all the three stakeholders, *i.e.* the surrogate mother, the surrogate child and the egg donor. The Committee would, therefore, like the Department of Health Research to provide for insurance for the surrogate child in case of unforeseen contingencies like accidental death of the commissioning parents or divorce during the process of surrogacy. Accordingly, the definition of insurance for the surrogate child may also be incorporated in the Bill. (Para 5.61)

The Committee would also like to recommend to the Department to consider incorporating the provision of Maternity Benefits to the surrogate mother as well as the intending mother as both of them are involved in child birth and child rearing respectively. They both should be entitled to maternity benefits to ensure the continuity of their service and to cover loss of wages. (Para 5.62)

The Committee is of the view that suggestion of the stakeholders can be considered on the justification that the word 'legal' before the parents in the definition of the 'intending couple' will have binding effect on the couple and it will reduce the scope of exploitation of surrogate mother or the child born out of surrogacy either directly or indirectly. The suggestion on inclusion of the word "legal" before the word "parents" in Clause 2(r) of the Bill may, therefore, be examined in consultation with the Legislative Department to explore its inclusion, if necessary. (Para 5.67)

The Committee notes that the Clause 2(zb) is not clear and explicit in articulating the procedure of surrogacy holistically. The Clause does not refer to the manner of achieving surrogate

pregnancy by a surrogate mother. It does not mention pregnancy through the assisted reproductive technology either which is essentially a medical procedure by way of "in-vitro fertilization or IVF". Also, there is no mention of origin of gamete either from the intending couples or gamete donors. The definition of surrogacy provided under the Bill does not specify whether gestational or traditional surrogacy is permissible, though the Department of Health Research in its written submissions has submitted that only gestational surrogacy is allowed under the Bill. The Committee observes that the definition of surrogacy should be precise, explicit and descriptive with no scope of arbitrary interpretation. The definition of surrogacy in the draft ART Bill is inclusive of all the relevant ingredients as required to understand the surrogacy in its entirety. The Committee recommends that the definition of surrogacy as provided in the ART Bill, 2014 be included in Clause 2(zb) of the Surrogacy Bill, with specific provision for gestational surrogacy. (Para 5.71)

The Committee notes that despite Department's clarification, the way Clause 2 (ze) is worded, it would make it appear that the surrogate mother should be genetically related to the intending couple. The Committee observes that such ambiguity in the Clause would lead to arbitrariness in interpretation of the law. The Committee, therefore, recommends that necessary drafting modifications be carried out in the said Clause to stipulate that the surrogate child and not the surrogate mother will be genetically related to the intending couple. It also needs to be clarified in the Clause that only gestational surrogacy will be permissible. Other consequential changes in relevant Clauses of the Bill may also be made. (Para 5.76)

The Committee is also dismayed to observe that on the one hand the Department asserts that only gestational surrogacy is permitted under the Bill, whereas Clause 4(iii)(b)(III) advocates the concept of Traditional Surrogacy. Thus, there is an apparent contradiction between the Department assertions and provisions of Clause 4(iii)(b)(III). The Committee, therefore, recommends that the infirmity in Clause 4(iii)(b)(III) be rectified and the Clause be amended suitably so as to spell out in unambiguous terms that the surrogate mother will not donate her eggs for the surrogacy. (Para 5.77)

The Committee notes that as per Clause 4 (iii) (b) (II), only a close relative of couples is permitted to act as a surrogate mother. According to the Department this provision has been proposed with a view to avoid commercialization and stop exploitation of surrogates. The Committee is, however, of the view that the proposition of a close relative becoming a surrogate mother overlooks the various social, legal, emotional and ethical dynamics of this issue and is fraught with numerous disruptive issues for several reasons. (Para 5.78)

Curbing exploitation of surrogates has been touted as the main objective of the proposed legislation. The Bill seeks to operate from the understanding that just by changing the nature of surrogacy from commercial to altruistic and confining the practice of surrogacy in the private domain of family would end the exploitation of surrogates. Such a proposition, however, ignores the ground reality that in Indian marital homes the decision making power rarely rests with women and not so privileged or financially weak relatives who can be coerced into becoming

surrogate mothers and the chances of coercion and exploitation are even more in case of close relatives due to family pressures. (Para 5.79)

This Clause also disregards the social and cultural ethos of our country. The restriction that the surrogate mother must be a close relative of the intending couples may also result in the surrogate mother and the child developing an emotional bond given that the commissioning couple and the surrogate are accessible and related and the child is always in proximity. Such an attachment will not only have the detrimental psychological and emotional impact on the child who could feel divided between the two mothers, it may also lead to parentage and custody issues apart from inheritance and property disputes within the family. (Para 5.80)

Infertility is a real stigma in our society but undergoing surrogacy and IVF is a taboo even today in our country. For these reasons, surrogate pregnancy is a private affair and majority of the patients seeking parenthood through surrogacy want to keep their treatment private and confidential. This precondition of only close relatives to become surrogate mothers would tend to compromise their privacy by way of forcing them to declare their infertility within family. This is violative of the basic rights of privacy and reproductive autonomy of the medically infertile persons who whilst maintaining the privacy of their medical problems have the right to surrogacy from women who volunteer to be surrogate mothers. (Para 5.81)

In today's social order of nuclear families, it would be unrealistic to expect that all infertile persons will have a close relative between 25 and 35 years of age, having one child, satisfying all conditions as prescribed in the Bill and would voluntarily consent to be a surrogate mother altruistically for the infertile couples. This condition of close relative being surrogate mother will therefore cause acute dearth and unavailability of women to act as a surrogate mother and shut all options for the medically infertile for whom surrogacy is the only option to have their biological child. (Para 5.82)

Keeping in view the facts as stated above, the Committee is convinced that limiting the practice of surrogacy to close relatives is not only non pragmatic and unworkable but also has no connect with the object to stop exploitation of surrogates envisaged in the proposed legislation. The Committee, therefore, recommends that this Clause of "close relative" should be removed to widen the scope of getting surrogate mothers from outside the close confines of the family of intending couple. In fact, both related and unrelated women should be permitted to become a surrogate. Appropriate modifications may be carried out in the provisions of Clause 4(iii)(b)(II) and other relevant Clauses of the Bill to address the concerns as pointed out in the preceding paras. (Para 5.83)

Provisio to Clause 4(iii)(b)(III) mandates that the number of attempts for surrogacy procedure shall be prescribed. The Committee also takes note of the suggestion that there should not be more than four cycles of surrogacy procedures on the surrogate mother. The Committee is aware that there are risks with IVF and fertility medications and the more the cycles, greater the risks. The Committee, therefore, expresses agreement with the suggestion that 'the number of attempts for surrogacy procedures on the surrogate mother should be three cycles of assisted/ artificial reproduction techniques with a 4th, if necessary, as the last cycle'. (Para 5.86)

The Committee would, however, like to emphasize in this regard that this is a procedural aspect of surrogacy which may require periodic revision depending on the various scientific advances and progress. The Committee would like this aspect to remain in the domain of delegated legislation to ensure that frequent amendments are not warranted in the governing statute. (Para 5.87)

Any pregnancy carries with it multiple risks and surrogate pregnancy also involves the same, even more risks due to potential reaction to fertility drugs. Taking this risk for someone else is a huge commitment. Taking all factors into account, the Committee is not in favour of providing the surrogate the option of being the surrogate more than once in her lifetime. The Committee is, however, inclined to accept the suggestion on raising the upper age limit of the surrogate mother from 35 years to 39 years. (Para 5.88)

The Committee understands that if the pregnancy of a woman, who has acted as a surrogate mother, does not mature due to abortion, she will be allowed to volunteer to be a surrogate mother again. However, there are no explicit provisions in the Bill to this effect. It is a cardinal principle of law that there should be no ambiguity in the law and therefore, suitable changes be made in the definition of the surrogate mother encompassing the above stated position to avoid any ambiguity on this aspect. (Para 5.89)

The Committee notes that there is no mention of egg or sperm donor in the Bill. This suggests that both gametes should come from the couple. However, this cannot be possible in all cases of infertility. Clause 4(ii)(a) lays down that surrogacy can be availed "when either or both members of the couple is suffering from proven infertility". Needless to say that in case of one of the commissioning couple being infertile, the gamete will be required to be donated by somebody. Gamete donation also assumes significance in view of the fact that the option of surrogate parenthood should also be open to widows and divorced women. Since the lack of provision for gamete donation will greatly narrow down the category of people who can avail surrogacy, the Committee recommends that appropriate modifications be made and provision for gamete donation be incorporated in the Bill. (Para 5.90)

The Committee would like to point out that there are no separate surrogacy clinics as such. Generally ART clinics offer surrogacy services as well. It would be difficult to monitor ART clinics as it would not be easy to distinguish between a surrogate pregnancy and other pregnancy through IVF. The other IVF clinics which are not involved in surrogacy are out of the purview of the Bill. The need of the hour, hence, is to regulate all ART clinics. The Committee learns that the Department would be bringing forth the draft ART Bill after the Surrogacy (Regulation) Bill, 2016 for regulation of ART Clinics. In this context, the Committee opines that bringing ART Bill before the Surrogacy (Regulation) Bill, 2016 would have been an ideal attempt for regulation of such clinics. (Para 5.94)

In view of the concerns raised by the stakeholders, the Committee would like the Department to review the requirement of approval of the appropriate authority for abortion. The time factor is crucial in such cases of medical emergencies where there would be no time left

to ask for permission from an authority for performing abortion to save the life of the surrogate. Since Medical Termination of Pregnancy Act imposes restrictions to safeguard the interests of pregnant woman and child, the rationale behind seeking permission from appropriate authority is not clear. The role of appropriate authority can be envisaged where abnormalities of any kind have been detected in the unborn surrogate child. In such cases, it may be statutorily mandated upon the appropriate authority to state categorically the reasons for permitting abortion within a specified time-frame taking into account the consent of the intending couple and the physical well-being of the surrogate mother. The Committee, therefore, recommends that suitable modifications be made in Clause 3(vi) on the above lines. Consequential changes in other relevant Clauses of the Bill may also be incorporated. (Para 5.98)

The Committee notes that Section 53 of the draft ART Bill, 2014 mandates highest possible standards in the storage and handling of human gametes and embryos for the duration of not more than five years on a prescribed fee after which such embryo shall be allowed to perish or donated to a research organization registered for research purposes. The Committee understands that generally three or more embryos are created during the process of surrogacy and in-vitro fertilization. Out of them either two or three embryos are transferred in the womb of the surrogate mother during one cycle and remaining embryos are cryo-preserved so that if the first cycle fails, then the remaining embryos can be used in subsequent cycles. The success rate of implantation of embryos in one singular attempt is around 30% under the best of circumstances. Gamete (either oocytes or sperm or both) also need to be cryo-preserved before creating the embryos as the timing of the creation of the embryos in-vitro has to be in line with the menstrual cycle of the surrogate mother. The Committee notes that repeated extraction of eggs and fertility medicines that stimulate egg production may lead to the risk of Ovarian Hyperstimulation for the intending mother or the donor. There may be several situations like the surrogate mother aborting on the way, the baby being born still or dying early or turning out to be congenitally abnormal, which may warrant storage of embryos. (Para 5.102)

Keeping in view the facts as stated above the Committee fails to comprehend the rationale behind such limitations on the storage of human gametes and embryos. The Committee feels that the infertile couple and the surrogate mother should not undergo same trauma repeatedly. This can be avoided with the storage facilities. The Committee, therefore, recommends that the storage of embryos should be permitted and Clause 3(vii) be amended appropriately permitting storage of embryos on the lines of ART Bill 2014. (Para 5.103)

The Committee supports the compensated surrogacy and expects the Department to carry out necessary amendments to Clause 4 (ii) (b) and (c) in consonance with the concept of compensated surrogacy. The Committee endorses the suggestion seeking a provision in the Bill mandating on the rights of the surrogate child and the interest of the child so that the child is not ill-treated, abused, sold or trafficked or exploited in any way. The Committee, therefore, recommends that the Surrogacy Bill must incorporate enabling provisions on screening of intending couple seeking medical assessment of their fitness to be parent, social economic background, criminal records in past, age, family information and related checks before they are permitted

to commission surrogacy. There should be a provision to ensure that the intending parents have not been involved in any child trafficking or child abuse. (Para 5.108)

The Committee notes that Clause 4(ii)(e) has left certain conditions for surrogacy to be specified through regulations by the National Surrogacy Board and observes that this Clause is couched too much in ambiguities and generalities. The Committee is of the considered view that the substantive purposes for which surrogacy will be allowed should be enshrined in the statute itself and not left to be covered under regulations. If required, an exhaustive list of purposes for surrogacy may be provided by way of regulations. The Committee, therefore, recommends that Clause 4(ii)(e) may be amended suitably and the substantive purposes for surrogacy be clearly delineated therein. (Para 5.109)

The Committee notes that certificate of essentiality is required to be obtained by the intending couple from the Appropriate authority after giving the reasons to commission surrogacy. This certificate of essentiality would include three conditions that need to be fulfilled *viz.* certificate of proven infertility, order on parentage and custody of child from court. This further requires an insurance coverage in favour of surrogate mother from an insurance company or an agent recognized by Insurance Regulatory and Development Authority (IRDA). The Committee observes that childless couples in India try various medical treatment options including assisted reproductive methods before they go for surrogacy as the last resort. Infertility is considered a taboo in our society and infertile couples go through a lot of mental agony and psychological trauma due to infertility. The couples who are already reeling under such emotional trauma of infertility and huge costs of the surrogacy treatment would be additionally burdened with the requirement of certificate of infertility from appropriate authority causing further distress and hardships. Besides, certificate of infertility has a negative impact psychologically and is considered derogatory for women in India. A certificate of infertility may also act as an evidence for filing divorce in case one partner is certified to be infertile. Hence, the Committee is of the view that once the couple has had all the procedures under assisted reproductive technology without any success, certificate of infertility from appropriate authority is unwarranted. The Committee, therefore, recommends that requirement of having certificate for infertility from an appropriate authority should be done away with and instead medical reports and prescription of the couple certifying repeated failures in conception or inability to carry the baby to full term should be allowed as a proof for their decision to commission surrogacy. Necessary modifications may accordingly be made in Clause 4(iii) (a)(I). (Para 5.114)

The Committee notes that neither any time-limit has been prescribed for issuing an essentiality certificate by the District Medical Board nor there is any appeal or review procedure, in case the application for surrogacy is rejected. This confers huge discretionary powers to the District Medical Board for issuance of essentiality certificate. It would, therefore, be in the fitness of things if suitable safeguards are built in the Bill and it is mandated that the essentiality certificate will be issued within a specified time-frame. Also, there is an imperative need for an appellate authority to be provided for in case of refusal of such an order. The Committee, therefore, recommends that suitable enabling amendments may accordingly be made in Clause 4 and other relevant Clauses of the Bill. (Para 5.115)

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The Committee observes that there is huge disparity in the bargaining power of surrogates *vis-à-vis* commissioning parents due to surrogates' impoverishment, illiteracy and the resultant lack of access to legal representation. Surrogate mothers are not informed of the effects of fertility medications and treatment protocols and as a result thereof, they are left completely unprotected and vulnerable in the matter. Therefore, mere explaining of all side effects of surrogacy procedure does not hold good in this context. The Committee, therefore, recommends an elaborate mechanism for obtaining full informed consent by a competent authority after comprehensive medical, social and psychological conselling and the risks associated with ART procedures, fertility medications and surrogate pregnancy. The competent authority should consist of independent functionaries including civil society members and NGOs working on women's health and rights. The Committee also feels that consent from the husband of surrogate mother is also important. The Committee accordingly recommends that suitable amendments be made in the Bill, incorporating the provisions for mandatory appointment of a competent authority to obtain full informed consent of surrogate mothers. (Para 5.121)

The Committee is also of the view that a mandatory consent from intending couple would be legally binding on all the stakeholders of the surrogacy arrangement. The Committee endorses the suggestion of the Ministry of Women and Child Development that a surrogate mother should have an option to withdraw from the surrogacy arrangement if she chooses to do so before the start of the procedure. Empanelment of women wanting to be a surrogate by the State is a good suggestion of the Ministry as the surrogates can be identified, traced and counselled before giving their consent. The Committee, therefore, recommends to the Department to incorporate the changes in the proposed Bill on the above lines. (Para 5.122)

The Committee notes that the proposed Bill does not specify the number of embryo transfer with respect to the number of attempts or number of cycles or number of embryos that are implanted in the surrogate's body. The Committee is of the view that considering the complexities of the procedures and scope of exploitation of a woman's body, there should be a prescribed limit to number of embryo implants. However, the Committee is not in favour of including the number of embryos to be implanted in the main statute. Since the Department has assured to consider the suggestion while framing rules, the Committee recommends that the requisite safeguard limiting the number of embryos to be implanted, be provided in the Rules. (Para 5.126)

The Committee notes that there are twenty four members in the Board representing various Government bodies and specialized fields. They may be from amongst medical geneticists, human embryologist, gynaecologist, obstetrician, experts from stri-rog, prasuti-tantra, social science, women welfare organization, and representatives from the civil society working on women's health and child issues possessing requisite prescribed qualifications and experience. The Committee also notes that the National Board of Assisted Reproductive Technology in the draft ART Bill, 2014 is represented by experts from the field of assisted reproduction, andrology, mammalian reproduction, biomedical sciences, embryology, bioethics, gynaecology, social science, law or human rights, public health and civil society representatives apart from the officials from

Government bodies. Since the National Surrogacy Board is a critical instrument for advising the Government on policy matters relating to surrogacy and supervising various bodies constituted under the Act, it is important that there should be appropriate mix of different categories of professionals in the Board who could help the Board play its designated role effectively. The Committee, therefore, recommends that the composition of the National Surrogacy Board may be modelled on that of the National Board of Assisted Reproductive Technology in the ART Bill, 2014. The Committee also sees logic in having a Registrar at the national level Board having in-depth legal knowledge of the concerned subject. The Committee, accordingly, recommends to the Department to include a Registrar in the Board who would facilitate the surrogacy procedure informing the legal implications of the surrogacy agreement to the concerned parties.

(Para 5.131)

Keeping in mind the complexities and ambit of the surrogacy procedures and to effectively regulate and monitor the entire spectrum of this field, the Committee appreciates the need to keep a record of all the cases of surrogacy from the beginning of the process till its end. Having a centralized database at the National level would be a step in right direction so as to monitor the surrogates, surrogacy clinics and the commissioning parents. All State Surrogacy Boards should be required to submit to the National Surrogacy Board, data on the surrogacy services and arrangements. Therefore, the Committee is in unison with the suggestion of keeping a registry at the national level having details of the registration and conduct of every surrogacy clinic, surrogacy arrangements, including its stakeholders, taking place across the country. Such a registry will also help in tracking the surrogate mothers who will act as surrogate only once in their lifetime. The Committee, therefore, recommends the Department that a National Registry should be maintained on similar lines as in the ART Bill, 2014 which contains details of all the ART clinics and ART banks, nature and type of services provided, outcome of the services etc.

(Para 5.135)

The Committee recommends that the State/Union Territory Surrogacy Board may be structured on the lines of the Committee's recommendation made in respect of the National Surrogacy Board. (Para 5.140)

The Committee agrees with the suggestion of having a wide representation of members from surrogacy related fields. The Committee recommends to the Department to include experts having knowledge and experience of bioethics and assisted reproduction and also have more than one civil society member as the whole arrangement of surrogacy has social, psychological, physical and emotional implications for all involved in the procedures. The Committee also recommends that a single window system should be set up for registration and reporting of surrogacy clinics so that it is easier for the clinics to follow the law. (Para 5.145)

The Committee in the earlier part of this Report has recommended that compensated surrogacy be permitted. The Committee recommends that the spirit of the Committee's recommendation in this regard be captured and Clause 35 be modified accordingly. As regards the exploitation of surrogate mothers and children born through surrogacy, the Committee notes

that the Bill lacks clarity about certain specific offences like human trafficking, abduction or inter-country movement of surrogate mother or child for surrogacy purposes. Therefore, the Committee recommends that the Bill should have explicit provisions prohibiting inter-country movement of surrogate mother or child. (Para 5.149)

The Committee has noticed that although Clause 7 provides for prohibition to abandon the child born through surrogacy on the reasons of the sex of the child; it nowhere prohibits sex selective surrogacy. It again does not prohibit conduct of sex selective techniques (pre-natal, post natal) in the name of surrogacy to have a child of desired sex and on use of pre-genetic diagnosis for detection of sex-linked genetic disorder. In view of the above, the Committee feels that the whole purpose of the Bill would get defeated if there is no provision on sex selective techniques/ surrogacy which may lead to exploitation of surrogate mother and child. Therefore, the Committee recommends that the provisions of the Bill may be harmonized with relevant provisions of Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 and suitable drafting changes be made in the Bill. (Para 5.150)

The Committee treats the practice of twiblings as a grave offence which directly leads to exploitation of the surrogate mother. Considering the high chances of such misconduct and its associated risks for the well being of the surrogate mother, the Committee recommends that the Bill should have specific provisions for prohibition of such a practice and penalization of couples and clinics on utilizing two surrogates for same intending couple at same time. (Para 5.151)

The Committee notes that selling and buying human gametes or embryos for surrogacy is prohibited as per the provisions of the Bill and involvement of a third party *i.e.* donors who would donate egg/sperm are nowhere mentioned in the Bill. The Committee has already dealt with this issue in the earlier part of this Report and therefore, recommends even at the cost of sounding repetitive that the Bill should include adequate provision of donors for gametes for the use of intending couple during surrogacy procedure. (Para 5.152)

The Committee notes that Clause 36(1) deals with punishment for surrogacy professionals or any other person who owns a surrogacy clinic or employed with such a clinic or centre etc and renders his professional or technical services. This Clause stipulates imprisonment for minimum five years and fine upto ten lakh rupees. The Committee would like to emphasize that transgressions which are purely procedural or technical in nature should be viewed in a broader perspective and should not invite stringent provisions. On the other hand, the fraudulent practices and activities should be dealt with severely and in a deterrent fashion. The Committee would therefore, recommend that the gravity of punishment in Clause 36(1) be modified suitably. (Para 5.159)

The Committee agrees with the contention of the stakeholders that surrogacy and its related procedures are not criminal activities. It is a procedure which is an advancement in the medical science in the field of assisted reproductive technology to have a biological child for infertile couple or for those who are unable to have their own child due to medical reasons. It is also true that the concerned parties are neither criminals nor are they threat to the society.

Moreover, penal sanctions on the commissioning parents would have a definite impact on the surrogate child. The child would be separated from his/her own biological parents, and would be denied of custody care arrangement defeating the very purpose of the Bill. (para 5.160)

In view of the above, the Committee is of the view that punishment should be commensurate with the level or degree of infraction committed. Minor infractions of law should be considered in mild manner and not carry any criminal liability. Also, if default is unintentional, the same should be taken into consideration without rigidly giving a harsh punishment. The Committee, accordingly, recommends that Clause 37 may be modified suitably, keeping in view the best interest of the surrogate child. (Para 5.161)

The Committee also notes that the criminal provisions as contained in Clauses 35, 36, 37 and 38 provide for a minimum punishment and no maximum punishment, which is unheard of in any criminal legislation. This is indicative of the fact that the Department has not exercised the required due diligence at the time of drafting the Bill. The Committee, therefore, recommends that the necessary modifications relating to the maximum punishment be incorporated in the Bill. (Para 5.162)

VI. MISCELLANEOUS POINTS

(i) SURROGACY AGREEMENT

The Committee is of the view that mere parentage order issued by the first class magistrate will not suffice. If the intent of the Bill is to protect the surrogate mothers and children, it must provide a legal frame-work for a comprehensive surrogacy agreement containing all safeguards. The agreement should mandatorily provide insurance, monetary compensation to surrogates, the manner of its disbursement and pre/post delivery care of the surrogates. It should also contain a provision for nourishment of the surrogates not just during the pregnancy but also in the post partum period; comprehensive healthcare for a period of five years starting from the date any medication for surrogacy procedure is begun; legal, medical and psychological counselling etc. Since the surrogates are predominantly uneducated, the contract should be made available in the language they fully understand and should be explained properly to them. The surrogacy agreement should be registered also. The jurisdiction for registration should lie before the Registrar where surrogate mother resides or where the intending parents reside or where the agreement is executed. Since a surrogacy agreement is a legal document, it will act as bedrock of the surrogacy arrangement and shall have a legal binding on all the parties involved in the surrogacy and help in solidifying the rights and duties of both the participants to the arrangement. Therefore, the Committee recommends that an agreement of surrogacy among all the stakeholders of the facility *i.e* the intending parents, surrogate mother and the surrogacy clinic should be made a mandatory document for the surrogacy arrangement for them. Necessary amendments/alternate Clauses may accordingly be incorporated in the Bill. (Para 6.6)

(ii) CHILD RIGHTS

The Committee strongly believes that the interest of the surrogate child needs to be secured in all situations including unforeseen contingencies. The Committee, therefore,

recommends that the Bill should have a comprehensive provision entailing adequate insurance coverage for the unborn child. The Committee is of the view that mere insurance for the surrogate child would not suffice and recommends that the Bill should contain provisions for Bank guarantees/fixed deposits for taking care of the expenses of the surrogate child in any emergent situation. Such a cover would ensure financial support for the surrogate child in case of any eventuality. It would also ensure cover for a child born with any abnormality/disability. It would also be the responsibility of the State Government to take care of all abandoned children born out of surrogacy. (Para 6.11)

The Committee recommends that surrogate child is defined separately in the Bill so as to distinguish the surrogate child from a child born to a couple who have undergone ART procedures themselves. (Para 6.12)

(iii) PROVISION FOR BREAST MILK FOR SURROGATE CHILD

The Committee observes that the provision of breastfeeding or making available breast milk for child born out of surrogacy finds no place in the proposed Bill. It is the right of the child to have mother's milk for adequate nutrition for his/her well being. As regards the way mother's milk is provided to the child, the Committee is of the view that the provision of breast milk should be allowed by way of Human Milk Bank services only and not by direct breastfeeding by surrogate mother as six months of breast feeding will establish an emotional attachment of surrogate child with the surrogate mother. It would be very difficult for the surrogate mother to give up the child leading to complications. Therefore, the Committee suggests that the surrogate child should get mother's milk for initial six months and recommends the Department to include a provision in the Bill for providing breast milk to the surrogate child through Human Milk Bank services only. (Para 6.15)

(iv) BIRTH CERTIFICATE

The Committee notes that there is no such provision regarding birth certificate in the Surrogacy Bill while such provision is there in the draft ART Bill, 2014. The Committee notes that the Bill provides for an intending couple to get a parentage order from Court to establish their parentage over the surrogate child. The Committee recommends that the Bill should also have the provision of birth certificate which is a legal document for the child born out of surrogacy with the names of the commissioning parents on it and for the requirement of date of birth of the surrogate child. Since in surrogacy arrangement, the birth mother is not genetically related to the child, logically her name should not be written on the birth certificate. Therefore, the Committee agrees with the suggestion of making an amendment in the Birth Registration Act for the cases of surrogacy arrangements in order to avoid legal complexities related to parentage of the child born out of surrogacy. Therefore, the Committee recommends to the Department to incorporate the provision of birth certificate of the surrogate child in the Surrogacy Bill and to take up the matter with relevant authorities to make necessary amendments in the existing rules of registration of birth. (Para 6.19)

(v) DEFINITION OF GAMETE DONORS

The Committee notes that the Bill allows only Gestational surrogacy wherein the surrogate mother would only assist in carrying pregnancy and hand over the surrogate child to the intending couple. However, there is no definition of gamete donors in the Bill and no mention of process of seeking human gamete donors for the purpose of surrogacy. Since gamete donation is part of surrogacy procedure and may entail huge scope of exploitation associated with the related procedures, the Committee feels that it is important to specify the role of gamete donors in the Surrogacy Bill. Also, as recommended earlier, the national registry would have a database of such donors too. Therefore, the Committee recommends to the Department to include the definition of gamete donors in the Bill appropriately. The Committee also recommends that egg donation should not be allowed as a profession and a woman should be permitted to donate her eggs only once in her lifetime. (Para 6.22)

(vi) DISPUTE RESOLUTION SYSTEM

The Committee notes that the Bill does not provide for any dispute resolution mechanism between the surrogate mother, intending parents and the clinic. In case of any conflict of interest or disagreement between the surrogate mother and the intending couple, the surrogate mother has no one to advocate her case. To handle such issues that can be dealt at the clinic level, there is a need to have an independent agency for resolution of disputes or redressal of any grievances of any of the parties involved in surrogacy process. The authority so created should have quasi-judicial powers to get its orders implemented. The Committee, accordingly, recommends to the Department to have an agency/body for the said purpose and incorporate enabling provisions to this effect in the Bill. (Para 6.25)

(vii) PROVISION FOR DNA TESTING

The Committee notes that there is no provision in the proposed Bill to have a scientific proof to establish parentage of the intending couple over their child born through surrogacy. In order to avoid any kind of custody disputes between the surrogate mother and the intending couple or to confirm the genetic connection between the child and intending couple, there should be a scientific mechanism to establish the fact that the child born through surrogacy is the biological child of the intending couple which can be done through DNA testing. The Committee also feels that DNA testing can help in determining parenthood of intending couple so that surrogacy clinics do not indulge in any kind of unethical practices. The Committee, therefore, recommends to the Department to incorporate the provision allowing DNA testing in the Bill in circumstances where there is need to have genetic determination of parenthood in any surrogacy arrangement so that surrogacy clinics do not indulge in any kind of fraud. (Para 6.27)

(viii) ASSISTED REPRODUCTIVE TECHNOLOGY (ART) (REGULATION) BILL

The Committee observes that the Assisted Reproductive Technologies (Regulation) Bill, 2008 had been drafted in 2008 and revised in 2010 and 2014. Since then, it has been lying with the Government. Moreover, the draft ART Bill also included provisions on regulation of surrogacy

facilities. The Committee takes note of the inordinate delay in bringing forth the draft ART Bill especially in view of the fact that there has been mushrooming of ART clinics across the country offering various services from IVF to surrogacy etc. The Committee fails to comprehend the reasons behind bringing a fresh Bill specifically on surrogacy, when a detailed, comprehensive and all en-compassing Bill on ART services had already been drafted by the Department. The Committee, therefore, would like to be apprised of the reasons behind such prompt decision to bring a separate legislation for surrogacy without the ART Bill. (Para 6.32)

The Committee strongly believes that with the rapid advancement of science and technology in all spheres of life, there is an urgent need to regulate the use of modern techniques especially *w.r.t.* assisted reproduction and use of ART for surrogacy. Hence, the Committee feels that along with surrogacy regulation, there is urgent need to regulate the ART clinics across the country. It is a fact that surrogacy procedures cannot be conducted without assisted reproduction techniques and therefore, mere enactment of the Surrogacy Bill would not serve the purpose of controlling commercialization of the surrogacy facilities across the country in the absence of regulation of assisted reproductive clinics and banks where surrogacy is being conducted as ART Clinics and Surrogacy Clinics are not separate. The Committee, therefore, strongly recommends that the ART Bill should be brought forth before the Surrogacy (Regulation), Bill, 2016. (Para 6.33)

MINUTES

*V

FIFTH MEETING

(2017-18)

The Committee met at 2.30 P.M. on Thursday, the 2nd March, 2017 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Dr. Vikas Mahatme
4. Shri Jairam Ramesh
5. Shri Ashok Siddharth
6. Shri Gopal Narayan Singh
7. Dr. C. P. Thakur

LOK SABHA

8. Shri Dasrath Tirkey
9. Dr. Sanjay Jaiswal
10. Dr. K. Kamaraj
11. Shri Arjunlal Meena
12. Shri J. Jayasingh Thiyagaraj Natterjee
13. Shri M. K. Raghavan
14. Dr. Manoj Rajoria
15. Dr. Shrikant Eknath Shinde
16. Shri Kanwar Singh Tanwar
17. Shrimati Rita Tarai
18. Shri Manohar Untwal

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Joint Director*

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* Minutes of I to IV meetings relate to other matters.

Shri Dinesh Singh, *Joint Director*

Shrimati Harshita Shankar, *Assistant Director*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

WITNESSES

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Opening Remarks

2. At the outset, the Chairman welcomed the Members and stated that a Bill *viz.* the Surrogacy (Regulation) Bill, 2016 has been referred to the Committee on 12th January, 2017 for examination and report within three months and the relevant papers received from the Department of Health Research had been circulated by the Secretariat to the Members *vide* its letter dated 24th January, 2017. He apprised the Members that the Committee would have the initial presentation of the Secretary, Department of Health Research on the Bill tomorrow *i.e.* 03rd March, 2017. * * *

3. * * *

4. * * *

5. * * *

6. * * *

7. The Committee then adjourned at 4.53 P.M. to meet again at 11.00 A.M. on 3rd March, 2017

*** relate to other matters.

VI

SIXTH MEETING

(2017-18)

The Committee met at 11.00 A.M. on Friday, the 3rd March, 2017 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Dr. Vikas Mahatme
3. Shri Jairam Ramesh
4. Shri Gopal Narayan Singh
5. Shri K. Somaprasad
6. Dr. C. P. Thakur

LOK SABHA

7. Dr. (Smt.) Heena Vijay Gavit
8. Dr. Sanjay Jaiswal
9. Dr. K. Kamaraj
10. Shri Arjunlal Meena
11. Shri J. Jayasingh Thiyagaraj Natterjee
12. Dr. Manoj Rajoria
13. Dr. Shrikant Eknath Shinde
14. Shri Akshay Yadav

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Joint Director*

Shri Dinesh Singh, *Joint Director*

Shrimati Harshita Shankar, *Assistant Director*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

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WITNESSES

Representatives from the Department of Health Research

1. Dr. Soumya Swaminathan, Secretary & Director General, ICMR
2. Shri Manoj Pant, Joint Secretary
3. Shri V. K. Gauba, Joint Secretary
4. Ms. Bharati Das, Chief Controller of Accounts
5. Shri Sachin Mittal, Director (Budget)

Representatives from Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel
3. Shri I. C. Sharma, Deputy Legislative Counsel
4. Shri T. K. Malik, Deputy Legislative Assistant

Representatives from Department of Legal Affairs

Shri Ramayan Yadav, Additional Secretary

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and briefed them about the agenda of the meeting *i.e.* * * * and presentation on the Surrogacy (Regulation) Bill, 2016 by the representatives of Department of Health Research. The Committee decided to issue a Press Release on the Bill to elicit the views of the general public.

3. * * *

4. * * *

Presentation on the Surrogacy (Regulation) Bill, 2016

5. The Secretary then made a presentation on the Surrogacy (Regulation) Bill, 2016. The Joint Secretary, Department of Health Research gave a brief background of the Surrogacy (Regulation) Bill, 2016. He apprised the Committee that there are nearly 2000 centres rendering surrogacy services in the country wherein females rent their womb to give birth to a child for a childless couple. In the last three years, it was estimated that around 2000 babies were born out of surrogacy. He also informed the Committee that surrogacy has been regulated all over the world except in India. The National Law Commission has strongly recommended to introduce Surrogacy Regulation Bill. The Joint Secretary submitted that 90% of surrogacy services beneficiaries are foreigners as it costs them 5-6 times lesser as compared to the rest of the world. Since there is no regulatory framework for surrogacy services

*** relate to other matters.

in India; there is no check over medical care, post delivery of the surrogate mother. He further submitted that while drafting the said Bill, two things were kept in mind *i.e.* (i) interest of surrogate mother like rights and insurance, and (ii) security of baby born out of surrogacy apart from other factors like responsibilities of intended couple, responsibilities of society, legal provisions to secure child's future etc.

(The Committee then adjourned at 1.20 P.M. for lunch and assembled again at 2.10 P.M.)

6. * * *

7. * * *

8. * * *

9. A verbatim record of the proceedings of the meeting was kept.

10. The Committee then adjourned at 3.45 P.M.

*** relate to other matters.

VII

SEVENTH MEETING

(2017-18)

The Committee met at 10.00 A.M. on Friday, the 17th March, 2017 in Room "62", First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Dr. R. Lakshmanan
4. Dr. Vikas Mahatme
5. Shri Jairam Ramesh
6. Shri Ashok Siddharth
8. Shri Gopal Narayan Singh
9. Shri K. Somaprasad

LOK SABHA

10. Shri Thangso Baite
11. Shri Nandkumar Singh Chauhan
12. Dr. (Smt.) Heena Vijay Gavit
13. Dr. Sanjay Jaiswal
14. Dr. K. Kamaraj
15. Shri Arjunlal Meena
16. Shri M.K. Raghavan
17. Dr. Shrikant Eknath Shinde
18. Shri R.K. Singh (Arrah)
19. Shrimati Rita Tarai

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shimati Arpana Mendiratta, *Director*

Shri Dinesh Singh, *Joint Director*

Shri Rakesh Naithani, *Joint Director*

Shrimati Harshita Shankar, *Assistant Director*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

Opening Remarks

2. * * *

3. * * *

Examination of the Surrogacy (Regulation) Bill, 2016 and * * *

4. The Chairman, thereafter, informed that since the Committee has been busy in the examination of Demands for Grants (2017-18), it has not been able to hear the views of various stakeholders on the Surrogacy (Regulation) Bill, 2016 referred to the Committee for examination and report by 11th April, 2017. As the Bill is very crucial for regulating commercial surrogacy and in protecting the interests of surrogate mother and child, the Committee decided that it may also hear the views of some experts/ stakeholders on it. The Committee also felt that it would not be possible for it to complete all stages of examination of the Bill and present its Report thereon by 11th April, 2017. The Committee, accordingly, decided to seek extension of time upto 11th July, 2017 for presentation of Report on the Bill and authorized its Chairman to approach the Hon'ble Chairman, Rajya Sabha for the purpose.

5. The Committee also decided that the views of the State Governments may be sought on (i) the Surrogacy (Regulation) Bill, 2017; and (ii) * * * which is being examined by the Committee. * * *

6. * * *

7. The Committee then adjourned at 10:30 A.M.

*** relate to other matters.

VIII

EIGHTH MEETING

(2017-18)

The Committee met at 4.00 P.M. on Thursday, the 30th March, 2017 in Room "63", First Floor, Parliament House, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Dr. Vikas Mahatme
4. Shri Gopal Narayan Singh
5. Shri K. Somaprasad

LOK SABHA

6. Shri Thangso Baite
7. Shri Dasrath Tirkey
8. Dr. (Smt.) Heena Vijay Gavit
9. Dr. Sanjay Jaiswal
10. Dr. Shrikant Eknath Shinde
11. Shri R.K.Singh (Arrah)
12. Shri Bharat Singh
13. Shrimati Rita Tarai

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Dinesh Singh, *Joint Director*

Shri Rakesh Naithani, *Joint Director*

Shrimati Harshita Shankar, *Assistant Director*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

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WITNESSES

Representatives from the Department of Health Research

1. Dr. Soumya Swaminathan, Secretary and Director General, ICMR

2. Shri Manoj Pant, Joint Secretary

3. Dr. R S Sharma, Scientist ' G' , ICMR

Representatives from Legislative Department

1. Shri R. Sreenivas, Additional Legislative Counsel

Representatives from Department of Legal Affairs

1. Shri Inder Kumar, Additional Secretary

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* oral evidence of the representatives of Department of Health Research in connection with examination of the Surrogacy (Regulation) Bill, 2016.

Oral Evidence of the Secretary, Department of Health Research on the Surrogacy (Regulation) Bill, 2016

3. Thereafter, the Committee took oral evidence of the representatives of the Department of Health Research. At the outset, the Joint Secretary, Department of Health Research made a power point presentation on the genesis of the Bill and its salient features.

4. During the course of the power point presentation, the Joint Secretary *inter-alia* highlighted the fact that though surrogacy was being practised in India for past few years, in the absence of a proper legislation, a large number of surrogacy clinics had come up offering surrogacy services mostly to foreigners. However, serious complaints regarding malpractices / commercialisation of surrogacy, exploitation of surrogate mothers and abandonment of children through surrogacy have been raised. The issue had resonated in Supreme Court in 2015, and the Court had been informed of the commitment of the Government to bring a Legislation early in this regard. He also apprised the Committee about:- (i) details of IVF / ART clinics in India; (ii) number of surrogacy births in the country in last 3 years; (iii) several reported cases of exploitation and reported complaints of surrogacy clinics; (iv) court cases in India regarding surrogacy; (v) issues related to surrogacy by Foreign Nationals *viz.* abandoning the baby, citizenship issues, etc. (vi) international scenario with respect to different countries where surrogacy (commercial / altruistic) was legal / or was allowed; (viii) process of drafting of Surrogacy Regulation Bill which involved inter-ministerial consultations with a cross section of stakeholders etc.

5. Apart from these, the Joint Secretary apprised the Committee about the proposed provisions of the Bills and submitted that the Bill proposes to ban commercial surrogacy and allow altruistic surrogacy only to infertile Indian married couples.

6. Thereafter, Members raised certain queries on the Bill. The Secretary, Department of Health Research and other officials replied to some of the queries raised by the Members. The Chairman directed the Secretary to furnish detailed written replies to the queries left unanswered within a week.

7. A verbatim record of the proceedings of the meeting was kept.

8. The Committee then adjourned at 5:45 P.M.

IX

NINTH MEETING

(2017-18)

The Committee met at 3.00 P.M. on Thursday, the 27th April, 2017 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Shri Rajkumar Dhoot
4. Dr. R. Lakshmanan
5. Dr. Vikas Mahatme
6. Shri Jairam Ramesh
7. Shri Ashok Siddharth
8. Shri K. Somaprasad

LOK SABHA

9. Shri Thangso Baite
10. Dr. Sanjay Jaiswal
11. Dr. K. Kamaraj
12. Shri C. R. Patil
13. Shri M. K. Raghavan
14. Dr. Manoj Rajoria
15. Shri R.K.Singh (Arrah)
16. Shri Bharat Singh
17. Shri Kanwar Singh Tanwar
18. Shrimati Rita Tarai
19. Shri Akshay Yadav

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Additional Director*

Shri Dinesh Singh, Additional Director

Shrimati Harshita Shankar, Under Secretary

Shri Pratap Shenoy, Committee Officer

Shrimati Gunjan Parashar, Research Officer

WITNESSES

Ministry of Women and Child Development

1. Shri Chetan B. Sanghi, Joint Secretary
2. Smt. Shipra Roy, Deputy Secretary
3. Ms. Risha Syed, Senior Consultant

Ministry of External Affairs

Shri Upender Singh Rawat, Joint Secretary (CPV)

Ministry of Home Affairs

Shri Mukesh Mittal, Joint Secretary

National Commission for Women

1. Smt. Lalitha Kumaramangalam, Chairperson
2. Smt. Vandana Gupta, Joint Secretary

Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

1. Shri Inder Kumar, Additional Secretary
2. Shri O. Venkateswarlu, Deputy Legal Adviser

Department of Health Research

1. Smt. Indira Sharma, Deputy Secretary
2. Dr. Kavitha Rajsekar, Scientist-D

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* to hear the views of the representatives of the Ministries of Women and Child Development, External Affairs, Home Affairs and National Commission for Women in connection

with the Surrogacy (Regulation) Bill, 2016. He also informed that representatives of Ministry of Law and Justice and Department of Health Research were also present for assisting the Committee in its deliberations.

3. Before calling in the witnesses, the Chairman informed the Members that in pursuance of the directions of the Hon. Supreme Court passed on 2nd May, 2016, an Oversight Committee was constituted for a period of one year to oversee the functioning of the Medical Council of India in all matters considered by the Parliamentary Standing Committee on Health and Family Welfare in its 92nd Report on functioning of Medical Council of India (MCI). He was of the view that even though the period was going to expire on 02nd May, 2017, the Committee has not been apprised of any further movement in this regard. In view thereof, the Chairman felt that a questionnaire may be sent to the Department for seeking the factual position on the functioning of MCI, which was agreed upon by the Committee.

Oral Evidence of the representatives of Ministries of Women and Child Development, External Affairs, Home Affairs and National Commission for Women on the Surrogacy (Regulation) Bill, 2016

4. Thereafter, the Committee first heard the views of the representatives of Ministry of Women and Child Development on the Surrogacy (Regulation) Bill, 2016. The Joint Secretary of the Ministry informed the Committee that when the Ministry of Health and Family Welfare had circulated the cabinet note on the Assisted Reproductive Technology Bill (ART Bill) to the Ministry of Women and Child Development (WCD), it had furnished its views on the said Bill. He further submitted that even though his Ministry had not been consulted on the Surrogacy (Regulation) Bill, 2016, the inputs provided by Ministry of WCD on ART Bill had been used as inputs in the Surrogacy (Regulation) Bill, 2016. On being asked specifically about the Surrogacy (Regulation) Bill, 2016, he was of the view that though Surrogacy needs to be regulated, its ambit should be widened to include single women, divorced female and widows. Further, the Bill should include both genetic and gestational surrogacy. He felt that the altruistic surrogacy proposed in the Bill would defeat the purpose of the Bill as in India familial ties would jeopardize the future of the surrogate child and even lead to property disputes.

5. The Committee then heard the views of the Chairperson of the National Commission for Women. The Chairperson while articulating the views of the Commission on the said Bill was *per se* against commercial surrogacy as it meant exploitation of poor by the rich and just another byname for commodification of poor and hapless women.

6. Thereafter, the Committee heard the views of the representatives of the Ministry of External Affairs and Home Affairs. The Joint Secretary of the Ministry of External Affairs while explaining his Ministry's stand on the Bill, stated that role of the Ministry was to control ' foreigners' from availing surrogacy services in India by bringing about a change in visa rules. The Joint Secretary of the Ministry of Home Affairs apprised the Committee that earlier foreigners were coming on tourist visa and availing surrogacy services. However, guidelines were issued that Indian Missions in foreign countries should not grant visa to foreign nationals for commissioning surrogacy. Further, the missions were also advised that

no permission should be granted by Foreigners Regional Registration Offices (FRROs) to Overseas Citizen cardholders to commission surrogacy in India. Also, directions were given for not allowing any ‘ exit permits’ to child born out of surrogacy.

7. Thereafter, Members raised certain queries on the Bill. The officials replied to some of the queries raised by the Members. The Chairman directed the officials to furnish detailed written replies to the queries left unanswered within a week.

8. A verbatim record of the proceedings of the meeting was kept.

9. The Committee then adjourned at 4:15 P.M. to meet at 11.00 A.M. on 28th April, 2017.

X

TENTH MEETING

(2017-18)

The Committee met at 11.00 A.M. on Friday, the 28th April, 2017 in Committee Room ' D' , Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Dr. R. Lakshmanan
4. Dr. Vikas Mahatme
5. Shri Jairam Ramesh
6. Shri Ashok Siddharth
7. Shri K. Somaprasad

LOK SABHA

8. Shri Thangso Baite
9. Dr. Sanjay Jaiswal
10. Shri Arjunlal Meena
11. Shri J. Jayasingh Thiyangaraj Natterjee
12. Shri C. R. Patil
13. Shri M. K. Raghavan
14. Dr. Manoj Rajoria
15. Shri R.K.Singh (Arrah)
16. Shri Bharat Singh
17. Shrimati Rita Tarai

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Additional Secretary*

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Additional Director*

Shri Dinesh Singh, *Additional Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

WITNESSES

Representatives from Indian Society of Third Party Assisted Reproduction (INSTAR)

1. Dr. Rita Bakshi, Vice-President
2. Dr. Shivani Sachdev Gour, General Secretary
3. Mr. Saurabh Kumar
4. Dr. Samit Shekhar

Indian Society for Assisted Reproduction (ISAR) and Federation of Obstetric and Gynaecological Societies of India (FOGSI)

1. Dr. Rishma Pai, President, FOGSI and Vice-President, ISAR
2. Dr. Sarita Sukhija, Vice President, Delhi Chapter, ISAR
3. Dr. Nandita Palshetkar
4. Dr. Jaydeep Tank
5. Mr. Amit Karkhanis

Expert

1. Mrs. Jayashree Wad, Supreme Court Lawyer

Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

1. Shri Inder Kumar, Additional Secretary
2. Shri O. Venkateswarlu, Deputy Legal Adviser

Department of Health Research

1. Shrimati Indira Sharma, Deputy Secretary
2. Dr. Kavitha Rajsekar, Scientist-D

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* to hear the views of representatives of the (i) Indian Society of Third

Party Assisted Reproduction (INSTAR); (ii) Federation of Obstetric and Gyaecological Societies of India (FOGSI) and Indian Society for Assisted Reproduction and (iii) Mrs. Jayashree Wad, Supreme Court Lawyer in connection with the Surrogacy (Regulation) Bill, 2016.

Oral Evidence of the stakeholders/experts on the Surrogacy (Regulation) Bill, 2016

3. The Committee first heard the views of Dr. Rishma Pai, President, Federation of Obstetric and Gyaecological Societies of India (FOGSI) and Vice President, Indian Society for Assisted Reproduction on the Surrogacy (Regulation) Bill, 2016. She informed about medical and social indications/reasons to opt for surrogacy. Thereafter, Dr. Jaydeep Tank, FOGSI explained the following points like (i) Report of Ernest & Young (July, 2015) highlighting the fact that surrogacy cycles constituted approximately 1% of the total IVF cycles indicating expanding IVF treatment in India; (ii) approximate expenditure involved in full term surrogacy procedure; and (iii) pros and cons of surrogacy; etc. They requested that a well meaning and balanced regulation is preferable to the current legal vacuum. The need of the hour is to focus on data collection, situational analysis, meeting with stakeholders for dissemination and discussions to arrive at a consensus in this regard.

4. Thereafter, the Committee heard the views of representatives of INSTAR. Dr. Rita Bakshi, Vice President, Indian Society of Third Party Assisted Reproduction (INSTAR) pointed out various Clauses of the Bill and *inter alia* gave suggestions thereon like (i) altruistic surrogacy is practically not possible; (ii) close relative should not be the only choice but only an option; (iii) permission to OCI/PIO cardholders/ foreigners/single parents for surrogacy; (iv) arbitrary and unreasonable punishment for doctors; (v) storage of embryos/gametes should be allowed with the consent of the parents, etc. Dr. Shivani Sachdev Gour, General Secretary (INSTAR) further elaborated on the statistics of surrogacy from northern, southern and western India, number of babies born through surrogacy till date, ways in which compensation is used by surrogate mothers, reasons of surrogacy and details of questionnaire based survey of 170 women who opted for surrogacy.

5. The Committee then heard the views of Mrs. Jayashree Wad, Supreme Court Lawyer. She further drew the Committee's attention on technicalities of the Bill from legal point of view like abandonment of child, definition of adoption, surrogacy agreement etc. Apart from this, she also suggested that some provision of depositing the amount in the court to take care of health related expenses of surrogate during the pregnancy period should be there and emphasized the need of having surrogacy agreement registered in a court of law.

6. Thereafter, Members raised certain queries on the Bill. The witnesses replied to some of the queries raised by the Members. The Chairman directed the witnesses to furnish detailed written replies to the queries left unanswered within a week.

7. A verbatim record of the proceedings of the meeting was kept.

8. The Committee then adjourned at 12.58 P.M.

XI

ELEVENTH MEETING

(2017-18)

The Committee met at 3.00 P.M. on Wednesday, the 24th May, 2017 in Committee Room ' C', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shri Rajkumar Dhoot
3. Dr. Vikas Mahatme
4. Shri Jairam Ramesh
5. Shri Ashok Siddharth
6. Shri K. Somaprasad
7. Dr. C. P. Thakur

LOK SABHA

8. Shri Dasrath Tirkey
9. Dr. Sanjay Jaiswal
10. Dr. K. Kamaraj
11. Shri Arjunlal Meena
12. Shri J. Jayasingh Thiyagaraj Natterjee
13. Shri C. R. Patil
14. Shri R. K.Singh (Arrah)
15. Shri Bharat Singh

SECRETARIAT

Shri Rakesh Naithani, *Additional Director*

Shri Dinesh Singh, *Additional Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

WITNESSES

1.	Dr. Kamini Rao,	Member, National Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology
2.	Ms. Pinki Virani,	Journalist and Human Rights Activist
3.	Ms. Sonali Kusum,	Member, International Surrogacy Forum

Department of Health Research

1.	Ms. Sarita Mittal,	Joint Secretary
2.	Ms. Indira Sharma,	Deputy Secretary
3.	Dr. Kavitha Rajsekar,	Scientist ' D'

Department of Legal Affairs

	Shri Ramayan Yadav,	Additional Secretary

Legislative Department

1.	Dr. N. R. Battu,	Joint Secretary
2.	Shri R. Sreenivas,	Additional Legislative Counsel

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* to hear the views of: (i) Dr. Kamini Rao, Member, National Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology; (ii) Ms. Pinki Virani, Journalist and Human Rights Activist; and (iii) Ms. Sonali Kusum, Member, International Surrogacy Forum, on the Surrogacy (Regulation) Bill, 2016.

Oral Evidence of the stakeholders/experts on the Surrogacy (Regulation) Bill, 2016

3. The Committee first heard the views of Ms. Sonali Kusum, Member, International Surrogacy Forum on the Surrogacy (Regulation) Bill, 2016. She informed about the gaps in the Bill and also gave a comparative analysis of the surrogacy laws in Australia and Canada. She *inter alia* highlighted the following points namely (i) need for inclusion of rights based perspective in the Preamble of the Bill for stakeholders (child as well as surrogate mother); (ii) need to expand the insurance coverage for altruistic surrogacy (section 2 of the Bill) to include other expenses as specified in the Law Commission Report of 2009 such as nutrition, maternity clothing, crèches and other facilities for the child of surrogate mother; (iii) compensated surrogacy more suitable where standard amount of money may be fixed to be provided to surrogate mother; (iv) in the definition of infertility, the five years of waiting period may be reduced to one year as per World Health Organisation (WHO) guidelines as five years of waiting period is a breach of reproductive rights of the intending couple; (v) surrogacy agreement should be notarised; (vi) rights of children born out of surrogacy should be ensured by setting up breast banks for providing breast milk to surrogate child; (vii) need to include single mothers/unmarried/divorced/

widowed females in the ambit of the Bill; (viii) need to include a provision on strict control over sex determination; (ix) need to include provision relating to switching of gametes or mixing to prevent such malpractices, etc.

4. Thereafter, Ms. Pinki Virani, Journalist and Human Rights Activist made her submissions. She *inter alia* highlighted the following points like (i) There should be no commodification of women and children; (ii) the 5 year Clause for certifying infertility is suitable and should stay; (iii) embryos are being switched to accomodate intending parents which is unethical and should not be allowed; (iv) donor should agree for surrogacy only for altruistic reasons; (v) Insurance cover for surrogate mother should be for a period of six years because there have been medical complications like surrogate mothers developing cancers and child developing eye cancer, etc; (vi) Only one embryo should be allowed to be inserted.

5. Thereafter, Dr. Kamini Rao, Member, National Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology made her submissions and highlighted the following points namely (i) ART Bill needs to be passed before Surrogacy Bill; (ii) need to reduce the five year Clause for proving infertility as the period is too long; (iii) the term ‘ close relative’ needs to be properly defined with proper safeguards as it may lead to exploitation of surrogate mother and also result in emotional insecurity of the intending mother; (iv) genetic determination of parenthood needs to be established; (v) provision to ensure that two surrogate mothers for the same intending couple may not be used.

6. Thereafter, Members raised certain queries on the Bill. The witnesses replied to some of the queries raised by the Members. The Chairman directed the witnesses to furnish detailed written replies to the queries left unanswered within a week.

7. A verbatim record of the proceedings of the meeting was kept.

8. The Committee then adjourned at 5.30 P.M. to meet again at 11.00 A.M. on 25th May, 2017.

XII

TWELFTH MEETING

(2017-18)

The Committee met at 11.00 A.M. on Wednesday, the 25th May, 2017 in Committee Room ' C', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Dr. Vikas Mahatme
3. Shri Jairam Ramesh
4. Shri Ashok Siddharth
5. Shri K. Somaprasad
6. Dr. C. P. Thakur

LOK SABHA

7. Shri Dasrath Tirkey
8. Dr. K. Kamaraj
9. Shri Arjunlal Meena
10. Shri C. R. Patil
11. Shri R.K.Singh (Arrah)
12. Shri Manohar Untwal

SECRETARIAT

Shri Rakesh Naithani, *Additional Director*

Shri Dinesh Singh, *Additional Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

WITNESSES

Representatives from Surrogacy Laws India

1. Shri Anurag Chawla, Advocate
2. Ms. Diksha Bhatia, Advocate

Representatives from Trust Legal, Advocates and Consultants

1. Ms. Petal Chandhok, Advocate

Representatives from Amity Law School, Delhi

1. Ms. Aparajita Amar, Student
2. Shri Arjun Aggarwal, Student

Surrogate Mothers

1. * * *
2. * * *
3. * * *
4. * * *

Commissioning Parent

* * *

Department of Health Research

1. Ms. Sarita Mittal, Joint Secretary
2. Ms. Indira Sharma, Deputy Secretary
3. Dr. Kavita Raj Shekhar, Scientist ' D'

Legislative Department

1. Dr. N.R. Battu, Joint Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

Shri Ramayan Yadav, Additional Secretary

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* to hear the views of: (i) Shri Anurag Chawla, Advocate, Surrogacy Laws India; (ii) Ms.Petal Chandhok, Trust Legal, Advocates and Consultants; (iii) Ms. Aparajita Amar and Shri Arjun Aggarwal, Amity Law School, Delhi; (iv) * * *, Commissioning Parent and (v) four Surrogate Mothers, namely * * * to hear their views on the Surrogacy (Regulation) Bill, 2016.

Oral Evidence of the stakeholders/experts on the Surrogacy (Regulation) Bill, 2016

3. The Committee first heard the views of Shri Anurag Chawla, Advocate, Surrogacy Laws India on the Surrogacy (Regulation) Bill, 2016. He *inter-alia* highlighted the following points namely (i) limiting the Bill to Indian married couples, Indian citizens is not good; (ii) need to expand the definition of close

*** Identities withheld to protect privacy

relative; (iii) need to expand the surrogacy services to foreigners also subject to a set of conditions and subject to the approval by National Law Board; (iv) NRIs, OCIs holders are part of India; they should not be deprived of surrogacy services.

4. Thereafter, Ms.Petal Chandhok, Trust Legal, Advocates and Consultants submitted that (i) Provisions of the Bill are violative of privacy rights like provision of close relative would lead to two mothers in a home which could lead to unpleasant situation; (ii) the Bill is violative of Fundamental Rights like Article 14 and 22 as singles cannot avail surrogacy; (iii) commercial surrogacy industry needs to be regulated and not banned as it will lead to a black market leading to exploitation; etc.

5. Thereafter, Ms. Aparajita Amar, Amity Law School highlighted the following points (i) the Bill should incorporate a provision for ' Home Study" which would help in a background check of the intending parents; (ii) only gestational surrogacy should be allowed; (iii) provision for breast milk banks should be made in the Bill; (iv) the five years waiting period was arbitrary; (v) compensatory surrogacy is feasible and the formula in Assisted Reproductive Technology (ART) Bill regarding the remuneration/ compensation to the surrogate mother should be adopted.

6. Thereafter the surrogate mothers *viz.* * * * shared their experiences as surrogate mother and highlighting the reasons for adopting surrogacy stated that surrogacy provided the right avenue for people who want to earn money for their family and education of their children, but the present remuneration of ₹ 3.50 lakhs for surrogacy needs to be increased. Thereafter, one Commissioning Parent, namely, * * * shared his experiences as a commissioning parent and *inter-alia* highlighted the following points (i) close relatives are not ready to be surrogates; (ii) state should not have a right on the number of children to be born; (iii) The price of egg varies from ₹ 30,000 to ₹ 6 lakhs based on the socio- economic background of the donor and premium egg costs up to ₹ 6 lakhs; etc.

7. Thereafter, Members raised certain queries on the Bill. The witnesses replied to some of the queries raised by the Members. The Chairman directed the witnesses to furnish detailed written replies to the queries left unanswered within a week.

8. A verbatim record of the proceedings of the meeting was kept.

9. The Committee then adjourned at 12.22 P.M.

*** Identities withheld to protect privacy.

XIII

THIRTEENTH MEETING

(2017-18)

The Committee met at 11.00 A.M. on Tuesday, the 04th July, 2017 in Committee Room ' B', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Shrimati Renuka Chowdhury
3. Dr. Vikas Mahatme
4. Shri Jairam Ramesh
5. Shri Ashok Siddharth
6. Shri Gopal Narayan Singh
7. Shri K. Somaprasad
8. Dr. C. P. Thakur

LOK SABHA

9. Shri Thangso Baite
10. Shri Dasrath Tirkey
11. Dr. (Smt.) Heena Vijay Gavit
12. Dr. Sanjay Jaiswal
13. Dr. K. Kamaraj
14. Shri Arjunlal Meena
15. Shri J. Jayasingh Thiyagaraj Natterjee
16. Shri C. R. Patil
17. Dr. Manoj Rajoria
18. Shri Bharat Singh
19. Shri R.K.Singh (Arrah)
20. Shri Kanwar Singh Tanwar
21. Shrimati Rita Tarai

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SECRETARIAT

Shrimati Arpana Mendiratta, *Director*

Shri Rakesh Naithani, *Director*

Shri Dinesh Singh, *Additional Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

WITNESSES

Representative from National Law University, Delhi

Dr. Mrinal Satish, Associate Professor of Law, Executive Director, Centre for Constitutional Law, Policy and Governance, National Law University, Delhi

Department of Health Research

1. Dr.(Mrs.) Soumya Swaminathan, Secretary
2. Ms. Sarita Mittal, Joint Secretary
3. Ms. Indira Sharma, Deputy Secretary
4. Dr. Kavitha Rajshekar, Scientist-D

Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

1. Shri Ramayan Yadav, Additional Secretary
2. Shri O. Venkateswarlu, Deputy Legal Adviser

Opening Remarks

At the outset, the Chairman welcomed the Members of the Committee and informed them about the agenda of the meeting, *i.e.* to hear the views of: (i) Dr. Mrinal Satish, Associate Professor of Law, Executive Director, Centre for Constitutional Law, Policy and Governance, National Law University, Delhi and (ii) concluding evidence of the Secretary, Department of Health Research on ‘ The Surrogacy (Regulation) Bill, 2016’ .

2. The Chairman, thereafter, apprised that though the Committee had held extensive deliberations with a cross section of experts and stakeholders including the Secretary, Department of Health Research in

order to examine the entire spectrum of views on the Surrogacy (Regulation) Bill, 2016. The Department of Health Research has been asked to furnish detailed clarifications on the numerous concerns/queries raised by experts and Members of the Committee. The Department is yet to furnish its clarifications on a large number of Clauses of the Bill. On receipt of clarifications, a detailed and comprehensive examination of the Bill will need to be carried out and thereafter the Committee will consider the Bill Clause-by-Clause and finalise its report on the Bill. The Committee, therefore, felt it would not be possible for it to complete all stages of consideration of the Bill and present its Report before 11th July, 2017. The Committee, accordingly, decided to seek extension of time for two months *i.e.* upto 11th September, 2017 for presentation of Report on the Bill and authorized its Chairman to approach the Hon'ble Chairman, Rajya Sabha for the purpose.

3. * * *

Oral Evidence of the stakeholder/expert on the Surrogacy (Regulation) Bill, 2016

4. The Committee thereafter heard the views of Dr. Mrinal Satish, Associate Professor of Law, Executive Director, Centre for Constitutional Law, Policy and Governance, National Law University, Delhi on the Surrogacy (Regulation) Bill, 2016. He submitted that National Law University in collaboration with Cornell University, United States of America had conducted a study on the Surrogacy practice in India as well as in New York State and the report on the same was in the final stages of drafting. Regarding the methodology adopted for research, he informed that it was a mix of desk research involving legal cases in the country and legal cases outside the country and field visits in Delhi, Haryana and Anand, Gujarat. He *inter-alia* highlighted the following findings based on the study namely (i) need to regulate surrogacy by means of law as there was inconsistent application of ICMR guidelines in the country; (ii) lack of informed consent of the surrogate as they are unaware of the terms of agreements as well as the entire process of surrogacy including probable side effects of medication, etc. (iii) the contract entered into with the surrogate followed the 'free market principle' which meant that each contract was negotiated separately and the contract was devoid of the post natal care, life insurance coverage and informed consent provision thereby entailing huge bargaining power disparity between the intending parents / clinics and the surrogate mothers.

5. As regards the Surrogacy (Regulation) Bill, 2016, he was of the view that banning commercial surrogacy was not the way forward. The practice of surrogacy was being exploited due to the lack of a binding regulatory regime. He suggested that instead of banning commercial surrogacy, a stringent regulatory framework should be put in place to protect the rights of surrogates. He was also of the view that the Bill was mostly based on moralistic assumptions and beliefs thereby placing a burden on the infertile couples and surrogate mothers. On the provision regarding 'altruistic surrogacy', he stated that the term compensatory should be included in the Bill instead of the term 'altruistic'. He also highlighted the fact that in the process of framing the present Bill, the voices of surrogates were not heard. He also delineated certain issues in the current Bill like (i) absence of the definition of 'close relative' in the Bill; (ii) the complications altruistic surrogacy could create in the Indian family set-up. He concluded by submitting that owing to the issues pointed out by him, the Bill in the present form needed to be rejected. Thereafter, Members raised certain queries on the Bill. The witness replied to some of the queries raised by the Members.

***relate to others matter.

Oral Evidence of the Secretary, Department of Health Research on the Surrogacy (Regulation) Bill, 2016

6. The Committee, thereafter had the concluding evidence of Smt. Soumya Swaminathan, Secretary and other officials of the Department of Health Research on the Surrogacy (Regulation) Bill, 2016. She apprised the Committee about the rationale behind bringing altruistic surrogacy as proposed in the Bill. To a query on why the Surrogacy Bill was introduced in isolation of the Assisted Reproductive Technology Bill, she submitted that the Department would shortly move the ART Bill which had overlapping features with the Surrogacy Bill.

7. Thereafter, Members raised certain queries regarding lack of consultation with the Ministry of Women and Child Development, condition of close relative to become a surrogate mother, rationale behind the five year waiting Clause for infertile couples, etc. The Secretary/Officials of the Department replied to some of the queries raised by the Members. The Chairman directed the witnesses to furnish detailed written replies to the queries left unanswered within a week.

8. A verbatim record of the proceedings of the meeting was kept.

9. The Committee then adjourned at 12.30 P.M. to meet again at 11.00 A.M. on 11th July, 2017.

*XV

FIFTEENTH MEETING

(2017-18)

The Committee met at 4.00 P.M. on Tuesday, the 8th August, 2017 in Main Committee Room, Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Prof. Ram Gopal Yadav — *Chairman*

RAJYA SABHA

2. Dr. R. Lakshmanan
3. Dr. Vikas Mahatme
4. Shri Jairam Ramesh
5. Shri Gopal Narayan Singh
6. Shri K. Somaprasad
7. Dr. C.P. Thakur

LOK SABHA

8. Shri Thangso Baite
9. Dr. (Smt.) Heena Vijay Gavit
10. Dr. Sanjay Jaiswal
11. Shri J. Jayasingh Thiyagaraj Natterjee
12. Dr. Manoj Rajoria
13. Shri Bharat Singh
14. Shri Kanwar Singh Tanwar
15. Shrimati Rita Tarai

SECRETARIAT

Shri Jagmohan Sundriyal, *Joint Secretary*

Shri Rakesh Naithani, *Director*

Shri Dinesh Singh, *Joint Director*

Shrimati Harshita Shankar, *Under Secretary*

Shri Pratap Shenoy, *Committee Officer*

Shrimati Gunjan Parashar, *Research Officer*

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* Minute of XIVth meeting relate to other matters.

Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and briefed them about the agenda of the meeting *i.e.,* to consider and adopt draft 102nd Report of the Committee on the Surrogacy (Regulation) Bill, 2016.

Consideration and adoption of draft 102nd Report of the Committee

3. The Committee then considered and discussed the draft 102nd Report of the Committee on the Surrogacy (Regulation) Bill, 2016. The Chairman briefed the Members regarding the salient issues dealt with in the Report *viz.* altruistic *vs.* commercial surrogacy, safeguarding the interest of the surrogate mother, feasibility of having a close relative as a surrogate, need for a legally binding surrogacy agreement, need for a National Registry for the surrogates and the surrogacy clinics across the country, issue of inclusion or exclusion of Foreigners, NRIs, PIOs, OCIs within the ambit of the Bill.

4. After some discussion, the Committee adopted the said Report with the following additions/ modifications as suggested by Members for incorporation in the Report: (i) ART Bill should come forth before the Surrogacy Bill; (ii) 2 step comprehensive insurance for the surrogate; (iii) upper age of surrogate should be raised to 39 years; (iv) Bank Guarantee/Fixed Deposits for safeguarding interests of surrogate child in emergent situations; (v) some modifications were suggested in the definition of the term ‘ eligibility certificate’ , etc.

5. The Committee, thereafter, decided that the Report may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Thursday, the 10th August, 2017. The Committee authorized its Chairman, Shri Jairam Ramesh and Dr. Vikas Mahatme to present the Report in Rajya Sabha, and Dr. Sanjay Jaiswal and Dr. Manoj Rajoria to lay the Report on the Table of the Lok Sabha.

6. * * *

7. The Committee then adjourned at 4.54 P.M.

***relate to other matters

ANNEXURES

ANNEXURE I

To be introduced in Lok Sabha

Bill No. 257 of 2016

THE SURROGACY (REGULATION) BILL, 2016

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Sixty-seventh Year of the Republic of India as follows:—

CHAPTER I

PRELIMINARY

Short title, extent and commencement.

1. (1) This Act may be called the Surrogacy (Regulation) Act, 2016.

(2) It extends to the whole of India except the State of Jammu and Kashmir.

(3) It shall come into force on such date as the Central Government may, by notification in the official Gazette, appoint.

Definitions.

2. In this Act, unless the context otherwise requires,—

(a) "abandoned child" means a child —

(i) born out of surrogacy procedure;

(ii) deserted by his intending parents or guardians; and

(iii) who has been declared as abandoned by the appropriate authority after due enquiry;

(b) "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

(c) "appropriate authority" means the appropriate authority appointed under section *32*;

(d) "Board" means the National Surrogacy Board constituted under section *14;*

(e) "clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010;

23 of 2010.

(f) "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

(g) "couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;

(h) "egg" includes the female gamete;

(i) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;

(j) "fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;

(k) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;

(l) "gamete" means sperm and oocyte;

(m) "gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994;

57 of 1994

(n) "human embryologist" means a person who possesses any post-graduate medical qualification in the field of human embryology recognised under the Indian Medical Council Act, 1956 or who possesses a post-graduate degree in human embryology from a recognised university with not less than two years of clinical experience; 102 of 1956

(o) "implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;

(p) "infertility" means the inability to conceive after five years of unprotected coitus or other proven medical condition preventing a couple from conception;

(q) "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for specified loss, damage, illness or death of surrogate mother during the process of surrogacy;

(r) "intending couple" means a couple who have been medically certified to be an infertile couple and who intend to become parents through surrogacy;

(s) "Member" means a Member of the National Surrogacy Board or a State Surrogacy Board, as the case may be;

(t) "notification" means a notification published in the Official Gazette;

(u) "oocyte" means naturally ovulating oocyte in the female genetic tract;

(v) "Paediatrician" means a person who possess a post-graduate qualification in paediatrics as recognised under the Indian Medical Council Act, 1956; 102 of 1956

(w) "prescribed" means prescribed by rules made under this Act;

(x) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section *2* of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register; 102 of 1956

(y) "regulation" means regulations made by the Board under this Act;

(z) "State Board" means the State Surrogacy Board constituted under section *23;*

(za) "State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under Article 239 of the Constitution;

(zb) "surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;

(zc) "surrogacy clinic" means surrogacy clinic or centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called conducting surrogacy procedures in any form;

(zd) "surrogacy procedures" means all gynaecological or obstetrical or medical procedures, techniques, tests, practices or services involving handling of human gametes and human embryo in surrogacy;

(ze) "surrogate mother" means a woman bearing a child who is genetically related to the intending couple, through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause *(b)* of clause *(iii)* of section *4;*

(zf) "zygote" means the fertilised oocyte prior to the first cell division.

CHAPTER II

REGULATION OF SURROGACY CLINICS

3. On and from the date of commencement of this Act,—

Prohibition and regulation of surrogacy clinics.

(i) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;

(ii) no surrogacy clinic, paediatrician, gynaecologist, human embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;

(iii) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess such qualifications as may be prescribed;

(iv) no registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;

(v) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(a) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(b) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(c) seeks or aimed at seeking a woman to act as a surrogate mother;

(d) states or implies that a woman is willing to become a surrogate mother; or

(e) advertises commercial surrogacy in print or electronic media or in any other form;

(vi) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:

Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971;

34 of 1971

(vii) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, human embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:

Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

4. On and from the date of commencement of this Act,—

Regulation of surrogacy and surrogacy procedures.

(i) no place including a surrogacy clinic shall be used or caused to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause *(ii)* and after satisfying all the conditions specified in clause *(iii)*;

(ii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(a) when either or both members of the couple is suffering from proven infertility;

(b) when it is only for altruistic surrogacy purposes;

(c) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(d) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(e) any other condition or disease as may be specified by regulations made by the Board;

(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(a) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying for itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(I) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board.

Explanation.—For the purposes of this item, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(II) an order concerning the parentage and custody of the child to be born through surrogacy, have been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and surrogate mother;

(III) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;

41 of 1999

(b) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(I) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(II) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;

(III) no women shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime:

Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed;

(IV) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(c) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(I) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(II) the intending couple are married for at least five years and are Indian citizens;

(III) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board;

(IV) such other conditions as may be specified by the regulations.

Prohibition of conducting surrogacy.

5. No person including a relative or husband of a surrogate mother or intending couple shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause *(ii)* of section *4.*

Written informed consent of surrogate mother.

6. No person shall seek or conduct surrogacy procedures unless he has—

(i) explained all known side effects and after effects of such procedures to the surrogate mother concerned;

(ii) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

Prohibition to abandon child born through surrogacy.

7. The intending couple shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like:

Provided that any child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple and the said child shall be entitled to all the rights and privileges available to a natural child under any law for the time being in force.

Number of oocytes or embryos to be implanted.

8. The number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.

Prohibition of abortion.

9. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.

CHAPTER IV

REGISTRATION OF SURROGACY CLINICS

Registration of surrogacy clinics.

10. *(1)* No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.

(2) Every application for registration under sub-section *(1)* shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(3) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in clause *(ii)* of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:

Provided that such clinic shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(4) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

Certificate of registration.

11. *(1)* The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act, rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.

(2) Where, after the enquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(3) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

(4) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Cancellation or suspension of registration.

12. *(1)* The appropriate authority may, *suo motu*, or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provision of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(3) Notwithstanding anything contained in sub-sections *(1)* and *(2)*, if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section *(1)*.

Appeal.

13. The surrogacy clinic may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section *12*, prefer an appeal against such order to—

(a) the State Government, where the appeal is against the order of the appropriate authority of a State;

(b) to the Central Government, where the appeal is against the order of the appropriate authority of a Union Territory, in such manner as may be prescribed.

CHAPTER V

NATIONAL SURROGACY BOARD

Constitution of National Surrogacy Board.

14. *(1)* The Central Government shall, by notification, constitute a Board to be known as the National surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(2) The Board shall consist of—

(a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio;*

(b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;

(c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio;*

(d) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs not below the rank of Joint Secretary, Members, *ex officio;*

(e) the Director-General of Health Services of the Central Government, Member, *ex officio*;

(f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(i) eminent medical geneticists or human embryologists;

(ii) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra;*

(iii) eminent social scientists;

(iv) representatives of women welfare organisations; and

(v) representatives from civil society working on women's health and child issues, possessing of such qualifications and experience as may be prescribed;

(g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio;*

(h) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio.*

Term of office of Members.

15. *(1)* The term of office of a Member, other than an *ex officio* Member, shall be—

(a) in case of nomination under clause (c) of sub-section (2) of section 14, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and

(b) in case of appointment under clause *(f)* of sub-section (2) of section 14, one year:

Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

(2) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(3) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of Board.

16. *(1)* The Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the Board shall meet at least once in six months.

(2) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

(3) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

(4) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meeting of the Board.

Vacancies, etc., not to invalidate proceedings of Board.

17. No act or proceeding of the Board shall be invalid merely by reason of—

(a) any vacancy in, or any defect in the constitution of, the Board; or

(b) any defect in the appointment of a person acting as a Member of the Board; or

(c) any irregularity in the procedure of the Board not affecting the merits of the case.

Disqualifications for appointment as Member.

18. *(1)* A person shall be disqualified for being appointed and continued as a Member if, he—

(a) has been adjudged as an insolvent; or

(b) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or

(c) has become physically or mentally incapable of acting as a Member; or

(d) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(e) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(f) is a practicing member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(g) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(2) The Members referred to in clause (f) of section 14 shall not be removed from his office except by an order of the Central Government on the ground of his proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

(3) The Central Government may suspend any Member in respect of whom an inquiry under sub-section (2) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with Board for particular purposes.

19. *(1)* The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(2) A person associated with the Board under sub-section *(1)* shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of Board.

20. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Eligibility of Member for re-appointment.

21. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Functions of Board.

22. The Board shall discharge the following functions, namely:—

(a) to advise the Central Government on policy matters relating to surrogacy;

(b) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein;

(c) to lay down code of conduct to be observed by persons working at surrogacy clinics; to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(d) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(e) to supervise the functioning of State Surrogacy Boards; and

(f) such other functions as may be prescribed.

Constitution of State Surrogacy Board.

23. Each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union Territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(i) to review the activities of the appropriate authorities functioning in the State or Union Territory and recommend appropriate action against them;

(ii) to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(iii) to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and

(iv) such other functions as may be prescribed.

Composition of State Board.

24. The State Board shall consist of—

(a) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;

(b) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;

(c) Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, Members, *ex officio*;

(d) the Director-General of Health and Family Welfare of the State Government, Member, *ex officio*;

(e) three women Members of the State Legislative Assembly or Union Territory Legislative Council, Members, *ex officio*;

(f) ten expert Members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(i) eminent medical geneticists or human embryologists;

(ii) eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra;*

(iii) eminent social scientists;

(iv) representatives of women welfare organisations; and

(v) representatives from civil society working on women's health and child issues, possessing of such qualifications and experiences as may be prescribed;

(g) an officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, *ex officio.*

Term of office of Members.

25. *(1)* The term of office of a Member, other than an *ex officio* Member, shall be—

(a) in case of nomination under clause *(e)* of section 24, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a Member of the House from which she was elected; and

(b) in case of appointment under clause *(f)* of section 24, one year:

Provided that the person to be appointed as Member under this clause shall be of such age, as may be prescribed.

(2) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(3) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of State Board.

26. *(1)* The State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the State Board shall meet at least once in four months.

(2) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

(3) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

(4) The Members, other than, *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Vacancies, etc., not to invalidate proceedings of State Board.

27. No act or proceeding of the State Board shall be invalid merely by reason of—

(a) any vacancy in, or any defect in the constitution of, the State Board; or

(b) any defect in the appointment of a person acting as a Member of the State Board; or

(c) any irregularity in the procedure of the State Board not affecting the merits of the case.

Disqualifications for appointment as Member.

28. *(1)* A person shall be disqualified for being appointed and continued as a Member if, he—

(a) has been adjudged as an insolvent; or

(b) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or

(c) has become physically or mentally incapable of acting as a member; or

(d) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(e) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(f) is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(g) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(2) The Members referred to in clause *(f)* of section 24 shall not be removed from his office except by an order of the State Government on the ground of his proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the Member ought on any such ground to be removed.

(3) The State Government may suspend any Member in respect of whom an inquiry under sub-section *(2)* is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with State Board for particular purposes.

29. *(1)* The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(2) A person associated with it by the State Board under sub-section *(1)* shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of State Board.

30. All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Eligibility of Member for re-appointment.

31. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

CHAPTER VI

APPROPRIATE AUTHORITY

Appointment of appropriate authority.

32. *(1)* The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union Territories for the purposes of this Act.

(2) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or part of the State for the purposes of this Act.

(3) The appropriate authority, under sub-section *(1)* or sub-section *(2)*, shall,—

(a) when appointed for the whole of the State or the Union territory, consist of—

(i) an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson;

(ii) an eminent woman representing women's organisation—Member;

(iii) an officer of Law Department of the State or the Union Territory concerned not below the rank of a Deputy Secretary—Member; and

(iv) an eminent registered medical practitioner—Member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(b) when appointed for any part of the State or the Union Territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Functions of appropriate authority.

33. The appropriate authority shall discharge the following functions, namely:—

(a) to grant, suspend or cancel registration of a surrogacy clinic;

(b) to enforce the standards to be fulfilled by the surrogacy clinics;

(c) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act;

(d) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter;

(e) to supervise the implementation of the provisions of this Act, rules and regulations made thereunder;

(f) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(g) to take action after investigation of complaints received by it against the surrogacy clinics; and

(h) to consider and grant or reject any application under clause *(vi)* of section 3 and sub-clauses *(a)* to *(c)* of clause *(iii)* of section 4.

Powers of appropriate authority.

34. (1) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, rules and regulations made thereunder;

(b) production of any document or material object relating to clause *(a);*

(c) search any place suspected to be violating the provisions of this Act, rules and regulations made thereunder; and

(d) such other powers as may be prescribed.

(2) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of licence, etc., of the surrogacy clinics in such format as may be prescribed.

CHAPTER VII

OFFENCES AND PENALTIES

Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

35. *(1)* No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(a) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(b) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(c) abandon or disown or exploit or cause to be abandoned, exploited or disowned in any form the child or children born through surrogacy;

(d) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(e) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(f) import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures.

(2) Notwithstanding anything contained in the Indian Penal Code, 45 of 1860
contraventions of the provisions of clauses *(a)* to *(f)* of sub-section *(1)* by any person shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

(3) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Punishment for contravention of provisions of Act.

36. *(1)* Any registered medical practitioner, gynaecologists, paediatrician, human embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in section *(35)*, rules and regulations made thereunder shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to ten lakh rupees.

(2) In case of subsequent or continuation of the offence referred to in sub-section *(1)*, the name of the registered medical practitioner

shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Punishment for initiation of commercial surrogacy.

37. Any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, paediatrician, human embryologist or any other person for commercial surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

38. Whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which shall not be less than three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Presumption in case of surrogacy.

39. Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the woman or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause *(ii)* of section *4* and such person shall be liable for abetment of such offence under section *37* and shall be punishable for the offence specified under that section. 1 of 1872.

Offence to be cognizable, non-bailable and non-compoundable.

40. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable. 2 of 1974.

Cognizance of offences.

41. *(1)* No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—

(a) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or

(b) a person including a social organisation who has given notice of not less than fifteen days in the manner prescribed, to the

appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

(2) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Certain provisions of the Code of Criminal Procedure, 1973 not to apply.

42. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXIA of the said Code relating to plea of bargaining shall not apply to the offences under this Act. 2 of 1974.

CHAPTER VIII

MISCELLANEOUS

Maintenance of records.

43. *(1)* The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed:

Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

(2) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Power to search and seize records, etc.

44. *(1)* If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(2) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act. 2 of 1974.

Protection of action taken in good faith.

45. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate

authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provision of this Act.

Application of other laws not barred.

46. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Power to make rules.

47. *(1)* The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(a) the minimum qualifications for persons employed at a registered surrogacy clinic under clause *(iii)* of section *3*;

(b) the manner in which a person shall store human embryo or gamete under clause *(vii)* of section *3*;

(c) the insurance coverage in favour of the surrogate mother from an insurance company under item *(iii)* of sub-clause *(a)* of clause *(iii)* of section *4*;

(d) the number of attempts of surrogacy or providing of gametes under the proviso to item *(iii)* of sub-clause *(b)* of clause *(iii)* of section *4*;

(e) the form in which consent of a surrogate mother has to be obtained under clause *(ii)* of section *6*;

(f) the number of oocytes or embryos to be implanted in the surrogate mother under section *8*;

(g) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section *9*;

(h) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section *(2)* of section *10*;

(i) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section *(4)* of section *10;*

(j) the period, manner and form in which a certificate of registration shall be issued under sub-section *(1)* of section *11;*

(k) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section *(3)* of section *11;*

(l) the manner in which an appeal may be preferred under section *13;*

(m) the qualifications and experiences to the Members as admissible under clause *(f)* of sub-section *(2)* of section *14;*

(n) the procedures for conducting an inquiry against the Members under sub-section *(2)* of section *18;*

(o) the conditions under which a Member of the Board eligible for re-appointment under section *21;*

(p) the other functions of the Board under clause *(e)* of section *22;*

(q) the manner in which reports shall be furnished by the State and Union territory Boards to the Board and the Central Government under clause *(iii)* of section *23;*

(r) the other functions of the State Board under clause *(iv)* of section *23;*

(s) the qualifications and experiences to the Members as admissible under clause *(f)* of section *24;*

(t) the age of the person to be appointed as a Member, referred to in clause *(f)* of section *24*, under the proviso to clause (b) of sub-section *(1)* of section *25;*

(u) the procedures for conducting an inquiry against the members under sub-section *(2)* of section *28*;

(v) the conditions under which the members of the State Board eligible for re-appointment under section *31*;

(w) empowering the appropriate authority in any other matter under clause *(d)* of section *33*;

(x) the other powers of appropriate authority under clause *(d)* of sub-section *(1)* of section *34*;

(y) the particulars of the details of registration of surrogacy

clinics, cancellation of registration, etc., in such format under sub-section *(2)* of section *34;*

(z) the manner of giving notice by a person under clause *(b)* of sub-section *(1)* of section *41;*

(za) the period up to which records, charts, etc., shall be preserved under sub-section *(1)* of section *43;*

(zb) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section *(1)* of section *44;* and

(zc) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

Power to make regulations.

48. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—

(a) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under Item (IV) of sub-clause *(c)* of clause *(iii)* of section *4;*

(b) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section *(1)* of section *16;*

(c) the manner in which a person may be temporarily associated with the Board under sub-section *(1)* of section *19;*

(d) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section *(1)* of section *26;*

(e) the manner in which a person may be temporarily associated with the Board under sub-section *(1)* of section *29;*

(f) any other matter which is required to be, or may be, specified by regulations.

Rules and regulations to be laid before Parliament.

49. Every rules and every regulations made under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which

may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

Transitional provision.

50. Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Power to remove difficulties.

51. *(1)* If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the official Gazette make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

STATEMENT OF OBJECTS AND REASONS

India has emerged as a surrogacy hub for couples from different countries for past few years. There have been reported incidents of unethical practices, exploitation of surrogate mothers, abandonment of children born out of surrogacy and import of human embryos and gametes. Widespread condemnation of commercial surrogacy in India has been regularly reflected in different print and electronic media for last few years. The Law Commission of India has, in its 228th Report, also recommended for prohibition of commercial surrogacy by enacting a suitable legislation. Due to lack of legislation to regulate surrogacy, the practice of surrogacy has been misused by the surrogacy clinics, which leads to rampant of commercial surrogacy and unethical practices in the said area of surrogacy.

2. In the light of above, it had become necessary to enact a legislation to regulate surrogacy services in the country, to prohibit the potential exploitation of surrogate mothers and to protect the rights of children born through surrogacy.

3. The Surrogacy (Regulation) Bill, 2016, *inter alia*, provides for the following, namely:—

(a) to constitute the Surrogacy Boards at National and State level;

(b) to allow ethical altruistic surrogacy to the intending infertile Indian married couple between the age of 23-50 years and 26-55 years for female and male respectively;

(c) the intending couples should be legally married for at least five years and should be Indian citizens to undertake surrogacy or surrogacy procedures;

(d) to provide that the intending couples shall not abandon the child, born out of a surrogacy procedure, under any condition and the child born out of surrogacy procedure shall have the same rights and privileges as are available to the biological child;

(e) the surrogate mother should be a close relative of the intending couple and should be an ever married woman having a child of her own and between the age of 25-35 years;

(f) to provide that the surrogate mother shall be allowed to act as surrogate mother only once;

(g) to constitute the Surrogacy Board at National level which shall exercise and perform functions conferred on it under the Act. It is also proposed to constitute Surrogacy Boards at the State and Union Territory level to perform similar functions in respective States and Union Territories;

(h) to appoint one or more appropriate authorities at State and Union Territory level which shall be the executive bodies for implementing the provisions of the Act;

(i) to provide that the surrogacy clinics shall be registered only after the appropriate authority is satisfied that such clinics are in a position to provide facilities and can maintain equipments and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be provided in the rules and regulations;

(j) to provide that no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall undertake commercial surrogacy, issue advertisements regarding commercial surrogacy, abandon the child born through surrogacy, exploit the surrogate mother, sell human embryo or import human embryo for the purpose of surrogacy and contravention of the said provisions shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

4. The Notes on Clauses explain in detail the various provisions contained in the Surrogacy (Regulation) Bill, 2016.

5. The Bill seeks to achieve the above objectives.

NEW DELHI; JAGAT PRAKASH NADDA

The 28*th October,* 2016.

Notes on clauses

Clause 1.—This clause relates to Short title, Extent and Commencement of the proposed legislation.

Clause 2.—This clause contains the definitions of various expressions used in the proposed legislation.

Clause 3.—This clause relates to prohibition and regulation of surrogacy clinics.

Sub-clause *(i)* of this clause provides that no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures.

Sub-clause *(ii)* of this clause provides that no surrogacy clinic, pediatrician, gynaecologist, human embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form.

Sub-clause *(iii)* of this clause provides that no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess such qualifications as may be prescribed.

Sub-clause *(iv)* of this clause provides that no registered medical practitioner, gynaecologist, pediatrician, human embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act.

Sub-clause *(v)* of this clause provides that no surrogacy clinic, registered medical practitioner, gynaecologist, pediatrician, human embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which —

(a) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(b) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(c) seeks or aimed at seeking a woman to act as a surrogate mother;

(d) states or implies that a woman is willing to become a surrogate mother; or

(e) advertises commercial surrogacy in print or electronic media or in any other form.

Sub-clause *(vi)* of this clause provides that no surrogacy clinic, registered medical practitioner, gynaecologist, pediatrician, human embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned. However, that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971.

Sub-clause *(vii)* of this clause provides that no surrogacy clinic, registered medical practitioner, gynaecologist, pediatrician, human embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy. However, that nothing contained in this sub-clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed.

Clause 4.—This clause relates to regulation of surrogacy and surrogacy procedures.

Sub-clause *(i)* of this clause provides that no place including a surrogacy clinic shall be used or caused to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in sub-clause *(ii)* and after satisfying all the conditions specified in sub-clause *(iii)*.

Sub-clause *(ii)* of this clause provides that no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—*(a)* when either or both members of the couple is suffering from proven infertility; *(b)* when it is only for altruistic surrogacy purposes; *(c)* when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures; *(d)* when it is not for producing children for sale, prostitution or any other form of exploitation; and *(e)* any other condition or disease as may be specified by regulations made by the Board.

Sub-clause *(iii)* of this clause provides that no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(a) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying for itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(I) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board;

(II) an order concerning the parentage and custody of the child to be born through surrogacy, have been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and surrogate mother;

(III) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;

(b) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(I) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(II) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;

(III) no women shall act as a surrogate mother or help in surrogacy in any way, by providing gametes or by carrying the pregnancy, more than once in her lifetime. However, that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed;

(IV) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(c) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(I) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(II) the intending couple are married for at least five years and are Indian citizens;

(III) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier. However, that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(IV) such other conditions as may be specified by the regulations.

Clause 5.—This clause relates to prohibition of conducting surrogacy.

This clause provides that no person including a relative or husband of a surrogate mother or intending couple shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in sub-clause *(ii)* of clause 4.

Clause 6.—This clause relates to written informed consent of surrogate mother.

This clause provides that no person shall seek or conduct surrogacy procedures unless he has — *(i)* explained all known side effects and after effects of such procedures to the surrogate mother concerned; *(ii)* obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

Clause 7.—This clause relates to prohibition to abandon child born through surrogacy.

This clause provides that the intending couple shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like. However, that any child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple and the said child

shall be entitled to all the rights and privileges available to a natural child under any law for time being in force.

Clause 8.—This clause relates to number of oocytes or embryos to be implanted.

This clause provides that the number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.

Clause 9.—This clause relates to prohibition of abortion.

This clause provides that no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.

Clause 10.—This clause relates to registration of surrogacy clinics.

Sub-clause *(1)* of this clause provides that no person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.

Sub-clause *(2)* of this clause provides that every application for registration under sub-clause *(1)* shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

Sub-clause *(3)* of this clause provides that every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in sub-clause *(ii)* of clause 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration. However, that such clinic shall cease to conduct any such counseling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

Sub-clause *(4)* of this clause provides that no surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

C1ause 11.—This clause relates to certificate of registration.

Sub-clause *(1)* of this clause provides that the appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act, rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.

Sub-clause *(2)* of this clause provides that where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

Sub-clause *(3)* of this clause provides that every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

Sub-clause *(4)* of this clause provides that the certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Clause 12.—This clause relates to cancellation or suspension of registration.

Sub-clause *(1)* of this clause provides that the appropriate authority may, *suo motu* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

Sub-clause *(2)* of this clause provides that if after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provision of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

Sub-clause *(3)* of this clause provides that notwithstanding anything contained in the sub-clauses *(1)* and *(2)* of clause 12, if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section *(1)* of clause *12*.

Clause 13.—This clause relates to appeal.

This clause provides that the surrogacy clinic may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under clause 12, prefer an appeal against such order to—*(a)* the State Government, where the appeal is against the order of the appropriate authority of a State; *(b)* to the Central Government, where the appeal is against the order of the appropriate authority of a Union territory, in such manner as may be prescribed.

Clause 14.—This clause relates to constitution of National Surrogacy Board.

Sub-clause *(1)* of this clause provides that the Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

Sub-clause *(2)* of this clause provides that the Board shall consist of—*(a)* the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio; (b)* the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio; (c)* three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio; (d)* three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs not below the rank of Joint Secretary, Members,

ex officio; (e) the Director General of Health Services of the Central Government, Member, *ex officio;* (f ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—*(i)* eminent medical geneticists or human embryologists; *(ii)* eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra; (iii)* eminent social scientists; *(iv)* representatives of women welfare organisations; and *(v)* representatives from civil society working on womens' health and child issues, possessing of such qualifications and experience as may be prescribed; *(g)* four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio; (h)* an officer, not below the rank of a Joint Secretary to the Central Government, in charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio.*

Clause 15.—This clause relates to term of office of Members.

Sub-clause *(1)* of this clause provides that the term of office of a Member, other than an *ex officio* Member, shall be—*(a)* in case of nomination of three women Members of Parliament, three years. However, that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; *(b)* in case of appointment of ten expert Members, one year. However, that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

Sub-clause *(2)* of this clause provides that any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

Sub-clause *(3)* of this clause provides that the Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Clause 16.—This clause relates to meetings of Board.

Sub-clause *(1)* of this clause provides that the Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations. However, that the Board shall meet at least once in six months.

Sub-clause *(2)* of this clause provides that the Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

Sub-clause *(3)* of this clause provides that all questions which come up before any meeting of the Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

Sub-clause *(4)* of this clause provides that the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meeting of the Board.

Clause 17.—This clause relates to vacancies, etc., not to invalidate proceedings of Board.

This clause provides that no act or proceeding of the Board shall be invalid merely by reason of—*(a)* any vacancy in, or any defect in the constitution of the Board; or *(b)* any defect in the appointment of a person acting as a Member of the Board; or *(c)* any irregularity in the procedure of the Board not affecting the merits of the case.

Clause 18.—This clause relates to disqualifications for appointment as Member.

Sub-clause *(1)* of this clause provides that a person shall be disqualified for being appointed and continued as a Member if, he—*(a)* has been adjudged as an insolvent; or *(b)* has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or *(c)* has become physically or mentally incapable of acting as a Member; or *(d)* has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or *(e)* has so abused his position, as to render his continuance in office prejudicial to the public interest; or *(f)* is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or *(g)* is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

Sub-clause *(2)* of this clause provides that the Members referred to in item *(f)* of sub-clause *(2)* of clause 14 shall not be removed from his office except by an order of the Central Government on the ground of his proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

Sub-clause *(3)* of this clause provides that the Central Government may suspend any Member in respect of whom an inquiry under sub-clause *(2)* of clause 18 is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Clause 19.—This clause relates to temporary association of persons with Board for particular purposes.

Sub-clause *(1)* of this clause provides that the Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

Sub-clause *(2)* of this clause provides that a person associated with the Board under sub-clause *(1)* of clause 19 shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.

Clause 20.—This clause relates to authentication of orders and other instruments of Board.

This clause provides that all orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Clause 21.—This clause relates to eligibility of Member for reappointment.

This clause provides that subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for reappointment as such Member. However, that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Clause 22.—This clause relates to functions of Board.

This clause provides that the Board shall discharge the following functions, namely:—*(a)* to advise the Central Government on policy matters relating to surrogacy; *(b)* to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein; *(c)* to lay down code of conduct to be observed by persons working at surrogacy clinics; to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics; *(d)* to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance; *(e)* to supervise the functioning of State Surrogacy Boards; and *(f)* such other functions as may be prescribed.

Clause 23.—This clause relates to Constitution of State Surrogacy Board.

Sub-clause *(1)* of this clause provides that the each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—*(i)* to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them; *(ii)* to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board; *(iii)* to send such consolidated reports as may be prescribed in respect of the various activities undertaken in the State under the Act to the Board and the Central Government; and *(iv)* such other functions as may be prescribed.

Clause 24.—This clause relates to composition of State Board.

This clause provides that the State Board shall consist of—*(a)* the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*; *(b)* the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio; (c)* Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, Members, *ex officio; (d)* Director General of Health and Family Welfare of the State Government, Member, *ex officio; (e)* three women Members of the State Legislative Assembly or Union territory Legislative Council, Members, *ex officio; (f)* ten expert Members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—*(i)* eminent medical geneticists or human embryologists; *(ii)* eminent gynaecologists and obstetricians or experts of *stri-roga* or *prasuti-tantra; (iii)* eminent social scientists; *(iv)* representatives of women welfare organisations; and (v) representatives from civil society working on womens' health and child issues, possessing of such qualifications and experiences as may be prescribed; *(g)* an officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Clause 25.—This clause relates to term of office of Members.

Sub-clause (1) of this clause provides that the term of office of a Member, other than an *ex officio* Member, shall be—*(a)* in case of nomination of three women Members of the State Legislative Assembly or Union Territory Legislative Council, Members, *ex officio,* three years. However, that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a Member of the House from which she was elected; *(b)* in case of appointment of ten expert Members, one year. However, that the person to be appointed as Member under this clause shall be of such age, as may be prescribed.

Sub-clause (2) of this clause provides that any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

Sub-clause (3) of this clause provides that the Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Clause 26.—This clause relates to meetings of State Board.

Sub-clause (1) of this clause provides that the State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations. However, that the State Board shall meet at least once in four months.

Sub-clause (2) of this clause provides that the Chairperson shall preside at the meeting of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

Sub-clause (3) of this clause provides that all questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the Members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.

Sub-clause (4) of this clause provides that the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Clause 27.—This clause relates to vacancies, etc., not to invalidate proceedings of State Board.

This clause provides that no act or proceeding of the State Board shall be invalid merely by reason of—*(a)* any vacancy in, or any defect in the constitution of the State Board; or *(b)* any defect in the appointment of a person acting as a Member of the State Board; or *(c)* any irregularity in the procedure of the State Board not affecting the merits of the case.

Clause 28.—This clause relates to disqualifications for appointment as Member.

Sub-clause (1) of this clause provides that a person shall be disqualified for being appointed and continued as a Member if, he—*(a)* has been adjudged as an insolvent; or *(b)* has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or *(c)* has become physically or mentally incapable of acting as a Member; or *(d)* has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or *(e)* has so abused his position, as to render his continuance in office prejudicial to the public interest; or *(f)* is a practicing Member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or *(g)* is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

Sub-clause (2) of this clause provides that the Members referred to in sub-clause *(f)* of clause 24 shall not be removed from his office except by an order of the State Government on the ground of his proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the Member ought on any such ground to be removed.

Sub-clause (3) of this clause provides that the State Government may suspend any Member in respect of whom an inquiry under sub-clause (2) of clause 28 is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Clause 29.—This clause relates to temporary association of persons with State Board for particular purposes.

Sub-clause (1) of this clause provides that the State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

Sub-clause (2) of this clause provides that a person associated with it by the State Board under sub-clause (1) of clause 29 shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a Member for any other purpose.

Clause 30.—This clause relates to authentication of orders and other instruments of State Board.

This clause provides that all orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

Clause 31.—This clause relates to eligibility of Member for reappointment.

This clause provides that subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for reappointment as such Member. However, that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Clause 32.—This clause relates to appointment of appropriate authority.

Sub-clause (1) of this clause provides that the Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union Territories for the purposes of this Act.

Sub-clause (2) of this clause provides that the State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or part of the State for the purposes of this Act.

Sub-clause (3) of this clause provides that the appropriate authority, under sub-clause (1) or sub-clause (2) of clause 32, shall,—*(a)* when appointed for the whole of the State or the Union Territory, consist of—*(i)* an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson; *(ii)* an eminent woman representing womens' organisation—Member; and *(iii)* an officer of Law Department of the State or the Union Territory concerned not below the rank of a Deputy Secretary—Member; *(iv)* an eminent registered medical practitioner —Member. However, that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy; *(b)* when appointed for any part of the State or the Union Territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

Clause 33.—This clause relates to functions of appropriate authority.

This clause provides that the appropriate authority shall discharge the following functions, namely:—*(a)* to grant, suspend or cancel registration of a surrogacy clinic; *(b)* to enforce the standards to be fulfilled by the surrogacy clinics; *(c)* to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act; *(d)* to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, suo motu or brought to its notice, and also to initiate independent investigations in such matter; *(e)* to supervise the implementation of the provisions of this Act, rules and regulations made thereunder; *(f)* to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions; *(g)* to take action after investigation of complaints received by it against the surrogacy clinics; and *(h)* to consider and grant or reject any application under the provisions of this Act.

Clause 34.—This clause relates to powers of appropriate authorities.

Sub-clause (1) of this clause provides that the appropriate authority shall exercise the powers in respect of the following matters, namely:—*(a)* summoning of any person who is in possession of any information relating to violation of the provisions of this Act, rules and regulations made thereunder; *(b)* production of any document or material object relating to sub-clause *(a); (c)* search any place suspected to be violating the provisions of this Act, rules and regulations made thereunder; and *(d)* such other powers as may be prescribed.

Sub-clause (2) of this clause provides that the appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of licence, etc., of the surrogacy clinics in such format as may be prescribed.

Clause 35.—This clause relates to prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

Sub-clause (1) of this clause provides that the no person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—*(a)* undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place; *(b)* issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise; *(c)* abandon or disown or exploit or cause to be abandoned, exploited or disowned in any form the child or children born through surrogacy; *(d)* exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever; *(e)* sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy; *(f)* import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures.

Sub-clause (2) of this clause provides that the notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of sub-clause (1) of clause 35 by any person shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

Sub-clause (3) of this clause provides that the for the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Clause 36.—This clause relates to punishment for contravention of provisions of Act.

Sub-clause (1) of this clause provides that the any registered medical practitioner, gynaecologists, pediatrician, human embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in clause 35), rules and regulations made thereunder shall be punishable with imprisonment for a term which shall not be less than five years and with fine which may extend to ten lakh rupees.

Sub-clause (2) of this clause provides that the in case of subsequent or continuation of the offence referred to in sub-clause (1) of clause 36, the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Clause 37.—This clause relates to punishment for initiation of commercial surrogacy.

This clause provides that any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynecologist, pediatrician, human embryologist or any other person for commercial surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which shall not be less than five years and

with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Clause 38.—This clause relates to penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

This clause provides that whoever contravenes any of the provisions of this Act, rules or regulations made thereunder for which no penalty has been elsewhere provided in this Act, shall be punishable with imprisonment for a term which shall not be less than three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Clause 39.—This clause relates to presumption in the case of surrogacy.

This clause provides that notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in sub-clause *(ii)* of clause 4 and such person shall be liable for abetment of such offence under clause 37 and shall be punishable for the offence specified under that clause.

Clause 40.—This clause relates to offence to be cognizable, non-bailable and non-compoundable.

This clause provides that notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable.

Clause 41.—This clause relates to cognizance of offences.

Sub-clause (1) of this clause provides that no court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—*(a)* the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or *(b)* a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

Sub-clause (2) of this clause provides that the no court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Clause 42.—This clause relates to certain provisions of the Code of Criminal Procedure, 1973 not to apply.

This clause provides that notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea of bargaining shall not apply to the offences under this Act.

Clause 43.—This clause relates to maintenance of records.

Sub-clause (1) of this clause provides that the surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be

preserved for a period of twenty-five years or such period as may be prescribed: However, that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

Sub-clause (2) of this clause provides that all such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Clause 44.—This clause relates to power to search and seize records, etc.

Sub-clause (1) of this clause provides that if the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

Sub-clause (2) of this clause provides that the provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act.

Clause 45.—This clause relates to protection of action taken in good faith.

Sub-clause (1) of this clause provides that no suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provision of this Act.

Clause 46.—This clause relates to application of other laws not barred.

This clause provides that the provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Clause 47.—This clause relates to power to make rules.

This clause provides that the Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

Clause 48.—This clause relates to power to make regulations.

This clause provides that the Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder.

Clause 49.—This clause provides that every rule, regulation and notification made under the proposed legislation shall be laid, as soon as may be after it is made, before the House of Parliament.

Clause 50.—This clause relates to transitional provision.

This clause provides that subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Clause 51.—This clause relates to power to remove difficulties.

Sub-clause (1) of this clause provides that if any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty. However, that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

Sub-clause (2) of this clause provides that the every order made under this clause shall be laid, as soon as may be after it is made, before each House of Parliament.

FINANCIAL MEMORANDUM

Clause (4) of section 16 and section 26 of the Surrogacy (Regulation) Bill, 2016 provides that for meetings of the National Surrogacy Board and State Surrogacy Board, the Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of such Boards. There will not be any financial implications except for the meetings of the National, State Surrogacy Boards and appropriate authorities which will be met out of the regular budget of the Central Government and State Governments.

2. The Bill does not involve any other expenditure of recurring or non-recurring nature from the Consolidated Fund of India.

MEMORANDUM REGARDING DELEGATED LEGISLATION

Clause 47 of the Bill seeks to empower the Central Government, by notification and subject to the condition of pre-publication, to make rules for carrying out the provisions of this Act. In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—*(a)* the minimum qualifications for persons employed at a registered surrogacy clinic under clause *(iii)* of section 3; *(b)* the manner in which a person shall store human embryo or gamete under clause *(vii)* of section 3; *(c)* the insurance coverage in favour of the surrogate mother from an insurance company under item *(III)* of sub-clause *(a)* of clause *(iii)* of section 4; *(d)* the number of attempts of surrogacy or providing of gametes under the proviso to item *(III)* of sub-clause *(b)* of clause *(iii)* of section 4; *(e)* the form in which consent of a surrogate mother has to be obtained under clause *(ii)* of section 6; *(f)* the number of oocytes or embryos to be implanted in the surrogate mother under section 8; *(g)* the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 9; *(h)* the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section *(2)* of section 10; *(i)* the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (4) of section 10; *(j)* the, manner and form in which a certificate of registration shall be issued under sub-section *(1)* of section 11; *(k)* the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (3) of section 11; *(l)* the manner in which an appeal may be preferred under section 13; *(m)* the qualifications and experiences to the Members as admissible under clause *(f)* of sub-section (2) of section 14; *(n)* the procedures for conducting an inquiry against the Members under sub-section (2) of section 18; *(o)* the terms and conditions under which a Member of the Board eligible for re-appointment under section 21; *(p)* the other functions of the Board under clause *(f)* of section 22; *(q)* the reports to be sent by the State and Union Territory Boards to the Board and the Central Government under clause *(iii)* of section 23; *(r)* the other functions of the State Board under clause *(iv)* of section 23; *(s)* the qualifications and experiences to the members and the manner of their appointment under clause *(f)* of section 24; *(t)* the age of the person to be appointed as a member, referred to in clause *(f)* of section 24, under the proviso to clause *(b)* of sub-section *(1)* of section 25; *(u)* the procedures for conducting an inquiry against the members under sub-section *(2)* of section 28; *(v)* the conditions under which the members of State Board eligible for re-appointment under section 31; *(w)* appropriate legal action by appropriate authority under clause *(d)* of section 33; *(x)* the other powers of appropriate authority under clause *(d)* of sub-section (1) of section 34; *(y)* the particulars of the details of registration of surrogacy clinics, cancellation of registration etc. in such format under sub-section (2) of section 34; *(z)* the manner of giving notice by a person under clause *(b)* of sub-section *(1)* of section 41; *(za)* the period up to which records, charts, etc., shall be preserved under sub-section (1) of section 43; *(zb)* the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (1) of section 44; and *(zc)* any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

2. Clause 48 of the Bill empowers the Board, with the prior approval of the Central Government, by notification, to make regulations not inconsistent with the provisions of this Act and the rules made

thereunder to provide for—*(a)* the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under Item (IV) sub-clause *(c)* of clause (iii) of section 4; *(b)* the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (1) of section 16; *(c)* the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 19; *(d)* the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (1) of section 26; *(e)* the manner in which a person may be temporarily associated with the Board under sub-section (1) of section 29; and *(f)* any other matter which is required to be, or may be, specified by regulations.

3. The matters in respect of which the said rules and regulations may be made are matters of procedure and administrative detail, and as such, it is not practicable to provide for them in the proposed Bill itself. The delegation of legislative power is, therefore, of a normal character.

LOK SABHA

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

———————

(Shri Jagat Prakash Nadda, Minister of Health and Family Welfare)

GMGIPMRND—3014LS(S3)—11-

LOK SABHA

CORRIGENDA

To

THE SURROGACY (REGULATION) BILL, 2016

[To be/As introduced in Lok Sabha]

1. Page 3, line 12,-

   for "regulation" means regulations'

   read ' "regulations" means the regulations'

2. Page 21, line 18,-

   for "pediatrician"

   read "paediatrician"

3. Page 21, line 22,-

   for "pediatrician"

   read "paediatrician"

4. Page 21, line 32,-

   for "pediatrician"

   read "paediatrician"

5. Page 21, line 38,-

   for "pediatrician"

   read "paediatrician"

6. Page 23, line 5 from the bottom,-

   for "counseling"

   read "counselling"

7. Page 27, line 6,-

   for "Sub-clause (1) of this clause"

   read "This clause"

8. Page 27, line 34,-

   for "in case of"

   read "in the case of"

9. Page 28, line 23,-

for “that the a person”

read “that a person”

10. Page 30, line 28,-

for “that the for the”

read “that for the”

11. Page 30, line 2 from the bottom,-

for “gynecologist”

read “gynacologist”

12. Page 31, line 31,-

for “not less that”

read “not less than”

13. Page 32, line 17,-

for “Sub-clause (1) of this clause”

read “This clause”

NEW DELHI;

November 16, 2016

Kartika 25, 1938 (Saka)

ANNEXURE-II

List of Witnesses Heard by the Committee

3rd March, 2017

WITNESSES

Representatives from the Department of Health Research

1. Dr. Soumya Swaminathan, Secretary & Director General, ICMR
2. Shri Manoj Pant, Joint Secretary
3. Shri V. K. Gauba, Joint Secretary
4. Ms. Bharati Das, Chief Controller of Accounts
5. Shri Sachin Mittal, Director (Budget)

Ministry of Law and Justice

Representatives from Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel
3. Shri I. C. Sharma, Deputy Legislative Counsel
4. Shri T. K. Malik, Deputy Legislative Assistant

Representatives from Department of Legal Affairs

Shri Ramayan Yadav, Additional Secretary

28th April, 2017

WITNESSES

Representatives from Indian Society of Third Party Assisted Reproduction (INSTAR)

1. Dr. Rita Bakshi, Vice-President
2. Dr. Shivani Sachdev Gour, General Secretary
3. Mr. Saurabh Kumar
4. Dr. Samit Shekhar

Indian Society for Assisted Reproduction (ISAR) and Federation of Obstetric and Gynaecological Societies of India (FOGSI)

1. Dr. Rishma Pai, President, FOGSI and Vice-President, ISAR
2. Dr. Sarita Sukhija, Vice President, Delhi Chapter, ISAR
3. Dr. Nandita Palshetkar

4. Dr. Jaydeep Tank

5. Mr. Amit Karkhanis

Expert

Mrs. Jayashree Wad, Supreme Court Lawyer

Department of Health Research

1. Shrimati Indira Sharma, Deputy Secretary

2. Dr. Kavitha Rajsekar, Scientist-D

Ministry of Law and Justice

Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary

2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

1. Shri Inder Kumar, Additional Secretary

2. Shri O. Venkateswarlu, Deputy Legal Adviser

24th May, 2017

WITNESSES

1. Dr. Kamini Rao, Member, National Advisory Committee for Drafting of Guidelines on Assisted Reproductive Technology

2. Ms. Pinki Virani , Journalist and Human Rights Activist

3. Ms. Sonali Kusum, Member, International Surrogacy Forum

Department of Health Research

1. Ms. Sarita Mittal, Joint Secretary

2. Ms. Indira Sharma, Deputy Secretary

3. Dr. Kavita Raj Shekhar, Scientist ' D'

Ministry of Law and Justice

Department of Legal Affairs

Shri Ramayan Yadav, Additional Secretary

Legislative Department

1. Dr. N.R. Battu, Joint Secretary

2. Shri R. Sreenivas, Additional Legislative Counsel

25th May, 2017

WITNESSES

Representatives from Surrogacy Laws India

1. Shri Anurag Chawla, Advocate
2. Ms. Diksha Bhatia, Advocate

Representatives from Trust Legal, Advocates and Consultants

Ms. Petal Chandhok, Advocate

Representatives from Amity Law School, Delhi

1. Ms. Aparajita Amar, Student
2. Shri Arjun Aggarwal, Student

Surrogate Mothers

1. * * *
2. * * *
3. * * *
4. * * *

Commissioning Parent

* * *

Department of Health Research

1. Ms. Sarita Mittal, Joint Secretary
2. Ms. Indira Sharma, Deputy Secretary
3. Dr. Kavita Raj Shekhar, Scientist ' D'

Ministry of Law and Justice

Legislative Department

1. Dr. N.R. Battu, Joint Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

Shri Ramayan Yadav, Additional Secretary

4th July, 2017

WITNESSES

Representative from National Law University, Delhi

1. Dr. Mrinal Satish, Associate Professor of Law, Executive Director, Centre for Constitutional Law, Policy and Governance, National Law University, Delhi

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***Identities withheld to protect privacy.

Department of Health Research

1. Dr.(Mrs.) Soumya Swaminathan, Secretary
2. Ms. Sarita Mittal, Joint Secretary
3. Ms. Indira Sharma, Deputy Secretary
4. Dr. Kavitha Rajshekar, Scientist-D

Legislative Department

1. Dr. Reeta Vasishta, Additional Secretary
2. Shri R. Sreenivas, Additional Legislative Counsel

Department of Legal Affairs

1. Shri Ramayan Yadav, Additional Secretary
2. Shri O. Venkateswarlu, Deputy Legal Adviser

Court Cases – Surrogacy in India

Sl.No	Date	Place of Country of occurrence	Country of Surrogate Mother	Country of Commissio-ning Parents	Brief of the matter	Court's intervention
1	2	3	4	5	6	7
1.	April, 2015	India, New Delhi	India	India	WP (C) No. 95/2015 PIL filed by Smt. Jayashree Wad in the Supreme Court of India for protecting the surrogate mothers and with prayer to ban commercial surrogacy in India. Govt. of India have issued necessary Notifications dated 04.11.2015 for surrogacy in India. Commercial surrogacy is not supported and banned in India.	Hon'ble Court have accepted the actions of the Government to ban commercial surrogacy in India.
2.	January, 2008	India, Gujarat	India	Germany	Civil Appeal No.8714/2010 filed by Jan Balaz in the Supreme Court of India. Two baby boys were born out of Indian surrogate mother. Commissioning parents applied for citizenship but the authorities denied because in the Birth Certificate, name of the father was the German national and name of the mother was the surrogate mother. Both the surrogate children were left without citizenship.	Court intervened into the matter and directed the authorities to issue Passports in the name of both the babies as Indian citizens.
3.	July, 2008	India, Gujarat	India	Japan	W.P.(C)369/2008 filed by Manji Yamada in the Supreme Court of India. The commissioning parents refused to accept the surrogate child born out of surrogacy due to divorce and break of marriage between them. The surrogate mother was also not	Court intervened into the matter and directed the custody of the child to the grandmother of the surrogate child to take care.

1	2	3	4	5	6	7
					capable to accept the child. The child was left without parents and no one to take care.	
4.	September, 2012	India, Kerala	India	India	OP (FC) No.2488/2012 filed by Shri Harihara Vaarma in the High Court of Kerala at Ernakulam. A surrogate mother was harassed by claiming that a verbal agreement of surrogacy was executed with her for amount of ₹ 5 lakh and advance of ₹ l lakh was given to her. The surrogate mother denied.	The Court intervened into the matter to protect the surrogate mother and dismissed such claim.
5.	December, 2012	India, Delhi	India	Australia	National Inquiry was initiated by the Hon'ble Chief Justice of the Family Court, Sydney. Australian couple arbitrarily rejected one of the twins born out of Indian surrogate mother and took home only one sibling. The Australian couple mislead the Indian authorities and applied for Australian citizenship for only one child. The other child was left behind by the Australian couple without official parents or citizenship of elher country.	The Chief Justice of the Family Court, Diana Bryant, has called for a national inquiry into commercial surrogacy after highlighting the case.
6.	June, 2013	India, Chandigarh	India	Sudan	CWP No.26485/2014 filed by Shihabeldin in the Hon'ble High Court of Punjab and Haryana. Surrogacy was tried to be executed with surrogate mother by a single parent of Sudan which was not disclosed to the surrogate mother.	Court intervened into the matter and stopped the surrogacy process with immediate effect.
7.	March, 2014	India, Chennai	India	United States	WP No. 26485/2014 filed by Smt. Anandhi in the High Court of Chennai. During the surrogacy process and after delivery of the surrogate child, no medical attention was given to the surrogate mother when she suffered from various complications.	Court intervened into the matter and directed the clinic to take care of the surrogate mother.

ANNEXURE-IV

(1) Ernst and young study (CALL FOR ACTION:
expanding IVF treatment in India, July 2015)

- 10-15% of the indian couple are infertile that amounts to 27.5 million couple.
- 1%, that is about 270,000 infertile couples come forward for infertility evaluation.
- 20-25% of these total couples registering at an infertility center undergo IVF treatment (this represents only 10% of the total infertile couple seeking to opt for a fertility treatment).
- So, if we advice the infertile couples to opt for adoption- is adoption system in our country strong enough to cater to as many as 27.5 million infertile couples? Do we have enough babies for so many desperate infertile couple in our country?
- The waiting time in India for adoption varies from 1-3 years.

[TRUE COPY]

As passed by Lok Sabha
on 05.08.2019

Bill No. 156-C of 2019

THE SURROGACY (REGULATION) BILL, 2019

ARRANGEMENT OF CLAUSES

CHAPTER I

PRELIMINARY

CLAUSES

1. Short title, extent and commencement.
2. Definitions.

CHAPTER II

REGULATION OF SURROGACY CLINICS

3. Prohibition and regulation of surrogacy clinics.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

4. Regulation of surrogacy and surrogacy procedures.
5. Prohibition of conducting surrogacy.
6. Written informed consent of surrogate mother.
7. Prohibition to abandon child born through surrogacy.
8. Number of oocytes or human embryos to be implanted.
9. Prohibition of abortion.

CHAPTER IV

REGISTRATION OF SURROGACY CLINICS

10. Registration of surrogacy clinics.
11. Certificate of registration.
12. Cancellation or suspension of registration.
13. Appeal.

CHAPTER V

NATIONAL AND STATE SURROGACY BOARDS

14. Constitution of National Surrogacy Board.
15. Term of office of Members.
16. Meetings of Board.
17. Vacancies, etc., not to invalidate proceedings of Board.
18. Disqualifications for appointment as Member.
19. Temporary association of persons with Board for particular purposes.
20. Authentication of orders and other instruments of Board.

CLAUSES

21. Eligibility of Member for re-appointment.

22. Functions of Board.

23. Constitution of State Surrogacy Board.

24. Composition of State Board.

25. Term of office of members.

26. Meetings of State Board.

27. Vacancies, etc., not to invalidate proceedings of State Board.

28. Disqualifications for appointment as member.

29. Temporary association of persons with State Board for particular purposes.

30. Authentication of orders and other instruments of State Board.

31. Eligibility of member for re-appointment.

CHAPTER VI

APPROPRIATE AUTHORITY

32. Appointment of appropriate authority.

33. Functions of appropriate authority.

34. Powers of appropriate authorities.

CHAPTER VII

OFFENCES AND PENALTIES

35. Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

36. Punishment for contravention of provisions of Act.

37. Punishment for initiation of commercial surrogacy.

38. Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

39. Presumption in the case of surrogacy.

40. Offence to be cognizable, non-bailable and non-compoundable.

41. Cognizance of offences.

42. Certain provisions of Code of Criminal Procedure, 1973 not to apply.

CHAPTER VIII

MISCELLANEOUS

43. Maintenance of records.

44. Power to search and seize records, etc.

45. Protection of action taken in good faith.

46. Application of other laws not barred.

47. Power to make rules.

48. Power to make regulations.

49. Rules and regulations to be laid before Parliament.

50. Transitional provision.

51. Power to remove difficulties.

As passed by Lok Sabha
on 05.08.2019

Bill No. 156-C of 2019

THE SURROGACY (REGULATION) BILL, 2019

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Seventieth Year of the Republic of India as follows:—

CHAPTER I
Preliminary

Short title, extent and commencement.

1. (*1*) This Act may be called the Surrogacy (Regulation) Act, 2019.

(*2*) It extends to the whole of India except the State of Jammu and Kashmir.

(*3*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

Definitions.

2. In this Act, unless the context otherwise requires,—

(*a*) "abandoned child" means a child born out of surrogacy procedure who has been deserted by his intending parents or guardians and declared as abandoned by the appropriate authority after due enquiry;

(*b*) "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;

(*c*) "appropriate authority" means the appropriate authority appointed under section 32;

(*d*) "Board" means the National Surrogacy Board constituted under section 14;

(*e*) "clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010; 23 of 2010.

(*f*) "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses incurred on the surrogate mother and the insurance coverage for the surrogate mother;

(*g*) "couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;

(*h*) "egg" includes the female gamete;

(*i*) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;

(*j*) "embryologist" means a person who possesses any post-graduate medical qualification in the field of human embryology recognised under the Indian Medical Council Act, 1956 or who possesses a post-graduate degree in human embryology from a recognised university with not less than two years of clinical experience; 102 of 1956.

(*k*) "fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;

(*l*) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;

(*m*) "gamete" means sperm and oocyte;

(*n*) "gynaecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*o*) "implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;

(*p*) "infertility" means the inability to conceive after five years of unprotected coitus or other proven medical condition preventing a couple from conception;

(*q*) "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for specified loss, damage, illness or death of surrogate mother during the process of surrogacy;

(*r*) "intending couple" means a couple who have been medically certified to be an infertile couple and who intend to become parents through surrogacy;

(*s*) "Member" means a Member of the National Surrogacy Board or a State Surrogacy Board, as the case may be;

(*t*) "notification" means a notification published in the Official Gazette;

(*u*) "oocyte" means naturally ovulating oocyte in the female genetic tract;

(*v*) "Paediatrician" means a person who possesses a post-graduate qualification in paediatrics as recognised under the Indian Medical Council Act, 1956; 102 of 1956.

(*w*) "prescribed" means prescribed by rules made under this Act;

(*x*) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (*h*) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register; 102 of 1956.

(*y*) "regulation" means regulations made by the Board under this Act;

(*z*) "sex selection" shall have the same meaning as assigned to it in clause (*o*) of section 2 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994; 57 of 1994.

(*za*) "State Board" means the State Surrogacy Board constituted under section 23;

(*zb*) "State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under article 239 of the Constitution;

(*zc*) "surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;

(*zd*) "surrogacy clinic" means surrogacy clinic, centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counselling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called, conducting surrogacy procedures in any form;

(*ze*) "surrogacy procedures" means all gynaecological, obstetrical or medical procedures, techniques, tests, practices or services involving handling of human gametes and human embryo in surrogacy;

(*zf*) "surrogate mother" means a woman bearing a child (who is genetically related to the intending couple) through surrogacy from the implantation of embryo in her womb and fulfils the conditions as provided in sub-clause (*b*) of clause (*iii*) of section 4;

(*zg*) "zygote" means the fertilised oocyte prior to the first cell division.

CHAPTER II

REGULATION OF SURROGACY CLINICS

Prohibition and regulation of surrogacy clinics.

3. On and from the date of commencement of this Act,—

(*i*) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;

(*ii*) no surrogacy clinic, paediatrician, gynaecologist, embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;

(*iii*) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment, who does not possess such qualifications as may be prescribed;

(*iv*) no registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;

(*v*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—

(*a*) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;

(*b*) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;

(*c*) seeks or aimed at seeking a woman to act as a surrogate mother;

(*d*) states or implies that a woman is willing to become a surrogate mother; or

(*e*) advertises commercial surrogacy in print or electronic media or in any other form;

(*vi*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:

Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971; 34 of 1971.

(*vii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:

Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed;

(*viii*) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall in any form conduct or cause to be conducted sex selection for surrogacy.

CHAPTER III

REGULATION OF SURROGACY AND SURROGACY PROCEDURES

Regulation of surrogacy and surrogacy procedures.

4. On and from the date of commencement of this Act,—

(*i*) no place including a surrogacy clinic shall be used or cause to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause (*ii*) and after satisfying all the conditions specified in clauses (*iii*);

(*ii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—

(*a*) when either or both members of the couple is suffering from proven infertility;

(*b*) when it is only for altruistic surrogacy purposes;

(*c*) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;

(*d*) when it is not for producing children for sale, prostitution or any other form of exploitation; and

(*e*) any other condition or disease as may be specified by regulations made by the Board;

(*iii*) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—

(*a*) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying itself, for the reasons to be recorded in writing, about the fulfilment of the following conditions, namely:—

(*I*) a certificate of proven infertility in favour of either or both members of the intending couple from a District Medical Board;

Explanation.—For the purposes of this sub-clause, the expression "District Medical Board" means a medical board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the district and comprising of at least two other specialists, namely, the chief gynaecologist or obstetrician and chief paediatrician of the district;

(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, has been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple and the surrogate mother; and

(*III*) an insurance coverage of such amount as may be prescribed in favour of the surrogate mother for a period of sixteen months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999; 41 of 1999.

(*b*) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;

(*II*) no person, other than a close relative of the intending couple, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;

(*III*) no woman shall act as a surrogate mother by providing her own gametes;

(*IV*) no woman shall act as a surrogate mother more than once in her lifetime:

Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed; and

(*V*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;

(*c*) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfilment of the following conditions, namely:—

(*I*) the age of the intending couple is between 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;

(*II*) the intending couple are married for at least five years and are Indian citizens;

(*III*) the intending couple have not had any surviving child biologically or through adoption or through surrogacy earlier:

Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by the appropriate authority with due medical certificate from a District Medical Board; and

(*IV*) such other conditions as may be specified by the regulations.

Prohibition of conducting surrogacy.

5. No person including a relative or husband of a surrogate mother or intending couple shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause (*ii*) of section 4.

Written informed consent of surrogate mother.

6. (*1*) No person shall seek or conduct surrogacy procedures unless he has—

(*i*) explained all known side effects and after effects of such procedures to the surrogate mother concerned; and

(*ii*) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.

(*2*) Notwithstanding anything contained in sub-section (*1*), the surrogate mother shall have an option to withdraw her consent for surrogacy before the implantation of human embryo in her womb.

Prohibition to abandon child born through surrogacy.

7. The intending couple shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like:

Provided that any child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force.

Number of oocytes or human embryos to be implanted.

8. The number of oocytes or human embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.

Prohibition of abortion.

9. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.

CHAPTER IV

Registration of surrogacy clinics

Registration of surrogacy clinics.

10. (*1*) No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.

(*2*) Every application for registration under sub-section (*1*) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.

(*3*) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, for the purposes referred to in clause (*ii*) of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:

Provided that such clinic shall cease to conduct any such counselling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.

(*4*) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipments and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed.

Certificate of registration.

11. (*1*) The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules and regulations made thereunder, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.

(*2*) Where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made thereunder, it shall, for reasons to be recorded in writing, reject the application for registration.

(*3*) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.

(*4*) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.

Cancellation or suspension of registration.

12. (*1*) The appropriate authority may, *suo motu* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(*2*) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of any of the provisions of the Act or the rules or regulations made thereunder, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.

(*3*) Notwithstanding anything contained in sub-sections (*1*) and (*2*), if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (*1*).

Appeal.

13. The surrogacy clinic may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section 12, prefer an appeal against such order to—

(*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;

(*b*) to the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,

in such manner as may be prescribed.

CHAPTER V

NATIONAL AND STATE SURROGACY BOARDS

Constitution of National Surrogacy Board.

14. (*1*) The Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.

(*2*) The Board shall consist of—

(*a*) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*;

(*b*) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;

(*c*) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio*;

(*d*) three Members of the Ministries of the Central Government in-charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, *ex officio*;

(*e*) the Director General of Health Services of the Central Government, Member, *ex officio*;

(*f*) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians or experts of stri-roga or prasuti-tantra;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experience as may be prescribed;

(*g*) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*; and

(*h*) an officer, not below the rank of a Joint Secretary to the Central Government, in-charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of Members.

15. (*1*) The term of office of a Member, other than an *ex officio* Member, shall be—

(*a*) in case of nomination under clause (*c*) of sub-section (*2*) of section 14, three years:

Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of sub-section (*2*) of section 14, one year:

Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of Board.

16. (*1*) The Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:

Provided that the Board shall meet at least once in six months.

(*2*) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.

(*3*) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the Board.

Vacancies, etc., not to invalidate proceedings of Board.

17. No act or proceeding of the Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the Board; or

(*b*) any defect in the appointment of a person acting as a Member of the Board; or

(*c*) any irregularity in the procedure of the Board not affecting the merits of the case.

Disqualifications for appointment as Member.

18. (*1*) A person shall be disqualified for being appointed and continued as a Member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a Member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office-bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or

(*g*) is an office-bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The Members referred to in clause (*f*) of section 14 shall not be removed from their office except by an order of the Central Government on the ground of their proved misbehaviour or incapacity after the Central Government has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.

(*3*) The Central Government may suspend any Member against whom an inquiry under sub-section (*2*) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with Board for particular purposes.

19. (*1*) The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with the Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote in a meeting of the Board and shall not be a Member for any other purpose.

Authentication of orders and other instruments of Board.

20. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.

Eligibility of Member for re-appointment.

21. Subject to other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:

Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.

Functions of Board.

22. The Board shall discharge the following functions, namely:—

(*a*) to advise the Central Government on policy matters relating to surrogacy;

(*b*) to review and monitor the implementation of the Act, and the rules and regulations made thereunder and recommend to the Central Government, changes therein;

(*c*) to lay down the code of conduct to be observed by persons working at surrogacy clinics;

(*d*) to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;

(*e*) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;

(*f*) to supervise the functioning of State Surrogacy Boards; and

(*g*) such other functions as may be prescribed.

Constitution of State Surrogacy Board.

23. Each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—

(*i*) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them;

(*ii*) to monitor the implementation of the provisions of the Act, and the rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;

(*iii*) to send such consolidated reports as may be prescribed, in respect of the various activities undertaken in the State under the Act, to the Board and the Central Government; and

(*iv*) such other functions as may be prescribed.

Composition of State Board.

24. The State Board shall consist of—

(*a*) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;

(*b*) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;

(*c*) Secretaries or Commissioners in-charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, *ex officio*;

(*d*) Director-General of Health and Family Welfare of the State Government, member, *ex officio*;

(*e*) three women members of the State Legislative Assembly or Union territory Legislative Council, members, *ex officio*;

(*f*) ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(*i*) eminent medical geneticists or embryologists;

(*ii*) eminent gynaecologists and obstetricians or experts of stri-roga or prasuti-tantra;

(*iii*) eminent social scientists;

(*iv*) representatives of women welfare organisations; and

(*v*) representatives from civil society working on women's health and child issues,

possessing such qualifications and experiences as may be prescribed;

(*g*) an officer not below the rank of Joint Secretary to the State Government in-charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.

Term of office of members.

25. (*1*) The term of office of a member, other than an *ex officio* member, shall be—

(*a*) in case of nomination under clause (*e*) of section 24, three years:

Provided that the term of such member shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to be a member of the House from which she was elected; and

(*b*) in case of appointment under clause (*f*) of section 24, one year:

Provided that the person to be appointed as member under this clause shall be of such age, as may be prescribed.

(*2*) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one month from the date on which such vacancy occurs by the State Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.

(*3*) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time.

Meetings of State Board.

26. (*1*) The State Board shall meet at such places and times and shall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be specified by the regulations:

Provided that the State Board shall meet at least once in four months.

(*2*) The Chairperson shall preside at the meetings of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.

(*3*) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have a second or casting vote.

(*4*) The members, other than *ex officio* members, shall receive only compensatory travelling expenses for attending the meetings of the State Board.

Vacancies, etc., not to invalidate proceedings of State Board.

27. No act or proceeding of the State Board shall be invalid merely by reason of—

(*a*) any vacancy in, or any defect in the constitution of, the State Board; or

(*b*) any defect in the appointment of a person acting as a member of the State Board; or

(*c*) any irregularity in the procedure of the State Board not affecting the merits of the case.

Disqualifications for appointment as member.

28. (*1*) A person shall be disqualified for being appointed and continued as a member if, he—

(*a*) has been adjudged as an insolvent; or

(*b*) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or

(*c*) has become physically or mentally incapable of acting as a member; or

(*d*) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a member; or

(*e*) has so abused his position, as to render his continuance in office prejudicial to the public interest; or

(*f*) is a practicing member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his functions as a member; or

(*g*) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.

(*2*) The members referred to in clause (*f*) of section 24 shall not be removed from their office except by an order of the State Government on the ground of their proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the member ought on any such ground to be removed.

(*3*) The State Government may suspend any member against whom an inquiry under sub-section (*2*) is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.

Temporary association of persons with State Board for particular purposes.

29. (*1*) The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.

(*2*) A person associated with it by the State Board under sub-section (*1*) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a member for any other purpose.

Authentication of orders and other instruments of State Board.

30. All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.

31. Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for re-appointment as such member: Eligibility of member for re-appointment.

Provided that no member other than an *ex officio* member shall be appointed for more than two consecutive terms.

CHAPTER VI

APPROPRIATE AUTHORITY

32. (*1*) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act. Appointment of appropriate authority.

(*2*) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or any part of the State for the purposes of this Act.

(*3*) The appropriate authority, under sub-section (*1*) or sub-section (*2*), shall,—

(*a*) when appointed for the whole of the State or the Union territory, consist of—

(*i*) an officer of or above the rank of the Joint Director of Health and Family Welfare Department—Chairperson;

(*ii*) an eminent woman representing women's organisation—member;

(*iii*) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—member; and

(*iv*) an eminent registered medical practitioner—member:

Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(*b*) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

33. The appropriate authority shall discharge the following functions, namely:— Functions of appropriate authority.

(*a*) to grant, suspend or cancel registration of a surrogacy clinic;

(*b*) to enforce the standards to be fulfilled by the surrogacy clinics;

(*c*) to investigate complaints of breach of the provisions of this Act, rules and the regulations made thereunder and take legal action as per provisions of this Act;

(*d*) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo motu* or brought to its notice, and also to initiate independent investigations in such matter;

(*e*) to supervise the implementation of the provisions of this Act and rules and regulations made thereunder;

(*f*) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(*g*) to take action after investigation of complaints received by it against the surrogacy clinics; and

(*h*) to consider and grant or reject any application under clause (*vi*) of section 3 and sub-clauses (*a*) to (*c*) of clause (*iii*) of section 4 within a period of ninety days.

Powers of appropriate authorities.

34. (*1*) The appropriate authority shall exercise the powers in respect of the following matters, namely:—

(*a*) summoning of any person who is in possession of any information relating to violation of the provisions of this Act, and the rules and regulations made thereunder;

(*b*) production of any document or material object relating to clause (*a*);

(*c*) search any place suspected to be violating the provisions of this Act, and the rules and regulations made thereunder; and

(*d*) such other powers as may be prescribed.

(*2*) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of license, etc., of the surrogacy clinics in such format as may be prescribed.

CHAPTER VII

Offences and penalties

Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

35. (*1*) No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—

(*a*) undertake or provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;

(*b*) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated, any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;

(*c*) abandon, disown or exploit or cause to be abandoned, disowned or exploited in any form, the child or children born through surrogacy;

(*d*) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;

(*e*) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organisation for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;

(*f*) import or shall help in getting imported in, whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures; and

(*g*) conduct sex selection in any form for surrogacy.

(*2*) Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of clauses (*a*) to (*g*) of sub-section (*1*) by any person shall be an offence punishable with imprisonment for a term which may extend to ten years and with fine which may extend to ten lakh rupees. 45 of 1860.

(*3*) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.

Punishment for contravention of provisions of Act.

36. (*1*) Any registered medical practitioner, gynaecologists, pediatrician, embryologists or any person who owns a surrogacy clinic or employed with such a clinic, centre or laboratory and renders his professional or technical services to or at such clinic, centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the

provisions of this Act (other than the provisions referred to in section 35) and rules and regulations made thereunder shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.

(*2*) In case of subsequent or continuation of the offence referred to in sub-section (*1*), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.

Punishment for initiation of commercial surrogacy.

37. Any intending couple or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynaecologist, pediatrician, embryologist or any other person for commercial surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.

Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.

38. Whoever contravenes any of the provisions of this Act or the rules or the regulations made thereunder for which no penalty has been provided in this Act, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.

Presumption in the case of surrogacy.

1 of 1872.

39. Notwithstanding anything contained in the Indian Evidence Act, 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause (*ii*) of section 4 and such person shall be liable for abetment of such offence under section 37 and shall be punishable for the offence specified under that section.

Offence to be cognizable, non-baliable and non-compoundable.

2 of 1974.

40. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable.

Cognizance of offences.

41. (*1*) No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—

(*a*) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or

(*b*) a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.

(*2*) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

Certain provisions of Code of Criminal Procedure, 1973 not to apply.

2 of 1974.

42. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea bargaining shall not apply to the offences under this Act.

CHAPTER VIII

MISCELLANEOUS

Maintenance of records.

43. (*1*) The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty-five years or such period as may be prescribed:

Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.

(*2*) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.

Power to search and seize records, etc.

44. (*1*) If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.

(*2*) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorised by it under this Act. 2 of 1974.

Protection of action taken in good faith.

45. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provisions of this Act.

Application of other laws not barred.

46. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.

Power to make rules.

47. (*1*) The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.

(*2*) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—

(*a*) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (*iii*) of section 3;

(*b*) the manner in which a person shall store human embryo or gamete under clause (*vii*) of section 3;

(*c*) the insurance coverage in favour of the surrogate mother from an insurance company under item (*III*) of sub-clause (*a*) of clause (*iii*) of section 4;

(*d*) the number of attempts of surrogacy or providing of gametes under the proviso to item (*III*) of sub-clause (*b*) of clause (*iii*) of section 4;

(*e*) the form in which consent of a surrogate mother has to be obtained under clause (*ii*) of section 6;

(*f*) the number of oocytes or embryos to be implanted in the surrogate mother under section 8;

(*g*) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section 9;

(*h*) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (*2*) of section 10;

(*i*) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (*4*) of section 10;

(*j*) the period, manner and form in which a certificate of registration shall be issued under sub-section (*1*) of section 11;

(*k*) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (*3*) of section 11;

(*l*) the manner in which an appeal may be preferred under section 13;

(*m*) the qualifications and experiences of the Members as admissible under clause (*f*) of sub-section (*2*) of section 14;

(*n*) the procedures for conducting an inquiry against the Members under sub-section (*2*) of section 18;

(*o*) the conditions under which a Member of the Board eligible for re-appointment under section 21;

(*p*) the other functions of the Board under clause (*g*) of section 22;

(*q*) the manner in which reports shall be furnished by the State and Union territory Boards to the Board and the Central Government under clause (*iii*) of section 23;

(*r*) the other functions of the State Board under clause (*iv*) of section 23;

(*s*) the qualifications and experiences of the members as admissible under clause (*f*) of section 24;

(*t*) the age of the person to be appointed as a member, referred to in clause (*f*) of section 24, under the proviso to clause (*b*) of sub-section (*1*) of section 25;

(*u*) the procedures for conducting an inquiry against the members under sub-section (*2*) of section 28;

(*v*) the conditions under which the members of State Board eligible for re-appointment under section 31;

(*w*) empowering the appropriate authority in any other matter under clause (*d*) of section 33;

(*x*) the other powers of appropriate authority under clause (*d*) of sub-section (*1*) of section 34;

(*y*) the particulars of the details of registration of surrogacy clinics, cancellation of registration, etc., in such format under sub-section (*2*) of section 34;

(*z*) the manner of giving notice by a person under clause (*b*) of sub-section (*1*) of section 41;

(*za*) the period up to which records, charts, etc., shall be preserved under sub-section (*1*) of section 43;

(*zb*) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under sub-section (*1*) of section 44; and

(*zc*) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.

Power to make regulations.

48. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made thereunder to provide for—

(*a*) the fulfilment of any other condition under which eligibility certificate to be issued by the appropriate authority under item IV of sub-clause (*c*) of clause (*iii*) of section 4;

(*b*) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (*1*) of section 16;

(*c*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 19;

(*d*) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (*1*) of section 26;

(*e*) the manner in which a person may be temporarily associated with the Board under sub-section (*1*) of section 29; and

(*f*) any other matter which is required to be, or may be, specified by regulations.

Rules and regulations to be laid before Parliament.

49. Every rule made by the Central Government and every regulation made by the Board under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.

Transitional provision.

50. Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.

Power to remove difficulties.

51. (*1*) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette, make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:

Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.

(*2*) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.

LOK SABHA

A

BILL

to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.

(*As passed by Lok Sabha)*

MGIPMRND—2447LS(S3)—05-08-2019.

[TRUE COPY]

PARLIAMENT OF INDIA

RAJYA SABHA

REPORT OF THE SELECT COMMITTEE

ON

THE SURROGACY (REGULATION) BILL, 2019

(*Presented to the Rajya Sabha on 5th February,* 2020)

Rajya Sabha Secretariat, New Delhi

February, 2020/Magha, 1941 (SAKA)

Website: http://rajyasabha.nic.in

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COMPOSITION OF THE COMMITTEE

(Constituted on 21st November, 2019)

1. Shri Bhupender Yadav - Chairman

2. Dr. Vikas Mahatme
3. Ms. Saroj Pandey
4. Shri Ashwini Vaishnaw
5. Shri Jairam Ramesh
6. Dr. Amee Yajnik
7. Shri Abir Ranjan Biswas
8. Shri A. Navaneethakrishnan
9. Shri Ravi Prakash Verma
10. Shri Prasanna Acharya
11. Shri Ram Chandra Prasad Singh
12. Dr. Banda Prakash
13. Shri K. Somaprasad
14. Shri R.S. Bharathi
15. Shri Veer Singh
16. Shrimati Vandana Chavan
17. Shri Anil Desai
18. Shri Naresh Gujral
19. Shri Sushil Kumar Gupta
20. Shri V. Vijayasai Reddy
21. Shri Hishey Lachungpa
22. Shri Parimal Nathwani
23. Shri Sambhaji Chhatrapati

SECRETARIAT

1.	Shri P.P.K. Ramacharyulu	Secretary
2.	Shri J. Sundriyal	Joint Secretary
3.	Shri V.S.P. Singh	Director
4.	Shri Bhupendra Bhaskar	Additional Director
5.	Shrimati Harshita Shankar	Under Secretary
6.	Shri Rajesh Kumar Sharma	Assistant Committee Officer
7.	Ms. Monika Garbyal	Assistant Committee Officer
8.	Shri Parth Gupta	Assistant Research Officer

PREFACE

I, the Chairman of the Select Committee on the Surrogacy (Regulation) Bill, 2019, having been authorized by the Committee to present the Report on its behalf, do hereby present this Report on the Bill.

2. The Surrogacy (Regulation) Bill, 2019 **(Annexure I)** as passed by the Lok Sabha on 5th August, 2019, was referred* to the Select Committee, comprising of 23 Members of Rajya Sabha on a Motion adopted by the House on the 21st November, 2019 for examination of the Bill and report thereon to the Rajya Sabha by the last day of the first week of the next Session.

3. The Committee issued a Press Release inviting memoranda/views from individuals and other stakeholders. In response thereto, 54 memoranda from different organizations/associations and individuals were received. These memoranda were forwarded to the Department of Health Research for their comments. The Committee also invited the views from the State Governments/ Governments of Union Territories and received response from two State Governments only.

4. The Committee undertook a study visit to Vadodra, Anand, Hyderabad and Mumbai from 21st to 24th January, 2020. A note on the study tour is at **Annexure** II. During the Study Visit, the Committee visited surrogacy clinics, had interaction with doctors, surrogate mothers, surrogate children and intending couples, etc. The Committee also heard the views of State Government of Gujrat, Telengana & Andhra Pradesh and Maharashtra.

5. The Select Committee held a total of 9 sittings for examination of the Bill, i.e., on 3rd, 9th, 12th, 20th 30th December, 2019, 10th, 21st, 31st January, 2020 and 3rd February, 2020. The list of witnesses heard by the Committee is at **Annexure-III**.

** Rajya Sabha Parliamentary Bulletin Part II, No.59420, dated 26th November, 2019.*

6. In its first meeting held on 3rd December, 2019, the Committee deliberated upon the future course of action for examination of the Bill and decided to hear the views of Secretary of Department of Health Research.

7. At its second meeting held on 9th December, 2019, the Committee heard the views of stakeholders. In its meeting, the Committee decided to issue a Press Release seeking views of the opinions of stakeholders, experts, organizations, etc. It was also decided to elicit the views of State Governments. Thereafter the Committee heard the views of Secretary, Department of Health Research.

8. The Committee in its third meeting held on 12th December, 2019 had a PowerPoint presentation on the recommendations made by the Parliamentary Standing Committee on Health & Family Welfare in its 102nd Report on the Surrogacy (Regulation) Bill, 2016, which have not been accepted by the Department. Clarifications were sought from the Department of Health Research on aforesaid recommendations.

9. In its fourth meeting held on 20th December, 2019, the Committee sought clarifications from the Department of Health Research.

10. In its fifth meeting held on 30th December, 2019, the Committee heard the views of representatives of National Human Rights Commission, National Commission for Protection of Child Rights, SAMA – Resource Group for Women and Health and Secretary, Ministry of Women and Child Development.

11. In its sixth meeting held on 10th January, 2020, the Committee heard the views of representatives of United Nations Population Fund, PRS Legislative Research, Dr. Prof. Neeta Singh, Expert, Division of Reproductive Medicine,

AIIMS, New Delhi and Dr. Kamini A. Rao, Milann (A Brand of BACC Health Care Pvt. Ltd.) on the Bill.

12. The Committee took up clause-by-clause consideration of the Bill in its meeting held on 1st February, 2020. The Committee considered the draft Report and adopted the same on 3rd February, 2020.

13. For examination of the Bill and finalisation of the Report thereon, the Committee considered and relied on the following documents placed before it:-

(i) The Surrogacy (Regulation) Bill, 2019;

(ii) Background Note on the Bill received from the Department of Health Research;

(iii) Presentation, clarifications and Oral evidence of Secretary, Department of Health Research and comments of the Legislative Department;

(iv) Replies to questionnaires received from the Department of Health Research and comments of the Legislative Department;

(v) Oral evidence and written submissions by various stakeholders/experts on the Bill;

(vi) Memoranda received on the Bill from various institutes/ bodies/ associations/ organizations/ experts and replies of the Department on the memoranda selected by the Committee for examination;

(vii) Feedback received during study visit.

14. Surrogacy per se and The Surrogacy (Regulation) Bill, 2019, in particular, is a unique amalgamation of social, ethical, moral, legal and scientific issues and it is necessary to harmonise the conflicting interests inherent in the process of surrogacy to ensure betterment of child while protecting rights of surrogate mother.

15. Legal issues relating to surrogacy get manifested in a number of court cases – the prominent being the Baby M case in USA, Jaycee B. Vs. Superior Court, Baby Manji Yamada Vs. Union of India, Israeli gay couple's case, etc. which were widely debated in the media. Baby Jaycee case is a classic example of legal complexities involved in the surrogacy procedure. The custody of the child was sought by five parents – genetic mother, the commissioning mother, the surrogate mother, the commissioning father and the genetic father.

16. These are the vexatious issues which are being discussed and debated all over the world. While some are of the opinion that both commercial and altruistic surrogacy be legalized and regulated to protect the rights and interests of all parties, others argue for blanket ban on surrogacy in all forms for the sake of human dignity keeping in view that surrogacy is inherently exploitative. While there are countries like Russian Federation, Columbia, Ukraine and some States of USA where commercial surrogacy is allowed, there are countries like France, Finland, Italy, Japan, Spain, Sweden, Switzerland, Hungry, Ireland, etc. where surrogacy in all forms is banned. But these two are extreme paths and therefore it was necessary to find a midway which facilitates surrogacy but in a regulated way. Hence, the other legal aspect attached with surrogacy lies in the challenge of finding a middle or more preferred path by striking a fine balance between the two squarely opposite ideas because law is to act both as an ardent defender of human liberty and an instrument of distributor of positive entitlements. Further, law must keep pace with the emerging/developing technologies so that their positive benefits could be availed by those in need.

17. The Surrogacy (Regulation) Bill, 2019 is a step in that direction which seeks to regulate surrogacy procedure in such a way as to stop exploitation of poor

vulnerable women; to ensure protection of rights of the child born out of surrogacy and to facilitate only needy infertile couple and widow and divorced women to have child to complete their family. To achieve the above objective, the Bill provides to prohibit commercial surrogacy and allow only altruistic surrogacy. Australia, Canada, Israel, Netherlands, New Zealand, South Africa, United Kingdom, Vietnam, etc. are some of the countries where similar surrogacy practices exist.

18. The Committee has in the process of examination of the Bill came across all sorts of views for and against the Bill and to synthesize and harmonize them to a standard acceptable to a majority, if not all, has undoubtedly been a daunting task which it could perform with the active cooperation, sustained support and untiring efforts of one and all involved in the process, especially the Members of the Select Committee, for which they truly deserve special commendation. I, on my behalf as well as on behalf of the Select Committee offer special thanks to the Secretary and other officers of the Department of Health Research, Legislative Department, various experts/ organizations/ institutions who contributed to the successful accomplishment of the detailed examination of and prepare a report on the Surrogacy (Regulation) Bill, 2019. I would also like to appreciate the untiring efforts of officers of Rajya Sabha Secretariat who accomplished the entrusted task within stipulated timeframe.

NEW DELHI
3rd February, 2020
Magha 14, 1941 (Saka)

Bhupender Yadav
Chairman,
Select Committee on Surrogacy
(Regulation) Bill, 2019,
Rajya Sabha

CHAPTER-I

Introduction

1.1 The Surrogacy (Regulation) Bill, 2019 was introduced in the Lok Sabha on 15th July, 2019 and passed by the same house on 5th August, 2019. The Rajya Sabha in its meeting held on Thursday, the 21st November, 2019 adopted a motion for reference of the Surrogacy (Regulation) Bill, 2019, as passed by Lok Sabha, to a Select Committee of the Rajya Sabha with the instructions to report to the Rajya Sabha by the last day of first week of the next session.

1.2 The Surrogacy (Regulation) Bill, 2019 seeks to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of Surrogacy and for matters connected therewith or incidental thereto.

1.3 According to the Statement of Objects and Reasons of the Bill as introduced in Lok Sabha, India has emerged as a Surrogacy hub for couples from different countries for past few years. There have been reported incidents of unethical practices, exploitation of surrogate mothers, abandonment of children born out of Surrogacy and import of human embryos and gametes. Widespread condemnation of commercial Surrogacy in India has been regularly reflected in different print and electronic media for last few years. The Law Commission of India, in its 228th Report, has also recommended for prohibition of commercial Surrogacy by enacting a suitable legislation. Due to lack of legislation to regulate Surrogacy, the practice of Surrogacy has been misused by the Surrogacy clinics, which leads to rampant commercial Surrogacy and unethical practices in the said area of Surrogacy. It had, therefore, become necessary to enact a legislation to regulate Surrogacy services in the country, to prohibit the potential exploitation of surrogate mothers and to protect the rights of children born through Surrogacy.

1.4 The Department of Health Research informed the Committee that Surrogacy has been practiced in India since last few decades. In the absence of regulation, India has emerged as a Surrogacy hub for couples from different countries. They submitted that there has been a plethora of reports concerning unethical practices, abandonment of children, exploitation of surrogate mothers, death of the surrogate mother, rackets of intermediaries in importing, exporting and selling of human embryos and gametes and unregularised clinics practicing Surrogacy.

1.5 The background note on Surrogacy (Regulation) Bill, 2019 as furnished by the Department of Health Research stipulates that Surrogacy is an arrangement where a woman (the surrogate) offers to carry a baby through pregnancy on behalf of a couple and then return the baby to the intended parent(s) once it is born. In Surrogacy, an embryo is created using an egg and sperm produced by the intended couple and is transferred into the surrogate's uterus. The surrogate has no genetic link to the child. Her eggs cannot be used to conceive the child.

Meaning of Surrogacy

1.6 The word 'Surrogate' has its origin in the Latin term Surrogatus' which means a woman acts as a substitute for another woman. To understand surrogacy in its proper perspective and plain language, it is a form of third party reproductive practice or an arrangement which the intending parents (unable to procreate on their own) and the surrogate mother mutually agree that the latter shall become pregnant, gestate and give birth to a child and shall legally and physically transfer the child to the intending parents without retaining any parentage or parental obligations.

Surrogacy comes as an important option to fulfill the desire to have a child of such couple for whom it is physically or medically impossible or undesirable to carry a baby to term on their own.

1.7 There are two types of surrogacy practices – (i) Traditional and (ii) Gestational. Gestational surrogacy which has been envisaged in the Bill occurs in the context of assisted reproductive technologies such as in-vitro fertilization and embryo transfer where the surrogate mother is not genetically related to the child. Further, there are two types of surrogacy arrangements:- (a) Altruistic: where the surrogate mother is the one, who cares for the intended person or couple and due to her concern in the interest of the person or couple, decides to help them to become parents. Altruistic surrogacy is based upon care, concern and the same has no space or scope for monetary compensation. In this arrangement the surrogate mother receives no financial rewards for her pregnancy or the relinquishment of the child to the genetic parents except for essential medical expenses; and (b) Commercial: where the surrogate mother is paid over and above the necessary medical expenses.

Background of the Bill

1.8 The Department of Health Research submitted that the 228th Report (2009) of Law Commission of India strongly recommended for prohibiting commercial Surrogacy and allowing ethical altruistic Surrogacy services by enacting a suitable legislation.

1.9 In the wake of a Public Interest Litigation by Smt. Jayashree Wad, filed in the Hon'ble Supreme Court, the Cabinet Secretariat took a meeting on 21.10.2015 and asked this Department to bring early the legislation to regulate Surrogacy. Subsequently, an Affidavit was filed in the Hon'ble Supreme Court undertaking to bring the legislation early.

1.10 While answering the Lok Sabha starred Question number 100 in the Parliament on 4th December, 2015, the Government took the stand not to support commercial Surrogacy.

1.11 The Department of Health Research informed that the draft Bill was circulated for inter-Ministerial consultation on 8th September, 2014. The Bill was also put on the website of the Department for a period of 45 days on 30th September, 2015 inviting comments. After receiving comments from stakeholders, including Central Ministries/Departments and State Governments, the comments were suitably incorporated in the draft Bill. The proposal for introduction of the Bill to the Parliament was submitted to the Cabinet on 21st April, 2016 for consideration. The Cabinet in its meeting held on 27th April, 2016 postponed any decision on the matter vide Secretariat communication No.19/CM/2016, dated 2nd May, 2016.

1.12 A decision was taken to constitute a Group of Ministers (GoM) comprising of Minister of External Affairs, Minister of Health and Family Welfare, Minister of Science and Technology and Earth Sciences, Minster of State for Commerce and Industry (Independent Charge), Minister of Communication and Information Technology, Minister of Food Processing Industries and Minister of State (Finance) for going through the provisions laid down in the draft Surrogacy (Regulation) Bill, 2016.The GoM held various meetings to examine the provisions of the draft Bill, on 5th May, 2016, 1st July, 2016, 8th July, 2016 and 14th July, 2016. Based on the suggestions on the GoM, the draft Surrogacy (Regulation) Bill 2016 was finalized after due consultation with the Ministry of Law and Justice. The Surrogacy (Regulation) Bill, 2016 was approved by the Cabinet on the 24th of August 2016.

102nd Report of Parliamentary Standing Committee

1.13 The Surrogacy (Regulation) Bill, 2016 was introduced in the Parliament on 21st of November, 2016. The Bill was referred to the Parliamentary Standing Committee on Health and Family Welfare on the 12th January, 2017. The 102nd report of the Departmental Related Parliamentary Standing Committee on Health and Family Welfare on Surrogacy (Regulation) Bill, 2016 was presented in the Rajya Sabha and simultaneously laid on the table of the Lok Sabha on 10th of August, 2017.

Major recommendations made by the Parliamentary Standing Committee

a) The Committee was of the view that the altruistic Surrogacy be replaced with Compensated Surrogacy and Surrogacy procedures should also be available to PIO, NRI, OCI, live in couples, divorced women and widows.
b) The Committee recommended that the definition of infertility should be made commensurate with the definition given by WHO. The words "five years" in Clause 2(p) and 4(iii)(c) II, be therefore, replaced with "one year" and consequential changes be made in other relevant Clauses of the Bill.
c) The Committee was of the view that limiting the practice of Surrogacy to close relatives is not only non pragmatic and unworkable but also has no connect with the object to stop exploitation of surrogates envisaged in the proposed legislation. The Committee, therefore, recommended that this Clause of "close relative" should be removed to widen the scope of getting surrogate mothers from outside the close confines of the family of intending couple.
d) Insurance coverage for a longer period of 6 years for the Surrogate mother.
e) The Committee recommended prohibiting sex selective Surrogacy.
f) The Committee also endorsed the suggestion of the Ministry of Women and Child Development that a surrogate mother should have an option to withdraw from the Surrogacy arrangement if she chooses to do so before the start of the procedure.
g) The Committee recommended prescribing time-limit for issuing an essentiality certificate by the District Medical Board and any appeal or review procedure, in case the application for Surrogacy is rejected.

1.14 The Department submitted that of total 42 recommendations made by the DRSC on Health and Family Welfare in its Report, 13 recommendations were accepted by the Department and 13 recommendations will be part of the rules and regulation. Four recommendations were already part of the Surrogacy Bill and 11 recommendations were not accepted by the Department. Details of the recommendations of the Standing Committee and Departments response on them are placed at **Annexure-IV.** The Surrogacy Regulation Bill was again approved by the Cabinet on the 21st day of March, 2018 for moving the official amendments recommended by the Parliamentary Standing Committee.

Bill Passed by Lok Sabha

1.15 The Bill approved by Cabinet was introduced in the 17th Lok Sabha on 15th July, 2019 and was also passed by it on the 5th August, 2019. The Bill was further placed in Rajya Sabha on the 6th November, 2019 for consideration and on 21st November, 2019 referred to the Select Committee.

1.16 A statement indicating distinction between the Surrogacy (Regulation) Bill, 2016 and the Surrogacy (Regulation) Bill, 2019 is placed at **Annexure-V**.

Salient Features of the Bill

1.17 The Objects and Reasons of the Surrogacy (Regulation) Bill, 2019 entails the objectives/ Salient Features of the Bill that inter alia includes:-

(i) The Bill proposes to allow altruistic ethical Surrogacy to the needy infertile married Indian couples including Non Resident Indians (NRIs).

(ii) Purposes and conditions of ethical Surrogacy as defined in the Bill provisions:-

- When either or both members of the couple are suffering from proven infertility.
- When it is only for altruistic Surrogacy purposes.
- When it is not for commercial purposes or for commercialization of Surrogacy or Surrogacy procedures.
- When it is not for producing children for sale, prostitution or any other form of exploitation.

(iii) The Bill prohibits commercial Surrogacy or commercialization of Surrogacy services including sale, purchase of human gametes, oocytes and human embryo.

(iv) Commercial Surrogacy" means

- commercialization of Surrogacy services or procedures
- selling or buying of human embryo for the purpose of Surrogacy
- trading in the sale or purchase of human embryo by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents

(v) A leaner structure of a National Surrogacy Board, State Surrogacy Boards and Appropriate Authorities at State/UT level is proposed.

A. National Surrogacy Board

1.18 National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Bill.

- The Board shall consist of the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson
- the Secretary to the Government of India in- charge of the Department dealing with the Surrogacy matter, Vice-Chairperson
- three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members

B. State Surrogacy Board

1.19 A similar State Surrogacy Board is to be constituted in the States and Union Territories

C. Appropriate Authority

1.20 The Appropriate Authority in States/UTs would be the Executive Committee with 4 members and the Joint Director of Health as the Chairperson. The appropriate authority shall discharge following functions:

- to grant, suspend or cancel registration of a Surrogacy clinic;
- to enforce the standards to be fulfilled by the Surrogacy clinics;
- to investigate complaints of breach of the provisions of this Act, rules and regulations and take legal action as per provision of this Act;
- to take appropriate legal action against the use of Surrogacy by any person at any place other than prescribed, *suo-moto* or brought to its notice, and also to initiate independent investigations in such matter;

(vi) **The Needy Infertile Intending Couple**

- The age of the intending couple is between 23 to 50 years in case of female member and between 26 to 55 years in case of male member on the day of certification;
- The intending couple are married for at least five years and are Indian citizens;
- The intending couple have not had any surviving child biologically or through adoption or through Surrogacy earlier except when they have a child and who is mentally or physically challenged or suffer from life threatening disorder or fatal illness.

(vii) **To prevent exploitation of surrogate mother, minimum criteria pertaining to age and medical conditions to be fulfilled by the surrogate mother has been specified in the Act.**

- The surrogate mother should be married with one child
- The age of the surrogate mother to be between25-35 years.
- The surrogate mother to be a close relative (this will be defined by the National Board).

(viii) The Bill also contains provisions to ensure that the intending couples do not abandon the child.

- A parentage order concerning the parentage and custody of the child to be born through Surrogacy to be issued by a court of magistrate of first class is made as a pre-requisite condition. This will also be an agreement.

(ix) **An insurance coverage for 16 months** is proposed for the Surrogate Mother to take care of all her medical needs emergency conditions/complications.

(x) **Registration of Surrogacy clinics:** Surrogacy clinics cannot undertake Surrogacy related procedures unless they are registered by the appropriate authority. Clinics must apply for registration within a period of 60 days from the date of appointment of the appropriate authority.

(xi) **Parentage and abortion of surrogate child**: A child born out of a Surrogacy procedure will be deemed to be the biological child of the intending couple. An abortion of the surrogate child requires the written consent of the surrogate mother and the authorization of the appropriate authority. This authorization must be compliant with the Medical Termination of Pregnancy Act, 1971. Further, the surrogate mother will have an option to withdraw from Surrogacy before the embryo is implanted in her womb.

(xii) **Offences and penalties:** The offences under the Bill include: (i) undertaking or advertising commercial Surrogacy; (ii) exploiting the surrogate mother; (iii) abandoning, exploiting or disowning a surrogate child; and (iv) selling or importing human embryo or gametes for Surrogacy. The penalty for such offences is imprisonment up to 10 years and a fine up to 10 lakh rupees. The Bill specifies a range of offences and penalties for other contraventions of the provisions of the Bill.

CHAPTER -II

Deliberations of the Select Committee

2.1 The Select Committee started deliberations on the said Bill on 3rd December, 2019 followed by the meetings held on 9th ,12th,20th& 30th December, 2019, 10th,21st, 31st January, 1st and 3rd February,2020.

FIRST MEETING ON 03.12.2019

2.2 Select Committee in its first meeting held on 3rd December had internal discussion on the Bill to decide the future course of action. The Chairman informed the members of the Committee that the Surrogacy (Regulation) Bill, 2016 has been extensively examined by the Department-related Parliamentary Standing Committee on Health and Family Welfare. He also informed the Members that out of 42 recommendations made in 102nd Report, 13 recommendations have been incorporated in the current Bill, 13 would be considered while framing rules and regulations and 11 recommendations were not accepted by the Government. The Committee decided to start the examination of the Bill by hearing the views of Secretary, Department of Health Research and other stakeholders in subsequent meeting.

SECOND MEETING ON 09.12.2019

2.3 In the meeting held on 9th December, 2019, the Committee decided to issue a Press Release on the said Bill to illicit views from stakeholders/experts, to undertake a study visit to places like Anand etc., to seek the views of the State Governments/UTs and to hear the views of the stakeholders viz. doctors, surrogates, intending couples, experts etc. The Committee also heard the views of Secretary, Department of Health Research. Giving a background of the Bill, the Secretary, Department of Health Research in his deposition before the Committee submitted that the Department had been working on this Bill for the last ten years and had taken all the best practices from different countries and the changing patterns in different countries. They had also taken into account the culture and tradition of the country to develop this Bill. The Department also showed a documentary film related to Surrogacy and plight of surrogate mothers. The representatives of Department of Legal Affairs and Department of Legislative Department attended the meetings to clarify the legal and legislative queries of the members.

2.4 The Joint Secretary, Department of Health Research then made a powerpoint presentation on the genesis of the Bill and its salient features wherein she highlighted the issues related to citizenship of commissioning couple and the surrogate child, issue of custody of the child born out of Surrogacy, issues related to Surrogacy by foreign nationals as reported by Ministry of External Affairs, rights of child and how these get abrogated in cases of Surrogacy, legitimacy of children born through Surrogacy, exploitation and compensation issue. She also informed the Committee about the reported cases of exploitation, reported complaints of Surrogacy clinics, court cases related to Surrogacy in India, need for regulation of Surrogacy in India, recommendations of the 228th Law Commission, international developments in Surrogacy, and major recommendations not accepted as made in 102nd Report of the Standing Committee on Health and Family Welfare.

2.5 The Joint Secretary, further, informed the Committee about the scenario of Surrogacy at the world level. The Committee was informed that in countries like Finland, France, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Nepal, Pakistan, Saudi Arabia, Serbia, Spain,

Sweden and Switzerland, all types of Surrogacy (both commercial and altruistic) was illegal. She, further, apprised the Committee of the countries where commercial Surrogacy was banned and only altruistic Surrogacy was allowed in countries like Australia, Canada, Georgia, Greece, Israel, Netherlands, Belgium, New Zealand, Portugal, South Africa, Thailand, United Kingdom and Vietnam. There were only few countries in the world where commercial Surrogacy was allowed like Russian Federation, Colombia, Ukraine and some states of USA like California, Illinois, Arkansas, Maryland, and New Hampshire. The reasons cited by various countries for the regulation of Surrogacy were also highlighted. Great Britain's ban on commercial Surrogacy arrangements was in part a reaction to Americans' use of English women as surrogate mothers. Thailand banned commercial Surrogacy after Baby Gammy case where Down's syndrome child was left behind with an unmarried surrogate mother. UK did not allow for anonymous donors as it was believed that a child had a right to know his/her origin and this was in consistence with the Convention on the Rights of the Child (Article 8). The New Jersey Supreme Court declared all Surrogacy contracts void and unenforceable as they were violative of several State laws and public policies. In R.R. vs. M. H., the Massachusetts Supreme Court looked into Massachusetts's adoption laws, which prohibit the payment of money in connection with an adoption beyond adoption-related expenses. Finding the policy underlying these statutes persuasive in a Surrogacy context, the Court held that "eliminating any financial rewards… is the only way to assure that… economic pressure will not influence a women to be a surrogate mother". European Parliament in its resolution of 17th December, 2015 condemned the practice of Surrogacy which undermined the human dignity of the women since her body and its reproductive functions were used as a commodity. 13th Law commission of UK proposed revision of the UK Surrogacy Act and emphasized that the most important aspect would be to safeguard the children born as a result of Surrogacy arrangements. Many countries have banned Surrogacy altogether.

THIRD MEETING ON 12.12.2019

2.6 In the meeting of the Committee held on 12th December, 2019 the Secretary made a power point presentation before the Committee wherein he highlighted reasons for not accepting the recommendations made by the DRSC on Health and Family Welfare w.r.t. altruistic Surrogacy or compensated Surrogacy, Surrogacy procedures to be made available to PIO, NRI, OCI, live in couples, divorced women and widows, 5 years waiting period for availing Surrogacy to be reduced to 1 year, surrogate mother to be a close relative to be removed, economic opportunities available to surrogates through Surrogacy, definition of Surrogacy be revised, raising the upper age limit of the surrogate mother, surrogate child be defined separately in the Bill, inclusion of Registrar in the board.

FOURTH MEETING ON 20.12.2019

2.7 The Committee, in its meeting held on 20th December, 2019, sought detailed clarification from the Department of Health Research on the issues raised by Members during the meetings of the Committee held on 9th and 12th December, 2019. The Department also stated various reasons for not accepting recommendations of the Standing Committee. It was pointed out that altruistic Surrogacy cannot be replaced by commercial or compensatory surrogacy because the 228th Report of Law Commission and Supreme Court directed to ban commercial surrogacy in the country. All the expenses for the surrogate mother are covered under one Clause where i.e. insurance period. The PIO/OCI and foreigners should not be allowed to avail surrogacy in India because the Home Ministry, Ministry of External Affairs issued a notification wherein PIO/OCI and foreigners were banned to avail surrogacy in India as it may lead to citizenship issues for the

child borne out of Surrogacy. The Department also stated the reasons for allowing only close relative to be a surrogate and surrogacy should not be looked at as one economic opportunity for a below poverty line women. The age limit of surrogate mother has been kept between 25-35 years because it is most suitable period for reproduction.

FIFTH MEETING ON 30.12.2019

2.8 In the meeting held on 30th December, 2019, the Committee held discussion with the representatives of Ministry of Women and Child Development, National Commission for Protection of Child Rights, National Human Rights Commission and representatives of SAMA (Resource Group for Women and Health) on various provisions of the Bill. Representatives of NHRC opposed total ban on Commercial Surrogacy and supported regulated commercial Surrogacy. They felt that regulatory mechanism may include legally binding agreements and reasonable compensation should be given as a part of the regulatory mechanism. The issue of certificates (Section 4) in respect of the surrogate mother and the intending couple should be kept outside the purview of the RTI Act keeping in view the Right of Privacy and the stigma attached to infertility in the Indian Society.

2.9 NCPCR submitted that the definition of "Surrogacy" provided in the Bill seems to be appropriate. The Commission was not in the support of defining Surrogate child as the surrogate children and biological children will get differentiated and this will come in conflict with existing laws. The commercial Surrogacy should not be permissible in the country to prevent exploitation and violation of women and also to prevent abuse and trafficking in Children. The Commission was of the view that there should be provision of putting bond in the name of child by the commissioning parents to take care of his needs, in case if they fail to take up the responsibility of the child in future. Further, if any kind of dispute arises, the child should be immediately produced before CWC and declared as child in need of care and protection and shall be entitled to all benefits provided under the Juvenile Justice (care and protection of Children) Act, 2015.

2.10 Representative of SAMA- Resource Group for Women and Health was of the view that regulation of commercial Surrogacy should begin with regulation of ART industry. The Bill should allow single, married, in a live-in relationship or queer to avail benefit of Surrogacy. The number of oocytes or embryos to be implanted in the surrogate mother for the purpose of Surrogacy shall be such as may be prescribed. Five year time period to prove infertility is a long time to wait before accessing Surrogacy services and suggested to review it.

SIXTH MEETING ON 10.01.2020

2.11 In the meeting of the Committee held on 10th January, 2020, the Committee held discussion with the representatives of United Nations Population Fund (UNFPA), PRS Legislative Research (PRS), Dr. (Prof.) Neeta Singh, Division of Reproductive Medicine, AIIMS Delhi and Dr. Kamini A. Rao, Milann (A Brand of BACC Healthcare Pvt. Ltd.), Bangalore.

2.12 Representative of UNFPA stated that the Surrogacy Regulation Bill needs to be positioned and understood in close conjunction with the ART Bill because the ART Bill deals with the mode, the procedures and the technology of reproductive medicine in surrogacy while the Surrogacy Bill deals with the implications and the ethical issues arising from such arrangements. Therefore, regulation of ART is a necessary pre-condition for effective implementation of the Bill. It was also pointed out that complete banning of the practice was going to drive it underground. Thus to avoid this risk, the law should instead introduce strict

regulation and protection mechanisms to regulate compensated surrogacy. Further, given the family setup, it may lead to conditions of exploitation and coercion for the surrogate mother. They, therefore, supported compensated form of surrogacy that must include consideration for a range of expenses including the expenses of the opportunity cost of wage laws for the surrogate mothers, and other post-delivery care cost. It is also stated that definition of infertility should be reconciled with the definition given in the ART Bill and with WHO definition which is to have a one year period as the time clause. They supported extending of surrogacy services to unmarried couples, single women including widows or divorced women, and single men. However, regarding the provisions related to the foreign nationals, PIOs and OCI cardholders who intend to commission surrogacy shall be retained as mention in the Bill.

2.13 Representatives of PRS legislative research stated that the Bill effectively prohibits the option of surrogacy to many couples as the altruistic arrangement in the Bill seems to be quite unrealistic. According to the Bill, the intending couple must prove failure to conceive in order to be eligible to undertake a surrogacy procedure. There may be other medical conditions that affect the ability to give birth to a child such as multiple miscarriages and other congenital issues. Such persons will not be eligible to undertake surrogacy. The intending couple and the surrogate mother needed to obtain certificates of eligibility and essentiality from the appropriate authority. There was no provision for the review or appeal process in case the application for such certificates is rejected. They also stated the surrogate mother needed to be a 'close relative' of the intending couple, however, the term 'close relative' has not been defined in the Bill. For an abortion, in addition to complying with the Medical Termination of Pregnancy Act, 1971, the approval of the appropriate authority and the consent of the surrogate mother was required. The Bill does not specify a time limit for granting such an approval. Further, the intending couple had no say in the consent to abort. Storage of embryos and gametes for the purpose of surrogacy was not permitted but assisted reproductive technologies used for enabling surrogacy arrangements require multiple attempts. These multiple attempts may need such storage of embryos and gametes. If a surrogate mother renders surrogacy services other than those permitted under the Bill, it is presumed that she was compelled to do so by: (i) her husband; (ii) the intending couple; or (iii) any other relative. The burden of proof is on these parties to establish that they did not compel the surrogate mother.

2.14 Dr. (Prof.) Neeta Singh, Division of Reproductive Medicine, AIIMS Delhi made a power point presentation before the Committee where she supported a blanket ban on the commercial surrogacy. She also pointed that altruistic surrogacy should not be replaced with compensated surrogacy as it will lead to commercialization, and the whole idea of banning commercial surrogacy will be abolished. The period of five years to avail surrogacy can be relaxed in special situations like if the cause of infertility is not treatable and in couples with late marriage and in cases of absent uterus or non functional uterus and in patients with chronic medical condition where pregnancy is contraindicated. Surrogacy can be allowed to widows and divorced women if an apparent cause is there like absent or malformed uterus but not to single unmarried women or men. The upper age limit of women should not be more than 35 years since the chances of obstetrical complications are higher with advanced maternal age thereby putting the surrogate mother at an unwanted high risk during pregnancy.

2.15 Dr. Kamini A. Rao, Milann (A Brand of BACC Healthcare Pvt. Ltd.), Bangalore stated that there is general conception that surrogate mother gets exploited at the hand of the intending parent. However, on many occasions intending parent were exploited by the surrogate herself. She requested the Committee to consider incorporating of ART Bill with the Surrogacy Bill. The separate Surrogacy boards and ART boards would lead to duplication of boards and would

only result in corruption. She was of the view that exploitation cannot be stopped by banning commercial surrogacy. It was only going to result in more black-marketing and going underground. She concluded that the ART Bill and the Surrogacy Bill should be passed together under a single board, so that, there can be a control on all the cases in the form of national registry by the ICMR.

SEVENTH MEETING ON 21.01.2020

2.16 In the meeting held on 21st Janauary,2020, the Committee heard the views of Smt. Kirron Kher, MP, Lok Sabha, Secretary, Ministry of Women and Child Development, Adv. Ranjit Malhotra, Malhotra and Malhotra Associates, Chandigarh, Dr.Sheela Sarvanan, Independent Researcher, Dr.Devika Singh, Co-Founder & CEO, Cohere Consultants,New Delhi. Smt Koirron kher deposed before the Committee that it is very difficult to prove infertility with certainty. She also submitted that five years waiting period to avail surrogacy is not appropriate where in certain medical conditions, it is clear that the couple will not be able to conceive. She emphatically pointed out that any Government or any law should not interfere with someone's personal life as what happens in a woman's body and a man's mind cannot be judged by a panel. Since science has taken giant leaps in giving hope to childless couples, it should be left to the couple to avail it. The provision of close relative also was inappropriate as in the age of nuclear families, it would be difficult to find close relative. The prerequisite of having medical and psychological fitness certificate is also cumbersome. She also put forth the concerns of live in couples, LGBT community wanting to go for surrogacy and they should be taken into account. She supported the recommendations made in 102nd Report of the DRSC on Health and Family Welfare wrt a comprehensive legally binding agreement between the intending parents and the surrogate mother providing for monetary compensation with a minimum and maximum cap. Reasonable expenses should be paid to the surrogate mother.

2.17 Adv Ranjit Malhotra, Malhotra & Malhotra Associates submitted that the stigmatic requirement of a certificate of proven infertility is like a bull in a China shop. It is interference with the right to reproductive autonomy. The provision of close relative needs to be re-looked in the age of nuclear families. He was of the view that it would be much easier to regulate surrogacy for NRIs, PIOs, OCIs with adequate safeguards like comprehensive medical insurance with dollar benchmarks commensurate with income. It should be on the lines of adoption process as by CARA entailing home study report etc. He also submitted that to avoid foreigners from exploiting surrogacy, instead of clamp down or shut down, surrogacy needs to be regulated. He further submitted that the National Surrogacy Board should have members of the Ministry of Law, Ministry of Legal and Treaties Division, Ministry of Women and Child Development, and representatives of the National Commission for Child Protection Rights. In case there is a default by an NRI, PIO, OCI, this nodal agency should be vested with the rights to liaise with the embassies and missions. A high-powered committee should also be a part of the National Surrogacy Board which looks at the changing conditions on a day to day basis. He also suggested that there has to be a surrogacy ombudsman and the bank account of the surrogate mother should be mentioned in the surrogacy agreements. He was also of the view that there should be a dedicated website of all registered surrogacy clinics and medical practitioners so that intending commissioning parents can have their own due diligence and, in case, there are some defaulters, their names are also put up on those websites. There should also be provision for mandatory testamentary conveyance of stored embryos.

2.18 Shri Rabindra Panwar, Secretary, Ministry of Women and Child Development submitted that there is a need to consider the possibility of any unforeseen situation or rift or divorce

between commissioning couple which may render a child abandoned. The Bill needs to be in consonance with the existing laws such as the Juvenile Justice (Care and Protection of Children) Act, 2015 (JJ Act) with regard to issues such as definition of child, definition of abandoned child, declaration of child as abandoned child and age requirement of intending couple etc. Clear provisions regarding roles and responsibilities of commissioning couples and surrogate mothers in cases of abandonment of surrogate children by commissioning parents, need to be provided in the Bill from the point of view of the best interest of such children as well as from the point of view of safeguarding of rights of the women. He further submitted that the need for surrogate mothers to be close relatives of couples commissioning surrogacy may lead to problems with family, social structures and norms. Provision for insurance cover or other welfare measures for child in such condition also needs to be considered. He also stated that the provision for breast feeding of the child needs to be taken care of from the point of view of proper nourishment, immunity and best interest of the child born to surrogate mother. There should also be a limit for women to undergo surrogacy procedure only once. Availability of surrogacy technique to only legally married infertile couple also needs to be reconsidered, in light of Section 57(3) of the JJ Act. The Secretary also submitted that wrt Section 112 of Indian Evidence Act; it needs to be ensured that a surrogate mother is not automatically construed as the mother of a child born by her through surrogacy, against her will, in case that child has been abandoned by the commissioning couple.

2.19 Dr. Sheela Sarvanan submitted that she had done two studies on surrogacy; one is 2009 and other in 2019. She also submitted that an upper age limit is important for surrogate mother because as the woman gets older, her fertility rate goes down and the possibility of risk to her life and health also rises. She was of the view that adoption should be encouraged over surrogacy which should be the last option because women's health is in question here. Surrogacy should not be looked as an economic opportunity. There are extraterritoriality laws all over the world, especially, in countries which have banned surrogacy. She further stated that some surrogate mothers opt for this just to buy an extra piece of land or to buy some buffalos. Most of the poor women accept to become a surrogate mother to come out of poverty.

2.20 Dr. Devika Singh, Co-Founder & CEO - Cohere Consultants, submitted that she had done about nine years of research in surrogacy as a legal subject from the Constitution's perspective. She was of the view that there is insufficient research to take a judgment call on surrogacy. She further submitted that an entire surrogacy industry has been established and if commercial surrogacy is banned, the entire industry will go underground and it will take the surrogate with it. The only countries in the world that support a binding contract on surrogacy are the countries that allow commercial surrogacy. There is not a single country that allows altruistic surrogacy and an enforceable contract. She further submitted that every country that allows altruistic surrogacy has got great safeguards for surrogates. She was also of the view that the birth mother be the legal mother on the birth certificate. Her name should be later removed from the certificate, and the intending parents' names should go on the certificate. In altruistic surrogacy, there should not be any nature of contract. It can be called an inter-parental arrangement or family arrangement. If there is a dispute on the child, then, the dispute on the child should be resolved under the Custody Law, not under the Contract Law. Dr. Devika Singh further submitted that the Surrogacy Regulation Bill-2019 talks about altruistic surrogacy, but market practice has been doing commercial surrogacy, therefore, there has to be a common minimum denominator, which is compensatory surrogacy. She further submitted that there needs to be a budgetary allocation for the functioning of the Surrogacy Board.

EIGHTH MEETING ON 31.01.2020

2.21 The Chairman of the Committee made a PowerPoint presentation on the Bill. Thereafter, the Committee had internal discussion on various aspects of the Bill.

NINTH MEETING ON 1.02.2020

2.22 The Committee took up clause-by-clause consideration and finalized its views on various provisions of the Bill.

TENTH MEETING ON 3.02.2020

2.23 The Committee considered and adopted the Report on the Bill with few modifications.

CHAPTER-III

Issues Raised

3.1 While deliberating on the Bill, the Committee came across various contentious issues that were raised by the members during the proceedings/meetings of the Committee. The Committee held detailed discussion on these issues and the same were raised before the Department of Health Research for detailed clarification. The Department in their replies clarified the queries/issues raised by the Members of the Committee on various provisions of the Bill. These issues have been dealt separately as given below:-

Altruistic Surrogacy *vs* Compensated Surrogacy

3.2 The Committee observes that a lot of debate has been going on *w.r.t.* model of Surrogacy to be practiced in the country with the objective to put a stop to commercial Surrogacy which results in exploitation of surrogate mother. However, concerns have been raised with respect to the model of surrogacy to be practiced in the country to achieve the desired objectives. Various viewpoints have been expressed in support of altruistic as well as compensated surrogacy (as recommended by 102nd report of DRSC n Health and Family Welfare) with the main concern to safeguard and protect the rights of the surrogate mothers. The present Bill proposes altruistic surrogacy which entails that a surrogate mother will be genetically related to either of the intending couple. Department of Health Research is of the view that compensated Surrogacy may lead to commercialization of Surrogacy which in turn may lead to exploitation of surrogate mother. The 228th report of the Law Commission of India had also recommended for prohibiting commercial Surrogacy and allowing only ethical altruistic Surrogacy by enacting a suitable legislation. Subsequently, Department of Health Research issued a notification dated 04.11.2015 for prohibiting commercial Surrogacy.

3.3 In a specific query with regard to the option of having a compensated Surrogacy within a legal regulatory oversight, the Department submitted that the compensation to the surrogate mother has been provisioned in the Bill by way of insurance coverage for expenses incurred by the surrogate mother, medical expenses, post-partum complications and situations of death. Beyond this, it will amount to commercialization of Surrogacy because demarcation between compensatory and commercial Surrogacy is diffused. The Government aimed to prevent altruistic Surrogacy from becoming "forced labour" by proposing that the Surrogate mother to be a close relative, allowing a woman to be a surrogate only once in her life time, stringent penal provisions and insurance coverage of medical and other necessitated expenses.

3.4 The Committee also wanted to be apprised as to how the Government would ensure that the blanket ban on commercial Surrogacy would not give rise to a black market in Surrogacy services and whether the provisions of stringent punishment would suffice for banning the commercial Surrogacy. The Department submitted that the stringent punishment in the provisions of the Bill and allowing any woman to be a surrogate only once would go a long way in stopping the black marketing in Surrogacy services. In addition, monitoring provisions have been kept in the Bill and additional measures /policy interventions made by the National Surrogacy Board would be need based.

Compensation to the surrogate mother

3.5 During the deliberation of the Committee, time and again, members have raised concerns related to the adequate compensation to the surrogate mother in lieu of the grand/noble gesture she would be making towards the intending couple. Demands have been raised to frame a robust system through which surrogate mother is supported monetarily and she is given enough protection both financially and health wise. The proposed legislation promises to give medical expenses incurred on surrogate mother and the insurance coverage to the surrogate mother. Demand has also been raised to reimburse surrogate the loss of wages during pregnancy if she would have been working during the time of carrying the pregnancy. However, there is no such provision in the Bill. It has also been argued that proper compensation to the surrogate should be given and be regulated by Government so that there is no scope for bargaining.

3.6 In response to a query regarding the quantum of compensation to the surrogate mother in the Bill, the Department submitted that the insurance coverage will be provisioned as a part of the rules and regulations which will be laid in the Parliament that will cover expenses incurred by the surrogate mother, medical expenses, post-partum complications, situations of death and unnatural abortions. It was, further, added that surrogate mother will be provided insurance right from the beginning of the procedure, throughout the gestational period and including any complications and seven months post delivery. The success rate of Surrogacy is only 30-40 %, so insurance coverage will have to be decided case wise by the IRDA authorities. The estimated average cost /medical expenses for Surrogacy will be worked out in consultation with IRDA authorities and open to revision by the National Surrogacy Board. The Department informed that the Bill provides for only altruistic Surrogacy which will prevent exploitation of Surrogate mother by any middle men.

Period of Insurance coverage

3.7 The Committee notes that varied suggestions have been received with regard to the insurance coverage for a period of sixteen months covering post partum delivery complications from an Insurance company recognized by IRDA as proposed in the Bill. Suggestions have also been received to incorporate provisions for the compensation of the surrogate mother after delivery.

3.8 As per the written submission of the Department, the insurance coverage of 16 months includes duration for screening and necessary treatment of the surrogate before establishment of the pregnancy, gestation period of nine months and seven months postpartum period. Generally, any pregnancy related complications are expressed within three to four months after delivery. The minimum amount of the insurance coverage for the surrogate mother will be fixed by an insurance company or an agent recognized by the Insurance Regulatory and Development Authority (IRDA) established under the Insurance Regulatory and Development Authority Act, 1999 for a period of 16 months covering post-partum delivery complications. The insurance coverage can be provided in 3 phases to protect the intending couple from any catastrophic expenditure:

i. 1st phase during initiation of Surrogacy procedures till the pregnancy is confirmed
ii. 2nd phase till delivery of the child by the Surrogate mother covering the gestational period
iii. 3rd Phase covering post-partum complications including death

Waiting period to establish infertility

3.9 Waiting period to establish infertility has been another debatable provision of the Bill. Concerns have been raised with regard to 5 years time period to establish infertility as provisioned in the Bill. The Committee notes that various suggestions have been received wherein the recommendation made under the 102nd report of the DRSC Health and Family Welfare to reduce the waiting period to one year has been supported widely. Due to a trend of late marriages, various sectors have suggested to reduce the time period to 2-3 years. Support has also been received to remove waiting period of five years for the women diagnosed with clinical issues due to which they cannot bear a child. It has also been pointed out that the definition of infertility in the Surrogacy Bill is inconsistent with the definition provided by WHO as well as the ART Bill, which describes infertility as the inability to conceive/achieve pregnancy after at least one year of unprotected sexual intercourse.

3.10 With respect to rationale behind five years waiting period to establish infertility, the Department submitted that the upper age limit of intending couple has been kept as 50 years for the female and 55 years for the male envisaging the trend of delayed marriages in India. The five years period is kept for the intending couple to avail all possible Assisted Reproductive Technology treatments (ART) and if no ART procedure results in live birth, then the couple finally may avail altruistic Surrogacy as the last resort. The age of the surrogate mother has been kept at 25-35 years and this does not get affected by the age of the intending couple. The Department stated that since the infertility cannot be proven in early years of marriage as sometimes conception happens even after 15 years, a reasonable time of 5 years has been kept.

Close relative to be a surrogate mother

3.11 The Committee observes that one of the most contentious issues raised by many members of the Committee and stakeholders has been the provision of having a close relative as a surrogate. However, the provision of "close relative" of couple to be a surrogate mother has not been defined in the Bill. This has received wide criticism and suggestions have been received to define close relative in such a way that it includes not only blood relatives but also people from amongst extended families too. Various viewpoints have been received opposing the condition of close relative to be a surrogate mother as it may lead to many problems including property feuds as recommended by DRSC on Health and Family Welfare. It has been, further, criticized on the grounds that it drastically reduces the number of women who can potentially carry the pregnancy for the intending couple. Since the close relative has to be between 25 and 35 years of age and be married with a child, such a close relative is likely to be a sister or the wife of either of the brothers, or their niece through a sibling or a cousin.

3.12 The Department has justified the provision of having a close relative as the surrogate as the proposed Bill seeks to avoid commercialization of Surrogacy and exploitation of below poverty line (BPL) women who are pushed into it even by their own families. Similar provisions finds mention in the Transplantation of Human Organs and Tissues Act 1994 as “Near relative including son, daughter, father, mother, brother or sister”. This is a robust Act and stood the test of time for twenty five years. In this Act, the provision for allowing organ donation by persons having emotional connect with the recipient is also incorporated. In the current Bill, close relative has been provisioned to cover a wider ambit of relatives even a distant relative could be close to any of the intending couple. In this context, the Department has kept the provision for

the National Surrogacy Board to work on similar lines to define close relative keeping in view the nature of issues involved in Surrogacy. The National Board along with State Boards would have Women Parliamentarians, eminent experts in the field, senior administrators and other stake holders to take care of all these aspects. Further, the Companies Act 2013, defines a relative as (i) members of a Hindu undivided family (ii) husband and also wife or (iii) other relations prescribed under the Act.

Need for a Contract/Tripartite Agreement

3.13 The need for a legally binding tripartite agreement has been expressed by various stakeholders including Members of Parliament. It has been stated that there should be provision for a contract or an arrangement. Clause 6(i) specifies the requirement of a written informed consent from the surrogate mother but it is limited to medical procedures and side effects. However, a more expansive contract or agreement is needed to govern the arrangements clearly spelling out the rights and duties of each party. It has also been argued that in order to minimize the role of the state, and clarify all possible grey areas, a tripartite agreement is necessary between the surrogate mother, the intending person or persons and the surrogacy clinic, which will be governed by the Indian Contract Act. The agreement will include elements of reasonable compensation contemplated in the altered definition of altruistic surrogacy - the timeline, details for bank transfer, a nominee who will care for the child in case of any eventuality, cases in which abortion and foetal reduction can take place.

3.14 The Department of Health Research submitted in this regard that the tripartite agreement mentioned is equivalent to the parental order to be issued by the Magistrate Court as mentioned in section 4.

3.15 The Department related Parliamentary Standing Committee in its 102nd Report on the Surrogacy (Regulation) Bill, 2016 made the following recommendation wrt to a surrogacy agreement:

> *"The Committee is of the view that mere parentage order issued by the first class magistrate will not suffice. If the intent of the Bill is to protect the surrogate mothers and children, it must provide a legal framework for a comprehensive surrogacy agreement containing all safeguards. The agreement should mandatorily provide insurance, monetary compensation to surrogates, the manner of its disbursement and pre/post delivery care of the surrogates. It should also contain a provision for nourishment of the surrogates not just during the pregnancy but also in the post partum period; comprehensive healthcare for a period of five years starting from the date any medication for surrogacy procedure is begun; legal, medical and psychological counselling etc. Since the surrogates are predominantly uneducated, the contract should be made available in the language they fully understand and should be explained properly to them. The surrogacy agreement should be registered also. The jurisdiction for registration should lie before the Registrar where surrogate mother resides or where the intending parents reside or where the agreement is executed. Since a surrogacy agreement is a legal document, it will act as bedrock of the surrogacy arrangement and shall have a legal binding on all the parties involved in the surrogacy and help in solidifying the rights and duties of both the participants to the arrangement. Therefore, the Committee recommends that an agreement of surrogacy among all the stakeholders of the facility i.e the intending parents, surrogate mother and the surrogacy clinic should be made a mandatory document for the surrogacy arrangement for them"*

3.16 There has been another viewpoint against having a contract citing legal aspects. In altruistic surrogacy, there should not be any nature of contract. It can be called an inter-parental arrangement or family arrangement. If there is a dispute on the child, then, the dispute on the child should be resolved under the Custody Law, not under the Contract Law. The only countries in the world that support a binding contract on surrogacy are the countries that allow commercial surrogacy. There is not a single country that allows altruistic surrogacy and an enforceable contract.

Economic Opportunity

3.17 The Committee observes that surrogacy has been considered as an economic opportunity by the women from economically weak background. Various stakeholders have advocated that women should have autonomy over her body and they should be allowed to undergo surrogacy to earn a good amount which might solve some of their immediate crucial problems. However, at the same time, various viewpoints have been received wherein it has been argued that the reproductive capacity of women cannot be viewed as an economic opportunity.
The Department of Health Research is of the view that surrogacy cannot be looked into as means to earn money. The Department also submitted that Government provides various alternative opportunities to such poor women who act as surrogate mothers to ensure their economic and social empowerment. The Ministry of Women and Child Development has initiated many new schemes for women empowerment in the last five years like Pradhan Mantri Matru Vandana Yojana (PMMVY), Mahila Shakti Kendra (MSK) Scheme, Training and Employment Programme (STEP) for Women, Beti Bachao & Beti Padao and other Ministries also have specific schemes for women empowerment.

Permission to PIO, OCI and foreigners to commission Surrogacy

3.18 The Committee notes that PIO, OCI and foreigners have not been allowed to commission surrogacy under the Bill. This provision had been debated widely both in and outside the Parliament of India. Various suggestions have been received arguing to consider PIO and OCI in a different way, since they are the people of Indian origin only. Under Adoption Act, even PIOs and OCIs are permitted. They should, therefore, be treated at par with NRIs because to say that there could be a possibility of abandonment of child borne out of surrogacy, it could be the same for an NRI. PIO and OCI may be allowed only if they have received NOC from their home country and that is how it is happening in the case of adoptions also. It has also been argued that situation like one partner being Indian and another being a foreigner should not be excluded from availing Surrogacy.

3.19 The Department of Health Research is of the view that allowing Surrogacy services to PIO, OCI and foreigners would amount to women of our country getting exploited by foreigners.

3.20 On a specific query regarding as to how the Government will ensure that surrogate child of a NRI couple will not be subjected to any child abuse/abandonment/right violation, the Department clarified that any NRI is an Indian citizen and the surrogate will be his/her relative and hence, the chances of any child abuse/abandonment/rights violation will not be there. Further, contraventions of the provisions of the Act have stringent penal provisions which will be applicable/ implementable on NRIs as they are Indian Passport holders. A notification no. 25022/74/2011-F-1 (Vol-111) dated 3rd November 2015 was issued by Ministry of Home affairs prohibiting foreign nationals ,PIO and OCI card holders from commissioning Surrogacy in India.

Issue of single women, widows and divorcees

3.21 Prohibition of single women from availing the benefits of Surrogacy has been another issue inviting lot of attention. There are many who have supported to extend surrogacy services to the single women, since they are allowed to adopt. The Department, while explaining the rationale behind prohibiting Surrogacy for single women asserted that this provision was kept with an intention of protecting the rights of the child/children born out of Surrogacy. The marriage is an institution where both partners have the mutual legal responsibility on child and vice versa. In case of married couple, the responsibility of upbringing a child is equally shared by both the parents. Although the aforesaid view cannot be accepted as there are conditions under which a single person genuinely needs to avail surrogacy option to have child. One such situation is young age widow, who is otherwise capable but cannot carry child because of fear of social stigma attached to pregnancy of a widow in our society. One cannot explain everyone that the child in her own womb is of surrogacy and therefore such single person should be given option of surrogacy within permitted regulation under the Bill. Similar situation is of a divorced lady who doesn't want to remarry but wants child.

Age limit for Surrogate Mother

3.22 The age limit of the surrogate mother as proposed in the Bill is yet another issue which has been widely discussed. Various parliamentarians and stakeholders have supported to increase the maximum age limit to 39 years as recommended by the DRSC on Health and Family Welfare in 102nd Report. However, at the same time some stakeholders have supported the age limit as given in the Bill.

3.23 The Department while justifying the upper age limit submitted that it has been provided keeping in view the health of mother & child because of the following reasons:-

- Implantation rate decreases sharply
- Increase in incidence in miscarriage
- Incidence of pregnancy related adverse effects increases for surrogate mother
- Incidence of abnormalities in the child born will also increase

Arrangements for breastfeeding

3.24 Concerns have been raised with regard to the breastfeeding of the surrogate child and provision for milk banks. The Department submitted that since the surrogate mother would be a close relative, this proviso would facilitate breast feeding. The Infant Milk Substitutes, Feeding Bottles and Infants Foods (Regulation of Production, Supply and Distribution) Act, 1992 which provides for the regulation of production, supply and distribution of infant milk substitutes, feeding bottles and infant foods with a view to the protection and promotion of breastfeeding and ensuring the proper use of infant foods will also be followed. The Department also stated that the recommendations of the Select Committee for breast feeding/ Milk banks will be kept in view while formulating the rules & regulations in this regard.

Rights of Child Borne out of Surrogacy

3.25 The rights of the child borne out of Surrogacy is another significant issue that has received attention from different MPs and stakeholders. It has been contended that rights of child has not been clearly elaborated in the Bill. Doubts have been raised regarding the provisions that

may prevent surrogate child from getting abandoned, ill-treated, abused, sold, trafficked or exploited in any way. Suggestions have also been received to insert provision related to the insurance of surrogate child, screening of intending couples, medical assessment of fitness, social-economic background, criminal record, age, family information and other checks before permitting commissioning of surrogacy.

3.26 The Department in this regard submitted that there are various provisions to safe guard the future of the surrogate child. Section 4 states *"when it is not for producing children for sale, prostitution or any other form of exploitation.* Section 7 clearly explains that the child born through surrogacy will be deemed to be the biological child of the intending couple and all other laws applicable for protection of the rights of the biological children would apply on these surrogate children as well. It also prohibits abandonment of the child by the intending couple. Further, a parental order will be issued as per section 4 from a Magistrate Court to prevent abandonment by intending couple or detainment by the Surrogate mother. Also, the custody of the child as per the above provision will be subject to proof of insurance coverage for the child by the intending couple.

ART Bill should come before Surrogacy Bill

3.27 It has been argued that surrogacy is a part and parcel of Assisted Reproductive Technology (ART) and hence the Surrogacy Bill should come into force only after the enactment of ART Bill. Bringing Surrogacy Bill before the ART will be irrelevant and also create duplication of Boards. Suggestions have been received to incorporate Surrogacy Bill within the ART Bill as proposed earlier in the draft ART Bill. The Surrogacy Regulation Bill needs to be positioned and understood in close conjunction with the ART Bill because the ART Bill deals with the mode, the procedures and the technology of reproductive medicine in surrogacy while the Surrogacy Bill deals with the implications and the ethical issues arising from such arrangements. Therefore, regulation of ART is a necessary pre-condition for effective implementation of the Surrogacy Bill. On being enquired about reason of bringing a separate Bill for surrogacy when the ART Bill encompassed all assisted reproductive techniques including surrogacy, the Department submitted that the Assisted Reproductive Technology Regulation Bill, 2019 has been drafted and is awaiting Cabinet approval. ART Bill is intended to address the unethical practices by the ART clinics and banks. On the other hand, Surrogacy involves a third person other than the intending couple and exploitation of this third party (Surrogate mother) is becoming rampant. The Surrogacy Bill is based on social, legal, ethical and moral aspects whereas ART regulation Bill addresses highly technical and medical aspects. Most of the countries have separate Acts to regulate ART and Surrogacy. Some countries also have a 3rd Act on Embryos for e.g. Netherlands, Germany, and UK.

CHAPTER-IV

CLAUSE BY CLAUSE EXAMINATION OF THE BILL

4.1 The Surrogacy (Regulation) Bill, 2019 has been scrutinized in the context of India being called a Surrogacy hub for couples from different countries and reported incidents concerning unethical practices, exploitation of surrogate mothers, abandonment of children born out of Surrogacy and rackets of intermediaries importing human embryos and gametes. The Committee has examined the Bill in detail on provision of altruistic surrogacy and rights of child, regulation of the practice of surrogacy so as to prevent exploitation of women mainly from the economically weaker section of the society and to ban the commercial surrogacy.

4.2 During the course of the examination of the Bill, the Committee received a number of memoranda in response to its Press Release. The memoranda were forwarded to the Department of Health Research for its response. The Committee's observations and recommendations contained in the Report reflect an extensive scrutiny of submissions and all the viewpoints put forth before it by various organizations/experts/State Governments and Members of Parliament. The Committee is of the view that certain provisions of the Bill need to be recast to serve the intended purpose of the Bill better. The Committee in its meeting held on 1st February, 2020 took up clause-by-clause consideration of the Bill. Various amendments to the Bill have been suggested by the Committee on clauses of the Bill which are discussed in the succeeding paragraphs:

Clause 2- Definitions

4.3 Clause 2(b) provides the definition of altruistic surrogacy and it remained the most contentious and the most extensively debated topics during the deliberations of the Committee. While, some of the Members/stakeholders were of the view that the concept of altruistic surrogacy is not at all a workable proposition, some others apprehended that allowing only altruistic surrogacy would lead to black marketing and the surrogacy procedure being done clandestinely. The Committee was informed that by banning commercial surrogacy, the Bill assumes that altruistic surrogates are not exploited, ignoring the fact that unpaid surrogacy is also exploitative. The Bill also ignores the potential loss of earnings of the surrogate because she will have to effectively put her life on hold for a period of two years to successfully complete the process of surrogacy. It was also submitted before the Committee that through this Bill, it is expected that a woman must act as a surrogate and go through all the physical and emotional tolls of this arrangement free of cost and only out of "compassion". The irony is that through its "altruistic model", it promotes forced labour. In view of the above, there was a strong view that 'compensatory surrogacy' would be more appropriate word to make good for the losses suffered by the surrogate mother in terms of health, wages, sufferings, and death, etc. and hence the word 'altruistic surrogacy' may be replaced with the word 'compensatory surrogacy'.

4.5 The Department of Health Research responded to these issues by stating that Compensatory Surrogacy was not incorporated in the Bill because:-

- It may lead to commercialization of surrogacy and commercialization leads to exploitation of surrogate mothers and this practice has become rampant and India has become a surrogacy Hub.

- The 228th report of the Law Commission of India also recommended for prohibiting commercial surrogacy and allowing ethical altruistic surrogacy by enacting a suitable legislation;

- This got substantiated by the Supreme Court ruling with respect to a PIL by Smt. Jayashree Wad;

- In fact, many countries have banned surrogacy altogether. We are adopting a middle path.

4.6 The Department also submitted that provisions for compensation to the surrogate mother has been made in the Bill by way of insurance coverage for medical expenses, postpartum complications and the illness or death of a surrogate mother and any compensation beyond this would amount to commercialization of surrogacy because demarcation between compensation and commercial surrogacy gets defused.

4.7 While responding to the query of compensating the surrogate mother of the number of work days lost and entitlement to enhance maternity leave, the Department stated that under the Maternity Benefit Act, 2017, maternity benefits could be extended to the surrogate mother. There is also a provision of extended leave benefits to the surrogate mother to ensure the continuity of their service and to cover loss of wages.

4.8 The Committee is of the opinion that surrogacy could be classified on the basis of the specific intention with which a woman agrees to be a surrogate mother. The intention could be to make money and to render a paid service or for to do so for altruistic reasons. In case, the intention is to earn money, it is a commercial service and if it is to render a paid service it would be considered as compensatory surrogacy. Both the commercial and compensatory surrogacy is fraught with the risk of exploitation and commodifying the noble instinct of motherhood.

4.9 Compensatory surrogacy gives rise to some of the teasing questions:- whether there could be or should be any compensation for the noble act of motherhood; how much compensation could be treated as condign for a woman who agrees to rent her womb; whether any standard price or cost for this noble act of motherhood could be fixed, whether renting out of her womb by a woman for some material consideration could be considered as an ethical practice and the woman would get the same respect as other women and mothers get in the society. The appropriate and judicious response to all these questions appears to be in the negative and it is in this background that the most acceptable option for surrogacy is the altruistic one. Altrustism signifies a behavior that is selfless and intended to help others. It is way of thinking or behaving that shows one's wish to help and care about other people. In a nutshell, it is an unselfish concern for the welfare of others. At the heart of the altruistic surrogacy lies the fact that it is bereft of any commercial consideration, it is a social and noble act of highest level. The surrogate mother shows a strong inclination to render selfless service and takes a forward step to abolish the stigma of infertility from the society. She willfully and voluntarily resolves to do something worthwhile for the society and she, instead of being considered as getting involved in an immoral and unethical practice, sets an example of being a model woman in the society indulging in altruistic and selfless service as other normal mothers do. In the eyes of the surrogate child such a mother would get the same respect and reverence as a normal mother would have got.

4.10 Women in general and mother and motherhood in particular, occupy a very exalted position in Indian socio-cultural context, so much so, that they have been deified, adored and revered as goddess and regarded as par excellence paradise – *'Janani Janmabhoomischa Swargadapi Gariyasi'.* The reason why a mother has been put on such a higher pedestal of divinity is not only because she is a biological creator but more so because of the selfless, sublime love and affection that a mother showers on her child which knows no boundaries. The kind of care and concern, the warmth, the unflinching feeling of oneness, unison and bond that the mother harbours for her child and the sense of security and safety that the child feels in the arms and lap of a mother can only be experienced and not expressed in words.

4.11 What needs to be pondered over here is that whether such a sublime and divine instinct of motherhood could be allowed to be turned into a mechanical paid service of procreation devoid of divine warmth and affection. To preserve the sanctity attached with the *'mother'* and *'motherhood'* it is imperative that surrogacy is altruistic. Hon'ble Justice Dr. A.R. Laxmanan, in the 228th Report of the Law Commission had opined – *'the need of the hour is to adopt pragmatic approach by legalizing altruistic service/ arrangements and prohibit commercial ones'.*

4.12 The Committee after deliberating the issue at length, decided that altruistic surrogacy be modified as in the succeeding para.

4.13 As far as, the requirement of reimbursement of all reasonable expenses is concerned, there could be no divided opinion on this. The Committee fully endorses the view that payment of all the required expenditure on surrogacy procedure including such other expenses like nutritional food required, maternity wear, etc. vital for the wellbeing and upkeep of the surrogate mother needs to be appropriately covered and compensated. The Committee, therefore, recommends that clause 2(b) may be amended as under:

> "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses **and such other prescribed expenses** incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative.

Clause 2(f):

4.14 Consequent to the amendment in Clause 2(b), the Committee recommends that Clause 2(f) may be amended as under:

> "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses **and such other prescribed expenses** incurred on the surrogate mother and the insurance coverage for the surrogate mother.

4.15 This Clause 2(j) defines embryologist. The Committee finds that the word *'embryologist'* has been defined as a person who possesses any postgraduate medical qualification in the field of 'human embryology' recognized under the Medical Council Act, 1956 or who possesses a postgraduate degree in 'human embryology' from a recognized university.

4.16 When the Committee enquired from the Department as to whether any university in the country awards postgraduate degree in human embryology recognized under the Indian Medical Council Act, 1956, as prescribed in the Bill, the Department replied in the negative and stated that as per the recommendations of the Parliamentary Standing Committee wherever the term *'human embryologist'* occurred, it was replaced by *'embryologist'* and the Clause will also be rectified accordingly.

4.17 The Committee finds that it is an inadvertent error which has occurred due to some oversight. **The Committee, therefore, recommends that Clause 2(j) may be amended as under:**

> **"embryologist" means a person who possesses any post-graduate medical qualification or doctoral degree in the field of embryology or clinical embryology from a recognised University with not less than two years of clinical experience;**

4.18 Clause 2(p) read with Clauses 2(r), 4(ii)(a) & 4(iii)(a)(*I*) provide the eligibility criteria for availing surrogacy procedure. A number of Members raised objections to the definition of the term *'infertility'* as the inability to conceive after 5 years of unprotected coitus on ground that it was too long a period for a couple to wait for child. They also argued that the World Health Organization defines infertility as a disease of the reproductive system defined by the failure to achieve a clinical pregnancy after 12 months or more by regular unprotected sexual intercourse. Some of the Members were of the view that there may be certain proven medical conditions like absence of uterus by birth, non-functional uterus, or patients with chronic medical condition where pregnancy is ruled out. They, therefore, were of the view that in these conditions, the 5 year period required for availing the procedure of surrogacy, needs to be relaxed. Some Members took umbrage to the Clause 4(iii)(a)(*I*) which provides for obtaining a certificate of infertility from a District Medical Board on the ground that why should such a certificate be required at all as it is quite offending and insulting. They were of the view that these Clauses need to be revisited.

4.19 The Department submitted that this particular definition of infertility has been specifically framed for infertility treatment through surrogacy. The intending couple needs to exhaust all other means of having a child of their own with the help of assisted reproductive technology, etc. because the joy of bearing one's own child can never be the same as can be had through surrogacy. So, this period of 5 years provides the intending couple the opportunity to exhaust all the possible means to have a child of their own rather than jump to the surrogacy procedure in haste. It was further submitted that infertility cannot be proven in early years of marriage as sometimes conception happens even after 15 years. That is why, a reasonable period of 5 years married life has been prescribed. The Department also submitted that provisions have been kept for individual cases with other conditions which may include birth anomalies and have only surrogacy as an option vide Clause 4(iii)(c)(*IV*).

4.20 The Committee was, however, not convinced with the arguments given by the Department and felt that five year waiting period is too long particularly in conditions like – absent or abnormal uterus, irreversible damage or destruction of uterus due to tuberculosis, removal of uterus due to cancer, fibroids, etc. or patients with chronic medical condition where normal pregnancy is ruled out and it is medically proven beyond any doubt that surrogacy is the only option. Besides, the Committee also felt that the requirement of obtaining certificate of proven infertility, is not at all justified.

4.21 **In view of the above, the Committee recommends that while Clause 2(p) may be deleted and after this, the clauses may accordingly be renumbered/rearranged.**

4.22 Clause 2(q) defines insurance to provide a guarantee of compensation to the surrogate mother. The Committee discussed this issue in the context of the clarification given by the Department that medical expenses incurred on surrogate mother would be provided by way of insurance coverage. The Committee, however, found that the word *'insurance'* as defined in Clause 2(q) did not cover medical expenses, as it provided a guarantee of compensation for specified loss, damage, illness or death of surrogate mother during the process of surrogacy. The Committee, therefore, recommends that the Clause 2(q) may be amended as under:

> "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for medical expenses, health issues, specified loss, damage, illness or death of surrogate mother and such other prescribed expenses incurred on such surrogate mother during the process of surrogacy.

4.23 Clause 2(r) defines 'intending couple' as the couple who have been medically certified an infertile couple. Consequent to the deletion of Clause 2(p) which defined infertility, the Committee recommends that this Clause may be amended as under:

> "intending couple" means a couple who have a medical indication necessitating gestational surrogacy and who intend to become parents through surrogacy;

4.24 The Committee understands that there are conditions under which a single person genuinely needs to avail surrogacy option to have child. One such situation is young age widow, who is otherwise capable but cannot carry child because of fear of social stigma attached to pregnancy of a widow in our society. One cannot explain everyone that the child in her own womb is of surrogacy and therefore such single person should be given option of surrogacy within permitted regulation under the Bill. Similar situation is of a divorced lady who doesn't want to remarry but wants child. In view of the above, single woman (divorcee or widow) has been made eligible for commissioning surrogacy by amending Clause 4 and the expression-single woman (divorcee or window) figures in various clauses of the Bill, insertion of definition of intending woman is essential. Accordingly, the Committee recommends that the word 'intending woman' may be defined as under by inserting Clause 2(r)(a) as under:

> Clause 2(r)(a)
>
> "Intending woman" means an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail surrogacy.

4.25 The definition of 'intending woman' has been inserted in view of the insertion of the said expression in the Bill. Consequential amendments have been made by inserting the said expression, besides the couple of Indian origin, wherever they occur.

4.26 Clause 2(zf) defines 'surrogate mother' and consequent to insertion of the word 'intending woman' in the Bill. The Committee recommends that this Clause may be amended as under:

> "surrogate mother" means a woman who agrees to bear a child (the Child who is genetically related to the intending couple or intending woman) through surrogacy from the implantation of embryo in her womb and fulfills the conditions as provided in sub-clause (b) of clause (iii) of section 4;

4.27 Clause 2 as amended is adopted.

Clause 3

4.28 Clause 3 has no amendment and is adopted.

4.29 Clause 4 – Regulation of surrogacy and surrogacy procedure

4.30 Clause 4 provides for regulation of surrogacy and surrogacy procedures, which *inter-alia* prescribes that the intending couple are Indian citizen.

4.31 Some Members/stakeholders also desired that debarring single man, single woman - divorcee or widow, live-in couples and gay couples from availing surrogacy is violative of their reproductive autonomy. They, therefore, demanded that the people of above categories may also be permitted to avail surrogacy.

4.32 Yet another objection to Clause 4 by the Members/stakeholders is that the intending couple for surrogacy have to be Indian Citizen thus effectively debarring or depriving foreigners and persons of Indian Origins of the opportunity to avail the surrogacy services in India. A strong demand has, therefore, been made that persons of Indian origin may be made eligible to avail the practice of surrogacy in India.

4.33 The main reasoning given behind making persons of Indian Origin eligible for surrogacy in India is that if they are permitted to adopt in India, why can't they be allowed to opt for surrogacy? The Department of Health Research gave the following reasons for not allowing them to avail surrogacy in India:- abandonment of children; citizenship laws in the home countries of persons of Indian origin not being supportive to migrating surrogate children; persons of Indian origin can avail surrogacy in their own countries as per prevalent laws; difficulty in their antecedent verification and lastly that it leads to Indian women getting exploited. They further submitted that Ministry of External Affairs have reported certain issues related to surrogacy by foreign nationals such as – suppression of facts during visa applications which results in trouble and inconvenience for the child, the surrogate mother, as well as, the Indian Mission; inconsistent DNA results from the surrogacy clinics/laboratories due to poor quality control, resulting in denial of Passport by some countries to the surrogate child, leading to the child getting stranded in India, etc. The Department has also referred to the Notification

No. – 25022/74/2011/F-1 Vol. III dated 3rd November, 2015 which was issued by Ministry of Home Affairs prohibiting foreign nationals, PIO and OCI cardholders from commissioning surrogacy in India. It was further added that after discussion with Ministry of Health & Family Welfare and Ministry of External Affairs, MHA has decided that no Visa should be issued to Indian Nationals intending to visit India for commissioning surrogacy and also that no permission should be granted by the foreigners regional registration offices to overseas Indian citizens cardholders to commission surrogacy in India and no exit permit to the child who is born by surrogacy would be issued. The notification of MHA is based on facts and hence cannot be undermined or overlooked. They also informed the Committee that the rules for availing surrogacy by persons of Indian origin were liberal up to the year 2015. But based on the developments, the MHA has to issue such a Notification.

4.34 When the Department was asked to clarify that if adoption is permissible for persons of Indian origin, why can't they be allowed to opt for surrogacy, the Department responded by saying that as informed by Ministry of External Affairs there is no international convention or multilateral agreement which defines and regulates surrogacy. They further submitted that Hague Convention on protection of Children and Co-operation in respect of Inter-country adoption which operates through a system of national central authorities, reinforces the UN convention on the Rights of the child (Article 21) and seeks to ensure that inter-country adoptions are made in the best interests of the child. Moreover, the process of adoption provides for a family to a homeless child whereas surrogacy involves a third party reproduction of a child with uncertain future.

4.35 The Committee extensively debated both the issues and came to a conclusion that keeping in view the interest of the child, only single woman (divorcee or widow) between the age of 35 to 45 years and persons of Indian origin may be permitted to avail surrogacy, provided they obtain a certificate of recommendations from the National Surrogacy Board on an application made by the above said persons in such manner and such format as may be prescribed. The format may contain No Objection Certificate for the Indian origin couple, country status regarding surrogacy, details of surrogate mother, parental order for the child to be born and clearance from Ministry of External Affairs and satisfying all provision of the Bill.

4.36 The Committee, however, after having detailed discussions on the matter feels that the facility to avail surrogacy procedure may be extended to persons of Indian origin because they have their ancestral root in India. Consequent to deletion of definition of infertility and keeping in view the above facts, the Committee recommends that Clause 4(ii)(a) may be amended as under:

> (a) **when an intending couple has a medical indication necessitating gestational surrogacy:**
>
> **Provided that a couple of Indian origin or an Intending woman who intends to avail surrogacy shall obtain a certificate of recommendation from the Board on an application made by the said persons in such form and manner as may be prescribed.**
>
> ***Explanation*.—For the purposes of this sub-clause, the expression "gestational surrogacy" means a practice whereby a surrogate mother carries a child for the**

intending couple through implantation of embryo in her womb and the child is not genetically related to the surrogate mother. 645

4.37 Clause 4(iii)(a)(*I*) needs to be modified consequent to deletion of definition of infertility as under:

> "a certificate of a medical indication in favour of either or both members of the intending couple or intending woman necessitating gestational surrogacy from a District Medial Board."

4.38 Clause 4(iii)(a)(*II*) provides for parental order for the custody of the child born through surrogacy. The Committee discussed that in order to protect the interest of the surrogate mother and the surrogate child, a Tripartite Surrogacy Agreement among the intending parents, the surrogate mother and the authority should be made.

4.39 The Department informed the Committee that the Tripartite Agreement is equivalent to the parental order to be issued by the Magistrate Court as mentioned in Clause 4, which will safeguard the future of the child. Apart from this, there are various other provisions to secure the future of the child viz. – Clause 7 clearly explains that the child born through surrogacy will be deemed to be the biological child of the intending couple and also prohibits abandonment of the child by the intending couple. Provisions for Offences and penalties have also been kept to ensure that surrogacy is not taken lightly and the child is not abandoned. Further, to protect the interest of the child, the Department has suggested that the parental order may also be treated as the birth certificate of the surrogate child.

4.40 The Committee discussed this issue and recommends to amend this Clause as under:

> "an order concerning the parentage and custody of the child to be born through surrogacy which shall be the birth affidavit after the surrogate child is born, has been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple or the intending woman and the surrogate mother; and"

4.41 Clause 4(iii)(a)(*III*) provides for the period of insurance coverage to a surrogate mother. Concerns have been raised on the insurance coverage for the surrogate mother being limited for a period of 16 months only, keeping in view the fact that the procedure of surrogacy poses the risks of medical complications and health hazards, post-partum.

4.42 The Department has stated that generally pregnancy related complications are expressed within 3 to 4 months after delivery. The insurance coverage of 16 months includes duration for screening and necessary treatment of the surrogate before establishment of the pregnancy, gestation period of 9 months and 7 months postpartum period. They have further stated that the insurance coverage can be provided in three phases – the first phase during initiation of surrogacy procedures till the pregnancy is confirmed; second phase till delivery of the child covering the gestational period; and the third phase covering postpartum complications. They have also assured that other medical emergencies will be dealt on case to case basis as per rules and regulations.

4.43 The Committee feels that a woman by agreeing to be a surrogate going by the altruistic concept is doing a gratuitous or benevolent act, therefore, it becomes imperative that she is financially secured of her health and wellbeing. This is all the more necessary to provide her a psychological satisfaction. The need to have insurance for longer duration is also felt because the Department has no authentic data on the ill-effects/after effects of surrogacy procedure on the health of the surrogate mothers. In such a scenario, the Committee feels that the period of insurance coverage needs to be so enhanced as to assure surrogate mother that her health is secured.

4.44 The Committee, therefore, recommends that the Clause 4(iii)(a)(*III*) may be amended as under:

> "an insurance coverage of such amount and in such manner as may be prescribed in favour of the surrogate mother for a period of thirty six months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999".

4.45 Clause 4(iii)(b)(*I*) provides for a woman to be of the age group of 25 to 35 years. Suggestions have been received by the Committee to the effect that the restriction of age limit i.e. between the age of 25 to 35 years of a surrogate mother on the day of implantation added by the pre-condition that she is having a child of her own would badly affect the availability of surrogate mothers. It has also been argued that there has been a sharp rise in the number of working women who tend to delay their own planning of family. There is also the rising phenomenon of late marriage. An argument has also been advanced that the Bill seeks to permit only gestational surrogacy in which the pregnancy is medically induced and obtained as a result of IVF where woman acting as surrogate does not contribute her eggs and hence a woman is reproductive as long as she has not attained menopause and can potentially act as surrogate provided she is deemed fit to do so by medical practitioner who would evaluate her obstetric health. The important criteria for deciding who can act as surrogate should, therefore, be through examination of physical and mental health to undergo the process and not merely her age. In view of the above, they have suggested that the age limit for a surrogate mother should be raised to 39 years.

4.46 The Department of Health Research held the view that the upper age limit of 35 years has been provided keeping in view the health of the mother and the child. The age between 25 to 35 years is proven to be the most suitable period for reproduction and the success of implantation reduces beyond 35 years of age. The chances of miscarriages and instances of pregnancy related adverse effects leading to more health hazard to the surrogate mother increase with age and at times even can be fatal, and more importantly the instance of abnormalities in the child born will also increase. Further, the success rate of surrogacy is not more than 30 to 40 per cent and that also in best clinics.

4.47 The Committee is of the opinion that to venture into this highly medical and specialized field by randomly suggesting increase in the age of a surrogate mother without any factual or material base would not be appropriate because by doing so both the life of the surrogate mother and the child to be born would be put to a risk**.**

4.48 The Committee, therefore, does not propose any amendment to this Clause.

4.49 Clause 4(iii)(b)(*II*) provides eligibility condition for a woman to be a surrogate mother. **647** This issue was discussed at length during the deliberations of the Committee and the requirement of only a close relative being a surrogate mother was contested on the following grounds:

- That these stipulations significantly reduce the availability of women to act as a surrogate mother;

- Surrogate pregnancy is a private affair and a majority of the patients seeking parenthood through surrogacy want to keep their treatment private and confidential and hence the pre-condition of close relative to be surrogate mother would be violative of basic right to privacy and reproductive autonomy of infertile couple;

- The close relative Clause ignores the ground reality of most Indian family where women have little decision making authority. This will create a situation where women in families, especially close relatives would be coerced into providing reproductive labour;
- Limiting the practice of surrogacy to a close relative is not only impractical, but also has no connect with the object to stop exploitation of surrogates envisaged in the proposed legislation;

- That the term *'close relative'* needs to be defined for the purpose of clarity; and

- That there is a change in the way Indians have their personal relationships. Younger married couples do not necessarily have close relatives anymore or they may be cut off from them, or the close relatives may not be geographically accessible.

4.50 To have an exact and authentic information on the enormity of cases of infertility, the Committee asked the Department of Health Research as to whether any survey on the infertile married couples and the cases of surrogacy in the country has been carried out and if so what is the outcome during the last 3 years. The Department responded by saying that there are published reports by researchers, but government survey has not been carried out. The National Family Health Survey 5 initiated this year – has included survey questions related to surrogacy and assisted reproductive technology.

4.51 However, the Committee finds that the Department-related Parliamentary Standing Committee on Health & Family Welfare in its 102nd Report on the Surrogacy (Regulation) Bill, 2016 has cited a study by Ernst and Young Study (Call for Action: expanding IVF treatment in India, July 2015), in India. According to this study, around 27.5 million couples in the reproductive age group are infertile and about one percent i.e. about 2,70,000 infertile couples seek infertility evaluation. Of the people seeking remedy for infertility, 20-25% undergo IVF treatment and of that small group, one percent may require surrogacy. Ten to Twelve per cent of surrogacy is commissioned because of irreversible destruction of uterus due to TB, 8 per cent because of absence of uterus, 12 per cent because of multiple failed IVF cycles, 12 per cent because of multiple miscarriages, 10 per cent because of removal of uterus due to cancers, fibroids, etc.

4.52 Further, the Department of Health Research has stated that the word 'close relative' has been provisioned to cover a wider ambit of relatives and is not as restrictive, as in Thailand where a surrogate mother has to be related either to the husband or the wife by blood. Here, close relative has been provisioned to cover a wider ambit of relatives so as to include even a

distant relative of any of the intending couple. The emotional connect of the surrogate mother with the intending couple has also been kept in view which strengthens the concept of altruistic surrogacy while minimizing the possibilities of exploitation.

4.53 The Committee finds that the term "close relative" potentially restricts the availability of surrogate mother and may affect the genuinely needy persons. The Committee is, therefore, of the view that it may be removed. The Committee, therefore, recommends that the Clause 4(iii)(b)(*II*) may be amended as under:

> **"a willing woman, shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act;**
>
> **Provided that intending couple or the intending woman shall approach the appropriate authority with a willing woman who agrees to act as a surrogate mother."**

4.54 Clause 4(iii)(c)(*I*) and 4(iii)(c)(*II*) provides for eligibility certificate for intending couple. Consequent to the deletion of Clause 2(p) on the ground that five year period is too long for a couple to have a child and that couples of Indian origin may also be permitted to avail surrogacy the **Committee recommends that Clause 4(iii)(c)(*I*) and 4(iii)(c)(*II*) may be amalgamated and amended as under:**

> "the intending couple are married and are between the age of 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification".

4.55 Clause 4 as amended is adopted.

Clauses 5 & 6

4.56 Clauses 5 & 6 have no amendment and are adopted.

Clause 7

4.57 Consequent to the insertion of proviso to Clause 4(ii)(a) making women who are divorced and widow or a couple of Indian origin eligible for surrogacy, the Committee recommends insertion of a new Clause as Clause 7(a) replacing proviso to Clause 7 as under:

> "A child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple or the intending woman and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force".

Clauses 8, 9, 10, 11 & 12

4.58 Clauses 8, 9, 10, 11 & 12 have no amendment and are adopted.

Clause 13

4.59 Clause 13 provides appeal against rejection of application etc. of surrogacy clinics. The Committee finds that the Bill does not contain any provision of appeal for the intending couple or the intending woman in case their application is rejected. The Committee, therefore, recommends that in order to provide the intending couple or the intending woman an opportunity to appeal, the Clause may be amended as under:

> The surrogacy clinic or the intending couple or the intending woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under Section 12 and communication relating to rejection of the certificates under section 4, prefer an appeal against such order to-
>
> (*a*) the State Government, where the appeal is against the order of the appropriate authority of a State;
> (*b*) the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,".
>
> In such manner as may be prescribed.

4.60 **Clause 13 as amended is adopted**.

Clause 14

4.61 Clause 14(2)(f)(ii) inter-alia provides for experts of *stri-roga* or *prasuti-tantra* to be appointed on the National Surrogacy Board. After some discussions on this issue, the Committee decided to delete the expression- *stri-roga* or *prasuti-tantra*. **Accordingly, this clause as amended is adopted.**

Clause 15

4.62 Clause 15(*I*)(b) specifies the term of ten experts Members to be appointed by the Central Government on the National Surrogacy Board for a period of one year. As provided in Clause 16(1) that the Board shall meet at least once in six months, the Committee feels that there would be no meaningful contribution of these experts to the effective functioning of the Board. When the opinion of the Department on this issue was sought, they agreed that the term of the experts can be similar to the other members. The Committee, therefore, recommends that the term of the expert members may be increased from one year to three years and Clause 15(*I*)(b) may be amended as under:-

> ***"in case of appointment under clause (f) of sub section (2) of section 14, three years".***

4.63 **Clause 15 as amended is adopted.**

4.64 Clauses16 to Clause 23 have no amendment and are adopted.

Clause 24

4.65 Clause 24(f)(ii) inter-alia provides for experts of *stri-roga* or *prasuti-tantra* to be appointed on the State Surrogacy Board. After some discussions on this issue, the Committee decided to delete the expression- *stri-roga* or *prasuti-tantra*.

4.66 **Accordingly, clause 24 as amended is adopted.**

Clause 25

4.67 Clause 25(*I*)(b) specifies the term of ten experts Members to be appointed by the State Government on the State Surrogacy Board for a period of one year. The Committee recommends that the term of the expert members may be increased from one year to three years on the lines of National Surrogacy Board and Clause 25(*I*)(b) may be amended as under:-

"in case of appointment under clause (f) of section 24, three years".

4.68 **Clause 25 as amended is adopted.**

Clause 26 to 31

4.69 Clause 26 to 31 have no amendment and are adopted.

Clause 32

4.70 Clause 32(3)(a)(i) provides for an officer of or above the rank of Joint Director to be the Chairperson of the appropriate authority. The Committee has been informed that the chairperson of the proposed appropriate authority should be a senior ranking officer as it has been assigned very significant functions. The Committee also feels that the appropriate authority forms the backbone of the implementation and regulation of surrogacy clinics on the ground level and hence it needs to have fairly senior ranking officer to act as chairperson. The Committee, therefore, recommends that Clause 32(3)(a)(i) may be amended as under:

(i) an officer of or above the rank of the Joint Secretary of Health and Family Welfare Department-Chairperson;

(i) an officer of or above the rank of the Joint Director of Health and Family Welfare Department- Vice Chairperson;

4.71 Clause 32 as amended is adopted.

4.72 Clause 33 has no amendment and is adopted.

Clause 34

4.73 Clause 34(2) provides that the appropriate authority shall maintain details of registration of surrogacy clinics, cancellation of registration, renewal of registrations, etc. The Committee has been apprised that in order to have transparency and the real time data base at the national level, it should be provided in the Bill that all the requisite data maintained by the appropriate authority as provided in Clause 34(2) must come to the National Surrogacy Board. The Committee finds merit in the argument and recommends that Clause 34(2) may be amended as under:-

> The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of license etc. of the surrogacy clinics in such format as may be prescribed **and submit the same to the National Surrogacy Board.**

4.74 Clause 34 as amended is adopted.

Clause 35 and 36

4.75 Clauses 35 and 36 have no amendment and are adopted.

Clause 37

4.76 Clause 37 as worded in the Bill, gives an impression that punishment is not being provided for not following altruistic surrogacy, but for initiation of commercial surrogacy which is not the spirit of the Bill. The Committee, therefore, recommends that this Clause alongwith short title may be amended as under:

> Any intending couple or intending woman or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynecologist, pediatrician, embryologist or any other person for not following altruistic surrogacy or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.
>
> **Short title**

4.77 Punishment for not following altruistic surrogacy.

4.78 **Clause 37 as amended is adopted.**

4.79 Clauses 38 to 46 have no amendment and are adopted.

Clause 47

4.80 Clause 47 deals with power to make rules. Due to various amendments recommended to be made in the Bill, consequential changes made in Clause 47(2) are adopted.

Clause 1: Short title, extent and commencement

4.81 The Committee discussed the short title and extent of the Bill and recommends that consequent upon change in the year; abrogation of Article 370 and Jammu & Kashmir becoming a Union Territory, while Clause 1(*2*) may be deleted, Clause 1(*1*) may be amended as under:

1. (1) This Act may be called the Surrogacy (Regulation) Act, **2020**.

4.82 Consequentially, the word *'extent'* after the word 'Short title' may also be deleted and only the 'Short-Title and Commencement' may be retained in the right margin of the Bill.
Clause 1 as amendment is adopted.

GENERAL RECOMMENDATION

Assisted Reproductive Technology (Regulation) Bill (ART Bill) vis-à-vis Surrogacy (Regulation) Bill, 2019.

4.83 Most of the experts/ stakeholders vociferously demanded that the Assisted Reproductive Technology (Regulation) Bill (ART Bill) could have been brought before the Surrogacy (Regulation) Bill, 2019. They contended that there is no separate surrogacy clinic to undertake surrogacy procedures. ART clinics are rather undertaking surrogacy procedures and hence they need to be regulated first.

4.84 The Department of Health Research informed the Committee that the Surrogacy Bill is based on social, legal, ethical and moral aspects, whereas Assisted Reproductive Technology Bill addresses highly technical, medical and scientific aspects. Further, surrogacy involves a third person other than the intending couple and exploitation of this third party (surrogate mother) is becoming rampant, while ART involved unethical practices by the ART clinics and banks. They also informed that most of the countries have separate acts to regulate ART and surrogacy. The Committee was also informed that the Assisted Reproductive Technology Bill 2019 has been drafted and is in advance stage and awaiting Cabinet approval.

4.85 The Committee have sought the opinion of the Department of Legal Affairs, Ministry of Law & Justice on the following points:

(i) Whether the Assisted Reproductive Technology Bill, 2019 (ART Bill, 2019) should be passed first before passing of Surrogacy (Regulation) Bill, 2019 and whether pendency of the above Bill was in the knowledge of this Ministry;

(ii) Whether this Ministry raised any such issue at the time of examination of the Surrogacy (Regulation) Bill, 2019;

(iii) Whether inter-ministerial was taken into account before tendering our opinion on the Surrogacy (Regulation) Bill, 2019.

They have responded with respect to point No. (i), as follows:

"it is for the administrative Ministry to explain with reasons as to whether Assisted Reproductive Technology Bill, 2019 (ART Bill, 2019) should be passed before the passing of Surrogacy (Regulation) Bill, 2019 or otherwise in terms of objectives of both legislations. Further, administrative Ministry may also explain as to whether pendency of the ART Bill, 2019 was in knowledge of that Ministry".

4.86 Responding to Point Nos. (ii) & (iii), they have stated that it is for the administrative Ministry to explain as to whether they have raised the issue of pendency of ART Bill, 2019 during the examination of Surrogacy (Regulation) Bill, 2019. During the examination of Cabinet Note on Surrogacy (Regulation) Bill, 2019 it is submitted that inter-ministerial consultations took place and this Ministry (Department of Legal Affairs as well as Legislative Department) also offered comments with approval of the Hon'ble Minister of Law & Justice.

4.87 The Committee agrees with the opinion of the Department of Health Research that the nature and the intent of two Bills are different and, hence these two Bills need to be dealt with separately. However, the Committee finds that the Surrogacy (Regulation) Bill, 2019 also involves highly technical, scientific and medical aspects, which would appropriately be addressed through ART Bill. There is hardly any clinic in the country which provides only surrogacy services. The Committee also finds that the surrogacy clinics as defined in Clause 2(zd) of the Bill includes centers or labs conducting ART services, in-vitro fertilization services, etc. The Surrogacy (Regulation) Bill also deals with such highly medical terminologies as storage of embryo, gamete, oocyte, etc. which could better be dealt with in the ART Bill for the purpose of their regulation.

4.88 In view of the above, the Committee recommends that ART Bill should be brought before the Surrogacy (Regulation) Bill, 2019, so that all the highly technical and medical aspects could be properly addressed in the Surrogacy (Regulation) Bill, 2019. The Committee also recommends that the National and State Boards constituted for regulation of surrogacy as proposed in the Bill shall act as the Boards for regulation of ART (Assisted Reproductive Technology).

THE SELECT COMMITTEE ON THE SURROGACY (REGULATION) BILL, 2019

(AS REPORTED BY THE SELECT COMMITTEE)

THE SURROGACY (REGULATION) BILL, 2020

[WORDS AND FIGURES UNDERLINED INDICATE THE AMENDMENTS AND (**) MARK INDICATES THE OMISSION SUGGESTED BY THE SELECT COMMITTEE]

	THE SURROGACY (REGULATION) BILL, <u>2020</u>	
	A	
	BILL	
	to constitute National Surrogacy Board, State Surrogacy Boards and appointment of appropriate authorities for regulation of the practice and process of surrogacy and for matters connected therewith or incidental thereto.	
	BE it enacted by Parliament in the **<u>Seventy-first</u>** Year of the Republic of India as follows:—	
	CHAPTER I **PRELIMINARY**	
	1. (1) This Act may be called the Surrogacy (Regulation) Act, **<u>2020</u>**.	Short title, (**) and commencement.
	(2) **(**)**	
	(3) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.	

Definitions.	**2.** In this Act, unless the context otherwise requires,—	
	(a) "abandoned child" means a child born out of surrogacy procedure who has been deserted by his intending parents or guardians and declared as abandoned by the appropriate authority after due enquiry;	
	(b) "altruistic surrogacy" means the surrogacy in which no charges, expenses, fees, remuneration or monetary incentive of whatever nature, except the medical expenses **and such other prescribed expenses** incurred on surrogate mother and the insurance coverage for the surrogate mother, are given to the surrogate mother or her dependents or her representative;	
	(c) "appropriate authority" means the appropriate authority appointed under section **33**;	
	(d) "Board" means the National Surrogacy Board constituted under section **15**;	
23 of 2010.	(e) "clinical establishment" shall have the same meaning as assigned to it in the Clinical Establishments (Registration and Regulation) Act, 2010;	
	(f) "commercial surrogacy" means commercialisation of surrogacy services or procedures or its component services or component procedures including selling or buying of human embryo or trading in the sale or purchase of human embryo or gametes or selling or buying or trading the services of surrogate motherhood by way of giving payment, reward, benefit, fees, remuneration or monetary incentive in cash or kind, to the surrogate mother or her dependents or her representative, except the medical expenses **and such other prescribed expenses** incurred on the surrogate mother and the insurance coverage for the surrogate mother;	
	(g) "couple" means the legally married Indian man and woman above the age of 21 years and 18 years respectively;	
	(h) "egg" includes the female gamete;	
	(i) "embryo" means a developing or developed organism after fertilisation till the end of fifty-six days;	

	(j) "embryologist" means a person who possesses any post-graduate medical qualification **or doctoral degree** in the field of (**) embryology or **clinical embryology** (**) from a recognised University with not less than two years of clinical experience;	
	(k) "fertilisation" means the penetration of the ovum by the spermatozoan and fusion of genetic materials resulting in the development of a zygote;	
	(l) "foetus" means a human organism during the period of its development beginning on the fifty-seventh day following fertilisation or creation (excluding any time in which its development has been suspended) and ending at the birth;	
	(m) "gamete" means sperm and oocyte;	
57 of 1994.	(n) "gynecologist" shall have the same meaning as assigned to it in the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994;	
	(o) "implantation" means the attachment and subsequent penetration by the zona-free blastocyst, which starts five to seven days following fertilisation;	
	(p) (**)	
	(**q**) "insurance" means an arrangement by which a company, individual or intending couple undertake to provide a guarantee of compensation for **medical expenses, health issues,** specified loss, damage, illness or death of surrogate mother **and such other prescribed expenses incurred on such surrogate mother** during the process of surrogacy**;**	
	(**r**) "intending couple" means a couple who have (**) **a medical indication necessitating gestational surrogacy** and who intend to become parents through surrogacy;	
	(s) "intending woman" means an Indian woman who is a widow or divorcee between the age of 35 to 45 years and who intends to avail the surrogacy ;	
	(**t**) "Member" means a Member of the National Surrogacy Board or a State Surrogacy Board, as the case may be;	

	(**u**) "notification" means a notification published in the Official Gazette;	
	(**v**) "oocyte" means naturally ovulating oocyte in the female genetic tract;	
	(**w**) "Pediatrician" means a person who possesses a post-graduate qualification in pediatrics as recognised under the Indian Medical Council Act, 1956;	102 of 1956.
	(**x**) "prescribed" means prescribed by rules made under this Act;	
	(**y**) "registered medical practitioner" means a medical practitioner who possesses any recognised medical qualification as defined in clause (h) of section 2 of the Indian Medical Council Act, 1956 and whose name has been entered in a State Medical Register;	102 of 1956.
	(**z**) "regulation" means regulations made by the Board under this Act;	
	(**za**)"sex selection" shall have the same meaning as assigned to it in clause (o) of section 2 of the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994;	57 of 1994.
	(**zb**) "State Board" means the State Surrogacy Board constituted under section **24**;	
	(**zc**) "State Government" in relation to Union territory with Legislature, means the Administrator of the Union territory appointed by the President under article 239 of the Constitution;	
	(**zd**) "surrogacy" means a practice whereby one woman bears and gives birth to a child for an intending couple with the intention of handing over such child to the intending couple after the birth;	
	(**ze**) "surrogacy clinic" means surrogacy clinic, centre or laboratory, conducting assisted reproductive technology services, invitro fertilisation services, genetic counseling centre, genetic laboratory, Assisted Reproductive Technology Banks conducting surrogacy procedure or any clinical establishment, by whatsoever name called, conducting surrogacy procedures in any form;	
	(**zf**) "surrogacy procedures" means all gynecological, obstetrical or medical procedures, techniques, tests,	

	practices or services involving handling of human gametes and human embryo in surrogacy;	
	(**zg**) "surrogate mother" means a woman who agrees to bear a child (who is genetically related to the intending couple **or intending woman**) through surrogacy from the implantation of embryo in her womb and fulfills the conditions as provided in sub-clause (b) of clause (iii) of section 4;	
	(**zh**) "zygote" means the fertilised oocyte prior to the first cell division.	
	CHAPTER II **REGILATION OF SURROGACY CLINICS**	
	3. On and from the date of commencement of this Act,—	Prohibition and regulation of surrogacy clinics.
	(i) no surrogacy clinic, unless registered under this Act, shall conduct or associate with, or help in any manner, in conducting activities relating to surrogacy and surrogacy procedures;	
	(ii) no surrogacy clinic, paediatrician, gynaecologist, embryologist, registered medical practitioner or any person shall conduct, offer, undertake, promote or associate with or avail of commercial surrogacy in any form;	
	(iii) no surrogacy clinic shall employ or cause to be employed or take services of any person, whether on honorary basis or on payment who does not possess such qualifications as may be prescribed;	
	(iv) no registered medical practitioner, gynecologist, pediatrician, embryologist or any other person shall conduct or cause to be conducted or aid in conducting by himself or through any other person surrogacy or surrogacy procedures at a place other than a place registered under this Act;	
	(v) no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, embryologist or any other person shall promote, publish, canvass, propagate or advertise or cause to be promoted, published, canvassed, propagated or advertised which—	

	(a) is aimed at inducing or is likely to induce a woman to act as a surrogate mother;	
	(b) is aimed at promoting a surrogacy clinic for commercial surrogacy or promoting commercial surrogacy in general;	
	(c) seeks or aimed at seeking a woman to act as a surrogate mother;	
	(d) states or implies that a woman is willing to become a surrogate mother; or	
	(e) advertises commercial surrogacy in print or electronic media or in any other form;	
	(vi) no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, embryologist, intending couple or any other person shall conduct or cause abortion during the period of surrogacy without the written consent of the surrogate mother and on authorisation of the same by the appropriate authority concerned:	
	Provided that the authorisation of the appropriate authority shall be subject to, and in compliance with, the provisions of the Medical Termination of Pregnancy Act, 1971;	34 of 1971.
	(vii) no surrogacy clinic, registered medical practitioner, gynecologist, pediatrician, embryologist, intending couple or any other person shall store a human embryo or gamete for the purpose of surrogacy:	
	Provided that nothing contained in this clause shall affect such storage for other legal purposes like sperm banks, IVF and medical research for such period and in such manner as may be prescribed;	
	"(viii) no surrogacy clinic, registered medical practitioner, gynaecologist, paediatrician, embryologist, intending couple or any other person shall in any form conduct or cause to be conducted sex selection for surrogacy.".	
	CHAPTER III **REGULATION OF SURROGACY AND SURROGACY PROCEDURES**	
	4. On and from the date of commencement of this Act,—	Regulation of surrogacy and

		surrogacy procedures.
	(i) no place including a surrogacy clinic shall be used or caused to be used by any person for conducting surrogacy or surrogacy procedures, except for the purposes specified in clause (ii) and after satisfying all the conditions specified in clauses (iii);	
	(ii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or availed of, except for the following purposes, namely:—	
	(a) **when an intending couple has a medical indication necessitating gestational surrogacy:**	
	Provided that a couple of Indian origin or an intending woman who intends to avail surrogacy, shall obtain a certificate of recommendation from the Board on an application made by the said persons in such form and manner as may be prescribed.	
	***Explanation*.—For the purposes of this sub-clause and item (I) of sub-clause (a) of clause (iii), the expression "gestational surrogacy" means a practice whereby a surrogate mother carries a child for the intending couple through implantation of embryo in her womb and the child is not genetically related to the surrogate mother;**	
	(b) when it is only for altruistic surrogacy purposes;	
	(c) when it is not for commercial purposes or for commercialisation of surrogacy or surrogacy procedures;	
	(d) when it is not for producing children for sale, prostitution or any other form of exploitation; and	
	(e) any other condition or disease as may be specified by regulations made by the Board;	
	(iii) no surrogacy or surrogacy procedures shall be conducted, undertaken, performed or initiated, unless the Director or in-charge of the surrogacy clinic and the person qualified to do so are satisfied, for reasons to be recorded in writing, that the following conditions have been fulfilled, namely:—	

	(a) the intending couple is in possession of a certificate of essentiality issued by the appropriate authority, after satisfying itself, for the reasons to be recorded in writing, about the fulfillment of the following conditions, namely:—	
	(*I*) a certificate of **a medical indication** in favour of either or both members of the intending couple **or intending woman necessitating gestational surrogacy** from a District Medical Board**.**	
	Explanation.—For the purposes of this **item**, the expression "District Medical Board" means a Medical Board under the Chairpersonship of Chief Medical Officer or Chief Civil Surgeon or Joint Director of Health Services of the District and comprising of at least two other specialists, namely, the chief gynecologist or obstetrician and chief pediatrician of the District;	
	(*II*) an order concerning the parentage and custody of the child to be born through surrogacy, **which shall be the birth affidavit after the surrogate child is born,** has been passed by a court of the Magistrate of the first class or above, on an application made by the intending couple **or the intending woman** and the surrogate mother; and	
41 of 1999.	(*III*) an insurance coverage of such amount **and in such manner** as may be prescribed in favour of the surrogate mother for a period of **thirty-six** months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999;	
	(b) the surrogate mother is in possession of an eligibility certificate issued by the appropriate authority on fulfillment of the following conditions, namely:—	

	(*I*) no woman, other than an ever married woman having a child of her own and between the age of 25 to 35 years on the day of implantation, shall be a surrogate mother or help in surrogacy by donating her egg or oocyte or otherwise;	
	(II) **a willing woman (**)** shall act as a surrogate mother and be permitted to undergo surrogacy procedures as per the provisions of this Act:	
	Provided that the intending couple or the intending woman shall approach the appropriate authority with a willing woman who agrees to act as a surrogate mother;	
	(III) no woman shall act as a surrogate mother by providing her own gametes;	
	(IV) no woman shall act as a surrogate mother more than once in her lifetime;	
	Provided that the number of attempts for surrogacy procedures on the surrogate mother shall be such as may be prescribed; and	
	(*V*) a certificate of medical and psychological fitness for surrogacy and surrogacy procedures from a registered medical practitioner;	
	(c) an eligibility certificate for intending couple is issued separately by the appropriate authority on fulfillment of the following conditions, namely:—	
	(*I*) **the intending couple are married and between the** age of 23 to 50 years in case of female and between 26 to 55 years in case of male on the day of certification;	
	(II) (**)	
	(*III*) the intending couple have not had any child biologically or through adoption or through surrogacy earlier:	
	Provided that nothing contained in this item shall affect the intending couple who have a child and who is mentally or physically challenged or suffers from life threatening disorder or fatal illness with no permanent cure and approved by	

	the appropriate authority with due medical certificate from a District Medical Board; and	
	(*IV*) such other conditions as may be specified by the regulations.	
Prohibition of conducting surrogacy.	**5.** No person including a relative or husband of a surrogate mother or intending couple **or intending woman** shall seek or encourage to conduct any surrogacy or surrogacy procedures on her except for the purpose specified in clause (ii) of section 4.	
Written informed consent of surrogate mother.	**6.** (1) No person shall seek or conduct surrogacy procedures unless he has —	
	(i) explained all known side effects and after effects of such procedures to the surrogate mother concerned; and	
	(ii) obtained in the prescribed form, the written informed consent of the surrogate mother to undergo such procedures in the language she understands.	
	(2) Notwithstanding anything contained in sub-section (1), the surrogate mother shall have an option to withdraw her consent for surrogacy before the implantation of embryo in her womb.	
	7. The intending couple **or intending woman** shall not abandon the child, born out of a surrogacy procedure, whether within India or outside, for any reason whatsoever, including but not restricted to, any genetic defect, birth defect, any other medical condition, the defects developing subsequently, sex of the child or conception of more than one baby and the like.	Prohibition to abandon child born through surrogacy.
	(**)	
	8. A child born out of surrogacy procedure, shall be deemed to be a biological child of the intending couple or intending woman and the said child shall be entitled to all the rights and privileges available to a natural child under any law for time being in force.	**Rights of surrogate child.**
	9. The number of oocytes or embryos to be implanted in the surrogate mother for the purpose of surrogacy, shall be such as may be prescribed.	Number of oocytes or embryos to be implanted.
	10. No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall force the surrogate mother to abort at any stage of surrogacy except in such conditions as may be prescribed.	Prohibition of abortion.

	CHAPTER IV **REGISTRATION OF SURROGACY CLINICS**	
	11. (1) No person shall establish any surrogacy clinic for undertaking surrogacy or to render surrogacy procedures in any form unless such clinic is duly registered under this Act.	Registration of surrogacy clinics.
	(2) Every application for registration under sub-section (1) shall be made to the appropriate authority in such form, manner and shall be accompanied by such fees as may be prescribed.	
	(3) Every surrogacy clinic which is conducting surrogacy or surrogacy procedures, partly or exclusively, referred to in clause (ii) of section 4 shall, within a period of sixty days from the date of appointment of appropriate authority, apply for registration:	
	Provided that such clinic shall cease to conduct any such counseling or procedures on the expiry of six months from the date of commencement of this Act, unless such clinic has applied for registration and is so registered separately or till such application is disposed of, whichever is earlier.	
	(4) No surrogacy clinic shall be registered under this Act, unless the appropriate authority is satisfied that such clinic is in a position to provide such facilities and maintain such equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed. (5)	
Certificate of registration.	**12.** (1) The appropriate authority shall after holding an enquiry and after satisfying itself that the applicant has complied with all the requirements of this Act and the rules and regulations made there under, grant a certificate of registration to the surrogacy clinic, within a period of ninety days from the date of application received by it, in such form, on payment of such fees and in such manner, as may be prescribed.	
	(2) Where, after the inquiry and after giving an opportunity of being heard to the applicant, the appropriate authority is satisfied that the applicant has not complied with the requirements of this Act or the rules or regulations made there under, it shall, for reasons to be recorded in writing, reject the application for registration.	

	(3) Every certificate of registration shall be valid for a period of three years and shall be renewed in such manner and on payment of such fees as may be prescribed.	
	(4) The certificate of registration shall be displayed by the surrogacy clinic at a conspicuous place.	
Cancellation or suspension of registration.	**13.** (1)The appropriate authority may, *suo-moto* or on receipt of a complaint, issue a notice to the surrogacy clinic to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.	
	(2) If after giving a reasonable opportunity of being heard to the surrogacy clinic, the appropriate authority is satisfied that there has been a breach of the provision of the Act or the rules or regulations made there under, it may, without prejudice to any criminal action that it may take against such clinic, suspend its registration for such period as it may think fit or cancel its registration, as the case may be.	
	(3) Notwithstanding anything contained in sub-sections (1) and (2), if the appropriate authority is of the opinion that it is necessary or expedient to do so in the public interest, it may, for reasons to be recorded in writing, suspend the registration of any surrogacy clinic without issuing any notice under sub-section (1).	
	14. (1) The surrogacy clinic **or the intending couple or the intending woman** may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the appropriate authority under section **13 and communication relating to rejection of the certificates under section 4,** prefer an appeal against such order to-	Appeal.
	(a) the State Government, where the appeal is against the order of the appropriate authority of a State;	
	(b)the Central Government, where the appeal is against the order of the appropriate authority of a Union territory,	
	in such manner as may be prescribed.	
	CHAPTER V **NATIONAL AND STATE SURROGACY BOARDS**	
	15. (1) The Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board to exercise the powers and perform the functions conferred on the Board under this Act.	Constitution of National Surrogacy Board.

	(2) The Board shall consist of—	
	(a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, *ex officio*;	
	(b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, *ex officio*;	
	(c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, *ex officio*;	
	(d) three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs**,** not below the rank of Joint Secretary, Members, *ex officio*;	
	(e) the Director General of Health Services of the Central Government, Member, *ex officio*;	
	(f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—	
	(i) eminent medical geneticists or embryologists;	
	(ii) **eminent gynecologists and obstetricians (**)**	
	(iii) eminent social scientists;	
	(iv) representatives of women welfare organisations; and	
	(v) representatives from civil society working on women's health and child issues,	
	possessing such qualifications and experience as may be prescribed;	
	(g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, *ex officio*; and	

	(h) an officer, not below the rank of a Joint Secretary to the Central Government, in charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, *ex officio*.	
	16. (1)The term of office of a Member, other than an *ex officio* Member, shall be—	Term of office of Members.
	(a) in case of nomination under clause (c) of sub-section (2) of section 14, three years:	
	Provided that the term of such Member shall come to an end as soon as the Member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the House of the People, or the Deputy Chairman of the Council of States or ceases to be a Member of the House from which she was elected; and	
	(b) in case of appointment under clause (f) of sub-section (2) of section **15**, **three** years:	
	Provided that the person to be appointed as Member under this clause shall be of such age as may be prescribed.	
	(2) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled by the Central Government by making a fresh appointment within a period of one month from the date on which such vacancy occurs and the Member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.	
	(3) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time;	
	17. (1) The Board shall meet at such places and times andshall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be determined by the regulations:	Meetings of Board.
	Provided that the Board shall meet at least once in six months.	
	(2) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairperson is unable to attend the meeting of the Board, the Vice-Chairperson shall preside at the meetings of the Board.	

	(3) All questions which come up before any meeting of the Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice-Chairperson shall have and exercise a second or casting vote.	
	(4) The Members, other than *ex officio* Members, shall receive only compensatory travelling expenses for attending the meetings of the Board.	
Vacancies, etc., not to invalidate proceedings of Board.	**18.** No act or proceeding of the Board shall be invalid merely by reason of—	
	(a) any vacancy in, or any defect in the constitution of, the Board; or	
	(b) any defect in the appointment of a person acting as a Member of the Board; or	
	(c) any irregularity in the procedure of the Board not affecting the merits of the case.	
Disqualifications for appointment as Member.	**19.** (1) A person shall be disqualified for being appointed and continued as a Member if, he—	
	(a) has been adjudged as an insolvent; or	
	(b) has been convicted of an offence, which in the opinion of the Central Government, involves moral turpitude; or	
	(c) has become physically or mentally incapable of acting as a Member; or	
	(d) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a Member; or	
	(e) has so abused his position, as to render his continuance in office prejudicial to the public interest; or	
	(f) is a practicing member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a Member; or	

	(g) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.	
	(2) The Members referred to in clause (f) of section **15** shall not be removed from their office except by an order of the Central Government on the ground of their proved misbehaviour or incapacity after the Central Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the Central Government, come to the conclusion that the Member ought on any such ground to be removed.	
	(3) The Central Government may suspend any Member against whom an inquiry under sub-section (2) is being initiated or pending until the Central Government has passed an order on receipt of the report of the inquiry.	
	20. (1) The Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.	Temporary association of persons with Board for particular purposes.
	(2) A person associated with the Board under sub-section (1) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the Board and shall not be a Member for any other purpose.	
	21. All orders and decisions of the Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the Board shall be authenticated by the signature of the Member-Secretary of the Board.	Authentication of orders and other instruments of Board.
	22. Subject to other terms and conditions of service as may be prescribed, any person ceasing to be a Member shall be eligible for re-appointment as such Member:	Eligibility of Member for re-appointment.
	Provided that no Member other than an *ex officio* Member shall be appointed for more than two consecutive terms.	
	23. The Board shall discharge the following functions, namely:—	Functions of Board.
	(a) to advise the Central Government on policy matters relating to surrogacy;	

	(b) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, changes therein;	
	(c) to lay down code of conduct to be observed by persons working at surrogacy clinics;	
	(d) to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by the surrogacy clinics;	
	(e) to oversee the performance of various bodies constituted under the Act and take appropriate steps to ensure their effective performance;	
	(f) to supervise the functioning of State Surrogacy Boards; and	
	(g) such other functions as may be prescribed.	
Constitution of State Surrogacy Board.	**24.** (1) Each State and Union territory having Legislature shallconstitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be, which shall discharge the following functions, namely:—	
	(i) to review the activities of the appropriate authorities functioning in the State or Union territory and recommend appropriate action against them;	
	(ii) to monitor the implementation of the provisions of the Act, rules and regulations made thereunder and make suitable recommendations relating thereto, to the Board;	
	(iii) to send such consolidated reports as may be prescribed**,** in respect of the various activities undertaken in the State under the Act**,** to the Board and the Central Government; and	
	(iv) such other functions as may be prescribed.	
Composition of State Board.	**25**. The State Board shall consist of–	
	(a) the Minister in-charge of Health and Family Welfare in the State, Chairperson, *ex officio*;	
	(b) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, *ex officio*;	

	(c) Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, *ex officio*;	
	(d) Director General of Health and Family Welfare of the State Government, member, *ex officio*;	
	(e) three women members of the State Legislative Assembly or Union territory Legislative Council, members, *ex officio*;	
	(f) ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—	
	(i) eminent medical geneticists or embryologists;	
	(ii) eminent gynecologists and obstetricians (**)	
	(iii) eminent social scientists;	
	(iv) representatives of women welfare organisations; and	
	(v) representatives from civil society working on women's health and child issues,	
	possessing such qualifications and experiences as may be prescribed;	
	(g) an officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare, who shall be the Member-Secretary, *ex officio*.	
	26.(1)The term of office of a member, other than an *ex officio* member, shall be—	Term of office of members.
	(a) in case of nomination under clause (e) of section **25**, three years:	
	Provided that the term of such member shall come to an end as soon as the member becomes a Minister or Minister of State or Deputy Minister, or the Speaker or the Deputy Speaker of the Legislative Assembly, or the Deputy Chairman of the Legislative Council or ceases to	

	be a member of the House from which she was elected; and	
	(b) in case of appointment under clause (f) of section **25**, **three** years:	
	Provided that the person to be appointed as member under this clause shall be of such age, as may be prescribed.	
	(2) Any vacancy occurring in the office whether by reason of his death, resignation or inability to discharge his functions owing to illness or other incapacity, shall be filled within a period of one months from the date on which such vacancy occurs by the State Government by making a fresh appointment and the member so appointed shall hold office for the remainder of the term of office of the person in whose place he is so appointed.	
	(3) The Vice-Chairperson shall perform such functions as may be assigned to him by the Chairperson from time to time;	
Meetings of State Board.	**27.** (1) The State Board shall meet at such places and times andshall observe such rules of procedure in regard to the transaction of business at its meetings (including the quorum at its meetings) as may be specified by the regulations:	
	Provided that the State Board shall meet at least once in four months.	
	(2) The Chairperson shall preside at the meeting of the Board and if for any reason the Chairman is unable to attend the meeting of the State Board, the Vice-Chairperson shall preside at the meetings of the State Board.	
	(3) All questions which come up before any meeting of the State Board shall be decided by a majority of the votes of the members present and voting, and in the event of an equality of votes, the Chairperson, or in his absence, the Vice Chairperson shall have a second or casting vote.	
	(4) The members, other than *ex officio* members, shallreceive only compensatory travelling expenses for attending the meetings of the State Board.	
	28. No act or proceeding of the State Board shall be invalid merely by reason of—	Vacancies, etc., not to invalidate proceedings of State Board.

	(a) any vacancy in, or any defect in the constitution of, the State Board; or	
	(b) any defect in the appointment of a person acting as a member of the State Board; or	
	(c) any irregularity in the procedure of the State Board not affecting the merits of the case.	
	29. (1) A person shall be disqualified for being appointed and continued as a member if, he—	Disqualifications for appointment as member.
	(a) has been adjudged as an insolvent; or	
	(b) has been convicted of an offence, which in the opinion of the State Government, involves moral turpitude; or	
	(c) has become physically or mentally incapable of acting as a member; or	
	(d) has acquired such financial or other interest, as is likely to affect prejudicially his functions as a member; or	
	(e) has so abused his position, as to render his continuance in office prejudicial to the public interest; or	
	(f) is a practicing member or an office bearer of any association representing surrogacy clinics, having financial or other interest likely to affect prejudicially, his function as a member; or	
	(g) is an office bearer, heading or representing, any of the professional bodies having commercial interest in surrogacy or infertility.	
	(2) The members referred to in clause (f) of section **25** shall not be removed from their office except by an order of the State Government on the ground of their proved misbehaviour or incapacity after the State Government, has, on an inquiry, held in accordance with the procedure prescribed in this behalf by the State Government, come to the conclusion that the member ought on any such ground to be removed.	

	(3) The State Government may suspend any member against whom an inquiry under sub-section (2) is being initiated or pending until the State Government has passed an order on receipt of the report of the inquiry.	
Temporary association of persons with State Board for particular purposes.	**30.**(1) The State Board may associate with itself, in such manner and for such purposes as may be determined by the regulations, any person whose assistance or advice it may desire in carrying out any of the provisions of this Act.	
	(2) A person associated with it by the State Board under sub-section (1) shall have a right to take part in the discussions relevant to that purpose, but shall not have a right to vote at a meeting of the State Board and shall not be a member for any other purpose.	
Authentication of orders and other instruments of State Board.	**31.** All orders and decisions of the State Board shall be authenticated by the signature of the Chairperson and all other instruments issued by the State Board shall be authenticated by the signature of the Member-Secretary of the State Board.	
Eligibility of member for re-appointment.	**32.** Subject to the other terms and conditions of service as may be prescribed, any person ceasing to be a member shall be eligible for re-appointment as such member:	
	Provided that no member other than an *ex-officio* member shall be appointed for more than two consecutive terms.	
	CHAPTER VI **APPROPRIATE AUTHORITY**	
Appointment of appropriate authority.	**33.**(1)The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for each of the Union territories for the purposes of this Act.	
	(2) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more appropriate authorities for the whole or any part of the State for the purposes of this Act.	
	(3) The appropriate authority, under sub-section (1) or sub-section (2), shall,-	
	(a) when appointed for the whole of the State or the Union territory, consist of—	

	(**i**) **an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department - Chairperson, *ex officio*;**	
	(**ii**) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department - **Vice Chairperson, *ex officio*;**	
	(**iii**) an eminent woman representing women's organisation – member;	
	(**iv**) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary – member; and	
	(**v**) an eminent registered medical practitioner – member:	
	Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;	
	(b) when appointed for any part of the State or the Union territory, be officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.	
	34. The appropriate authority shall discharge the following functions, namely:—	Functions of appropriate authority.
	(a) to grant, suspend or cancel registration of a surrogacy clinic;	
	(b) to enforce the standards to be fulfilled by the surrogacy clinics;	
	(c) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provision of this Act;	
	(d) to take appropriate legal action against the use of surrogacy by any person at any place other than prescribed, *suo-moto* or brought to its notice, and also to initiate independent investigations in such matter;	
	(e) to supervise the implementation of the provisions of this Act and rules and regulations made there under;	

	(f) to recommend to the Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions; and	
	(g) to take action after investigation of complaints received by it against the surrogacy clinics; and	
	(h) to consider and grant or reject any application under clause (vi) of section 3 and sub-clauses (a) to (c) of clause (iii) of section 4 within a period of ninety days.	
Powers of appropriate authorities.	**35.** (1) The appropriate authority shall exercise the powers in respect of the following matters, namely:—	
	(a) summoning of any person who is in possession of any information relating to violation of the provisions of this Act **a**nd rules and regulations made there under;	
	(b) production of any document or material object relating to clause (a);	
	(c) search any place suspected to be violating the provisions of this Act and the rules and regulations made there under; and	
	(d) such other powers as may be prescribed;	
	(2) The appropriate authority shall maintain the details of registration of surrogacy clinics, cancellation of registration, renewal of registration, grant of certificates to the intending couple and surrogate mothers or any other matter pertaining to grant of license etc. of the surrogacy clinics in such format as may be prescribed **and submit the same to the National Surrogacy Board.**	
	CHAPTER VII **OFFENCES AND PENALTIES**	
	36.(1) No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall—	Prohibition of commercial surrogacy, exploitation of surrogate mothers and children born through surrogacy.

	(a) undertake commercial surrogacy, provide commercial surrogacy or its related component procedures or services in any form or run a racket or an organised group to empanel or select surrogate mothers or use individual brokers or intermediaries to arrange for surrogate mothers and for surrogacy procedures, at such clinics, laboratories or at any other place;	
	(b) issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated, any advertisement in any manner regarding commercial surrogacy by any means whatsoever, scientific or otherwise;	
	(c) abandon or disown or exploit or cause to be abandoned, disowned or exploited in any form, the child or children born through surrogacy;	
	(d) exploit or cause to be exploited the surrogate mother or the child born through surrogacy in any manner whatsoever;	
	(e) sell human embryo or gametes for the purpose of surrogacy and run an agency, a racket or an organization for selling, purchasing or trading in human embryos or gametes for the purpose of surrogacy;	
	(f) import or shall help in getting imported in whatsoever manner, the human embryo or human gametes for surrogacy or for surrogacy procedures; and	
	(g) conduct sex selection in any form for surrogacy.	
43 of 1860.	(2) Notwithstanding anything contained in the Indian Penal Code, contraventions of the provisions of clauses (a) to (g) of sub-section (1) by any person shall be an offence punishable with imprisonment for a term which may extend to ten years and with fine which may extend to ten lakh rupees.	
	(3) For the purposes of this section, the expression "advertisement" includes any notice, circular, label, wrapper or any other document including advertisement through internet or any other media, in electronic or print form and also includes any visible representation made by means of any hoarding, wall-painting, signal light, sound, smoke or gas.	

Punishment for contravention of provisions of Act.	**37.**(1) Any registered medical practitioner, gynecologists, pediatrician, embryologists or any person who owns a surrogacy clinic or employed with such a clinic or centre or laboratory and renders his professional or technical services to or at such clinic or centre or laboratory, whether on an honorary basis or otherwise, and who contravenes any of the provisions of this Act (other than the provisions referred to in section **36**) and rules and regulations made there under shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to ten lakh rupees.	
	(2) In case of subsequent or continuation of the offence referred to in sub-section (1), the name of the registered medical practitioner shall be reported by the appropriate authority to the State Medical Council concerned for taking necessary action including suspension of registration for a period of five years.	
Punishment for not following altruistic surrogacy.	**38.** Any intending couple **or intending woman** or any person who seeks the aid of any surrogacy clinic, laboratory or of a registered medical practitioner, gynecologist, pediatrician, embryologist or any other person **for not following the altruistic surrogacy** or for conducting surrogacy procedures for commercial purposes shall be punishable with imprisonment for a term which may extend to five years and with fine which may extend to five lakh rupees for the first offence and for any subsequent offence with imprisonment which may extend to ten years and with fine which may extend to ten lakh rupees.	
	39. Whoever contravenes any of the provisions of this Act, rules or regulations made there under for which no penalty has been provided in this Act, shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to five lakh rupees and in the case of continuing contravention with an additional fine which may extend to ten thousand rupees for every day during which such contravention continues after conviction for the first such contravention.	Penalty for contravention of provisions of Act or rules for which no specific punishment is provided.
1 of 1872.	**40.** Notwithstanding anything contained in the Indian Evidence Act 1872, the court shall presume, unless the contrary is proved, that the women or surrogate mother was compelled by her husband, the intending couple or any other relative, as the case may be, to render surrogacy services, procedures or to donate gametes for the purpose other than those specified in clause (ii) of section 4 and such person shall be liable for abetment of such offence under section **38** and shall be punishable for the offence specified under that section.	Presumption in the case of surrogacy.

2 of 1974.	**41.** Notwithstanding anything contained in the Code of Criminal Procedure, 1973, every offence under this Act shall be cognizable, non-bailable and non-compoundable.	Offence to be cognizable, non-bailable and non-compoundable.
	42. (1) No court shall take cognizance of any offence punishable under this Act except on a complaint in writing made by—	Cognizance of offences.
	(a) the appropriate authority concerned, or any officer or an agency authorised in this behalf by the Central Government or the State Government, as the case may be, or the appropriate authority; or	
	(b) a person including a social organisation who has given notice of not less that fifteen days in the manner prescribed, to the appropriate authority, of the alleged offence and of his intention to make a complaint to the court.	
	(2) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.	
Certain provisions of Code of Criminal Procedure, 1973 not to apply.	**43**. Notwithstanding anything contained in the Code of Criminal Procedure, 1973, Chapter XXI A of the said Code relating to plea of bargaining shall not apply to the offences under this Act.	2 of 1974.
	CHAPTER VIII **MISCELLANEOUS**	
Maintenance of records.	**44.** (1) The surrogacy clinic shall maintain all records, charts, forms, reports, consent letters, agreements and all the documents under this Act and they shall be preserved for a period of twenty five years or such period as may be prescribed:	
	Provided that, if any criminal or other proceedings are instituted against any surrogacy clinic, the records and all other documents of such clinic shall be preserved till the final disposal of such proceedings.	
	(2) All such records shall, at all reasonable times, be made available for inspection to the appropriate authority or to any other person authorised by the appropriate authority in this behalf.	

Power to search and seize records, etc.	**45.** (1) If the appropriate authority has reason to believe that an offence under this Act has been or is being committed at any surrogacy clinic or any other place, such authority or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable times with such assistance, if any, as such authority or officers considers necessary, such surrogacy clinic or any other place and examine any record, register, document, book, pamphlet, advertisement or any other material object found therein and seize and seal the same if such authority or officer has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act.	
	(2) The provisions of the Code of Criminal Procedure, 1973 relating to search and seizure shall apply, as far as may be, to all action taken by the appropriate authority or any officer authorized by it under this Act.	2 of 1974.
Protection of action taken in good faith.	**46.** (1) No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the appropriate authority or any officer authorised by the Central Government or the State Government or by the appropriate authority for anything which is in good faith done or intended to be done in pursuance of the provision of this Act.	
	47. The provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.	Application of other laws not barred.
	48. (1)The Central Government may, by notification and subject to the condition of pre-publication, make rules for carrying out the provisions of this Act.	Power to make rules.
	(2) In particular, and without prejudice to the generality of the foregoing power, such rules may provide for—	
	(a) the prescribed expenses under clauses (b), (f) and (q) of sub-section (1);	
	(b) the minimum qualifications for persons employed at a registered surrogacy clinic under clause (iii) of section 3;	
	(c) the manner in which a person shall store human embryo or gamete under clause (vii) of section 3;	

	(d) the form and manner of application for obtaining certificate of recommendation from the Board under proviso to sub-clause (a) of clause (ii) of section 4;	
	(e) the insurance coverage in favour of the surrogate mother from an insurance company **and the manner of such coverage** under **item (III**) **of** sub-clause (a) of clause (iii) of section 4;	
	(f) the number of attempts of surrogacy or providing of gametes under the proviso to **item (III) of** sub-clause (b) of clause (iii) of section 4;	
	(g) the form in which consent of a surrogate mother has to be obtained under clause (ii) of section 6;	
	(h) the number of oocytes or embryos to be implanted in the surrogate mother under section **9**;	
	(i) the conditions under which the surrogate mother may be allowed for abortion during the process of surrogacy under section **10**;	
	(j) the form and manner in which an application shall be made for registration and the fee payable thereof under sub-section (2) of section **11**;	
	(k) the facilities to be provided, equipment and other standards to be maintained by the surrogacy clinics under sub-section (4) section **11**;	
	(l) the period, manner and form in which a certificate of registration shall be issued under sub-section (1) section **12**;	
	(m) the manner in which the certificate of registration shall be renewed and the fee payable for such renewal under sub-section (3) of section **12**;	
	(n) the manner in which an appeal may be preferred under section **14**;	
	(o)the qualifications and experiences of the Members as admissible under clause (f) of sub-section (2) of section **15**;	

	(p) the procedures for conducting an inquiry against the Members under sub-section (2) of section **19**;	
	(q) the conditions under which a Member of the Board eligible for re-appointment under section **22**;	
	(r) the other functions of the Board under clause (g) of section **23**;	
	(s) the manner in which reports shall be furnished by the State and Union territory Boards to the Board and the Central Government under clause (iii) of section **24**;	
	(t) the other functions of the State Board under clause (iv) of section **24**;	
	(u) the qualifications and experiences **of** the members as admissible under clause (f) of section **25**;	
	(v) the age of the person to be appointed as a member, referred to in clause (f) of section **25**, under the proviso to clause (b) of sub-section (1) of section **26**;	
	(w) the procedures for conducting an inquiry against the members under sub-section (2) of section **29**;	
	(x) the conditions under which the members of State Board eligible for re-appointment under section **32**;	
	(y) empowering the appropriate authority in any other matter under clause (d) of section **34**;	
	(z) the other powers of appropriate authority under clause (d) of sub-section (1) of section **35**;	
	(za) the particulars of the details of registration of surrogacy clinics, cancellation of registration etc. in such format under sub-section (2) section **35**;	
	(zb) the manner of giving notice by a person under clause (b) of sub-section (1) of section **42**;	
	(zc) the period up to which records, charts, etc., shall be preserved under sub-section (1) of section **44**;	
	(zd) the manner in which the seizure of documents, records, objects, etc., shall be made and the manner in which seizure list shall be prepared and delivered under	

	sub-section (1) of section **45**; and	
	(ze) any other matter which is to be, or may be, or in respect of which provision is to be made by rules.	
	49. The Board may, with the prior approval of the Central Government, by notification, make regulations not inconsistent with the provisions of this Act and the rules made there under to provide for—	Power to make regulations.
	(a) the fulfillment of any other condition under which eligibility certificate to be issued by the appropriate authority under sub-clause (d) of clause (v) of section **4**;	
	(b) the time and place of the meetings of the Board and the procedure to be followed for the transaction of business at such meetings and the number of Members which shall form the quorum under sub-section (1) of section **17**;	
	(c) the manner in which a person may be temporarily associated with the Board under sub-section (1) of section **20**;	
	(d) the time and place of the meetings of the State Board and the procedure to be followed for the transaction of business at such meetings and the number of members which shall form the quorum under sub-section (1) of section **27**;	
	(e) the manner in which a person may be temporarily associated with the Board under sub-section (1) of section **30**; **and**	
	(f) any other matter which is required to be, or may be, specified by regulations.	
Rules and regulations to be laid before Parliament.	**50**. (1) Every rule made by the Central Government and every regulation made by the Board under this Act shall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or regulation or both Houses agree that the rule or regulation should not be made, the rule or regulation shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that	

	any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule or regulation or notification.	
Transitional provision.	**51.** Subject to the provisions of this Act, there shall be provided a gestation period of ten months from the date of coming into force of this Act to existing surrogate mothers' to protect their well being.	
Power to remove difficulties.	**52.** (1) If any difficulty arises in giving effect to the provisions of this Act, the Central Government may, by order published in the Official Gazette make such provisions not inconsistent with the provisions of the said Act as appear to it to be necessary or expedient for removing the difficulty:	
	Provided that no order shall be made under this section after the expiry of a period of two years from the date of commencement of this Act.	
	(2) Every order made under this section shall be laid, as soon as may be after it is made, before each House of Parliament.	

[TRUE COPY]

REPORT NO.

129

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

ONE HUNDRED AND TWENTY-NINTH REPORT

ON

THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) BILL, 2020

(*Presented to the Rajya Sabha on 19th March,* 2021)
(*Laid on the Table of Lok Sabha on 19th March,* 2021)

Rajya Sabha Secretariat, New Delhi
March, 2021/ Phalguna, 1942 (SAKA)

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COMPOSITION OF THE COMMITTEE
(2020-21)

1. Prof. Ram Gopal Yadav - Chairman

RAJYA SABHA

2. Shri A.K. Antony
3. Ms. Indu Bala Goswami
4. Dr. L. Hanumanthaiah
5. Shri Suresh Prabhu
6. Dr. Santanu Sen
7. Shri Bashistha Narain Singh
8. Shri K. Somaprasad
9. Dr. Subramanian Swamy
10. Shrimati Sampatiya Uikey

LOK SABHA

,

11. Ms. Bhavana Gawali (Patil)
12. Ms. Ramya Haridas
13. Dr. Chandra Sen Jadon
14. Shrimati Maloth Kavitha
15. Dr. Amol Ramsing Kolhe
16. Dr. Sanghamitra Maurya
17. Shri Arjunlal Meena
18. Shrimati Pratima Mondal
19. Dr. Pritam Gopinath Munde
20. Dr. Mahendrabhai Kalubhai Munjpara
21. Shri K. Navaskani
22. Dr. Bharati Pravin Pawar
23. Adv. Adoor Prakash
24. Shri Haji Fazlur Rehman
25. Dr. Rajdeep Roy
26. Dr. Subhas Sarkar
27. Dr. DNV Senthilkumar. S
28. Shri Anurag Sharma
29. Dr. Mahesh Sharma
30. Dr. Sujay Radhakrishna Vikhepatil
31. Dr. Krishna Pal Singh Yadav

SECRETARIAT

Dr. P.P.K. Ramacharyulu	Secretary
Shri J. Sundriyal	Joint Secretary
Shri V.S.P.Singh	Director
Shri Bhupendra Bhaskar	Additional Director
Shrimati Harshita Shankar	Under Secretary
Shri Rajesh Kumar Sharma	Assistant Committee Officer
Ms. Monika Garbyal	Assistant Committee Officer
Ms. Somya Yadav	Assistant Research Officer

PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this One Hundred Twenty-Ninth Report of the Committee on the Assisted Reproductive Technology (Regulation) Bill, 2020.

2. In pursuance of Rule 270 of the Rules of Procedure and Conduct of Business in the Council of States relating to the Department-related Parliamentary Standing Committees, on 3rd October, 2020 the Chairman, Rajya Sabha, in consultation with Speaker, Lok Sabha has referred* the Assisted Reproductive Technology (Regulation) Bill, 2020 **(Annexure I)**, as introduced and pending in Lok Sabha, to the Department-related Parliamentary Standing Committee on Health and Family Welfare, for examination and report within three months i.e. 2nd January, 2021.

3. The Committee started the examination of the Bill and held its first sitting on 17th November, 2020 where it heard the views of the Secretary, Department of Health Research on the ART Bill, 2020. The Committee also sought the views of the stakeholders and the State Governments on the Bill. The Committee in its meeting held on 30th December, 2020 heard the views of the stakeholders on the Bill. The Committee also decided to seek extension of time for three months, i.e, till 1st April, 2021 for presentation of Report on the Assisted Reproductive Technology (Regulation) Bill, 2020, keeping in view that the examination of the Bill required more time. The request for extension of time for presentation of the Report on ART Bill till 1st April, 2021 was acceded to by Hon'ble Chairman#.

4. The Committee in total held 4 sittings during the course of examination of the Bill, i.e., on 17th November, 2020, 30th December, 2020, 11th January, 2021 and 17th March, 2021. The list of witnesses heard by the Committee is at **Annexure-II**. The Committee in its meeting held on 17th March, 2021, took up the clause by clause examination of the Bill.

5. The Committee considered the draft Report and adopted the same on 17th March, 2021.

6. The Committee relied on the following documents in finalizing its Report:-

(i) The Assisted Reproductive Technology Bill 2020;
(ii) 228th Law Commission Report;
(iii) 102nd Report on Surrogacy (Regulation) Bill, 2016 of DRSC on Health & Family Welfare;
(iv) Select Committee's Report on Surrogacy (Regulation) Bill, 2019;
(v) Background Note on the Bill received from the Department of Health Research;
(vi) Presentation, clarifications and oral evidence of Secretary, DHR;
(vii) Memoranda received on the Bill from various institutes/bodies/associations/organizations/experts/State Governments and replies of the Ministry on the memoranda selected by the Committee for examination;

** Rajya Sabha Parliamentary Bulletin Part II, No.60262, dated 6th October, 2020.*
 # Rajya Sabha Parliamentary Bulletin Part II, No.60333, dated 6th January, 2021.

(viii) Oral evidence and written submissions by various stakeholders/experts on the Bill; and

(ix) Replies received from the DHR to the questions/queries raised by Members during the meetings on the Bill.

7. On behalf of the Committee, I would like to acknowledge with thanks the contributions made by those who deposed before the Committee and also those who gave their valuable suggestions to the Committee through their written submissions.

8. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

NEW DELHI
17 March, 2021
.....Phalguna, 1942 (Saka)

Prof. Ram Gopal Yadav
Chairman,
Department-related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha

CHAPTER - I

INTRODUCTION

MISSION STATEMENT OF THE BILL

1.1 The Assisted Reproductive Technology (Regulation) Bill, 2020 provides for the regulation and supervision of the assisted reproductive technology clinics and the assisted reproductive technology banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services and for matters connected therewith or incidental thereto. The Bill intends to protect the affected women and children from exploitation, support the oocyte donor with an insurance cover, regulate multiple embryo implantation and protect the children born through ART. The Bill, further, aims to regulate cryopreservation of sperm, oocytes and embryo by the ART Banks and intends to make Pre-Genetic Implantation Testing mandatory for pre-existing, heritable or genetic diseases only for the benefit of the child born through assisted reproductive technology.

NECESSITY OF THE BILL

1.2 According to the Statement of Objects and Reasons (SOR) of the Bill, the Assisted Reproductive Technology (ART) has grown rapidly in the last few years and India has registered the highest growth in the ART centres and the number of ART cycles performed every year. Assisted Reproductive Technology (ART), including In Vitro Fertilization (IVF), has given hope to a many persons suffering from infertility but introduced a plethora of legal, ethical and social issues.

1.2.1 As per the background note on the Bill furnished by the Ministry, India has become one of the major centres of this global fertility industry over the years, with reproductive medical tourism becoming a significant activity. Clinics in India offer nearly all the ART services—gamete donation, intrauterine insemination (IUI), In-vitro fertilization (IVF), Intracytoplasmic sperm injection (ICSI), Pre-implantation Genetic Testing (PGT) and gestational surrogacy. The reproductive segment of the Indian medical tourism market is valued at more than $450 million a year and was forecast by the ICMR to be a six billion dollar a year market in 2008. India’s fertility industry in is an integral part of the country's growing medical tourism industry, which experienced 30% growth in 2000 and 15% growth between 2005 and 2010. Despite so much activity in India, there is no standardisation of protocols yet and reporting is still very inadequate. Furthermore, there are only guidelines of ART, and no law still exists. There has been debate on the medical, ethical and legal aspects of ARTs.

OBJECTIVES OF THE BILL

1.3 The ART Bill seeks to provide the following:

(i) To regulate the ART services and protect the affected women and children from exploitation.

(ii) To support the oocyte donor by an insurance cover and protection from multiple embryo implantation.
(iii) To provide rights to children born through assisted reproductive technology equivalent to rights provided to biological children.
(iv) To regulate cryopreservation of sperms, oocytes and embryos by the ART banks.
(v) To make Pre-Implantation Genetic Testing mandatory for the benefit of the child born through assisted reproductive technology.
(vi) To ensure proper registration of ART clinics and banks.

ORIGIN OF THE BILL

1.4 The world's first test tube baby, Louise Brown was born on 25th July 1978. About two months later, the world's second and India's first IVF baby, Kanupriya alias Durga was born in Kolkata. Since then the field of Assisted Reproductive Technology (ART) has grown exponentially. India has become one of the major centers of the ART resulting in multitude of legal, ethical and social issues and there were no standardizing protocols available. The ICMR drafted the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India in 2005 as the first ever national guidelines for laying down standards of conduct for surrogacy in India. The Law Commission of India *suo motu* took up the subject of the need for legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parties to a surrogacy. The Commission presented its 228th Report in 2009 which stated that an active legislative intervention is required to facilitate correct uses of the new technology, i.e. ART and legalization of surrogacy.

1.4.1 The Departmental-Related Standing Committee on Health and Family Welfare, in its One Hundred Second Report on Surrogacy Regulation Bill, 2016 had observed as follows:

> *"The Committee strongly believes that with the rapid advancement of science and technology in all spheres of life, there is an urgent need to regulate the use of modern techniques especially w.r.t. assisted reproduction and use of ART for surrogacy. Hence, the Committee feels that along with surrogacy regulation, there is urgent need to regulate the ART clinics across the country. It is a fact that surrogacy procedures cannot be conducted without assisted reproduction techniques and therefore, mere enactment of the Surrogacy Bill would not serve the purpose of controlling commercialization of the surrogacy facilities across the country in the absence of regulation of assisted reproductive clinics and banks where surrogacy is being conducted as ART Clinics and Surrogacy Clinics are not separate. The Committee, therefore, strongly recommends that the ART Bill should be brought forth before the Surrogacy (Regulation), Bill, 2016."*

1.4.2 Furthermore, the Select Committee on the Surrogacy (Regulation) Bill, 2019, has recommended that ART Bill should be brought before the Surrogacy (Regulation) Bill, 2019, so that all the highly technical and medical aspects could be addressed adequately in the Surrogacy (Regulation) Bill, 2019. It also recommended that the National and State

Boards constituted for the regulation of surrogacy as proposed in the Bill shall act as the Boards for regulation of ART.

1.4.3 Consequently, the ART (Regulation) Bill, 2020 was introduced in Lok Sabha on September 14, 2020 and was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare, Rajya Sabha by Chairman, Rajya Sabha in consultation with the Speaker, Lok Sabha on October 3rd, 2020 for examination and Report. On further recommendation of the Committee, the Hon'ble Chairman, Rajya Sabha has extended the time of submission of Report by 1st April, 2021.

THE SALIENT FEATURES OF THE BILL

1.5 As per information provided by the Department of Health Research, the salient features of the Bill are as follows:

1) **"assisted reproductive technology"** means all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive tract of a woman;
2) **"assisted reproductive technology clinic"** means any premises equipped with requisite facilities and medical practitioners registered with the National Medical Commission of India for carrying out the procedures related to the assisted reproductive technology;
3) **"commissioning couple"** means an infertile Married couple who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining services that the assisted reproductive technology clinic or the assisted reproductive technology bank is authorized to provide;
4) **"Woman"** means any woman above the legal age of marriage who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining services that the assisted reproductive technology clinic or the assisted reproductive technology bank is authorized to provide;
5) **The National Board** shall be the same Board as proposed in the Surrogacy Bill with 24 members, which will be chaired by Minister in Charge of Health and Family Welfare.
6) **The State Board** shall be the same Board as proposed in the Surrogacy Bill with 21 Members. The Board will be chaired by Minister-in-charge of Health and Family Welfare in the State.
7) The existing assisted reproductive technology clinics and the assisted reproductive technology banks, as on the date of the enactment of the Act, conducting Assisted reproductive technology procedures partly or exclusively shall make an application to the State authority and after registration submit the same to the National Registry within such period and in such form, manner and with such fee as may be prescribed within a period of sixty days from the date of appointment.

8) The assisted reproductive technology services shall be available to a woman above the legal age of marriage and below the age of fifty years.
9) The assisted reproductive technology services shall be available to a man above the legal age of marriage and below the age of fifty five years.
10) An oocyte donor shall be an ever married woman having at least one live child of her own with a minimum age of three years and shall donate oocytes only once in her life and not more than seven oocyte shall be retrieved from the oocyte donor.
11) The assisted reproductive technology clinics shall provide professional counselling to commissioning couple about all the implications and chances of success of assisted reproductive technology procedures in the clinic and shall also inform the commissioning couple of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple arrive at an informed decision that would most likely be the best for the couple.
12) The assisted reproductive technology clinics and assisted reproductive technology banks shall ensure that commissioning couple and donors of gametes are eligible to avail of assisted reproductive technology procedures.
13) The child born through Assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to a natural child only from the commissioning couple under any law for the time being in force.
14) Sex selection shall not be permitted as per clause- 26.
15) The Pre-implantation Genetic testing shall be used only to screen the human embryo for known, pre-existing, heritable or genetic diseases or for such other purposes as may be prescribed.
16) Contraventions to the provisions of the Act for sex selection shall be punishable with a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both.
17) Abandoning or exploiting the child/children, selling embryo/gamete, exploiting commissioning woman and couple, shall invite a penalty with imprisonment for a term which shall not be less than eight years but may extend to twelve years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees.

1.6 As per the background note received from the Department of Health Research, the proposed Bill seeks to have the following legislative impact:

1) Registration of all ART clinics and Banks
2) Control of unethical Assisted Reproductive Technology practices including gamete donation;

3) Improve the quality of Assisted Reproductive Technology services;
4) Decrease the cost of Assisted Reproduction treatment;
5) Conduct research on new emerging areas of Assisted Reproduction and develop low cost Assisted Reproductive Technology for the economically weaker section of the society;
6) Develop policies and guidelines from time to time on Assisted Reproduction;
7) Infertile couples will be more sure of the ethical practices in ART clinics and Banks;
8) Medical Tourism will have more assurances of ethical practice in India.

1.6.1 Summarizing the overall legislative impact of the ART Bill, the representative of DHR stated as under:

> " The impact would be that it would bring about the registration of all the clinics, it would control unethical ART practices, it would improve the quality of ART services, it would facilitate framing of requisite policies as we would be having all the data and, most importantly, the needy couples would be more sure of the ethical practice of ART."

INTERNATIONAL SCENARIO

1.7 As per information provided by the Ministry of External Affairs, there are no international conventions or treaties in force to deal with ART and States are regulating ART at domestic level. For instance, in June 2020, Australia adopted the Assisted Reproductive Treatment Amendment Act 2020 to amend the Assisted Reproductive Treatment Act 2008, to remove the requirement for police checks and child protection order checks before a woman (and if applicable, her partner) can start assisted reproductive treatments.

1.7.1 In May 2020, Ireland amended the Child and Family Relationship Act 2015. These amendments relate to ART and include, among other matters, the possibility for same-sex female partners to establish legal parentage from birth and the prohibition of anonymous gamete donation.

1.7.2 The state of New York, USA, in April 2020 passed the Child-Parent Security Act (CPSA). The CPSA aims to regulate the establishment of legal parentage, in particular in the context of children conceived through ART. In state of Rhode Island, USA, the Uniform Parentage Act was scheduled to take effect in January 2021. It includes regulations of ART (including access to information on gamete donors) and (commercial) surrogacy arrangements (where it provides that the intending parents are to be recognized as the child's legal parents from birth).

1.7.3 France, Philippines and Switzerland are also considering Bills/legislations in this area. In France, the Parliament is considering a bill that would extend access to fertility treatments, including gamete donations, to single women and female same-sex couples. The bill would also put an end to anonymity in gamete donations so that children born through ART can

have access to non-identifying information about their donor(s). Philippines is considering a bill that will remove the distinction between 'legitimate' and 'illegitimate' children (which has consequences on their rights, in particular, to inheritance). The bill also seeks to add clarity for children born as a result of ART (including where a third-party donor is involved) or as a result of an altruistic surrogacy arrangement by deeming such children as being born within the wedlock of the intending parents. The Parliament of Switzerland is considering a bill that would extend access to fertility treatments to single women and female same-sex couples.

1.7.4 Taking into consideration the international Legislative march towards regulating the ART services and the incidental issues, the Committee feels that it is incumbent upon Government of India to proceed ahead with the progressive legislation on ART services as proposed through the Assisted Reproductive Technology (Regulation) Bill, 2020.

CHAPTER - II

VIEWS OF THE DEPARTMENT OF HEALTH RESEARCH

2.1 The Committee started its deliberations on the said Bill by hearing the views of the Department of Health Research on the objectives envisaged and the likely impact including challenges to be faced in the implementation of the various provisions of the Bill, necessity of having two separate legislations for ART and Surrogacy etc. The Department of Health Research informed the Committee that in 2015 deliberations were held regarding the Surrogacy Bill and Assisted Reproductive Technology Bill and it was decided that these Bills should be separate but should be placed for consideration simultaneously. It was further informed that at the time of deliberations on the Surrogacy Bill, it was felt that these two Bills are related and there should be a common Board to have control over it both at Central and State level.

2.1.2 During the course of the presentation before the Committee, the Department of Health Research apprised that in one of the studies of trend analysis by ICMR, it is estimated that the fertility industry would be a 6 billion USD industry by the year 2030. It is all the more substantiated by the fact that fertility rate has declined from 2.7 children in 2005-06 to 2.1 per woman as per the National Health Family Survey.

2.1.3 The ART services include the following services :-

a) Ovarian stimulation,
b) Egg Retrieval,
c) Invitro fertilisation-IVF,
d) Intra-Uterine Insemination-IUI,
e) Intracytoplasmic sperm injection-ICSI,
f) Embryo transfer,
g) Gamete Intrafallopian Transfer-GIFT,
h) Zygote Intra fallopian transfer-ZIFT,
i) Microsurgical epididymal sperm aspiration -MESA,
j) Testicular sperm extraction-TESE,
k) Percutaneous epididymal sperm aspiration-PESA,
l) Cryopreservation of gametes and embryo.

2.1.4 The Ministry highlighted that ART procedures could be exploited in the following ways:

a) Negligence in performing surgical procedure of harvesting eggs from a woman's body.
b) Egg retrieval is done from young unmarried girls in many parts of the country.
c) Unethical preservation of ovum and sperm in ART banks,
d) Sex selection in procedures of ART clinics,
e) Multiple embryo implantation,
f) ART banks advertising for Caucasian donor gamete,

g) Mixing of sperm samples by banks,
h) Commercialization of ovum and sperm donation.

2.1.5 Due to plethora of legal, ethical and social issues with no standardisation of protocols and reporting, the 228th Law Commission Report of 2009 recommended bringing an active legislative intervention to facilitate the correct use of ART. There have been many of Parliamentary assurances on the matter and the Departmental-Related Standing Committee of Health and Family Welfare while examining the Surrogacy Regulation Bill, 2016, had also recommended bringing a regulation for the Assisted Reproductive Technology Clinic and Banks along with the Surrogacy Regulation Bill.

2.1.6 The Ministry has informed that the Bill was drafted with the objectives of registration of ART clinics and banks, specify age of the couple or woman who can avail ART, provide insurance coverage for donors, specify the number of embryos to be planted, disallow sex selection at every stage of embryo fertilisation, allow pre-implantation genetic testing and screen the embryo for preventing births with genetic disorders, ensure appropriate storage of embryos and gametes, have penal provisions for unethical practices in clinics etc.

2.1.7 The Department of Health Research further informed that based on the recommendations made by the Select Committee on Surrogacy (Regulation) Bill, 2019, the National Board, State Board and National Registry would be common for both Surrogacy and ART Bills. The Assisted Reproductive Technology could be availed by following:-

(i) Indian Married Couple, (Man and Woman)
(ii) Indian Single Woman and
(iii) Foreigners as a couple (man and woman) or a single woman.

2.1.8 While highlighting the provisions of the Bill, the Committee was apprised as follows:-

(i) **Composition of National Board**

(a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, ex officio;
(b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, ex officio;
(c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, ex officio;
(d) three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs, not below the rank of Joint Secretary, Members, ex officio;
(e) the Director General of Health Services of the Central Government, Member, ex officio;
(f) ten expert Members to be appointed by the Central Government

(g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, ex officio; and

(h) an officer, not below the rank of a Joint Secretary to the Central Government, in charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, ex officio

(ii) **Composition of State Board**

(a) the Minister in-charge of Health and Family Welfare in the State, Chairperson, ex officio;

(b) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, ex officio;

(c) Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, ex officio;

(d) Director General of Health and Family Welfare of the State Government, member, ex officio;

(e) three women members of the State Legislative Assembly or Union territory Legislative Council, members, ex officio;

(f) ten expert members to be appointed by the State Government

(g) an officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare, who shall be the Member-Secretary, ex officio.

(iii) **Functions of the Board**

a) Advise the Central Government on policy matters relating to ART,
b) Review and monitor the implementation of the Act,
c) Lay down code of conduct to be observed by persons working at ART Clinics and Banks,
d) Set the minimum standards of physical infrastructure for ART Clinics and Banks ,
e) Oversee the performance of various bodies constituted under the Act,
f) Ensure updating of the National Registry,
g) Act as Appellate Authority for the National Registry and State Boards,
h) Pass orders as per the provision made under this Act,
i) such other functions as may be prescribed.

(iv) **Composition of State/UT Registration Authority**

a) an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department—Chairperson, ex officio;
b) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department — Vice-Chairperson, ex officio;

c) an eminent woman representing women's organization- member;
d) an officer of Law Department of the State or the Union territory
e) concerned not below the rank of a Deputy Secretary—member, ex officio;
f) an eminent registered medical practitioner—member

(v) **Procedure of registration of ART clinics and banks**

a) Every application for registration under sub-section (1) shall be made to State Registration authority
b) Every clinic or bank which is conducting assisted reproductive technology, partly or exclusively shall, within a period of sixty days from the date of notification of the registration authority may apply for registration
c) The Registration shall be provided , within a period of one month
d) The registration granted under this section shall be valid for a period of five years
e) The National Board and State Board shall have the power to inspect, any premises relating to assisted reproductive technology
f) There is provision for appeal against rejection of registration

(vi) **The ART Clinics would ensure that:-**

a) the woman is above the legal age of Marriage and below the age of fifty years;
b) the man is above the legal age of Marriage and below the age of fifty five years;
c) the oocytes donor is between twenty-three years of age and thirty-five years of age;
d) an insurance coverage is provided for the oocyte donor
e) professional counseling is made available
f) written consent of all the parties seeking ART is obtained;
g) The Pre-implantation Genetic testing is used only to screen the human embryo for known, pre-existing, heritable or genetic diseases
h) Storage and handling of human gametes and embryos is done as prescribed
i) No sex selection is resorted to.

(vii) **Offences and Penalties**

a) Penal provisions are for abandoning or exploiting the child/children, selling embryo/gamete, exploiting commissioning woman and couple.
b) Penalty is imprisonment for a term which shall not be less than eight years but may extend to twelve years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees.

c) Contraventions to the provisions of the Act for sex selection is punishable for a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both.

(viii) **Safeguards provided in the Bill**

a) The child born through Assisted Reproductive Technology shall be deemed to be a biological child of the commissioning couple
b) The child shall be entitled to all the rights and privileges available to a Biological child
c) Insurance coverage for the oocyte donor
d) Professional Counselling for Commissioning Couple and Woman donor of State Government to issue directions to State Board
e) No sex selection to prevent female foeticides
f) No foetal Reduction as the number of embryos to be implanted will be carefully governed
g) No mixing of gametes during embryo fertilisation
h) Provisions for proper Storage of Embryos and Gametes.

2.1.9 The Department of Health Research informed the Committee that the ART Bill has been aligned with related Acts like Pre-conception and Pre-Natal Diagnostic Techniques Act, the Registration of Births and Deaths Act, the Hindu Marriage Act, Article 14 and 21 of the Constitution and the Medical Termination of Pregnancy Act.

2.2 Comparison between Surrogacy (Regulation) Bill 2019 and the Assisted Reproductive Technology (Regulation) Bill 2020

The Ministry of health and Family welfare has submitted to the Committee in writing a brief comparison between the Surrogacy (Regulation) Bill 2019 and the Assisted Reproductive Technology (Regulation) Bill 2020 as reflected in the following table:

SNo	Surrogacy (Regulation) Bill 2019	Assisted Reproductive Technology (Regulation) Bill 2020
1.	Surrogacy is an infertility treatment where a third person (woman) is involved who is the surrogate mother	Assisted Reproductive technology treatments can be availed by the commissioning couple themselves and no third person is involved
2.	Surrogacy is allowed for only **Indian Married Couple**	ART procedures are open to **married, live in partners, Single Woman and also foreigners**
3.	Commercial surrogacy is not allowed in the country	Commercial donors not allowed
4.	As per the Notification no.25022/74/2011-F-1 (Vol III) dated 3rd November, 2015	Foreigners can visit India under medical tourism to avail ART services

	commissioning of Surrogacy in India by Foreigners/OCI/PIO cardholders are prohibited **NRIs holding Indian Citizenship can avail surrogacy**	
5.	The estimated number of Clinics practising Surrogacy may in all likelihood be less than **1000** in the Country	The estimated number of Clinics practising ART may likely be more than **40,000** in the country
6.	The age of the intending couple is between **23 to 50 years** in case of female and between **26 to 55 years** in case of male on the day of application for such treatment and should be **married for 5 years**	The age of the commissioning couple is between **19 to 50 years** in case of female and between **22 to 55 years** in case of male on the day of application for such treatment and should be **married for 1 year**
7.	National Surrogacy Board, at the centre would be the policy making and supervisory body and the State Boards will be executive bodies. Appropriate authority to be the implementing body	The National Board in the Central level will be the Apex Regulatory body with the **powers as are vested in a civil court under the Code of Civil Procedure and function along with the State Boards and National Registry**
8.	No additional structures will be created as it is proposed to set the Board within the existing framework and infrastructure. The National Board will be chaired by the Hon'ble Minister of Health and Family Welfare in the centre and the State board will be chaired by the State Minister of Health and Family Welfare	Besides Chairperson, 3 full time members will be appointed as part of the National Board and 2 full time members for the State Board besides setting up of a National Registry under the National Board
9.	**Parental Order** is required for the intending couple and the surrogate mother so as to safe guard the child born through surrogacy	No such orders required
10.	Offences and penalties are stringent to prevent commercial surrogacy, abandonment of the child, exploitation of the surrogate mother, sex selective surrogacy	Offences and penalties are to prevent exploitation of gamete donor and safeguard the rights of the commissioning couple and child.
11.	The likely number of cases per year may be few in hundreds	The likely number of cases per year may be in lakhs

2.3 The Committee, in its meeting held on 17th November, 2020, interacted with the Secretary, Department of Health Research and other officers, wherein the Committee was apprised of the provisions, necessity and origin of the Bill. During the detailed examination of the Bill, Chairman and Members raised certain issues upon which the Department of Health Research furnished the written comments as under:-

Issue raised

How the ART Bill, 2020 complements Surrogacy (Regulations) Bill and the scope of overlapping in terms of administrative and regulatory structure and steps to streamline the working of the proposed legislation.

Response of DHR

The Assisted Reproductive Technology (ART) and Surrogacy Regulation Bill will have the same National Board, State Board and National Registry. The Board will be the policy making authority. The National Registry will be the central database in the country through which the details of all the clinics and banks of the country including nature and types of services provided by them, outcome of the services and other relevant information shall be obtained on regular basis for both ART regulation Bill and Surrogacy Regulation Bill. Similar to Surrogacy Regulation Bill, maintenance of records will be for a period of 25 years. Surrogacy services will be provided on the basis of medically necessitated condition but ART services will be provided on the basis of infertility. Accordingly, the definitions will be specific to each of the Bill. The terms of penalties are also different for both the bills. The implementing Agency in the State/UTs is different for both the Bill. The Appropriate Authority is the implementing authority in the Surrogacy Regulation Bill where as Registration Authority is the implementing Authority for the ART Bill.

Issue raised

The criteria of selection of beneficiaries of the proposed ART Act. The Surrogacy Regulation Bill allows only divorced women and widows to avail benefit of surrogacy but what is the rationale behind ART Bill allowing all single women but disallowing live-in couples, same-sex couples etc.

Response of DHR

The DHR clarified that the beneficiaries of ART Bill are:

(i) Indian Married Couple (man and woman)
(ii) Indian Single woman
(iii) Foreigners

The beneficiaries are based on infertility and the age limit is as below:

(i) to a woman above the legal age of marriage and below the age of fifty years;
(ii) to a man above the legal age of marriage and below the age of fifty-five years;

Single woman as divorced, widowed and unmarried are allowed to avail ART services. The Bill allows single unmarried woman to avail ART services keeping in view that adoption is allowed for single woman. As per constitutional Article -21,

"No person shall be deprived of his life or personal liberty except according to procedure established by law, nor shall any person be denied equality before the law or the equal protection of the laws within the territory of India."

Abortion and Reproductive Autonomy

The Puttaswamy judgment specifically recognized the constitutional right of women to make reproductive choices, as a part of personal liberty under Article 21 of the Indian Constitution. The bench also reiterated the position adopted by a three-judge bench in Suchita Srivastava v Chandigarh Administration, which held that reproductive rights include a woman's entitlement to carry a pregnancy to its full term, to give birth, and to subsequently raise children; and that these rights form part of a woman's right to privacy, dignity, and bodily integrity. The Supreme Court has been extremely progressive on women's reproductive rights. By decriminalizing adultery and homosexuality in the landmark judgment of Navtej Johar, the court has held clearly, that women have a right to sexual autonomy, which is an important facet of their right to personal liberty. In the case of Independent Thought v. Union of India in the context of reproductive rights of girls, the Supreme Court held, "the human rights of a girl child are very much alive and kicking whether she is married or not and deserve recognition and acceptance". These judgments have an important bearing on the sexual and reproductive rights of women. With respect to live in couple and same sex couple, they have been decriminalized but not yet legalized.

Issue raised

Procedure of informed consent and counseling of oocyte donors, safeguards and the compensation packages/insurance coverage being envisaged in ART Bill for oocyte retrieval that requires risky ovarian stimulation, anaesthesia and surgical procedure.

Response of DHR

The DHR affirmed the procedure of egg retrieval as risky. It was added that the safeguards are provided in Section 22 of the Bill which are enumerated as under:

(i) an oocyte donor shall be an ever married woman having at least one live child of her own with a minimum age of three years and to donate oocytes only once in her life and not more than seven oocyte shall be retrieved from the oocyte donor.

(ii) the written consent of all the parties seeking assisted reproductive technology is a must.

(iii) an insurance coverage is provided for such amount and for such period as may be prescribed in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999.

Issue raised

Whether the prohibition of commercialization of ovum and sperm donation would not lead to scarcity of donors.

Response of DHR

The DHR emphasized that the bill aims to prohibit commercialization of ART services, however, the ART banks shall obtain:

(a) semen from males between twenty-one and fifty-five years of age, both inclusive;
(b) oocytes from females between twenty-three and thirty-five years of age; and
(c) examine the donors for such diseases, as may be prescribed

The Banks may ensure availability of donors.

Issue raised

The monitoring mechanism to ensure prohibition of unethical preservation of ovum and sperm in ART Banks and mechanism for ensuring appropriate storage of embryos.

Response of DHR

The DHR pointed out that clause 28 of ART Bill spells out the standards for the storage and handling of gametes, gonadal tissues and human embryos in respect of their security, recording and identification shall be such as may be prescribed. The gamete of a donor or embryo shall be stored for a period of not more than ten years and at the end of such period such embryo or gamete shall be allowed to perish or be donated to a research organisation registered under this Act for research purposes with the consent of the commissioning couple or individual, in such manner as may be prescribed. The above provision will ensure appropriate storage and there are penalties for contravention of the provision of the Act in section 33. There is also provision for search and seize in section 40. According to clause 40, if the National Board, the National Registry or the State Board has reason to believe that an offence under this Act has been or is being committed at any facility using assisted reproductive technology, such Board or any officer authorised in this behalf may, subject to such rules as may be prescribed, enter and search at all reasonable time.

Issue raised

System to safeguard the interests of the couple undergoing ART procedures.

Response of DHR

The Committee has been apprised by DHR that the safeguards provided for the couple or single woman is ensured under clause 21 which is enumerated as below:

(i) The assisted reproductive technology clinics shall provide professional counselling to commissioning couple about all the implications and chances of success of assisted reproductive technology procedures in the clinic.

(ii) inform the commissioning couple of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter.

(iii) help the couple arrive at an informed decision that would be most likely to be the best for the couple.

(iv) ensure that information about the commissioning couple, woman and donor shall be kept confidential and the information about treatment shall not be disclosed to anyone except to the database to be maintained by the National Registry.

(v) any of the commissioning couple may withdraw his or her consent any time before the human embryos or the gametes are transferred to the concerned woman's uterus.

Issue raised

Provision prohibiting the practice of sex-selection in ART procedure by the clinics.

Response of DHR

The DHR pointed out that clause 26 of ART Bill prohibits sex selection. Moreover, stringent penalties are provided in clause 32 of the Bill that spells out that the contraventions on the provisions of the Act for sex selection will be a punishable term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both. The prohibition for sex selection is also in alignment with the Pre-conception and pre-natal diagnostic techniques (PCPNDT) Act.

Issue raised

Provisions relating to protection of rights and interests of a child born through ART procedure and the safeguards to prevent the abandonment of the child born through ART procedure by the commissioning couple.

Response of DHR

The DHR clarified that the protection of the rights and interests of the child born through ART has been ensured vide mechanism as enumerated under clause 31 that spells out the provision that the child born through assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to a natural child of the commissioning couple under any law for the time being in force. Moreover, the Bill provides deterring provisions by spelling out stringent punishment in clause 33. For cases of abandonment or exploitation of the child/children, selling embryos/gametes, exploitation of commissioning woman and couple, there shall be a penalty with imprisonment for a term which shall not be

less than eight years but may extend to twelve years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees.

Issue raised

Procedure for reviewing and monitoring of the implementation of the Act by the State Boards.

Response of DHR

The Department mentioned that the State Board shall be the same Board as proposed in the Surrogacy Bill with 21 Members. The Board will be chaired by State Health Minister. The clause 8 of the Bill provides that the State Board will co-ordinate the enforcement and implementation of the policies and guidelines for assisted reproduction. The State Board can also give directions or pass such orders as directed by the National Board. The State Board is also supported by the Registration Authority, which is the implementing authority in the State and will monitor the implementation of the provisions of the Act. It comprises of State Health department officials not below the rank of Joint Secretary as the Chairperson.

Issue raised

The criteria of deciding/selecting donor- whether the commissioning couple would be choosing the donor or the ART Clinic would be deciding about the donor.

Response of DHR

The screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done only by an ART bank registered as an independent entity under the provisions of this Act as per section 27.

Issue raised

Complaint redressal mechanism under the ART Bill and whether the provision that only the National Board, State Board or any officer, authorized by State Board can approach the courts would not amount to denying a person's access to justice directly through Courts.

Response of DHR

The clinic or bank or the commissioning couple or the woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the Registration Authority as per section 19, prefer an appeal against such order to—

(a) the State Government, where the appeal is against the order of the Registration Authority of a State;

(b) the Central Government, where the appeal is against the order of the Registration Authority of a Union territory, in such manner as may be prescribed in rules.

The need to approach the court is not denied, as the bill provides a provision in Section 21 e which states that "in a medical emergency the commissioning couple to whom the information relates, or by an order of a court of competent jurisdiction may request for information from the National Registry"

Issue raised

If an unmarried woman wants to have a child, whether the proposed legislation will allow the same. If so, whether the Department has considered the sociological implications of the provision and what mechanism has been adopted to ensure that the child does not suffer in schools or when he grows up.

Response of DHR

The DHR replied that in adoption, an unmarried woman is allowed to adopt a child so that is why a provision has been made in the ART Bill wherein a woman would be bearing the child herself so there are more chances of her taking care of the child born through ART services than in adoption.

Issue raised

The concern was expressed over commercialization of ART services and mentioning of the word "industry" as mentioned in Statement of Objects and Reasons (SOR) having the prospects of billion dollars in the fertility industry that lends the business orientation/aspects of the ART Bill which kills the altruistic spirit of the Bill.

Response of DHR

The Department accorded the views of the Members by maintaining that ART services should not be treated as an "industry" is a very valuable point/suggestion.

Issue raised

Need for formulating Standard Operating Procedure (SOP) for ART services.

Response of DHR

The Department subscribing to the views of the Committee maintained that the point of making SOPs is also absolutely important that Standard Operating Procedures, cost, the registration part and quality will have to be ensured at every level, right from the Board as well as at each and every clinic.

2.4 The suggestions of the Committee have been included in recommendations contained in Chapter on clause by clause examination of the Bill and in General Observations/Recommendations of the Committee. The Committee desires the Department to consider the suggestions of the Committee while framing the rules and regulations made under the ART Act.

CHAPTER - III

VIEWS OF STAKEHOLDERS/EXPERTS

3. The Committee invited the views of stakeholders, organizations/experts/NGOs on various provisions of the Assisted Reproductive Technology (ART) 2020. In response, the Committee received a number of memoranda. Further, the Committee also held deliberations with representatives of Associations/Organizations/Councils/Institutes as well as renowned experts and professionals in the field of assisted reproductive technology in its meetings held on 30th December, 2020 and 11th January, 2021. The views of Experts/Organizations/Associations that submitted their written views in response to the letters and organizations that presented their oral evidence before the Committee are enumerated as under:

3.1 ORGANIZATIONS/EXPERTS/NGOs AND OTHERS

3.1.1 SAMA- Resource Group for Women and Health

During their deposition before the Committee, Executive Director, Sama Resource Group for Women and Health, Delhi, supported the ART Bill. The representative of SAMA expressed views as under:

(i) The Surrogacy Bill would be incomplete without the passage of ART Bill.

(ii) The overlapping amongst PCPNDT Act 1994, the Surrogacy (Regulation) Bill, 2019 and ART Bill should be addressed.

(iii) The bill is discriminatory against LGBTQ community, single men and live-in couples and advocated that the beneficiaries of the proposed bill should be modified to include them.

(iv) Insurance and compensation should not be equated; the donor and the child born should be guaranteed both the insurance and compensation.

(v) In respect of Registration Authority, it was opined that all the proceedings of the Registration Authority should be recorded and available in public domain and an independent authority must oversee the proceedings to eliminate the possibility of any bias.

(vi) Regular inspection of the ART banks and clinics should be done and there needs to be a proper mechanism for carrying out the inspection.

(vii) Minimum age must explicitly be written in the Bill for a woman approaching an ART centre for any procedure as the legal age for marriage varies among different religions.

(viii) With regard to the information submitted by all the clinics and banks to National Registry, it was stated that the information needs to be anonymized if it is merely for monitoring else it has a scope for misuse.

(ix) As regards the pre-implantation genetic diagnosis, there should be very clear ethical protocols and guidelines and proper procedure for genetic testing and treatment as per international norms as such screening can lead to "made-to-order" or "tailor-made" babies.

(x) As regards obtaining consent of all parties seeking ART, it was suggested that informed consent that requires detailed information and explanation all the risks, alternatives, possible outcomes, procedures, costs, should be obtained from them to enable an informed decision in form and language that is understood by persons accessing ART services.

3.1.2 CENTRE FOR SOCIAL RESEARCH

The Head, Research & Knowledge Management, Centre for Social Research, submitted the views on the Bill as enumerated below:

(i) The Bill is silent on "Embryo Factory" that ART clinics and infertility physicians have generated which could create huge confusion regarding the parentage issue of children.
(ii) The Bill is non-inclusive in nature as the access to ART is limited to only married couples and leaves out LGBTQ community.
(iii) For one commissioning parents, at a given period, not more than one donor woman may be administered with the ART procedure to rule out the 'twibling' factor.
(iv) The donors should be properly counselled and adequately compensated.
(v) The provision of health insurance and maternity benefit may be provided to donor women.
(vi) A legal document should be signed in a language which is understood by both parties involved in ART procedure to avoid issues of parentage and inheritance in future.

3.1.3 Indian Society for Assisted Reproduction

The Representative of ISAR expressed its comments on ART Bill as under:

(i) The Bill does not contain any provision for safeguarding the interests of donors and fails to mention criteria for selection of donors.

(ii) Regarding the renewal of registration by the National Registry, it was suggested that it should be done every ten years.

(iii) In the context of appointment of members to the National Board, it was pleaded that it should not necessarily be done from the Government

institutions but also from private hospitals with people having at least five years experience in the field of ART as not many government hospitals have IVF facilities.

(iv) Doctors should not be held responsible for abandoning of child by commissioning couple instead the onus should be fixed on the couple.

(v) All offences should be non-cognizable except those deemed to be severe in nature like sex-determination and offences of gross negligence.

3.1.4 On the direction of Chairman of the Committee in its meeting held on 30th December, 2020, a group of stakeholders present during the meeting submitted a common memorandum expressing their views on ART Bill as under:

(i) The bill is well formatted and the efforts by the Ministry of Health and Family Welfare, ICMR and Department of Health and Research are appreciable however, the bill needs to safeguard the interest of healthcare providers which takes care of the interest of infertile couples and gamete donors.

(ii) The ART Bill should be a comprehensive legislation and a forward looking Bill in dealing with the advances in the field with rapid pace.

(iii) Constitution of a National body called Indian ART authority instead of proposal of creating National and State Boards. It was stated that excessive, rigid / redundant, or too bureaucratic model would hinder or prevent the very purpose of giving a law to address the issues of Reproduction and forming families. It was proposed one body at national level should have representatives from States and shall form sub-committees for the purposes as and when required. The National Body should consist of (a) Eminent Reproductive Specialist with at least 15 years of experience (b) 2 Gynaecologists with at least 15 years of experience (c) A legal practitioner with at least 15 years of experience. (d) An Embryologist (e) A Social Scientist.

(iv) oocyte retrieval has special needs and has requirements of a good ART center- from the clinicians to the embryologist and infrastructure of lab which is beyond the scope of an ART bank. Medical procedures should only be performed at ART Clinics. The ART Clinic shall be responsible for retrieving oocytes, collecting them, freezing them and storing them.

(v) The Provisions of Medical Termination of Pregnancy Act shall be made applicable and accordingly provision should be introduced as there could be instances of multiple pregnancy, foetal reduction, abortions etc.

(vi) A woman whether married, or single who is above 21 and below 35 years of age should be allowed to donate the eggs. A woman has a right of autonomy

on her body. A woman has a good pool of eggs and should be allowed to donate thrice in her life time.

(vii) Infertility is a public health issue and a public health risk, accordingly an amendment be made in the Insurance Act for having insurance cover for ART treatment.

(viii) Since there could be scenarios of multiple defects in both the partners hence the Bill may contain the provision for embryo donation as per the existing provisions of Indian Council of Medical Research in its guidelines, 2005.

(ix) Oocyte sharing should be allowed as it helps couples and can make the treatment cost effective as already allowed by Indian Council of Medical Research in its guidelines, 2005.

(x) Import and export of embryos should be allowed for therapeutic Purposes as the same would help foreigners and international patients and Indians residing abroad to take fertility treatments in India.

(xi) ART Clinic is not responsible for abandonment of child since any child arising from a fertility treatment is the responsibility of the intending parents.

(xii) The Bill should have graded punishment as each and every offence cannot be penalized with the same punishment. PCPNDT violations punishments are already in existence. Therefore, there is no need for additional punishment as mentioned in the Bill.

(xiii) Clinics or officers should not be presumed guilty unless the offence is proved. The offences should be non-cognizable and bailable. Officers should also be penalised if they act unreasonably and in an arbitrary manner as all the acts of officers cannot be protected in good faith.

(xiv) The representative of ISAR added treatment for infertility should be included under the Ayushman Bharat Scheme; Uniform Software is needed for National Registry for better management and integration and compensation should be provided to donor.

(xv) The Director, Mother and Child Clinic, during the deposition before the Committee, highlighted that the ART Clinics are already registered under the PC&PNDT Act, therefore, there is no need for their further registration under the ART Bill. It was advocated for coordination between PC&PNDT Act and the Registration Board to minimize wastage of manpower and resources. It was suggested that insurance amount should be specified so that it is uniform across all centres as it could increase the cost of IVF treatment. It was viewed that maintaining the records of donors who were not accepted for egg donation is impractical and further advocated for maintenance of records in soft copy format which could be sent to National Registry on yearly basis for detailed evaluation of ART procedures, success rate and complications.

It was viewed that the amount of insurance to be given should be clearly mentioned in the Bill. The right to appeal should be given to the medical practitioners. It was suggested that the number of oocyte retrieval from donors should be increased as world statistics state that minimum 10 oocytes are needed for pregnancy but the Bill mentions only 7 oocytes.

(xvi) An IVF Specialist, suggested that the donors should be provided with a central ID so that a record of their donation of gametes may be kept. It was also added that the number of embryos to be placed in the uterus of a woman during the treatment cycle needs to be clearly specified, preferably it should be one or two and at the most limited to three.

3.1.5 The Advocate, Fertility Law Care, pointed out that the object of the Bill should address the issues related to reproductive health. The Bill must also incorporate the relevant provisions of Medical Termination of Pregnancy Act that would be applicable in the Bill. She suggested that the expressions -"Natural and legal child" should be used in the Bill instead of biological child as it would be legally sound.

3.1.6 A Senior Consultant & Professor, AIIMS and the representative from the Department of Reproductive Medicine, Christian Medical College & Hospital, Vellore, submitted the lower age limit for woman seeking ART services should be more than 20 years and the upper age limit for the women/men should be decided based on the factors viz risk to maternal health due to pregnancy at advanced maternal age; care of child until 18 years and average life expectancy in India. It was pointed out that the structure of ART clinic and bank is not clearly described in the Bill and ART bank will need a gynaecologist/embryologist and IVF lab to perform the functions assigned.

3.2 ACTIVIST/LAWYERS/AUTHORS/ASSOCIATIONS

3.2.1 A Writer and Social Activist viewed that the minimum age of men in the Bill should be the same as that of women. It was emphasized that there should be no donation, sale, adoption or transfer of embryos to other commissioning couples. The biological and genetic records of all children born from the process of assisted reproduction in India should be maintained and made available to the child upon turning 18 or later for several reasons including emotional and medical.

3.2.2 A Research and Advocacy Officer, Indian Law Society, Pune, suggested following comments on provision of the Bill:

(i) The Bill should include live-in couples, same-sex couples, persons with intersex characteristics; couples with pre-existing genetic diseases or any other health condition and transgender, under its ambit.

(ii) The Bill provides for ‘prior consent’ of the commissioning couple before posthumous collection of gametes can take place. However, question of

posthumous collection of gametes will arise mostly in situations of sudden death where no prior gamete retrieval has been performed by clinics or banks. Since, it is very unlikely that the deceased person would have provided any written consent for posthumous reproduction, in such cases, inferred consent may be ascertained form the surviving partner of the deceased to determine if the deceased had discussed a wish for posthumous gamete retrieval and would have approved of such a procedure.

(iii) The Bill must specify a period for which personal medical records are to be kept with the clinics/banks, non-transfer medical records to the National Registry, online public access to clinic-specific data containing standardized and comparable statistics and information on success rates, staff and infrastructure and services.

(iv) The Bill contains stringent punishment and prescribes a mandatory minimum sentence of eight years thereby depriving the court from having discretion in imposing a proportionate sentence, including a lesser sentence.

(v) The registration authority should have the power to initiate proceedings against the clinics/banks either based on a complaint or *suo motu,* and if found guilty, maximum period of suspension may be specified.

3.2.3 The Coordinator, Indian Law Society, Pune, stressed upon the following provisions of the Bill:

(i) Underscoring the importance of privacy and data protection, it was stated that the confidentiality of data should conform to the law as laid down in the landmark judgment of Justice K.S Puttaswamy (Retd.) v. UOI, the Personal Data protection Bill, 2019 and the National Digital Health Blueprint (NDHB) issued by the Ministry of Health & Family Welfare.

(ii) For the purpose of analysis, research, or policy formulation, only non-identifiable data (unlinked and anonymized form) need be uploaded to the National Registry or the National Board.

(iii) The Bill may contain the provisions for payment to gamete donors, counselling and informed consent of clients, monitoring of bank and clinics, and restricting donor eligibility criteria.

(iv) The criteria for availing ART procedures, period of insurance coverage for oocyte donors, and the maximum number of oocytes or embryos that can be placed in the uterus of a woman undergoing treatment are substantial and vital matters which require clear legislative articulation. Since these procedures have direct impact on the health, safety and rights of the parties seeking ART services, therefore, must be unambiguously incorporated/ addressed in the Bill itself.

3.2.4 The Director, NIRRH-ICMR, viewed that the Bill is unclear on whether the ART Bank will just screen the oocyte donors and then provide them to the ART clinic for stimulation and oocyte aspiration or not. It was maintained the bill should contain the definition of qualified embryologist for performing laboratory procedures. Proper safeguards should be in place in cases of separation of commissioning couples whose embryos have been stored. It was also suggested that provision of storage of oocytes or sperms should be there in case of individuals undergoing cancer therapy.

3.2.5 Dean, BJ Govt. Medical College & Sassoon General Hospital, Pune, suggested that National Board should include a Gynaecologist who should be an expert in handling ART cases. It was viewed that definition of oocyte should be updated to "oocyte ovulating naturally or by induction in the female genital tract".

3.2.6 A Gynaecologist, was of the view that the punishments proposed in the Bill are too harsh and should be relaxed. The limitation on the number of oocytes (7) is not possible to be followed in practice. He cited that even with the most well controlled of stimulations, there may be more oocytes which start growing in the oocyte donor, it would then be incumbent upon the operator to remove all the oocytes at the time of retrieval and such limitation is not practical. As technology evolves, this may become a reality and the limitation on the number of oocytes may be included in regulations that could be modified later. It was suggested that the inclusion of a provision of compensation for oocyte donor as oocyte retrieval is a complicated process which entails the donor getting injected with medicines daily for eleven days and ultimately she has to undergo a surgical procedure of egg retrieval under anaesthesia which could result in loss of wages and sometimes leading to death.

3.2.7 A Senior Consultant & Gynaecologist advocated to remove the capping of oocytes retrieval from oocyte donor and added that clinician/ART bank should be careful in taking all the precautions to avoid ovarian hyper stimulation.

3.2.8 A Professor and Head, suggested that the National/ State Board should have both reproductive endocrinologists and embryologists as experts. It was opined that restricting of donation of egg once in lifetime of donor would open up huge racket since there is no system to track the donors. The Bill lacks clarity on the duration of cryopreservation of gametes/embryos, ethical use of PGD services and fertility preservation aspects among vulnerable population.

3.2.9 Prof & HOD, Department of Obs & Gyn, INHS Asvini, Mumbai, suggested that cryopreservation of sperms, oocytes and ovarian cortex in case of cancer patients. The Committee was given to understand that the term "pre-implantation genetic testing" would be catastrophic and detrimental for embryo and should instead be replaced with Universal Prenatal Genetic Diagnosis. It was pointed out that the possibility of chromosomal anomalies increases with age and therefore, advocated for reducing the upper age limit of donors.

3.2.10 A representative from Department of Reproductive medicine, Govt Medical College, advocated increasing the age of donor woman to 23 years and upper age limit to 45 years for

women and 50 years for men. It was viewed that men should be allowed to donate 10-15 times. The cap on number of oocytes to be retrieved from a donor woman should be kept at 10-15.

3.2.11 The President, Peoples Movement, suggested for a grievance redressal facility should be present and stated that grievance redressal in the process of registration /de-registration should be made mandatory. It was further suggested that protocols or procedure for winding up or closing down Bank or Clinic has to be clarified clearly to protect rights of donor and to avoid misuse of samples in the bank.

3.2.12 The Consultant, Health System Transformation Platform (HSTP) opined for the provisions of the Bill as under:

(i) Registration Authority should consist of at least one eminent Obstetrician and Gynaecology (OBG) specialist with ART specialization or at least MS OBG (instead of just an eminent medical practitioner as mentioned in the bill).

(ii) The cost of treatment and compliance with standard treatment guidelines should be regulated by bringing the ART clinics/banks within the purview of the Clinical Establishment Act.

(iii) The minimum standards for ART counselling, clinics, laboratories, personnel, and procedures should be explicitly mentioned in the Bill.

(iv) A grievance redressal mechanism should be set up for addressing the rights of all involved parties, criteria for approval/rejection of clinics, screening for medical complications.

(v) Training for ART centre co-ordinators/doctors regarding Standard Treatment Protocols for the procedures should be made mandatory and certification must be given.

(vi) Standardized Special Insurance Policy for ART related donors should be considered instead of multiple options by different insurance agencies and minimum extent of coverage should be prescribed.

(vii) Prior informed consent form should be devised and adopted across all facilities.

(viii) Public notice of approved and rejected clinics for ART services should be put up by the Registration Authority.

(ix) The Bill fails to mention the criteria of selection of donor(s) and the selection should be in such a way which could eliminate the chances of bias based on reinforcing caste/class/religion/ethnicity.

(x) Under the proposed legislation, an aggrieved party cannot directly approach the court thus takes away rights of doctors/clinics/establishments to take the legal route in case of harassment meted out to them by the officials.

(xi) The Bill is silent on the health risks to donors and does not provide adequate safeguards to them.

(xii) Clarity on marital status of foreign couples should be provided and whether they need to provide a marriage registration certificate should be clarified.

3.2.13 The representative of Centre for Legislative Research and Advocacy furnished following comments on the provisions of the Bill":

(i) Majority of ART clinics and banks are run by private entities and endanger the life of people availing these services just for the sake of fulfilling their motives, therefore, there is a need for standardized protocols for treatment and services binding on them and inflict liability in case of non-compliance of norms.

(ii) The Bill limits transgender and live-in partners from exercising their reproductive autonomy by neglecting their rights and foster discrimination as well as encroaches upon their participation in society.

(iii) In context of maintenance of National Registry of ART clinics wherein all ART Clinics would showcase their services and outcomes thereof, it was maintained that this provision infringes upon fundamental right to medical privacy under Article 21 of the Indian Constitution as laid down in the landmark judgment of Justice K.S. Puttaswamy vs. UOI. However, the provision to provide outcome of services to infertile parents is fruitful for the couples seeking ART services.

(iv) Counselling should not be a one-time affair rather a continuous process so that even after procreating a child, the beneficiaries could get expert advice in case of any complications.

(v) Promoting altruistic form of gamete donation and the restriction imposed on eligibility of an oocyte donor to be married and having at least one live child of her own with a minimum age of three years would contribute to paucity of gamete donors.

3.3 MINISTRIES/GOVERNMENT OFFICERS/APPOINTEES

3.3.1 Ministry of External Affairs

The Secretary, Consular Passport Visa Division (CPV) & Overseas Indian Affairs (OIA), Ministry of External Affairs was of the view that as the bill involves foreign, OCI and

mixed couples, Standard of Procedures (SOPs) for each of these categories should be made and NRI couples should be treated at par with Indian nationals. It was cited that the movement of foreign nationals and OCI couples should be on the basis of a medical visa. It was underlined that children of OCI couples born using ART should be eligible for both foreign as well as OCI passport; Children with one Indian parent and other a foreign/OCI national is eligible for both Indian and foreign passport. The concern was expressed over child's welfare in foreign land as different countries have different data privacy laws. He suggested the need of Police Clearance Certificate (PCC) for verification of foreign couples coming to India for ART services. He further informed that MEA is relying on judicial judgments in case of family discords involving foreign or mixed couples as there is no legislation in this regard. In its written submission, Ministry of External Affairs suggested that the word 'oocyte' may be defined in the Bill and examine whether there is a need to define 'egg' in the Bill. The Ministry further submitted that there is a need to clearly state who are permitted to avail the services in the Bill. They also sought clarification on the meaning of 'ever married woman' as according to them it is not clear whether a divorcee or widow with a child of three years or above could be an oocyte donor. The Ministry opined that though the Bill also allows single woman to commission a child, it is silent about the parentage, rights and privilege of the child born to a single woman by ART.

3.3.2 Ministry of Women & Child Development

The Secretary of Ministry of Women & Child Development, highlighted the importance of clearly mentioning the rights and entitlements of beneficiaries and the child born through ART in the Bill. It was noted that coherence and consistency should be brought in Surrogacy (Regulation) Bill and ART Bill, donor eligibility should be relaxed, various definitions common in Surrogacy (Regulation) Bill, 2019 and ART Bill should have same meanings. In its written submission, Ministry of Women & Child Development welcomed the step of including single women to avail ART services in the Bill. The possibility of allowing all women to donate oocyte should be explored.

3.3.3 The Director Health Services (FWI) Punjab for Principal Secretary Health & Family Welfare, Punjab, suggested modifying the ambit of the Bill to include live-in partners, LGBTQ community. It was suggested that ART clinics and Banks should be separately registered to delegate proper responsibilities and avoid commercial conflict and also their premises should be different. Separate forum for Protection of Child Rights was also suggested. It was further stated that records of ART Clinics should be kept for minimum 10 years and should be later transferred to National & State Board permanently. It was advocated that transfer relevant information including digital data should be done to state and national authorities from time to time. It was mentioned that the ART Regulation, PC&PNDT, Surrogacy Acts could overlap and hence suggested that a single board should be constituted to handle all these centres.

3.3.4 The Principal Secretary, Government of Tamil Nadu, mentioned that the ART centres are registered under the purview of PC&PNDT Act, 1994 and Tamil Nadu Clinical Establishment Act 1997 and are monitored by the State Appropriate Authority as well as District Appropriate Authority. To regulate the collection of fees from patients, it was suggested that standard fee should be prescribed in the Bill. It was further stated that

centralized software for receiving complaints may be formulated and the State or District Appropriate Authority on receipt of such complaint may reply the status or action taken to the individual through online system.

` 3.3.5 Department of Medical Education, Health and Family Welfare, Government of Jharkhand suggested that up to five embryos should be created from which a maximum of two may be transferred at a time. It was submitted that the offences under the Bill should include- abandoning, or exploiting children born through ART; selling, purchasing, trading, or importing human embryos or gametes; using intermediates to obtain donor; exploiting commissioning couple women, or the gamete donor in any form, and transferring the human embryo into a male or an animal.

3.3.6 The office of the Chief Resident Commissioner, Government of Odisha, informed that 28 IVF clinics in Odisha have been registered under the PC&PNDT Act, 1994 and there is no functional ART Bank in the State. It was suggested that not more than three embryos should be transferred placed in the uterus of a woman during the treatment cycle and the gamete of a donor or embryo shall be stored for a period of not more than ten years and at the end of such period such embryo or gamete shall be allowed to perish or be donated to a research organization registered under this Bill for research purposes with the consent of the commission couple or individual. It was further stated that the offences under the act should be cognizable and non-bailable.

3.3.7 The Deputy Secretary, Health and Family Welfare Department, Government of Gujarat, submitted that the functions of National Board should include monitoring activities at Banks and clinics as per ICMR Guidelines and other evidence based documents. It was opined that the insurance provision in current ART bill and as per ICMR guidelines are adequate.

3.3.8 In a written submission from the Public Health Department, Government of Maharashtra informed that there are total 488 ART centres and 40 Banks in Maharashtra which are registered with Appropriate Authority under PCPNDT Act and the quarterly inspection of ART centres is currently being done by Appropriate Authority. The regional grievance redressal committee at each health division (circle) of the State may be constituted for speedy disposal of complaints regarding ART which should investigate the complaints received within 90 days and send its recommendations to the concerned Appropriate Authority for suitable action.

3.3.9 The Secretary, Health and Family Welfare Department, Government of West Bengal, submitted that the Registration Authority should consist of an eminent gynaecologist. It was suggested that specific instructions need to be given by both partners regarding the fate of cryo-preserved embryos in the event of divorce of the couple as there has been litigation on this point in other countries. It was also suggested that ART banks should obtain semen from males between 21-55 years and oocytes from females between 23-35 years of age. It was suggested that there should be a provision of storing gametes for more than ten years.

3.3.10 Addl. Sr. Medical Officer, for Director General Health Services, Government of Haryana, submitted the following suggestions on the provisions of the Bill:

(i) The responsibilities of ART banks should be restricted to retrieval and storage of semen only whereas the oocyte retrieval and storage should be done by ART clinics as it requires expertise and thus it was advocated that proper role of ART banks and clinics should be specified.

(ii) Qualification of personnel and infrastructure required for opening an ART bank and clinic should be defined.

(iii) The definition for "preservation of gametes for self use" or "social egg freezing" should be included in the Bill.

(iv) National Board should consist of two specialist doctors from registered National ART societies such as Indian Fertility Society (IFS) and ISAR.

(v) Timeline for disposal of complaints by the Registration Authority should be fixed to avoid unnecessary delays; State Government shall display the list of registered ART banks and clinics on the website of Health Department along with status/validity of their registration for information of public

(vi) The minimum period of coverage and amount of sum assured under insurance should be prescribed in the Bill.

(vii) To deal with paucity of donors each donor should be allowed to donate at least three times as is the practice across the globe.

(viii) Retrieval of oocytes should not be restricted to seven.

(viii) The provision of punishment prescribed under the Bill is draconian and out of proportion of offence and suggested that it should be as prescribed under the PCPNDT Act and also the offences under the Bill should be made non-cognizable.

3.3.11 Mission Director NHM & Special Secretary M.H. & FW, Government of Rajasthan, submitted that database of all clinics and banks should be made available in public domain. The registration authority should have representatives from women's rights organization with experience of working in health issues. It was suggested that in case of cancellation of registration, public notice should be issued and database should be updated within fixed time period and display notice should be placed in front of cancelled clinic. Right to information Act should not be applicable for private and confidential information of commissioning couples and donors. It was also mentioned that Pre-implantation genetic diagnosis needs cost consideration as there is price benchmarking at present.

3.3.12 Adviser to the Administrator, UT, Chandigarh, fully supported the proposed Bill. Assistant Secretary, Health, Andaman and Nicobar Administration responded with no comments.

3.3.13 During the course of the examination of the Bill, the Committee noted the concerns, suggestions and amendments expressed by various experts/stakeholders on the Bill and duly communicated them to the Department of Health Research for its response.

CHAPTER - IV

CLAUSE BY CLAUSE EXAMINATION OF THE BILL

4.1 The Committee, in its meeting held on 17th March, 2021, took up the clause by clause consideration of the Bill. The Committee's observations and recommendations contained in the Report reflect an extensive scrutiny of submissions by the Stakeholders vis-a-vis the response of DHR thereto. Upon scrutiny of the replies received from the Department, the Committee is of the view that certain provisions of the Bill need to be recast to serve the intended purpose of the Bill better. Various amendments to the Bill have been suggested by the Committee which are discussed in the succeeding paragraphs.

CLAUSE 2

4.2 Clause 2 (c) deals with the definition of **(c)** "assisted reproductive technology"

Clause 2(c) reads as under:

(c) "assisted reproductive technology" with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive system of a woman.

SUGGESTIONS:

4.2.1 The following are the suggestions of the stakeholders regarding the definition of "assisted reproductive technology":

(i) *"assisted reproductive technology"* with its grammatical variations and cognate expressions, means all techniques including but not limited to IVF, IUI, ICSI, Embryo Biopsy etc, that attempt to obtain a pregnancy or for preserving fertility or examining or managing the issues related to the reproduction or reproductive organs by handling the sperm or the oocyte or tissues/cells or germ lines outside the human body and transferring the gamete or the embryo into the reproductive system of a woman.

(ii) All treatments or procedures that include the in-vitro handling of both human oocytes and sperm, or embryos, for the purpose of establishing a pregnancy. This includes, but is not limited to, in-vitro fertilization and embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation, oocyte and embryo donation, and gestational surrogacy. ART does not include assisted insemination (artificial insemination) using sperm from either a woman's partner or a sperm donor.

(iii) ISAR suggested that clinics where only IUI is performed should ideally be excluded. If even these clinics are to be taken into the ambit of the Bill, a distinction should be made

for clinics which simply do the insemination vis a vis those which process sperm. Only the clinics which process sperm should be covered.

DEPARTMENT'S RESPONSE:

4.2.2 The Department submitted that the definition has been framed in consultation with experts.

OBSERVATIONS/RECOMMENDATIONS:

4.2.3 The Committee accords the existing definition of Assisted Reproductive Technology that envelops all techniques that attempt to obtain pregnancy.

4.2.4 Clause 2(d) deals with the definition of **(d)** "assisted reproductive technology bank"
Clause 2(d) reads as under:

(d)"assisted reproductive technology bank" means an organization that is setup to supply sperm or semen, oocytes or oocyte donors to the assisted reproductive technology clinics or their patients;

SUGGESTIONS:

4.2.5 The following are the suggestions of the stakeholders on the clause:

(i) SAMA- Resource Group for Women and Health submitted that the ART Bank cannot and ought not to be a place where oocyte donors can be 'supplied' from.

(ii) The Ministry of External Affairs sought clarification if the bank would supply sperm/semen and oocytes/oocyte donors or sperm/semen and oocytes/oocyte.

(iii) NIRRH-ICMR sought to know if the ART Bank would just screen the oocyte donors and then provide them to the ART clinic for stimulation and oocyte aspiration or the ART Bank is expected to do the stimulation of the donor and then have to send it to the ART Clinic for the oocyte aspiration.

(iv) Some stakeholders proposed the establishment of a third party recruitment agency which recruits donors and surrogates. The purpose of establishing ART bank is to assist the ART clinics and commissioning couple/intending parents/women for the sourcing/supply of egg donors or sperm donors. Medical procedures should only be performed at ART Clinics. Thus the ART Bank should function as Recruitment Agency and suggested using the term "ART Recruitment Agency" instead of Assisted Reproductive Technology Bank.

DEPARTMENT'S RESPONSE:

4.2.6 The Department submitted that ART Banks are also storage places for the gametes. This is provided in section 27 and the specific role will be elaborated in rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.2.7 The Committee notes that clause 27 (1) of the proposed Bill mentions that "*the screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done by a bank registered as an independent entity under the provisions of this Act.*"

4.2.8 The Committee observes that through the definition mentioned in the Bill, the role of ART banks is not clear. The Committee feels that the mechanism as well as the body responsible for screening of gamete donors should be clearly specified. It is also not clear as to who can open an ART Bank and who will man it. The screening of gamete donors is a complicated process involving testing for sexually transmitted infections, genetic diseases and psychological assessment. This process needs presence of specialized doctors which ART banks may not have. The Committee, therefore, recommends the Department to remove ambiguity in the definition and clearly demarcate the role of ART banks alongwith specialists required to do the job in these Banks. The Committee is of the view that the screening of gametes should be done by ART clinic while the Banks should be responsible for collection, storage and supply of gametes. Functional co-ordination and collaboration is required between ART clinics and banks to attain the objective of the proposed legislation.

4.2.9 Clause 2(g) deals with the definition of **(g)** "commissioning couple"

Clause 2(g) reads as under:

"commissioning couple" means an infertile married couple who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorized of the said clinic or bank;

SUGGESTIONS:

4.2.10 The following are the suggestions of the stakeholders on the clause:

(i) The Committee was given to understand by several witnesses/stakeholders that commissioning couple should not just include infertile married couple but also couples in live-in relationship and people in same sex relationship because excluding them would be discriminatory and violation of the right to life, personal liberty, reproductive autonomy and right to equality guaranteed under Article-14 to all persons under the Constitution of India. It was also

pointed out that the Hon'ble Supreme Court has recognized the status of live-in partners as a "relationship in the nature of marriage" and the children that are born to such couples are accepted as legitimate under the law.

(ii) Some stakeholders suggested that the word infertile married couple 'to be replaced by "couple or individual" to include singles, divorcees, people from LGBTQ communities.

(iii) One stakeholder submitted that the term infertile married couple is too restrictive a definition for commissioning couple. The commissioning couple's definition be broadened to include in stable relationship at least for 2 years and for whom opportunity for adoption has been provided. One could ask for additional verification process to ensure that they are in a stable relationship, or if single, in a situation to take care of the child- but they should be eligible.

(iv) SAMA submitted that restricting it to only married couples is discriminatory and would be volatile of the right to life and right to equality guaranteed to all persons under Articles 21 and 14 of the Constitution of India. Recognition and respect needs to be accorded to the reproductive right of each person to reproductive health and the right to form a family. The Supreme Court of India, very recently, ruled that "in the modern time, live-in relationship has become an acceptable norm. It is not a crime." Even the children that are born to such couples are accepted as legitimate under the law. Moreover, single persons are eligible to adopt children under Indian law. Irrespective of marriage, the Bill should include everyone who wants to avail ART.

DEPARTMENT'S RESPONSE:

4.2.11 The Department submitted the following:

(i) The definition has been provided after consultation with experts.

(ii) The Bill provides ART services to - married couple (man and woman), single woman. The bill by including single woman above the legal age of marriage has included all women to avail ART services.

(iii) The definition for infertility is as per WHO recommendations.

(iv) Live-in couple and same sex couple have been decriminalized but not yet legalized.

OBSERVATIONS/RECOMMENDATIONS:

4.2.12 The Committee takes into account that even though the Supreme Court has decriminalized same sex relationship, it did not introduce any special provisions or

grant any additional rights to same sex couples. The same applies for people who are in live in relationships.

4.2.13 The Committee took into account the submission of various stakeholders who cited the case Navtej Singh Johar & Ors vs Union of India decriminalised gay sex between consenting adults by reading down Section 377 of the Indian Penal Code. Similarly, in S. Khushboo vs. Kanniammal & Anr., Supreme Court of India, relying on its earlier decision in Lata Singh vs. State of U.P. & Anr held that live-in relationship between two consenting adults of heterogenic sex does not amount to any offence, with the obvious exception of 'adultery'. Also, in Justice K.S. Puttaswamy vs. Union of India, Supreme Court held that the rights of LGBT and sexual minorities are not "so-called" but are "real rights founded on sound constitutional doctrine".

4.2.14 In 102nd report on the Surrogacy (Regulation) Bill 2016, the Committee endorsed that that couples who can avail Surrogacy services should not be restricted to legally married couples but needs to be widened to include live-in couples. However, the Select Committee on Surrogacy (Regulation) Bill 2019, retained the definition of "couple" but people in live-in relation and same sex couples were excluded from availing Surrogacy services.

4.2.15 The Committee, keeping in view its recommendations made in 102nd Report, judgements of Supreme Court and recommendations of Select Committee on Surrogacy (Regulation) Bill, 2019, pondered over the issue that live-in and same sex couples even though de-criminalized by the Hon'ble Supreme Court, should be given such reproductive rights through ART services. Given Indian family structure and social milieu and norms, it will not be very easy to accept a child whose parents are together but not legally married. The Committee feels that keeping the best interest of that child born through ART services and other parentage issues in case of their separation, it would not be appropriate to allow live-in couples and same sex couples to avail the facility of ART. The Committee, however, feels that since the rights of people in same sex relationship and live-in relationships frequently keep getting redefined, however, the ART Bill endorsed the recommendations of Select Committee on Surrogacy (Regulation) Bill 2019, wherein the definition of "couple" has been retained and live-in couples and same sex couples have been excluded from availing surrogacy services.

4.2.16 Clause 2(h) deals with the definition of (h) "egg"

Clause 2(h) reads as under:

(h) "egg" means the female gamete

SUGGESTIONS:

4.2.17 The Ministry of External Affairs suggested to consider deleting the definition of egg from the Bill as word 'egg' is not used in the entire text of the Bill.

DEPARTMENT'S RESPONSE:

4.2.18 The Department submitted that the above said suggestion can be considered.

OBSERVATIONS/RECOMMENDATIONS:

4.2.19 The Committee agrees with the suggestion of the Ministry of External Affairs to remove the definition of "egg" as it has not been used in entire text of the Bill.

4.2.20 Clause 2(x) deals with the definition of (x) "woman"

Clause 2(x) reads as under:

(x) "woman" means any woman above the legal age of marriage who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the authorized services of the clinic or bank.

SUGGESTIONS:

4.2.21 With respect to clause 2(x) stakeholders have made the following suggestions:

(i) SAMA- Resource Group for Women and Health suggested removing "woman above the legal age of marriage" from the proposed definition. Though 18 years is the legal age of marriage for woman, in some religions a lower age is acceptable. It was accordingly suggested that a woman approaching an ART centre for any procedure should be above 21 years of age.

(ii) Another Stakeholder submitted that through the definition of "woman", it is not clear if unmarried women are allowed to use ART services. While clause 2(x) indicates that women above the legal age of marriage can approach ART banks and clinics for using ARTs, other provision of the Bill (such as clause 22(4), 27(5) and 31) do not include “woman" leading to a possible conclusion that unmarried women cannot avail ART services. Such ambiguity and vagueness must be avoided and clear, precise and consistent language should be used.

DEPARTMENT'S RESPONSE:

4.2.22 The Department agreed to the suggestion to remove the phrase "legal age of marriage" from the definition of "woman".

4.2.23 The Department while giving clarification on whether Bill allows single unmarried women to avail the service of ART submitted that single woman as divorced, widowed and unmarried are allowed availing ART services. The Bill allows single unmarried woman to avail ART services keeping in view that adoption is allowed for single woman. As per Article-21 of the Constitution of India,

"No person shall be deprived of his life or personal liberty except according to procedure established by law, nor shall any person be denied equality before the law or the equal protection of the laws within the territory of India."

4.2.24 The Department submitted that the Puttaswamy judgment specifically recognized the constitutional right of women to make reproductive choices, as a part of personal liberty under Article 21 of the Indian Constitution. The bench also reiterated the position adopted by a three-judge bench in Suchita Srivastava v Chandigarh Administration, which held that reproductive rights include a woman's entitlement to carry a pregnancy to its full term, to give birth, and to subsequently raise children; and that these rights form part of a woman's right to privacy, dignity, and bodily integrity. The Supreme Court has been extremely progressive on women's reproductive rights. By decriminalizing adultery and homosexuality in the landmark judgment of Navtej Johar, the court has held clearly, that women have a right to sexual autonomy, which is an important facet of their right to personal liberty.

4.2.25 The Department further submitted that in the case of Independent thought v. Union of India in the context of reproductive rights of girls, the Supreme Court held, "the human rights of a girl child are very much alive and kicking whether she is married or not and deserve recognition and acceptance". These judgments have an important bearing on the sexual and reproductive rights of women.

OBSERVATIONS/RECOMMENDATIONS:

4.2.26 The Committee agrees with the views of the Stakeholders when they exhort the need for consistent and precise language for terms such as "the legal age of marriage". This would signal that marriage is a pre-requisite to avail the ART services which is untrue for women as justified by the Department of Health & Family. The Committee, therefore, recommends removal of the term "legal age of marriage" and instead recommends that specific age i.e. 21 years for woman should be mentioned in the Bill.

4.2.27 The Committee, therefore, recommends the following changes in clause 2(x). Clause 2(x) will be read as under:

"woman" means any woman above 21 years of age who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the authorized services of the clinic or bank."

Appropriate alterations may be made accordingly in clause 21(g) of the Bill.

4.2.28 The Committee is of the view that the Bill needs to incorporate the following definitions:

1) **Oocyte - oocyte ovulating naturally or by induction in female genital tract.**
2) **Embryologist**

4.2.29 Subject to the above recommendations, the clause is adopted.

CLAUSE 3

4.3 Clause 3 spells out that the National Board to be constituted under sub-section (1) of section 15 of the Surrogacy Act shall be the National Board for the purposes of this Act.

OBSERVATIONS/RECOMMENDATIONS:

4.3.1 Since, the National Surrogacy Board will also regulate the ART services, therefore, the Committee strongly recommends that the National Board should be named as "National ART and Surrogacy Board".

4.3.2 Subject to the above recommendation, the clause is adopted.

CLAUSE 4

4.4 Clause 4 deals with application of provisions of Surrogacy Act with respect to National Board. The DRSC would like to draw attention towards composition of National Surrogacy Board, as contained in Surrogacy (Regulation) Bill 2019 as reported by the Select Committee. Subject to the provisions of this Act and the rules made thereunder, the provisions of the Surrogacy Act relating to—

S. No	*Clause of Surrogacy(Regulation) Bill 2020*	*Provisions*
(i)	*Clause 15*	*constitution of the National Surrogacy Board;*
(ii)	*Clause 16*	*term of office of Members of the National Board*
(iii)	*Clause 17*	*meetings of the National Board*
(iv)	*Clause 18*	*vacancies, etc., not to invalidate proceedings of the National Board*
(v)	*Clause 19*	*disqualifications for appointment as Member of the National Board*
(vi)	*Clause 20*	*temporary association of persons with the National Board for particular purposes*
(vii)	*Clause 21*	*authentication of orders and other instruments of the National Board*
(viii)	*Clause 22*	*eligibility of Members of the National Board for re-appointment, shall, mutatis mutandis, apply, so far as may be, in relation to assisted reproductive technology as they apply in relation to surrogacy, as if they are enacted under this Act*

4.4.1 Clause 15(1) of the Surrogacy (Regulation) Bill 2020 stipulates that the Central Government shall, by notification, constitute a Board to be known as the National Surrogacy Board.

According to Clause 15(2) the Board shall consist of—

(a) the Minister in-charge of the Ministry of Health and Family Welfare, the Chairperson, ex officio;

(b) the Secretary to the Government of India in-charge of the Department dealing with the surrogacy matter, Vice-Chairperson, ex officio;

(c) three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of States, Members, ex officio;

(d) three Members of the Ministries of Central Government in charge of Women and Child Development, Legislative Department in the Ministry of Law and Justice and the Ministry of Home Affairs,not below the rank of Joint Secretary, Members,ex officio;

(e) the Director General of Health Services of the Central Government, Member, ex officio;

(f) ten expert Members to be appointed by the Central Government in such manner as may be prescribed and two each from amongst—

(i) eminent medical geneticists or embryologists;
(ii) eminent gynecologists and obstetricians(**)
(iii) eminent social scientists;
(iv) representatives of women welfare organisations; and
(v) representatives from civil society working on women's health and child issues,possessing such qualifications and experience as may be prescribed;

(g) four Chairpersons of the State Boards to be nominated by the Central Government by rotation to represent the States and the Union territories, two in the alphabetical order and two in the reverse alphabetical order, Member, ex officio; and

(h) an officer, not below the rank of a Joint Secretary to the Central Government, in charge of Surrogacy Division in the Ministry of Health and Family Welfare, who shall be the Member-Secretary, ex officio

SUGGESTIONS:

4.4.2 ISAR submitted that there should be inclusion of regional, renowned and committed ART practitioners in the National Board in administrative post so that the correct

interpretation and effective application of the provisions of the bill is facilitated and the conflicting issues of PCPNDT Bill are avoided. The appointment of the above persons should not necessarily be from Government institutions but also from private hospitals and having at least 5 years experience in the field of ART as not many Govt hospitals have IVF facilities.

DEPARTMENT'S RESPONSE:

4.4.3 The Department submitted that the provision is included in clause 4 of the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.4.4 The Committee notes that the Clause 4(i) provides composition of National Board. It has been clarified by the Department that the National Board constituted for the regulation of surrogacy as proposed in the Bill shall act as the Board for regulation of ART also. The Committee understands that since the National Board for Surrogacy and ART would be common and the Select Committee has already recommended for inclusion of eminent medical geneticist or embryologist, gynaecologist and obstetrician in the National Board, therefore, there services would automatically be availed during ART services. The Committee, however, recommends that while appointing ten expert members of the National Board, the Central Government should assure that eminent reproductive specialists i.e. embryologists, gynaecologist, legal practitioners, social scientist must have at least ten years of experience in the field.

4.4.5 Subject to the above recommendation, the clause is adopted.

CLAUSE 5

4.5 Clause 5 deals with the Powers and functions of National Board.

Clause 5 reads as under:

The National Board shall exercise and discharge the following powers and functions, namely:— (a) to advise the Central Government on policy matters relating to the assisted reproductive technology;

(b) to review and monitor the implementation of the Act, rules and regulations made thereunder and recommend to the Central Government, any suitable changes therein;

(c) to lay down code of conduct to be observed by persons working at clinics, to set the minimum standards of physical infrastructure, laboratory and diagnostic equipment and expert manpower to be employed by clinics and banks;

(d) to oversee the performance of various bodies constituted under this Act and take appropriate steps to ensure their effective performance;

(e) to supervise the functioning of the National Registry and liaison with the State Boards;

(f) to pass orders as per the provisions made under this Act; and

(g) such other powers and functions as may be prescribed.

SUGGESTIONS:

4.5.1 CSR submitted that systematic monitoring committees/bodies of the Hospital and clinics involved in ART to track negligence during the treatment has to be established at the Central and State levels with active involvement of civil society partnership.

DEPARTMENT'S RESPONSE:

4.5.2 The National Board is a Central Body and State Board will be a State body. As per Section 5(b), the National Board shall review and monitor the implementation of the Act, rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.5.3 The National Board is entrusted with the responsibility of monitoring the implementation of the Act, rules and regulations. The National Board consists of eminent experts in the field, representatives of women welfare organizations, representatives from civil society working on women's health and child issues. The Committee believes that the representations of these stakeholders and experts in National Board would ensure systematic monitoring of the implementation of the Act which would also include redressal of complaints and negligence by ART and Surrogacy clinics of all Stakeholders involved in ART and Surrogacy procedures.

4.5.4 The clause is adopted without any change.

CLAUSE 6 & 7

4.6 Clause 6 stipulates that the State Board shall be constituted under sub-section (1) of section 24 of the Surrogacy Act shall be the State Board for the purposes of the proposed legislation.

4.6.1 Clause 7 seeks to provide that subject to the provisions of the proposed legislation and the rules made thereunder, the provisions of the Surrogacy Act will apply relating to-

S. No	*Clause of Surrogacy(Regulation) Bill 2020*	*Provisions*
(i)	*Clause 24*	*constitution of the State Surrogacy Board;*

(i)	*Clause 25*	*composition of the State Board;*
(ii)	*Clause 26*	*term of office of Members of the State Board*
(iii)	*Clause 27*	*meetings of the State Board*
(iv)	*Clause 28*	*vacancies, etc., not to invalidate proceedings of the State Board*
(v)	*Clause 29*	*disqualifications for appointment as Member of the State Board*
(vi)	*Clause 30*	*temporary association of persons with the State Board for particular purposes*
(vii)	*Clause 31*	*authentication of orders and other instruments of the State Board*
(viii)	*Clause 32*	*eligibility of Members of the State Board for re-appointment, shall, mutatis mutandis, apply, so far as may be, in relation to assisted reproductive technology as they apply in relation to surrogacy, as if they are enacted under this Act*

Clause 24(1) of the Surrogacy (Regulation) Bill 2020 stipulates that each State and Union territory having Legislature shall constitute a Board to be known as the State Surrogacy Board or the Union territory Surrogacy Board, as the case may be.

According to Clause 25, the State Board shall consist of—

(a) the Minister in-charge of Health and Family Welfare in the State, Chairperson, ex officio;

(b) the Secretary in-charge of the Department of Health and Family Welfare, Vice-Chairperson, ex officio;

(c) Secretaries or Commissioners in charge of the Departments of Women and Child Development, Social Welfare, Law and Justice and Home Affairs or their nominees, members, ex officio;

(d) Director General of Health and Family Welfare of the State Government, member, ex officio;

(e) three women members of the State Legislative Assembly or Union territory Legislative Council, members, ex officio;

(f) ten expert members to be appointed by the State Government in such manner as may be prescribed, two each from amongst—

(i) eminent medical geneticists or embryologists;

(ii) eminent gynecologists and obstetricians (**)
(iii) eminent social scientists;
(iv) representatives of women welfare organisations; and
(v) representatives from civil society working on women's health and child issues, possessing such qualifications and experiences as may be prescribed;

(g) an officer not below the rank of Joint Secretary to the State Government in charge of Family Welfare, who shall be the Member-Secretary, ex officio.

SUGGESTIONS:

4.6.2 ISAR submitted that there should be inclusion of regional, renowned and committed ART practitioners in the State Board in administrative post so that the correct interpretation and effective application of the provisions of the bill is facilitated and the conflicting issues of PCPNDT Bill are avoided.

4.6.3 The appointment of the above persons should not necessarily be from Government institutions but also from private hospitals and having at least 5 years experience in the field of ART as not many Government hospitals have IVF facilities.

DEPARTMENT'S RESPONSE:

4.6.4 The Department submitted that the provision is included in clause 7 of the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.6.5 The Committee notes that the Clause 7(ii) provides composition of State Board. The DHR clarified that the State Board constituted for the regulation of surrogacy as proposed in the Bill shall act as the Board for regulation of ART. The Committee observes that the suggestion of the stakeholder for inclusion of ART experts in the Bill have already been included in State Board for proper implementation of ART services. The Committee, therefore, recommends that while appointing ten expert members of the State Board, the State Government should assure inclusion of ART experts having ten years of experience in the State Board.

4.6.6 Since, the State Surrogacy Board will also regulate the ART services, therefore, the Committee strongly recommends that the State Board should be named as "State ART and Surrogacy Board".

4.6.7 Subject to the above recommendation, the clause is adopted.

CLAUSE 9

4.7 Clause 9 deals with establishment of National Registry of clinics and banks

Clause 9 reads as under:

> *The Central Government may, by notification, establish for the purposes of this Act, a Registry to be called the National Registry of Clinics and Banks in India with effect from such date as may be specified in that notification.*

SUGGESTIONS:

4.7.1 A "National Registry" body may be created under the Ministry of Women & Children (MWCD), Government of India, for all cases under the ART preview to serve as a Data Bank for future research purposes.

4.7.2 The Bill must mandatorily enjoin the Central Government to establish the Registry within ninety days of the Bill becoming law.

DEPARTMENT'S RESPONSE:

4.7.3 As per Chapter II Section 5 (c) the experts to be employed by clinics and banks will be laid by the National Board.

4.7.4 As per Section 9, the Central Government may, by notification, establish for the purposes of this Act, a Registry to be called the National Registry of Clinics and Banks in India and will be a part of the Ministry handling the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.7.5 With regard to bring National Registry under MWCD, the Committee is in agreement with the view of the DHR that National Registry of Clinics and Banks should be a part of the Ministry implementing the provisions of the said legislation.

4.7.6 The Committee is of the view that since the National Registry will be dealing with the registration of ART and Surrogacy clinics, therefore, the National Registry may be named as "National ART and Surrogacy Registry".

4.7.7 The Committee recommends that the National Registry should commence its functioning within 90 days of the ART Act coming into force.

4.7.8 Subject to the above recommendation, the clause is adopted.

CLAUSE 10

4.8 Clause 10 deals with composition of National Registry.

Clause 10 reads as under:

The National Registry referred to in section 9 shall consist of such scientific, technical, administrative and supportive staff and the terms and conditions of their service shall be such as may be prescribed.

SUGGESTIONS:

4.8.1 Indian Law Society, Pune suggested that the National Registry must be mandatorily established. The Bill presently leaves it to the discretion of the Central Government to set up the Registry.

DEPARTMENT'S RESPONSE:

4.8.2 National Registry will be mandatorily established as per section 9, 10 and 11.

OBSERVATIONS/RECOMMENDATIONS:

4.8.3 The Committee subscribes to the view of the Department that the National Registry will be mandatorily established as per the provision of Clause 9, 10 and 11 and act as the central database for both.

4.8.4 The clause is adopted without any change.

CLAUSE 12

4.9 Clause 12 deals with appointment of Registration Authority.

The Committee finds that the appointment of Appropriate Authority under clause 31 of Surrogacy (Regulation) Bill 2020 as reported by the Select Committee are congruent to appointment of Registration Authority under clause 12(1) of the ART (Regulation) Bill 2019 in respect of composition and functions which are enumerated below:

(1) The Central Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more Registration Authorities for each of the Union territories for the purposes of this Act.

(2) The State Government shall, within a period of ninety days from the date of commencement of this Act, by notification, appoint one or more Registration Authorities for the whole or any part of the State for the purposes of this Act.

(3) The Registration Authority, under sub-section (1) or sub-section (2), shall,—

(a) when appointed for the whole of the State or the Union territory, consist of—

(i) an officer of or above the rank of the Joint Secretary of the Health and Family Welfare Department—Chairperson, ex officio;
(ii) an officer of or above the rank of the Joint Director of the Health and Family Welfare Department — Vice Chairperson, ex officio;
(iii) an eminent woman representing women's organisation—member;
(iv) an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary—member, ex officio; and
(v) an eminent registered medical practitioner—member: Provided that any vacancy occurring therein shall be filled within one month of the occurrence of such vacancy;

(b) when appointed for any part of the State or the Union territory, the officers of such other rank as the State Government or the Central Government, as the case may be, may deem fit.

(4) The members of Registration Authority, other than ex officio members, shall receive only compensatory travelling expenses for attending the meetings of such Authority.

The Committee further finds that the functions of the Registration Authority as mentioned in clause 13 of ART (Regulation) Bill 2020 and the functions of Appropriate Authority as enumerated under clause 34 of the Surrogacy (Regulation) Bill 2020 are similar as enumerated below:

a) to grant, suspend or cancel registration of a clinic or bank;

(b) to enforce the standards to be fulfilled by the clinic or bank;

(c) to investigate complaints of breach of the provisions of this Act, rules and regulations made thereunder and take legal action as per provisions of this Act;

(d) to take appropriate legal action against the misuse of assisted reproductive technology by any person and also to initiate independent investigations in such matter;

(e) to supervise the implementation of the provisions of this Act and the rules and regulations made thereunder;

(f) to recommend to the National Board and State Boards about the modifications required in the rules and regulations in accordance with changes in technology or social conditions;

(g) to take action after investigation of complaints received by it against the assisted reproductive technology clinics or banks; and(h) such other functions as may be prescribed

SUGGESTIONS:

4.9.1 With respect to clause 12 stakeholders have made the following suggestions:

(i) The registration authority should have a gynaecologist with knowledge of ART.
(ii) The registering authority should have adequate capacity to ensure that the standards are followed. The personnel in this clinic are certified as trained and knowledgeable on these standards.
(iii) As the Registration Authority under Sec 12 has power to take disciplinary actions, conduct inquiry, summon and even carry out searches and seizures as per provisions of Code of Criminal Procedure (CrPC), 1973, presence of a person having background of law would ensure balanced and smooth during disciplinary procedure while conducting inquiry against doctors/clinics.
(iv) All clinics that apply for registration under this Act should be registered under the State Clinical Establishment Act (CEA) where promulgated. The cost of treatment and compliance with standard treatment guidelines could be regulated by bringing the ART clinics/banks within the purview of the Clinical Establishments Act.
(v) The inspection as mentioned in Section 16 (5) (Grant of Registration) should be the role of the Registration Authority instead of the State Board.

DEPARTMENT'S RESPONSE:

4.9.2 The Department agreed to the suggestion of having a gynaecologist with knowledge of ART in Registration Authority. With regard to having a person from judiciary background, the Department has clarified that the Registration authority has a law expert in the committee as per section 12. On the suggestion of registering clinics under Clinical Establishment Act (CEA), the Department submitted that the clinics will be registered by the Registration authority.

OBSERVATIONS/RECOMMENDATIONS:

4.9.3 The Committee finds the duplication of institutional arrangement almost having the same composition, functions and powers in the name of Appropriate Authority under clause 33 to clause 35 in Surrogacy (Regulation) Bill 2020 as reported by the Select Committee and the provision of Registration Authority under clause 12 to clause

14 in ART (Regulation) Bill 2020. The Committee does not appreciate the plethora of institutional structure in the regulation of Surrogacy/ART clinics and banks as the same would create stumbling block in implementing the provisions of the two Acts and Rules and Regulations made thereunder. The Committee, therefore, recommends that the Government should have one common institution in the State in place of Appropriate Authority and Registration Authority to discharge almost same and similar functions. The common institution for both ART and Surrogacy services may be named as "Appropriate ART and Surrogacy Registration Authority (AASRA)" as implementing agency for both ART Act and Surrogacy (Regulation) Act.

4.9.4 The Committee, subscribing to the views of the stakeholders, recommends that the Registration Authority must include a gynaecologist with adequate knowledge and ten years experience in the field of ART. As regards the suggestion to register clinics under Clinical Establishment Act (CEA), the Committee notes that CEA aims to streamline healthcare services across the country, while ensuring private hospitals do not engage in unethical practices. However, it has not been enforced across all the States/UTs. Each State has passed its own rules, and accordingly, the procedure followed for obtaining the license also varies. The Committee, therefore, endorses the view of the Department that registration of ART clinics should be done through Registration Authority.

4.9.5 Subject to the above recommendation, the clause is adopted.

CLAUSE 15

4.10 Clause 15 deals with registration of assisted reproductive technology clinic or assisted reproductive technology bank.

Clause 15 (2) reads as under:

Clause 15 (2) Every application for registration under sub-section (1) shall be made to the National Registry through State Board in such form, manner and shall be accompanied by such fees as may be prescribed.

OBSERVATIONS/RECOMMENDATIONS:

4.10.1 The Committee believes that clause 13 (a) and clause 15(2) contravenes each other. The Committee recommends that the application for registration should be made to National registry through Appropriate ART and Surrogacy Registration Authority instead through State Board as mentioned in clause 15(2). Accordingly, the Committee recommends that the clause may be amended as under:

"*Every application for registration under sub-section (1) shall be made to the National Registry through Appropriate ART and Surrogacy Registration Authority (AASRA) in such form, manner and shall be accompanied by such fees as may be prescribed."*

4.10.2 Subject to the above recommendation, the clause is adopted.

CLAUSE 16

4.11 Clause 16 deals with Grant of registration.

Clause 16(2) reads as under:

16 *(2) If the Registration Authority fails to grant the registration or reject the application, as the case may be, as provided under sub-section (1), the assisted reproductive clinic or bank shall be deemed to have been registered, and the Registration Authority shall within a period of seven days from the expiry of the said period of thirty days specified under sub-section (1), provide a registration number to the applicant.*

SUGGESTIONS:

4.11.1 One stakeholder suggested that deemed registration should not be given in case the Registration Authority fails to grant registration or reject the application within the stipulated period.

DEPARTMENT'S RESPONSE:

4.11.2 The Department agreed to the views of the Stakeholder.

OBSERVATIONS/RECOMMENDATIONS:

4.11.3 The Committee recommends that the Registration Authority may record in writing, the reasons for the failure to process the application within the prescribed period of thirty days. The Committee perceives that in provision under clause 16(2) can be used as double-edged sword as the provision entails undue discretionary power to the Registration Authority to linger the decision either in granting registration or not rejecting the application within 30 days and allow automatic registration. The Committee, therefore, recommends that the Registration Authority must act proactively in discharging its responsibilities with due diligence by having proper verification/inspection before granting registration within stipulated time of 30 days and in no case automatic registration be granted without ensuring adequate physical infrastructure and placement of ART expertise at the ART Banks and clinics. The Committee, therefore, recommends that the Clause 16(2) may accordingly be amended.

4.11.4 The Committee further recommends that for insertion of the sub clause (7) in clause 16 as under:

"The certificate of Registration shall be displayed by the ART clinic at a conspicuous place. The certificate must contain the validity of duration of registration certificate".

4.11.5 Subject to the above recommendation, the clause is adopted.

CLAUSE 18

4.12 Clause 18 deals with suspension or cancellation of registration.

Clause 18 reads as under:

(1) The Registration Authority may on receipt of a complaint, issue a notice to the clinic or bank to show cause as to why its registration should not be suspended or cancelled for the reasons mentioned in the notice.

(2) If after giving a reasonable opportunity of being heard to the clinic or bank, the Registration Authority is satisfied that there has been a breach of the provision of this Act or the rules or regulations made thereunder or if the data obtained from them periodically do not satisfy the provisions of this Act, the rules and regulations made thereunder, it may, without prejudice to any criminal action, suspend its registration for such period as it may deem fit or cancel its registration.

(3) On cancellation of registration, a copy of the cancellation letter shall be sent to the respective State Board and accordingly the State Board shall cancel the registration of such clinics and banks.

SUGGESTIONS:

4.12.1 With respect to clause 18, stakeholders have made the following suggestions:

(i) Registration Authority should not just act on receipt of complaint but should also conduct regular inspections of ART centres to ensure the standards are being maintained. The Registration Authority, responsible for enforcing minimum standards to be fulfilled by clinics or banks, may find deficiencies in the course of inspecting premises and documents of such clinics or banks. In these circumstances, the Registration Authority should be empowered to initiate appropriate action rather than wait for a complaint to be filed. As an example, the Human Fertilization and Embryology Authority in the UK has the power to initiate action either *suo moto* or on receipt of an application.

(ii) The Registration Authority is empowered to either suspend or cancel registration. The violations can result from cases of serious negligence, mistakes or be of a technical nature. In view of this, the Registration Authority should first determine the cause of the violation and thereafter impose any consequence.

(iii) The Registration Authority can suspend a license for such a period of time as it may be prescribed. In the interests of the rule of law, the Bill should specify the maximum period for which a suspension may be imposed. For example, licenses for clinics or banks in the UK cannot be imposed for a period exceeding three months at once.

(iv) The procedure and grounds for filing a complaint against ART clinic/bank to registration authorities should be clarified. Specification of grounds of complaint which may be taken/approved by registration authorities for issuing show cause notice to ART clinic will help the ART clinics to review their practices and protocols. It is in view of the fact that the assisted reproductive technology is unpredictable field where chances of conception and live birth rate depends on many factors and there can be many complaints just due to failure to achieve pregnancy.

DEPARTMENT'S RESPONSE:

4.12.2 The Department took the view that the details of modus operandi of Registration Authority will be elaborated in Rules and regulations. The clinics, banks, commissioning couple or any individual may also register a complaint in the court which has not been prohibited in the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.12.3 The Committee has taken into account the reply of DHR and is in agreement with the view that the clinics, banks, commissioning couple or any individual may also register a complaint with the judiciary system which has not been prohibited in the Bill. However, in order to avoid burdening of courts, redressal of grievances at the level of the Registration Authority may be explored. The Committee, in this regard, has been given to understand that as per clause 21(f) grievance cell will be part of every clinic and bank. However, the Committee believes that proper timeframe (within 30 days of receipt of complaint) should be provided within the Bill for proper redressal of grievances of patients concerned. The Committee understands that the procedure and grounds for filing a complaint against ART clinic/bank to registration authorities should be clarified. The specification of grounds of complaint which may be taken/approved by Registration Authorities for issuing show cause notice to ART clinic will help the ART clinics to review their practices and protocols. The Committee comprehends that the ART is unpredictable field where chances of conception and live birth rate depend on many factors and there can be many complaints due to failure to achieve pregnancy. The Committee, therefore, recommends for an Independent and Impartial Grievance Redressal cell should be established in the Registration Authority to deal with complaints against ART clinic/bank to Registration Authority.

4.12.4 The Committee is of the view that proactive action cannot be taken if Registration Authority merely acts on receipt of complaint and therefore, Committee feels that *suo moto* cognizance of offence should also be taken by the Registration Authority.

4.12.5 The Committee further notes that as per clause 18 (2), the Registration Authority can suspend or cancel the registration of clinic or bank while as per clause 18 (3), the copy of the cancellation letter shall be sent to respective State Board which shall cancel the registration of such clinics. Clauses 18 (2) and 18 (3) have raised ambiguity whether the State Board has the final authority to cancel registration or only

Registration Authority has the sole right to do so. Therefore, the Committee recommends that the language of clause 18 (3) should be made clear and it should specify that on cancellation of registration, a copy of the cancellation letter may be forwarded to State Board and accordingly State Board shall remove the name of that bank or clinic from list of registered clinics or banks. The Committee recommends that the word "cancel" in clause 18(3) should be replaced with "strike out".

4.12.6 Subject to the above recommendation, the clause is adopted.

CLAUSE 19

4.13 Clause 19 deals with Appeal.

Clause 19 reads as under:

The clinic or bank or the commissioning couple or the woman may, within a period of thirty days from the date of receipt of the communication relating to order of rejection of application, suspension or cancellation of registration passed by the Registration Authority under section 16 or section 18, prefer an appeal against such order to— (a) the State Government, where the appeal is against the order of the Registration Authority of a State; (b) the Central Government, where the appeal is against the order of the Registration Authority of a Union territory, in such manner as may be prescribed.

SUGGESTIONS:

4.13.1 The Bill designated the State or the Central Government as the appellate authority. In the interest of separation of powers, it is required that modern regulatory system requires a shift away from systems where appeals from regulatory decisions lie with the government. The composition of the grievance cell and that it should have appropriate number of neutral party/third party too, apart from, the clinic/bank representatives.

DEPARTMENT'S RESPONSE:

4.13.2 A provision for appeal has been kept in section 19. The clinics, banks, commissioning couple or any individual may also register a complaint with the court which has not been prohibited in the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.13.3 The Committee has already recommended for constitution of "Independent and Impartial Grievance Redressal Cell" for redressal of grievances of all Stakeholders involved in ART/ Surrogacy procedure. The Committee, however, also recommends that the clause may be modified to allow the aggrieved party to approach the court only after exhausting all the option of redressal of grievances at various forums, including the Grievance Redressal Cell by the clinics/banks or commissioning couple

before making an appeal under the provisions of the Bill in order to save the time of the courts from avoidable litigations.

4.13.4 Subject to the above recommendation, the clause is adopted.

CLAUSE 21

4.14 Clause 21 deals with general duties of assisted reproductive technology clinics and banks.

Clause 21(a) reads as under:

21 (a) The clinics and banks shall perform the following duties, namely:— (a) the clinics and banks shall ensure that commissioning couple, woman and donors of gametes are eligible to avail the assisted reproductive technology procedures subject to such criteria as may be prescribed.

SUGGESTIONS:

4.14.1 With respect to clause 21(a), the stakeholders have suggested that the following person should also be allowed to avail the services of ART:

(i) Person with HIV who is at risk of transmitting infection to the uninfected partner (and the foetus). Certain ART techniques can reduce the risk of transmission of HIV to the partner and the child. When the man is HIV+ and the female partner is uninfected, sperm washing, testing of washed sperm for HIV, IVF and ICSI (Intra Cytoplasmic Sperm Injection) have shown promising results in significantly reducing the risk of transmission of HIV to the partner and child. When the woman is HIV+, a combination of artificial insemination and antiretroviral therapy can help in avoiding transmission of the virus to the uninfected partner and offspring.

(ii) Person with intersex characteristics are often involuntarily subjected to medical interventions in order to make them conform to sex stereotypes. These medical procedures can also result in fertility loss. Infertility therefore affects many intersex individuals. They may need ARTs including donor gametes to fulfill reproductive desires.

(iii) Couples who wish to prevent transmission of genetic diseases to their child.

DEPARTMENT'S RESPONSE:

4.14.2 The Department submitted that this will be a part of rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.14.3 The Committee, therefore, recommends that people with medical conditions viz with genetic diseases should be allowed to access the facility of ART services. The Committee believes that the Department may consider incorporating the provision of ART services to individuals with any medical condition.

4.14.4 Clause 21(e) reads as under:

> *21 (e) the clinics and banks shall ensure that information about the commissioning couple, woman and donor shall be kept confidential and the information about treatment shall not be disclosed to anyone except to the database to be maintained by the National Registry, in a medical emergency at the request of the commissioning couple to whom the information relates, or by an order of a court of competent jurisdiction;*

SUGGESTIONS:

4.14.5 The stakeholders have submitted the following:

(i) Collection and storage of medical data must conform to the stipulations laid down by the Supreme Court in KS Puttaswamy (Retd.) v UOL, and the provision of National Digital Health Blueprint.

(ii) The Bill should also conform to the provisions of the Personal Data Protection (PDP) Bill 2019, once it becomes a law. The Bill must categorically state that only non-identifiable data can be collected by the Registry.

(iii) The personal Data must also be aligned with:

(a) The personal Data protection Bill, 2019 which codifies globally recognized data protection principles and rights of data principal that have also been quoted with approval in the Puttaswamy judgment; and

(b) The National Digital Health Blueprint (NDHB) issued by the MoHFW, which categorically states that all digital health data are head at 3 levels (national state and facility levels) in a decentralized manner, following the principle of minimality at each level. It further states that patient data shall be held at the point of care, which in this case would mean the registered Banks and ART clinics.

(c) SAMA submitted that it is imperative that the data given to the National Registry is not misused, and that the data provided to them should be anonymous and unlinked. If research is being

carried out by the ART Clinic or ART Bank, they need to follow the rules and regulations with regard to research under the Drugs and Cosmetics Act and Rules, and other guidelines too.

DEPARTMENT'S RESPONSE:

4.14.6 The Department submitted that confidentiality is already mentioned in clause 21(e) and clause 27(6) of the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.14.7 The Personal Data Protection (PDP) Bill 2019 states that the right to privacy is a fundamental right and it is necessary to protect personal data as an essential facet of informational privacy. The Committee feels that personal data should be transformed or converted to a form in which a data principal (owner/citizen) cannot be identified. The Committee notes that anonymization is a one-way process whereby the data once anonymized, cannot be related to any person subsequently. The Committee, therefore, recommends that provisions may be included in the Bill to ensure that data is anonymized at the primary source, mostly at the facility level so as to minimize its leakage while in transit. The Committee is of the considered view that confidentiality of data should conform to the law as laid down in the landmark judgment of Justice K.S Puttaswamy (Retd.) v. UOI, the personal Data protection Bill, 2019 and the National Digital Health Blueprint (NDHB) issued by the Ministry of Health & Family Welfare.

4.14.8 Clause 21(f) reads as under:

> *21 (f) every clinic and every bank shall maintain a grievance cell in respect of matters relating to such clinics and banks and the manner of making a complaint before such grievance cell shall be such as may be prescribed.*

SUGGESTIONS:

4.14.9 A grievance guidance document should be provided and the mechanism should be explained.

DEPARTMENT'S RESPONSE:

4.14.10 The Department submitted that the grievance cell will be a part of the Registration Authority.

OBSERVATIONS/RECOMMENDATIONS:

4.14.11 The Committee notes that clause 21(f) deals with grievance cell in ART Banks and clinics only. There is no reference of grievance cell in Registration Authority in the Bill. The Committee feels that mechanism, composition and functions of redressal of grievance in clinics and banks should be specified. The Committee recommends that the

grievance cell in Registration Authority should be also a part of the Bill and accordingly clause 21(f) (ii) may be added to include grievance cell for Registration Authority and amended to include a new provision for the same with details of its mechanism, composition and functions.

4.14.12 The Committee subscribes the view of the Stakeholders that grievance redressal guidelines may be provided to clinics/banks to strengthen the grievance redress machinery so as to make the administration more responsive to the needs of the people availing ART services. The time limit for disposal of complaints should be fixed and strictly adhered to and systemic changes should be incorporated to address grievances. The Committee, therefore, recommends that the Department may provide Grievance Guidelines Document to every clinic/bank to make the grievance cell more effective and robust with uniform structural and functional set-up.

4.14.13 Clause 21(g) reads as under:

> *21(g) the clinics shall apply the assisted reproductive technology services,— (i) to a woman above the legal age of marriage and below the age of fifty years; (ii) to a man above the legal age of marriage and below the age of fifty-five years*

SUGGESTIONS:

4.14.14 One stakeholder has informed that the complications of IVF (Ovarian hyperstimulation syndrome, OHSS) are higher in younger woman. The earlier guideline had kept the cut off at 21 years. It has been suggested to keep the lower age limit for woman more than 20 years to ensure their safety. The upper age limit for the women/man should be decided based on factors viz i) risk to maternal health due to pregnancy at advanced maternal age (ii) care of child until 18 years and average life expectancy in India.

4.14.15 The upper limit for woman should not be beyond 45 years and for man, it should be not be beyond 50 years. The combined age of the couple (woman and man) should not be beyond 90 years (this requirement is same as for adoption in India)

DEPARTMENT'S RESPONSE:

4.14.16 The criterion of age limit for a man and woman to avail ART services has been drafted in consonance with the provision of Surrogacy Bill 2019.

OBSERVATIONS/RECOMMENDATIONS:

4.14.17 The Committee observes that the DHR has agreed to the stakeholders' suggestions to remove the phrase "legal age of marriage" from the definition of woman for approaching an ART centre as lower age of marriage is acceptable in some religions. The Committee observes that the ICMR Guidelines stipulates minimum of 20 years age for woman availing ART services. The Committee has already recommended removal of the term "legal age of marriage" and prescribed that specific age i.e. 21 years in the definition of "woman" as mentioned in the Bill under clause 2(x), therefore,

the Committee reiterates the minimum age criteria of 21 years for woman and man for availing ART services. The upper age limit for woman and man may be 50 and 55 years, respectively, as recommended by the Select Committee on Surrogacy (Regulation) Bill 2020.

4.14.18 Subject to the above recommendation, the clause is adopted.

CLAUSE 22

4.15 Clause 22 deals with written informed consent.

Clause 22(a) reads as under:

22 (a) the written consent of all the parties seeking assisted reproductive technology

SUGGESTIONS:

4.15.1 The Committee has received a suggestion to have informed consent from persons availing ART services that requires detailed information and explanation all the risks, alternatives, possible outcomes, procedures, costs, to enable an informed decision in a form and language that is well understood by persons accessing ART services, including gamete donors.

DEPARTMENT'S RESPONSE:

4.15.2 This will be elaborated in rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.15.3 The Committee endorses the views of the stakeholders regarding informed consent for parties undergoing ART procedure due to medical, ethical and psychological issues of such treatment. The Committee is of the considered view that informed consent honours the principles of human autonomy and self determination and is an important aspect of health literacy. Such process of communication helps the patients to obtain relevant medical information about the risks, benefits, and alternatives of the proposed treatment from their health-care provider. The ART procedure involves invasive tests and treatments with significant risks. The Committee understands that parties concerned with ART services can make informed and voluntary choices to accept or decline the procedure. The Committee is of the firm view that informed consent is a mechanism through which parties are able to make autonomous choices about their health care and their safety. Since the Department has assured to consider the Stakeholders' suggestion while framing rules, the Committee recommends the inclusion of informed consent from all the persons concerned with ART services.

4.15.4 Clause 22(b) reads as under:

22 (b) an insurance coverage of such amount and for such period as may be prescribed in favour of the oocyte donor by the commissioning couple or woman from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the provisions of the Insurance Regulatory and Development Authority Act, 1999.

SUGGESTIONS:

4.15.5 With respect to clause 22(b), the stakeholders have made the following suggestions:

(i) Insurance of Child born out of this arrangement may also be ensured.
(ii) Maternity benefit may be provided to the donor woman in case she is working.
(iii) The bill should include compensation/reimbursement to cover the efforts of the gamete donor as oocyte donation entails the donor getting injectable medicines daily for 11 days, she has to regularly go to the clinic and ultimately undergo the surgical procedure of oocyte retrieval under anaesthesia which could result in loss of wages and sometimes even death.
(iv) In the definition of cryo-preserve, freezing of ovarian and testicular tissues must also be included alongwith the freezing of gametes, zygotes and the embryos.

DEPARTMENT'S RESPONSE:

4.15.6 The Department responded to the concerns of the stakeholders as under:

(i) Child insurance will be a part of Rules and Regulations.
(ii) The maternity benefit will be as per Medical Termination of Pregnancy Act 1971.
(iii) The Bill is following an Altruistic Approach similar to Human Transplantation Organ Act and the Surrogacy (Regulation) Bill 2019.

OBSERVATIONS/RECOMMENDATIONS:

4.15.7 As clarified by the Department, the maternity benefit will be provided to donor woman as per the MTP Act. However, the said Act has a provision of maternity benefit in case of a miscarriage. The Committee, therefore, recommends that the Department should clearly specify the provision for maternity benefit for donor woman in the Bill as the procedure of retrieval of oocytes is complex involving risks and simultaneously resulting in loss of wages for donor women if she is working. Further, with respect to providing insurance to oocyte donors, the Bill needs to specify the nature of insurance, period of insurance and the sum assured under the insurance coverage from an insurance company or an agent recognized by Insurance Regulatory and Development Authority (IRDA). The Committee finds that in the Surrogacy (Regulation) Bill 2020 as reported by the Select Committee, an insurance coverage for the period of 36 months have been provided to the surrogate mother where she has to sail through the whole

pregnancy period, however, oocyte donor has to undergo painful procedure where medicines are injected daily for 11 days and she has to regularly visit the clinic and ultimately undergo the surgical procedure of oocyte retrieval under anaesthesia. The medical procedure may entail side effect including infertility, therefore, the Committee recommends that an insurance coverage of such amount and in such manner as may be prescribed in favour of the oocyte donor for a period of at least 12 months may be mentioned in the Bill itself.

4.15.8 The Committee observes that the Bill does not provide for the social security insurance for the child in the event of death of commissioning couple. The Committee is of the view that social security insurance should be provided to both the child and the donor. The Committee would, therefore, like the Department of Health Research to provide for insurance for the child in case of unexpected contingencies like accidental death of the commissioning couple or divorce during the process of ART.

4.15.9 In clause 22 explanation (i), in the definition of "cryo-preserve", freezing of ovarian and testicular tissues should also be included alongwith the freezing of gametes, zygotes and the embryos as in case of cancer patients, after the treatment for malignancy patient can have their babies by seeking ART services.

4.15.10 Subject to the above recommendation, the clause is adopted.

CLAUSE 23

4.16 Clause 23 deals with duties of Assisted Reproductive Technology clinics and banks to keep accurate records.

Clause 23(b) reads as under:

23 (b) all clinics and banks shall, as and when the National Registry is established, submit by online-(i) all information available with them in regard to progress of the commissioning couple or woman; and (ii) information about number of donors (sperm and oocyte), screened, maintained and supplied and the like to the National Registry within a period of one month from the date of receipt of such information;

SUGGESTIONS:

4.16.1 Some stakeholders suggested that the information should be anonymized if it is merely for the purpose of monitoring the clinics and banks else, information/data submission has scope for misuse. If the information is needed for research purposes then data/information should be submitted following receipts of written research must also be put in place and followed stringently. It has been submitted that while it should be mandatory for ART Clinics and ART Banks to report any untoward incident or problem that might occur before, during or after the ART procedure, as has been stated through grievance mechanisms in the Bill. However, reporting online entails risks therefore, other safer methods and means should be followed.

DEPARTMENT'S RESPONSE:

4.16.2 The Department submitted that the suggestion may be considered.

OBSERVATIONS/RECOMMENDATIONS:

4.16.3 The Committee is in agreement with the views of the stakeholders that the data sent to the National Registry needs to be anonymized as it would help in protecting privacy of donor and commissioning couple. In this context, personal information of the donors such as name, address together with any other information which could lead to their identification by the recipient of the information could be removed. Planning of anonymization should be done before data collection as it would produce both informed consent and would require less resource intensive process during data anonymization. The Committee, therefore, recommends that safeguards should be in place before data is made available for research which include technical barriers to access that data, like encryption, user licenses, applying anonymization. The Committee, therefore, recommends the Department to make an express provision of punishment in case of data breaches. The Committee also recommends that a provision of Uniform Software for National Registry would ensure better integration, data management and privacy protection of donors and commissioning couple.

4.16.4 Clause 23(c) reads as under:

> *23(c) the records maintained under clause (a) shall be maintained for at least a period of ten years, upon the expiry of which the clinic and bank shall transfer the records to a central database of the National Registry.*

SUGGESTIONS:

4.15.5 Indian Law Society, Pune, submitted that the provision of clause 23 (c) as contrary to the principles of storage limitation and purpose limitation, and differs from the current practices of maintaining medical records for a specified time only. The Bill must specify a period for which personally identifiable medical records are to be kept with the clinics and banks. Such records should be destroyed after the expiry of that period. It has been suggested that the transfer of identifiable medical records to the National Registry should not be done.

4.15.6 Storing medical data permanently is contrary to the data protection principles of ‘purpose limitation’ and ‘storage limitation' which mean that personal data should be collected and processed for a specific purpose, be limited in time and should not be kept for longer period than necessary for the intended objective. Most laws only provide a certain mandatory period of storage of records beyond which the records are destroyed. The following instances may be considered to arrive at the conclusion in the matter:

(i) Regulation 1.3.1 of the Indian Medical Council (professional conduct, etiquette and Ethics) Regulations, 2002 requires physicians to maintain the medical records of a period of three years only.
(ii) Under the Pre conception and Pre Natal Diagnostic Techniques Act, 1994, all records of pregnant women who have undergone an ultra-sonography must be preserved for a period of two years.
(iii) Under the Medical of pregnancy Act 1971, hospitals have to maintain an admission Register of women who have terminated their pregnancy.
(iv) Under regulation 5 of the MTP Regulations 2003, the record must be destroyed on the expiry of a period of five years from the date of the last entry. The Act stresses the importance of security of information. Hospital is prohibited from disclosing the information contained to anyone. The admission register is considered 'secret' and stored in safe custody of the head of the hospital.

DEPARTMENT'S RESPONSE:

4.16.7 Confidentiality is already mention in Section 21(e) the clinics and banks shall ensure that information about the commissioning couple, woman and donor shall be kept confidential and the information about treatment shall not be disclosed to anyone except to the database to be maintained by the National Registry, in a medical emergency at the request of the commissioning couple to whom the information relates, or by an order of a court of competent jurisdiction;

4.16.8 Section 27(6) A bank shall obtain all necessary information in respect of a sperm or oocyte donor, including the name, identity and address of such donor, in such manner as may be prescribed, and shall undertake in writing from such donor about the confidentiality of such information.

OBSERVATIONS/RECOMMENDATIONS:

4.16.9 The Committee is in favour of the plea made by the stakeholders that storing medical data permanently is contrary to the data protection principles of 'purpose limitation' and 'storage limitation' which mean that personal data should be collected and processed for a specific purpose, be limited in time, and should not be kept for longer period than necessary for the intended objective. The Committee understands the maintenance of records for a period of ten years by clinics and banks for use in case of medical emergency for child born through ART and therefore can be utilized by the commissioning couple. The Committee, accordingly, recommends the Department to consider the suggestion of Stakeholders to fix time duration for which records are maintained in the central database of National Registry thus adhering to the principle of 'purpose limitation' and 'storage limitation'.

4.16.10 Subject to the above recommendation, the clause is adopted.

CLAUSE 24

4.17 Clause 24 deals with duties of assisted reproductive technology clinics using human gametes and embryos.

Clause 24(a) reads as under:

24 (a) the clinics shall harvest oocytes in such manner as may be specified by regulations.

SUGGESTIONS:

4.17.1 SAMA- Resource Group for Women and Health suggested deleting "harvest" and replacing it with "retrieve". The word harvest is misleading and implies a large number of oocyte retrieval and storage which should not be permitted. They supported the decision to retrieve seven oocytes from an egg donor as higher number of extraction of oocytes entails risk. It has also been submitted that the woman should be provided complete information in this regard in advance as to how many oocytes will be retrieved from her, as well as possible adverse events or Serious Adverse Events should also be communicated to her orally and in writing, prior to undertaking the ART procedure.

DEPARTMENT'S RESPONSE:

4.17.2 The Department submitted replacing the word "harvest" by "retrieve" is agreeable.

OBSERVATIONS/RECOMMENDATIONS:

4.17.3 The Committee is in agreement with the view of the stakeholder to substitute the word "harvest" with the word "retrieve" in clause 24(a). The Committee, therefore, recommends that the word "harvest" may be replaced by the word "retrieve" in the said clause and other relevant provision of the Bill. Necessary modifications may also be made in Clause 43(2) (a).

4.17.4 Clause 24(b) reads as under:

24 (b) the number of oocytes or embryos that may be placed in the uterus of a woman during the treatment cycle shall be such as may be specified by the regulations;

SUGGESTIONS:

4.17.5 The stakeholders submitted that the number of embryos permissible should be limited to a maximum of three because as per scientific evidence there appears no benefit of transferring more than three embryos. Current ART literature supports transfer of single or double embryos with three embryos transfer in exceptional cases. The risk of multiple pregnancies rises dramatically, which can affect mother's health and lead to premature births. With introduction of effective freezing protocol, the excess embryos can always be frozen and transferred later if the IVF is unsuccessful. Cryopreservation of extra embryos is ideal

when there are excess embryos and should be recommended as it will increase the cumulative pregnancy rate.

DEPARTMENT'S RESPONSE:

4.17.6 The Department submitted that the suggestion may be considered and transfer of not more than two embryos may be mentioned in the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.17.7 The Committee finds that the DHR is subscribing to the views of the Stakeholders that more number of embryo transfers can lead to multiple pregnancies which can be risky for both the mother and child. Also, according to the National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India by ICMR, not more than three oocytes or embryos may be placed in a woman in any one cycle. The Committee, taking into account the existing Guidelines of ICMR over the number of oocytes or embryos that may be placed in the uterus of a woman, recommends that not be more than three oocyte or embryos may be placed in the uterus of woman and it should be specified in Bill itself. The Committee understands that with introduction of effective freezing protocol the excess oocytes can always be frozen and used later in case IVF is not successful in earlier attempt.

4.17.8 Clause 24(f) reads as under:

> *24(f) the collection of gametes posthumously shall be done only if prior consent of the commissioning couple is available*

SUGGESTIONS:

4.17.9 One of the stakeholder submitted that Posthumous reproduction using ARTs can take place in two scenarios: (1) retrieval of gametes is done after death of a person, and subsequent fertilisation and pregnancy takes place by using the gametes of the deceased by their partner; and (2) retrieval of gametes and/or fertilisation and cryopreservation of embryos takes place before the death of a partner (i.e. the couple had already initiated ART procedures before the death of one partner). The first scenario may arise in the sudden and unanticipated death of the partner, and the decision to collect gametes from the deceased has to be made quickly as the gametes remain viable only for a limited duration after death. Sperm retrieval and oocyte collection have to be done within 24-36 hours after death.

4.17.10 Further, it has been pointed out that in such cases, inferred consent may be ascertained from the surviving partner of the deceased to determine if the deceased had discussed a wish for posthumous gamete retrieval and would have approved of such a procedure. For example, in Australia, the National Health and Medical Research Council's ethical Guidelines on the use of assisted reproduction technology in clinical practice and research allow for posthumous collection of gametes by the spouse/partner when it is

intended for use by the surviving spouse for the purpose of reproduction and when "there is some evidence that the dying or deceased person would have supported the posthumous use of their gametes by the surviving partner, or at the very least, there is no evidence that the deceased or dying person had previously expressed that they do not wish for this to occur".

DEPARTMENT'S RESPONSE:

4.17.11 The Ministry has submitted that Posthumous use of embryos may also be considered to be mentioned in the Bill.

OBSERVATIONS/RECOMMENDATIONS:

4.17.12 The Committee notes that posthumous retrieval of gametes raises diverse range of ethical and legal conundrum such as whether it is possible to presume the deceased's intentions or deceased's inferred consent; status of deceased's partner and parents in determining the deceased's interests; and whether posthumous reproduction is against the resulting child's best interests. The Committee is of the view that posthumous reproduction should be permitted, even in the absence of the deceased's prior consent unless the deceased person has previously objected to it or there are strong indications that the person would not have agreed the collection of gametes, posthumously. The Committee is of the opinion that decisions to prohibit posthumous reproduction should not be based solely on the principles of autonomy and bodily integrity, therefore, the deceased's inferred consent and the partner's interest in procreating and becoming a parent should be taken into account to arrive at the conclusion for posthumous retrieval of sperm and oocyte and its subsequent use for fertilization and pregnancy.

4.17.13 Subject to the above recommendation, the clause is adopted.

CLAUSE 25

4.18 Clause 25 deals with Pre-implantation Genetic Diagnosis.

Clause 25(1) reads as under:

25. (1) The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases or for such other purposes as may be prescribed.

SUGGESTIONS:

4.18.1 With respect to clause 25(1), stakeholders have made the following suggestions:

(i) One stakeholder submitted that the routine/ universal use of pre-implantation genetic testing (not diagnosis) is not supported by current scientific literature. The expertise/technical support is limited for the procedure and raises the cost factor and only few would be able to afford the procedure and will reduce access to IVF in the country where IVF is largely self-funded.

4.18.2 SAMA submitted that screening is premised eugenic consideration and allows for misuse and concerns of “designer babies” and suggested that issues like research ethics, permission from the appropriate authorities as far as research is concerned, all procedures that need to be followed for genetic testing and treatment are laid down in national and international rules and guidelines issued from time to time including ICMR guidelines should be added.

4.18.3 NIRRH-ICMR submitted that if PGT is made mandatory with the current technology being used, one would be causing damage to many embryos because of biopsy thereby reducing the chances of success for the patients.

DEPARTMENT'S RESPONSE:

4.18.4 The pre implantation genetic testing has been defined and is only screening pre-existing genetic diseases in couples with family history as mentioned in *25(1)*

OBSERVATIONS/RECOMMENDATIONS:

4.18.5 The Committee is aware that pre-implantation genetic diagnosis is used specifically when one or both genetic parents has a known genetic abnormality and is meant to prevent heritable genetic diseases in children born through ART, thereby, eliminating the option of pregnancy termination by unfavourable prenatal diagnosis. However, the Committee is of the view that the words "..or for such other purposes as may be prescribed" may be deleted to rule out scope for misuse of pre-implantation genetic testing. The word "only" may be used after "to screen the human embryo for known, pre-existing, heritable or genetic diseases including HIV, cancer, neurological disorders, down syndrome etc." Therefore, the amended provision may be read as under:

> ***“The Pre-implantation Genetic testing shall be used to screen the human embryo for known, pre-existing, heritable or genetic diseases only”***

4.18.6 Subject to the above recommendation, the clause is adopted.

CLAUSE 26

4.19 Clause 26 deals with Sex selection.

Clause 26(3) reads as under:

> *26 (3) A person shall not knowingly provide, prescribe or administer anything that shall ensure or increase the probability that an embryo shall be of a particular sex, or that shall identify the sex of an in-vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease.*

SUGGESTIONS:

4.19.1 With regard to use of pre-implantation genetic diagnosis to screen the embryo for pre-existing, heritable or genetic disease or as specified by the registration authority, some stakeholders submitted that caution needs to be taken before allowing and legalizing such pre-implantation genetic diagnosis in the Bill. Such screening can lead to "made-to-order" or "tailor-made" babies. There are a lot of ethical issues attached to such screening, and the power given to the Registration Authority to allow such specified diseases gives scope for any and every disease to be included in the pre-screening which could prove to be a dangerous proposition.

DEPARTMENT'S RESPONSE:

4.19.2 The Department has submitted that the suggestion of Stakeholders to take caution before allowing pre-implantation genetic diagnosis that may lead to manufacture of "tailor made babies" will be further elaborated in the rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.19.3 The Committee understands that if pre-implantation genetic testing is done as a part of infertility treatment and the information related to sex of the child is not gained through it, it will be free from problems of fairness in using the diagnosis. Nevertheless, the Committee believes that the sex linked disorders and diseases need specification in rules and regulations or the Bill risks promoting an impermissible programme of eugenics, inadvertently promoting sex determination & selection and resultantly could lead to unwarranted gender bias and social disorders. The Committee, therefore, believes that PCPNDT Act, 1994 should take care of sex-selection and the ART Bill must prevent sex-determination, with exceptions for treating the pre-existing disorders or genetic diseases. The Committee, therefore, is of the firm view that the Registration Authority must carefully evaluate each case and should only allow pre-implantation genetic diagnosis in cases where it is absolutely essential. The Committee emphasizes by reiterating that the ART legislation must prevent the scope for sex-determination and subsequent selection with stringent penal provisions. The Committee, therefore, accords the inherent spirit and intent of clause 26(3) but with a caution to prevent and prohibit the misuse of "Pre-implantation Genetic diagnosis" for 'made-to-order' or 'tailor-made babies' by retaining the penal provisions under clauses 32(2) and 33(2) of the ART Bill.

4.19.4 Subject to the above recommendation, the clause is adopted.

CLAUSE 27

4.20 Clause 27 deals with sourcing of gametes by assisted reproductive technology banks.

Clause 27(1) reads as under:

27 (1) The screening of gamete donors, the collection, screening and storage of semen; and provision of oocyte donor, shall be done only by a bank registered as an independent entity under the provisions of this Act.

SUGGESTIONS:

4.20.1 The Banks should be restricted to accepting and preserving eggs, sperms, etc. with adequate facilities for storage. The "bank" used in this Bill should mean a registered institution that receives and preserves/cryo-preserves sperm or semen, oocytes, towards providing these to registered ART clinics for ART procedures.

4.20.2 Given that the screening, examination of donors will require medical expertise, infrastructure, etc., the capacity of ART Banks to implement this needs more clarity and details whether such procedure for screening, expertise is envisaged in ART Banks.

DEPARTMENT'S RESPONSE:

4.20.3 The elaborate role of the ART Banks will be a part of rules and regulations.

OBSERVATIONS/RECOMMENDATIONS:

4.20.4 The attention of the Committee has been drawn to the role of ART Bank in supplying/arranging donors. The Committee fails to comprehend the mechanism through which oocyte donors would be arranged by ART Banks. The Committee with respect to clause 2 (d) has recommended for clear demarcation of the role of ART clinics and banks over procedure relating to screening, collection and storage. The Committee is of the view that the screening of gametes should be conducted under supervision of expert team while the Banks should be responsible for collection, storage and supply of gametes. The Committee underlines that ART procedure must be conducted at ART clinic only under supervision of ART experts. The Committee appreciates the apprehension of Stakeholders that ART experts are more likely to be available with ART clinics rather than ART Banks. The Committee, therefore, subscribing to the view of the Stakeholders, recommends that responsibility of screening of gamete donors may be assigned to ART clinics.

4.20.5 Clause 27(3) reads as under:

27 (3) *A bank shall not supply the sperm or oocyte of a single donor to more than one commissioning couple.*

SUGGESTIONS:

4.20.6 One stakeholder submitted that the limit of gamete donation should be specified (5-10) and this can only be made fool proof only if sperm donation is linked to Aadhar or other ID and sperm banks should be responsible for ensuring this.

DEPARTMENT'S RESPONSE:

4.20.7 The Department has submitted that the sharing of gametes is prohibited to avoid parental issues to multiple children and this will affect the future of the child.

OBSERVATIONS/RECOMMENDATIONS:

4.20.8 The Committee is in agreement with the view of the Department that the single source of sperm or oocyte should be supplied to single commissioning couple to avoid parental issues in future.

4.20.9 Clause 27(4) reads as under:

> *27 (4) An oocyte donor shall be an ever married woman having at least one live child of her own with a minimum age of three years and to donate oocytes only once in her life and not more than seven oocyte shall be retrieved from the oocyte donor.*

SUGGESTIONS:

4.20.10 Some stakeholders appreciated the move to limit the oocyte donation to only once in life time of oocyte donor. While some stakeholders argued that this would curb the personal autonomy of unmarried or childless women in decisions related to their bodily integrity. The view is taken that such restrictions are not medically necessary. It is being apprehended that there would also be a shortage of donor oocytes. If the intent of the Bill is to make ARTs more accessible and equitably governed then these restrictive notion should be removed. This need to be reconsidered in favour of respecting the autonomy and freedom of women's reproductive choices.

4.20.11 Keeping in mind many practical and technical problems related to nuances of the response of human body to controlled ovarian stimulation, it is well known that number of oocytes developing to a minimum of stimulation also cannot be controlled. The limit of retrieval of only seven oocyte following ovarian stimulation varies from person to person and once a procedure is planned, the doctor has to aspirate all the follicles to optimize the outcome/reduce complications. The chances of IVF success increase according to oocytes numbers retrieved and maximum live birth rate is achieved by retrieving 15 oocytes.

DEPARTMENT'S RESPONSE:

4.20.12 The Department has submitted that the provision has been made in the best interest of the oocyte donor as hyper stimulation of ovary may cause a lot of side effects and may even lead to infertility. For this reason ever married woman with one child has been kept as provision for oocyte donor and as a safe provision, an insurance coverage has been prescribed in the Bill.

4.20.13 Regarding the suggestion that the oocyte donor should donate more than once, the Department has stated that the sharing of gametes is prohibited to avoid parental issues to multiple children and this will affect the future of the child.

OBSERVATIONS/RECOMMENDATIONS:

4.20.14 The Committee agrees with the Department that oocyte donation has potential risks for the donor, including risk during ovarian stimulation, retrieval procedure under anesthesia. Due to the possible cumulative risks to the donor, it is prudent to limit the number of times a donor can donate oocytes, to once. Women (married or unmarried) who have not yet had children of their own should be made aware of the risks involved in oocyte retrieval process. The Committee is, also, of the view that the process of donation of oocytes should be choice based with a mandatory provision to seek medical advice of the risks it entails. Since the axiom of the ART Bill is altruistic and there is no monetary compensation for the oocyte donor, the possibility of exploitation of young unmarried/married women for retrieving oocytes, is eliminated. The Committee finds no harm if a woman wants to willingly donate her oocytes under proper medical guidance from the ART experts. The Committee, therefore, recommends that the restricting provision of ever married woman having at least one live child of her own with minimum age of three years may be deleted.

4.20.15 With regard to limiting the retrieval of oocytes per cycle to seven, the Committee is in agreement with the views limiting the oocytes retrieval to seven keeping in view the potential risk during ovarian stimulation. It is true that more oocytes will increase the chances for obtaining good quality embryos which in effect would improve the chances of successful pregnancy but oocyte donors cannot be allowed to undergo excessive ovarian stimulation as the same would risk her life or lead to infertility. The Committee therefore recommends that there needs to be a balanced approach regarding retrieving reasonable number of oocytes based on medical condition of the donor and so restricting it to retrieval of seven oocytes.

4.20.16 The Stakeholders have expressed apprehension over the availability of oocyte donors due to the fact that donation of oocytes consumes the time of donors, donors have to undergo inconvenience and discomfort associated with the procedure of screening, ovarian stimulation, and oocyte retrieval. The Committee has been given to understand that the dearth of oocyte donors would result in unethical practices and under-the-table transactions between ART banks and people seeking ART services which would defeat the very purpose of the Bill. The Committee believes that its recommendation for removal of the provision of an ever married woman with a child of not less than three years would overcome to some extent the dearth of oocyte donors. The Committee also believes that the ART clinics in tandem with ART banks would take appropriate steps for collection of oocytes and sperms. It is believed that commissioning couple or woman may also approach oocyte and sperm donor and in coordination with ART clinics/banks the availability of oocytes and sperms may be ensured.

4.20.17 Clause 27(6) reads as under:

> *27 (6) A bank shall obtain all necessary information in respect of a sperm or oocyte donor, including the name, identity and address of such donor, in such manner as may be prescribed, and shall undertake in writing from such donor about the confidentiality of such information.*

SUGGESTIONS:

4.20.18 With respect to clause 27(6) stakeholders have made the following suggestions:

(i) It was suggested that since ART banks also obtain donor gametes, there must be specific provision mandating written, informed consent and counselling procedures from and for gamete donors by any entity that collects and obtains donor gametes.
As regards the counselling, gamete donors should be informed of the risks and implications of gamete donation, including issues such as health effects of oocyte retrieval such as infertility, relinquishment of all parental rights, and the possibilities of a donor-conceived child wanting to know their identity for medical reasons, conflicts when donor is a friend or relative of the recipient, and use of their gametes for research.

(ii) With regard to obtaining written informed consent, one stakeholder suggested that consent should be obtained from donors for two separate acts: for medical screening and testing, and for gamete donation. Though the Bill does not specify the disease for screening of gamete donors therefore, presumably diseases may include conditions such as HIV, Hepatitis B and other communicable disease. It is imperative that donors be informed of these tests and their implications before being administered the same. Indeed, this is necessitated by the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017.

(iii) Indian Law Society, Pune, submitted that the Bill should also include liability and penalty clause for breach of confidentiality and privacy of personal medical record.

(iv) CSR submitted that sharing of information under ART bill may be included under Donor-privacy regulation. Need to highlight methodologies acquired to ensure confidentiality in the Bill.

DEPARTMENT'S RESPONSE:

4.20.19 The diseases for which gamete donors will be screened will be elaborated in rules and regulations. The suggestion for counselling for the donors may be considered.

OBSERVATIONS/RECOMMENDATIONS:

4.20.20 The Committee, keeping in view the assurance given by the Department to the Committee that the diseases for which gamete donors would be screened will be

elaborated in rules and regulations, recommends that the rules and regulations must conform to existing laws and proposed legislation for example Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017.

4.20.21 The Committee further recommends that written informed consent should be obtained at two stages of ART procedure i.e. at the stage of medical screening and testing and at stage two during gamete donation. The Committee believes that informed consent based mechanism would be vital especially in case of oocyte donors who undergo invasive procedures for oocyte donation. The Committee recommends that the donor must be apprised of the tests and their implication before administration of necessary medical intervention. The Committee agrees to the provision contained in the clause 27(6) for seeking written undertaking from the donor about confidentiality of all information sought.

4.20.22 Subject to the above recommendation, the clause is adopted.

CLAUSE 28

4.21 Clause 28 deals with storage and handling of human gametes and embryos.

Clause 28 (2) reads as under:

28 (2) The gamete of a donor or embryo shall be stored for a period of not more than ten years and at the end of such period such embryo or gamete shall be allowed to perish or be donated to a research organisation registered under this Act for research purposes with the consent of the commissioning couple or individual, in such manner as may be prescribed.

SUGGESTIONS:

4.21.1 Some stakeholders argued to extend the period of storage of gamete of a donor or embryo beyond ten years with permission from National Board in cases where gametes are frozen at young age and marriage/decision for family formation come much later. The time period for storing gametes or embryos should be relaxed in specific situations e.g., for cancer patients. This can be done with the permission of a medical Board or from National Board.

DEPARTMENT'S RESPONSE:

4.21.2 The time period is kept since excessive storage for a longer period will make the cells inactive.

OBSERVATIONS/RECOMMENDATIONS:

4.21.3 The Committee understands that due to several factors in modern-day societies such as lifestyle changes, educational opportunities and career choices, women decide to bear a child at later stage of their lives. The trend to delay childbearing often confronts

women with difficulties to conceive because of aging of the ovary resulting in a decline in the total number of oocytes, therefore, a resort of cryopreservation of oocytes have been provisioned under this Bill. The longest storage period of cryopreserved human oocytes resulting in a live birth is 14 years. (Urquiza *et al.*, 2014). The Committee, therefore, underlining the safer side of reproduction rate of gametes subscribes to the provision of cryopreservation of gametes for ten years or for such specific period as derived from latest scientific advancements in the field of cryo-preservation.

4.21.4 In case of cancer patients, there is chemotherapy and radiotherapy-induced infertility. In case of male cancer patients, cryopreservation if done before the start of treatment enables sperm to be stored, thereby preserving the man's potential fertility and bestows him with the right to procreate in future. Many patients who are requesting semen cryopreservation are young (median age 24 years; Blackhall *et al.*, 2002) and hence are likely to delay family formation process. Although there are some scientific data which indicate that cryopreservation can induce DNA damage in sperm, at least from infertile men (Donnelly *et al.*, 2001), however, there is no data to suggest that damage is increased by the period of storage.

4.21.5 In view of the foregoing, the Committee observes that there appears to be scientific study of cryopreservation of sperms for longer period of time. The Committee, accordingly, recommends the Department to consider latest scientific studies for time limit of cryopreservation of gametes and incorporate a provision in the clause if there is a breakthrough scientific discovery in this regard, the clause could be amended, accordingly.

4.21.6 Subject to the above recommendation, the clause is adopted.

CLAUSE 29

4.22 Clause 29 deals with restriction on sale, etc., of human gametes, zygotes and embryos.

Clause 29 reads as under:

29. The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party within or outside India shall be prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board.

SUGGESTIONS:

4.22.1 Indian Law Society, Pune submitted that the ambiguous wording renders the transfer and use of donor gametes itself questionable. A plain reading suggests that since only transfer of own gametes and embryos for personal use is permitted, gamete donation is seemingly impermissible. In the normal course, gametes of donors will be transferred from the donor to the recipient for use by the latter, not by the donor. The clause makes gamete donation and use of donor gametes a contravention. This contradicts clause 27, which

provides for the screening and the use of donor gametes. Presumably it is not the intent of the law to ban the use of donor gametes. Therefore, the wording of Clause 29 needs to be altered to clearly allow for the transfer and use of donor gametes.

OBSERVATIONS/RECOMMENDATIONS:

4.22.2 The Committee is of the view that the intention of this clause is general ban on sale and transfer of gamete (except specific donor-recipient transfer) in order to prevent unethical misuse of gamete transfer and sale for unbridled commercial purpose and not to ban the use of donor gametes who would be made available through the ART banks.

4.22.3 The clause is adopted without any change.

CLAUSE 31

4.23 Clause 31 deals with rights of child born through assisted reproductive technology.

Clause 31(1) reads as under:

31 (1) The child born through assisted reproductive technology shall be deemed to be a biological child of the commissioning couple and the said child shall be entitled to all the rights and privileges available to natural child from the commissioning couple under any law for the time being in force

SUGGESTIONS:

4.23.1 The following are the suggestion of the stakeholders on the Clause:

(i) CSR submitted that a legal document must be signed in languages easily comprehensible by both the parties involved to avoid any issue of parentage, inheritance and property dispute in future. A copy of this legal document must be made available to the donor-women.

(ii) As the Bill also allows single woman to commission a child, however it is silent about the parentage, rights and privilege of the child born to a single woman by ART. Further, the clause should also specifically provide for the status of a child born from posthumous reproduction, such a child should be considered the biological child of the couple and be entitled to all the rights and privileges available to a natural child of the couple.

(iii) SAMA suggested that commissioning couple should be replaced with commissioning parents.

(iv) Phrase "Natural and legal child" should be used instead of biological child.

(v) Child born through ART has the right to know the identity of donor (above age of 18 years) but no right of inheritance from the donor.

DEPARTMENT'S RESPONSE:

4.23.2 The Department submitted that this will be further elaborated in the rules and regulations. The child will be deemed to be similar to a biological child irrespective of the parent as a couple or single woman.

OBSERVATIONS/RECOMMENDATIONS:

4.23.3 The Committee subscribe to the views of the Department for retaining the word "biological child" instead of "natural and legal child" as supported by some Stakeholder as the expression "biological child" has been used in Surrogacy (Regulation) Bill 2019. The status of biological child would endow the child born with all the rights and privileges available to natural child from the commissioning couple under any law.

4.23.4 The Committee understands that the child born through ART when attains age of 18 years would have the right to know the identity of donor, an express provision must be added "the child born through ART would have no right of inheritance from rights and privileges of donor" to avoid any issue of inheritance and property disputes.

4.23.5 The Committee finds merit in the argument that legal document must be signed between the commissioning couple and donors in language comprehensible to both the parties regarding issue of parentage, parental responsibilities, and parties' rights and obligations towards the child so that a legal dispute could be avoided in future over custody between the commissioning couple and the donor. In case of child born to single woman, it is understood that he/she will be deemed as the biological child of that woman and same law apply for child born from posthumous reproduction.

4.23.6 Subject to the above recommendation, the clause is adopted.

CLAUSE 32

4.24 Clause 32 deals with Sex selective assisted reproductive technology

Clause 32(1) & (2) reads as under:

32. (1) The clinic, or bank or agent thereof, shall not issue, publish, distribute, communicate or cause to be issued, published, distributed or communicated any advertisement in any manner including internet, regarding facilities of sex selective assisted reproductive technology.

32 (2) Whoever contravenes the provisions of sub-section (1) shall be punishable with imprisonment for a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh rupees but may extend to twenty-five lakh rupees or with both.

SUGGESTIONS:

4.24.1 Some stakeholder submitted that the punishment should be as per provisions of Pre-conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

OBSERVATIONS/RECOMMENDATIONS:

4.24.2 The Committee understands that the provision of punishment available in PCPNDT Act 1994 relates to conveying of information regarding the existence of specific sex through ultrasound, while the misuse of ART services contains the potential of determining sex, therefore, possesses tremendous threat of altering the proportion of male and female ratio by adopting unethical medical procedures and techniques. Therefore, the Committee feels that nature and quantum of offence relating to sex selection and sex determination is not the same as provided in PCPNDT Act 1994 and the proposed legislation. The Committee is of the considered view that the quantum of punishment for two different categories of offence cannot be the same.

4.24.3 The Committee finds that clause 32 stipulates the various possible manner of propagating the misuse of ART facilities as sex selective assisted reproductive technology. The intention of the provision is to act as an deterrent factor that is to prohibit the clinic, bank or any agent thereof from issuing, publishing, distributing or communicating or cause to be issued, published, distributed or communicated any advertisement in any manner including internet, proliferating the idea of sex selective ART. The Committee, therefore, arrives at the conclusion that the objective and scope for prohibition of sex selection under PCPNDT Act and the proposed legislation is quite different implying differential quantum of offence, therefore, in all judicial rationality the punishment would be differential weighing the potential proportion of quantum of offence.

4.24.4 The Committee, however, finds that the clause 32(2) entails the quantum of punishment for contravening the provision of sub-section (1). The Committee observes that while punishment for violation of provision under clause 33(1) entails the graded punishment i.e, punishment for the offence at first time and the punishment for the offence at the subsequent stage. The Committee finds that for the first offence under clause 33(2) there is punishment with a fine which shall not be less than five lakh but may extend to ten lakh for the first contravention and the subsequent contravention calls punishment with imprisonment with staggered duration and with fine of specific amount. The Committee, however, finds that the punishment mentioned under clause 32(2) for contravention of provision of 32(1) spells out the punishment with imprisonment for a term which shall not be less than five years but may extend to ten years or with fine which shall not be less than ten lakh which shall extend to twenty five lakh or with both. The Committee, therefore, is of the considered view that the punishment under clause 32(2) must also be proposed in a graded manner as mentioned in clause 33(2). Moreover, a rational jurisprudence demands the gradation of penal provision proportionate to the commission of offence. On the other hand, the Committee also feels that the penal provision should not be too harsh or a hindering

factor impeding the professional pursuit. The Committee, accordingly, recommends that clause 32(2) may be amended as under:

Clause 32(2)

" whoever contravenes the provision of sub section (1) shall be punishable with a fine which shall not be less than five lakh rupees but may extend to ten lakh rupees for the first contravention and for the subsequent contravention, shall be punishable with imprisonment for a term which shall not be less than three years but may extend to five years or with fine which shall not be less than ten lakh rupees but may extend to twenty five lakh rupees or with both"

4.24.5 Subject to the above recommendation, the clause is adopted.

CLAUSE 33 & 34

4.25 Clause 33 deals with offences and penalties.

Clause 33 (1) reads as under:

33 (1) Any medical geneticist, gynaecologist, registered medical practitioner or any person shall not— (a) abandon, disown or exploit or cause to be abandoned, disowned or exploited in any form the child or children born through assisted reproductive technology; (b) sell human embryo or gametes, run an agency, a racket or an organization for selling, purchasing or trading in human embryos or gametes; (c) import or help in getting imported in whatsoever manner, the human embryos or human gametes; (d) exploit the commissioning couple, woman or the gamete donor in any form; (e) transfer human embryo into a male person or an animal; (f) sell any human embryo or gamete for the purpose of research; or (g) use any intermediates to obtain gamete donors or purchase gamete donors.

SUGGESTIONS:

4.25.1 The following are the suggestions of the stakeholders on the clause:-

(i) The basic intention of clause 33 is to prohibit the exploitation of the commissioning couple, woman or the gamete donor in any form, however, ISAR and other stakeholders pointed out that "exploitation" is subjective and can be both ways i.e. in reverse swing the woman or donor can also have mala fide intention.

(ii) One stakeholder submitted that clause 33(1) lists six types of disparate offences, only two of which concern offences against individuals and are non-lethal in nature. The equal treatment of dissimilar cases for harsh punishment amounts to arbitrariness in law, violating Article 14 of the Constitution. It was further pointed out that the principle of proportionality of sentencing in context

of the offence and the punishment is well-entrenched in criminal jurisprudence. In fact, proportionality is also a constitutional standard to test the substantive (nature of acts deemed to be an offence) as well as procedural (trial proceedings, including sentencing) features of a law which limit or deprive personal liberty under Article 21, as declared by the Supreme Court in KS Puttaswamy vs Union of India.

(iii) It is unclear how the gynecologist/ medical practitioner will be able to ensure the child born through assisted reproductive technology is not abandoned/ disowned. The responsibility should be fixed on the commissioning couple.

(iv) Some stakeholders suggested that import and export of embryos should be allowed for therapeutic purposes.

DEPARTMENT'S RESPONSE:

4.25.2 The section 33 provides penalties for the couple, clinic, donors and individuals/intermediates.

4.25.3 The proportionality of offences and penalties mentioned in Section 33 and 34 have been drafted ensure ethical practices of Assisted Reproductive services and safeguard the rights of the commissioning couple/woman and the child born through ART services.

4.25.4 On the concern raised by the Stakeholders that mala fide interest can be both ways it cannot be on the part of the Doctor/medical staff alone, the Department remarked that there are separate punishments for donors/individuals too.

OBSERVATIONS/RECOMMENDATIONS:

4.25.5 The Committee takes into account the assurance given by DHR that adequate provision has been made for the violation of the provision of the Act, rules and regulations made thereunder on the part of the commissioning couple in case of abandonment of the child and in case of sale of gametes by donors. Of course, the Committee believes that the gynaecologist/medical practitioner would not be responsible for abandonment or disownment of child born through ART services as in all cases the ultimate responsibility of the child born lies with the commissioning couple and any violation of the provision on the part of the commissioning couple or woman would attract the penal provision towards the commissioning couple or the woman. Similarly, sale of human embryos or gametes by donor will attract the penal provision in order to prohibit the commercialization of ART services as the main maxim or the spirit of the Act is the altruistic mode of providing ART services. The Committee understands that the intention of prohibition on import and export of human embryos or human gametes is to prevent unbridled marketization of human gametes as the same would open the flood gates for exploitation of one and all involved in the ART services.

4.25.6 Moreover, the Committee believes that Grievance cell will take care of the complaints against any party, be it medical geneticist/ gynaecologist/registered medical practitioner/clinics/ART banks/commissioning couples and donors. The Committee is

aware that "exploitation" is subjective and can be both ways. The Committee understands that unsuccessful cases may lead to discontentment on the part of the patients, thereby, cases may be lodged against a ART clinics/banks or medical geneticist/ gynaecologist/ registered medical practitioner, taking a toll on their time and hard earned reputation. The Committee is of the firm view that a fair inquiry must be conducted before a medical geneticist/ gynaecologist/ registered medical practitioner or any other person is held responsible for a fallacy/violation of the provision. However, the commissioning couples, woman or the gamete donor are on the receiving end in the whole process of ART services, therefore, the Committee is not in favour of deletion of word "exploit" from the said clause.

4.25.7 The Committee finds that clause 33(2) contains the penal provision for violation of provisions contained in clause 32(1). The clause 34 deals with the situation where the penalty has not been provided in the Act for violation of any provision of the ART Act or any rules made thereunder. Under such circumstances the offender will be punished as per sub section (2) of clause 33.

The clause 33(2) and clause 34 read as under:

> *33 (2) Whoever contravenes the provisions of clauses (a) to (g) of sub-section (1), shall be punishable with a fine which shall not be less than five lakh rupees but may extend to ten lakh rupees for the first contravention and for subsequent contravention, shall be punishable with imprisonment for a term which shall not be less than eight years but may extend to twelve years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees.*
>
> *34. Whoever contravenes any of the provisions of this Act or any rules made thereunder, for which no penalty has been provided in this Act, shall be punishable as per sub-section (2) of section 33.*

SUGGESTIONS:

4.25.8 With respect to clause 33(2) and 34 stakeholders have made the following suggestions:

(i) Some stakeholders have pointed out that the provision of clause 33(2) is out of proportion to the offence. The offences should be punishable if there is a criminal intent behind these acts. Unlike the PCPNDT act (where the offence is termination of a foetus above 20 weeks of gestation) while the offence in the ART Bill are mainly administrative ones. Therefore, these offences should be related to the administrative infringement of donor or surrogate aspects or the sex selection aspects of the ART Bill. Complications related to the medical aspects of the ART Bill i.e. anaesthesia and procedure related complications, disability or death of patients or donors due to medical/surgical complications or inadvertent mix ups should be, according to stakeholders, dealt with pre-existent civil courts or consumer courts or medical councils.

(ii) One stakeholder submitted that clause 33(2) and 34 of the ART Bill are vulnerable to constitutional challenge as they go against the general legislative policy and prescribe a mandatory minimum sentence of 8 years, thereby depriving the court of discretion in imposing a proportionate sentence, including a lesser sentence, in consideration of the mitigating/aggravating circumstances and relevant determinants in a case.

(iii) Some stakeholders submitted that clause 33(2) may be amended as under:

"*....shall be punishable with a fine which shall not be less than two lakh rupees but may extend to five lakh rupees for the first contravention and for subsequent contravention, shall be punishable with imprisonment for a term which shall not be less than three (3) years but may extend to five years and with fine which shall not be less than five lakh rupees but may extend to ten lakh rupees*."

DEPARTMENT'S RESPONSE:

4.25.9 The Ministry submitted that the offences mentioned in section 33 are related to-abandonment/exploitation of child, selling of embryos, exploitation of commissioning couple, donors and woman which need stringent provisions.

4.25.10 The Ministry further submitted that the proportionality of offences and penalties mentioned in Section 33 and 34 have been drafted to ensure ethical practices of assisted reproductive services and safe guard the rights of the commissioning couple/woman and the child born through ART services.

4.25.11 The Committee sought the opinion of the Legislative Department, Ministry of Law & Justice with regard to sub clause (2) of clause 33 of the ART Bill. The Legislative Department furnished its comments as under:

> "With respect to Chapter V relating to offence and penalties, the administrative Ministry, at the time of scrutiny of the proposal by this Department, has expressed the desire of strict implementation of the provisions of the proposed legislation to control the malpractice of the Assisted Reproductive Technology clinics and banks in the Assisted Reproductive Technology. The substantial rate of punishment shall apply only in case of repeated commission of same offence. However, the views of the administrative Ministry in this regard may also be relevant in this context."

OBSERVATIONS/RECOMMENDATIONS:

4.25.12 The Committee understands the general principles of jurisprudence spells out that the punishment for crimes should be in proportion to the severity of the crime. However, the Committee finds that the provision of penalty under clause 32(2) is intended to prevent and prohibit the severe offence of potential of misusing the pre-implantation genetic diagnosis for sex determination of 'made-to-order' or 'tailor-made' babies. The Committee is of the view that the nature of offence described in

clause 33(2) is not of administrative nature but entails the possibility of committing severe offence against the abandoned or disowned child born through ART services or exploitation of commissioning couple, woman or the gamete donor. The Committee believes that the severity of punishment as provided in clause 33(2) has been made in view of promoting the altruistic spirit of the Act and preventing the unbridled growth and commercialization of fertility industry. The Committee, in all its rationality, believes that the penal provision of clause 33(2) intends to address the plethora of legal, ethical and social issues and to streamline the reproductive medical tourism by enforcing standardization of protocols and regulation of ART activities.

4.25.13 The Committee finds that clause 33(2) stipulates penalties for offences mentioned in clause 33(1) in a graded manner. As is evident from the clause 33(2) that the persons/institutions contravening the provision of clauses (a) to (g) of sub section (1) shall be punishable with a fine which shall not be less than five lakh rupees but shall extend to ten lakh rupees for the first contravention. While the Committee finds that in the case of Surrogacy (Regulation) Bill 2020 as reported by the Select Committee, the contravention of the provision of clause (a) to (g) of sub section (1) of clause 36 attract more stringent punishment with imprisonment for a term which may extend to ten years and with fine which may extend to ten lakh rupees. Here at in the ART Bill 2020, the Committee finds lesser punishment in comparison to the punishment mentioned in the Surrogacy (Regulation) Bill 2020. It is only for subsequent contravention the violator of the provision (a) to (g) of sub section (1) of clause 33 of ART Bill shall be punished with imprisonment for a term which shall not be less than eight years but may extend to twelve years and with fine which may not be less than ten lakh rupees but may extend to twenty lakh rupees. The Committee, therefore, considers the monetary penalty commensurate to the volume of possible offences as described in (a) to (g) of clause 33, however, the provision of imprisonment is too harsh that needs further rationalization. During the course of interaction with the Stakeholders, the Committee was given to understand that the stringent provision of punishment hinders the professional pursuit of the medical practitioner or the ART experts as the fear may always prevail in the minds of the medical professional, practicing the ART services in the medico-legal environment of stringent penal provision. The Committee, therefore, is of the considered view that there is a need to strike a balance between the provision of extending functional autonomy to the medical geneticist/ gynaecologist/ registered medical practitioner and at the same time adhering to the principle of discharging the responsibilities with a sense of commitment and altruistic mode of serving the people. The Committee, in this regard, feels that the stringent provision should be made reasonably judicious making penal provision as per the proportion of offence committed.

4.25.14 The Committee is of the view that the clause 33(2) may be read as under:

> *"Whoever contravenes the provisions of clauses (a) to (g) of sub-section (1), shall be punishable with a fine which shall not be less than five lakh rupees but may extend to ten lakh rupees for the first contravention and for subsequent contravention, shall be punishable with imprisonment for a term which shall not*

be less than five years but may extend to ten years and with fine which shall not be less than ten lakh rupees but may extend to twenty lakh rupees."

4.25.15 Subject to the above recommendation, the clause is adopted.

CLAUSE 35 & 36

4.26 Clause 35 deals with cognizance of offences and clause 36 deals with offences to be cognizable and bailable.

Clauses 35 and 36 read as under:

35. (1) No court shall take cognizance of any offence punishable under this Act, save on a complaint made by the National Board or the State Board or by an officer authorised by it.

(2) No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall try any offence punishable under this Act.

36. All the offences under this Act shall be cognizable and bailable.

SUGGESTIONS:

4.26.1 Indian Law Society, Pune submitted that clause 35(1) needs to be modified to allow all person to file a complaint in respect of an offence punishable under the Bill.

4.26.2 Some stakeholders submitted that the clause 35(1) may be appended with "after conducting the inquiry and submitting its report".

4.26.3 Other stakeholders suggested that all the offences under this Act should be non-cognizable and bailable.

DEPARTMENT'S RESPONSE:

4.26.4 The Ministry submitted that the bill has not prohibited any person from filing complaint to any judiciary body.

OBSERVATIONS/RECOMMENDATIONS:

4.26.5 The Committee appreciates that the Department of Health Research is subscribing to the views of the stakeholders that the intention of the Bill is not to prohibit any person from filing complaint before any judicial body. The Committee, therefore, does not observe any contravention in the provision of the Bill that spells out the cognizance of offence by the court on the complaint made by the National Board or the State Board or by any officer authorized by it.

4.26.6 The Committee, however, is in agreement of insertion of words "after conducting the inquiry and submitting its report" in the end of clause 35(1). The Committee believes that insertion of the said proviso will give an assurance to the Stakeholders especially medical professionals, ART Banks and Clinics against the false allegations of misuse of the provision of the Act and rules and regulations made thereunder. The provision will also endow the fearless domain for pursuing medical and procedural skill or professional pursuit during treatment process. Moreover, insertion of the provision will give an additional opportunity of natural justice as the same will entail privilege to the Stakeholders for being heard. Thus, clause 35(1) may be read as under:

> ***"No court shall take cognizance of any offence punishable under this Act, save on a complaint made by the National Board or the State Board or by an officer authorised by it after conducting the inquiry and submitting its report"***

4.26.7 The Committee also recommends substitution of word "inferior" in clause 35(2) with the word "lower" to accord the dignified status to the judiciary.

4.26.8 With regard to the offences being categorized as cognizable, the Committee finds that in Surrogacy (Regulation) Bill 2020 as reported by the Select Committee also stipulates provision of the offence of similar nature as cognizable, the Committee, therefore, finds the categorization of offence as cognizable under ART Bill as appropriate. The Committee observes that since there is congruence of views between the stakeholders and the administrative Ministry to make provision the offence in the ART Bill as bailable, therefore, there is no contentious issue. The Committee, therefore, accords the provision of the Bill that all the offence under this Act shall be cognizable and bailable.

4.26.9 Subject to the above recommendations, clauses 35 & 36 are adopted.

CLAUSE 37

4.27 Clause 37 deals with offences by clinics or banks
Clause 37(1) reads as under:

> *37. (1) Where an offence under this Act has been committed by any clinic or bank, the executive head of such clinic or bank shall be deemed to be guilty of an offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he had exercised all due diligence to prevent the commission of such offence.*

SUGGESTIONS:

4.27.1 Some stakeholders suggested that the proviso of the Bill may be amended as follows:

> *"Where an offence under this Act has been alleged to have been committed by any clinic or bank, the executive head of such clinic or bank shall be deemed to be*

guilty only if it is proved that the offence was committed with his knowledge or that he had connived to commit the offence."

4.27.2 Further, the complaint should be registered only after inquiry is completed by National Board and has given an adverse report against the clinic or officer concerned. During the Committee's meeting held on 30th December, 2020, the Stakeholders wanted the protection for the Healthcare providers under Clause 41 that spells out protection of action taken in good faith.

OBSERVATIONS/RECOMMENDATIONS:

4.27.3 The Committee understands that clause 37 seeks to provide for the offences by the clinics and banks while clause 41 seeks to provide for the protection of action taken in good faith, therefore, the claim of the stakeholders for seeking protection under clause 41 does not hold ground. The Committee wills to point out that the clause 37 deals with the offences by clinics or banks stipulating that the executive head of such clinic or bank shall be deemed to be guilty of offence and shall be liable to be prosecuted against and punished accordingly unless he proves that the offence was committed without his knowledge. Thus, there is sufficient room for the executive head of the banks and clinics to express protection under clause 37 itself on the plea that the offence was committed without his knowledge. Moreover, he is further protected under the clause 37 itself, when he proves that he had exercised all due diligence to prevent commission of such offence. The Committee therefore arrives at the conclusion that clause 37 gives adequate protection to the executive head of ART Banks and clinics against the commission of offence which has been committed without his knowledge and due diligence has been exercised to prevent such offence. Therefore, seeking protection under clause 41 by the ART clinics and banks is unwarranted and undesirable.

4.27.4 The clause is adopted without any change.

CLAUSE 41

4.28 Clause 41 deals with Protection of action taken in good faith.

Clause 41 reads as under:

41. No suit, prosecution or other legal proceeding shall lie against the Central Government or the State Government or the National Board or the National Registry or the State Board or the Registration Authority or any other officer authorised by the Central Government or the State Government or the National Board or the National Registry or the State Board or the Registration Authority for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or the rules or regulations made thereunder.

SUGGESTIONS:

4.28.1 One stakeholder submitted that this clause should be re-examined as the mention of "good faith" is subject to interpretation. It takes away rights of doctors/clinics/establishments to take the legal route in case of harassment or wrong doing by the officials.

4.28.2 Some stakeholders submitted that the clause should be reframed as follows:

> "In the event the Central Government or the State Government or the Indian Human Fertilization and Embryology Authority or the National Registry or the committee constituted by Indian Human Fertilization and Embryology Authority or the Registration Authority or any other officer authorized by the Central Government or the State Government or the Indian Human fertilization and Embryology Authority or the National Registry or the committee or the Registration Authority act arbitrarily and does acts or omissions which are not done in good faith or intended to harass the doctors/ clinics in the garb to pursuance of the provisions of this Act or the rules or regulations made thereunder, then the strict disciplinary action shall be taken and inquiry be conducted in the said matter and against the said body or individual as the case may be."

DEPARTMENT'S RESPONSE:

4.28.3 The Department submitted that this clause has been framed in consultation with the Legislative Department. The Committee sought the comments of the Legislative Department, Ministry of law and Justice on the applicability of clause 41 of the ART Bill. In response to that the Legislative Department furnished its written comment as under:

> "With respect to acts done in good faith, clause 41 explicitly provide that the immunity is available only to the Central Government or the State Government or the National Board or the National Registry or the State Board or the State Government or the Registration Authority or any other officer authorised by the Central Government or the State Government or the National Board or the State Board or the Registration Authority for anything which is done in good faith or intended to be done in pursuance of the provisions of this Act or the rules or regulations made thereunder. It is not applicable to others like the Executive Head of ART bank and clinic, medical geneticist, gynaecologist and registered medical practitioners."

OBSERVATIONS/RECOMMENDATIONS:

4.28.4 The Committee is in agreement with the views of the Legislative Department with regard to the applicability of the clause 41 that extends immunity only to the officers of the Central government or the State Government or any other officers authorized by the Central Government or the State Government for the

responsibilities discharged in good faith or intended to be carried out in pursuance of the provision of the Act or rules and regulations made thereunder. Therefore, the Committee is of the considered view that the protection mentioned under clause 41 cannot be extended to other officers like the executive head of ART banks, clinics, medical geneticist, gynaecologist and registered medical practitioners.

4.28.5 The clause is adopted without any change.

SHORT TITLE, EXTENT AND COMMENCEMENT

4.29 Clause 1 deals with Short title and commencement.

Clause 1 reads as under:

1. (1) This Act may be called the Assisted Reproductive Technology (Regulation) Act, 2020.

(2) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

OBSERVATIONS/RECOMMENDATIONS:

4.29.1 The Committee is of the view that the clause 1 dealing with the short title and commencement is of procedural and consequential nature therefore, may be read as under:

(*1*) This Act may be called the Assisted Reproductive Technology (Regulation) Act, 2021.

(*2*) It shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint.

(3) It shall be applicable to the entire territory of India.

4.29.2 Subject to the above recommendation, short title, extent and commencement is adopted.

PREAMBLE & ENACTMENT

4.30 The Preamble of the Bill reads as follows:

"for the regulation and supervision of the assisted reproductive technology clinics and the assisted reproductive technology banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services and for matters connected therewith or incidental thereto.

Be it enacted by Parliament in the Seventy-first Year of the Republic of India as follows:- "

SUGGESTIONS:

4.30.1 Some stakeholders submitted that the Preamble spells out the intention of the Bill in a comprehensive manner, therefore, there is a need to modify the Preamble so as to incorporate all the objectives of the Bill. The Preamble should provide that the Bill intends to regulate and supervise the ART Banks and clinics. The Bill also intends to prevent the misuse of ART services and ensure safe and ethical practice of ART services. The Preamble should also address the issues of Reproductive Health where ART is required for becoming a parent and/or preserving/freezing gametes/embryos/embryonic tissues, cells for further or future use due to infertility, disease or social/medical concerns and also regulate and supervise the research & development activities and matters connected therewith and incidental thereto.

OBSERVATIONS/RECOMMENDATIONS:

4.30.2 The Committee is of the view that the Preamble mirrors the face of the Bill, therefore, the Preamble should reflect the comprehensive objective intention and activities connected with the provisions of the Bill. In the Committee's view, the ART Bill should be a comprehensive legislation covering not only the need of Assisted Reproductive Techniques for infertility but should also address the issues pertaining to disease, social concerns (like social egg freezing), safety of offspring, fertility preservation, aspect of research and training and be a forward looking Bill coping with the advances in the field with rapid pace.

4.30.3 The Committee, therefore, recommends amendment in the Preamble to the Bill which may read as under:

> **"*A Bill for regulation and supervision of the assisted reproductive technology clinics and the assisted reproductive technology banks, prevention of misuse, safe and ethical practice of assisted reproductive technology services; and to address the issues of Reproductive Health where Assisted Reproductive Technology is required for becoming a parent and/or preserving/freezing gametes/ embryos/embryonic tissues, cells for further or future use due to infertility, disease or social/ medical concerns; and for regulation and supervision of research and development and matters connected therewith and incidental thereto."***

4.30.4 The Committee also recommends the consequential change as under:

> **"Be it enacted by Parliament in the Seventy-second Year of the Republic of India as follows:-"**

4.30.5 Subject to the above recommendations, Preamble and Enactment are adopted.

4.31 The Committee also recommends for all consequential changes to be carried out in therelevant clauses of the Bill keeping in view the Committee's observations and recommendationscontained in the report.

CHAPTER - V

GENERAL OBSERVATIONS/RECOMMENDATIONS

5. The Committee understands that the legislation on ART services is the need of the hour to regulate and supervise ART clinics and Banks by establishing the National Board, the State Boards, the National Registry and the State Registration Authorities and for prevention of misuse and for safe ethical practices of ART services. The purpose is to oversee and ensure that the practices like commercialization of gametes, foetal reduction, multiple implantation by the rich and sex-selection are prohibited.

5.1 The Committee expresses its concern that the ART Bill treats of infertility as the prospective industry in the SOR and the Department exhibited the prospects of billion dollars industry a potential centre for business growth. This is a matter of great pain to the Committee as the altruistic spirit of the Bill is being killed by the increasing tendency of commercialization of pains of the poor and the prospects of the rich. ART services must be guided by humane approach and not in the fashion of industry outlook. The Committee, however, believes that the Government should make efforts to undertake a study to distill the cause of infertility instead of allowing the private sector racing for maximization of profit by marketing of ART services. The Committee, in this regard, also recommends that the Government should enhance ART facilities in each medical colleges or district hospitals by opening infertilty clinics so that the common poor masses can avail the ART facilities. The Committee strongly desires that the ART facilities should not be confined to the bourgeois class. In this regard, the Committee cautions the Government not to allow commercialization venture at IVF centre. Commercialization of gamete donation must be prohibited in letter and spirit by effective implementation of the provisions of the proposed legislation and ensuring that ART services does not spill over as a money making business.

5.2 The Committee expresses deep concern over high variation in ART cost. Reportedly, at times, three cycles cost one lakh rupees and on the other hand the clinics charge five lakh rupees for a single cycle. The Committee desires that there should be regulation of the protocol of IVF with regard to streamlined pricing of requisite number of IVF cycles in such a manner that common poor masses can avail the facility of ART. The Committee, therefore, desires that the DHR, while formulating rules and regulations, must make a pre-requisite condition of price registration as the same would give a sigh of relief to common poor couple willing to have a child at a reasonable cost.

5.3 The Committee wishes to draw the attention of the Government towards the tendency of prescribing differential hormonal injections that reflects high variation in hormonal dose thus raising the cost of the treatment. The Committee, therefore, recommends for rationalization of quantity of hormonal dose while prescribing hormonal injection as the existing pattern of treatment sparks too much variation. Therefore, the Committee understands that there is a need for regulation of protocol for cost of ART procedure, the mode of prescribing hormonal injections of good quality alongwith regulation of its cost.

5.4 The Committee expresses concern over the mushrooming growth of IVF centres without having trained and skilled ART experts. The Committee believes that the mission objective of the proposed legilation can be achieved only when ART Banks and Clinics have experts in storage and cryo-preservation of gametes and ART clinics have experts trained in that ART field. It should not be that CPS or diploma holder or MD is opening the IVF centres. The Committee, therefore, recommends for chalking out a specialization ART course of one or two years in the IVF field and only then the person be allowed to operate the IVF centre. Since there is a possibility of exploitation of poor common masses, there is need for regularization of the protocol of IVF centres.

5.5 The Committee is anguished to find that at present there is only six IVF clinics in Government sector viz AIIMS, Lady Hardinge, PGI, Chandigarh, KGMU Lucknow, Army Hospital Delhi and Pune while the remaining thousands of IVF centres are in the private sector. The Committee, therefore, recommends that the Government should ensure that each medical college or premier Government Hospital/ Institute must have IVF/ART facilities so as to enable the common poor masses to avail the services of ART.

5.6 The Committee believes that since the all the clinics of the country should have an Andrologist/Urologist, who specializes in male reproductive system and urogenital complaints including male infertility and sexual dysfunction is assured in the ART clinics. The Committee strongly believes that the presence of an andrologist would not only ascertain the best candidate for sperm retrieval but also assist in optimizing ART outcome by medical and surgical interventions. Such expert would also tackle potentially treatable underlying conditions. The Committee, therefore, recommends that Andrologist/Urologist should be present in ART clinics.

5.7 In a nutshell, the Committee feels that formulating Standard Operating Procedure (SOP) is absolutely required, Uniform cost of ART services, global standard quality have to be ensured at every level, right from ART Banks and clinics to get benefit of the proposed legislation. A monitoring mechanism under the overall guidance of the National Board has to be set up to prohibit unbridled commercialization of the ART services and maximization of profit extraction at various hubs of IVF centres in select cities especially in private sector where sex-determination is conducted that promote made-to-order babies and thus adversely affect the sex ratio in the country.

5.8 The Committee believes that Government through implementation of the Act would ensure maintenance of quality medical infrastructure of ART Banks and Clinics for ensuring standard treatment of infertility and assured pregnancy through ART facilities.

[TRUE COPY]

BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

CM. APPLICATION NO. 25487 of 2022

IN

WRIT PETITION (C) NO. 8448 OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. …PETITIONER(S)

VERSUS

UNION OF INDIA . …RESPONDENT

APPLICATION UNDER SECTION 151 OF THE CODE OF CIVIL PROCEDURE, 1908 SEEKING EXEMPTION FROM FILING CERTIFIED COPIES OR TYPED COPIES OF DIM ANNEXURES IF ANY.

TO

THE HON'BLE CHIEF JUSTICE AND HIS COMPANION JUSTICES OF THE HON'BLE DELHI HIGH COURT

THE HUMBLE APPLICATION OF THE APPLICANT ABOVENAMED

MOST RESPECTFULLY SHEWETH

1. That the present petition seeks the declaration that certain provisions of the Assisted Reproductive Technology (Regulation) Act, 2021 (Act No. 42 of 2021) and the Surrogacy (Regulation) Act, 2021 (Act No. 47 of 2021) be declared ultra vires the Constitution of India as the said

provisions are discriminatory against a single man desirous of being a father through surrogacy and a married woman who already has a child and is desirous of expanding her family through the means of surrogacy. As such the impugned Acts are ultra vires Article 14 and 21 of the Constitution of India.

2. That the facts of the case more extensively dealt with in the aforesaid Writ Petition and has explained the circumstances leading to filing of said petition and also the contentions of law. The Petitioner craves leave to treat said Petition as part and parcel of this application. For sake of brevity, the said facts and grounds are not repeated herein.

3. That the Petitioners crave the indulgence of this Hon'ble Court inasmuch as they may be exempted from exempted from filing the certified copies or typed copies of dim annexures given the paucity of time and the nature of relief sought in the accompanying writ petition.

4. That the Petitioners undertake to file typed copies of any annexure(s) as may be necessary if the occasion so arises during arguments.

5. That the present application is bona fide and in the interest of justice and equity.

PRAYER

In view of the above circumstances, it is respectfully prayed that the Hon’ble Court may be pleased to issue:

A. Exempt the Petitioners/Applicants from filing certified copies of annexures.

B. Exempt the Petitioners from filing typed copies of dim annexures, if any.

C. Pass such other order/orders as the court may deem fit and proper in the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE APPLICANT DUTY BOUND SHALL EVER PRAY

[redacted]
Karan Balraj Mehta
[Petitioner No.1]

[redacted]
Dr. Pankhuri Chandra
[Petitioner No.2]

Filed by:

[redacted]

New Delhi
Date 25.05.2022

Aditya Samaddar
Advocate for the Petitioner,
Off: B-7, Lower Ground Floor, Hazrat Nizamuddin (East), New Delhi, 110013; Email: aditya.samaddar@gmail.com; Ph. No. 9910013921

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BEFORE THE HIGH COURT OF DELHI AT NEW DELHI 785

EXTRAORDINARY CIVIL JURISDICTION

CM APPLICATION NO. _____ OF 2022

IN

WRIT PETITION (C) NO. _____OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. ...PETITIONER(S)

VERSUS

UNION OF INDIA . ...RESPONDENT

AFFIDAVIT

I, Karan Balraj Mehta, [redacted]

hereby solemnly affirm as hereinunder:

1. That I am the Petitioner No. 1 in the present matter. I am well conversant with the facts and circumstances of the case and as such am competent to swear the present affidavit.

2. That I have read the accompanying application seeking exemption from filing certified and true typed copies of annexures. Having understood the same I state that the contents thereof have been drafted on my instructions by my Counsel and the same are true and correct to the best of my knowledge.

NOTARY ALAKA NAYAK Advocate Reg. No. 10639 Period 27/06/2019 to 27/06/2024 GOVT. OF INDIA

[redacted]

DEPONENT

25 MAY 2022

VERIFICATION

Identified the deponent who has signed in my presence

NOTARY ALAKA NAYAR Advocate Regn. No. 10639 Period 27/06/2019 to 27/06/2024 GOVT. OF INDIA

Verified at New Delhi on this the 25th day of May, 2022 that the contents of paragraph numbers 1-2 hereinabove are true and correct to the best of my knowledge and records available and nothing material has been concealed thereform.

[redacted]

DEPONENT

25 MAY 2022

CERTIFIED THAT THE DEPONENT
Sri/Smt/Kum. Baby Meena
S/o, W/o, D/o. Sh. Mewa Lal
R/o
Identified by Sri/Smt.
has Solemnly affirmed before me at
New Delhi on 25 May 2022 at Sh. No. 13
That the contents of the affidavit which have
been read & explained to him are true and
Correct to this knowledge.

Notary Public

BEFORE THE HIGH COURT OF DELHI AT NEW DELHI

EXTRAORDINARY CIVIL JURISDICTION

CM APPLICATION NO. _____ OF 2022

IN

WRIT PETITION (C) NO. _____ OF 2022

IN THE MATTER OF:

KARAN BALRAJ MEHTA & ANR. ...PETITIONER(S)

VERSUS

UNION OF INDIA . ...RESPONDENT

AFFIDAVIT

I, Dr. Pankhuri Chandra, [redacted] years, [redacted], India 110048, hereby solemnly affirm as hereinunder:

NOTARY ALAKA NAYAK Advocate Reg. No. 10639 Period 2/08/2019 to 2/08/2024 GOVT. OF INDIA

1. That I am the Petitioner No. 2 in the present matter. I am well conversant with the facts and circumstances of the case and as such am competent to swear the present affidavit.

That I have read the accompanying application seeking exemption from filing certified and true typed copies of annexures. Having understood the same I state that the contents thereof have been drafted on my instructions by my Counsel and the same are true and correct to the best of my knowledge.

DEPONENT

VERIFICATION 25 MAY 2022

Verified at New Delhi on this the 25th day of May, 2022 that the contents of paragraph numbers 1-2 hereinabove are true and correct to the best of my knowledge and records available and nothing material has been concealed thereform.

[redacted]

DEPONENT

NOTARY
ALAKA NAYAK
Advocate
GOVT. OF INDIA

CERTIFIED THAT THE DEPONENT
Sri/Smt/Km.....
S/o, W/o, D/o
R/o.....
Identified by
has Solemnly affirmed before me at
New Delhi on.... No.....
That the contents of the affidavit which have been read & explained to him are true and Correct to this knowledge.

Notary Public

25 MAY 2022