



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)**

Website: <http://rajyasabha.nic.in>

E-mail : rs-chfw@sansad.nic.in

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CONTENTS

COMPOSITION OF THE COMMITTEE	(i)
PREFACE	(ii) - (iii)
*ACRONYMS	(iv)
REPORT	
Chapter- I Introduction	1 - 6
Chapter-II Views of the Department of Health Research	7- 18
Chapter - III Views of Organizations/ Associations/ Institutions/ Experts	19 - 31
Chapter - IV Clause-by-clause consideration of the Bill	32 - 88
Chapter- V General Recommendations	89 - 90
*RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE	
*MINUTES	
*ANNEXURES	

* to be appended at the circulation stage

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
Shri J. Sundriyal
Shri V.S.P.Singh
Shri Bhupendra Bhaskar
Shrimati Harshita Shankar
Shri Rajesh Kumar Sharma
Ms. Monika Garbyal
Ms. Somya Yadav

Secretary
Joint Secretary
Director
Additional Director
Under Secretary
Assistant Committee Officer
Assistant Committee Officer
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 3 rd 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 NRI's 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 safeguard 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 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.

- (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—

<i>S. No</i>	<i>Clause of Surrogacy(Regulation) Bill 2020</i>	<i>Provisions</i>
<i>(i)</i>	<i>Clause 15</i>	<i>constitution of the National Surrogacy Board;</i>
<i>(ii)</i>	<i>Clause 16</i>	<i>term of office of Members of the National Board</i>
<i>(iii)</i>	<i>Clause 17</i>	<i>meetings of the National Board</i>
<i>(iv)</i>	<i>Clause 18</i>	<i>vacancies, etc., not to invalidate proceedings of the National Board</i>
<i>(v)</i>	<i>Clause 19</i>	<i>disqualifications for appointment as Member of the National Board</i>
<i>(vi)</i>	<i>Clause 20</i>	<i>temporary association of persons with the National Board for particular purposes</i>
<i>(vii)</i>	<i>Clause 21</i>	<i>authentication of orders and other instruments of the National Board</i>
<i>(viii)</i>	<i>Clause 22</i>	<i>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</i>

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-

<i>S. No</i>	<i>Clause of Surrogacy(Regulation) Bill 2020</i>	<i>Provisions</i>
<i>(i)</i>	<i>Clause 24</i>	<i>constitution of the State Surrogacy Board;</i>

(i)	Clause 25	<i>composition of the State Board;</i>
(ii)	Clause 26	<i>term of office of Members of the State Board</i>
(iii)	Clause 27	<i>meetings of the State Board</i>
(iv)	Clause 28	<i>vacancies, etc., not to invalidate proceedings of the State Board</i>
(v)	Clause 29	<i>disqualifications for appointment as Member of the State Board</i>
(vi)	Clause 30	<i>temporary association of persons with the State Board for particular purposes</i>
(vii)	Clause 31	<i>authentication of orders and other instruments of the State Board</i>
(viii)	Clause 32	<i>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</i>

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-preserved 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 a 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 the relevant clauses of the Bill keeping in view the Committee's observations and recommendations contained 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 infertility 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 legislation 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.