

THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) BILL, 2020- A CRITICAL ANALYSIS

by

Ananya Singh

Research Scholar RMLNLU (II Year)

ABSTRACT

The Assisted Reproductive Technologies (Regulation) Bill, 2020 is a new legislation that aims to regulate the surrogacy industry for which India has become a preferred destination by foreign citizens looking for “wombs for rent”. This study intends to investigate the role of a surrogate in the Bill's overall scheme, which focuses on the assisted reproductive technology business as a whole, of which surrogates are a component. The author finds in this study that the Bill ignores most of the problems relevant to a surrogate's interests, making her a minor actor in a billion-dollar industry to which she contributes significantly. In explaining this position, the author has analysed other aspects of the Bill also in detail while concluding generally that the Bill mainly thrusts the power of regulating commercial surrogacy in private players of the ART industry instead of giving her an independent berth. In fact, the Bill has been framed according to the processes in which the industry runs at present and to which the surrogates thrust themselves for money keeping their bargaining power questionable. Other ancillary shortcomings of the Bill, necessary to understanding the role of a surrogate has also been dealt with in the paper by the author.

Introduction

This bill is a step towards safeguarding the reproductive rights of women in India which has long been in demand for regulating surrogacy services. Preamble of the bill clearly states that it has been drafted keeping in mind the primary goal of 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 major benefit of the Act would be that it will set up National Board to advise the centre on policy matters and regulate the surrogacy services in the country. While commercial surrogacy will be prohibited including sale and purchase of human embryos and gametes, ethical surrogacy to the Indian Married couple, Indian Origin Married Couple and Indian Single Woman (only widow or Divorcee) will be allowed on fulfillment of certain conditions. As such, it will control the unethical practices in surrogacy, prevent commercialization of surrogacy and will prohibit potential exploitation of surrogate mothers and children born through surrogacy¹. The Bill prohibits gender determination and gender selection. It also contains provisions to ensure confidentiality of the donor as well as recipient of such services².

Meaning of ART

Assisted reproductive technologies (ART) refer to a range of fertility treatments aimed at aiding reproduction for couples suffering from infertility or to persons who may wish to have a child through artificial methods. These arrangements include in-vitro fertilisation (fertilising an egg in the lab), gamete donation (sperm or egg), and gestational surrogacy (where the child is not biologically related to the surrogate mother). As per private estimates shared with the Standing Committee on Health and Family Welfare (2017), around 2.8 crore couples in the reproductive age group in India are infertile and about 1% of these seek infertility evaluation. Of the people

¹ PMIndia, https://www.pmindia.gov.in/en/news_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/ (Last visited May 15, 2021).

² Shushmi Dey, "Cabinet approves Assisted Reproductive Technology Regulation Bill, 2020" The Times of India, May 15, 2021.

seeking remedy for infertility, 20-25% undergoes in vitro fertilisation treatment and of that, 1% may require surrogacy³.

All fertility procedures in which eggs or embryos are treated are classified as ART. ART methods generally entail surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and either returning them to the woman's body or transferring them to another woman⁴. Although assisted reproductive technology (ART) helps millions of infertile couples become pregnant, it is linked to potential health risks for both the mother and the child⁵.

India has one of the highest growths in the number ART Centres and ART cycles performed every year. India has become one of the major centres of this global fertility industry, with reproductive medical tourism becoming a significant activity. This has also introduced a plethora of legal, ethical and social issues; yet, there is no standardisation of protocols and reporting is still very inadequate⁶. The bill is the most recent in a series of legislations that have been introduced to protect and safeguard the reproductive rights of women, including the Surrogacy Bill and the Medical Termination of Pregnancy amendment Bill⁷.

Journey of the Bill

The bill's origins can be traced back to “National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India” drafted by the ICMR in 2005⁸. It has been in the works for over a decade, with the initial draft being drawn up by the Indian Council of Medical Research in 2008⁹. The Surrogacy (Regulation) Bill, 2019, which was passed in the Lok Sabha in 2019, was referred to a Select Committee that suggested that the ART Bill be brought first, so that relevant

³ PRS Legislative Research, <https://prsindia.org/billtrack/prs-products/prs-legislative-brief-3512> (Last visited May 15, 2021).

⁴ What is Assisted Reproductive Technology?, <https://www.cdc.gov/art/whatis.html> (Last visited October 8, 2019)

⁵ Saswati Sunderam, Dmitry M. Kissin, Sara B. Crawford, Suzanne G. Folger, Denise J. Jamieson, Lee Warner and Wanda D. Barfield, Assisted Reproductive Technology Surveillance — United States, 2014 66 CDC 3 (2017).

⁶ Editorial, Assisted Reproductive Technology Regulation Bill proposes national registry of clinics, The Hindu, May 15, 2021.

⁷ Rhythm Kaul, “Assisted reproductive technology bill sent to standing committee” Hindustan Times, May 15, 2021.

⁸ Explained: The Assisted Reproductive Technology (Regulation) Bill, 2020, <https://www.indiatimes.com/explainers/news/assisted-reproductive-technology-regulation-bill-2020-556043.html> (Last visited Dec 06, 2021).

⁹ Sana Ali, “Explained: Assisted Reproductive Technology bill to regulate India's fertility industry” BusinessToday.In, Dec 01, 2021.

technical components could be included in the former¹⁰. In 2016, a Bill was introduced to regulate surrogacy procedures¹¹. It provided for the registration of surrogacy clinics, defined eligibility criteria of commissioning couples and surrogates, and set up National and State Boards to advise the government on surrogacy policies. This Bill was referred to the Standing Committee on Health and Family Welfare, which made certain recommendations. However, with the dissolution of the 16th Lok Sabha, the Bill lapsed and another Bill was introduced to replace it in 2019. This Bill was referred to a Select Committee of Rajya Sabha.

The Assisted Reproductive Technology (Regulation) Bill, 2020 was introduced by Union Health Minister Harsh Vardhan in Lok Sabha on September 14, 2020¹². The Bill seeks to provide for the regulation of Assisted Reproductive Technology services in the country. It was referred to Standing committee on October 03, 2020 after which a report was prepared. The Standing Committee on Health and Family Welfare (Chair: Mr. Ram Gopal Yadav) submitted its report on the Assisted Reproductive Technology (Regulation) Bill, 2020¹³. The Bill was finally passed by Lok Sabha on December 01, 2021 after few amendments and by Rajya Sabha on December 08, 2021. Currently the Bill awaits assent of President.

Background of the bill

The Assisted Reproductive Technology (Regulation) Bill 2020 is the most recent, in a series of legislations approved by the Union Cabinet to protect and safeguard the reproductive rights of women. The bill makes provisions for safe and ethical practice of assisted reproductive technology services in the country. Through the bill, the National Board, the State Boards, the National Registry and the State Registration Authorities respectively will regulate and supervise assisted reproductive technology clinics and assisted reproductive technology banks. The Bill, was passed by voice vote in Lok Sabha on December 01, 2021 after Health Minister Mansukh

¹⁰ Assisted Reproductive Technology (Regulation) Bill, 2021: An Explainer, <https://www.theleaflet.in/examining-the-assisted-reproductive-technology-regulation-bill-2021/> (Last visited on Feb 15, 2022).

¹¹ The Surrogacy (Regulation) Bill, 2016

¹² PRS Legislative Research, <https://prsindia.org/billtrack/the-assisted-reproductive-technology-regulation-bill-2020> (Last visited May 14, 2021).

¹³ PRS Legislative Research, <https://prsindia.org/billtrack/prs-products/prs-standing-committee-report-summary-3644> (Last visited May 15, 2021).

Mandaviya responded to the debate on the same¹⁴. The bill was finally passed in Rajya Sabha on December 08, 2021 in the absence of opposition¹⁵.

Assisted reproductive technology (ART) has grown by leaps and bounds in the last few years. India has one of the highest growths in the ART centers and the number of ART cycles performed every year. Assisted Reproductive Technology (ART), including In-Vitro Fertilization (IVF), has given hope to a multitude of persons suffering from infertility, but also introduced a plethora of legal, ethical and social issues. India has become one of the major centres of this global fertility industry, with reproductive medical tourism becoming a significant activity. Nearly all ART services are available in India's clinics —gamete donation, intrauterine insemination (IUI), IVF, ICSI, PGD and gestational surrogacy. However, in spite of so much activity in India, there is yet no standardisation of protocols and reporting is still very inadequate.

The need to regulate the Assisted Reproductive Technology Services is mainly to protect the affected Women and the Children from exploitation. The oocyte donor needs to be supported by an insurance cover, protected from multiple embryo implantation and children born through Assisted reproductive technology should be provided all rights equivalent to a Biological Children. The cryopreservation of sperm, oocytes and embryo by the ART Banks needs to be regulated and the bill intends to make Pre-Genetic Implantation Testing mandatory for the benefit of the child born through assisted reproductive technology¹⁶. According to the Health Ministry, India's estimated number of surrogacy clinics is less than 1,000, whereas the number of ART clinics is more over 40,000¹⁷. The time has come to take a practical approach and legalise altruistic surrogacy while prohibiting commercial surrogacy¹⁸.

In *B. K. Parthasarathi v. Government of Andhra Pradesh*¹⁹, AP High Court has upheld “the right of reproductive autonomy” of an individual as an aspect of his “right to privacy” and supported

¹⁴ Lok Sabha passes bill to regulate assisted reproductive technology services, <https://www.timesnownews.com/health/article/lok-sabha-passes-bill-to-regulate-assisted-reproductive-technology-services/837340> (Last visited Dec. 02, 2021).

¹⁵ Esha Roy, “Surrogacy regulation Bill and ART Bill passed by Rajya Sabha” *The Indian Express*, Dec. 09, 2021.

¹⁶ PMIndia, https://www.pmindia.gov.in/en/news_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/ (Last visited May 15, 2021).

¹⁷ Kaunain Sheriff M, “Explained: What’s in ART, Surrogacy Bills” *The Indian Express*, Dec. 02, 2021.

¹⁸ Law Commission of India, 228th Report on Need for Legislation to Regulate Assisted Reproductive Technology clinics as well as Rights and Obligations of Parties to a Surrogacy, 2009 (August, 2009).

¹⁹ AIR 2000 A.P. 156.

the decision of the US Supreme Court in *Jack T. Skinner v. State of Oklahoma*²⁰, which characterised the right to reproduce as “one of the basic civil rights of man”.

Observations of the Standing committee²¹

➤ ART banks

Under the Bill, an ART bank acts as a registered entity for: (i) screening of gamete donors, and (ii) collection, screening, and storage of semen. The Committee observed that the role of the ART bank is not clear in the definition. Further, screening of gamete donors is a complicated process, which needs the presence of specialised doctors. ART banks may not have such doctors. The Committee recommended that the Department of Health Research should clearly define the role of ART banks, and the specialists required in them. Further, gamete screening should be done by an ART clinic, and its collection, storage, and supply should be handled by banks.

➤ Bodies regulating ART and surrogacy

The Committee noted that the Appropriate Authority under the Surrogacy (Regulation) Bill, 2020 and the Registration Authority under the ART (Regulation) Bill, 2020 are similar in composition and certain functions. These functions include: (i) grant, suspension, or cancellation of registration of a clinic or bank, (ii) enforcing standards of operation for clinics and banks, and (iii) investigating complaints of violation of the Act and related rules. The Committee recommended that the central government should constitute a common institution called Appropriate ART and Surrogacy Registration Authority to discharge these similar functions under both the laws. Further, since the National Surrogacy Board will also regulate the ART services, the Committee recommended that it should be renamed as the National Surrogacy and ART Board.

➤ Grievance Redressal

As per the Bill, every ART clinic and bank will have a grievance redressal cell. The Committee recommended that a 30-day timeframe should be provided for addressing the concerns of patients. In addition, a person may file a complaint with the court about ART services. However, to avoid burdening the courts, the Bill must provide for setting up an

²⁰ 316 US 535.

²¹ PRS Legislative Research, <https://prsindia.org/billtrack/prs-products/prs-standing-committee-report-summary-3644> (Last visited May 15, 2021)

independent and impartial grievance redressal cell in the Registration Authority. Complaints about ART clinics and banks would be addressed as a result of this.

➤ Data protection and privacy

The Bill specifies that the data collected by ART clinics and banks (such as procedures being undertaken) must be transferred to a central database (National Registry) within a month of receiving the data. The ART clinics and banks must store this data for at least ten years. The National Registry must share this data with the National Board for the purpose of inspection. The Committee noted that these are personal data which may lead to the identification of the commissioning couples, women, or donors. The Committee recommended that the personal data of patients and commissioning couples should be converted to a form in which a data principal (individual to whom the data belongs) cannot be identified. The data should be collected for a specific purpose and kept for the period required for that purpose. Further, the Bill should include provisions for anonymising the data at the primary source.

➤ Posthumous reproduction

Posthumous reproduction refers to reproduction by using the gamete of a deceased person. The Committee suggested that posthumous reproduction should be permitted, even in the absence of prior consent of the deceased unless the deceased has previously objected to this.

➤ Standardisation

The Committee noted that the cost of ART services varies across clinics. It recommended that standard operating procedures should be formulated to ensure the uniform cost of ART services and global quality standards. Further, a monitoring mechanism should be set up under the National Board to prohibit commercialisation of the ART services by private service providers.

Shortcomings of the Bill

The Bill seems to be very useful to regulate commercial surrogacy but there are certain restrictions which make it a little restrictive:

- The law mandates the creation of a Registry to maintain a database of ART treatments across the country. In the absence of a comprehensive data protection regime and proper

regulations regarding the use and security of such data there may arise privacy concerns²².

- The couples opting for ART need to be married for a period of not less than 5 years which is an infringement upon the right to start a family. Other requirements are that the couple should constitute of a male of age 26 to 55 and a woman of age 25 to 50 years²³. They should both be Indians and not have any other biological or adopted or surrogate children. (Unless the child is mentally challenged or has a terminal disease.)
- The couple seeking to avail of ART need to fulfill other eligibility criteria such as a certificate of essentiality – proven infertility of one of the two persons, a court order on the parentage and custody of the child born through surrogacy. This requirement is not necessary in countries like UK²⁴, South Africa²⁵ and Canada²⁶.
- An oocyte donor can only donate only once for a commissioning couple in her lifetime²⁷ which seems very restrictive provision as there is no medical backing to it.

Suggestions

Following are some of the lacunae which should have been included in the bill:

- ✓ Inclusion of LGBTQ Community and single parent: it may be argued that the bill violates Art 14 of the Constitution of India as it allows only single women and Married couples to avail the services provided in the act and specifically excludes single men and same sex couples. After the landmark verdict of Supreme Court in Navtej Singh Johar v Union of India²⁸, enabling same sex couple to avail the ART services could have been a progressive step on the part of the legislators on recognizing their right to family.

²² Neeta Lal, India's New Reproductive Laws Trigger Debate, The Diplomat (Feb. 14, 2021, 02:23PM), <https://thediplomat.com/2022/01/indias-new-reproductive-laws-trigger-debate/>

²³ The Assisted Reproductive Technology (Regulation) Act, 2021, § 21 (g), No. 42, Acts of Parliament, 2021 (India).

²⁴ The Human Fertilisation and Embryology Act, 2008, No. 22 Acts of Parliament, 2008 (UK).

²⁵ National Health Act, 2003, No. 61 Acts of Parliament, 2003 (South Africa).

²⁶ Assisted Human Reproduction Act, 2004, No. 2 Acts of House of Commons, 2004 (Canada).

²⁷ The Assisted Reproductive Technology (Regulation) Act, 2021, § 27 (4), No. 42, Acts of Parliament, 2021 (India).

²⁸ AIR 2018 SC 4321

- ✓ **Members of the Appropriate Authority:** The bill stipulates that a licenced medical practitioner (which will give clinic and bank registration and enforce requirements to be met by them) must be a member of the authorised authorities at the national and state levels. While the discussions were going on in the house members argued that not every medical practitioner is acquainted with ART services. Hence, experts should also be included the list of members of the appropriate authority.
- ✓ **Data Sharing:** The obligation for ART clinics and banks to submit personal information about donors and commissioning parties with the National Registry may infringe on such individuals' right to privacy. While anonymous statistics may be valuable for policy formulation, it's questionable why personal information about the parties is required. This completely ignores the Right to privacy of the donor which has been read as a fundamental right after the Justice K.S. Puttaswamy (Retd.) v. Union of India²⁹.
- ✓ **Restricted rights of the Donors:** The bill provides for counseling services³⁰ to the commissioning parties and right to withdraw consent³¹ before the embryo or gamete is transferred to the woman's uterus. However, the donor does not have any right to withdraw her consent and no provision is made for the counseling of the donor which makes the rights provided in this bill one sided ignoring the situation in India where man women are forced into surrogacy or money.
- ✓ **Lack of clarity over appeal procedures:** The bill includes measures for ART clinic and bank registration in Chapter III. Section 19³² allows for appeals against the appropriate authorities' orders of rejection, suspension, or cancellation of registration. Clinics and commissioning parties can both file appeals under this clause. The commissioning parties' reasons for allowing such appeals are unclear.

Conclusion

The Bill is still flawed from many angles and have some way to go before it becomes properly inclusive. Even the newly amended MTP Act has been criticised for not giving all women their

²⁹ (2017) 10 SCC 1

³⁰ The Assisted Reproductive Technology (Regulation) Act, 2021, § 21 (c) (i), No. 42, Acts of Parliament, 2021 (India).

³¹ The Assisted Reproductive Technology (Regulation) Act, 2021, § 22 (4), No. 42, Acts of Parliament, 2021 (India).

³² The Assisted Reproductive Technology (Regulation) Act, 2021, No. 42 , Acts of Parliament, 2021 (India).

reproductive rights. Some of the provisions of the ART Bill and the Surrogacy Bill have also been challenged. For instance, allowing ART treatment for only infertile couples and putting an age limit on eligible couples eliminates whole groups of people who may most need the treatment. Also, there is no provision for LGBT Community to avail surrogacy. The right to reproduce is declared as the fundamental right of an individual according to the Supreme Court judgment³³, however this bill has not taken it into consideration.

Women activists have questioned this romantic perception of pregnancy and surrogacy. Surrogacy, they say, is a job like any other and as long as a woman is not forced into becoming a surrogate, she has every right to demand compensation for the job she is doing. Maybe calling it compensated surrogacy might make it more acceptable. Also, inclusion of LGBTQ community in the Bill could have been a step forward for recognizing their right to have a family. The restrictive nature of the bill could lead to growth of illegal black market services for egg donation and surrogacy rather than regulating it.



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³³Devika Biswas v. Union of India, AIR 2016 SC 4405.