THE ASSISTED REPRODUCTIVE TECHNOLOGY (REGULATION) BILL, 2021 – A TIMELY STEP OR A RESTRICTIVE SETBACK?

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Recently, the Lok Sabha has passed the Assistant Reproductive Technology (Regulation) Bill, 2021 on 1st December 2021, which was introduced on 14th September 2020. The ART Bill, 2021, along with the Surrogacy Bill is soon to be tabled in the Upper House, aims at the befitting administration and management of Assisted Reproductive Technology banks and clinics in the Country and to deter the exploitation of this technology in India. Though the drafters of this proposed piece have put in a commendable effort, the draft is not free of loopholes and carries major lacuna with it.

Let’s break down what the present ART Bill, 2021 is and its plausible impacts and consequences.

Background

India has become one of the major emerging hubs with regard to reproductive medical tourism and rise of ART clinics. Though the Indian Council of Medical Research, in 2005, has issued guidelines for management of ART clinics in India, there was a lack of legislative backup1 and standard protocols for the clinics.

The ART Bill, 2021 defines ART as “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.” An ART bank is defined as an organisation set up to supply sperm or semen, oocytes, or oocyte donors to ART clinics or their patients3.

Assisted Reproductive Technologies are a wide range of medical interventions that assist reproduction which includes procedures such as In-Vitro fertilization, intracytoplasmic sperm injection, intrauterine Insemination, Zygote intrafallopian transfer and Gamete intrafallopian transfer.

The present Bill is the new version of a sequence of akin legislations over the past 12 years. Assisted Reproductive Technologies acts as a method for those who are unable to reproduce and exercise their reproductive rights.

Important provisions of the ART Bill, 2021

Who shall avail Assisted Reproductive Technology services?

The Bill stipulates that a man wishing to donate semen must be between 21 and 55 years4 and a woman wishing to donate ovum must be between 23 and 35 years5.

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1 Indian Council of Medical Research, National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, 2005.
2 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 2(a).
3 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 2(b).
4 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 27 2(a).
5 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 27 2(b).
According to the current bill, a woman above 21 years and below the age of 50 and a man above the legal age of marriage and below the age of 55 can utilize the assisted reproductive technology services. In addition to that a bank cannot supply the gamete of a single donor to more than one commissioning couple.

Regulation of the practices of ART

Registration Authority

Under section 12(3) of the ART Bill, 2021 postulates that a Registration authority shall have a

- Chairperson, who will be an officer above the rank of Joint Secretary in the Health Department;
- a Vice-Chairperson, who will be above the rank of the Joint Director in the Health Department;
- an eminent woman representing a women’s organisation;
- an officer of the Law Department, and, an eminent registered medical practitioner.

National Board

The Bill proposes for the establishment of a National Board which refers to the National Assisted Reproductive Technology and Surrogacy Board under section 15 of the Surrogacy Act. The functions of the National Board are elaborated under section 5 of the Bill.

Safeguards

Written Informed Consent

ART services shall be provided only after obtaining written informed consent from all the parties seeking the services.

Rights: Child born through ART services

A child which is born using ART services is deemed to be the biological child of the commissioning couple and is entitled to the same privileges and rights as that of a natural child. The Bill also furnishes that the donor must relinquish all the parental rights over children born from the couple’s gamete.

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6 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 21 (g) (i).
7 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 21 (g) (ii).
8 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 27 (3).
9 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 11(a).
10 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 15(1).
11 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 15(3).
12 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 16(6).
13 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 22(1)(a).
14 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 31(1).
15 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 31(2).
Insurance cover

The Act provides for insurance cover for egg donors for a period of twelve months by the commissioning couple or woman from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority. This insurance will act as a guarantee of compensation for any specific losses, damages, complications or death of the donor during the entire ART process.

Professional counselling

The Act also stipulates that professional counselling on the chances of success and implications of the ART procedures shall be provided to the commissioning couple and woman.

Testing for disease

The Act imposes pre-implantation genetic testing to screen the embryo for known, pre-existing, heritable or genetic diseases to identify genetic defects created in embryos through IVF before pregnancy.

Penalties

The Bill proposes that a medical geneticist, gynaecologist, registered medical practitioner or any person shall not abandon, disown or exploit or cause to be abandoned, disowned or exploited in any form the child or children born through assisted reproductive technology, sell, import or transfer any human embryo or gamete. The Bill further lays down that the afore-said offences shall be punishable with a fine between Rs 5,00,000/- and Rs 10,00,000/- for the first contravention. For subsequent contraventions, these offences will be punishable with imprisonment for a term between 8 and 12 years, and a fine between Rs 10 and Rs 20 lakh.

The Bill set forth stringent punishment of imprisonment for a term not less than 5 years but shall extend to 10 years or with fine not less than 10,00,000/- rupees but may extend to 25,00,000/- rupees or with both, for those who practises the act of sex selection.

Difference: The ART Bill, 2021 and the Surrogacy (Regulation) Bill, 2019

The Surrogacy (Regulation) Bill, 2019, another crucial bill to protect the reproductive rights of women was passed by Lok Sabha on 5th August 2019. This Bill was later referred to the Select Committee, which suggested that the ART Bill, 2019 should be passed first, so that all the relevant exceptional technical and medical aspects shall be consolidated in the Surrogacy (Regulation) Bill passed in 2019.

The distinguishing characteristic of both the bills is that the Surrogacy (Regulation) Bill, 2019 is associated with the process of surrogacy, an infertility treatment, where a third party, a woman, feigns as a surrogate mother. Whereas, under the ART Bill, 2021, the treatments shall be availed by the

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16 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 22(1)(b).
17 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 21(c)(i).
18 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 25.
19 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 33(1).
20 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 33(2).
21 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 32(2).
22 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 32(1).
commissioning couple and it does not mandate the involvement of a third party.

The Surrogacy Regulation Bill lays down for the establishment of a National Surrogacy Board which act as a supervising body and involves in policy making and State Boards, which characterizes as an executive body. Whereas, the ART (Regulation) Bill, 2019 which stipulates for the foundation of a National Board, and State Board under section 3 and section 6 of the ART Bill, 2019 respectively.

Critical Analysis: What’s the Debate?

Interpretation of the term “Couple”

The ART Bill, 2019 defines the “Commissioning Couple” as an infertile married couple who approach an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the services authorised of the said clinic or bank. The main lacunae which exists here is that there is a certain ambiguity in the aforementioned definition, where the Bill talks about a relationship in the nature of marriage between male and female person, which discriminates against the same-sex couples, live-in couples and single parents, which moves against the spirit of the Hon’ble Apex Court decision in Navtej Singh Johar v. Union of India. The Hon’ble Supreme Court in Indra Sarma v. VKV Sarma, has laid out certain conditions which needs to be satisfied before considering a live-in-relationship to be a ‘relationship in the nature of marriage’. Thus, the Bill has completely turned a deaf ear to the social aspects of the people who are subject to legal recognition, who are forced to forgo their granted legal rights.

Inimical to single women

The ART Bill 2019 make the services of surrogacy available only to the commissioning couple, thereby making unmarried women and men unqualify to avail ART facilities, thereby violating their fundamental right to procreation as recognized by the Hon’ble Supreme Court in R Rajagopal v. State of Tamil Nadu. The Hindu Adoption and Maintenance Act and the Guardians and Wards Act allows unmarried single individuals to adopt children. Even the Juvenile Justice (Care and Protection of Children) Bill, 2014 speculates that a person may adopt a child irrespective of their marital status.

The Bill through its provisions has propagated the archaic values and beliefs thereby depriving single individuals from procreating through ART's facilities which denies their rights and personhood and further ensconcing their marginalization and exclusion.

Unsettled Repercussions: Breach of Surrogacy Agreement

One of the shortcomings of the act is that the Bill does not impart provisions in the cases of breach of surrogacy agreements, which might result in uncertain ramifications. Thus, it is suggested that the Bill should inculcate provisions, whereas in case of breach of surrogacy agreement, the surrogate may file

23 The Assistant Reproductive Technology (Regulation) Bill, 2021, § 2 (1)(e).
27 Juvenile Justice (Care and Protection of Children) Bill, 2014, § 60.
a complaint to the boards established under the Bill or to a civil or criminal court. Furthermore, the Bill should also bestow the police with the power to take cognizance of any complaint made by a surrogate mother against the commissioned couple.

Insurance of Surrogate: Vague and Inappropriate

Though the ART Bill, 2019 provides for insurance coverage for a period of 12 months in favour of the oocyte donor by the commissioning couple, it is silent with regard to the issue of post-delivery and the follow up care of surrogate mothers. It is suggested that the Bill should enunciate the standard of care and amount of compensation to be made to the surrogates by taking into account the medical checkups, procedures cost, etc. Additionally, there is lack of clarity as to the quantum of compensation to be awarded to the surrogate mother.

Privacy of the parties involved

It is necessary for the ART Bill, 2019 to provide a robust need for protection of client data. The Clinics and Banks are expected to furnish all the information’s related to client enrolment, procedures, complications and outcomes to the National Registry. The National Registry, in turn, shall accord the “data generated” with the National Board for Research and Policy Formulation, which raises certain concerns towards the party’s confidentiality and privacy. Thus, it is suggested that the information with regard to the individual clients and their treatment should remain decentralized with the respective banks and clinics and such details should be safeguarded by security protocols and measures and

Extrapolating the Rights of child born out of surrogacy

The Bill does not explore much about the rights of the child born out of surrogacy and miserably fails to deal with the instances which would poses legal hurdles for the child and as well as the commissioning couples. There is a lack of provision with regard to the rights of the child which was abandoned prior to the delivery of the couple and in case of the couple being divorced or separated. The Hon’ble Apex Court in Manji Yamada v. Union of India28, considering the circumstances of the case, held that custody of the child shall be given to father and grandmother of the concerned child upon the separation of the commissioning couple before its birth. Forbye, it is mandatory to have a watchdog to keep a check over such commissioning couples as to whether they indulge their children in any illegal act or whatsoever.

A bill to regulate the services of Assistant Reproductive Technology services is long awaited and need of the hour. But the current iteration may not be fully forceful to regulate the ARTs industry and address and unravel several legal, ethical and medical issues indicated in the use of ARTs facilities. Although, the absence of the control of the Government has enhanced the investment in this sector, on the other side, it has also resulted in the foundation of many unscrupulous unsavory clinics and exploiting the surrogate mothers. Therefore, it is necessary for the Government to call for a public consultation on the Bill and to get rid

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of all the adverse elements and amend the law that is responsive to the rights of the Assistance Reproductive Technology users.

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