

ASSISTED REPRODUCTIVE TECHNOLOGY IN INDIA: A CRITICAL LEGAL STUDY

Abstract of Thesis

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Sufiya Ahmed

SUPERVISOR

Dr. Pradeep Kumar

CO-SUPERVISOR

Dr. Anis Ahmad

DEPARTMENT OF LAW
SCHOOL FOR LEGAL STUDIES
BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY
(A CENTRAL UNIVERSITY)
VIDYA VIHAR, RAEBARELI ROAD
LUCKNOW-226 025

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ABSTRACT

In every society, family is rooted like a natural phenomenon. It has existed like an immutable and indispensable natural thing through the uncountable stories and non-transformed cultural roots. The family as a basic unit of society existed from the early history of human civilization. In every religion either in eastern society or in western society, the formation of family and procreation has been a sacred duty of human being. It is as fundamental as the existence of human being as no one can imagine a society where it can be ignored. The institution of family was also recognized in international instruments.¹

Besides it, God has bestowed human being with the natural instinct of reproduction. So, to fulfill this natural instinct, human being has established various institutions in the society. Marriage, being one such institution, facilitates this natural instinct among the human being in an acceptable manner. The couple is always encouraged to plan a baby immediately after the marriage. At this point of time the societal pressure is developed over the couple for the child bearing. Whosoever comes out of this pressure has been provided a due place in the society but who fails has been ascribed with a stigma of infertility.

Infertility is a worldwide problem affecting 8-12 percent couple (50-80 million) during their reproductive lives.² According to WHO multi centric studies in India, 40% women and 73% of men had no demonstrable cause of infertility.³ To overcome this grave problem of infertility, the couple goes to any large possible extent primarily from conventional method to advanced techniques of reproduction. The other viable alternative for the problem may be the concept of adopted children. The adopted children are permissible, from religious point of view, only on compliance of certain conditions. The concept of adopted children was confronted with certain complications in social norms and invites litigations also. Moreover, besides the availability of these alternatives, the people are very much desirous for purity of blood line to perpetuate the system of inheritance.

¹ The United Nations Declaration of Human Rights, 1948 Article 16.1 recognizes that, "*Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family*". The European Convention on Human Right also guarantees respect for family life and the right to find a family. Article 12 says: *Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.* Article 10.1 and 11.1 of The International Covenant on Economic, Social and Cultural Rights provides the human rights about family.

² (WHO, 1991), referred in Sujata Ganguly, Sayeed Unisa, "Trends of Infertility and Childlessness in India: Findings from NFHS Data", *F, V & V IN OBGYN*, (2010), 2 (2): 131-138, p. 131.

³ Anjali Widge, "Infertility" available at http://www.searo.who.int/LinkFiles/Reproductive_Health_Profile_infertility.pdf visited on 22 may 2012.

To give vent to this manifestation of human mind, the medical sciences made an acute introduction by way of medically assisted human reproduction. Assisted reproductive technologies (hereinafter referred as ART)⁴ are a group of technologies, which assist in conception and pregnancy. It includes a range of techniques for manipulating eggs and sperms in order to overcome infertility. It includes In vitro fertilization (IVF), gamete intra-fallopian transfer, zygote-intra fallopian transfer, surrogacy, posthumous procreation and most recent techniques like, intra-cytoplasmic sperm injection, (ICSI), cryopreservation of donated oocyte/sperm, in vitro maturation, pre-implantation genetic diagnosis and microsorting. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman. They do not include treatments in which only sperm are handled (i.e., intrauterine or artificial insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved⁵.

The ART has revolutionized the life of millions of infertile couple by satisfying the psychological desire of having genetically related sons and daughters. The promise of the reproductive technologies i.e. producing babies now goes beyond curing infertility and challenges our concept of family and parenthood. Creating a family, irrespective of whether you are an infertile husband and wife couple, a same-sex couples or a single person have deliberate choice. The possibility of choosing to form a family outside the traditional heterosexual married couple is controversial both practically and legally. Recognition of the legal relationship that results from the creation of families through ART has similarly developed in reaction to the stigma of illegitimacy.

The ART is the miracle of the new era where high-tech babies are produced through new reproductive technologies and genetic engineering. In vitro fertilization (IVF) started the science of assisted reproductive technology. Aldous Huxley introduced the term "test tube" babies in 1932 in his novel "*Brave New World*", in which he described a world where children were fertilized and incubated in artificial wombs. The term "test tube" baby refers to fertilization that take place outside of the womb.⁶ Loiuse J. Brown, the first test tube baby

⁴ According to Section 2(c) of ART (Regulation) Bill, 2010 "assisted reproductive technology" (ART), with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body, and transferring the gamete or the embryo into the reproductive tract.

⁵ "Assisted reproductive technology" available on <http://www.cdc.gov/art/> visited on 01/02/2012

⁶ France Winddance Twine, *Outsourcing the Womb: Race, Class, and Gestational Surrogacy in a Global market*, (2011, New York and London, Routledge, Taylor & Francis Group), at 4.

was born on July 25, 1978, in Oldham, England.⁷ Since then, the field of medically assisted reproduction has taken off, bringing increasingly new and innovative ways to create children, as well as increasingly more complex family relationships and ethically fraught medical practices. The births of the first English, Australian, American and Indian IVF babies (Louis J Brown in 1978, Candice Reed in 1980, Elizabeth Carr in 1981 and Harsha⁸ in 1986) started a revolution in medical technologies and the creation of family. Infertility which was once considered incurable is now medicalized which can be treated through ART.

The development and use of ART continues to raise a range of complex social, ethical, legal and moral questions. The important issues confronted to ART are related to the legitimacy of child born through ART, the responsibilities of ART clinics, the rights and duties of parties including parents, surrogate mother and the doctor, the role of state in facilitating ART, criteria for determining the deserve couple to use ART, restrictions on the use of ART, the commercialization and comodification of human organs, the malpractices and misuse of ART etc.

However, from the last few years there is a great debate in the Indian medical community whether there is any need to regulate ART through law. The ART is quite different from any other medical treatments because the process involves the formation of the family and the interest of the child. Since there is lack of laws in the area and it has been left unregulated, therefore, there are maximum chances of misconduct, irregularity, exploitation and malpractices. However, there is a significant effort for regulating this highly complex area by Indian council of medical research (herein after referred as ICMR) through providing non-binding guidelines from time to time. The first effort appeared in 2000 in the form of *Ethical Guidelines for Biomedical Research for Human Subjects*⁹. Subsequently in 2005 ICMR and National Academy of Medical Sciences (NAMS) framed *National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproductive Technology clinic*.¹⁰ Recently ICMR and Ministry of Health and Family Welfare (MOHFW) have proposed the

⁷ Debora L Spar; *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception*, (2006, Boston, Harvard Business School Press) at 24.

⁸ India's first scientifically documented IVF baby, Harsha, was born on August 6, 1986 in Mumbai, through the collaborative efforts of the ICMR's Institute for Research in Reproduction and the King Edward's Memorial Hospital (KEM).

⁹ *Ethical Guidelines for Biomedical Research on Human Subjects*. Indian Council of Medical Research. (2000, New Delhi).

¹⁰ *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India*, Indian Council of Medical Research National Academy of Medical Sciences (India), (2005, New Delhi)

draft *Assisted Reproductive Technology Bill and Rules 2008* which was latter modified in 2010.¹¹

The legal issues in the field of ART in Indian scenario seem very remarkable and controversial. First time, it was the case of *Baby Manji*¹² came before the apex court of India when the absence of law on ART in India was observed. This case, for the first time raised the ethical issues regarding commercial surrogacy and fertility tourism. Later, in the case of *Jan Balaz*¹³, again the nationality of the surrogate twins born through Indian surrogate was raised. These two cases arose unexpected problems where the foreign genetic parents have been restricted to bring the children in their own country. The reason was only lack of legal regulation in India.

The researcher has selected the topic because of popular acceptability of the ART in the society and the area has been left open without sufficient regulation. The non binding ethical and professional guidelines are not able to tackle the problem arising from the use of ART. Due to insufficiency of rule and regulation, there are every chance of misuse and exploitation. An attempt has been made under the study to make a critical study of huge unregulated ART industry in India. The study also examines the development and use of ART, legal issues attached with ART, and its commercialization. The ethical, moral, legal, religious and social issues surrounding the practice of ART have been also discussed.

Through a qualitative research process, the study aimed:

- To discuss the historical background, conceptual framework and the causes of infertility and its treatment through various conventional and other methods.
- To discuss in detail various techniques of ART and the procedures thereof.
- To analyze the development of ART by which, persons who have not been able to produce their child by natural means and by using these technologies they can procreate their own child who is biologically or genetically linked with them.
- To analyze the laws of different countries related to ART through which they regulate and manage the procedure of ART.

¹¹ Draft The Assisted Reproductive Technology Bill and Rules 2010, Ministry of Health and Family Welfare, Govt. of India ,New Delhi, and Indian Council of Medical Research, New Delhi. Available on <http://icmr.nic.in/guide/ART%20REGULATION%20Draft%20Bill1.pdf>.

¹² *Baby Manji Yamada v. Union of India* 2008, 13 SCC 518

¹³ *Jan Balaz v. Anand Municipality* 2010(2) ALL MR. (JOURNAL) 14

- To critically analyze the response of the judiciary in India and abroad towards the disputes arising out from the use of ARTs and also the role of judiciary in developing the law related to ART.
- To analyze the ethical, moral, social and religious issues involved in the ART.
- To analyze the commercialisation of ARTs and also to discuss the misuse and malpractices and exploitation by the parties involved in ART.
- To critically analyze the existing system of regulation of ART, especially the Draft Bill and Rules prepared by ICMR and MOHFW.
- To provide certain suggestions and recommendations for regulating ART through a comprehensive legislation. This will be highly beneficial for the society at large.

In order to achieve the above mentioned objectives, the following hypothesis has been framed by the researcher:

- The problem of infertility is a social stigma in our Indian society and the use of new reproductive technology in the form of ART is very helpful to overcome the problem of infertility.
- The existing regulatory framework is not sufficient to solve complex legal issues arising out of the use of ART so there is an urgent need to regulate the ART through a comprehensive legislation.

The methodology employed for this work is doctrinal. In particular, analytical and descriptive methods have been adopted to draw the inference and conclusions. Materials for the study have been collected from both primary as well as secondary sources.

To obtain the aforesaid objectives the entire work has been divided into seven chapters:

Chapter I titled “**Introduction**” is as usual introduces the research topic and focuses on the genesis and development of assisted reproductive technology for infertility treatment. It also deals with aim and objectives put forth for the research. It also highlights briefly various issues confronting to ART.

Chapter II titled “**Conceptual Framework of Infertility and Assisted Reproductive Technology**” discusses the problem of infertility, its causes and consequences, its treatment through various means, the social construction of motherhood, treatment of infertility through medical technologies and the development and scientific understanding of medically assisted reproductive technology and its processes like in vitro fertilization, intra cytoplasmic sperm injection, sperm donation, egg donation, surrogacy, pre implantation genetic diagnosis, micro sorting, cryopreservation and posthumous procreation.

Chapter III titled “**Regulation of Assisted Reproductive Technology in India**” analyses the background of regulation of ART, need for regulation of this controversial area of law. Aspects such as role the state should play in providing individuals and families with access to reproductive technologies, the criteria to determine, who deserves to have medically assisted reproduction, the restrictions to impose on ARTs are some issues which cannot be answered in isolation. Law always plays a significant role in determining the role of state, public or private agencies and individuals. This chapter tries to find out the more specific answers to these questions through analyzing the Guidelines, Bills and Rules in India. It contains the critical analysis of *Ethical Guidelines on Biomedical Research 2000*, *National Guidelines on Accreditation, Supervision and Regulation of ART Clinics in India 2005*, and *Draft Assisted Reproductive Technologies (Regulation) Bill & Rules 2010*.

Chapter IV titled “**Laws in Different Countries on Assisted Reproductive Technology**” is a comparative study of the ART regulation in different countries such as UK, USA, Australia, Sweden, Israel, Italy etc. Scientific societies around the world, such as the ASRM, ESHRE and IFFS, have drawn up guidelines for the safe and ethical practice of ART. The European Union and the Governments of several countries like Australia, the UK and the USA have taken steps to accredit and supervise the performance of infertility clinics. While most industrialized nations ban commercial surrogacy others such as Brazil, Israel, and the U.K. have established regulatory regimes or partial bans to control access to it. This chapter tries to analyze comparatively the regulatory regime at international level.

Chapter V titled “**Ethical-Moral and other Issues in Assisted Reproductive Technology**” analyzes the social, medical, ethical, moral, religious and commercial issues involved in ART. Ethical discussion of reproductive technologies began in the early 1970s, when techniques such as in vitro fertilization became a real possibility. Access to ARTs is available primarily to the wealthy, upper middle class, or those able and willing to borrow the money required. Apart from obvious commercial, and ethical concerns, ARTs entail potentially serious health risks for women, which could even be life threatening. Such aspects of ARTs pose important challenges for us today. Another controversial issue is use of genetic testing for tissue matching to produce a savior sibling.

Chapter VI titled “**Judicial Response and Assisted Reproductive Technology**” examines the response of the judiciary regarding assisted reproductive technologies. Although access to ART is the first step in assisted reproduction, it receives considerably less attention than issues of parentage or authority over reproductive materials. Further, some complex legal issues relating to legitimacy and paternity are involved in the use of

oocyte/sperm donation and posthumous reproduction. Gestational surrogacy also involves issues of international adoption and compensation. The study of relevant case law is significant in this context. The famous *Baby Manji Case*¹⁴, *Jan Balaj Case*¹⁵, *K. Kalaiselvi v. Chennai Port Trust*¹⁶ and the most recent *Shihabeldin v Union of India and Ors*¹⁷ are discussed. Apart from these, some leading American cases and British cases like *A v. C (Baby Cotton Case)*¹⁸, *R v Sheffield HA ex p Seale*¹⁹, *R v Ethical committee of st. Mary's hospital (Manchester) ex p Harriott*²⁰, *North Coast Women's Care Medical Group. Inc. et al. v. S.C.(Benitez)*²¹, *Mrs. U v. Centre for Reproductive medicine*²², *Evans v. Amicus Healthcare Ltd. And others*²³, *Hadley v Midland Fertility Services Ltd*²⁴., *R v. Human Fertilisation and Embryology Authority ex p blood*²⁵, *The Leeds Teaching Hospitals NHS Trust v. Mr. and Mrs. A and Others*²⁶, *U v W (Attorney General Intervening)*²⁷, *U.S. v. Mata*²⁸, *The case of A v. C*²⁹, *Re C (A minor) (Wardship: Surrogacy)*³⁰, *In Re an adoption application (surrogacy)*³¹, *Johnson v. Calvert*³², *In Belsito v. Clark*³³, *In Soos v. Superior Court of Maricopa*³⁴, *In Re Marriage of Buzanca*³⁵, *Briody v. st. Helens and Knowsley Area Health Authority*³⁶, *Re C (Application by Mr. and Mrs. X under s.30 of the Human Fertilization and Embryology Act 1990)*³⁷, *Baby M Case*³⁸, *In Re Q (Parental Order)*³⁹, *In re D (A Child Appearing by her Guardian ad Litem*⁴⁰, *Davis v. Davis*⁴¹, *Kass v. Kass*⁴², *Roman v. Roman*⁴³, *Gillett-Netting v.*

¹⁴ *Baby Manji Yamada v. Union of India* 2008, 13 SCC 518

¹⁵ *Jan Balaz v. Anand Municipality* 2010(2) ALL MR. (JOURNAL) 14

¹⁶ Judgment delivered on 04.03.2013, High Court of Madras.

¹⁷ CWP-15490/2013

¹⁸ F.L.R. 445 [1985] Fam. Law 241

¹⁹ (1994) 25 BMLR 1

²⁰ (1988) FLR 512,HC

²¹ (2008) Cal. LEXIS 10756

²² [2002] EwcA Civ 565, [22]

²³ (2004) 3 All ER 1025

²⁴ [2003] EWHC 2161 (Fam)

²⁵ (1997) 2AllER 687 (CA)

²⁶ (2003) 1FLR 1091.

²⁷ [1997] 2 FLR 282, FD

²⁸ 18 Phil. 490 (1911).

²⁹ F.L.R. 445 [1985] Fam. Law 241

³⁰ [1985]FLR846,HC

³¹ [1987] Fam. 81

³² 851 P.2d 776 (Cal. 1993).

³³ 644 NF 2d 760 (Ohio Com Pl 1994)

³⁴ 897 P2d 1356 (Ariz App Div 1 1994)

³⁵ 72 Cal. Rptr. 2d 280 (Cal. Ct. App. 1998).

³⁶ [2001] EWCA Civ 1010, [2002] QB856

³⁷ (1990) [2002] EWHC 157 (Fam.),

³⁸ 537 A.2d 1227 (N.J. 1988).

³⁹ [1996] 1 FLR 369

⁴⁰ [2005] UKHL 33

⁴¹ 842 S.W.2d 588 (Tenn. 1992).

*Barnhart*⁴⁴, *R (on the application Bruno quintaville on behalf of pro life alliance) v. secy for health*⁴⁵, *Elisa B. vs. Emily B*⁴⁶, *K.M. v. E.G*⁴⁷ etc. are also discussed among other cases.

Chapter VII titled “**Conclusion and Suggestions**” contains the conclusions and suggestions for regulating the practice and use of ART. The field of assisted reproductive technology (ART) is fast growing and changing and it will continue to dominate the future due to its widespread use. By changing the ways families were created, IVF and the assisted reproductive technologies have given birth to a host of novel legal issues, tensions, and challenges as well as an emerging body of sometimes inconsistent law and policy. After examining the history, development, various aspects and different issues as well as challenges arising out of ARTs, this chapter reframes the issues and recommends the ways to help in framing, addressing and resolving some of the most pressing challenges.

It is found that since the infertility is known from a very long period but over the past several decades, its meaning has been slightly changed. Social implication of infertility such as isolation, denial of social status, contempt and abandonment are the byproduct of patriarchal society where motherhood is treated as essential part of being a woman. This concept is strongly established by religion and its scriptures. So the infertility also relates with psychological elements. Through the introduction of new scientific methods in the form of ART now child bearing is not in the hands of nature only. An egg can now be forced to fertilize outside the body by ICSI. The study reveals that India with its strong patriarchal structure, son preference and the practice of sex selection became suitable ground for introducing ART. By taking the help of ART, the motherhood may be provided to women, which will prove a boon for her. Now she may be out of the social stigma of infertility. ART does not only provide a treatment of infertility to the women at large but also provide her a social recognition in the society.

The serious issue related to lack of legal regulation in the area of ART has also been discussed that due to lack of regulation now ART has been used as a tool of exploitation by medical professionals. It has also been suggested that there is an urgent need to have an effective legislation to check the misuse of ART and also to provide the relief to general public at large. It is also found that fertility treatments confined primarily to the private sector and tertiary public sector institutions accessible to selected few. The basic health care system

⁴² 696 N.E.2d 174 (N.Y. 1998).

⁴³ 193 S.W.3d 40 (Tex. App. 2006).

⁴⁴ 371 F.3d 595 (9th Cir. 2004)

⁴⁵ (2002)2wlr550,ca

⁴⁶ 117 P.3d 660 (Cal. 2005).

⁴⁷ 117 P.3d 673 (Cal. 2005).

has no strategy to deal with infertility. Infertility is a worldwide problem affecting millions of people therefore it is suggested that the accessibility, availability and affordability of ART must be ensured to each and every people in the society irrespective of their financial status. The role of public sector's Health Care institution is significant in this area.

The study reveals that due to lack of legally binding guidelines, the fast mushrooming of ART clinics may be seen in India. There are no standard treatment protocols for ART procedures. In order to ensure quality of care it is imperative that a proper and compulsory accreditation procedure with standardized guidelines should be followed in the establishment of ART centers. Legitimate social issues that go beyond the exclusive expertise of doctors and scientists or market choice by patients need to be accommodated within the regulatory regime. The accreditation, supervision and regulation of ART clinic is the need of the hour. The study also reveals that the medical professionals dealing with ART are governed only by the norms of ethics and non-binding guidelines. The liabilities and responsibilities of medical and technical professionals are major issues which should be dealt by the specific legal norms and principles.

The study also includes the examination of the two guidelines namely; the *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005* and *the Ethical Guidelines for Biomedical Research on Human Subjects, 2000*. Since there is no law and legally binding regulation to govern ARTs, only these non-binding guidelines of ICMR govern the use of ART. An analysis of these guidelines reveals serious inconsistencies and ambiguities and lacunae on the important issues. A revision of these guidelines is therefore urgently required in India.

Apart from that the draft ART Bill 2010 proposed by ICMR and MOHFW has also been discussed. The draft Bill lacks clarity at various levels and full of ambiguous language. It creates obstructions in effective implementation of the Bill. The draft Bill contains contradictions at various places and also left certain critical questions unanswered, like issues involved in surrogacy, surrogacy contract, the payment to surrogate etc. The draft Bill also lacks proper mechanism to ensure the responsibilities of the parents and interests of the children born through ART. There is a need to make special provisions to ensure the welfare of children. In this regard, the various recommendations of Law Commission has also been examined and discussed with an objective to propose an effective legislation in this area. The new recommendations made by different ministries seem like a clash of international and national interests in this transnational ART industry. A legislation that is purely domestic in nature, in reality has far reaching consequences globally. The Draft Bill should effectively

regulate and monitor ART providers, consultancies, private agencies and other people involved in offering and promoting ART and surrogacy services.

The study also reveals that adoption is recognized amongst the Hindus only in India. The other communities do not recognize it. *The Hindu Adoption and Maintenance Act, 1956* read with *the Hindu Minority and Guardianship Act, 1956* applies only to Hindus, Buddhists, Jains and Sikhs. In 1990, the Central Adoption Resource Agency (CARA) was established by the Union Ministry of Social Justice and Empowerment for regulation of adoption within India, and international adoptions of children from India. In 1995, it issued guidelines on adoptions which provided that all registered/licensed adoption agencies are required to follow these guidelines. A Bill for a uniform law governing adoption was introduced in the *Lok Sabha* in 1980, but unfortunately, it was opposed due to lack of consensus and the bill was eventually lapsed. The legal position is thus very complex, and no general provisions can be made to all couple having children by ARTs or surrogacy. Therefore, there is an urgency to pass a uniform law relating to adoption of the child born through ARTs, which give an equal opportunity to the couple of all community to adopt the child.

The study reveals that few nations of the world have made laws and policies to regulate ART within their own regulatory framework which either allow it or impose some restrictions on it. It is found that most industrialized nations ban commercial surrogacy. The countries like Brazil, Israel, and the United Kingdom have established regulatory regimes or partial ban to control access to it. The study further reveals that the surrogacy market is unregulated in the United States. The federal government has left the issue on individual States to develop regulatory policies. Although the use of ART is prevalent in many countries of the world, India has become one of the preferred destinations for fertility tourism in the world. The reason behind it is that the treatment in western countries comparatively involves high cost where the middle class people find it difficult to afford infertility treatment. To them India is the best option where they can avail the treatment at comparatively low cost. Another reason is that commercial surrogacy is banned in many countries and India offers an open market access and easy destination due to lack of legal regulation. Therefore, there is an urgent need for regulation of transnational surrogacy and fertility tourism through international norms. The same may also be formulated in such a way that it should also regulate international adoption and resolve the issue of nationality of the children born out of surrogacy.

The study indicates that the social ethical and religious norms should not be overlooked by undergoing the infertility treatment. The ART technology has posed a danger

to the social institutions also. It should only be permitted to the extent to which the social, ethical and religious norms allow it. It has also been suggested that ART should not be allowed to be misused in such a way that it will de-shape the face of the society. The feminist's perspective of ART has also been discussed with the objective that glamorous approach should not be allowed to distort female organs and the health of mother. It has also been suggested that commercial surrogacy should not be allowed at any cost. It should be made voluntary only (altruistic).

The study further shows that the cases related to ART involve complicated issues of well settled family laws. The decisions attempted to make variations from the above settled principles like access to ART treatment, consent to use of gametes or embryos, artificial insemination, surrogacy, frozen embryos, posthumous reproduction, same sex parentage. The study also indicates that the judiciary has played dynamic role while resolving ART related issues. The courts have also touched the issues like limitation on number of embryos transferred, fetal reduction in the case of multiple pregnancy, the maximum number of IVF procedure on a women, the use of sperm after the death of husband, the use of P.G.D. for sex-selection, the maternity and paternity in the case of sperm and egg donation and the same sex parentage and tried to resolve it by propounding new formulations in the area. The judiciary has also insisted legislating effective laws in the area of ART.⁴⁸ Recently, the Madras High Court has extended the benefit of maternity leave to genetic mother in the matter of child born through surrogate baby.⁴⁹ After the thorough exercise of the study following suggestions are mooted out:-

Suggestions:

- ART has been involving a big business incorporating \$3-4 billion-per-year. It has various participants like oocyte/sperm donor, surrogate mothers and major drug companies; families using donor gametes, etc. it is submitted that a strong law required to be legislated for controlling its misuse.
- The malpractices, misuse and exploitation of ARTs may also be regulated by developing a code of conduct with participation of medical professionals, religious leaders and the members of civil society and academicians.

⁴⁸*Baby Manji Yamada v. Union of India* 2008, 13 SCC 518, *Jan Balaz v. Anand Municipality* 2010(2) ALL MR. (JOURNAL) 14

⁴⁹ *K .Kalaiselvi vs Chennai Port Trust*, Judgment delivered on 04.03.2013, high court of Madras.

- Transnational surrogacy is one of the most controversial issues, especially in India; which has secure favourite destination for the infertile couple all around the world because of easy and cheap availability of surrogate mother and lack of legal regulation. The silence on the part of government and policy makers have created legal disputes resulted in legal battle in the court of law. In this way it can be suggested that there should be a monitoring agency to check transnational surrogacy which can supervise, control and counsel the infertile couple from abroad.
- The Government of India should established special fast track court for the speedy trial of the cases related to transnational surrogacy. It will be in the best interest of the child.
- There is a lack of legally binding regulatory mechanism to deal with the complex legal, ethical issues surrounding ART such as sex selection, PGD, multiple embryo implantation, fetal reduction and inducement of pregnancy in post menopausal women. These issues are needed to be addressed by law.
- There is lack of legally binding guidelines regarding the fast mushrooming of ART clinics and there quality, cost and safety. In the light of *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005*, a new law is also required to be legislated to regulate and restrict the fast growth of ART clinics in India.
- Studies show that women hiring themselves out as surrogates almost invariably do so out of economic necessity and indeed, are exploited by range of middle men and women.⁵⁰ The Commercialization of female body parts in the name of surrogacy should not be allowed, therefore commercial surrogacy should be banned.
- The process of adoption must be simplified and there should be counseling for the infertile couple so that they can understand the risk of IVF and other technologies. The complexities and legal hurdle in the process of adoption must be removed and there should be a uniform law on adoption for all people of various communities.
- A National database must be maintained by the Ministry of Family Welfare (MOHFW) regarding the number of couples coming to India for surrogacy.

⁵⁰ Amrita Pande, “Commercial Surrogacy in India: Manufacturing a Perfect Mother-Worker”, *Signs* 35(4) (Summer): 969-92.

Suggestions Relating to Draft ART Bill 2010

The draft ART Bill and Rules 2010 is yet to become law. The following suggestions may be proposed to make the Bill more comprehensive:

- The Draft Bill in its present form is unacceptable, and there is an urgent need for regulation of present practices of ARTs, not only regularization.
- There is a need to review the Bill on ARTs within the framework of the India's health policy other relevant policy.
- A provision in the draft ART Bill should be incorporated that before undergoing ART procedure, a counselling by medical and technical professionals should be made compulsory and a responsibility should be fixed on them that they should revealed to patient about all sort of hazards, health risks and complications of ART. The Draft Bill should clearly indicate the various health risks and adverse results of ARTs.
- There should be a provision in the draft ART Bill for health insurance and rights of surrogate mother and child born out of surrogacy arrangement. It is also suggested that the government should initiate a scheme for compulsory insurance for health of surrogate mother and child born out of surrogacy and the premium should be made payable by the genetic parents.
- The Bill should permit genetic surrogacy, and not restrict to the more complicated, expensive and invasive gestational surrogacy. The upper age limit for undergoing ART procedure should be clearly stated by the Bill.
- The Draft Bill must ensure that the commissioning parents understand and agree to the fact that the surrogate has a right to physical integrity and bodily autonomy, i.e. she cannot be forced for abortion, go for foetal reduction or made to follow certain diet. After the birth of the child, the birth must be officially documented.
- Considering the fact that these technologies do not treat or cure infertility, and keeping the potential risks for the mother and child in mind, a responsible legislation regarding infertility and ARTs must encourage adoption and present it as a course of action as significant as ARTs.
- The various medical procedures and the steps involved need to be laid down in detail.
- The central database as mentioned in the Draft Bill should also keep a record of live birth rate/take home rate, number of implantation rate, number of still births, number of healthy IVF children born etc.

- The requirement of cryo bank in terms of the facilities needed, kind of personnel and qualification to run a cryo bank must be clearly spelt out and explained in the Draft Bill. It should also make adequate provision for the inspection, monitoring and regulation of cryo banks.
- The Draft Bill must ensure that the act of taking ‘informed consent’ should be a continuous process. It should include explanation and interaction over a period of time and not merely restricted to taking a signature of the concerned person.
- The Draft Bill should also deal with the issue of sex-selection more stringently. Further, the use of techniques such as Pre implantation Genetic Diagnosis should be strictly monitored.
- The draft ART Bill should not be taken as final. There should be an open debate and discussion across the country, at various levels and regions. The government should incorporate the suggestions while materializing the proposed Bill.
