



2021

COUNTERPRODUCTIVE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES: A REVIEW OF THE ASSISTED REPRODUCTIVE TECHNOLOGIES BILL, 2020

Prabha Kotiswaran

Sneha Banerjee

Follow this and additional works at: <https://repository.nls.ac.in/nlsir>

Recommended Citation

Kotiswaran, Prabha and Banerjee, Sneha (2021) "COUNTERPRODUCTIVE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES: A REVIEW OF THE ASSISTED REPRODUCTIVE TECHNOLOGIES BILL, 2020," *National Law School of India Review*. Vol. 33: Iss. 2, Article 7.
Available at: <https://repository.nls.ac.in/nlsir/vol33/iss2/7>

This Article is brought to you for free and open access by Scholarship Repository. It has been accepted for inclusion in National Law School of India Review by an authorized editor of Scholarship Repository.



COUNTERPRODUCTIVE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGIES: A REVIEW OF THE ASSISTED REPRODUCTIVE TECHNOLOGIES BILL, 2020

—Prabha Kotiswaran* and Sneha Banerjee**

Abstract — This article critically engages with the Assisted Reproductive Technologies (Regulation) Bill, 2020 (‘ART Bill 2020’), which is set to draw curtains on a regulatory journey of more than a decade and a half to culminate in a highly restrictive approach. Engaging with the provisions of this Bill, the article foregrounds that one of the important ways in which this restrictive approach finds articulation is by defining eligibility criteria that are exclusionary and seek to regiment the possibilities that technology opens for founding families beyond the strict realms of heteronormative marriage. The article also argues that there are several lacunae in the Bill that exacerbate concerns around implementation and operationalisation if it is passed in its current form. Moreover, it shows that such gaps and inconsistencies also open adequate grounds for the legislation to be challenged on constitutional grounds. With the objective of addressing exploitation, recent regulatory steps with regard to reproduction facilitated by technology have taken a stance that reeks of hetero-patriarchal moralist undertones. In this context, this article also views the ART Bill 2020 in tandem with the Surrogacy (Regulation) Bill, 2019 where it demonstrates how there is a lack of complementarity between the provisions of the two Bills.

* Prabha Kotiswaran is a Professor of Law and Social Justice at the Dickson Poon School of Law at King’s College London, UK. Dr. Kotiswaran’s research for this article has received funding from the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation programme (grant agreement No 772946).

** Sneha Banerjee is an Assistant Professor in the Department of Political Science at the University of Hyderabad, India.

I. INTRODUCTION

The Indian state has sought to regulate assisted reproductive technologies ('ARTs'), including surrogacy, for the last 15 years now.¹ Indeed, regulation of ARTs, including surrogacy as one of its subsets, started from 2005, when the Indian Council for Medical Research ('ICMR') issued the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India² and continued through with various iterations of the ART Bill in 2008, 2010, 2013, and 2014. It was only in 2016, that given the sensationalised media coverage of surrogacy, especially in its transnational avatar, and in view of a public interest litigation that sought a ban on commercial surrogacy,³ that the regulation of surrogacy was separated from the ART Bill, and was prioritised for regulation in a silo, with the ART Bill to follow. Thus, the first version of the Surrogacy Regulation Bill was announced in 2016⁴ and its most recent iteration, namely, the Surrogacy (Regulation) Bill 2019 ('SRB 2019'),⁵ has been scrutinised by two parliamentary committees. Both committees called for the introduction of a companion Bill in the form of the ART Bill. Thus, the Health Minister, Dr. Harsh Vardhan, introduced the Assisted Reproductive Technology (Regulation) Bill, 2020, ('ART Bill 2020') in the Lok Sabha in the monsoon session of 2020.⁶ On October 3, 2020, the ART Bill 2020 was referred to a Parliamentary Standing Committee ('PSC') which submitted its report on March 17, 2021. Even though the introduction of the ART Bill 2020 has followed that of the SRB 2019, it is the ART Bill which is wider in scope, covering several manifestations and uses of ARTs, of which gestational surrogacy (the focus of SRB 2019) is merely one. In this sense, the two bills are complementary and ideally, the ART Bill should be the umbrella legislation that the SRB 2019 uses as a point of reference. Ironically, the approach adopted is the reverse of the ideal. Although both Bills promise approximately 27 million Indian infertile couples the possibility of forming a family by accessing medical technology, they leave much to be desired.⁷

¹ The law detailed in this article is accurate as of its date of online publication, December 2, 2021. The Assisted Reproductive Technology (Regulation) Bill, 2021 and Surrogacy (Regulation) Bill, 2021 were passed by both houses of Parliament during the winter session and were given Presidential assent in late December. The Assisted Reproductive Technology (Regulation) Act, 2021 and Surrogacy (Regulation) Act, 2021 have been published in the Official Gazette and are in force with effect from 25 January 2022. Wherever the Acts diverge from the Bills, we have included a footnote in the article.

² Ministry of Health and Family Welfare, 'National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India' (ICMR, 2005) <https://main.icmr.nic.in/sites/default/files/art/ART_Pdf.pdf> accessed on 25 February 2021.

³ *Jayashree Wad v Union of India* Writ Petition (Civil) No 95 of 2015 (Pending) (SC).

⁴ Press Information Bureau, 'Cabinet approves introduction of the "Surrogacy (Regulation) Bill, 2016"' (*PIB*, 24 August 2016) <<https://pib.gov.in/newsite/PrintRelease.aspx?relid=149186>> accessed on 25 February 2021.

⁵ Surrogacy (Regulation) Bill 2019.

⁶ Assisted Reproductive Technologies (Regulation) Bill 2020.

⁷ Himani Chandna, 'Modi cabinet approves bill to regulate fertility clinics offering IVF & other services' (*The Print*, 19 February 2020) <<https://theprint.in/health/>

In this article, we take a critical look at the provisions of the ART Bill 2020 and engage with its increasingly constricted regulatory approach, laden with moralist undertones towards the use of reproductive technologies as a mode of founding families. In particular, we discuss who can access ARTs or donate gametes and on what terms. We ask if the stated goals of the Bill to address exploitation are achieved. We give thought to whether the key provisions of the ART Bill 2020 can be operationalised. We then test the complementarity between the ART Bill 2020 and the SRB 2019 to find significant dissonance between the two Bills. We conclude by arguing that the two Bills need to be deliberated upon in tandem with each other but also that several provisions of both Bills likely violate the Indian Constitution. Notwithstanding some valuable recommendations made by the PSC which examined the ART Bill 2020 and which we refer to throughout the article, both Bills need to be revisited as a matter of urgency.

II. WHO CAN(NOT) USE ASSISTED REPRODUCTIVE TECHNOLOGIES?

ARTs offer infertile couples a way to form their families. ARTs often involve the donation of male and female gametes which are fertilised in a laboratory environment for implantation in the womb of either the genetic mother or a surrogate. As such, it involves various stakeholders including gamete banks, in-vitro fertilisation (‘IVF’) clinics, gamete donors, commissioning parents, and surrogates. Therefore, the first crucial question is who can access ARTs. In a departure from its earlier versions, the ART Bill seeks to re-centre the role of marriage for founding families. In Section 2(1)(g) and (q), the ART Bill defines the ‘commissioning couple’ to mean “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” and ‘patients’ to mean an “individual or couple who comes to any registered assisted reproductive technology clinic for management of infertility”, respectively. Though it does not prohibit the use of ARTs outside of ‘marriage’ in so far as individuals are allowed to use ARTs, a ‘couple’, unless married, cannot use ARTs. This means that cohabiting couples and same-sex couples cannot access ARTs. There is no definition of ‘man’, but Section 2(1)(x) includes a definition for ‘woman’ as “any woman above the legal age of marriage who approaches an assisted reproductive technology clinic or assisted reproductive technology bank for obtaining the authorised services of the clinic or bank.”⁸ Throughout the text of the ART Bill, phrases like “infertile couple

[modi-cabinet-approves-bill-to-regulate-fertility-clinics-offering-ivf-other-services/368054/>](#) accessed 4 December 2020.

⁸ Under the ART Act, 2021, Section 2(1)(u) defines a ‘woman’ as any woman above the age of 21 years. The definition is thus not linked to the legal age of marriage.

or woman”⁹ and “commissioning couple and woman”¹⁰ are used, thereby making clear that a single woman can access ARTs but not a single man.

The Statement of Objects and Reasons of the ART Bill 2020 claims that while ART, including IVF, has given hope to a multitude of persons suffering from infertility, it has also introduced a plethora of legal, ethical, and social issues. There are a few issues relevant to this context-setting for the regulation, which the Bill has overlooked. *First*, ‘infertility’ as a disease is defined in multiple ways. For example, the World Health Organisation (‘WHO’) defines the term¹¹ in three different ways: clinical, demographic, and epidemiological; it also seeks to view it as a disability, and identifies some typologies like primary and secondary infertility.¹² However, the ART Bill, under Section 2(1)(m), defines ‘infertility’ as the “inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception”. Therefore, the simplistic and narrow way in which the ART Bill defines and engages with infertility itself falls short of ameliorating the ‘suffering’ that it identifies with the condition.

Second, the hope that ARTs present for people who desire to have children but otherwise cannot, is not just limited to those who might suffer from clinical ‘infertility.’ By presenting the possibility of gamete donation, IVF, and gestational surrogacy, ARTs make it possible for queer individuals and same-sex couples to have children. In this sense, ARTs facilitate reproduction beyond heteronormative marriage and regardless of people’s sexual orientation. However, the ART Bill 2020 has regimented the usage of ARTs within the institution of heteronormative marriages. As we have argued elsewhere¹³ in relation to similar exclusions under the SRB 2019, the exclusion of single men, cohabiting and same-sex couples, and transgender persons from accessing

⁹ Section 2(1)(k) defines a ‘gamete donor’ as “a person who provides sperm or oocyte with the objective of enabling an infertile couple or woman to have a child” – it implicitly excludes men as beneficiaries of the use of ARTs to have children.

¹⁰ For example, Section 21 that enlists the “General duties of assisted reproductive technology clinics and banks” repeatedly uses this phrase, as also “donors”, thereby implicitly excluding men as users of ARTs but does include their role as gamete donors.

¹¹ For clinical purposes, infertility is considered to be the inability to conceive within 12 months of contraception-free sex, while to understand it in the sense of a demographic indicator or in the form of a ‘Reproductive Health Indicator’ for “monitoring and surveillance” of women in the age group of 15-49 years, it is seen as non-conception of pregnancy with contraception-free sex for ‘five years’ and ‘two years or more’ respectively. *See*, World Health Organisation, ‘Infertility definitions and terminology’ (*World Health Organisation*) <<https://www.who.int/teams/sexual-and-reproductive-health-and-research/key-areas-of-work/fertility-care/infertility-definitions-and-terminology>> accessed 2 December 2020.

¹² *ibid*. Primary infertility refers to the inability to ever conceive, while secondary infertility is the inability to conceive following a previous instance of conception or carrying a pregnancy to term.

¹³ Sneha Banerjee and Prabha Kotiswaran, ‘Divine labours, devalued work: the continuing saga of India’s surrogacy regulation’ (2020) 5(1) *Indian Law Review* <<https://doi.org/10.1080/24730580.2020.1843317>> accessed 2 December 2020.

ARTs violates Article 14 of the Constitution. Article 14 guarantees equality and equal protection before the law. For any legislative classification to be reasonable under Article 14 of the Constitution, the classification must be founded on intelligible differentia and the differentia must have a rational nexus to the objective sought to be achieved by the legislation.¹⁴

The ART Bill 2020 permits only heterosexual, married couples, and single women to access ARTs and thus, form their families. It does not afford single men, heterosexual co-habiting couples, and same-sex couples this option. This differentia seems unintelligible in assuming that a heterosexual married couple or single woman are inherently capable of being a parent and forming a family whereas a single man or cohabiting couple or same-sex couple cannot do the same. This differentia has no rational nexus with the objective of the ART Bill 2020 which is “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.” Moreover, single and divorced persons are allowed to adopt children as per Section 57 of the Juvenile Justice Act, 2015.¹⁵ Finally, Section 3(e) of the Transgender Persons (Protection of Rights) Act, 2019, requires that transgender persons not be discriminated against in terms of “access to, or provision or enjoyment or use of any goods, accommodation, service, facility, benefit, privilege opportunity dedicated to the use of the general public or customarily available to the public”. Hence, the denial of ART services to transgender persons will violate the 2019 Act.

Similarly, the restrictions imposed on who can access ART services will violate the right to privacy jurisprudence of *Puttaswamy*,¹⁶ where the Supreme Court of India held that “the sanctity of marriage, the liberty of procreation, the choice of a family life and the dignity of being” concerned all individuals irrespective of their social status and were aspects of privacy. In *Navtej Singh Johar*, Justice Chandrachud exhorted the state to take positive steps for equal protection for same-sex couples.¹⁷ Moreover, unlike the SRB 2019, there is no prohibition in the ART Bill 2020 on foreign citizens accessing ARTs. Thus, foreigners can access ART, but Indian citizens in loving relationships cannot. This is an illogical result failing to reflect the true spirit of the Constitution.

Interestingly, marital status is the key not just to having a child by using ARTs, but also in order to be a gamete donor, despite there being no scientific explanation for its significance. While there is no clause detailing who can be

¹⁴ *State of West Bengal v Anwar Ali Sarkar* AIR 1952 SC 75.

¹⁵ Arijeet Ghosh and Nitika Khaitan, ‘A Womb of One’s Own: Privacy and Reproductive Rights’ (2017) 52(42-43) EPW Engage <<https://www.epw.in/engage/article/womb-ones-own-privacy-and-reproductive-rights>> accessed 9 September 2020.

¹⁶ *KS Puttaswamy v Union of India* (2017) 10 SCC 1.

¹⁷ *Navtej Singh Johar v Union of India* (2018) 10 SCC 1.

a sperm donor, Section 27(4) of the ART Bill stipulates who can be an oocyte/egg donor. The egg donor is supposed to be an ‘ever-married’ woman, who has at least one living child not less than 3 years old.¹⁸ Further, she can donate gametes only once in her lifetime. These conditions necessitate, at least in theory, that such a woman is 18 years old and above – a welcome step. However, by omitting an age-based criterion to instead include criteria based on marital and motherhood status, it in effect opens up the possibility of very young women acting as gamete donors since early marriages are not uncommon in the Indian context.¹⁹ Further, this provision is paternalistic to its core in dictating to women when and under what circumstances they can manage their bodies, not unlike mandates on women to make reproductive decisions only with the consent of their husbands or only towards procreative ends. Notably, the PSC in its report has recommended that eligibility for egg donation be delinked from marital status and be linked to the age criterion (21 years) instead.²⁰

III. ADDRESSING EXPLOITATION?

In its Statement of Objects and Reasons, the ART Bill 2020 also identifies that “[t]he need to regulate the Assisted Reproductive Technology Services is mainly to protect the affected women and children from exploitation”. The ART Bill 2020, as well as the SRB 2019, selectively target commercialisation which is presumed to be exploitative per se. Hence, they deny remuneration for women’s reproductive labour and any form of reasonable monetary compensation for their time, involvement, and contribution in these processes. Thus, an egg donor would receive no compensation or reimbursement of expenses for loss of salary, time, and effort under the ART Bill 2020, just like a woman acting as a surrogate under the SRB 2019. In other words, egg donors and surrogates are expected to be altruistic. It is ironic that the ART Bill 2020 seeks to address commercialisation by prohibiting payment to women, who render their bodies, bodily material, and reproductive labour, but does not recognise that the immediate context for ARTs in India is a profit-driven, private healthcare sector.²¹

In the context of surrogacy, let us consider how the two parliamentary committees that reviewed the SRB 2019 dealt with this issue. The PSC sought to channelise the debate beyond the commercial versus altruistic trope to make

¹⁸ The ART Act, 2021 dispenses with this requirement.

¹⁹ The ART Act, 2021 now incorporates an age-based criterion and Section 27(2)(b) of the ART Act, 2021 requires the oocyte donor to be between the ages of 23 and 35 years.

²⁰ Parliamentary Standing Committee, *Report on the ART Bill 2020* (Parliamentary Standing Com No 129, 2021) paras 4.2.27 and (‘PSC Report’).

²¹ Tulsi Patel, ‘Assisted Reproductive Technologies (ARTs) and Public Health: Exploring the Oxyoron’ (2013) 43(1) *Indian Anthropologist* 65-78.

a case for “compensated” surrogacy.²² This was meant to account for the time, loss of wages, cost of health, and non-provisioning of reproductive labour for her own family during the pregnancy by a surrogate as factors justifying compensation over and above the insurance and expenses incurred that are to be borne by the commissioning couple.²³ In contrast, the Rajya Sabha Select Committee, found it unacceptable to put what it saw as a “price tag” on motherhood, whether in the capacity of a surrogate or not, which ought to be “altruistic and selfless” performed “wilfully and voluntarily”.²⁴

In consonance with the approach espoused by the PSC which reviewed the SRB 2019, we emphasise that the lack of compensation for providing reproductive labour is arguably violative of Article 23 of the Constitution of India, which prohibits forced labour. We note that courts in India,²⁵ in accounting for women’s unpaid domestic work, have considered child-bearing as a form of labour. Thus, reproductive labour is involved in making one’s bodily services available for surrogacy and egg donation. Further, in *PUDR v. Union of India*,²⁶ also referred to as the ‘Asiad Games case’, Justice Bhagwati elaborated on the meaning of the term ‘force’ under Article 23 of the Constitution and concluded that “any factor which deprives a person of a choice of alternatives and compels him to adopt one particular course of action may properly be regarded as ‘force’ and if labour or service is compelled as a result of such ‘force’, it would be ‘forced labour’”.²⁷ Since only a person suffering from hunger or starvation would accept a job where the remuneration is less than the minimum wage, the court reasoned that any labour remunerated at a level less than the minimum wage would be considered to be forced labour under Article 23. We believe that not allowing for compensation for egg donors therefore amounts to state approval of forced labour.

While eliminating compensation for women acting as surrogates or egg donors, the ART Bill 2020 and the SRB 2019 underscore the need for insurance cover as a protective measure against exploitation. However, the nature of such coverage is left vague in the relevant section,²⁸ without detailed guidelines

²² Rajya Sabha, ‘Department-Related Parliamentary Standing Committee on Health and Family Welfare – One Hundred Second Report: The Surrogacy (Regulation) Bill, 2016’ (*PRS*, 2017) para 5.22 <https://www.prsindia.org/sites/default/files/bill_files/SCR-%20Surrogacy%20Bill%2C%202018.pdf> accessed on 25 February 2021.

²³ *ibid* para 5.24.

²⁴ Rajya Sabha, ‘Report of The Select Committee On The Surrogacy (Regulation) Bill, 2019’ (*PRS*, 2020) para 4.9 <https://www.prsindia.org/sites/default/files/bill_files/Select%20Comm%20Report-%20Surrogacy%20Bill.pdf> accessed on 25 February 2021.

²⁵ Relevant here are various cases pertaining to determination of compensation to families under the Motor Vehicles Act, 1988, and cases such as *National Insurance Co Limited v Deepika* 2009 SCC OnLine Mad 828.

²⁶ *People’s Union for Democratic Rights v Union of India* (1982) 3 SCC 235: AIR 1982 SC 1473.

²⁷ *ibid* para 5.10.

²⁸ In Section 22(1)(b) of the ART Bill 2020, there is provision of an insurance coverage of such amount and for such period as may be prescribed in favour of the oocyte donor by the

on the scope, duration, and amount of insurance. Even as insurance provisions are being considered, it is glaring that more basic protections to the egg donor are not available under the ART Bill 2020. The Bill requires an egg donor's written consent but does not provide for her counselling or ability to withdraw her consent before or during the procedure (unlike for commissioning parties).²⁹ This is problematic because egg donation may appear to be straightforward but in fact involves the harvesting of eggs, which is an invasive process. It involves administering ovarian stimulation hormones which can result in over stimulation, and even death.³⁰ In such a context, the absence of basic protections coupled with a prohibition on remuneration means that egg donors' vulnerabilities are in fact compounded. The stated aim of protecting them from exploitation is hardly met.³¹ The PSC addresses some of these concerns by requiring that informed consent of the gamete donor be procured twice, at the screening stage and the donation stage. The PSC also recommends that the Bill specify an extension in insurance coverage for the donor to "at least 12 months".³² Unfortunately, the PSC recommends that the requirements regarding informed consent be included in the rules rather than in the body of the Bill, which indicates that minimal changes to the ART Bill 2020 are preferred.

The low success rate of ART procedures, the need for repeated cycles, ethical concerns surrounding the procedure, and the unequal bargaining power between the parties are likely to give rise to disputes. Anticipating this, the Bill requires clinics and banks to maintain a grievance cell,³³ but there are no further provisions on how these will be regulated. It is highly likely that these grievance cells will be one-sided as they are run by clinics. Clinics must instead have ethics committees where problematic cases are discussed with experts from within and outside the clinic. Similarly, while mandated counselling services is a positive feature of the Bill, counselling should ideally be independent of the clinic.³⁴ Also, although clinics and banks are required to keep information about commissioning parents or women and donors

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.

²⁹ ART Bill 2020, s 22(1)(a).

³⁰ Priyanka Vora, 'Swelling, bleeding and even death – women who donate their eggs face many medical risks' (*Scroll*, 20 June 2018) <<https://scroll.in/pulse/881927/swelling-bleeding-and-even-death-women-who-donate-their-eggs-face-many-medical-risks>> accessed on 25 February 2021.

³¹ It is important to note here that not just women but even the children that the ART Bill 2020 claims to protect are not provided some basic guarantees. For example, children born from ARTs do not have the right to know their parentage. The right to know their parentage was protected under previous versions of the ART Bill but does not find a place in the ART Bill 2020.

³² PSC Report (n 16), para 4.15.7. This has been incorporated into the ART Act, 2021.

³³ ART Bill 2020, s 21(f).

³⁴ Section 21(c)(i) of the ART Bill, 2020, refers to those who seek access to ARTs, but is silent about gamete donors.

confidential,³⁵ barring exceptional circumstances as listed in Section 21(e) of the Bill, there is no such obligation imposed on the National Registry with which the banks and clinics are supposed to share such information. This can lead to breaches of privacy of the parents and donors, resulting in serious consequences in a country where infertility is a mark of social stigma. Notably, the PSC in this report recommends that data about the commissioning couple and donors be anonymised at the primary source so as to protect data privacy and that there be a fixed time duration for which records are maintained at the National Registry to comply with data protection principles of purpose limitation and storage limitation.

Finally, it is noteworthy that despite the state's concern around the agony of infertility, it stops short of assuming the responsibility of state-sponsored provisioning of ARTs at subsidised levels for disadvantaged sections of society. For instance, Chapter 7 of the National Guidelines for the Accreditation, Supervision, and Regulation of ART Clinics in India, 2005, issued by the ICMR, spoke of providing ART to the economically weaker sections of society, including through clinics in the public sector, by addressing the high cost of ovarian stimulation hormones and reducing dependence on multi-national corporations for these drugs. Such a vision has been side-lined ever since. Instead, the Bill merely limits itself to regulating private establishments specialising in these techniques in very broad terms like "duties" of ART Clinics and Banks (in Chapter 4 of the ART Bill 2020). Significantly, while the PSC Report points to the fact that there were only six IVF clinics in the public sector and calls for increased access to ARTs in public institutions for the poor and for price regulation, it again suggests that these be incorporated in the rules and regulations rather than being mandated within the body of the ART Bill 2020.

IV. GAMETES & EMBRYOS

A crucial element of ARTs involves the transfer of gametes both from the commissioning parents and/or the gamete donors. Section 29 of the ART Bill 2020 is a poorly worded provision which prohibits the sale, transfer, or use of gametes and embryos. In earlier versions of the Bill there was a provision that prohibited the transfer or sale of gametes across borders in order to ensure that there was no indiscriminate sale of biogenetic material through the export and import of gametes.³⁶ There was, however, an exception offered for commission-

³⁵ ART Bill 2020, s 21(e).

³⁶ For example, in an earlier version, the ART Bill, 2014, under Section 55(1) laid down that "The sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India is prohibited except in the case of transfer of own gametes and embryos for personal use with the permission of the National Registry of Assisted Reproductive Technology Clinics and Banks in India of the Indian Council of Medical Research."

ing parties that were transferring their own biogenetic materials across state borders. Under previous Bills, gametes could be transferred within the country for compensation. However, under the ART Bill 2020, the sale or transfer of gametes across borders and within the country is not permitted unless it is the transfer of one's own embryo.³⁷ Where commissioning parties rely on donated gametes before they are fertilised to form an embryo, the Bill does not permit the transfer of these gametes which produces an absurd outcome. This provision will also cause confusion for foreign commissioning parents who are allowed to access ARTs in India. Complicating matters is the fact that the Ministry of Commerce & Industry of the Government of India has issued a notification dated June 12, 2020,³⁸ permitting the export of human embryos from India. Recollect that when the government banned transnational surrogacy in 2015, it also prohibited the import of embryos into the country. But commissioning parents were even unable to export their own embryos outside the country once transnational surrogacy was banned. This led to lawsuits. The 2020 notification of the Ministry of Commerce & Industry now allows the export of embryos but it is unclear whether the import of embryos is permitted. This is testament to the contradictory position of the government on various aspects of ARTs and surrogacy, which has caused considerable anxiety and uncertainty for parents.

Even more perplexing is how the state visualises the political economy of the ART sector. Earlier drafts of the ART Bill envisaged compensation for gamete donation and proposed documentary evidence of such arrangements. However, the ART Bill 2020 seems to align with the SRB 2019 in proposing an altruistic model of gamete donation. In previous drafts, gametes could not be gifted between known friends and relatives.³⁹ Has this changed since the ART Bill 2020 has now shifted to an altruistic model of gamete donation? It is not clear. Either way, gamete shortage is likely. As the proprietor of an ART Bank, Dilip Patil recently lamented⁴⁰ that the provisions of the ART Bill require gametes from one donor to only be given to one commissioning party. Where screening of several sperm donors results only in a few potential donors, restricting the distribution of gametes to one commissioning party could lead to gamete shortage. And where gamete donation itself is not

³⁷ Section 29 of the ART Bill 2020 states “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.”

³⁸ GR Hari, ‘India Allows Import and Export Of Human Embryos’ (*Indian Surrogacy Law Centre*, 12 October 2020) <<http://blog.indiansurrogacylaw.com/author/grhari/>> accessed 2 December 2020.

³⁹ In the ART Bill 2014, s 46(12) stated, “No assisted reproductive technology clinic shall obtain or use sperm or oocyte donated by a relative or known friend of either of the parties seeking assisted reproductive technology treatment or procedures.”

⁴⁰ In an intervention during the webinar ‘Troubling ‘Gifts’: Revisiting the Indian ART and Surrogacy Bills’, organised by the Laws of Social Reproduction Project, funded by the European Research Council and hosted at the King’s College London, on 16 October 2020.

compensated, what is the incentive for donors to donate their gametes? This raises the question of how ART banks will remain financially viable. One can only surmise that since the ART Bill 2020 does not require a separation between ART clinics and banks as previous drafts did, that perhaps clinics will be allowed to operate banks and subsidise them through their ART services.⁴¹ The PSC has recommended that egg donors need not be married in a bid to address the issue of supply. However, this only partially removes obstacles to donation and in the absence of compensation for the inconvenience and risk involved, shortages are still likely.

Finally, the 2020 ART Bill requires pre-implantation genetic testing and where the embryo suffers from “pre-existing, heritable, life-threatening or genetic diseases”, it can be donated for research with the commissioning parties’ permission.⁴² These disorders may well be subsequently specified in delegated legislation, but they need some specification in the body of the Bill itself, otherwise it risks promoting a eugenic approach to reproduction which is deeply problematic. Thus, the PSC recommends that pre-implantation genetic diagnosis be undertaken only in case it is essential and that too as allowed by the registration authority. Interestingly, in previous versions of the Bill, there were detailed provisions for the donation or destruction of embryos which were found to have serious defects. In the ART Bill 2020, there is a reluctance to acknowledge that unused embryos might be destroyed. Similarly, there seems to be an aversion to conducting research on them, although the possibility of donation for research is conceded. The drafters of ART Bill 2020 thus exhibit moral discomfort with medical intervention when it comes to embryos. However, the Bill needs to reincorporate provisions from previous bills relating to the regulation of research using embryos. These pertained to the prohibition of the sale of gametes and embryos abroad for research, research on embryos created in-vitro and a prohibition of human reproductive cloning, the need for permission from the National Registry for research using embryos, and the need for registration of research institutions.

V. ARTS & SURROGACY

As noted earlier, the ART and surrogacy sectors are closely interrelated. However, the ART Bill 2020 and the SRB 2019 as they stand today, do not work in tandem. It is therefore necessary that these bills align with each other

⁴¹ Previous versions of the ART Bill required independence between ART banks and ART clinics. The goal there was to break up the one-stop service that surrogacy clinics often provided to transnational reproductive tourists, from picking up commissioning parents from the airport, to supplying gametes and surrogates, to running surrogate hostels to performing the delivery of the babies by surrogates. The multimodal nature of the process meant that there were various points for extraction of surplus value by fertility doctors. Commercialisation and commodification of bodily capital and reproductive labour seemed to run amok. There is no such distinction between the ART banks and clinics in the SRB 2019 or the ART Bill 2020.

⁴² ART Bill 2020, s 25(2).

in terms of important definitions, and respect to the regulation of ART clinics and banks as well as surrogacy clinics, and the institutions that regulate these clinics and banks and their relationship with patients, surrogates, and gamete donors. Let us start with definitions. Core ART processes are not defined under the ART Bill 2020; several of these are however defined in the SRB 2019. Definitions of the terms ‘commissioning couple’, ‘infertility’, ‘ART clinics’ and ‘banks’ need to be synchronised between the Bills.⁴³ The ART Bill 2020 defines ‘commissioning couple’ but the SRB 2019 defines ‘couple’ and ‘intending couple’; there is no uniformity in the terminology used. The two bills define ‘infertility’ differently. While the ART Bill considers failure to conceive within ‘one year of unprotected coitus’ as constituting infertility, the SRB 2019 uses a time period of ‘five years’ for the same outcome.⁴⁴ No definitions of ‘ART Clinics’ and ‘ART Banks’ are included in the SRB 2019, which only defines a more generic ‘clinical establishment’. There are also glaring discrepancies between the substantive provisions of the two Bills. A single woman cannot commission surrogacy but can access ARTs.

The ARTs Bill 2020 designates surrogacy boards under the SRB 2019 to function as advisory bodies for ART. This is desirable because it avoids duplication of the key policy making bodies under both Bills. Nevertheless, a provision on how these Boards would be funded would have been ideal. Further, both Bills set up multiple bodies for registration, which will inevitably result in duplication, or worse, lack of regulation. An example of duplication is where clinics claim administrative burden because they are already required to be registered under the Clinical Establishments (Registration and Regulation) Act,

⁴³ Under the ART Bill, a ‘commissioning couple’ is defined as an infertile married couple; the SRB defines the term ‘couple’ as a married heterosexual couple and the ‘intending couple’ as a couple who are medically certified as infertile and who want to resort to surrogacy. The ART Bill defines ‘infertility’ as the inability to conceive after one year of unprotected coitus or other proven medical condition preventing a couple from conception whereas the SRB defines ‘infertility’ as the inability to conceive after five years of unprotected coitus or other proven medical condition preventing a couple from conception. The ART Bill defines an ‘assisted reproductive technology clinic’ as any premises with facilities and medical practitioners registered with the National Medical Commission whereas the SRB defines ‘surrogacy clinic’ far more broadly as a surrogacy clinic, centre or laboratory, conducting ART services and in-vitro fertilisation services, genetic counselling centre, genetic laboratory, ART Banks conducting surrogacy or any clinical establishment conducting surrogacy. Clinical establishment in turn has the meaning assigned to it under the Clinical Establishments (Registration and Regulation) Act, 2010. The ART Bill defines ‘assisted reproductive technology bank’ as an organisation that is set up to supply sperm or semen, oocytes or oocyte donors to the assisted reproductive technology clinics or their patients. The SRB does not define the term ART Bank. Thus the SRB has an expansive definition for a surrogacy clinic so as to bring all establishments conducting surrogacy under the purview of the law whereas the ART Bill defines an ART clinic in terms of its registration status under state law. These approaches are inconsistent and need to be aligned better. The inconsistencies have now been addressed by the ART Act, 2021 and the Surrogacy (Regulation) Act, 2021, which cross reference definitions.

⁴⁴ The Surrogacy (Regulation) Act, 2021 dispenses with this requirement. Section 2(1)(r) now requires the couple to have a “medical indication necessitating gestational surrogacy.”

2010, which is in force in certain states. An example of the lack of regulation is that the ART Bill 2020 requires ART banks and clinics to report procedures to the National Registry. However, there is no such provision under the SRB 2019. Thus, ART clinics need to report ART procedures, but a surrogacy clinic is not required to report a major procedure such as surrogacy to the National Registry. The PSC in its report attempts to rationalise the regulatory frameworks of the SRB 2019 and ART Bill 2020 to some extent.⁴⁵ It also calls for the creation of an independent and impartial grievance redressal cell within the registration authority to deal with complaints against ART banks and clinics.

The ART Bill 2020 has an unusual provision⁴⁶ which requires that all bodies set up under the Bill be bound by directions of central and state governments in the national interest, and in the interest of friendly relations with foreign states, public order, decency, or morality. On the one hand, such a provision is superfluous as it is presumed that bodies set up under a statute will not contravene state policy. On the other hand, these provisions are broadly phrased and could potentially undermine the independence of the bodies set up under the Bill. Possibly, the government is cognisant of the liberal disposition of the medical community, which in the absence of a statute on ARTs and surrogacy, developed a thriving industry in reproductive tourism in the late 1990s and through 2015. Still, statutory provisions need to be commensurate with the goals of the statute which is to regulate and supervise ART Clinics and ART Banks. This requires a regulatory framework which gives private actors some notice of how they should comply with the statutory provisions. But the possibility of ad-hoc orders issued by the central and state governments on vague grounds such as “national interest” undermines the Bill itself as it requires actors to comply with government orders often at short notice. This was borne out when transnational surrogacy was abruptly banned overnight in 2015 by a Ministry order.

Last but not the least, the provisions on punishment for violation of the Bills are problematic. Doctors have for long protested high levels of punishment under the law. Both the SRB 2019 and the ART Bill 2020 impose high sentences (for example, 8-12 years)⁴⁷ and hefty fines.⁴⁸ But here, legislators must heed lessons from the regulation of reproductive health. Consider for example, the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse)

⁴⁵ See, Sneha Banerjee and Prabha Kotiswaran, ‘Regulating Reproductive Technologies: A Blow to Inclusive Family Forms’ 2021 56(25) Economic and Political Weekly 21-24. The recommendations of the PSC have been accepted in this respect and incorporated into the ART Act, 2021.

⁴⁶ Sections 38(2) and 39(2) require the National and State level bodies, respectively, to be bound by such directions.

⁴⁷ These punishments have been reduced in both Bills but they continue to remain high (between 3-10 years).

⁴⁸ Chapter VII of the SRB 2019 and Chapter V of the ART Bill 2020 delineate these offences and penalties.

Act, 1994, which has been poorly implemented over more than 25 years. This demonstrates that enhanced punishments do not always secure compliance. Moreover, lawyers and judges also lack medical expertise in order to appreciate the nuances of medical processes and to decide whether doctors had dispensed the appropriate medical treatment. Patients already routinely sue fertility clinics in consumer redressal fora for negligence, an approach preferable to prosecution for negligence under Section 34 of the ART Bill 2020, which is a catch-all provision.⁴⁹

Apart from the high punishment levels, the same offending behaviours under the ART Bill 2020 and SRB 2019 are punished differently.⁵⁰ Offences under the ART Bill 2020 are bailable but not under the SRB 2019. Under the ART Bill 2020, a court can take cognisance of a case only based on a complaint by the Boards set up under the Bill whereas under the SRB 2019, notice of complaint by a third party would be enough for a court to take cognisance of a case. Finally, records have to be maintained for 10 years under the ART Bill 2020 but for 25 years under the SRB 2019. The same actions taken by a surrogacy clinic and ART clinic (likely to be the same entity) attract varied regulation. Here again, the prioritisation of surrogacy as warranting urgent legislative intervention because of the outright commodification of women's bodies by doctors has meant more stringent provisions against surrogacy clinics when compared to ART clinics. The reality, however, is that surrogacy clinics are involved in performing ART and hence, treating them differently under the ART Bill 2020 and the SRB 2019 amounts to the violation of Article 14 and its guarantee of equal protection under the law.

VI. CONCLUSION

In conclusion, we argue that there are several issues in the ART Bill 2020 that need to be thought through more critically. Although a PSC headed by Professor Ram Gopal Yadav, who chaired the Parliamentary Standing Committee on the SRB (2016 version), has deliberated on the ART Bill 2020 and recommended several useful changes, significant issues remain on who can access ARTs/offer reproductive services and under what conditions. As we demonstrate in this article, there are several aspects where the ART Bill

⁴⁹ See, *Varghese Silvester v Archana Dhawan* 2014 SCC OnLine NCDRC 431; *M Kochar v Ispita Seal Leisure Valley Apartment Society* 2017 SCC OnLine NCDRC 1189. There are several other unreported cases before consumer redressal fora in various states. Section 34 of the ART Bill 2020 reads as follows:

Whoever contravenes any of the provisions of this Act or any rules made there under, for which no penalty has been provided in this Act shall be punishable as per sub-section (2) of section 33. This would cover negligent behaviour on the part of fertility clinics and doctors.

⁵⁰ For example, Sections 33(1), (2) of the ART Bill 2020 and Sections 35(1), (2) of the SRB 2019 lay down the prohibition of and penalties for very similar acts. However, the former has provision of imprisonment between eight to twelve years but the latter has provision for up to ten years.

2020 needs fine-tuning to be in tandem with the SRB 2019, given the inter-linked political economies of the two sectors. Duplication and non-consonance of implementation and enforcement mechanisms of the two bills will create an unfortunate situation where despite attempts at regulation being brought to fruition after decades, effective regulation will remain elusive. Moreover, the Bill falls short on its stated objectives of providing respite to those suffering from infertility by creating barriers to access for many. Similarly, while it seeks to protect women from exploitation, it fails to do so by devaluing their reproductive labour. On both these counts, there is adequate scope for the Bill to be challenged on grounds of violating constitutional provisions regarding equality, right to life, and protection against forced labour.