

# RECONCEPTUALISING PARENTHOOD: A MODEL REGULATORY FRAMEWORK FOR ASSISTED REPRODUCTION IN INDIA

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*The idea of the modern-day family is constantly evolving, as is the conception of reproductive rights. While the right to have a family or the right to family life remain largely uncodified in India, these rights find a strong basis in other pre-existing rights. Through an analysis of three assisted reproductive techniques, namely, surrogacy, in-vitro fertilisation, and genetic manipulation, we study the interplay of technology, health, gender, commerce and sexuality and in turn, its implications for public health rights, gender justice, sexual rights, disability rights, child rights, and bioethics. We argue that medical professionals, infertile individuals or couples, children born as a result of assisted reproduction, donors and surrogates across India suffer greatly due to the lack of a legal framework which adequately addresses their needs. These needs, such as protection of bodily autonomy for surrogates and donors, equitable access for commissioning couples or individuals, assurance of legal status for children, among many others, remain unaddressed in both individual and collective capacities. In an attempt to remedy this, we extensively discuss the various ways in which assisted reproduction ought to be regulated. We contextualise the concerns with assisted reproduction to the Indian context and suggest the core principles that should be a part of a national legally binding regulatory framework in the country.*

## TABLE OF CONTENTS

I.	INTRODUCTION .....	2
II.	PROLIFERATION OF ASSISTED REPRODUCTION IN INDIA.....	5
III.	ASSISTED REPRODUCTIVE TECHNOLOGIES FROM A SOCIAL LENS.....	9
A.	FEMINIST DISCOURSE ON ART.....	9
B.	RELIGIOUS DISCOURSE ON ART.....	15
IV.	NAVIGATING THE MEDICO-LEGAL LANDSCAPE OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN INDIA.....	18
A.	GENE THERAPY.....	18
B.	SURROGACY.....	21
C.	IN-VITRO FERTILISATION.....	24
V.	GAPS IN THE EXISTING REGULATORY FRAMEWORK .....	25
A.	GENE THERAPY.....	26
B.	SURROGACY.....	28
1.	The Interplay between ART Bill and Surrogacy Bill .....	33
C.	IN-VITRO FERTILISATION.....	37
VI.	A MODEL LEGISLATION FOR ASSISTED REPRODUCTION IN INDIA: SUGGESTIONS FOR LAWMAKERS .....	40
A.	A UNIFORM LEGISLATION ON ASSISTED REPRODUCTIVE TECHNOLOGIES..	40

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B. GENE THERAPY..... 43  
 C. SURROGACY..... 44  
 D. IN-VITRO FERTILISATION..... 46  
 VII. CONCLUSION..... 46

I. INTRODUCTION

Globally, there has been an increase in the usage and the popularity of assisted reproductive technologies (‘ARTs’), as more emphasis is laid on ideas of reproductive rights and justice, and as accessibility to medical technology increases.<sup>1</sup> Not only do these technologies and techniques find use in addressing problems of infertility for couples or individuals who are unable to conceive in the form of fertility treatment, but they also exist as an option for those who want to experience parenthood without necessarily going through childbirth. Traditional ideas and notions of what motherhood or paternity meant are slowly evolving. Through this evolution, the separation of biological and sociological parenthood is becoming starker.<sup>2</sup> Modern, fast-paced lifestyles and higher disposable incomes have also allowed more people belonging to mostly the upper middle class across the globe to have meaningful access to these technologies.<sup>3</sup>

The rise of ARTs in India, peaking at a compound annual growth rate of 28 percent,<sup>4</sup> has been credited to the ubiquitous nature of surrogates and donors,<sup>5</sup> highly specialised medical science, widespread infertility,<sup>6</sup> and the constant reinforcement of the importance of children as part of traditional familial structures. Coupled with the absence of regulatory frameworks and lacunae in the law, these factors have also allowed for the reproductive medical tourism industry to boom in India, especially with locations like Anand in Gujarat serving as hotbeds for surrogacy hostels and clinics.<sup>7</sup> Both heterosexual and homosexual couples have sought refuge in countries such as India and Thailand with weak regulation to fulfil their desires of becoming parents, which were otherwise restricted by their

<sup>1</sup> P R NEWSWIRE, *Global Fertility Treatments Industry Report 2020 – Growth in the Median age of First-Time Motherhood is Driving Demand*, April 21, 2020, available at <https://www.prnewswire.com/news-releases/global-fertility-treatments-industry-report-2020---growth-in-the-median-age-of-first-time-motherhood-is-driving-demand-301044493.html> (Last visited on August 20, 2020).

<sup>2</sup> Gerda Neyer & Laura Bernardi, *Feminist Perspectives on Motherhood and Reproduction*, Vol.36(2), HISTORICAL SOCIAL RESEARCH, (2011).

<sup>3</sup> James F. Smith et al., *Socioeconomic Disparities in the Utilization and Success of Fertility Treatments: Analysis of Data from a Prospective Cohort in the United States*, Vol.96(1), FERTIL. STERIL. (2011). ; Katie Harris et al., *Socio-economic disparities in access to assisted reproductive technologies in Australia*, Vol.33(5), REPRODUCTIVE BIOMEDICINE ONLINE, (2016); Sahil Gupta, *The Challenges for fertility treatment in India*, THE INDIAN EXPRESS, November 4, 2019, available at <https://indianexpress.com/article/parenting/health-fitness/fertility-treatment-in-india-challenges-6102164/> (Last visited on August 20, 2020).

<sup>4</sup> Manish Banker, *41 Years of IVF – the revolution of Assisted Reproductive Technology!*, ET HEALTH WORLD, July 25, 2019, available at <https://health.economictimes.indiatimes.com/news/industry/41-years-of-ivf-the-revolution-of-assisted-reproductive-technology/70380646> (Last visited on August 20, 2020).

<sup>5</sup> Julie Bindel, *Outsourcing pregnancy: a visit to India’s surrogacy clinics*, THE GUARDIAN, April 1, 2016, available at <https://www.theguardian.com/global-development/2016/apr/01/outsourcing-pregnancy-india-surrogacy-clinics-julie-bindel> (Last visited on August 20, 2020).

<sup>6</sup> Mini Muringatheri, *Infertility: Blame it in genetic factors*, THE HINDU, September 21, 2017, available at <https://www.thehindu.com/news/national/kerala/increasing-infertility-blame-it-on-genetic-factors/article19721918.ece> (Last visited on August 20, 2020); Gupta, *supra* note 3.

<sup>7</sup> Mansi Thapliyal, *Surrogacy in India*, January 20, 2014, available at <https://widerimage.reuters.com/story/surrogacy-in-india> (Last visited on August 20, 2020).

extremely religious or conservative parent states.<sup>8</sup> Concrete data on these assisted reproduction pregnancies, however, remains scarce due to heightened concerns of privacy and lack of clear regulations to be followed by medical centres.

With the intervention of the Indian State, and subsequent outlawing of commercial surrogacy by the Surrogacy (Regulation) Bill, 2016, the visibility of these clinics in Anand has definitely reduced,<sup>9</sup> but to say with certainty that it has resulted in drastic changes in the usage of ART will be difficult, due to the influence of the surrogacy industry in the State, and the widespread network of surrogates and commissioning couples that has been established by medical practitioners.

Considering the stigma around childlessness and the availability of ART, as discussed in depth in *Part II*, it may be said that the denial of reproductive assistance can be a violation of one's human rights.<sup>10</sup> Across the globe, but especially in India, childless women and couples face ostracisation at the hands of their families, and even communities. An apathetic attitude adopted by the State in addressing concerns of infertility, and providing subpar fertility treatment or care can be seen as a violation of the right to found a family as under the International Covenant on Civil and Political Rights,<sup>11</sup> and the Universal Declaration of Human Rights,<sup>12</sup> the right to health, and the right to reproductive autonomy, all subsets of the larger right to life.<sup>13</sup> With the advent of various technologies, however, modern science has been able to take the right of having a family one step further.<sup>14</sup> It is practical and possible to now have children that are genetically modified or engineered. These babies are often called 'designer babies'.<sup>15</sup> Modifications can range from ones that are medically desirable to ones that are purely cosmetic.<sup>16</sup> The understanding of the right to have a family, thus, now must necessarily coexist with the right against exploitation of not only birth-giving individuals or donors, but also children born as a result of these procedures.

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<sup>8</sup> Andrea Whittaker, *Merit and Money: The Situated Ethics of Transnational Commercial Surrogacy in Thailand*, Vol.7(2), INTERNATIONAL JOURNAL OF FEMINIST APPROACHES TO BIOETHICS, (2014); Sally Howard, *Taming the International Commercial Surrogacy Industry*, Vol.349 BRITISH MEDICAL JOURNAL, (2014); THE TIMES OF INDIA (Madhavi Rajadhyaksha), *Israeli gay couple gets a son in India*, November 18, 2008, available at <https://timesofindia.indiatimes.com/india/Israeli-gay-couple-gets-a-son-in-India/articleshow/3724754.cms> (Last visited on August 20, 2020); BBC NEWS (Jonathan Head), *'Baby factory' mystery: Thailand's surrogacy saga reaches uneasy end*, February 26, 2018, available at <https://www.bbc.com/news/world-asia-43169974> (Last visited on August 20, 2020).

<sup>9</sup> THE GUARDIAN (Vidhi Doshi), *'We pray that this clinic stays open': India's surrogates fear hardship from embryo ban*, January 3, 2016, available at <https://www.theguardian.com/world/2016/jan/03/india-surrogate-embryo-ban-hardship-gujarat-fertility-clinic> (Last visited on August 20, 2020).

<sup>10</sup> *Costa and Pavan v. Italy*, ECHR 327 (2012) (European Court of Human Rights); Sharmila Rudrappa & Caitlyn Collins, *Altruistic Agencies and Compassionate Consumers: Moral Framing of Transnational Surrogacy*, Vol.29(6), GENDER AND SOCIETY, (2015); Vida Panitch, *Surrogate Tourism and Reproductive Rights*, Vol.28(2), HYPATIA (2012); Lauren B. Paulk, *Embryonic Personhood: Implications for Assisted Reproductive Technology in International Human Rights Law*, Vol.22(4), JOURNAL OF GENDER SOCIAL POLICY AND LAW (2014).

<sup>11</sup> International Covenant on Civil and Political Rights, December 16, 1966, Article 23(2), 999 U.N.T.S. 171.

<sup>12</sup> Universal Declaration of Human Rights, Article 16, G.A. Res. 217A, U.N. Doc. A/180 (December 12, 1948).

<sup>13</sup> Willem Ombelet, *Global access to infertility care in developing countries: a case of human rights, equity and social justice*, Vol.3(4), FACTS VIEWS VIS OBGYN (2011).

<sup>14</sup> *Supra* note 11, Article 23(3); *Supra* note 12.

<sup>15</sup> Laura Hercher, *Designer babies aren't futuristic. They're already here*, October 22, 2018, available at <https://www.technologyreview.com/s/612258/are-we-designing-inequality-into-our-genes/> (Last visited on August 20, 2020).

<sup>16</sup> THE WASHINGTON POST (Joel Achenbach), *NIH and top scientists call for moratorium on gene-edited babies*, March 13, 2019, available at <https://www.washingtonpost.com/science/2019/03/13/nih-top-scientists-call-moratorium-gene-edited-babies/> (Last visited on August 20, 2020).

Furthermore, on a macro-level, the widespread usage of these technologies also has the potential to accelerate the changes in the way societies perceive parenthood.<sup>17</sup>

It is crucial to acknowledge that medicine has progressed faster than the law, and the law has been unable to catch up with the advances in reproductive medicine. Regulatory frameworks with respect to ART, especially in India, are severely lacking. There exists a dire need of acknowledgement, and subsequent regulations from the law to prevent exploitative practices, or unfettered use. Exploitative practices in the world of ART are plenty, and affect different stakeholders differently. For surrogates, or donors, these practices can take the form of being forced to stay in inhuman conditions, not receiving adequate monetary compensation, and blurred lines of consent. For commissioning couples and individuals, there can be concerns of inequitable access due to socioeconomic status, marital status, gender identity, or sexual orientation, or even the absence of infertility treatment altogether. For children born out of ART, concerns of their legal status and parentage are plenty, along with privacy related factors. Medical professionals are also greatly disadvantaged due to the lack of clarity on what is permissible by law, and to what extent. These are traced in greater detail in *Part V*.

It is argued in this paper that the acknowledgement of these technologies must be looked at from an unprejudiced and long-term perspective, devoid of the moral panic surrounding some of these techniques. Discussions on the medical merits of these techniques will be outside the scope of this paper. Instead, our focus will be on how to best adapt these techniques to the current framework in India, while still understanding the serious limitations they pose. This modified adaptation will be dependent on various factors, including the collective religious, cultural, and social beliefs of Indian society. As a result, there are many legal and ethical questions that arise, and these will be subsequently addressed.

Based on our understanding of the aforementioned legal and ethical concerns, we will be arguing for formal regulation of the various techniques of assisted reproduction. All these concerns will be understood and analysed from various different perspectives to provide a holistic understanding of ART. These perspectives will include their impacts on the commissioning parent(s), on the individual that gives birth to the child or facilitates the process by becoming a donor, on the child born as a result of these procedures, the medical industry, and finally, on the society as a whole. Discussing the scope of intellectual property rights that may be inevitably attached with ARTs like gene therapy will not be a part of this article.

In *Part II* of this paper, we will attempt to understand the reasons behind the spike in the adoption of ARTs globally, with a special focus on India. This will be done by looking at the various factors that have contributed to the growth of ART in the past decade. Additionally, an attempt will be made to trace the historical evolution of the various ways in which ART has been adopted in the country. In *Part III*, an attempt will be made to provide a more holistic understanding of how assisted reproduction is viewed by religious texts and priests in different contexts. This will be supplemented with the feminist legal understanding of ARTs as both oppressive and liberating for those involved. *Part IV* will be dedicated to understanding three forms of ART- gene therapy, surrogacy, and in-vitro fertilisation ('IVF'). The process and implementation of these techniques will be understood in detail. In *Part V*, the current regulations that govern these techniques, either in the form of legislation,

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<sup>17</sup> Neyer, *supra* note 2.

attracting legal sanctions, or medical guidelines published by the Indian Council of Medical Research ('ICMR'), attracting revocation of professional licenses, will be studied. Gaps in these regulations will be subsequently identified. In Part VI we discuss the best practices surrounding the administration, use and implementation of ART, drawing from both international and domestic legislation and guidelines. This will be an attempt to accommodate both the ethical and legal concerns that have been identified. We then identify the core principles that must be part of any regulatory framework that seeks to govern and regulate ART. Part VII presents the conclusion.

## II. PROLIFERATION OF ASSISTED REPRODUCTION IN INDIA

21<sup>st</sup> Century India, labouring under the affliction of widespread infertility, stands witness to an upsurge in the proliferation of ARTs promising to ameliorate the situation.

The characterisation of infertility as an 'impairment' not only flows from the definition attached to it by the World Health Organisation ('WHO'), but also from the deep-rooted understanding of child-bearing being a woman's primary obligation, especially in India.<sup>18</sup> According to WHO, infertility is defined as a "*disease* of the reproductive system designed by the failure to achieve clinical pregnancy after 12 months or more, of regular unprotected sexual intercourse".<sup>19</sup> Its connotation as a malady has driven people across the globe to seek medical cures and treatments for it. However, as will be explored below, in the Indian context, it is predominantly the societal construction of infertility as a social, cultural and economic *disease*, that has provided the market for ARTs an impetus to grow.

Presently, India faces a peculiar paradoxical situation with a rising population simultaneously being accompanied by a fall in the total fertility rates, as calculated by the National Family Health Survey.<sup>20</sup> A rising population should not be understood as the absence of infertility. This is because, in the backdrop of a decrepit public health system, although the fertility rate has dropped, even a small annual population growth rate when applied to India's large population of 1.3 billion,<sup>21</sup> yields a huge absolute increase in population.

Now, there are a host of factors that have contributed to the spread of infertility, affecting an estimated 22 to 33 million couples in the reproductive age.<sup>22</sup> These range from untreated sexually transmitted infections causing pelvic inflammatory diseases

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<sup>18</sup> Jayita Poduwal & Murali Poduwal, *Working Mothers: How Much Working, How Much Mothers and Where is the Womanhood*, Some Issues in Women's Studies and Other Essays, Vol.7(1), MSM, Jan-Dec 2009, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3151456/> (Last visited on August 19, 2020).

<sup>19</sup> Infertility Definitions and Terminology, Sexual and Reproductive Health, WORLD HEALTH ORGANISATION, available at: <https://www.who.int/reproductivehealth/topics/infertility/definitions/en/> (Last visited on August 19, 2020) ('WHO Definition').

<sup>20</sup> Anthony Cilluffo and Neil G. Ruiz, *World's Population is Projected to Nearly Stop Growing by the End of the Century*, June 17, 2019, available at: <https://www.pewresearch.org/fact-tank/2019/06/17/worlds-population-is-projected-to-nearly-stop-growing-by-the-end-of-the-century/> (Last visited on August 19, 2020); THE DIPLOMAT (Neeta Lal), *India's Hidden Infertility Struggles*, May 30, 2018, available at: <https://thediplomat.com/2018/05/indias-hidden-infertility-struggles/> (Last visited on August 19, 2020).

<sup>21</sup> THE WORLD BANK, *Data: Population, Total India*, available at: <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=IN> (Last visited on August 19, 2020).

<sup>22</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, ¶4.5, Dr. Rishma Pai, August 10, 2017.

leading to tubal damage,<sup>23</sup> to unsafe abortions and poor maternal healthcare resulting in malnutrition,<sup>24</sup> anaemia, and other dietary deficiencies for women.<sup>25</sup> Additionally, India's public health system does not provide for adequate preventive, curative, and counselling services for infertility, as will be explored below. Extraneous factors like lifestyle, late marriages,<sup>26</sup> environmental pollution,<sup>27</sup> and occupational hazards have also contributed to the spike in infertility rates. Having acknowledged the existence of rising infertility, it becomes imperative to analyse the social and interpersonal ramifications it holds for women.

Traditionally, Indian societies have functioned as patriarchal units seeking to relegate women to the domestic sphere with the sole duty of bearing a child, preferably a son.<sup>28</sup> As a result of gender socialisation over time, women have been brought up with the notion that their life's purpose is to be a 'good wife', one who is subservient to the whims and fancies of her husband and her marital family. By corollary, a woman is expected to dutifully provide her marital family with a rightful heir and perform her role of being a 'good mother'. In light of these patriarchal beliefs being firmly entrenched in the societal fabric of India,<sup>29</sup> infertility is viewed as a failure of the woman alone to perform her duty, resulting in her being labelled as '*vanzhooti*' (infertile) and '*banj*' (barren).<sup>30</sup> On account of this derogatory categorisation and glorification of motherhood, infertile women face severe backlash.<sup>31</sup> They are made to undergo a loss of status and acceptance both in their home, as well as in the society at large.<sup>32</sup> It is this view of infertility being an impediment in the life of the woman as well as the family, that has greatly contributed to the growth of the ART sector in India.<sup>33</sup>

Apart from the social stigma "reducing a woman from a whole and usual person to a tainted and discounted one",<sup>34</sup> the perception of children as 'economic assets' has

<sup>23</sup> Dr. Aruna Rastogi, *Infertility*, NATIONAL HEALTH PORTAL OF INDIA, August 5, 2016, available at: <https://www.nhp.gov.in/disease/reproductive-system/infertility> (Last visited on August 19, 2020).

<sup>24</sup> The Times of India, *Unsafe Abortion Poses Threat to Infertility*, May 23, 2013, available at: <https://timesofindia.indiatimes.com/home/science/Unsafe-abortion-poses-threat-to-fertility/articleshow/20228285.cms> (Last visited on August 19, 2020).

<sup>25</sup> P Singh, S Singh, R Singh & R Raghuvanshi, *Anaemia As A Cause of Infertility: Focus on Management of Anaemia As First Line Management of Infertility*, Vol. 8(1), THE INTERNET JOURNAL OF GYNECOLOGY AND OBSTETRICS, (2006).

<sup>26</sup> S. Ganguly & S. Unisa, *Trends of Infertility and Childlessness in India: Findings from NFHS Data*, Vol. 2(2), FACTS, VIEWS VIS OBGYN, (2010).

<sup>27</sup> The National Institute of Environmental Health Services, *Environment and Infertility*, Vol. 104(2), ENVIRONMENTAL HEALTH PERSPECTIVES, 137 (February, 1996).

<sup>28</sup> Sukumari Bhattacharji, *Motherhood in Ancient India*, Vol. 25(42), ECONOMIC AND POLITICAL WEEKLY, 50-57 (October 20-27, 1990).

<sup>29</sup> Amrita Nandy, *Outliers of Motherhood: Incomplete Women or Fuller Humans*, Vol. 48(44), ECONOMIC AND POLITICAL WEEKLY, 56 (November 2, 2013).

<sup>30</sup> Meghana Joshi, *Correcting the Reproductive 'Impairment': Infertility Treatment Seeking Experiences of Low Income Group Women in Mumbai Slums*, Vol.57(2), SOCIOLOGICAL BULLETIN, 15 (May-August 2008).

<sup>31</sup> MAITHREYI KRISHNARAJ, *MOTHERHOOD IN INDIA: GLORIFICATION WITHOUT EMPOWERMENT*, (Delhi: Routledge, 2010).

<sup>32</sup> Catherine Kohler Riesmann, *Stigma and Everyday Resistance Practices: Childless Women in South India*, Vol. 14(1), BOSTON UNIVERSITY GENDER & SOCIETY, (February 2000).

<sup>33</sup> Sital Mohanty & Subhasis Sahoo, *The ART of Manufacturing: Ethical Considerations in Quest of a Child*, Vol. 65(3), SOCIOLOGICAL BULLETIN, 391 (December 2016).

<sup>34</sup> E. Goffman, *STIGMA: NOTES ON THE MANAGEMENT OF A SPOILED IDENTITY*, (New York: Simon & Schuster, 1963).

also markedly contributed to the demand for ARTs.<sup>35</sup> The Preamble to the Draft Assisted Reproductive Technology Bill, 2010 ('2010 Draft ART Bill') prepared by the Indian Council for Medical Research ('ICMR') clearly recognises the eminence of children as 'old-age insurance' as being an instrumental facet of the introduction of ARTs in India.<sup>36</sup> Families in India wholeheartedly embark on the quest for children since they are expected to provide social security through labour contributions and function as assets in the longer run, by ensuring a net flow of money from the younger to the older generation.<sup>37</sup> Thus, the gynaecological complication of childlessness has effectively been medicalised by society into a financial condition in need of correction.

Although the International Conference on Population and Development Programme of Action explicitly states that reproductive health services should include prevention and appropriate treatment of infertility,<sup>38</sup> the social burden of infertility is yet to attract the attention of the Government of India and its treatment is currently missing from the reproductive services available under the public healthcare system.<sup>39</sup> The lack of fertility treatment services in the governmental and public health system coupled with a snowballing demand for progeny has provided the stimulus for a private health sector for ART to emerge in India.<sup>40</sup>

Currently, the private healthcare sector is thriving on account of the scourge of infertility and its societal construction, acquiring a ubiquitous global nature and possessing the ability to permeate through geographical borders of countries.<sup>41</sup> In 2017, India saw the arrival of 4,95,056 foreign tourists for medical purposes.<sup>42</sup> Foreigners have increasingly been opting to undergo assisted reproductive operations in India owing to the exceptional standard of medical expertise in the private sector, low costs of living and the overall affordability of the treatment procedures.<sup>43</sup> Additionally, the unregulated proliferation of ART, in the absence of binding governmental legislation, has helped India emerge as a global hub of medical tourism. A recent study conducted by the Federation of Indian Chambers of Commerce and Industry ('FICCI') and Intercontinental Medical Statistics (IMS) Health India has shown that with the help of effective allocation of funds, India's Medical Value Travel (MVT) has the

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<sup>35</sup> Theodore W. Schultz, *The Value of Children: An Economic Perspective*, Vol. 81(2), JOURNAL OF POLITICAL ECONOMY, S5, (1973).

<sup>36</sup> The Draft Assisted Reproductive Technologies (Regulation) Bill, 2010, The Preamble.

<sup>37</sup> Clem Tisdell, *Children and Economic Development: Family Size, Gender Preferences and Human Capital Formation - Theory and Indian Cases*, Report No. 25, WORKING PAPERS ON SOCIAL ECONOMICS, POLICY AND DEVELOPMENT, (2002).

<sup>38</sup> The United Nations Population Fund [UNFPA], International Conference on Population and Development, September 5-13, 1994, *Programme of Action*, ¶7.6.

<sup>39</sup> Mohanty & Sahoo, *supra* note 33, 384 at 6.

<sup>40</sup> LOK SABHA, *Unstarred Question No. 1166 (d) and (e) answered on 10.02.2020*, available at: <http://tourism.gov.in/sites/default/files/usq%201166%20for%2010022020.pdf> (Last visited on August 19, 2020).

<sup>41</sup> Jacky Bolvin, et al., *International Estimates of Infertility Prevalence and Treatment-Seeking: Potential Need and Demand for Infertility Medical Care*, Vol. 22(6), HUM REPROD., (2007) available at: <https://pubmed.ncbi.nlm.nih.gov/17376819/> (Last visited on August 19, 2020).

<sup>42</sup> RAJYA SABHA, *Unstarred Question No. 449 answered on 25.06.2019*, available at: <http://tourism.gov.in/sites/default/files/usq%20449%20for%2025062019.pdf>. (Last visited on August 19, 2020).

<sup>43</sup> Swati Gola, *Reproductive Tourism in "Incredible India": Socio-Ethical and Legal Side-Effects of Market Oriented Fertility Services*, August 2013, Vol. 4(40), JOURNAL OF LAW TEACHERS IN INDIA, (2013).

capacity to be a 9 Billion USD market by 2020.<sup>44</sup> These lump sum contributions made by medical tourism to the GDP have incentivised big players to expand the market for ARTs, further stimulating its growth. Notwithstanding the demand for reproductive technologies, India also has an ample supply of women interested in selling their gametes and bodily labour, providing the commercial surrogacy market with a much-needed boost.<sup>45</sup>

Moreover, the advancement in reproductive technology has led to the rapid increase in demand for gene therapy, a process geared towards the alteration of the human genetic blueprint for cosmetic, medical or therapeutic reasons. The widespread prevalence of genetic disorders afflicting innumerable Indian households coupled with the glorification of gene editing by the global medical community, has provided this operation a significant boost.<sup>46</sup> In this process, the changes made to the DNA sequence in the genome of a living cell may be in the form of deletion of certain DNA to eradicate diseases or in the form of insertion of desirable DNA for cosmetic enhancement. The rationale behind the former, stems from the increased focus of the medical community to treat genetically spread diseases such as sickle-cell anaemia, muscular dystrophy,<sup>47</sup> Huntington's disease,<sup>48</sup> Thalassaemia,<sup>49</sup> and cancer in their formation stages as they presently lack effective pharmaceutical or surgical solutions, post their contraction.<sup>50</sup> Alternatively, the simmering down of panic surrounding the interference of the medical community in the process of childbirth has made individuals more open towards technological intervention even for non-therapeutic cosmetic purposes.<sup>51</sup> Primarily, people have begun viewing gene editing as a means of 'fulfilling reproductive desires',<sup>52</sup> as it enables them to create designer babies by making their child's genetic blueprint reflective of their own beauty standards. Gene editing has become popular as it allows individuals to bring their own notions of desirable characteristics such as fair skin

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<sup>44</sup> FEDERATION OF INDIAN CHAMBERS OF COMMERCE AND INDUSTRY ('FICCI'), *Knowledge Paper on Medical Value Travel in India: Enhancing Value in MVT*, available at: <http://www.ficci.in/Medical-Value-Travel-Report.pdf> (Last visited on August 19, 2020).

<sup>45</sup> Diksha Munjal-Shankar, *Commercial Surrogacy in India: Vulnerability Contextualised*, Vol. 53(3), JOURNAL OF THE INDIAN LAW INSTITUTE, (July-September 2016).

<sup>46</sup> THE HINDU BUSINESS LINE (Dinesh C Sharma), *Indian Scientists Achieve High Precision in Gene Editing*, October 1, 2019, available at: <https://www.thehindubusinessline.com/news/science/indian-scientists-achieve-high-precision-in-gene-editing/article29566560.ece> (Last visited on August 19, 2020).

<sup>47</sup> The muscular dystrophies (MD) are a group of inherited genetic conditions that gradually cause the muscles to weaken, leading to an increasing level of disability. See United Kingdom National Health Services, *Muscular Dystrophy*, available at <https://www.nhs.uk/conditions/muscular-dystrophy/> (Last visited on August 19, 2020).

<sup>48</sup> Huntington's disease is a condition that stops parts of the brain working properly over time. See United Kingdom National Health Services, *Huntington's Disease*, available at <https://www.nhs.uk/conditions/huntingtons-disease/#:~:text=stumbling%20and%20clumsiness,difficulty%20moving> (Last visited on August 19, 2020).

<sup>49</sup> Thalassaemia is the name for a group of inherited conditions that affect a substance in the blood called haemoglobin. See United Kingdom National Health Services, *Thalassaemia*, available at <https://www.nhs.uk/conditions/thalassaemia/> (Last visited on August 19, 2020).

<sup>50</sup> Vijay Chandru, Co-Founder and Director, Strand Life Services, *Gene Editing in India: The Technology and its Governance*, Carnegie Endowment for International Peace, July 25, 2019, available at: <https://carnegieindia.org/2019/07/25/gene-editing-in-india-technology-and-its-governance-event-7161> (Last visited on August 19, 2020).

<sup>51</sup> DNA INDIA, *AIIMS Doctors Seek Laws Against Designer Babies*, January 17, 2019, available at: <https://www.dnaindia.com/india/report-aiims-doctors-seek-laws-against-designer-babies-2708798> (Last visited on August 19, 2020).

<sup>52</sup> Gyngell C, Bowman-Smart H & Savulescu J, *Moral Reasons to Edit the Human Genome: Picking Up from the Nuffield Report*, Vol. 45., JOURNAL OF MEDICAL ETHICS, (2019).



and light eyes, that are structurally embedded in Indian society owing to its rich history of racism, classism and colonialism, to life.<sup>53</sup>

Thus, it is observed that in contemporary India, the process of opting for ART procedures is primarily propelled by the reinforcement of gender norms of motherhood accompanied by a woman's subsequent apprehension of not being able to meet the fertility expectations of her husband, marital family, and the society at large. Simultaneously, the private healthcare sector has developed the ART network by capitalising on this societal construction of motherhood and the resulting demand for procreation. In this manner, we see that it is a combination of the aforementioned factors that has spawned off the reinvention of the idea of reproductive rights and justice through the use of technology.

### III. ASSISTED REPRODUCTIVE TECHNOLOGIES FROM A SOCIAL LENS

In this Part, we will attempt to trace ART from feminist and religious perspectives. Part III (A) will be dedicated to a discussion on how feminists have examined the various forms of assisted reproduction, and Part III (B) will mirror this discussion from a religious lens.

#### A. FEMINIST DISCOURSE ON ART

In this part, we have attempted to provide an overview of the various perspectives that feminists have offered on different forms of ART over the years. This includes comments on commercial assisted reproduction, the moral panic surrounding ART, reproductive autonomy, and the accommodation of heteronormative ideas of an ideal family. Some scholars have understood assisted reproduction as a dehumanising process for the women involved, while others have understood it as empowering, and we have attempted to juxtapose these arguments against the different social realities of women's lives. We engage with these schools of thought on their disagreements over the nature and impacts of ART. We conclude by discussing the ways in which ART allows for the separation of biological motherhood from social motherhood. This part is not intended to cover all the discourse on ART that feminist scholars have engaged in over the years, but seeks to provide an overview of the approaches that can be adopted while examining assisted reproduction in India.

*In Re Baby M* was the first case in the United States where an adjudication on surrogacy was delivered.<sup>54</sup> The case involved a commercial surrogacy contract, and in its adjudication, the court traced moral, ethical, and social consequences of upholding the validity of such a contract. The background in which Baby M's case was legislated upon, in the United States of America, was one where there was extreme moral panic amongst the populace due to the large-scale lack of understanding of what surrogacy entailed, and what its consequences could be.<sup>55</sup> In her work *The Politics of Commodification*, Elizabeth Scott borrows heavily from the media reportage of the Baby M case to bolster her claim that the

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<sup>53</sup> Ananth Padmanabhan, R. Shashank Reddy & Shruti Sharma, *Modern Biotechnology and India's Governance Imperatives*, CARNEGIE ENDOWMENT FOR INTERNATIONAL PEACE, 6 (2017).

<sup>54</sup> *In re Baby M*, 537 A.2d 1227, 109 N.J. 396, (Supreme Court of New Jersey); Clyde Haberman, *Baby M and the question of surrogate motherhood*, THE NEW YORK TIMES, March 23, 2014, available at <https://www.nytimes.com/2014/03/24/us/baby-m-and-the-question-of-surrogate-motherhood.html> (Last visited on August 20, 2020).

<sup>55</sup> Elizabeth S. Scott, *Surrogacy and the Politics of Commodification*, Vol.72(3), LAW AND CONTEMPORARY PROBLEMS (2009).

common perception of surrogacy was one riddled with skepticism and rejection of such supposed commodification of motherhood.<sup>56</sup> She further argues that even scholars, journalists, lawyers, and physicians who identified as feminists, including Jean Clark, Linda Bowker, and Sidney Callahan, actively spoke out against surrogacy contracts.<sup>57</sup>

Scott points out that it was a deliberate attempt by the lawyers in the case to paint surrogacy as an activity of baby-selling, and to portray the mothers as being exploited and influenced.<sup>58</sup> As a result, there were plenty of misconceptions on what the procedure was, often leading to a false equivalence being drawn with prostitution.<sup>59</sup> Andrea Dworkin, in her work *Right-Wing Women*, draws this equivalence by focusing on the idea that surrogacy allows society to emphasise on the need for women's identity to necessarily be tied to their sexual or reproductive capacity.<sup>60</sup> Just as in prostitution there was a brothel and a pimp, in surrogacy there was a medical clinic and a broker, Dworkin argues.<sup>61</sup> This led to an understanding among feminists such as Dworkin and Catherine MacKinnon that not only was surrogacy dangerous, but also immoral.<sup>62</sup> The court, in the case of Baby M held that the surrogacy contract violated public policy on the grounds of not being in the best interest of the child due to the involvement of a monetary transaction, and that the rights of the parents were also compromised.<sup>63</sup> The court went on to hold the surrogacy contract in question unenforceable and illegal, and hoped that this judgement would act as a deterrent against surrogacy arrangements overall.<sup>64</sup>

Scholars like MacKinnon who are in opposition of ART procedures find the basis of their pivotal argument in the fact that across the globe, but specifically in the Global South, the women who offer to become contractual surrogates or donate gametes, do so under

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<sup>56</sup> Iver Peterson, *Fitness test for Baby M's Mother unfair, Feminists say*, THE NEW YORK TIMES, March 20, 1987, available at <https://www.nytimes.com/1987/03/20/nyregion/fitness-test-for-baby-m-s-mother-unfair-feminists-say.html> (Last visited on August 20, 2020); James Barron, *Views on Surrogacy harden after Baby M Ruling*, THE NEW YORK TIMES, April 2, 1987, available at <https://www.nytimes.com/1987/04/02/nyregion/views-on-surrogacy-harden-after-baby-m-ruling.html> (Last visited on August 20, 2020); Kimberly D. Krawiec, *Show me the Money: Making Markets in Forbidden Exchange*, Vol.72(3), LAW AND CONTEMPORARY PROBLEMS (2009).

<sup>57</sup> Iver Peterson, *Baby M Trial splits ranks of Feminists*, THE NEW YORK TIMES, February 24, 1987, available at <https://www.nytimes.com/1987/02/24/nyregion/baby-m-trial-splits-ranks-of-feminists.html> (Last visited on August 20, 2020).

<sup>58</sup> Scott, *supra* note 55, at 116.

<sup>59</sup> Amrita Pande, *"At Least I Am Not Sleeping with Anyone": Resisting the Stigma of Commercial Surrogacy in India*, Vol.36(2), FEMINIST STUDIES, 293 (2010).

<sup>60</sup> ANDREA DWORKIN, *RIGHT-WING WOMEN: THE POLITICS OF DOMESTICATED FEMALES* (Women's Press, 1983).

<sup>61</sup> Jean M. Sera, *Surrogacy and Prostitution: A Comparative Analysis*, Vol.5(2), WCL JOURNALS & LAW REVIEWS, 319 (1997).

<sup>62</sup> Mary E. Becker, *Four Feminist Theoretical Approaches and the Double Bind of Surrogacy*, Vol.69, CHICAGO-KENT LAW REVIEW, 307 (1993); See also DWORKIN, *supra* note 60 (The arguments as to the social and moral appropriateness of this new kind of sale simply reiterate the view of female will found in discussions of prostitution: does the state have a right to interfere with this exercise of individual female will (in selling use of the womb)? If a woman wants to sell the use of her womb in an explicit commercial transaction, what right has the state to deny her this proper exercise of femininity in the marketplace? Again, the state has constructed the social, economic, and political situation in which the sale of some sexual or reproductive capacity is necessary to the survival of women; and yet the selling is seen to be an act of individual will—the only kind of assertion of individual will in women that is vigorously defended as a matter of course by most of those who pontificate on female freedom).

<sup>63</sup> *In re Baby M*, 537 A.2d 1227, 109 N.J. 396, ¶¶110, 118, 152 (Supreme Court of New Jersey).

<sup>64</sup> *Id.*, ¶152.

extreme pressure.<sup>65</sup> There is economic coercion in the choice that these women make to offer their bodies for these procedures, either as surrogates or donors, as oftentimes, they cannot afford to provide for their own families without monetary compensation from these arrangements. It is a replication of the power-imbalance that exists between men and women in society otherwise.

It is argued that even when there is economic compensation that is offered to, say, surrogate mothers in the Global South, it is often not at par with global standards.<sup>66</sup> Furthermore, the care that surrogates or donors in the region would receive for their own pregnancies is significantly worse than the care they receive for a surrogate arrangement, strengthening the idea that the level of care is dependent on whose foetus they carry.<sup>67</sup> ART can also reinforce traditional hierarchies of race, caste, and colour. This has been seen in the preferences of commissioning parents where they will, more often than not, prefer surrogates or donors who conform to their ideas of biological superiority.<sup>68</sup> It has also been seen in the various traits that parents are likely to eliminate from their child, if given an option. The modification of the colour of a child's hair, skin, and eyes often finds its basis in deep rooted casteism, colourism, and racism.<sup>69</sup>

Furthermore, the contractual nature of any technique that requires a woman to be a donor or carrier, or carry out any work that is temporary in nature, is also criticised heavily. This is because it encourages a feeling of alienation as the surrogate mother transfers the baby to the commissioning couple or the donor is disallowed from establishing contact with the baby, and this alienation, or separation, is unnatural to women.<sup>70</sup> It is cruel to the donor or carrier mother to be forced to suppress her feelings for the child that is born out of such an arrangement. It is argued that the sanctity of motherhood is breached when it becomes transactional and devoid of human emotion.<sup>71</sup> The value of life, as it is traditionally understood, is cheapened.

The terms of the contracts that surrogate mothers, or donors in IVF are bound by can also have many nuances that they do not fully appreciate due to their lack of

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<sup>65</sup> RACHEL ROSEN & KATHERINE TWANLEY, *FEMINISM AND THE POLITICS OF CHILDHOOD*, Chp. 11 (UCL Press, 2018).

<sup>66</sup> Sharmila Rudrappa & Caitlyn Collins, *Altruistic Agencies and Compassionate Consumers: Moral Framing of Transnational Surrogacy*, Vol.9(6), *GENDER AND SOCIETY* (2015).

<sup>67</sup> Alison Bailey, *Reconceiving Surrogacy: Toward a Reproductive Justice Account of Indian Surrogacy*, Vol.26(4), *HYPATIA* (2011).

<sup>68</sup> Aarti Dhar, *'Beautiful and Fair' preferred among surrogate mothers too*, *THE HINDU*, October 25, 2012, available at <https://www.thehindu.com/sci-tech/health/policy-and-issues/beautiful-and-fair-preferred-among-surrogate-mothers-too/article4028640.ece> (Last visited on August 20, 2020); *THE TELEGRAPH* (Dean Nelson), *Fair-skinned Indian Women paid £1,000 extra to be surrogates*, October 25, 2012, available at <https://www.telegraph.co.uk/news/worldnews/asia/india/9633142/Fair-skinned-Indian-women-paid-1000-extra-to-be-surrogates.html> (Last visited on August 20, 2020); *REUTERS* (Roli Srivastava), *Indian surrogate mothers grab last chance to make babies ahead of impending ban*, January 19, 2017, available at <https://www.reuters.com/article/us-india-women-surrogacy/indian-surrogate-mothers-grab-last-chance-to-make-babies-ahead-of-impending-ban-idUSKBN1530FL> (Last visited on August 20, 2020).

<sup>69</sup> SAYANTANI DASGUPTA & SHAMITA DAS DASGUPTA, *GLOBALIZATION AND TRANSNATIONAL SURROGACY IN INDIA: OUTSOURCING LIFE* (Lexington Books, 2015).

<sup>70</sup> Amrita Banerjee, *Reorienting the Ethics of Transnational Surrogacy as a Feminist Pragmatist*, Vol.5(3), *THE PLURALIST*, (2010). ; Richard J. Arneson, *Commodification and Commercial Surrogacy*, Vol.21(2), *PHILOSOPHY AND PUBLIC AFFAIRS*, (1992).

<sup>71</sup> ELEANOR MARIE LAWRENCE BROWN, *BLACK WOMEN AND INTERNATIONAL LAW: DELIBERATE INTERACTIONS, MOVEMENTS AND ACTIONS*, Chp. 12 (Cambridge University Press, 2015).

understanding of legal documents and absence of any legal support.<sup>72</sup> It has also been argued that the contractual nature of surrogacy or donation leads to commodification of an act, i.e., motherhood, that must not be commodified at any cost, especially when this commodification is a result of false consciousness. The contractual nature of reproductive assistance is known to have been heavily influenced by the patriarchal society, since norms of contracts are dictated by men, as discussed by Carol Smart.<sup>73</sup> Smart has argued that such legislations and regulatory frameworks that do not involve participation of women cannot be truly reflective of women's needs or grievances. Further, those who govern these contracts in the form of law-makers or judges, especially in India, are also more often than not, men.<sup>74</sup>

The control that women have been able to exercise over their bodies has never been much, but the increased intervention by the medical industry can be dangerous if compounded with the intervention by the State.<sup>75</sup> Women's bodies are detached from their personhood, but are only seen as objects on which experiments can be carried out. Foucault has understood this as the medicalisation of the human body, and the creation of what is known as the 'medical gaze', i.e., looking at human bodies without paying any attention to their personal identities.<sup>76</sup> Amrita Pande, in her work *Commercial Surrogacy in India: Manufacturing a Perfect Mother-Worker*, has also borrowed from Foucault's analysis. She has described surrogacy hostels run by fertility doctors in regions like Anand, Gujarat, as sites of extreme control.<sup>77</sup> These hostels are so tightly regulated to create a perfect surrogate-one that is docile, cheap, nurturing, submissive, but also lives with the knowledge of her disposability. This makes the transaction much simpler for everybody involved but especially so for the commissioning parents and the doctors. They are allowed to establish boundaries and levels of control over the surrogate mothers to ensure that these women conform to their guidelines for the duration of the pregnancy, are satisfied with a meagre compensation, and remain indifferent to the child after its delivery.

The dehumanisation of a woman's body in not only surrogacy, but other ART procedures, is also rampant, especially by way of increased medicalisation, stringent control over their choices, the temporary nature of such work, and the possible commodification that follows. The control that women exercise over their bodies, thus, continually shifts from the lawmaker to the judge to the medical professional to the State, but never truly rests with them.

Another very strong criticism that ART has received from scholar Kristin E. Cheney is that it works towards accommodating heteronormative and patriarchal ideas of what families should look like. This involves preservation of a genetic link of the child to the father, since it preserves one's lineage even if genetic linkages with the mother may be

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<sup>72</sup> Panitch, *supra* note 10.

<sup>73</sup> CAROL SMART, FEMINISM AND THE POWER OF LAW, Chp. 4 (Routledge, 1989); Martha A. Field, *The Case against Enforcement of Surrogacy Contracts*, Vol.8(2), POLITICS AND THE LIFE SCIENCES (1990).

<sup>74</sup> Nirmal Kumar Mohandoss, *State of Women in Judiciary: Time to celebrate or introspect?*, THE QUINT, June 20, 2020, available at <https://www.thequint.com/voices/women/women-in-judiciary-supreme-court-high-court-analysis> (Last visited on August 20, 2020).

<sup>75</sup> Sital Mohanty & Subhasis Sahoo, *The Art of Manufacturing: Ethical Considerations in Quest of a Child*, Vol.65(3), SOCIOLOGIST BULLETIN, 391 (2016); Amrita Pande, *Commercial Surrogacy in India: Manufacturing a perfect Mother-Worker*, Vol.35(4), SIGNS, 970 (2010).

<sup>76</sup> MICHAEL FOUCAULT & FRANCISCA PERUJO, THE BIRTH OF THE CLINIC: AN ARCHAEOLOGY OF MEDICAL PERCEPTION (Vintage, 1963); Jennifer A. Parks, *On the Use of IVF by Post-Menopausal Women*, Vol.14(1), HYPATIA (1999).

<sup>77</sup> Pande, *supra* note 75.

difficult, or in some cases, impossible.<sup>78</sup> Even for same-sex male couples, the importance of genetic linkages to their children was found to be significant.<sup>79</sup> The medical industry working towards creating what an ideal, and more importantly, complete family, looks like further stigmatises those who cannot, or do not have children. ART can also be severely damaging to LGBTQ people in some instances.<sup>80</sup> More and more same sex-couples are being pushed to buying into this heteronormative idea of a traditional family either through marriage,<sup>81</sup> or child-rearing. As a result, opting for ART to have children only to achieve what society understands as the ‘complete family’ is becoming increasingly common.

It can also be extremely damaging to women and the idea of womanhood as a whole. The propagation of ART furthers the false equivalence of motherhood being a prerequisite to achieve womanhood, instead of trying to destabilise it.<sup>82</sup> Women are subject to procedures that can be extremely invasive in nature, all to fit into patriarchal moulds of what society demands of them. In some situations, especially in the absence of strong regulations, these procedures can also be carried out by undertrained staff, under unsafe conditions, or without the woman fully understanding the nature of the procedure itself. These procedures may also not be out of medical necessity, but only exist to strengthen the role of a woman as a mother in society.<sup>83</sup>

On a macro-level, the focus on development of ART may also move away the focus of the State and the medical fraternity from identifying the causes and cures of the widespread infertility that plagues the populace, since reproductive health is already underfunded in many developing countries, including India.<sup>84</sup> Limited resources and forced reprioritisation may allow the State to shrug its responsibility to mitigate a global health crisis by providing readily available alternatives, ignoring that these alternatives can be exploitative, invasive, expensive, or simply undesirable.<sup>85</sup>

On the flip side, theorists like Elizabeth Scott mentioned above, and German feminist-scholars Gerda Neyer and Laura Bernardi discussed below, who have propagated

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<sup>78</sup> ROSEN, *supra* note 65, at 166.

<sup>79</sup> L. Blake et al., *Gay father's motivation for and feelings about surrogacy as a path to parenthood*, Vol.32(4), HUMAN REPRODUCTION (2017).

<sup>80</sup> Daisy Deomampo, *Gendered Geographies of Reproductive Tourism*, Vol.27(4), GENDER AND SOCIETY, (2013).

<sup>81</sup> Oxford Union, *Menaka Guruswamy and Arundhati Katju*, YOUTUBE, April 25, 2020, available at <https://www.youtube.com/watch?v=-Lp6H4YYN-k> (Last visited on August 20, 2020).

<sup>82</sup> Greta Gaard, *Reproductive Technology, or Reproductive Justice?: An Ecofeminist, Environmental Justice Perspective on the Rhetoric of Choice*, Vol.15(2), ETHICS & ENVIRONMENT, (2010); Sarojni N. & Vrinda Marwah, *Reinventing Reproduction, Re-conceiving Challenges: An Examination of Assisted Reproductive Technologies in India*, Vol.46(43), ECONOMIC AND POLITICAL WEEKLY, (2011).

<sup>83</sup> THE TIMES OF INDIA (Sunitha Rao R), *Bengaluru: Infertility business under scanner as women conceive after IVF failure*, September 12, 2019, available at <https://timesofindia.indiatimes.com/city/bengaluru/infertility-biz-under-scanner-as-women-conceive-after-ivf-failure/articleshow/71087355.cms> (Last visited on August 20, 2020); INSIDER (Jennifer Gerson), *Fertility clinics are offering 'add-on' treatments to desperate couples that are expensive and potentially dangerous*, November 5, 2019, available at <https://www.insider.com/ivf-add-on-treatments-are-pricey-unproven-and-unsafe-studies-2019-11> (Last visited on August 20, 2020).

<sup>84</sup> International Conference on Population and Development, *Sexual and Reproductive Health and Rights: An essential element of Universal Health Coverage*, UNITED NATIONS POPULATION FUND, 2019, available at [https://www.unfpa.org/sites/default/files/pub-pdf/SRHR\\_an\\_essential\\_element\\_of\\_UHC\\_SupplementAndUniversalAccess\\_27-online.pdf](https://www.unfpa.org/sites/default/files/pub-pdf/SRHR_an_essential_element_of_UHC_SupplementAndUniversalAccess_27-online.pdf) (Last visited on August 20, 2020).

<sup>85</sup> Guido Pennings, *Ethical issues of infertility treatment in developing countries*, Vol.2008(1), ESHRE MONOGRAPHS (2008).

ART have often cited how it is now possible to pass on the gift of life to those who have been deprived of it – biologically or socially. LGBTQ people are also allowed to navigate their identities as parents within this framework.<sup>86</sup> Couples or individuals who suffer from problems of infertility, disease, or are unable to copulate due to other reasons find a lot of value in ART. They are able to have children that are biologically related to them despite the circumstances. Their right and ability to have a family is not curtailed. From some lenses, the deprivation of fertility assistance can also be seen as a violation of one's human rights, especially because of the value attached to what a complete family ought to be, as discussed above.<sup>87</sup>

It has been argued that all choices that women make with respect to motherhood in a highly patriarchal and pro-natal world are influenced by the circumstances around them.<sup>88</sup> The choice to have a biological child is just as heavily influenced as the choice to opt for ART. Similarly, the choice to engage in any kind of professional work is just as driven by economic coercion as is the choice to engage in an arrangement to be a carrier or a donor for ART.

An important factor to consider here is that often, the amount of agency that women exercise in donating their gametes or acting as surrogates is the most amount of reproductive control they are capable of exercising in their social environments. It also gives a new meaning to what it means to exercise ownership over one's own body, where one can trade their honest services for a monetary compensation. Reproductive control is handed back to women, as in a lot of families across the globe, the decision to have a child, or to not have a child is heavily influenced by their partners, their families, and even the State. This force manifests itself in the form of stringent family planning policies in countries like China,<sup>89</sup> strict abortion regulations in the United States of America,<sup>90</sup> or even India,<sup>91</sup> and a lack of criminalisation of marital rape in India.<sup>92</sup> In contrast to these regulations and frameworks, women *opting* to become surrogates and donors can be an empowering choice. Thus, in the absence of an ideal scenario of complete freedom of choice, the agency that women as commissioning parents and surrogates/donors exhibit must be respected.<sup>93</sup> There is inherent value in the exercise of this agency, and one must not take away from it.

Amrita Pande, while being highly critical of the surrogacy hostels, is also simultaneously appreciative of the sisterhood that it encourages among the women who are

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<sup>86</sup> Dana Berkowitz & William Marsiglio, *Gay Men: Negotiating Procreative, Father, and Family Identities*, Vol.69(2), JOURNAL OF MARRIAGE AND FAMILY, 379 – 380 (2007).

<sup>87</sup> Ombelet, *supra* note 13; William A. Sieck, *In Vitro Fertilization and the Right to Procreate: The Right to No*, Vol.147(2), UNIVERSITY OF PENNSYLVANIA LAW REVIEW, 475 (1998).

<sup>88</sup> Neyer, *supra* note 2.

<sup>89</sup> Laney Zhang, *China: No Immediate plan to delete family planning from laws*, February 25, 2019, available at <https://www.loc.gov/law/foreign-news/article/china-no-immediate-plan-to-delete-family-planning-from-laws/> (Last visited on August 20, 2020).

<sup>90</sup> THE NEW YORK TIMES (K. K. Rebecca Lai), *Abortion Bans: 9 States Have Passed Bills to Limit the Procedure This Year*, May 29, 2019, available at <https://www.nytimes.com/interactive/2019/us/abortion-laws-states.html?mtrref=www.google.com&gwh=24CEE54A853FE4195FC495CF96FD70E8&gwt=pay&assetType=REGIWALL> (Last visited on August 20, 2020).

<sup>91</sup> Dipika Jain, *Time to rethink criminalization of abortion? Towards a gender justice approach*, Vol.12(1), NUJS L. REV. (2019).

<sup>92</sup> Medha Dutta Yadav & Namita Bajpai, *What's wrong with the Indian Male?*, THE INDIAN EXPRESS, December 14, 2019, available at <https://www.newindianexpress.com/magazine/2019/dec/15/whats-wrong-with-the-indian-male-2075525.html> (Last visited on August 20, 2020).

<sup>93</sup> Scott, *supra* note 55.

its inhabitants.<sup>94</sup> Women support other women through the duration of their pregnancies, plan ahead, and develop options for work after their terms are over. Their collectivisation, as envisaged by Pande, may also play a huge role in exercising more control while bargaining for higher wages, more rights, and better living conditions with the medical professionals who run these clinics.<sup>95</sup> These women from the Global South, thus, are accorded with an opportunity to break away from the shackles of exploitation on their own merit, without their white sisters acting as saviours.

Furthermore, the separation of biological and social motherhood achieved in assisted reproduction can be extremely empowering, as well, in direct contrast with the Baby M-era dehumanisation that was associated with ART. In cultures where one's womanhood is equated with their ability to become a mother, women who cannot conceive are looked down upon as less feminine, and as lesser women. For these women to find joy and solace in motherhood, even if it does not involve childbirth, can be a liberating experience, pointed out Gerda Neyer and Laura Bernadi, where they heavily rely on the work of Michelle Stanworth and Robyn Roland.<sup>96</sup> As per Stanworth,<sup>97</sup> and Roland,<sup>98</sup> there was a unique classification of ovarian mothers who provided eggs, uterine mothers who carried the pregnancy, and social mothers who raised the child. This deconstruction of motherhood as a whole was courtesy of ART.

Drawing from this, for surrogates and donors to be active participants in the biological process of the birth of the child, but completely isolated from the social aspects of childrearing can also be seen as an act of rebellion.<sup>99</sup> To take something that has been thrust upon women as a responsibility to fulfil and an extremely labourious chore to compulsorily carry out, and convert it into an economic activity where both parties involved can extract joy, puts back the control in the hands of women. The detachment that they exhibit is not a sign of alienation, but one of control over their own emotions, where ideas of motherhood undergo a revolution. A woman is a complete mother even if she does not undergo childbirth in its entirety, or at all, and a woman can choose to *not* be a mother even if she does undergo childbirth.

## B. RELIGIOUS DISCOURSE ON ART

In this part, there is an attempt to trace the various ways in which religion has shaped the views of society with respect to assisted reproduction. The permeation of such influence on regulatory and policy framework is also discussed. Further, we examine the conundrums faced by religious groups and individuals in reconciling the advancement of medical science with scriptural values. Borrowing from Part III(A), we conclude by offering the unique perspective of religion facilitating the separation of biological and social motherhood. The scope of this Part has been limited to discussing how Abrahamic religions, mainly Islam and Christianity, perceive assisted reproduction. This limitation is set because these religious groups have been vocal about their opinions on various forms of ART. Delving into other religions' ideas will require an undesirable amount of speculation, and is

<sup>94</sup> Pande, *supra* note 75.

<sup>95</sup> *Id.*

<sup>96</sup> Neyer, *supra* note 2, at 167 – 168.

<sup>97</sup> MICHELLE STANWORTH, REPRODUCTIVE TECHNOLOGIES: GENDER, MOTHERHOOD AND MEDICINE, Chp. Reproductive technologies and the Deconstruction of Motherhood (Cambridge Polity Press, 1987).

<sup>98</sup> ROBYN ROWLAND, LIVING LABORATORIES: WOMEN AND REPRODUCTIVE TECHNOLOGY (Lime Tree, 1992).

<sup>99</sup> Neyer, *supra* note 2.

thus avoided. There is some mention of assisted reproduction in the mythological text of the Mahabharata, but this has not been developed further by religious groups, and is thus outside the purview of our discussion.

While the role played by religious lobby groups in determining policy frameworks around the subject has been limited in India, this is not the case in the United States of America. As discussed in Part III (A), the case of Baby M attracted a variety of public opinion. Christian religious groups were largely vocal about their opposition to surrogacy,<sup>100</sup> while some understood that the matter was more complex than it initially seemed.<sup>101</sup> Even in 2020, religious lobbies in the United States of America are able to exercise vast amounts of control on the administration of reproductive health services. This is evident in the application of the Religious Freedom Restoration Act, 1993, which allows healthcare service providers to refuse patients services that may infringe their personal religious beliefs.<sup>102</sup> Instances of this have included denial of abortion services, hormone therapy, and IVF.<sup>103</sup>

In India, while religion does not play a pivotal role in determining healthcare policies, it is often a strong determinant of what may constitute public morality. Further, the Supreme Court has recognised that religion may even form a part of constitutional morality.<sup>104</sup> Thus, across jurisdictions, religion is not disconnected from our social realities. As an extension, religion has been crucial in determining the ways in which people regulate their lives and bodies. Women, and especially devout women, rely heavily on what religious scriptures and preachers say when exercising their right to bodily autonomy and reproductive justice.<sup>105</sup> This happens even more in the absence of cohesive legislation on the subject of ART. In the absence of law or social codes dictating practices, more and more people look to religion.

The Catholic Church has expressed its reservations against the use of various ARTs on the grounds that babies are supposed to be a product of marriage, a union between a man and a woman that has permanence attached to it.<sup>106</sup> Human intervention in this process is seen as unnecessary and invasive. Further, the destruction of some embryos during the

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<sup>100</sup> Carol Sanger, *Developing Markets in Baby-Making: In the Matter of Baby M*, Vol.30, HARV. J. L. & GENDER, 83 (2007).

<sup>101</sup> Iver Peterson, *Baby M's Future*, THE NEW YORK TIMES, April 5, 1987, available at <https://www.nytimes.com/1987/04/05/weekinreview/baby-m-s-future.html> (Last visited on August 21, 2020).

<sup>102</sup> Adam Sonfield, *Learning from experience: Where religious liberty meets reproductive rights*, Vol.19, GUTTMACHER POLICY REVIEW (2016).

<sup>103</sup> *Id.*

<sup>104</sup> Gautam Bhatia, *The Supreme Court's Triple Talaq Judgement*, August 22, 2017, available at <https://indconlawphil.wordpress.com/2017/08/22/the-supreme-courts-triple-talaq-judgement/> (Last visited on August 21, 2020); Gautam Bhatia, *Nine Judges, Seven Questions*, February 16, 2020, available at <https://indconlawphil.wordpress.com/category/freedom-of-religion/essential-religious-practices/> (Last visited on August 21, 2020); Gautam Bhatia, *The Sabarimala Judgement – II: Justice Malhotra, Group Autonomy, and Cultural Dissent*, September 29, 2018, <https://indconlawphil.wordpress.com/2018/09/29/the-sabarimala-judgement-ii-justice-malhotra-group-autonomy-and-cultural-dissent/> (Last visited on August 21, 2020).

<sup>105</sup> Linda Greenhouse, *Let's Not forget the Establishment Clause*, THE NEW YORK TIMES, May 23, 2019, available at <https://www.nytimes.com/2019/05/23/opinion/abortion-supreme-court-religion.html> (Last visited on August 21, 2020).

<sup>106</sup> R. A. Ajayi & O. J. Dibosa-Osador, *Stakeholders' Views on Ethical Issues in the Practice of In-Vitro Fertilisation and Embryo Transfer in Nigeria*, Vol.15(3), AFRICAN JOURNAL OF REPRODUCTIVE HEALTH (2011).



process is equated to abortion and the end of some sort of life form, which is antithetical to the principles adopted by the Church.<sup>107</sup>

For Sunni Muslims, the maintenance of one's patrilineal descent is crucial. Thus, processes that involve the donation of sperm or cut off the link of the father from the baby are not welcome.<sup>108</sup> Techniques that involve sex selection are also prohibited as they may cause grave injustices and cause tears in the social fabric of communities.<sup>109</sup> On a macro-level, the encouragement of sex-identification and subsequent sex-selection procedures can lead to extremely skewed sex ratios, as well. The facilitation of ART to allow post-menopausal women is also usually frowned upon in some Muslim communities, since a lot of importance is laid on the presence of parents till the child matures.<sup>110</sup> Similar to Christianity, Muslims also seek to preserve the structures of traditional families with little to no intervention from medical sciences. The involvement of a third person in matters of marriage or procreation is often unacceptable.<sup>111</sup>

Religion also casts doubt on who the actual parents of the child will be in ART processes. This can be an extremely complex question to address, since it is contextual and can vary from case to case. The degree and level of contribution of the commissioning parents, and the surrogate/donor can vary, leading to different conclusions. In his work *Islam, Kinship and New Reproductive Technology*, Morgan Clarke discusses how the gestational carrier is to be considered the mother of the child for Sunni Muslims even though modern science has proven that this gestational carrier may not have any genetic linkages to the child at all.<sup>112</sup> There is a clear disconnect in how religion and medical professionals have perceived parentage. Further, due to the increased importance attached to establishing clear parentage for children born out of such circumstances, the difficulty that arises out of revocation of a surrogacy contract can be hard to reconcile from a religious perspective. How there is complete detachment of the surrogate mother from the child conceived is also a grey area.<sup>113</sup>

However, the increased understanding of ART has brought about a shift in how traditional societies view both paternity and motherhood. More emphasis is laid on social childrearing than on childbirth or the genealogical makeup of the child. While some men and women deeply value complete biological connection to their child, for infertile

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<sup>107</sup> Susan L. Crockin, *The 'Embryo' Wars: At the Epicenter of Science, Law, Religion, and Politics*, Vol.39(3), FAMILY LAW QUARTERLY (2005).

<sup>108</sup> G. I. Serour, *What is it to practice good medical ethics? A Muslim's perspective*, Vol.41(1), JOURNAL OF MEDICAL ETHICS (2015); Marcia C. Inhorn, "He Won't Be My Son": Middle Eastern Muslim Men's Discourses of Adoption and Gamete Donation, Vol.20(1), MEDICAL ANTHROPOLOGY QUARTERLY (2006).

<sup>109</sup> Ya'arit Bokek-Cohen & Mahdi Tarabeih, *Forbidden medically assisted sex selection in Sunni Muslims: a qualitative study*, REPRODUCTIVE BIOMEDICINES ONLINE (2020); Hassan Chamsi-Pasha, *Assisted Reproductive Technology: Islamic Sunni perspective*, Vol.18(2), HUMAN FERTILITY (2015).

<sup>110</sup> Inhorn, *supra* note 108, at 123.

<sup>111</sup> Morgan Clarke, *Islam, Kinship and New Reproductive Technology*, Vol.22(5), ANTHROPOLOGY TODAY (2006).

<sup>112</sup> *Id.*, 18.

<sup>113</sup> Ayman Shabana, *Foundations of the Consensus against Surrogacy Arrangements in Islamic Law*, Vol.22(1), ISLAMIC LAW AND SOCIETY (2015); Shirin Garmaroudi Naef, *The Iranian Embryo Donation Law and Surrogacy Regulations: The Intersection of Religion, Law and Ethics*, Vol.55(3), DIE WELT DES ISLAMIS, (2015).

couples, it is becoming common to accept their paternity and maternity even if their child is born as a result of ART, and even if it does not find acceptance in their religions.<sup>114</sup>

Furthermore, religion has a great impact on the roles that women adopt when understanding what motherhood means to them. Some infertile women, or women in childless marriages go ahead with ART as they are able to reconcile religious dictates and modern science. This allows them to exercise independent decision-making while still maintaining religiosity.<sup>115</sup> Others completely reject invasive techniques as they believe that their infertility is a part of God's plan.<sup>116</sup> Infertility is accepted as their destiny, and couples find contentment in childless marriages or relationships. This choice, although may seem coerced, can be extremely liberating for women. It allows women to focus on their non-maternal identities and detach their womanhood from expected motherhood.<sup>117</sup> There is also an option to develop their maternal identities without actually having children, but through other forms of care. Devout women are able to find solace in religion through the idea that one is not cursed, but in fact, complete even without having to give birth or raising a child. Reproductive control is handed back to women, and their religious identities do not clash with their decision making in this scenario, but only facilitate it.

#### IV. NAVIGATING THE MEDICO-LEGAL LANDSCAPE OF ASSISTED REPRODUCTIVE TECHNOLOGIES IN INDIA

In this chapter, there will be an attempt to trace the forms in which gene therapy, surrogacy, and IVF exist in India. There is an introduction to what each of these techniques entail from a medical standpoint, in order to understand the process involved. This is followed by a discussion on the current regulation governing these techniques in India.

##### A. GENE THERAPY

Technological advancement has reached a stage where the genetic makeup of babies can be altered. In non-medical terms, the two ways in which gene manipulation happens can be understood as gene selection and gene editing. Gene selection is done through pre-implantation genetic testing or diagnosis.<sup>118</sup> It is the process by which chromosomes and genes of an embryo are tested outside the human body, and then the embryos free of genetic disorders like sickle cell anemia, or Down syndrome, are chosen to be implanted back into

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<sup>114</sup> THE WASHINGTON POST (Ariana Eujung Cha), *How religion is coming to terms with modern fertility methods*, April 27, 2018, available at <https://www.washingtonpost.com/graphics/2018/national/how-religion-is-coming-to-terms-with-modern-fertility-methods/> (Last visited on August 21, 2020).

<sup>115</sup> Danielle Czarnecki, *Moral Women, Immoral Technologies: How Devout Women Negotiate Gender, Religion, and Assisted Reproductive Technologies*, Vol.29(5), GENDER AND SOCIETY (2015).

<sup>116</sup> *Id.*

<sup>117</sup> Alan Jotkowitz, *Surrogate Motherhood Revisited: Maternal Identity from a Jewish Perspective*, Vol.50(4), J. RELIG. HEALTH (2011); Hilla Haelyon, "Longing for a Child": *Perceptions of Motherhood among Israeli-Jewish Women Undergoing in Vitro Fertilization Treatments*, Vol.12, NASHIM: A JOURNAL OF JEWISH WOMEN'S STUDIES & GENDER ISSUES (2006).

<sup>118</sup> Pre-implantation genetic diagnosis (PGD) is a technique that involves testing cell(s) from embryos created outside the body by IVF for a genetic disorder. Tests are carried out for the specific disorder that the embryos are known to be at significant risk of inheriting. Unaffected embryos are selected for transfer to the uterus in the hope that a normal birth will ensue. See NATIONAL HEALTH SERVICE ('NHS'), *Clinical Commissioning Policy: Pre-implantation Genetics Diagnosis* (April, 2013), available at <https://www.england.nhs.uk/wp-content/uploads/2013/04/e01-p-a.pdf> (Last visited on August 21, 2020).

the womb of the mother. The re-implantation of the embryo happens through IVF, which is discussed subsequently. Thus, all medical risks associated with IVF will apply.<sup>119</sup>

The other form of genetic manipulation is gene editing. This is further divided into two parts – somatic gene therapy and germ-line editing. Somatic gene therapy involves the editing of non-reproductive cells, and cells other than gametes, germ cells, or gametocytes. The implication of this is that the manipulation is not passed on to the descendants of the patient on whom it is performed. It is more commonly used than germ-line therapy, and is shown to be successful in tackling conditions like cystic fibrosis,<sup>120</sup> adenosine diseases,<sup>121</sup> some forms of cancer, and hemophilia. The procedure involves the placement of a normal or healthy gene into the individual, resulting in a permanent cure. The insertion is either through viruses or fat-like molecules called liposomes. Germ-line editing involves the manipulation of reproductive cells, meaning that all changes are passed on to future generations of the person whose genes are edited.<sup>122</sup>

Gene editing, whether somatic or germ-line, can be done through procedures like mitochondrial replacement therapy and the recently developed CRISPR-Cas9 (short for clustered regularly interspaced short palindromic repeats and CRISPR-associated protein 9).<sup>123</sup> In mitochondrial replacement therapy, the unhealthy mitochondria of the mother are replaced with the mitochondria from a healthy donor.<sup>124</sup> It can be done via a pronuclear transfer, which involves the fertilisation of the mother's eggs and the donor's eggs via IVF.<sup>125</sup>

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<sup>119</sup> *Pre-implantation genetic diagnosis (PGD)*, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, available at <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/pre-implantation-genetic-diagnosis-pgd/> (Last visited on August 21, 2020).

<sup>120</sup> Cystic fibrosis is an inherited condition that causes sticky mucus to build up in the lungs and digestive system. This causes lung infections and problems with digesting food. See NATIONAL HEALTH SERVICE, *Cystic Fibrosis*, February 13, 2018, available at <https://www.nhs.uk/conditions/cystic-fibrosis/#:~:text=Cystic%20fibrosis%20is%20an%20inherited,newborn%20screening%20heel%20prick%20test> (Last visited on August 21, 2020).

<sup>121</sup> ADA-SCID is caused by mistakes (mutations) in the ADA gene, which result in absent or very low levels of the enzyme ADA. Enzymes are protein substances that help speed up chemical reactions in the body. Lack of the ADA enzyme causes a build-up of a toxic substance called deoxyadenosine. This prevents cells from dividing effectively. See NATIONAL HEALTH SERVICE, *Adenosine deaminase deficient severe combined immunodeficiency (ADA-SCID)*, February, 2018, available at <https://www.gosh.nhs.uk/conditions-and-treatments/conditions-we-treat/adenosine-deaminase-deficient-severe-combined-immunodeficiency-ada-scid> (Last visited on August 21, 2020).

<sup>122</sup> National Guidelines for Gene Therapy Product Development & Clinical Trials (November, 2019), Chp. 4, at 10.

<sup>123</sup> The CRISPR/Cas9 system occurs naturally in bacteria and attains its DNA-cutting abilities from its role as part of the bacterial immune system. Snippets of DNA from invading viruses are cut and stored in the bacterial genome as part of the CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats) array. The Cas9 protein (short for CRISPR associated protein 9) uses those snippets to recognize future invaders and cuts their genetic material, killing them. The CRISPR/Cas9 array allows the bacteria to recognize future attacks and, because it becomes part of the bacterial genome, to pass that immunity on to its offspring. See Alvin Powell, *CRISPR's breakthrough implications*, THE HARVARD GAZETTE, May 16, 2018, available at <https://news.harvard.edu/gazette/story/2018/05/crispr-pioneer-jennifer-doudna-explains-gene-editing-technology-in-prather-lectures/> (Last visited on August 21, 2020); *What are genome editing and CRISPR-Cas9?*, GENETICS HOME REFERENCE, August 17, 2020, available at <https://ghr.nlm.nih.gov/primer/genomeresearch/genomeediting> (Last visited on August 21, 2020).

<sup>124</sup> *Mitochondrial Replacement Therapy*, UNITED MITOCHONDRIAL DISEASE FOUNDATION, available at <https://www.umdf.org/mitochondrial-replacement-therapy/> (Last visited on August 21, 2020).

<sup>125</sup> In Pronuclear Transfer, one's eggs are fertilised with sperm in a lab to create embryos. The nuclear genetic material within each embryo is then transferred into embryos created using donated eggs and sperm from the sperm provider. Again, the nuclear genetic material will have been removed from the donated eggs. See *Mitochondrial donation treatment*, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, available at

After this, the nucleus of the mother's egg is destroyed and replaced with the nucleus of the donor's eggs. Alternatively, the method of spindle transfer may be used.<sup>126</sup> This involves the replacement of the donor's DNA from her egg with that of the mother. This new egg is fertilised by the sperm of the commissioning father through an injection.<sup>127</sup>

CRISPR-Cas9 is a new technique of gene editing, which is highly sophisticated and a complex technique in nature. It involves the creation of RNA with a sequence that binds to the target sequence of DNA in a genome. It also binds to the Cas9 enzyme. The Cas9 enzyme is a protein that plays an immunological role in the body. The modified RNA recognizes the DNA sequence, while the enzyme cuts the DNA at the targeted location. Once this process is over, the DNA repair machinery is used to alter the genetic material of the cell. Existing segments of DNA can also be replaced with a customised sequence.<sup>128</sup>

While this technique has garnered a lot of attention, it has also found itself in the midst of controversy.<sup>129</sup> A large part of the controversy on gene editing stems from the research and experiment carried out by Chinese scientist and doctor, He Jiankui. He used the aforementioned CRISPR-Cas9 technique to modify the genes of a pair of twin girls to prevent them from being susceptible to HIV positivity. This manipulation was in the form of germ-line editing, and gathered world-wide attention.<sup>130</sup> Over a year later, there was speculation that the procedure was not in conformity with medical ethics. It was ridden with unethical practices, false claims, and imperfect knowledge. It is suspected that the commissioning parents did not fully understand the nature of the procedure, and nor did the doctors performing the initial parts of the procedure.<sup>131</sup> The threats to the lives of the children were not fully explained to the parties involved, including the threat of mosaicism, whereby a person has multiple genetically different cells in their bodies.<sup>132</sup> It was also said to be medically unnecessary, and the initially exclaimed success was ridden with doubt. As of December 30, 2019, it has been reported that he has been sentenced to prison for a period of 3 years.<sup>133</sup> The medical community is also threatened by Russian expert Denis Rebrikov following He's footsteps in using CRISPR-Cas9 for germ-line editing.<sup>134</sup>

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<https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/mitochondrial-donation-treatment/> (Last visited on August 21, 2020).

<sup>126</sup> In Maternal Spindle Transfer, your nuclear genetic material is removed from your eggs and transferred into donated eggs which have had their nuclear genetic material removed. The eggs are then fertilised with sperm to create embryos. *See Id.*

<sup>127</sup> *Id.*; A. S. Reznichenko et al., *Mitochondrial transfer: Implications for assisted reproductive technologies*, Vol.11, APPLIED & TRANSLATIONAL GENOMICS (2016).

<sup>128</sup> GENETICS HOME REFERENCE, *supra* note 123.

<sup>129</sup> Henry T. Greely, *CRISPR'd babies: human germline genome editing in the 'He Jiankui affair'*, Vol.6(1), J. LAW BIOSCI. (2019).

<sup>130</sup> *Crossing ethical red lines in gene editing*, FINANCIAL TIMES, available at <https://www.ft.com/content/6218346c-258d-11ea-9f81-051dbffa088d> (Last visited on August 21, 2020).

<sup>131</sup> Antonio Regalado, *China's CRISPR babies: Read exclusive excerpts from the unseen original research*, MIT TECHNOLOGY REVIEW, December 3, 2019, available at <https://www.technologyreview.com/s/614764/chinas-crispr-babies-read-exclusive-excerpts-he-jiankui-paper/> (Last visited on August 21, 2020).

<sup>132</sup> *Medical Genetics: Mosaicism*, STANFORD CHILDREN'S HEALTH, available at <https://www.stanfordchildrens.org/en/topic/default?id=mosaicism-90-P02132> (Last visited on August 21, 2020).

<sup>133</sup> Antonio Regalado, *He Jiankui faces three years in prison for CRISPR babies*, MIT TECHNOLOGY REVIEW, December 30, 2019, available at <https://www.technologyreview.com/s/614997/he-jiankui-sentenced-to-three-years-in-prison-for-crispr-babies/> (Last visited on August 21, 2020).

<sup>134</sup> FINANCIAL TIMES, *supra* note 130.

In response to He's experiment, one of the lead researchers of the technique, Jennifer Doudna, has developed ways to counter unethical and unbridled usage of CRISPR-Cas9.<sup>135</sup> A global moratorium has been suggested by some experts,<sup>136</sup> while other consequences of misuse like loss of funding and revocation of publication privileges have also been suggested.<sup>137</sup> The US National Academy of Medicine, US National Academy of Sciences, and the UK Royal Society have set up the International Commission on the Clinical Use of Human Germline Genome Editing to develop guidelines for safe and ethical use of this technological marvel.<sup>138</sup> In India, there exists no binding legislative framework to govern or regulate gene therapy, but the ICMR has published the National Guidelines for Gene Therapy Product Development and Clinical Trials ('Gene Therapy Guidelines') in November 2019. The National Guidelines on Stem Cell Research published by the ICMR in 2017 may also govern genetic manipulation.

## B. SURROGACY

Surrogacy in the Indian context, refers to the legal arrangement wherein a woman consents to a pregnancy in which she is implanted with the sperm of a man and oocyte<sup>139</sup> of a woman or donates the oocyte herself.<sup>140</sup> She undertakes the term of pregnancy with the intention of delivering the child to the commissioning parents.<sup>141</sup> Thus, surrogacy may be traditional or gestational, depending on whether the surrogate mother's egg is fertilised in the process or not, respectively.<sup>142</sup> In the medical process of gestational surrogacy, the surrogate mother simply acts as a carrier or host for the development of the zygote and upon giving birth, relinquishes the child to its biological parents. Thus, the child born to her is neither genetically nor biologically related to her.<sup>143</sup>

<sup>135</sup> THE STANFORD DAILY (Hannah Shelby), *Renowned scientists address ethics, 'twin scientific revolutions' of AI and CRISPR*, November 21, 2019, available at <https://www.stanforddaily.com/2019/11/21/renowned-scientists-address-ethics-twin-scientific-revolutions-of-ai-and-crispr/> (Last visited on August 21, 2020); Antonio Regalado, *The search for the kryptonite that can stop CRISPR*, MIT TECHNOLOGY REVIEW, May 2, 2019, available at <https://www.technologyreview.com/s/613309/the-search-for-the-kryptonite-that-can-stop-crispr/> (Last visited on August 21, 2020).

<sup>136</sup> Niall Firth, *CRISPR experts are calling for a global moratorium on heritable gene editing*, MIT TECHNOLOGY REVIEW, March 13, 2019, available at <https://www.technologyreview.com/s/613120/crispr-experts-are-calling-for-a-global-moratorium-on-heritable-gene-editing/> (Last visited on August 21, 2020).

<sup>137</sup> Carolyn Brokowski & Mazhar Adli, *CRISPR ethics: moral considerations for applications of a powerful tool*, Vol.431(1), J. MOL. BIOL. (2019).

<sup>138</sup> *International Commission on the clinical use of human germline genome editing*, THE ROYAL SOCIETY, available at <https://royalsociety.org/topics-policy/projects/genetic-technologies/international-commission/> (Last visited on August 21, 2020); *International Commission on the clinical use of human germline genome editing*, THE NATIONAL ACADEMIES OF SCIENCE, ENGINEERING, MEDICINE, available at <https://nationalacademies.org/gene-editing/international-commission/index.htm> (Last visited on August 21, 2020).

<sup>139</sup> An egg before maturation. See Merriam Webster, *Oocyte*, available at <https://www.merriam-webster.com/dictionary/oocyte#:~:text=%3A%20an%20egg%20before%20maturation%20%3A%20a%20female%20gametocyte> (Last visited August 22, 2020)

<sup>140</sup> The Surrogacy (Regulation) Bill, 2019, §4(iii)(b)(I).

<sup>141</sup> The Surrogacy (Regulation) Bill, 2019, §2(zc).

<sup>142</sup> SURROGATE.COM, *About Surrogacy: The Different Types of Surrogacy*, available at: <https://surrogate.com/about-surrogacy/types-of-surrogacy/types-of-surrogacy/> (Last visited on August 19, 2020).

<sup>143</sup> Bhupendar Yadav, *The New Surrogacy Bill Protects the Interests of All*, THE HINDUSTAN TIMES, February 6, 2020, available at: <https://www.hindustantimes.com/analysis/the-new-surrogacy-bill-protects-the-interests-of-all/story-F4DJy6L5QsfYk57npKVB3H.html> (Last visited on August 19, 2020).

Generally, surrogacy may be commercial or altruistic, depending on whether the process involves any *sale* of embryos or gametes and includes monetary remuneration for the surrogate mother in the form of fees, reward, benefit or cash/kind incentive,<sup>144</sup> or is devoid of such charges and expenses.<sup>145</sup> The Lok Sabha had passed the Surrogacy (Regulation) Bill, 2019 only allowing for the medical practice of the latter, which is still echoed in the 2020 Bill.<sup>146</sup> Importantly, this procedure cannot be availed by couples for whom the possibility of conception exists, unless the prospect of such conception is found to be unsafe or medically undesirable.<sup>147</sup>

Surrogacy is mostly prevalent in the private healthcare sector, due to the high costs associated with the proliferation of ART in India. The cost of the entire procedure ranges from INR 10 – 16 lakhs, determined by the location and degree of technological advancement of clinics,<sup>148</sup> thereby exacerbating the problem of accessibility, availability and affordability of ART procedures for lower income individuals battling infertility. On the whole, the advancements in the medical field of ART have brought about effective techniques such as donor insemination and embryo transfers,<sup>149</sup> increasing the popularity of surrogacy as a reproductive process, amongst Indian couples.<sup>150</sup>

Internationally as well, India has emerged as the globalised bio-economy of assisted reproduction,<sup>151</sup> as has been noted above, owing its credit to the global epidemic of infertility.<sup>152</sup> This has facilitated the trade and commercialisation of reproductive tissues around the world, with people looking onto India to fulfil their desire for progeny, on account of its inexpensive setup.<sup>153</sup> However, the greatest catalyst that has enabled India to emerge as a USD 2.3 billion international hub of surrogacy,<sup>154</sup> is the lack of regulation and legislative due diligence.

Initially, the legal framework on surrogacy only consisted of the non-binding ICMR National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2002 ('ART Guidelines'). These guidelines were subjected to public debate and

<sup>144</sup> The Surrogacy (Regulation) Bill, 2019, §2(f).

<sup>145</sup> The Surrogacy (Regulation) Bill, 2019, §2(b).

<sup>146</sup> The Surrogacy (Regulation) Bill, 2019, §3(ii).

<sup>147</sup> The Draft Assisted Reproductive Technology (Regulation) Bill, 2010, §20(10).

<sup>148</sup> Natalia Alvarez & Romina Packan, *Surrogacy Laws in India – Cost, Process & Requirements*, BABYGEST, September 30, 2019, available at <https://babygest.com/en/india/> (Last visited on August 19, 2020).

<sup>149</sup> The transfer of one or more embryos, selected from a larger cohort of available embryos. See World Health Organization, *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology*, 2009 available at [https://www.who.int/reproductivehealth/publications/infertility/art\\_terminology2.pdf?ua=1](https://www.who.int/reproductivehealth/publications/infertility/art_terminology2.pdf?ua=1) (Last visited August 22, 2020)

<sup>150</sup> CENTRE FOR SOCIAL RESEARCH, *Report on Surrogate Motherhood - Ethical or Commercial*, 13, available at: <http://www.womenleadership.in/Csr/SurrogacyReport.pdf> (Last visited on August 19, 2020).

<sup>151</sup> Jyotsna Agnihotri Gupta, *Reproductive Biocrossings: Indian Egg Donors and Surrogates in the Globalised Fertility Market*, Vol. 5(1), INTERNATIONAL JOURNAL OF FEMINIST APPROACHES TO BIOETHICS, 26 (Spring 2012).

<sup>152</sup> Tulsi Patel, *Assisted Reproductive Technologies (ARTs) and Public Health: Exploring the Oxymoron*, Vol. 43(1), INDIAN ANTHROPOLOGIST: SPECIAL ISSUE ON ANTHROPOLOGY AND PUBLIC HEALTH, 73, (January-June 2013).

<sup>153</sup> THE ET HEALTH WORLD, *Surrogacy Bill and Transparency in Assisted Reproductive Technology in India*, January 18, 2017, available at: <https://health.economicstimes.indiatimes.com/news/policy/surrogacy-bill-and-transparency-in-assisted-reproductive-technology-in-india/56613629> (Last visited on August 19, 2020).

<sup>154</sup> Flavia Agnes, *Surrogacy Bill Reflects Regressive Family Ethos*, THE TRIBUNE, January 4, 2019, available at: <https://www.tribuneindia.com/news/archive/surrogacy-bill-reflects-regressive-family-ethos-708282> (Last visited on August 19, 2020).

numerous surveys were conducted across the subcontinent to achieve consensus on the most ethical manner to regulate this field.<sup>155</sup> In 2005, comments from the National Commission for Women and National Human Rights Commission were combined with the results from the surveys and the ICMR National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India were published. These non-binding guidelines along with the 2010 Draft ART Bill provided the perfect backdrop for extensive proliferation of commercial surrogacy and the emergence of India as a reproductive marketplace.<sup>156</sup> However, the aforementioned guidelines, rules and bills never took the form of legally binding regulation, to protect the rights and interests of the surrogate mother, child or commissioning parents.

This absence of a legally binding regulatory mechanism, facilitated instances of rampant exploitation of poor women, through widespread disregard for informed consent, unethical treatment and poor living conditions of surrogates,<sup>157</sup> piecemeal information about medical implications of surrogacy, and instances of forced implantation in post-menopausal women.<sup>158</sup> Numerous health concerns such as preeclampsia,<sup>159</sup> gestational diabetes, postpartum complications like hemorrhaging and depression, including the risk of mortality of the surrogate mothers, went unaddressed.<sup>160</sup> Moreover, as the business of commercial surrogacy expanded and supply of surrogate mothers increased, these poor women were financially exploited and received meagre fees from the commissioning parents, for agreeing to rent their wombs.<sup>161</sup> Further, there were multiple instances of forced commodification of human embryos and gametes as also widespread abandonment of children by the commissioning parents.<sup>162</sup>

This dire situation opened the floor for the Surrogacy (Regulation) Bill ('2016 Bill') to be tabled in the Lok Sabha on November 21, 2016, which banned the practice of commercial surrogacy and disallowed foreigners from hiring Indian surrogate mothers. However, this Bill was widely criticised on grounds of enforcing patriarchal, heteronormative and conservative notions of family and motherhood and paved the way for the Surrogacy (Regulation) Bill of 2019 ('2019 Surrogacy Bill') to be drafted. In February 2020, the Select Committee on the Surrogacy (Regulation) Bill, 2019 ('Select Committee') presented its report to the Rajya Sabha.<sup>163</sup> The Union Cabinet then approved the Surrogacy (Regulation) Bill, 2020 ('2020 Surrogacy Bill'), which incorporated all the changes suggested by the Select Committee. This happened in conjunction with the approval of the Assisted

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<sup>155</sup> R.S. Sharma, *Social, Ethical, Medical and Legal Aspects of Surrogacy: An Indian Scenario*, Vol. 140(Supp. 1), INDIAN JOURNAL OF MEDICAL RESEARCH, (November 2014), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4345743/> (Last visited on August 19, 2020).

<sup>156</sup> Julie Daoud, Alana Ghent & Catherine Sherron, *Do the 'right' thing: Achieving Family at Home and Abroad*, Vol. 8(1), INTERNATIONAL JOURNAL OF FEMINIST APPROACHES TO BIOETHICS, 124 (Spring 2015).

<sup>157</sup> Shankar, *supra* note 45, at 7.

<sup>158</sup> Vrinda Marwah & Sarojini N, *Reinventing Reproduction, Reconceiving Challenges: An Examination of Assisted Reproductive Technologies in India*, Vol. 46(43) ECONOMIC AND POLITICAL WEEKLY 107 (October 22-28, 2011).

<sup>159</sup> M. Simopolou, *Risks in Surrogacy Considering the Embryo: From the Preimplantation to the Gestational and Neonatal Period*, BIOMED RESEARCH INTERNATIONAL (2018).

<sup>160</sup> Kristine Schanbacher, *India's Gestational Surrogacy Market: An Exploitation of Poor Uneducated Women*, Vol. 25(2) HASTINGS WOMEN'S LAW JOURNAL 205 (Summer 2014).

<sup>161</sup> Law Commission of India, *Need for Legislation to Regulate Assisted Reproductive Technology Clinics as well as the Rights and Obligations of Parties to a Surrogacy*, Report No. 228, 11, August 2009, available at: <http://lawcommissionofindia.nic.in/reports/report228.pdf> (Last visited on August 19, 2020).

<sup>162</sup> *Statement of Object & Reasons*, The Surrogacy (Regulation) Bill, 2019.

<sup>163</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, (February 5, 2020).

Reproductive Technology (ART) Regulation Bill, 2020, and the Medical Termination of Pregnancy (Amendment) Bill, 2020.<sup>164</sup> However, in light of the COVID-19 outbreak, both Houses were prematurely adjourned sine die on March 23, 2020.<sup>165</sup> None of these Bills, thus, have been discussed in the Parliament as of April 2020. Notwithstanding the same, Part V(B) of the paper seeks to trace this evolution of legislations introduced in the Parliament, to regulate the practice of Surrogacy in India and analyses the drafting and amendment of specific clauses. It highlights gaps within the existing framework, that ought to be remedied, in order to afford effective protection to the stakeholders, for whom these legislations were enacted.

### C. *IN-VITRO FERTILISATION*

IVF is a method of ART that is commonly used across India.<sup>166</sup> It involves medical assistance for the process of fertilisation. Once the egg is fertilised, this egg is implanted in the uterus of the commissioning mother. It is one of the techniques that can be used to conceive in cases of either male or female infertility, including cases of blocked fallopian tubes, ovulation disorders, or for individuals who have genetic disorders.<sup>167</sup> Additionally, those with tubal diseases, endometriosis, unexplained infertility, immunological reasons, cervical conditions, male infertility, or uterine disorders are also recommended IVF.<sup>168</sup> In India, the costs of IVF can range from INR 1-2.5 lakhs depending on the clinic or hospital opted for. This cost, or other fertility treatments are generally not covered by health insurance, and thus, have to be borne by those opting for it from their own pockets.<sup>169</sup> IVF, although very common now, can be a risky procedure as the gametes are exposed *in vitro*, and the initial development of the embryos occurs outside of the human body.<sup>170</sup> Other risks for any ART procedure, including IVF, include multiple gestation,<sup>171</sup> ectopic pregnancies,<sup>172</sup> spontaneous abortions, and preterm birth.<sup>173</sup>

There are various steps involved in an IVF cycle. The first step is where the commissioning mother is made to take medication to mature the eggs in her body. This process is called ovulation induction, and the body of the patient is under immense scrutiny,

<sup>164</sup> PM INDIA NEWS UPDATES, *Cabinet Approves the Assisted Reproductive Technology Bill, 2020*, February 19, 2020, available at: [https://www.pmindia.gov.in/en/news\\_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/](https://www.pmindia.gov.in/en/news_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/) (Last visited on August 19, 2020).

<sup>165</sup> Press Release, PRESS INFORMATION BUREAU, March 23, 2020, available at: [https://prsindia.org/files/covid19/notifications/133.IND\\_Parliament\\_Adjourned\\_Mar\\_23.pdf](https://prsindia.org/files/covid19/notifications/133.IND_Parliament_Adjourned_Mar_23.pdf) (Last visited on August 19, 2020).

<sup>166</sup> Sanchita Sharma & Anonna Dutt, *40 years of IVF: See how fertility tech has changed the world, and India*, THE HINDUSTAN TIMES, July 21, 2018, available at <https://www.hindustantimes.com/india-news/40-years-of-ivf-see-how-fertility-tech-has-changed-the-world-and-india/story-ow9SKhft9Z9ZUJXo9jTtvO.html> (Last visited on August 21, 2020).

<sup>167</sup> *IVF – In Vitro Fertilization*, AMERICAN PREGNANCY ASSOCIATION, April 24, 2012, available at <https://americanpregnancy.org/infertility/in-vitro-fertilization/> (Last visited on August 21, 2020).

<sup>168</sup> National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), Chp. 2.3.1, at 43.

<sup>169</sup> Gupta, *supra* note 3.

<sup>170</sup> National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), Chp. 2.3.3, at 45.

<sup>171</sup> A pregnancy with more than one fetus. See F. Zegers-Hochschild et al., *International Committee for Monitoring Assisted Reproductive Technology (ICMART) and the World Health Organization (WHO) revised glossary of ART terminology, 2009*, Vol.92(5), FERTILITY AND STERILITY (2009).

<sup>172</sup> A pregnancy in which implantation takes place outside the uterine cavity. See *Id.*

<sup>173</sup> National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), Chp. 2.4, at 46.



with regular tests to check hormones and production of eggs. The drugs taken to stimulate hormones include follicle-stimulating hormone (FSH) or lutenizing hormone (LH), but may differ.<sup>174</sup> These hormones must be administered with utmost caution to avoid Ovarian Hyperstimulation Syndrome.<sup>175</sup> These eggs are then taken out of the body as part of egg retrieval. It involves the use of a needle inserted into one's vagina where a suction device connected to the needle pulls out the eggs. These eggs are then mixed with sperm, which could be of the commissioning father, or a donor. This process, called insemination, is done to attempt to fertilise the egg.<sup>176</sup> Then, the fertilised eggs, now in the form of embryos, are taken and injected into the uterus after a period of 3-5 days. If the embryos are successfully implanted in the uterus, pregnancy is experienced.<sup>177</sup> The pregnancy is tested by assessing the level of the human chorionic gonadotropin hormone.

Currently, there is no legislative framework that regulates the process of IVF in India. In 2005, however, the Indian Council of Medical Research had published the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India.<sup>178</sup> The Assisted Reproductive Technology Bill, 2017, ('2017 ART Bill')<sup>179</sup> is still pending. The Assisted Reproductive Technology Bill was first introduced in 2008, but lapsed thereafter. After that, the Bill was reintroduced in 2010, but lapsed again. Until February 2020, the 2017 version of the Bill was the latest. In February 2020, the Assisted Reproductive Technology (ART) Regulation Bill, 2020 was approved by the Union Cabinet,<sup>180</sup> but both the Houses of the Parliament have been adjourned sine die due to the COVID-19 outbreak.<sup>181</sup> This Bill has not been introduced in Parliament either, and its text has not been published. Thus, the discussion in the paper will be limited to the 2017 ART Bill.

## V. GAPS IN THE EXISTING REGULATORY FRAMEWORK

Drawing from the discussion in Part IV, this Part seeks to identify the gaps that exist in the current regulatory framework governing gene therapy, surrogacy, and IVF in India. This analysis includes identifying the challenges that come with the absence of clear and lucid guidelines in some instances, and the omission of various crucial factors by legislators in other instances.

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<sup>174</sup> Gottumukkala Achyuta Rama Raju et al., *Luteinizing hormone and follicle stimulating hormone synergy: A review of role in controlled ovarian hyper-stimulation*, Vol.6(4), J. HUM. REPROD. SCI. (2013).

<sup>175</sup> An exaggerated systemic response to ovarian stimulation characterized by a wide spectrum of clinical and laboratory manifestations. It is classified as mild, moderate, or severe according to the degree of abdominal distention, ovarian enlargement, and respiratory, hemodynamic, and metabolic complications. See Zegers-Hochschild, *supra* note 171. National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), Chp. 1.6.11.1, at 32.

<sup>176</sup> National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), Chp. 1.6.4, at 25.

<sup>177</sup> *What is IVF?*, PLANNED PARENTHOOD, available at <https://www.plannedparenthood.org/learn/pregnancy/fertility-treatments/what-ivf> (Last visited on August 21, 2020).

<sup>178</sup> National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India (2005).

<sup>179</sup> The Assisted Reproductive Technology Bill, 2017.

<sup>180</sup> PM INDIA, *Cabinet approves the Assisted Reproductive Technology Bill, 2020*, February 19, 2020, available at [https://www.pmindia.gov.in/en/news\\_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/](https://www.pmindia.gov.in/en/news_updates/cabinet-approves-the-assisted-reproductive-technology-regulation-bill-2020/) (Last visited on August 21, 2020).

<sup>181</sup> THE HINDU, *Parliamentary Panels have started scrutinizing handling of COVID-19 in India: Naidu*, July 19, 2020, available at <https://www.thehindu.com/news/national/parliamentary-panels-have-started-scrutinising-handling-of-covid-19-in-india-naidu/article32129485.ece> (Last visited on August 21, 2020).

## A. GENE THERAPY

The ICMR published the Gene Therapy Guidelines in November 2019.<sup>182</sup> Currently, there are no laws in place that govern gene therapy, and thus, only a critique of these guidelines is offered. Indian jurisprudence on the subject is also in its nascent stages, and thus there are no decisions delivered by the Indian judiciary on the subject.

While the scope of these guidelines extends beyond the use of various forms of gene therapy ART, the discussion of the guidelines for the purpose of this paper will be restricted to the impacts and consequences it may have on ART. There will be no attempt to critique medical techniques or their administration either, but a purely policy view will be taken to understand the impacts of the guidelines. The impacts will be assessed beyond the trial stages as well.

The first consideration that merits attention in the Gene Therapy Guidelines is that, while it is stated that germ-line therapy is prohibited in India due to ethical and social considerations, there is little clarity on how and why this was done.<sup>183</sup> There is no mention of any rule with legal backing prohibiting germ-line therapy. ICMR guidelines are not binding in nature, and do not carry legally binding sanctions within their framework. The Gene Therapy Guidelines stand to greatly benefit if the considerations on the basis of which germ-line therapy is prohibited are clearly laid down. Reasons for such a ban could include the inability of regulators to effectively control and monitor the situation,<sup>184</sup> however, it is argued that Indian medicine must strengthen its infrastructure in order to equip itself to meaningfully regulate modern scientific techniques instead of shrugging such responsibilities.

While medical risks and undue advantages are mentioned as reasons for prohibiting gene therapy for non-therapeutic purposes in the Gene Therapy Guidelines, there is no mention of the idea of consent as a factor for the aforementioned prohibition. Artificial and human modification with permanent consequences can be carried out in germ-line therapy procedures, and if allowed, this would happen without any consent from the persons it affects. Thus, it would be immaterial as to whether these consequences will be positive or negative, as the inherent value of consent is severely undermined if it is not considered a determinant at all. Furthermore, this could be against the principles of voluntariness and non-exploitation codified in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 published by the ICMR, if an exception is not carved out.<sup>185</sup> A thorough assessment of consent in this context, thus, is necessary. This assessment could be helpful in determining the extent and nature of modifications allowed. Consent could be undermined in some cases where the prevention of life-threatening diseases is possible, but be upheld in cases of purely cosmetic enhancements.

Furthermore, the Gene Therapy Guidelines maintain that the use of gene therapy must be restricted to therapeutic uses, for correction of conditions, and for tackling diseases. It excludes enhancement or cosmetic modifications from the purview of what will

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<sup>182</sup> National Guidelines for Gene Therapy Product Development & Clinical Trials (November, 2019), Chp. 4, at 10.

<sup>183</sup> *Id.*, Chp. 4.1, at 10.

<sup>184</sup> Farhad Udawadia & Shivam Singh, *Starting the conversation: CRISPR's role in India*, Vol. 4(4), INDIAN J. MED. ETHICS (2019).

<sup>185</sup> National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (October, 2017), 3.

be permitted. However, the guidelines also state that gene therapy for the purposes of the augmentation may be permitted if there is a scientific or ethical justification that is socio-ethically acceptable, and enjoys the backing of the law.<sup>186</sup> It may not be wholly inaccurate to say that the vagueness of this part is intentional. There is no description or explanation accompanying this statement. There is no standard for socio-ethical acceptability that is chartered out, or any situation mentioned, in which this form of the therapy will find justification. It leaves wriggle room and scope for legislative changes that permit augmentation via gene therapy, even if the other conditions like acceptability and justifications are not met. Any legislation introduced in the future will end up superseding these guidelines due to the lack of legal backing for the guidelines. The Gene Therapy Guidelines must include specific exceptions, if at all, or set a standard so that there is no room for exploitation of loosely worded guidelines. While disease-specific guidelines are anticipated shortly,<sup>187</sup> this process must be expedited. The absence of a clear definition as to what may constitute a ‘disease’, especially in an embryo, may also be stretched for the purposes of augmentation. Even purely cosmetic characteristics like baldness may be classified as conditions meriting intervention if guidelines continue to remain vague.

There are also many questions related to the global use of a technique like this that remain unaddressed. International collaborations must be in accordance with Indian guidelines if there is a conflict between the guidelines governing the participating parties as per the Gene Therapy Guidelines.<sup>188</sup> The consequences of this may result in severe isolation of Indian research and scholarship if most States adopt more lenient, or stricter guidelines. It is unclear if Indian parents will be allowed to use germ-line therapy or somatic therapy for the purposes of cosmetic enhancement on human embryos if they choose to have their children abroad. If the Indian State outlaws these forms of gene therapy for social or ethical considerations, then the validity of the baby born as a result of such a procedure as an Indian citizen may come into question. If not, then the government will be drawing artificial lines between babies born as a result of germ-line therapy, or gene therapy for the purposes of augmentation, purely on the basis of place of birth. Furthermore, there is a need to synthesise which forms of gene therapy will be available to non-residents or non-citizens in the country, which forms will allow for commercial transactions, and which forms will be allowed for potential single parents, or unmarried couples.

The Gene Therapy Guidelines also recognise the far-reaching impact of genetic disorders and conditions on the Indian populace, but suggest no mechanism to make these therapies widely available. The sophisticated nature of the therapy, coupled with restricted usage indicates that costs of the therapy will be steep once available to the public. Especially in the context of using gene therapy to correct genetic conditions in embryos, it will again become an ART that only the rich will have access to. This will have great impact with respect to how genetic disorders and conditions will then remain a problem only the poor are plagued by, creating an even starker class divide. This class divide, further, will be based on genetic capabilities and capacities. It is also unclear if insurance companies will cover the costs of gene therapy, or if the costs of procedures and medication will be subsidised. Questions of bridging gaps in access, thus, remain unaddressed.

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<sup>186</sup> National Guidelines for Gene Therapy Product Development & Clinical Trials (November, 2019), Chp. 5 at 11.

<sup>187</sup> *Id.*, Chp. 2, at 7.

<sup>188</sup> *Id.*, Chp. 12.2, at 60.

The Gene Therapy Guidelines must also provide for the protection of the privacy of the genetic data that is collected and stored. More stringent, and more specific privacy safeguards should exist not only for the commissioning parents, but also for the babies born as a result of these procedures. The misuse of genetic information can have disastrous consequences, including denial of health insurance,<sup>189</sup> and application in fighting crime using long-range familial searching.<sup>190</sup> Furthermore, when in-vitro embryonic stem cells will be the target of gene manipulation or editing, the National Guidelines on Stem Cell Research published by the ICMR in 2017 will also apply. These guidelines allow for the monetisation and commercialisation of research and any products developed.<sup>191</sup> This commercialisation is allowed in status quo, but the Gene Therapy Guidelines only see commercialisation as an eventual goal. Thus, there are no specific guidelines on how products or research will be monetised as far as the Gene Therapy Guidelines are concerned, except that approval must be sought from the local Ethics Committees.<sup>192</sup> Thus, it remains unclear as to what procedure must be followed in case doctors, pharmaceutical companies, or research organisations want to commercialise their research right now.

The prohibited areas of research listed in the National Guidelines on Stem Cell Research 2017 must also be updated and synthesised with the Gene Therapy Guidelines for effective development of gene therapy techniques.<sup>193</sup>

## B. SURROGACY

As has been discussed in the previous Part, the dearth of binding regulation has created an atmosphere conducive to the proliferation of unethical and exploitative practices in surrogacy procedures. Thus, there is a pressing need to understand the focus of successive legislations drafted to regulate the process of surrogacy and identify their loopholes, in order to develop a binding model regulatory framework for its proliferation in India.

As has been highlighted, the surge of exploitative practices led to the tabling of the 2016 Bill. The foremost design of the 2016 Bill was to ban the practice of commercial surrogacy, disallow foreigners from hiring Indian surrogate mothers, and only allow for ‘altruistic surrogacy’,<sup>194</sup> under which the surrogate ought to be a close relative of the infertile couple that has been married for at least five years and can produce a certificate as proof of their infertility.<sup>195</sup> However, the 2016 Bill was met with severe criticism on account of its failure to adequately define and uphold the rights of the surrogate mother, the child born out of surrogacy, and the commissioning couple. Thus, it was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare (‘the Committee’) by the Chairman of Rajya Sabha on January 12, 2017.

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<sup>189</sup> Kelly Song, *4 Risks consumers need to know about DNA testing kit results and buying life insurance*, CNBC, August 4, 2018, available at <https://www.cnbc.com/2018/08/04/4--risks-consumer-face-with-dna-testing-and-buying-life-insurance.html> (Last visited on August 21, 2020).

<sup>190</sup> Meghan Molteni, *The Future of Crime-Fighting is Family Tree Forensics*, WIRED, December 26, 2018, available at <https://www.wired.com/story/the-future-of-crime-fighting-is-family-tree-forensics/> (Last visited on August 21, 2020).

<sup>191</sup> National Guidelines on Stem Cell Research (October, 2017), Chp. 4.2.4, at 18 – 19.

<sup>192</sup> National Guidelines for Gene Therapy Product Development & Clinical Trials (November, 2019), Annexure 3, at 83.

<sup>193</sup> National Guidelines on Stem Cell Research (October, 2017), Chp. 8.3, at 25.

<sup>194</sup> The Surrogacy (Regulation) Bill, 2016, §35.

<sup>195</sup> The Surrogacy (Regulation) Bill, 2016, §2(b).

The Committee proceeded to critically analyse the backdrop in which the 2016 Bill had been enacted, the objectives of the legislation and the proposed changes to the practice of surrogacy, by issuing a press release gathering the opinion of the public on the same.<sup>196</sup> Amidst its interactions with medical professionals and surrogate mothers, the Committee reached a crucial finding that women who chose to become surrogate mothers, made this decision out of economic duress.<sup>197</sup> It simultaneously found the practice of commercial surrogacy to be exploitative as it was characterised by occurrences of deteriorating health due to repeated pregnancies, instances of surrogates not having rights against the commissioning parents and doctors, and the phenomenon of unequal bargaining power and socio-economic capital of surrogates vis-à-vis the surrogacy agencies reducing the remuneration received by the surrogate to pittance. It is this acknowledgment of the duality of commercial surrogacy as being both exploitative and remunerative, that creates a need to draft guidelines for the practice of ethically regulated surrogacy involving some form of a monetary component to create a compensated model of surrogacy. Instead of banning it completely, the Committee recommended heavy regulation of the same.<sup>198</sup> This was to ensure that women who opted to be surrogate mothers, continued to enjoy their livelihood with a new safe work environment. It is crucial to understand the deplorable state of the women belonging to the poor strata of society and the nature of duress under which they undertake pregnancies for nine months. They require the commissioning fees they receive to sustain their families.<sup>199</sup> Additionally, the market mechanism for surrogacy is well established in different pockets of India, especially prominent in areas such as Anand, Surat and Jamnagar.<sup>200</sup> Thus, a complete ban on commercial surrogacy would, in effect, work to further exacerbate the problem for the very women the legislation was enacted. This is because the well-established nature of the surrogacy market mechanism makes such a ban difficult to enforce and therefore possesses a high propensity to drive the entire operation underground, where no legislation operates to check exploitative practices.

The Committee also recommended the clause restricting altruistic surrogacy to close relatives, to be recast on several grounds and herein lies the most glaring flaw of the 2016 Bill. First, despite having recognised the ubiquitous stigma attached to fertility in India, the Bill makes an improbable conjecture that couples will be forthcoming with information regarding their reproductive states and choices, with their close relatives.<sup>201</sup> The entrenched misconception of infertility being the fault of the women, could also expose them to heightened risks of domestic abuse within traditional family structures. Additionally, the term ‘close relative of the intending couple’ has been left undefined and the 2016 Bill does not specify the range of degrees of genetic relations within which an eligible surrogate mother falls. The Committee observed that such ambiguity in the law would lead to arbitrariness in

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<sup>196</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*.

<sup>197</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶4.14., August 10, 2017.

<sup>198</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶5.13., August 10, 2017.

<sup>199</sup> THE STRAITS TIMES (Nirmala Ganpathy), *India's Move to Ban Commercial Surrogacy Sends Industry into Panic*, August 19, 2019, available at: <https://www.straitstimes.com/asia/south-asia/indias-move-to-ban-commercial-surrogacy-sends-industry-into-panic> (Last visited on August 19, 2020).

<sup>200</sup> CENTRE FOR SOCIAL RESEARCH, *Report on Surrogate Motherhood - Ethical or Commercial*, available at: <http://www.womenleadership.in/Csr/SurrogacyReport.pdf> (Last visited on August 19, 2020).

<sup>201</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶5.11., August 10, 2017.

its interpretation.<sup>202</sup> Second, even if the requirement of ‘close relative’ is done away with, the terminology ‘altruistic’ by itself, creates a new mode of exploitation wherein women can now be coerced into the process under the guise of it being their selfless obligation to do so. The moralistic platitudes of the 2016 Bill impose on women the expectation that it is their inherent right to give birth, but deny them the ability to be remunerated for offering their services for the same. This gives rise to the third infirmity of altruistic surrogacy; the promotion of forced labour, wherein close female relatives would be subjected to immense emotional pressure to undertake the bodily labour of gestation without any payment.<sup>203</sup>

Moreover, by norm, pregnancies take huge tolls on the physical, emotional and psychological health of women, by making them undergo immense bodily labour. The complex procedures involved in surrogacy further increase the risk of maternal mortality and other health complications for the surrogate mother.<sup>204</sup> This necessitates the provision to compensate the surrogate mothers for their services and incentivise them to offer their wombs. Together, these factors of stigma attached to infertility and the lack of incentive to become a surrogate, preclude the possibility of womb-sharing between close relatives.<sup>205</sup>

The 2016 Bill also makes an incomplete assessment of the costs incurred by the surrogate mother while undertaking pregnancy. It reduces the ambit of monetary compensation, merely to medical expenses and insurance coverage.<sup>206</sup> There is a clear disregard for the fact that the surrogate mother has elected to forego her own livelihood, her commitments to her own immediate family, and has undertaken severe mental, psychological and physical health risks to deliver a child to the commissioning parents. The model law needs to be made accommodative and reflective of these costs by creating a provision to compensate the same.

Additionally, the 2016 Bill is grounded in patriarchal and conservative undertones, as it only allows heterosexual couples who have been married for five years, to opt for surrogacy, upon the production of a certificate of infertility issued by the District Medical Board.<sup>207</sup> This entrenchment of the traditional institution of marriage not only impinges on the rights of single persons, transgender couples, same-sex couples and couples in live-in relationships, to have a family but also infringes on the rights of persons to preserve their personal intimacies as was upheld as part of the Right to Privacy by Justice Chandrachud.<sup>208</sup> This poses the constitutional challenge of right to privacy under Article 21 and right to equality under Article 14,<sup>209</sup> on account of the apex court having recognised the rights relating to reproduction to be personal decisions,<sup>210</sup> the right to reproduction being a

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<sup>202</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶5.76., August 10, 2017.

<sup>203</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶5.8., August 10, 2017.

<sup>204</sup> Simopolou, *supra* note 159, at 23.

<sup>205</sup> FIRST POST (Ankita Virmani), *Blanket Ban on Commercial Surrogacy eliminates aspects of privacy; unfair to couples who marry late, homosexuals*, December 27, 2018, available at: <https://www.firstpost.com/india/blanket-ban-on-commercial-surrogacy-eliminates-aspect-of-privacy-unfair-to-couples-who-marry-late-homosexuals-5799601.html> (Last visited on August 19, 2020).

<sup>206</sup> The Surrogacy (Regulation) Bill, 2019, §2(b).

<sup>207</sup> The Surrogacy (Regulation) Bill, 2019, §4(iii)(c)(II).

<sup>208</sup> K. S. Puttuswamy v. Union of India, (2017) 10 SCC 1, ¶323 (per D.Y. Chandrachud J.).

<sup>209</sup> Alice George & Aviral Chauhan, *Surrogacy Bill and ART Bill: Boon or Bane?*, INDIA CORPORATE LAW, April 1, 2019, available at: <https://corporate.cyrilamarchandblogs.com/2019/04/surrogacy-bill-and-art-bill-boon-or-bane/> (Last visited on August 19, 2020).

<sup>210</sup> B.K Parthasarthi v. Govt. of A.P., AIR 2000 AP 156.

part of right to life,<sup>211</sup> the right to maintain same-sex relationships,<sup>212</sup> and the right to be full citizens as transgenders in India.<sup>213</sup> Thus, if the law itself recognises the right to equality and the right to intimacy as a core component of autonomy and privacy, then arguably, it ought to maintain neutrality between the various forms of intimate relationships whose existence it recognises.<sup>214</sup>

The 2016 Bill also makes a deviation from the definition of infertility given by WHO as also under the 2017 ART Bill,<sup>215</sup> arbitrarily increasing the requisite period of infertility from one year to five years. The Department of Health Research explained the rationale behind five years as being facilitative of the efforts of couples to “exhaust all other means of having a child of one's own because the joy of bearing one's own child can never be the same as can be had through surrogacy”.<sup>216</sup> Such a law reeks of the paternalistic attitude of the State and by passing value judgement on the respective ‘joys’ attained through different modes of child bearing, it violates the right to reproductive autonomy of an individual. The waiting period of ‘five years’ ought to be struck off and replaced with a more suitable time frame. This may be in tune with the characterisation of infertility as the inability to achieve pregnancy after ‘12 months or more’ of regular unprotected sexual intercourse, as recognised by the WHO<sup>217</sup> and the National Health Portal of India.<sup>218</sup> Further, the definition only extends to the inability to conceive. However, there may be medical complications that allow a woman to conceive but preclude her from seeing the pregnancy through, such as fibroids in the uterus and hypertension or a history of multiple miscarriages, that are not recognised by the Bill. Moreover, there may be instances of secondary infertility which refers to the inability to conceive after the birth of a child previously.<sup>219</sup> These arise due to factors such as advanced age, damage to fallopian tubes, uterine conditions, and impaired sperm function,<sup>220</sup> among several others. Currently, the bar on initiation of surrogacy in the event a surviving child exists, refuses to recognise a prevalent form of infertility, thereby infringing upon the scope of reproductive autonomy enjoyed by individuals.<sup>221</sup>

The 2017 ART Bill has also added a massive obstacle in the abortion process for surrogate mothers by creating the requirement for them to get authorisation from the ‘appropriate authority’ in addition to complying with the Medical Termination of Pregnancy Act, 1971 (‘the MTP’).<sup>222</sup> Since the MTP sufficiently imposes restrictions to safeguard the

<sup>211</sup> *Devika Biswas v. Union of India*, (2016) 10 SCC 726.

<sup>212</sup> *Navtej Johar v. Union of India*, (2018) 10 SCC 1.

<sup>213</sup> *National Legal Services Authority v. Union of India*, (2014) 5 SCC 438.

<sup>214</sup> Arijeet Ghosh & Diksha Sanyal, *How Can Families be Imagined Beyond Kinship & Marriage?*, Vol. 54(45), ECONOMIC AND POLITICAL WEEKLY (2019).

<sup>215</sup> The Draft Assisted Reproductive Technology (Regulation) Bill, 2017, §2(s).

<sup>216</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶4.19, 24 (February 5, 2020).

<sup>217</sup> WHO Definition, *supra* note 19, at 5.

<sup>218</sup> Disease A-Z, *Infertility*, NATIONAL HEALTH PORTAL OF INDIA, available at: <https://www.nhp.gov.in/disease/reproductive-system/infertility> (Last visited on August 26, 2020).

<sup>219</sup> THE INDIAN EXPRESS, *Struggling to Conceive the Second Time? What You Should Know About Secondary Infertility*, August 29, 2019, available at: <https://indianexpress.com/article/parenting/health-fitness/secondary-infertility-pregnancy-5916181/> (Last visited on August 26, 2020).

<sup>220</sup> MAYO CLINIC, *Secondary Infertility: Why Does it Happen?*, January 30, 2020, available at: <https://www.mayoclinic.org/diseases-conditions/infertility/expert-answers/secondary-infertility/faq-20058272> (Last visited on August 26, 2020).

<sup>221</sup> The Surrogacy (Regulation) Bill 2020, §4(iii)(c)(III).

<sup>222</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶2.13, 10 (February 5, 2020).

interests of pregnant women and children, the additional requirement of approval from the appropriate authority is unreasonable. Further, the Bill has not provided the time period by which such authorisation for abortion has to be given, worsening the situation for when a surrogate mother is facing a life-threatening health emergency during her pregnancy.

Moreover, the Committee critiqued the restriction on Non-Residents of India ('NRIs'), Persons of Indian Origin ('PIOs') and Overseas Citizenship of India ('OCI') Cardholders to initiate surrogacy procedures in India, as being arbitrary.<sup>223</sup> Further, no explanation for the debarment of these individuals was provided. Since this classification made for determining the eligibility of individuals has no reasonable nexus with the objective of the act, it is violative of the Article 14 right against discrimination on grounds of marital status and nationality and the Article 21 right of reproductive autonomy. Further since such persons are allowed inter-country adoptions under the Adoptions Regulations, 2017,<sup>224</sup> it is unreasonable for them to be subjected to different parameters under acts that seek to grant the same gift of parenthood.

Although the Parliamentary Committee submitted its report on August 10, 2017, their crucial recommendations were overlooked in the amended 2019 Surrogacy Bill introduced in the Lok Sabha on July 15, 2019. The same was passed on August 5, 2019 and continues to remain under the scanner for the same glaring loopholes, in achieving its objectives. Several stakeholders argue that it further marginalises the very people it aims to protect, as it displays a "complete lack of comprehension of the lived realities of the people for whom it is meant".<sup>225</sup>

The 2019 Surrogacy Bill, too suffers from similar infirmities and further disregards ICMR guidelines without providing sound rationale for deviating from the same. It takes a step back by disallowing single women to benefit from ART,<sup>226</sup> and imposing a legal bar on unmarried women<sup>227</sup> from adopting ART procedures as is progressively envisaged by the ICMR National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India. It does not take the minimum physical requirement for ART Clinics and essential qualification for ART teams and procedures into account, all of which are fundamental to the continued healthy proliferation of ART in India. It further prohibits the storage of embryos and gametes (unfertilised egg and sperm) for the purpose of surrogacy as opposed to the current ICMR guidelines (2005) which allow the storage of embryos for a period of five years.<sup>228</sup> The prohibition on storage of egg or sperm may have adverse health implications for the intending mother, given the dismal success rate of surrogacy procedures. Typically, for surrogacy, the eggs are extracted from the intending mother and are implanted in the surrogate mother's uterus. Given that the success rate of one implantation is below 30%,

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<sup>223</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, ¶5.42, August 10, 2017.

<sup>224</sup> The Adoption Regulations, 2017, §8.

<sup>225</sup> Indian Council of Medical Research, *Media Report on Surrogacy Bill Regulation: Dear Lok Sabha, Stop Criminalising Our Bodies and Lives*, (26 December, 2017 – 5 January, 2018), available at: [https://main.icmr.nic.in/sites/default/files/Surrogacy\\_bill\\_Regulation\\_december\\_to\\_january.pdf](https://main.icmr.nic.in/sites/default/files/Surrogacy_bill_Regulation_december_to_january.pdf) (Last visited on August 19, 2020).

<sup>226</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶3.5.2, 62 (February 5, 2020).

<sup>227</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶3.16.4, 75 (February 5, 2020).

<sup>228</sup> The Assisted Reproductive Technologies (Regulation) Bill, 2010, §27(2).



therefore, multiple implantation attempts may be required,<sup>229</sup> a possibility which is now precluded through the prohibition of storage.

The 2019 Surrogacy Bill was then referred to a select-committee of the Rajya Sabha to make recommendations.<sup>230</sup> This committee submitted its report to the Rajya Sabha in February, 2020, and the Bill took the form of the 2020 Surrogacy Bill. However, due to the premature adjournment of the Session, the 2020 Surrogacy Bill remains undiscussed in the Parliament.<sup>231</sup>

While the recommendations of the Select Committee seek to address multiple grievances, several considerations go undiscussed and yet newer concerns crop up in the 2020 Surrogacy Bill. Firstly, although the step to increase the ambit of commissioning parents from only heterosexual married couples to widowed and divorced women is welcomed, the absolute requirement of having been previously married is arbitrary, unexplained and restrictive of the reproductive autonomy of single women and couples in live-in relationships who have never been married but harbour the desire for progeny. This Bill also lists eligibility requirements for commissioning couples,<sup>232</sup> but does not lay down the conditions that single women must meet, despite having created a provision for them to avail surrogacy benefits.<sup>233</sup> This Bill is silent on whether the requirement of no biological children will apply to single women commissioning surrogacy either. Secondly, the mere abolishment of the requirement of being a close relative under altruistic surrogacy arrangements does little to remedy the continuing concerns of pregnancy being understood as the selfless and compassionate obligation of a woman that propagates forced labour, as discussed above. Moreover, the modified understanding of a surrogate mother as any woman ‘willing’<sup>234</sup> to undertake the heavy mental, psychological and physical costs and burdens of pregnancy is unrealistic, in the absence of any financial incentive to do the same. Furthermore, the restriction on advertising both the willingness to become a surrogate mother<sup>235</sup>, as well as the need for a surrogate mother,<sup>236</sup> further reduces accessibility to surrogacy procedures. However, the effective demand for surrogates creates a dangerously high propensity for exploitation and trafficking. Thus, the act of making altruistic and compassionate traits the eligibility criteria for surrogate mothers, works to further complicate and restrict the availability of and accessibility to surrogacy.

## 1. The Interplay between ART Bill and Surrogacy Bill

The 2017 ART Bill proposes to establish a National Board, State Boards and National Registry of Assisted Reproductive Technology in India for the accreditation and supervision of ART clinics and ART Banks,<sup>237</sup> ensuring that the services provided by these are ethical. While the 2017 ART Bill functions to regulate the technology of reproductive medicine in surrogacy, the 2020 Surrogacy Bill aims to protect the medical, social and legal

<sup>229</sup> Chapter 1, National Guidelines for Accreditation, Supervision & Regulation of ART Clinics in India, Indian Council of Medical Research, 2015.

<sup>230</sup> PRS LEGISLATIVE RESEARCH, *The Surrogacy (Regulation) Bill Track*, available at: <http://prsindia.org/billtrack/surrogacy-regulation-bill-2019> (Last visited on August 19, 2020).

<sup>231</sup> Press Release, *supra* note 165, at 23.

<sup>232</sup> The Surrogacy (Regulation) Bill, 2020, §4(iii) (c)(I)-(IV).

<sup>233</sup> The Surrogacy (Regulation) Bill, 2020, §2(s).

<sup>234</sup> The Surrogacy (Regulation) Bill, 2020, §4(iii)(b)(II).

<sup>235</sup> The Surrogacy (Regulation) Bill, 2020, §3(v)(d).

<sup>236</sup> The Surrogacy (Regulation) Bill, 2020, § 3(v)(c).

<sup>237</sup> *Statement of Objective and Reasons*, The Assisted Reproductive Technology (Regulation) Bill, 2017.

rights of all stakeholders, giving them maximum benefit within a recognised framework of ethics and good medical practices. Additionally, since surrogacy procedures are in fact initiated under ART clinics,<sup>238</sup> the regulation of ART becomes a mandatory precondition for the effective implementation of the 2020 Surrogacy Bill.<sup>239</sup> Thus, it is important to understand the manner in which both these Bills will interact with each other and identify progressive facets of the 2017 ART Bill that ought to be subsumed within the 2020 Surrogacy Bill.

It is widely known that surrogacy entails high rates of maternal mortality due to the introduction of chemicals and technologies.<sup>240</sup> Like any other pregnancy, it not only carries the risk of maternal mortality but involves aggravated health risks including negative drug reaction or allergies, nausea and vomiting, stomach pains and swelling, shortness of breath, faintness, and Ovarian Hyperstimulation Syndrome which may be life-threatening following hormonal treatment or IVF for facilitating conception in surrogate mothers.<sup>241</sup> However, the 2019 Surrogacy Bill does not factor these health risks as costs borne by the surrogate mother and only covers actual medical expenses and insurance coverage as her monetary compensation for a defined period of sixteen months after the pregnancy, as opposed to the 2014 ART Bill, that accounts for all medical expenses that are generated during the pregnancy, although their effects may be observed at any later unspecified time.<sup>242</sup> While the 2020 Surrogacy Bill widens the ambit to include ‘other such prescribed expenses’, it is unclear as to the extent of costs that may be included under this category of expenses. Moreover, under the 2020 Surrogacy Bill, the intending couple becomes eligible to initiate the surrogacy procedure upon presenting any insurance coverage whose amount may be prescribed by any agent or company recognised under the Insurance Regulatory and Development Authority Act, 1999 (‘IRDA Act’).<sup>243</sup> Here, the amount of insurance set aside for the thirty six months has no connection to reasonability or fairness but only depends on whether the insurance agent prescribing the same is recognised under the IRDA Act or not.

Further, the provisions of ART Bill direct that the life of surrogate mother be protected over the life of the unborn child in life-threatening situations.<sup>244</sup> This is one of the most potent reproductive and maternal health safeguards for the surrogate mother, which is not found in the Surrogacy Bill.<sup>245</sup>

The cause for the discrepancies between the 2017 ART Bill and the 2019 Surrogacy Bill can be attributed to the fact that none of the ART Bill Drafting Committee

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<sup>238</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶4.83 (February 5, 2020).

<sup>239</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶2.12, UNFPA Representative (February 5, 2020).

<sup>240</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, ¶2.19, August 10, 2017.

<sup>241</sup> *Id.*

<sup>242</sup> The Draft Assisted Reproductive Technology (Regulation) Bill, 2014, §60(2)(a).

<sup>243</sup> The Surrogacy (Regulation) Bill, 2020, §4(iii)(a)(III), “an insurance coverage of such amount and in such manner as may be prescribed in favour of the surrogate mother for a period of thirty-six months covering postpartum delivery complications from an insurance company or an agent recognised by the Insurance Regulatory and Development Authority established under the Insurance Regulatory and Development Authority Act, 1999”.

<sup>244</sup> The Draft Assisted Reproductive Technology (Regulation) Bill, 2014, § 60(30).

<sup>245</sup> Sonali Kusum, *What if the Surrogate Mother Dies?*, ETHEALTH WORLD, April 24, 2018, available at: <https://health.economictimes.indiatimes.com/news/industry/what-if-the-surrogate-mother-dies-sonali-kusum/63897209>(Last visited on August 19, 2020).

members were invited to be members of the Surrogacy Bill Drafting Committee. This is despite widespread recognition of the fact that surrogacy cannot be carried out without ART procedures and hence the bill cannot be passed in isolation.<sup>246</sup> However, a greater cause of concern afflicting both the committees, is their exclusionary composition, which, in the absence of adequate representation from women and the LGBT community, leads to an insufficient assessment of their socio-cultural and economic needs.

Moreover, in the absence of any binding legislation and gaps in the existing regulations, all legal considerations surrounding the ethical practice of surrogacy, including but not limited to matters of custody, determination of nationality, maternity leave for the surrogate and commissioning mother and viability of surrogacy contracts, have been decided through the adjudication of courts. These are pertinent issues that ought to be covered by one holistic model regulatory framework as opposed to being adjudged differently across high courts.

For instance, the issue of grant of maternity leave to commissioning mothers has been hotly debated across several high courts, based on the state specific Civil Services (Leave) Rules. In *K. Kalaiselvi v. Chennai Port Trust*,<sup>247</sup> a surrogacy commissioning mother was judicially equated with an adoptive mother, thereby extending the applicability of maternity leave under the Madras Leave Regulations on an adoptive mother to the commissioning mother as well. Similarly, in *Rama Pande v. Union of India*,<sup>248</sup> the Delhi High Court upheld the grant of maternity leave to commissioning mothers. It ruled out the simplistic notion of the objective of maternity leave only being to assist women who undergo mental and physical fatigue due to pregnancy and recognised the fact that all women, irrespective of their manner of begetting a child, face challenges of child-bearing in the postnatal stages. Relying on this judgement, in *Hema Vijay Menon v. State of Maharashtra*,<sup>249</sup> the Bombay High Court interpreted the term 'maternity' as motherhood, and deemed the denial of maternity leave to *mothers* of surrogate children as discriminatory on this count. Additionally, it held that maternity leave protects the interests of both the mother and the child as envisaged under the Right to Life under Article 21, which includes the right to motherhood as also the right of every child to full development. An understanding of the fact that entitlement to maternity leave is not solely linked to the welfare of the child's mother but must necessarily account for the best interests of the child as well, highlights the urgency with which matters concerning both maternity and paternity leave ought to be sufficiently addressed by any model legislation on surrogacy.

The apex court too has decided on matters such as custody and recognition of the intending couple as the legal parents of the surrogate child, as was the case in *Baby Manji Yamada v. Union of India*,<sup>250</sup> wherein there was a commercial surrogacy agreement between a Japanese intending couple, that had since divorced, and an Indian surrogate mother. The Supreme Court directed the Central Government to expeditiously dispose off the application for issuance of passports for the grandmother of the child and the child. The subsequent grant

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<sup>246</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, Dr. Kamini Rao, National Advisory Committee for Drafting of Guidelines of Assisted Reproductive Technology, ¶4.10, August 10, 2017.

<sup>247</sup> *K. Kalaiselvi v. Chennai Port Trust*, 2013 SCC OnLine Mad 811; (2013) 2 CTC 400; (2013) 2 LW 530; (2013) 3 Mad LJ 493; (2013) 138 FLR. 55; (2013) 1 CLR 969.

<sup>248</sup> *Rama Pande v. Union of India*, 2015 SCC OnLine Del 10484; (2015) 221 DLT 756.

<sup>249</sup> *Hema Vijay Menon v State of Maharashtra*, 2015 SCC OnLine Bom 6127; (2015) 5 AIR Bom R 370; AIR 2015 Bom 231; 2015 Lab IC 3470; (2015) 3 CLR 904.

<sup>250</sup> *Baby Manji Yamada v Union of India*, (2008) 13 SCC 518.

of an 'Identity Certificate' to the baby by the regional passport office was an implicit recognition of the legal status of a single parent as the custodian of the surrogate child, herein the divorced father. It is imperative for surrogacy legislations to conclusively express the law on all foreseeable legal considerations that may arise out of the process.

However, the courts too are largely restricted from adjudicating on matters relating to the rights and obligations of parties to a surrogacy procedure, due to the absence of any legally enforceable contract drawn to that effect. The existence of a contract and its mandated requirement by the legislative framework would primarily help settle matters revolving around the idea of consent. Presently, all drafts of the Surrogacy Bill that have been introduced in the parliament only recognise the right of a surrogate mother to consent, both to the initiation of the procedure as well as to the decision to abort. It was only through the filing of a case in the Bombay High Court in 2019, that issues relating to the power of the intending couple to consent to the initiation of the procedure and the legally viable stage for exercising this power, began to be discussed.<sup>251</sup> Currently, there is no law that exists on whether the intending couple may withdraw their consent after the implantation of the embryo, whether the withdrawal of consent to the procedure may be only given by one parent or whether the incidence of divorce during the gestational pregnancy makes the decision of one parent to withdraw their consent, permissible.

Additionally, there is another lacuna in the legislative framework, relating to the phenomenon of commissioning multiple surrogacies, that the judiciary is yet to adjudicate upon. It is important to note that the Surrogacy Bill only recognises the child “born out of surrogacy procedure”<sup>252</sup> as the biological child of the intending couple and only requires the explicit consent of the surrogate in the decision for abortion. Both these factors along with the usage of the terminology of surrogate “mother” lead to the understanding that during the process of gestational pregnancy, starting from the implantation of the embryo till the birth of the child, the intending couple are not recognised as already having a child. By corollary, they are not hit by the restriction under §4(iii)(c)(III) that disallows intending couples who have a surviving child either through adoption or surrogacy, to initiate the surrogacy procedure. Hence, the law allows for people to misuse the provision and surreptitiously gain a certificate of eligibility at a different surrogacy clinic, without disclosing the knowledge about the previously commissioned surrogacy. The simultaneous commissioning of multiple surrogacies ought to be explicitly outlawed so as to maintain the spirit of the 2020 Bill which only allows for one child born through surrogacy per commissioning parties. If couples are allowed simultaneous surrogacies, in an attempt to maximise their chances of pregnancy, they are likely to commission multiple at the same time. This could encourage the idea of the disposability and replaceability of a surrogate, dehumanising the women who undergo the process. Further, it could also result in a sharp rise in the demand for surrogates. Coercive methods may be adopted to fulfil this demand.

Presently, surrogacy, shrouded as a labour of love continues to operate as a weapon of exploitation while leaving those impoverished and in need of a livelihood, devoid of empowerment and legislative protection. Thus, there is a need to bring about binding legally enforceable policy changes that effectively foreground the right to family and

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<sup>251</sup> THE TIMES OF INDIA, *Couple Wants to Go Ahead with Surrogacy Process, to Have Dead Son's Child, Moves HC*, March 22, 2019, available at: <https://timesofindia.indiatimes.com/city/mumbai/couple-wants-to-go-ahead-with-surrogacy-process-to-have-dead-sons-child-moves-hc/articleshow/68516501.cms> (Last visited on August 19, 2020).

<sup>252</sup> The Surrogacy (Regulation) Bill, 2020, §8.

livelihood of persons, in general and women, in specific, within a recognised framework of ethics.

### C. *IN-VITRO FERTILISATION*

IVF, like other ARTs, continues to be a matter that remains unlegislated.

The 2017 ART Bill, as discussed above, seeks to set up a National Board and a National Registry to oversee matters of assisted reproduction in the country, IVF being one of the most popular ones. It further seeks to make the registration of ART clinics and centers centralised to prevent quacks from performing medically complex procedures.<sup>253</sup> It also outlaws sex-screening,<sup>254</sup> sets age limits,<sup>255</sup> emphasises on informed consent for those involved,<sup>256</sup> and provides qualifications for both commissioning couples<sup>257</sup> and donors<sup>258</sup>. However, it still leaves some provisions unexplained, and some concerns unaddressed.

As per §2(f),<sup>259</sup> biological parents are described as couples who use their own gametes in producing their own children using ART procedures. It is unclear if the use of IVF with donor sperm but eggs from the commissioning mother will come under the ambit of this definition, as the sperm of the ‘father’ will not be used for the procedure at all. The legal status of ‘father’ in this case, thus, may be uncertain.

§2(h) also restricts the usage of ART to only infertile couples. Thus, fertile couples who suffer from non-fertility related conditions that make it difficult to conceive,<sup>260</sup> or couples that simply do not want to undergo a natural pregnancy, are wholly excluded from IVF. The 2017 ART Bill also adopts a heteronormative tone, only allowing heterosexual couples – married, or otherwise living together – to qualify as couples as per §2(i).<sup>261</sup> The exclusion of same sex couples may also not be in line with recent pronouncements of the Supreme Court of India, which call for the end of discrimination on the basis of gender and sexual identity, but still do not explicitly create parenthood rights.<sup>262</sup> Furthermore, the restriction of the usage of such technologies to women between the ages of 18 and 45,<sup>263</sup> and men between the ages of 21 and 50,<sup>264</sup> may be seen as a serious violation of an individual’s right to family life, regardless of their age.<sup>265</sup> Further, §43(4) states that only married women with at least one child will be allowed to donate oocytes, but it is unclear as to why.<sup>266</sup>

§14 of the 2017 ART Bill also provides for the duties of the National Board constituted to regulate ART in the country.<sup>267</sup> The National Board is allowed to establish a code of conduct to be followed by professionals in the field, but the 2017 ART Bill leaves it

<sup>253</sup> The Assisted Reproductive Technology Bill, 2017, §14.

<sup>254</sup> *Id.*, §42.

<sup>255</sup> *Id.*, §7.

<sup>256</sup> *Id.*, §38.

<sup>257</sup> *Id.*, §2(h).

<sup>258</sup> *Id.*, §43(4).

<sup>259</sup> *Id.*, §2(f).

<sup>260</sup> *Id.*, §2(h).

<sup>261</sup> *Id.*, §2(i).

<sup>262</sup> *Navtej Singh Johar v. Union of India*, (2018) 1 SCC 791.

<sup>263</sup> The Assisted Reproductive Technology Bill, 2017, §7(a).

<sup>264</sup> *Id.*, §7(b).

<sup>265</sup> *Devika Biswas v. Union of India*, (2016) 10 SCC 726.

<sup>266</sup> The Assisted Reproductive Technology Bill, 2017, §43(4).

<sup>267</sup> *Id.*, §14.

extremely ambiguous as to what this code of conduct will be, and what all will be covered by it. If the scope of this code of conduct is left too wide, it may allow for moral policing and judgement to permeate in the dealings of medical professionals. Further, the 2017 ART Bill also allows for the creation of a National Registry.<sup>268</sup> This Registry will be responsible for keeping records of the clinics and centers granted registration under this Bill, and the subsequent review of their registration. It will also store information about the technologies available across all clinics and banks in the country, and statistics of the outcome of these services.<sup>269</sup> The existence of this Registry may become threatening. As per §39,<sup>270</sup> the Registry is to store information about all commissioning couples, including their medical and reproductive information. These records are to be maintained for a period of ten years, before they can be destroyed. The 2017 ART Bill is silent on protections and safeguards provided to ensure that there is no misuse or leak of information preserved by the Registry. A robust mechanism to keep privacy concerns in check must be established.

As per §37(3) of the 2017 ART Bill,<sup>271</sup> counselling is provided to the commissioning couple only, while the donors or even surrogates are excluded from this process. It is crucial to note that the process of donating gametes or carrying a child can be an extremely stressful experience as well, and the 2017 ART Bill must provide for counselling to all those involved.

In addition to the 2017 ART Bill, IVF is also governed by the ART Guidelines published by the ICMR. The ART Guidelines released by ICMR are divided into 9 chapters, each addressing a different area of concern. The Guidelines act as a primer for all the various techniques available in India that are covered by ART.<sup>272</sup>

The ART Guidelines list the physical infrastructure required for a clinic to function as a designated ART clinic. The ART Guidelines also provide the qualifications that professionals must fulfil to run a fully equipped ART clinic. The clinic must be staffed with a gynecologist, an andrologist, a clinical embryologist, a counsellor, and a programme coordinator.<sup>273</sup> There are various levels of infertility care units, ranging from Level 1 to Level 3, with sublevels, depending on the quality of care and extent of procedures that they can provide.<sup>274</sup> The ART Guidelines state that if a new method or technique for ART is developed, it must be approved by the Clinics Ethics Committee before it is put into practice.<sup>275</sup>

The ART Guidelines, in § 2.1, provide for screening procedures to ensure the physical health of the commissioning couple, and the causes of their infertility.<sup>276</sup> This includes male infertility, female infertility, and unexplained infertility as well. Determination of the kind of infertility will aid the consultation on what kind of ART to opt for, if at all. Medical and physical qualifications for donors for oocytes and sperm have also been laid down. §3.9.2 lays down that financial compensation for oocyte donors is permissible,<sup>277</sup> but it

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<sup>268</sup> *Id.*, §15.

<sup>269</sup> *Id.*, §18(2).

<sup>270</sup> *Id.*, §39.

<sup>271</sup> *Id.*, §37(3).

<sup>272</sup> Nation Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005).

<sup>273</sup> *Id.*, Chp. 1.5, at 17.

<sup>274</sup> *Id.*, Chp. 2.5, at 48.

<sup>275</sup> *Id.*, Chp. 1.6, at 23.

<sup>276</sup> *Id.*, Chp. 2.1, at 39.

<sup>277</sup> *Id.*, Chp. 3.9.2, at 68.

is unclear if this has been overridden by the 2016 Surrogacy Bill. Further, the Guidelines mandate that spare embryos must be either returned to the commissioning couple, donated, or discarded to prevent misuse or sale. The propensity for sale of embryos abroad or to commissioning couples outside of the country is very high, and the Guidelines seek to curb this market.

Chapter 7 of the ART Guidelines also recommend the subsidising of costs of drugs and procedures for those belonging to the economically weaker sections of society, in an attempt to increase access to fertility treatment in the country, but the appropriate branch of the Government has not taken any steps towards this.<sup>278</sup>

While the ART Guidelines provide a comprehensive understanding of the roles of clinics, the State, the commissioning parents, donors, and surrogates, its biggest drawback is the lack of legal backing. It still remains in the form of guiding principles, without any sanctions. The Guidelines were also formulated in 2005, and have not been updated since, rendering them outdated. As a result, they are not in conformity with new legislative frameworks, or up to date with the latest medical technologies.

There are various concerns that are also not addressed by the 2017 ART Bill. There is no mechanism provided for the reduction of costs of these services. IVF can be an extremely expensive service, and while the ART Guidelines lay emphasis on providing for infertility as part of primary healthcare, there is no subsidy provided at any stage.<sup>279</sup> At this point, it is also unclear if medication involved in the process will be available at subsidised rates.

Currently, there are no restrictions on single women becoming mothers through procedures such as IVF,<sup>280</sup> even as they struggle with administrative hurdles in not listing the biological father of their children.<sup>281</sup> However, the 2017 ART Bill and the ART Guidelines both adopt a heteronormative tone, only allowing married heterosexual couples to go through with IVF, even though other forms of expansion of one's families, such as adoption, is allowed for non-couples as per the guidelines issued by the Central Adoption Resource Authority.<sup>282</sup> The ART Bill defines patients as both individuals and couples,<sup>283</sup> but the mention of individuals is wholly replaced with commissioning couple throughout the rest of the text of the Bill. While the ART Guidelines, in the section on desirable practices, mention that single women should not be denied access to ART, this singular statement is not in conformity with either the rest of the guidelines or the ART Bill. It is thus, unclear as to how single women will be able to avail the benefits of ART when no provisions have been carved out by the regulatory frameworks.

Homosexual couples and single men are wholly excluded from the purview of IVF, even though they enjoy rights to a family life via adoption, pointing to another

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<sup>278</sup> *Id.*, Chp. 7, at 109.

<sup>279</sup> *Id.*, Introduction, at 3.

<sup>280</sup> Shrabonti Bagchi, *Two's Company: Single women in search of motherhood*, LIVE MINT, October 20, 2018, available at <https://www.livemint.com/Leisure/PfWgIPTXJMcTvSGaitskwM/Two's-Company-Single-women-in-search-of-motherhood.html> (Last visited on August 21, 2020).

<sup>281</sup> *Vibhas Arora v. Regional Passport Officer*, 2016 SCC OnLine Del 4752; *Manguben Chanduji Thakor v. State of Gujarat*, 2015 SCC OnLine Guj 3841.

<sup>282</sup> *Eligibility criteria for prospective adoptive parents*, CENTRAL ADOPTION REGULATORY AUTHORITY (CARA), available at [http://cara.nic.in/Parents/eg\\_ri.html](http://cara.nic.in/Parents/eg_ri.html) (Last visited on August 21, 2020).

<sup>283</sup> The Assisted Reproductive Technology Bill, 2017, §2(za).

inconsistency in the synthesis of regulatory frameworks across the board.<sup>284</sup> Furthermore, the rights of foreign nationals also fall in a grey area. It is unclear if foreign national couples will be allowed access to ART in India at all. Private health practitioners have taken full advantage of the lack of any sort of mechanism to govern IVF, especially for foreign nationals. The absence of these restrictions or any regulation of medical tourism, thus, allows for the creation of a large exploitative market of assisted reproduction, such as the one in Anand, Gujarat.

## VI. A MODEL LEGISLATION FOR ASSISTED REPRODUCTION IN INDIA: SUGGESTIONS FOR LAWMAKERS

As highlighted in the previous Parts, the biggest setback that India is currently facing in the realm of assisted reproduction is that there is no cohesive and legally binding regulatory framework. This is despite the fact that the first baby born through an ART procedure in India took birth many decades ago.<sup>285</sup> The apex court has also not ruled on any fundamental issues directly related to ART, even as there are some judgements on matters of custody,<sup>286</sup> or the separation of biological and social motherhood that have ART considerations in the periphery.<sup>287</sup> The ICMR has published many sets of guidelines but the implementation of these guidelines is flimsy as they lack enforceability. As a penalty, the ICMR has authority to revoke licenses of medical practitioners if found in violation of ICMR guidelines, but this is a very rare occurrence.<sup>288</sup> The effectiveness of these guidelines, thus, is diluted greatly.

It is crucial to note that the following suggestions for legally binding regulatory frameworks to govern ART in India are not exhaustive. These suggestions will be helpful in plugging the gaps that exist in the current frameworks, but are limited by the scope of current technology. Any advancements in technology and science must be adequately dealt with in a timely manner. The suggestions are also restricted to questions of policy and governance of three techniques, namely, surrogacy, IVF, and gene therapy. Questions on the merits of the techniques themselves, and modifications of the techniques used, are outside the scope of the following suggestions. We will begin by offering suggestions and comments on ART legislation as a whole, followed by specific suggestions for gene therapy, surrogacy, and IVF respectively.

### A. A UNIFORM LEGISLATION ON ASSISTED REPRODUCTIVE TECHNOLOGIES

It is suggested that there be a legislation on assisted reproduction in India. This will allow for cohesion in the ways that ART is regulated across the country. The probability for inconsistencies in the rights granted in availing one ART versus another will be minimised. It will also prevent misuse of techniques of assisted reproduction, and ensure that exploitation of innocent patients at the hands of improperly trained doctors is reduced.

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<sup>284</sup> CARA, *supra* note 280.

<sup>285</sup> THE HINDUSTAN TIMES, *Destiny's Child: India's First Test-Tube Baby is 32, a Mom and a Ray of Hope*, July 22, 2018, available at: <https://www.hindustantimes.com/india-news/destiny-s-child-india-s-first-test-tube-baby-is-32-a-mom-and-a-ray-of-hope/story-MwWvWK3DsS8omC59rJBMnK.html> (Last visited on August 19, 2020).

<sup>286</sup> *Baby Manji Yamada v Union of India*, (2008) 13 SCC 518; *Kiran Lohia v. State Govt. of NCT*, 2018 SCC OnLine Del 8686; *Rama Pandey v Union of India*, 2015 SCC OnLine Del 10484: (2015) 221 DLT 756.

<sup>287</sup> *Hema Vijay Menon v. State of Maharashtra*, 2015 SCC OnLine Nom 6127; *Rama Pandey v. Union of India & Ors Respondents*, (2015) 221 DLT 756.

<sup>288</sup> Code of Medical Ethics (Regulations), 2002, Cl. 7.2 & 8.2.



The goal of regulatory frameworks in India must be to ensure that the highest level of care is provided in India at reasonable rates so that those seeking fertility treatment need not go abroad to seek treatment. Following this, existing legislations on issues involving families and children must also be amended to be in synthesis with ART regulation.

At the outset, the definition of infertility when assessing fitness for fertility treatment needs to be revamped in order to ensure that the benefits of ART may be availed by all individuals unable to bring their own biological children into the world by themselves. Therefore, the scope of infertility should be expanded beyond the mere 'inability to conceive', to include all medical conditions that may eventually cause miscarriages, in spite of successful conception. The mandatory requirement of infertility ought to be expanded to include medical complications of individuals that preclude the birth of a healthy child as well as the incidence of secondary infertility. Further, the duration of time for which individuals ought to be found labouring under infertility should be in tune with the definition of WHO and the requirement under the ART Bill 2017.<sup>289</sup> Any model law pertaining to ART, additionally, should have clearer instructions on how parentage of the child will be described. This is important to ensure that the child, once born, is not subject to a battle of custody between the commissioning parent(s), the donors, or the surrogates. The status of donors and the commissioning parents must be clearly charted out in legislation. The law must also define the legal status of parentage if there is a breakdown of marriage or domestic relationship during the course of the procedure, especially in cases of assisted reproduction where the commissioning father's sperm is not used at all. The law must also address situations where one parent does not consent to the procedure, or withdraws consent midway. The Registration of Births and Deaths Act, 1969 in India must accommodate these situations.

It is suggested that regulatory frameworks must also address who will be allowed to be beneficiaries of ART in India itself. Inclusion of foreign nationals, PIOs, OCI Cardholders, and NRIs must be thoroughly assessed. Any distinctions drawn in these categories must not be arbitrary in nature, and must be uniformly applied through various ART and adoption procedures. In terms of increasing access to assisted reproduction procedures for a wider spectrum of people affected by infertility, the model law ought to alter the existing eligibility requirements for the commissioning parents. ART should be made an option for all infertile individuals and couples in sexual relationships that are legal in India, as was progressively envisaged by the ART Bill, 2010.<sup>290</sup> As of 2020, this modified equitable definition would enable all infertile individuals in live-in relationships, same-sex relationships, transgender individuals, divorcees, widows and widowers, unmarried individuals and married individuals to make effective use of ART. The Hindu Adoption and Maintenance Act, 1956 as well as the Juvenile Justice (Care and Protection of Children) Act, 2015,<sup>291</sup> also enable single parents to adopt and raise children. Laws in the United Kingdom allow for legal parentage for single individuals, those in civil partnerships, those in domestic relationships, and those who are merely co-parenting.<sup>292</sup>

Further, the Government must work towards setting up a dedicated fund for ART in India. Often, couples and single parents are unnecessarily burdened by the costs of

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<sup>289</sup> The Assisted Reproductive Technology Bill, 2017, §2(s).

<sup>290</sup> The Assisted Reproductive Technologies (Regulation) Bill, 2010, §§2(g), §2(h).

<sup>291</sup> The Juvenile Justice (Care and Protection of Children) Act, 2015, §57(3).

<sup>292</sup> THE TELEGRAPH, *Same Sex Couples Names to Appear on Birth Certificates*, April 6, 2009, available at: <https://www.telegraph.co.uk/news/uknews/5113069/Same-sex-couples-names-to-appear-on-birth-certificates.html> (Last visited on August 19, 2020).

these complex procedures, costs of medication, and costs of optional add-ons like time lapse imaging.<sup>293</sup> Infertility healthcare must be subsidised by the Government to ensure that something as primary as the right to have a family is not restricted to those who are able to spend generous amounts of money to undergo these procedures.

The model law also needs to be recast along the lines of the right to have a child as also to not have a child. The recognition of the health perils and economic costs attached to ART necessitates a provision for the mandatory counselling of the intending couples.<sup>294</sup> Thus, there must be mandated counselling services for those involved in the process, including both the commissioning couple and the donor(s). Trained medical professionals must thoroughly educate all those involved in the process on issues of consent to ensure that only those with free, fully informed consent go ahead with ART procedures. These services can be imperative in dealing with loss, learning how to cope with pregnancy, and in contributing to postnatal care.

Additionally, a centralised body to oversee all matters of ART must be created via legislation. A similar centralised body exists for adoption in India in the form of the Central Adoption Resource Authority. Similarly, in the United Kingdom, like in many other countries, all assisted reproduction is controlled by a centralised statutory body. The Human Fertilisation and Embryology Authority (HFEA) was set up in 1990 as part of the Human Fertilisation and Embryology Act, 1990. Not only does HFEA have a Code of Practice that all registered medical centers are mandated to follow,<sup>295</sup> it also allows for complaint-resolution for patients directly.<sup>296</sup> Licenses to clinics and healthcare providers are provided by HFEA after strict scrutiny, and regular inspections are the norm.

This body may look into policy considerations, be instrumental in establishing a mechanism and route to avail ART, and also regulate the practice on a national scale. This body may play an especially crucial role in ensuring that contracts for commercial ART are properly regulated, in an attempt to balance the power that a commissioning couple and the surrogate/donor would have. This regulation may be in the form of ensuring a minimum compensation to be awarded, along with laying down the standard of care and conditions to be provided to the surrogate or donor. Redressal mechanisms in cases of violation of the terms of the contract must also be made available. Additionally, it is important that these contracts find basis in a feminist understanding of the law. As it currently exists, the law is a site of power that discounts the lived experiences and accounts of women, as discussed by Carol Smart in her article *The Quest for a Feminist Jurisprudence*.<sup>297</sup> Since any law on ART is bound to regulate personal and intimate parts of the lives of women, it is important that not only does it ensure prevention of exploitation, but is also constructed from a feminine and feminist lens, as opposed to the highly masculine nature of current legal frameworks.<sup>298</sup> To

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<sup>293</sup> THE IRISH TIMES, *The High, Mysterious and Added Costs of IVF*, April 10, 2019, available at: <https://www.irishtimes.com/life-and-style/health-family/the-high-mysterious-and-added-costs-of-ivf-1.3845858> (Last visited on August 19, 2020).

<sup>294</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, Deposition of Ministry of Child and Development ¶4.1, August 10, 2017.

<sup>295</sup> Human Fertilisation and Embryology Authority, Code of Practice, 2018.

<sup>296</sup> Complaints Policy, HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY, available at: <https://www.hfea.gov.uk/media/2970/2017-07-27-hfea-complaints-policy-rebranded-active-final.pdf> (Last visited on August 19, 2020).

<sup>297</sup> SMART, *supra* note 73, *The Quest for a Feminist Jurisprudence*, at 11.

<sup>298</sup> *Id.*

achieve this, community consultation and consultation with experts is necessary. The inclusion of women, transgender individuals, those who do not conform to the gender binary, and same sex couples in consultations is of utmost importance, especially if there is an attempt to draft a law that is not tone deaf.

## *B. GENE THERAPY*

For gene therapy specifically, including gene editing, gene selection, and gene manipulation, the legally binding regulatory framework must lay down the ethical and social concerns that have been considered in drafting them. These concerns can be many, and range from prevention of eugenics to the cultural idea of parenthood. This will greatly assist in assessing the outlook towards gene therapy that the State has adopted. It is also imperative that the State balance funding gene therapy to eradicate diseases or conditions, with technological advancements to cure these conditions and diseases. Solely funding research into gene therapy may allow the State to defund research into cures, greatly disadvantaging those who live with these conditions, or those whose parents do not opt for gene therapy as a corrective measure. Furthermore, eradication of some genetic conditions in the coming generation may result in a society that is less tolerant to those who currently live with these conditions. Thus, the social impacts of the extent to which gene therapy is to be funded must be carefully assessed in any legislative framework.

An important area for any regulatory framework to assess is that of consent. In all cases of medical decision-making, but especially in gene therapy, consent must be carefully explained to the commissioning couple. The State must go the extra mile to educate the populace about the ways in which their bodies can be impacted through gene therapy in the context of ART. The impacts of their children, and future generations must also be discussed. Gene therapy is not only a life altering medical decision taken by the commissioning parents, but also involves the permanent change of a person's genetic makeup, giving it a different character to other decisions taken by parents for their children. Thus, unless medically necessary, gene therapy must be looked at with extreme scrutiny by regulators.

Another area that legislation on gene therapy must address is that of commercialisation and the subsequent monetisation of the technique and the product. A proper framework that will lay down the stage at which commercialisation of the technique will be allowed, the compensation that will be given to those who undergo the procedure, if at all, and the clear demarcation of who the intellectual property rights will vest in is the need of the hour. Additionally, model law on gene therapy must provide for strict privacy safeguards, owing to the sensitive nature of genetic information. Strict penalties in the form of fines, compensation to patients or subjects, and imprisonment must be laid down with dispute resolution and adjudication by a body competent to understand the complex nature of the procedures.

To make this process more transparent and free from subjective bias, any model law on gene therapy must clearly lay down exactly what conditions it will be available for, what the extent of modification will be, and what conditions must be met for there to be any exception to allow for gene therapy for the purposes of augmentation. Vague and loosely worded legislation, as discussed in the previous Part, will end up doing more harm than good.

### C. SURROGACY

For surrogacy, although the 2019 Surrogacy Bill has been passed by the Lok Sabha, and the recommendations of the Rajya Sabha Select Committee have been received, it is hoped that when both the Houses sit to vote on the 2020 Surrogacy Bill, they will be mindful of the moral, legal, social and ethical considerations discussed in the previous Part and accordingly incorporate these in tune with the needs of all those for whom it is meant. It is hoped that they will help give effect to a *model law* on surrogacy that effectively solidifies the rights of the intending couple, the surrogate mother and the surrogate child and makes them actionable.

It is imperative to understand that the recognition of the duality of exploitation of women and economic duress being the prime motivation behind becoming surrogate mothers, prompts the creation of a system that ensures the extermination of the former and effective addressal of the latter. Thus, it points to a model of compensated surrogacy, wherein the legal and economic rights of the surrogate mother are comprehensively addressed. However, if it continues to be reduced to the arrangement of altruistic surrogacy, wherein a ‘willing woman’ is eligible to be a surrogate mother, the law ought to create a consensual facilitative mechanism that ensures the availability of surrogates without the forceful trafficking of women to act as such. Further, the law ought to tackle this issue of availability of surrogates in an altruistic setup keeping in mind that it is unrealistic to assume that women will ‘willingly’ become surrogate mothers, in the known presence of mental, psychological and physical burdens of pregnancy and the absence of financial incentives that cover the enormous opportunity costs of livelihood, wages and health undergone in the process. Thus, drafting a legislation for a compensated surrogacy model is essential.

An essential facet of the model law ought to be the legislative intent to respect and uphold the rights and dignity of the surrogate mother. While the Select Committee has recommended an increase in the duration of coverage from 16 months,<sup>299</sup> to 36 months,<sup>300</sup> the ambit of monetary compensation awarded to her, too needs to be increased from mere ‘medical expenses and insurance cover’ to include all reasonable expenses that may be borne by her on account of this pregnancy, including but not limited to costs of health and loss of wages during the period of pregnancy, in addition to those already prescribed. This model of compensated surrogacy ought to comprise an insurance package that covers medical complications, *firstly*, between the initiation of the surrogacy procedure and the confirmation of pregnancy, *secondly*, during the period of gestational pregnancy, and *thirdly*, after the pregnancy, inclusive of postpartum complications as well as death. It ought to cover the reasonable cost of the health of the surrogate mother and may be drafted along the lines of the United Kingdom Surrogacy Arrangements Act, 1985. Here, compensation to the surrogate mother is viewed as any expense “reasonably attributable” to her, while undertaking the pregnancy.<sup>301</sup>

As for abortion, there exists a blanket ban on the initiation of abortion<sup>302</sup> that may be reviewed only upon securing approval from the appropriate authority. This must be done away with to ensure that the reproductive autonomy of the surrogate mother is kept intact and that the abortion may be available to her in case of life-threatening complications

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<sup>299</sup> The Surrogacy (Regulation) Bill, 2019, §4(iii)(a)(III).

<sup>300</sup> The Surrogacy (Regulation) Bill, 2020, §4(iii)(a)(III),

<sup>301</sup> The Surrogacy Arrangements Act, 1985, §2(2C) (U.K.).

<sup>302</sup> The Surrogacy (Regulation) Bill, 2020, §10.

during the pregnancy, devoid of red-tapism. Thus, the requirement for abortion under surrogacy law must simply be the compliance with the provisions of the Medical Termination of Pregnancy Act, 1971.

The model law must also enact provisions that make breastfeeding services, in the form of their total or partial substitutes such as infant milk substitutes,<sup>303</sup> available to children born out of surrogacy. These children require additional nutritional care as they are reportedly prone to more health risks and are often born premature or underweight.<sup>304</sup> Early initiation of breastfeeding within an hour after birth is imperative to protect the health and ensure the survival of the newly born child. Thus, having recognised the benefits of breastfeeding, substitute means may be explored for the same, under the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1982. Currently, this Act only allows for the distribution of infant milk substitutes, feeding bottles and infant foods if it is in the form of a donation to an orphanage or if it is routed to a mother who cannot resort to breastfeeding,<sup>305</sup> through the “healthcare system”, defined as an institution engaged in the health of mothers.<sup>306</sup> If the model law is made constitutive of the same, “surrogacy clinics”<sup>307</sup> may be recognised as part of the “healthcare system” and children born out of surrogacy may be equipped to avail the requisite nutrition.

As for commercial surrogacy, the nature of exploitation of women and the probability of the creation of an unethical and unregulated black market for wombs needs to be assessed collectively and thoroughly. For this purpose, it is imperative to enact legislation in tune with the Report of the United Nations Convention of Rights of Child. While it recognised the exploitative nature of commercial surrogacy in India,<sup>308</sup> instead of banning the practice altogether, it attributed the cause of exploitation to the dearth of regulation and hence recommended the enactment of a binding legislation to “define, regulate and monitor surrogacy arrangements”.<sup>309</sup>

Most importantly, in light of the widespread instances of exploitation of the surrogate mother and abandonment of children, there is a need to create a legal requirement for a comprehensive tripartite surrogacy agreement that effectively lays down the rights and duties of the intending couple or woman, the surrogate mother, and the surrogacy clinic. Since the multitudinous legal issues arising out of surrogacy point towards the need for a standardised contract, the absence of consideration within an altruistic framework, precluding the formation of a contract, ought to be remedied through the recognition of a compensated

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<sup>303</sup> The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1982, §2(g).

<sup>304</sup> *Baby Manji v. Union of India* (2008) 13 SCC 518.

<sup>305</sup> The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1982, §8(4).

<sup>306</sup> The Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1982, §2(d).

<sup>307</sup> The Surrogacy (Regulation) Bill, 2019, §2(zd).

<sup>308</sup> Clause 57(d), Concluding Observations on the Combined Third and Fourth Periodic Reports of India, United Nations Convention on the Rights of the Child, CRC/C/IND/CO/3-4, July 7, 2014, [https://tbinternet.ohchr.org/\\_layouts/15/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fIND%20%2fCO%2f3-4&Lang=en](https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fIND%20%2fCO%2f3-4&Lang=en).

<sup>309</sup> Clause 58(d), Concluding Observations on the Combined Third and Fourth Periodic Reports of India, United Nations Convention on the Rights of the Child, CRC/C/IND/CO/3-4, July 7, 2014, [https://tbinternet.ohchr.org/\\_layouts/15/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fIND%20%2fCO%2f3-4&Lang=en](https://tbinternet.ohchr.org/_layouts/15/treatybodyexternal/Download.aspx?symbolno=CRC%2fC%2fIND%20%2fCO%2f3-4&Lang=en).

surrogacy model. Under the agreement, the details of the names of all parties, location of surrogacy clinic, amount and nature of the insurance coverage, the manner of its disbursement, protocol in case of termination of pregnancy, consequence of withdrawal of consent from the process and the pre/post-delivery care of the surrogate mothers, ought to be listed. It should contain a comprehensive health care plan for the surrogate mother inclusive of medical and psychological counselling and a comprehensive nourishment plan for the surrogate child.<sup>310</sup> The agreement ought to safeguard the rights of children and hence must include the listing of a nominee who will be entrusted in case of any eventuality.<sup>311</sup> Moreover, the agreement should also be registered with the Surrogacy Boards as a legal document, so as to be enforceable.

#### D. *IN-VITRO FERTILISATION*

In Denmark, even though commercial transactions of donating sperm for IVF are outlawed,<sup>312</sup> donors are allowed to be compensated for their time and the inconvenience caused to them in the process of such a donation.<sup>313</sup> This greatly incentivises more and more people to donate their sperm, making IVF a very accessible and commonly used procedure in the country. Model regulation on IVF, thus, must seriously consider financial incentives in an attempt to increase the number of donors across the country. India may also greatly benefit from an efficient and functioning regulatory authority modelled on the HFEA. The National Board mentioned in the 2017 ART Bill seeks to serve a similar purpose, but its true success will only be measured by its efficiency.

### VII. CONCLUSION

ART procedures have been instrumental in challenging traditional ideas of parenthood, family structures, and especially what it means to be a mother. The right to have a family, to family life, to go through childbirth in some cases, and receive assistance in others, is continually expanding. In understanding how this right and its extensions evolve, we have focussed on how the relationship that women have with ideas of parenthood has undergone a drastic change. Women are able to find meaning in motherhood without having gone through childbirth, while other female donors have been able to effectively delink childbirth with the societal notion of what it means to be a mother. This transformation, facilitated by ART, has paved the way for delinking social parenthood from biological childbirth. In ARTs like gene therapy, there has also been a restructuring of how far the right to have a family can extend. The degree of modifications to embryos allowed has encouraged the idea that the right to have a family must also accommodate the right to have the *kind* of family that one desires.

However, with the fast-paced advancement of medical science and evolution of society's understanding of what it means to have a family, the law is playing catch up.

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<sup>310</sup> RAJYA SABHA DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE, *102nd Report on The Surrogacy (Regulation) Bill, 2016*, III, August 10, 2017.

<sup>311</sup> SHRI BHUPENDER YADAV COMMITTEE, *Report of the Select Committee on The Surrogacy (Regulation) Bill, 2019*, ¶3.13, pp. 17 (February 5, 2020).

<sup>312</sup> European Union, Directorate-General Health and Consumer Protection, *Report on the Regulation of Reproductive Cell Donation in the European Union*, February 2006, available at: <https://pmanonyme.asso.fr/wp-content/uploads/2015/12/rapporteurpeuen2006.pdf> (Last visited on August 19, 2020).

<sup>313</sup> TIME (Naina Bajekal), *Why So Many Women Travel to Denmark for Fertility Treatment*, January 3, 2019, available at: <https://time.com/5491636/denmark-ivf-storklinik-fertility/> (Last visited on August 19, 2020).

Despite the development of various ART procedures and their ever-rising popularity, most of them remain outside the purview of legally binding regulatory frameworks in India. Unique problems present themselves when the nature of ARTs is highly sophisticated. The gaps and lacunae in regulation allow for the exploitation of donors or surrogates, insufficient protections for children born out of these arrangements, rampant unregulated medical tourism, and subpar treatment with no recourse for commissioning couples. At this crucial juncture of the intersection of medical science and the law, interests of various stakeholders need to be accounted for. The commissioning couples, the children, the donors or surrogates, the medical fraternity, and society often find themselves at crossroads with conflicting interests. The consideration of the overall society as a stakeholder is critical, and this is why medical guidelines do not suffice. It is here that the role of regulatory frameworks becomes imperative.

Through this paper, we have attempted to highlight the insufficiency of current regulations in effectively addressing the complex problems that come with sophisticated forms of ART. We have emphasised on the need for a comprehensive, cohesive, and legally binding framework that will be able to regulate the assisted reproduction industry in India. We have provided suggestions that must be incorporated in a common regulatory framework that addresses various forms of ART and accounts for the interests of the aforementioned stakeholders. Following this, we have provided suggestions specific to the three techniques that have formed the basis of this paper, namely, gene therapy, surrogacy, and IVF. We believe that specific situations merit carefully constructed and well-thought out responses, and thus, we have attempted to be mindful of these contextual realities while offering our comments. In doing so, we have identified some core principles that any model legislation on assisted reproduction must have. These principles must serve as the starting point for legislators and policymakers to develop an exhaustive legally binding regulatory framework.