ASSISTED REPRODUCTIVE TECHNOLOGY IN INDIA: A CRITICAL LEGAL STUDY

Thesis

SUBMITTED TO

BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY

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BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY

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Dedicated

To

My Parents

DECLARATION

I hereby declare that the research work embodied in this Ph.D. thesis titled **"Assisted Reproductive Technology in India: A Critical Legal Study"** has been carried out by me under the supervision of Dr. Pradeep Kumar and co-supervision of Dr. Anis Ahmad. This research work is an original work and it has not been previously submitted in part or full for any other degree or diploma in this university or any other university.

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CERTIFICATE

This is to certify that the thesis titled **"Assisted Reproductive Technology in India: A Critical Legal Study"** submitted by **Ms. Sufiya Ahmed** in the Department of Law, School for Legal Studies, Babasaheb Bhimrao Ambedkar University, Lucknow in fulfillment of the requirement for the award of the Degree of Doctor of Philosophy in Law. "The candidate has completed the research work for the full period prescribed and as per her declaration the thesis embodies the results of her investigation conducted during the period she worked as a Ph.D. research scholar."

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PREFACE

Infertility is a worldwide problem affecting a large number of couples during their reproductive lives. On August 6, 1986, just after 8 years from the birth of the world's first IVF baby; Luise J. Brown, India's first documented Test Tube Baby Harsha was born. Since then, the fertility industry in India is fast growing and now it is a business of millions and billions. Fertility tourism transformed this market into a high-tech International surrogacy destination for couple from all over the world. The rise of assisted reproduction draws strength and encouragement from concepts deeply rooted in our tradition and culture-patriarchal stereotypes, the notion that motherhood is an essential part of being a woman, and the deep rooted preference for male children. Infertility which was once considered incurable is now medicalized which can be treated through Assisted Reproductive Technology (hereinafter referred as ART). ART is now going far beyond treating the infertile couple and it challenges our traditional concept of family and parenthood.

Due to lack of legally binding norms, the dispute has arisen regarding nationality and parentage of child born through surrogacy in India. There has been much confusion in the medical and legal community about the legal regulation of ART until the decision in the case of Baby Manji[1], wherein the absence of law on surrogacy in India was acknowledged. In September, 2008, Health Minister, Honourable Ambumani Ramdas, Govt. of India called for national surrogacy legislation. A week later, the ICMR presented a draft bill which was later modified in 2010[2] in the light of opinions and comments of public and civil society. The Bill is still pending before the parliament and presently ART is regulated only by the non-binding guidelines of ICMR of 2005[3].

In view of the above development, it is right time to examine the infertility and the regulation of ART in its current socio-legal perspective of India. It seemed to the researcher that the time had come to discuss and analyze the present legal framework and

[1] *Baby Manji Yamada v. Union of India* (2008), 13 SCC 518.
[2] *Draft Assisted Reproductive Technologies (Regulation) Bill & Rules 2010.*
[3] *Ethical Guidelines on Biomedical Research, 2000 and National Guidelines on Accreditation, Supervision and Regulation of ART Clinics in India, 2005*

the response of courts regarding issues surrounding the use of new reproductive technology. The present thesis discusses and analyses a vast array of issues including the issues of infertility, its consequences, and the role of assisted reproductive technology, the legal response towards ART, the ethical, moral challenges and the implications of ART on the health of women and other related issues.

The research work is a contribution to the current debate on the legal regulation of ART in India. It offers detailed information and insight to policy makers, academicians and every one interested in the historical development, legal response, ongoing debate and future directions in the field of ART. This will help to guide the policy makers to make sound law and policy to meet the challenges of this area.

ACKNOWLEDGEMENTS

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Above all I would like to acknowledge the tremendous selfless sacrifices that my parents made to ensure that I had an excellent education. The paramount affection and constant moral support of my family can't be justified by words. For this and much more, I shall be indebted to them forever.

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At last I thank to Prem Shanker Rama Shanker Printers for the completion of the manuscript on time.

(Sufia Ahmed)

LIST OF ABBREVIATIONS

ART	:	Assisted Reproductive Technology
IVF	:	In Vitro Fertilization
AI	:	Artificial Insemination
FSH	:	Follicle Stimulating Hormone
OHSS	:	Ovarian Hyper Stimulation Syndrome
HCG	:	Human Chorionic Gonadotropin
IVM	:	In-vitro Maturation
PGD	:	Pre-implantation Genetic Diagnosis
ICMR	:	Indian Council of Medical Research
CARA	:	Central Adoption Resource Agency
MOHFW	:	Ministry of Health and Family Welfare
ASRM	:	American Society of Reproductive Medicine
ET	:	Embryo Transfer
GIFT	:	Gamete Intra Fallopian Transfer
ZIFT	:	Zygote Intra Fallopian Transfer
ICSI	:	Intra Cytoplasmic Sperm Injection
IUI	:	Intra Uterine Insemination
KEM	:	King Edward's Memorial Hospital
NHRM	:	National Rural Health Mission

NAMS	:	National Academy of Medical Sciences
TET	:	Tubal Embryo Transfer
HFEA	:	Human Fertilization and Embryology Authority
RTAC	:	Reproductive Technology Accreditation Committee
AIH	:	Artificial Insemination by Husband
AID	:	Artificial Insemination Donor
AIHD	:	Artificial Insemination Husband Donor
SUZI	:	Sub Zonal Insemination
CHC	:	Community Health Centre
NIRR	:	National Institute for Research in Reproduction
ICPD	:	International Conference on Population and Development
DHS	:	Demographic and Health Survey

LIST OF CASES

R v Sheffield HA ex p Seale (1994) 25 BMLR 1

R v Ethical committee of St. Marry's Hospital (Manchester) ex p Harriott (1998) FLR 512,HC

North Coast Women's Care Medical Group. Inc. et al. v. S.C.(Benitez) (2008) Cal. LEXIS 10756

Liberty Mutual Fire Ins. Co. V. (name withheld) (2001) Del. Super. LEXIS 216

Mrs U v. Centre for Reproductive medicine [2002] EwcA Civ 565, [22]

Evans v. Amicus Healthcare Ltd. And others (2004) 3 All ER 1025

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In re D (A Child Appearing by her Guardian ad Litem) [2005] UKHL 33

*R (on the application Bruno quintaville on behalf of pro life alliance) v. secy for health (*2002)2wlr550,ca

People v. Sorenson, 68 Cal. 2nd 280, 437 P.2d 495 (1968)

Gursky v. Gursky, 39 Misc. 2d 1083, 242 N.Y.S. 2d 406 (Sup. Ct.1963).

Thomas S. V. Robin J., 209 A.D.2d 298, 618 N.Y.S.2d356(1st Dept. 1994)

Johnson v. Superior Court, 80 Cal. App. 4th 1050, 95 Cal. Rptr. 2d 864 (2d Dist. 2000)

Hecht v. Superior Court, 16 Cal. App. 4th 836, 20 Cal. Rptr.2d 275 (2d Dist. 1993)

Gillett-Netting v.Barnhart,371 F.3d 593 (9th Cir. 2004).

Hecht v. Superior Court, 16 Cal. App. 4th 836, 20 Cal. Rptr.2d 275 (2d Dist. 1993)

Gillett-Netting v.Barnhart,371 F.3d 593 (9th Cir. 2004).

Re C (Application by Mr. and Mrs. X under s. 30 of the Human Fertilization and Embryology Act 1990) [2002] EWHC 157 (Fam.), [2002] 1 FLR 909

In Re Q (Parental Order) [1996] 1 FLR 369

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

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

Davis v. Davis 842 S.W.2d 588 (Tenn. 1992).

Kass v. Kass 696 N.E.2d 174 (N.Y. 1998).

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Gillett-Netting v. Barnhart 371 F.3d 595 (9th Cir. 2004)

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Introduction

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

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[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/Reporductive_Health_Profile_infertility.pdf* visited on 22 may 2012.

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.

To give vent to this manifestation of human mind, the medical sciences made an acute introducement 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 retrieved[5].

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

[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

(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 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 Harsha[8] 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*

[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.
[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).

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 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.

Aims and Objectives

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.

[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)
[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 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.
- 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.

Hypothesis

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.

Research Methodology

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. The existing literatures comprises of various books, articles, law journals, dictionaries, encyclopedia, law reports, newspapers, and other materials available at

websites have been used. Secondary data such as the Report of Law Commission of India, Ethical Guidelines of Indian Council of Medical Research, Five Year Plans of Government of India, *Warnock* Committee Report etc. has been consulted.

Scheme of Chapters

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 the role 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 of the 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 scheme 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.*

[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

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. 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.

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[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).
[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).

Chapter-II

Chapter-II

Conceptual Framework of Infertility and Assisted Reproductive Technology

2.1. Introduction

From the time immemorial women have been considered as a child bearer. The identity of women has always been confined with her ability to have a child. It was as essential as her inability to bear a child is considered as a social stigma. In primitive societies, the women's inability to conceive a child was called as barrenness. The inability to have a child caused cultural, social and religious pressure upon the married couples compelled them to go to any possible extent to remove this social stigma of barrenness. In India, the sacred duty of a women, enshrined in religious scriptures of Hindus, Muslims, Sikhs and Christians is to bear a child. In ancient India, a husband could tie up his childless wife and burn her.[1] A woman who does not give birth to a child, or is unable to have a child, is automatically relegated to a low status in the family and may also face social ostracism and desertion. Women without children are viewed as inauspicious and excluded from certain religious functions.[2] This chapter provides conceptual framework to infertility, its causes, its consequences and the role of ART in treating infertility, its development, various techniques and procedures also.

2.2. Historical account of Infertility

Historically, hysteria was the earliest reason of barrenness. It was felt that women would develop hysteria which at the time thought to a wondering uterus because of being deprived of sexual relation. Later it was felt that it was God's will that made women childless, it was up to God only to bless them with children like he did for *sarah* & other barren women in the Bible. The ancient world looked harshly on women like Rachel. Because fertility remained so closely tied to womanhood, childless women regarded with a mixture of pity and scorn. The Bible paints childless women as tragic and incomplete; ancient Egyptians described them as "mothers of the missing ones". Frequently, infertile or "barren," wives were compared with their

[1] Debora L Spar; *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception,* (2006, Boston, Harvard Business School Press) at 7.
[2] Sandhya Srinivasan, *Making Babies: Birth Markets and Assisted Reproductive Technologies in India*, (2010, New Delhi, Zubaan) at XII.

agricultural equivalents: a "field without crops" according to many depictions, or a "tree without leaves."[3]

For thousands of years and millions of infertile women, therefore, infertility remained a silent and irrevocable curse. Shamed by their condition, childless wives confessed their problem to midwives or shamans or quacks, willing to engage in whatever remedies were thrust upon them. They drank potions of mule urine and rabbit blood and doused themselves with herbs believed to induce pregnancy. They kissed trees, slid on stones, and bathed themselves in brackish water, thought to resemble the blood of childbirth. When all else failed, they prayed, adopted, or, like Rachel, employed another woman to bear her child. [4] This situation was gradually changed in the late seventeenth century, when science described procreation as a physical blending of male and female "semence", the seeds that were purportedly released by both partners in conception. Now infertility was treated not as an act of God, sin, or malice but rather as a physical condition amenable to scientific remedy.

In the eighteenth and nineteenth centuries, women who suffered from "obstructions" or "female weakness" were regularly advised to get exercise, take cold baths, or confine themselves to bed. By the 19th century, people were turning to physician for treatment of infertility. During World War II the bearing of children was seen as a patriotic duty and it soon became an obsession. During this time, childless couple was seen as socially maladjusted. The post world war was the period of pronatalism. Pronatalist believed that a couple who doesn't want to have a child is not normal but by bearing children a couple could be seen as normal. It shifted the childlessness as being a medical problem. Thus, the social construction of parenthood has forced the medicalisation of infertility. Now infertility was considered as a fairly straightforward, utterly physical condition. Childlessness which was once seen as a social problem has now become a medical problem.

In a patriarchal society like India where motherhood and child bearing is closely associated with identity of a woman, childlessness and infertility is perceived as a stigma. Infertility can be threaten a women's identity, status and economic security and consequently, be a major source of anxiety leading to lowered self-esteem and a sense of powerlessness. The infertile women could also be victims of

[3] Supra note 1 at 06.
[4] Id at 8.

violence, desertion and social and religious exclusion. In India, a wide of fertility technologies-that can include everything from herbs to homeopathic pills to hormone injections and microsurgery –are easily available and are provided by licensed and unlicensed practitioners.

The patriarchal notion of women being destined to bear children, that too at the "right time" and of the "right gender" is the driving force behind the anxiety that is created around infertility. The socially constructed compulsion to procreate and the extreme forms of ostracism and victimisation that it can take, drive women to fertility clinics. Consequently, the anxiety about fertility is such that women who do not conceive within a few month of marriage often seek help from practitioners of various systems of medicine, and participate in religious rituals, all aimed at enabling them to give birth to a child. Women who approach western or allopathic providers are likely to be subjected to various tests, drugs and procedures. They might be given drugs to induce ovulation, they might undergo artificial insemination, or they may have surgery to open up blocked fallopian tubes.[5]

2.3. Defining Infertility

Essentially, infertility results when a given couple is unable to produce a viable embryo- a sixteen-cell mingling of egg and sperm that will subsequently embed itself in the mother's womb and evolved into a living child. [6] The American Society for Reproductive Medicine (ASRM) defines infertility as, "a marriage is to be considered barren or infertile when pregnancy has not occurred after a year of coitus without contraception."[7] Infertility is a worldwide problem affecting 8- 12 percent couple (50-80 million) during their reproductive lives.[8] The WHO definition drawn up by the scientific group on epidemiology of infertility has classified infertility into primary and secondary and defined as:

- Infertility can be primary if the couple has never conceived despite cohabition and exposure to pregnancy (not contracepting) for a period of two years; primary infertility is also referred as primary sterility.

[5] Supra note 2 at XII.
[6] Supra note 1 at 14.
[7] Melvin L. Taymor, *Infertility: A Clinician's Guide to Diagnosis and Treatment,* (1990, New York, Plenum Medical Book Company) at 11, Quoted in supra note 1
[8] (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, at 131.

- Infertility can be secondary if a couple fails to conceive following a previous pregnancy, despite cohabition and exposure to pregnancy (in absence of contraception, breast feeding or postpartum amenorrhoea) for a period of two years that is also known as secondary sterility.

While WHO defines infertility as failure to conceive despite two years of cohabitation and exposure to pregnancy, many studies adopt their own definitions. Childlessness is defined as the proportion of couples who have not had a live birth by the time of interview, despite at least five years of cohabitation and exposure to pregnancy, and in the absence of contraception, breastfeeding or postpartum amenorrhoea. Unlike a couple with primary infertility, a childless couple also includes those who have successfully conceived but have failed to deliver a live birth. Similarly, secondary sterility to couples having difficulty bearing a second or higher order birth, despite usually five years of exposure, as in the definition above. The five year reference period is typically used, but not necessarily, in demographic surveys.[9]

A simple definition of infertility may be that a couple have failed to conceive after twelve months of unprotected sexual intercourse or have suffered three or more miscarriages.

2.4. Causes of Infertility

The exact cause of infertility is unknown. According to National Institute of Clinical Excellence (NICE) in 27 per cent of cases the medical cause is ovulatory disorders; in 14 percent tubal damages; in 19 per cent low sperm count or quality; and in 30 per cent of cases it is not possible to identify a physical cause. The Human Fertility and Embryology Authority (HFEA) state that in 49 per cent of cases the medical cause of the infertility rest with the man. What is unknown is what causes these problems to arise. There is, no doubt, a plethora of different reasons ranging from obesity; smoking; heavy alcohol use; tight underwear; to delaying the age at which women seek to start a family.[10] The three most important risk factors for infertility in both men and women are advancing age, smoking and obesity. In India,

[9] Shireen J. Jejeebhoy. "Infertility in India - levels, patterns and consequences : Priorities for social science research", *Journal of Family Welfare*, June (1998), 44 (2). at 15-24.
[10] Johnathan Herring , *"Medical Law and Ethics",* (2010, Oxford, Oxford University Press).

the exact cause of infertility may be varying. According to WHO multi centric studies in India, 40% women and 73% of men had no demonstrable cause of infertility. [11]

It is commonly accepted that infertility affects more than 80 million people worldwide. The Human Fertilisation and Embryology Authority states that in 32 percent of the cases the medical cause of infertility rests with men, 32 percent with the women, and 10 percent with both.[12] In the US, according to the National Survey of Family Growth, 17 per cent of all married women suffered from infertility impaired fecundity in 2002.[13]

There is little evidence on the levels and patterns of infertility in India. According to studies conducted by WHO, the extent of primary and secondary infertility in India is 3 and 8 per cent respectively. Recent NEHS data, using childlessness as an indicator, estimates that 3.8 per cent of currently married women between the ages of 40-49 are childless. Based on 1981 Census data, childlessness amongst ever-married women in India is estimated to be about 6 per cent.[14] A range of demographic, behavioral and socio cultural factors have been identified as potential determinants of infertility. Among the recognizable correlates of infertility are:

1. Sexually transmitted diseases which account for an increasing proportion of infertility in developing countries. In particular, previous history of STDs is associated with such conditions as tubal factors in the female partner (in particular tubal occlusion or pelvic adhesions) and obstruction or gland infection in the male partner; the major STDs being gonorrhoea and chlamydial.

2. Maternal health factors such as unhygienic delivery, postpartum infection, and unsafe obstetric and abortion procedures are observed to be linked to sepsis and pelvic infections; severe malnutrition and anemia are also observed to affect infertility; as do such morbidities as tuberculosis. Women's poor health and nutrition status can lead to repeated miscarriages and foetal wastage. The most commonly observed link is that between post-partum or post abortion complication and tubal blockages or pelvic infection that in turn cause infertility.

[11] Anjali Widge, "Infertility" available at *http://www.searo.who.int/LinkFiles/Reporductive_Health_Profile_infertility.pdf* visited on 22 may 2012.
[12] The Human Fertilization and Embryology Authority, (1990).
[13] Supra note 1 at 02.
[14] Supra note 2 at 08.

3. Age, adolescents are frequently observed to be temporarily in fecund (adolescent sterility); so also, infertility increases among older women who become prematurely menopausal. A woman's fertility peaks between ages twenty and twenty-four. By age thirty-five, her fertility is only 80 percent of what it was at her peak. By age forty-five, a woman may be 95 percent less fertile than she was at age twenty.[15]

4. Lifestyle is sometimes held to be related to infertility -- smoking, alcohol consumption, drug use and even over exercise. Smoking contributes to infertility in women by increasing the rate at which their eggs deteriorate. This leaves fewer ova to mature to ovulation. It also increases a woman's risk for miscarriage and ectopic pregnancy (when the embryo implants inappropriately in the fallopian tube). The chemical by-products of smoking may keep female fetuses from forming normal amounts of ovarian tissue, so they then have far fewer primordial follicles at birth. Smoking contributes to infertility in men as well. Male smokers have many more misshaped and non motile (not capable of moving) sperm than nonsmokers.[16]

5. Side effects of previous contraceptive use: for example large numbers of women with pelvic infections in India had undergone vaginal tubectomy or minilaparotomy.

6. Marriage patterns: eg. cross cousin marriages.

7. Occupational patterns and exposure to noxious chemicals or pesticides in the work place.

To this list we can add, as background determinants, the availability, accessibility and quality of reproductive health services, including information and referrals on the one hand, and levels of education, household economic status and women's autonomy on the other. This list is not exhaustive, since determinants of infertility vary widely with culture.

2.4.1. Causes of Male Infertility

Infertility is a widespread problem. For about one in five infertile couples the problem lies solely in the male partner (male infertility). A man may be infertile if he does not produce enough sperm or if many of the sperm he produces are misshaped or non motile. Falling sperm counts are a "serious public health warning", and the trend could be linked to diet, lifestyle and possibly even tight underwear, a major French

[15] Linda Bickerstaff, *Technology and Infertility: Assisted Reproduction and Modern Society*, (2009, New York, Rosen Publishing), at 14.
[16] Ibid

study has revealed. The study showed that sperm counts and quality have fallen sharply since the start of the 1990s. Between 1989 and 2005, average sperm counts fell by a third in the study of 26,000 men, increasing their risk of infertility.[17] A variety of disorders ranging from hormonal disturbances to physical problems, to psychological problems can cause male infertility.

2.4.1.1. Hormonal Problems:

A small percentage of male infertility is caused by hormonal problems. The hypothalamus-pituitary endocrine system regulates the chain of hormonal events that enables testes to produce and effectively disseminate sperm. The following is a list of hormonal disorders which can disrupt male infertility:

I) Hyperprolactinemia
II) Hypothyroidism
III) Congenital Adrenal Hyperplasia
IV) Hypogonadotropic Hypopituitarism
V) Panhypopituitafism

2.4.1.2. Physical Problems

A variety of physical problems can cause male infertility. These problems either interfere with the sperm production process or disrupt the pathway down which sperm travel from the testes to the tip of the penis. These problems are usually characterized by a low sperm count and/or abnormal sperm morphology. Causes of low sperm production range from serious problems such as pituitary gland dysfunction to genetic disorder. The following is a list of the most common physical problems that cause male infertility:

I) Variocoele
II) Damaged Sperm Ducts
III) Torsion
IV) Infection and Disease
V) Klinefelter's Syndrome
VI) Retrograde Ejaculation

[17]Diet, tight underwear blamed for male infertility, The Times of India, available at *http://articles.timesofindia.indiatimes.com/2012-12-26/health/35646346_1_sperm-counts-male-infertility-tight-underwear* visited on 18/2/2013 at 12:14 pm

2.4.1.3. Psychological/Physical/Behavioral Problems:

Several sexual problems exist that can affect male fertility. These problems are most often both psychological and physical in nature: it is difficult to separate the physiological and physical components.

I) Erectile Disfunction (ED)

II) Premature Ejaculation

III) Ejaculatory Incompetence

2.4.2. Causes of Female Infertility

Ovulatory disorders are one of the most common reasons why women are unable to conceive, and account for 30% of women's infertility. Fortunately, approximately 70% of these cases can be successfully treated by the use of drugs such as Clomiphene and Menogan/Repronex. The causes of failed ovulation can be categorized as follows:

2.4.2.1. Hormonal Problems

These are the most common causes of an ovulation. The process of ovulation depends upon a complex balance of hormones and their interactions to be successful, and any disruption in this process can hinder ovulation. There are three main sources causing this problem:

- Failure to produce mature eggs
- Malfunction of the hypothalamus
- Malfunction of the pituitary gland

2.4.2.2. Scarred Ovaries

Physical damage to the ovaries may result in failed ovulation. For example, extensive, invasive, or multiple surgeries, for repeated ovarian cysts may cause the capsule of the ovary to become damaged or scarred, such that follicles cannot mature properly and ovulation does not occur. Infection may also have this impact.

2.4.2.3. Premature Menopause

This presents a rare and as of yet unexplainable cause of anovulation. Some women cease menstruation and begin menopause before normal age. It is hypothesized that their natural supply of eggs has been depleted or that the majority of cases occur in extremely athletic women with a long history of low body weight and extensive exercise. There is also a genetic possibility for this condition.

2.4.2.4. Follicle Problems

Although currently unexplained, "unruptured follicle syndrome" occurs in women who produce a normal follicle, with an egg inside of it, every month yet the follicle fails to rupture. The egg, therefore, remains inside the ovary and proper ovulation does not occur.

2.4.2.5. Environmental and Occupational Factors:

The ability to conceive may be affected by exposure to various toxins or chemicals in the workplace or the surrounding environment. Substances that can cause mutations, birth defects, abortions, infertility or sterility are called reproductive toxins. Disorders of infertility, reproduction, spontaneous abortion, and teratogenesis are among the top ten work-related diseases and injuries in the U.S. today. Despite the fact that considerable controversy exists regarding the impacts of toxins on fertility, four chemicals are now being regulated based on their documented infringements on conception.

- ***Lead***

Exposure to lead sources has been proven to negatively impact fertility in humans. Lead can produce teratospermias (abnormal sperm) and is thought to be an abortifacient, or substance that causes artificial abortion.

- ***Medical Treatments and Materials***

Repeated exposure to radiation, ranging from simple x-rays to chemotherapy, has been shown to alter sperm production, as well as contribute to a wide array of ovarian problems.

- ***Ethylene Oxide***

A chemical used both in the sterilization of surgical instruments and in the manufacturing of certain pesticides, ethylene oxide may cause birth defects in early pregnancy and has the potential to provoke early miscarriage.

- ***Dibromochloropropane (DBCP)***

Handling the chemicals found in pesticides, such as DBCP, can cause ovarian problems, leading to a variety of health conditions, like early menopause, that may directly impact fertility.

2.5. Consequences of Infertility

Infertility has severe consequences for men and particularly for women's wellbeing. Childlessness has serious demographic, social and health implications. The

ease with which women can be labelled infertile or resist the label, the experiences of childless women and the process of seeking solutions for infertility all go beyond the biological fact of reproductive impairment.[18] Infertility almost always leads to decreased levels of personal well-being and for many individuals it causes significantly more severe consequences. The "blame" for infertility is unquestioningly placed on the woman. Some of the more commonly expressed consequences of infertility include:

2.5.1 Marital Instability

A study in Andhra Pradesh, reported that 70% of women experiencing infertility would be punished with physical violence for their "failure" and nearly 20% of these women reported that they suffered severe violence at the hands of their husbands as a result of being childless. Some Indian women have reported not being allowed to hold new-born relatives or participate in infant naming ceremonies because of superstitious fears that a new child will die in the arms of an infertile woman. In Andhra Pradesh infertile women reported feeling isolated and ashamed with actual and anticipated rude comments at social functions forcing some women into social reclusion [19]

2.5.2. Emotional Harassment

Harassment comes in many forms: ostracism from family celebrations, taunting and stigmatisation, negative attitudes, as well as beating, withholding of food and health care. One study of gynaecological morbidity in the slums of Baroda has observed in focus group discussions and case studies that emotional harassment is often expressed by infertile women.[20] As a result of taking responsibility for the emotional impact of the infertility, the woman experiences intense feelings, such as pain, anger, fear, etc., which, combined with the messages that her way of dealing with things is in some way dysfunctional or "crazy", causes her to feel an anxious depression.

2.5.3 Loss of Self-esteem

Infertility is clearly a major event, and often perceived as a crisis. Studies have highlighted the low self-esteem, security and self-confidence that prevail among the

[18] Supra note 8 at 132.
[19] Emily McDonald Evens, A Global Perspective on Infertility: An Under Recognized Public Health Issue , available at *http://cgi.unc.edu/uploads/media_items/a-global-perspective-on-infertility-an-under-recognized-public-health-issue*.original.pdf visited on 3/3/13 at 6:37 P.M.
[20] Supra note 8

childless women. The inability to perform their roles as child bearers and rearers, and the common misconception that infertility is always the shortcoming of the female is observed to take a huge toll on the woman in terms of loss of self esteem, grief, and feelings of failure. Incidents reported in India in which the presence of childless women at joyful occasions is perceived as inauspicious must reinforce feelings of inferiority. Yet, few of these consequences have been studied in the South Asian context. [21]

2.6 Treatment of Infertility

By the turn of twentieth century, however, matters had begun to change. For the first time, doctors and scientists started to grapple with the physical cause of childlessness and with various treatments that actually worked. As these treatments evolved, they formed the critical supply side of the fertility industry, allowing demand at last to meet its match. Three developments in particular gave birth to the baby business. First was the increased understanding of the biology of reproduction. Second were the discovery of hormones and the development of endocrinology. Third, and the most spectacular, was the invention of in vitro fertilization, a technique that shocked the world in 1978 and thrust the business of baby-making into a political and social maelstrom. [22]

Amongst the different stages involved in human reproduction, the process of fertilization is one of the most important. During sexual intercourse, the sperm of a man enters the female body's vagina via the cervix. The process of ovulation also has a very important role to play in human fertilization. It is during ovulation that a mature ovum is released into the fallopian tube. It is important for an ovum to be available for the process of fertilization to be initiated. It is the ovum which is fertilized by the sperm and which results in the formation of the zygote, embryo and finally the foetus. During the sexual intercourse, millions of sperms are released. But only one of the sperms is able to fertilize the ovum or the female egg. The process of human fertilization of the ovum by the sperm takes place in the fallopian tube. Fertilization involves the fusion of the nuclei of the sperm and the ovum leading to the formation of the zygote. Once the zygote is formed, it moves towards the uterus. After numerous transformations, the zygote is transformed into an embryo which

[21] Supra note 1 at 17
[22] Ibid

remains attached to the inner linings of the uterus. Finally the embryo develops into a foetus and about nine months later childbirth takes place.[23] Assuming the both partners produce normal gametes, timing becomes the key element in conception. An egg and sperm have to merge at just the right time and in just the right place for normal conception to occur.[24]

2.6.1. Hormonal Balance

Technically human reproduction depends on a complex and intimate blend of hormones. The hypothalamus and the pituitary gland together regulate the formation and release of hormones. The process begins in the brain, where tiny hypothalamus gland secretes a substance known as gonadotropin-releasing hormone. This hormone prompts the pituitary gland to produce two other hormones: follicle-stimulating hormone (FSH) and luteinizing hormone (LH). This "push-pull" interplay of messages and responses produces the cyclical hormonal environment in the woman that is designed solely to promote pregnancy. There are two primary sex hormones in the female, estrogen and progesterone. Essentially, estrogen is a substance that launches conception: once the ovarian follicles receive the appropriate hormonal signal, they produce estrogen and release an egg into the fallopian tubes. Progesterone, by contrast, typically ends the cycle, preparing the womb for pregnancy and preventing more eggs from ripening. In men, FSH and LH trigger the production of testosterone and influence the production and maturation of sperm. For conception to occur, all these hormones must be secreted in the right amount and concentrations, at precisely the right time. If any of the hormones is missing or weak or overactive, the entire process stalls and pregnancy becomes virtually impossible. [25] In about 10 to 15 percent of all pregnancies, the embryo fails to implant because the amount of hormones produced and the timing of their release were not perfectly synchronized.[26] These processes became better understood due to scientific experiments, so actual "cures" for infertility suddenly seem possible. Because if the reproductive cycle depended on the interaction of particular hormones and if these hormones could be extracted or synthesised in the laboratory, then treatment became akin, theoretically at

[23] Available at *http://www.pregnancyxl.com/pregnancy/fertilization-process/* visited on 30/08/2012 at 5:20 P.M.
[24] Supra note 15 at 10.
[25] Supra note 1 at 20.
26 Geoffrey Sher, Virginia Marrage Davis, Jean Stoess. *In Vitro Fertlization: The A.R.T. of Making Babies*, (2005, New York, Checkmark Books).

least, to normal pharmaceutical procedure of identifying the problem, prescribing the proper medication, dosing to patient and awaiting the result. Such treatments made it possible to re-create the hormones in the laboratory and controlling the amounts also.

2.6.2 The Test Tube Baby

The third major development in the field of infertility was the announcement by John Rock, in 1944, that he and his research assistant had managed to fertilize four human eggs in vitro. Using egg donated from women undergoing hysterectomies, Rock and his assistant had matched the eggs in a petridish with semen left over from earlier artificial inseminations. After more than a hundred attempts, four of the matches worked, combining to create tiny fertilized ova. The results were greeted, not surprisingly, with a mixture of awe and horror.[27] Aldous Huxley introduced the term the term "test tube" babies in his 1932 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. [28] In vitro (literally means in glass) fertilization started the science of assisted reproductive technology. On July 25, 1978, Louise Brown the first test tube baby was born in Oldham, England. Only two years after Louise Brown's birth, doctors in Melbourne, Australia, announced the birth of Candice Elizabeth Reed. Eighteen months later, America's first test tube child, Elizabeth Jordan Carr, entered the world. By the spring of 1983, roughly one hundred fifty babies have been conceived in vitro.[29] In India, the first test tube baby was born on August 6, 1986. Three decade have passed since, the first test tube baby was born. Since 1978, IVF has led to the birth of approximately three million infants worldwide. IVF has made it possible for same sex lesbian and gay male couples to have children biologically related to them.

Women in India go through various treatments to avoid the adverse consequences of infertility ranged from traditional methods to modern technologies. The rise of assisted reproduction draws strength and encouragement from concepts deeply rooted in our tradition and culture-patriarchal stereotypes, the notion that motherhood is an essential part of being a woman, and the deep rooted performance for male children. The importance of and desire for having a biological child cuts

[27] Supra note 1 at 22.
[28] 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
[29] Supra note 1at 28.

across all class, caste and community groups and couples are willing to go to considerable lengths to achieve this.[30] In 2004, more than one million Americans underwent some form of fertility treatment, participating in what had become a nearly $3 billion industry.[31]

However, the medical profession has hailed ARTs (assisted reproductive technology) as "miracle cures" that "treat" infertility successfully. While underplaying the potentially serious risks and concerns that the use of these technologies posses to the health of the women subjected to them, the medical profession has actually joint hands in the promotion of these technologies. The Godlike status accorded to doctors puts them in a privileged position to use these technologies without much questioning from couples seeking help. And they-the doctors, that is- dismiss these ethical and health concern by claiming that if the couples wish to have this particular treatment, who are the doctors to decide otherwise or deny it to them? After all, they explain, it is the greatest accomplishment to help a women have a baby-to give her the joy of motherhood. When doctors make such statements they are retelling the mythology of motherhood: society's insistence that a woman is not a woman until she becomes a mother.[32]

The United Nations Declaration of Human Rights, 1948 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". [33] The European Convention on Human Right also guarantees respect for family life and the right to find a family.[34] In all societies reproduction is considered one of the main rationales for marriage. Likewise, the family is the most widely approved social context for having children. The family gives a person a legitimate legal status and social approval for parenthood and reproduction. A family is never complete without a child and infertile couples go for various methods to have a child. The assisted reproductive technologies challenge traditional understandings of family and have thus entered the debate about family with great force.

[30] Supra note 15 at 10.
[31] Supra note 1 at 3.
[32] Supra note 5 at xiv.
[33] The UN Declaration of Human Rights, Article 16.1
[34] The European Convention on Human Rights, Article 12 said*: 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.*

For many years, adoption was the only way that an infertile couple could build a family. It was seen as a last resort for an infertile couple. Though not perceived as an acceptable option, very few couple go for it as a last resort. Most of the infertile couples had a negative attitude towards adoption because of strongly rooted desire of biological progeny. While modern Hindu law does not prohibit any such arrangement, Islam and Christianity do. The Islam doesn't permit mixing of genes and require each child to be related to a known father and mother. Islam does not allow a third party to intrude the marital function of sex and procreation. So, couples may feel that the bond between them is deepened if they have a biological link to the next generation, or they may simply feel shame at the inability to do something as natural as producing a baby. Some people without partners are content to stay single, but want to have their own-not someone else's-children. Whatever the reason, it is clear that people will go to considerable lengths to have children of their own.

Until recently, the treatment for fertility was mainly by medications to correct hormonal deficiency, or by surgery to correct anatomical defects. These treatments were mostly non-controversial from an ethical or religious point of view. Today, there is a vast variety of technologies. The recent advent of medically assisted reproductive technologies (ARTs), however, changed this situation dramatically. These technologies transferred the process of procreation from a private, personal relation between husband and wife, into artificial means in a lab, and, in many instances, involving a third or fourth party in the process. Assisted Reproductive technology is a significant development of medical science for formation of family and parenting. As Debora Spar says in *The Baby Business*, The science of procreation is new. It is a modern phenomenon, a post industrial miracle that emerged from the high technologies of bio-chemistry, microsurgery, and genetic engineering." [35]

Before the development of in vitro fertilization, infertile couple had few options for treatment. The three most effective procedures were intrauterine insemination, ovulation induction, and controlled ovarian hyper stimulation.[36]

2.6.3 Intrauterine Insemination (IUI)

In an Intrauterine Insemination cycle, a sample of motile sperm is prepared by the embryologist and placed directly inside the uterus using a very fine catheter. The

[35] Supra note 1 at xvii.
[36] Supra note 15 at 24.

sperm is deposited before the release of an egg or eggs, in a natural or stimulated cycle. Conception occurs naturally inside the body. IUI can be offered on a natural or stimulated cycle. On a stimulated cycle (super ovulation), the size and number of follicle are measured using ultrasonography; a Human Chorionic Gonadotrophin (HCG) injection is given to mature the eggs when the follicles reach a certain size. IUI is performed 24-36 hours after the administration of the HCG injection. The intrauterine insemination success rate is up to 20% per cycle. It is recommended that at least 3-4 cycles of treatment are attempted before considering other options.[37]

Some men have low sperm counts but are potentially fertile if more sperm could reach their spouses' fallopian tubes. The procedure of intrauterine insemination takes all the sperm in an ejaculated specimen, washes out the semen, and concentrates all the sperm in a very small volume of fluid. This fluid is then injected into the uterine cavity of the woman at the time of ovulation. In addition to overcoming some of the sub-fertility associated with low sperm counts, IUI is also used in cases of cervical mucus problem and antisperm antibodies and for non specifically enhancing fertility. Intrauterine insemination (IUI) involves the placement of washed sperm into the uterus under ultrasound guidance to bypass the natural cervical mucus barrier. It is performed as an outpatient procedure with or without COH (Controlled ovarian hyper stimulation).[38] It is designed to bring a high concentration of sperm into close contact with one oocyte after natural ovulation or with multiple oocytes after COH.

2.6.4 Ovulation Induction

Ovulation induction is initially recommended for infertile women who do not ovulate on a regular basis. Oral medication that stimulate the pituitary gland to secrete large amounts of follicle stimulating hormone are prescribed for these women. Ovulation induction is usually combined with IUI to ensure that the large quantities of sperm are available at just and right time to fertilize the egg. Using this combination of treatments, about 8 percent of women get pregnant per cycle of medication. There is a 10 percent increased risk of conceiving twins. [39]

[37] Assisted Reproductive Techniques available at http://www.ivf-services.com/intrauterine-insemination-iui.html visited on 01/12/2011 at 11:14 a.m.
[38] IVF Clinics- Asia, *http://www.ivf.net/ivf/asia-b401_0-en.htm* visited on 02 March 2011.
[39] Supra note 15 at 25.

2.6.5 Controlled Ovarian Hyper Stimulation

It is a procedure where ovaries are stimulated directly by large doses of injected FSH. Women usually ovulate as many as twenty to twenty-five eggs during the same cycle with this treatment. When combined with IUI, about 12 percent of women will conceive per cycle.[40] It is a method of assisted reproductive technology consisting of carefully monitored administration of agents designed to induce ovulation by a greater number of ovarian follicles and thus increase the probability of an oocyte being fertilized, also called as controlled ovarian stimulation.[41]

2.7 Assisted Reproductive Technology (ART) [42]

Baby making, according to Debora L. Spar, in her book *The Baby Business*, is the oldest production known to the humankind, a process that is programmed into the biological fiber of our beings and defines our very survival.[43] In the later years of 20th century infertility has been treated as a medical problem that could be solved with medically assisted reproductive technologies (ART). Assisted Reproductive Technologies 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. The term assisted reproduction refers to artificial insemination, IVF, GIFT, ZIFT, gestational surrogacy and other reproductive procedures. *According to 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. [44] *According to Uniform Parentage Act 2002* "Assisted reproduction" means a method of causing pregnancy other than sexual intercourse. The term includes: i) intrauterine insemination; ii) donation of eggs; iii) donation

[40] Ibid
[41] Available at *http://medical-dictionary.thefreedictionary.com/controlled+ovarian+hyperstimulation* visited on 9.8.12 at6:48 PM
[42] The term generally refers to asexual reproduction-achieving pregnancy and birth without sexual intercourse. According to *World Health Organization (WHO)* definition, assisted reproductive technology refers to infertility treatments where both eggs (oocytes) and sperm are handled to achieve a live birth.
[43] Supra note 1 at 01.
[44] Sec.2 (c) of ART (Regulation) Bill 2010,

of embryos; iv) in vitro fertilization and transfer of embryos; and v) intracytoplasmic sperm injection etc.[45]

Although various definitions have been used for ART, the definition used by CDC is based on the 1992 Fertility Clinic Success Rate and Certification Act that requires CDC to publish the annual ART Success Rates Report. According to this definition, ART includes all fertility treatments in which both eggs and sperm are handled. 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 or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved.[46] Linda Bickerstaff recommends ART as a primary choice of treatment for a couple if there is the following:[47]

- A female partner over the age of thirty-five
- A female partner with blocked fallopian tubes
- A female partner who does not ovulate
- A male partner who has a low sperm count

Assisted reproductive technologies are meant to address the agonizing problem of infertility and the powerful desire that many people have for children of their own, especially children with whom they have a biological link.[48] The following are the different techniques of ART:

2.7.1. Artificial Insemination (AI)[49]

It is the most commonly known method of medically assisted reproduction which has been defined as "the introduction of semen into the vagina other than by coitus." In majority of the cases, the husband's sperm is used. The sperm is artificially placed into a woman's cervix (intracervical insemination) or uterus (intrauterine insemination). During artificial insemination treatment, the woman's menstrual cycle

[45] Sec.160.102 Uniform Parentage Act 2002.
[46] "Assisted reproductive technology" *http://www.cdc.gov/art/* visited on 01/02/2012 at 10:54 a.m.
[47] Supra note 15 at 28.
[48] **"**Chapter 8: Reproductive Technology", at 354 available at *http://www.oup.com/us/images/hesamplechapters/vaughnchapter8.pdf* visited16/9/2011 at 4:48 p.m.
[49] "Artificial insemination", means the procedure of artificially transferring semen into the reproductive system of a woman and includes insemination with the husband's semen or with donor semen;

is closely monitored using ovulation prediction kits (OPK), ultrasounds, and blood tests. The semen to be implanted is "washed" in a laboratory, which increases the chances of fertilization while removing unnecessary, potentially harmful chemicals. The semen is inserted into the woman, and if the procedure is successful, she conceives.[50]

According to strict medical definitions, artificial insemination refers to the manipulation of sperm in order for a woman to conceive, a doctor or non-professional places semen into the woman's vagina or uterus with a syringe, facilitating contact with an egg aiding fertilization. Artificial insemination can be used for many kinds of fertility problems. It's a popular infertility treatment for men who have very low sperm counts or sperm that aren't strong enough to swim through the cervix and up into the fallopian tubes. Artificial insemination is also sometimes an option for women who have endometriosis or abnormalities of any of their reproductive organs.[51]

Classification of Artificial Insemination according to the Source of the Seeds (Sperm).[52]

2.7.1.1. A.I.H. (Artificial Insemination by Husband or Homologous Insemination) –

The sperm comes from the husband. If a man is impotent i.e. unable to have normal sexual intercourse, his sperm may be injected into his wife artificially, known as artificial insemination by husband. [53]

Warnock committee report explained artificial insemination by husband as:

The term artificial insemination is used to refer to the placing of semen inside a women's vagina or uterus by means other than sexual intercourse. The principal of this technique has been unknown for centuries in the veterinary context. The simplicity of artificial insemination contrasts sharply with the technical complexity of more recent developments such as in vitro fertilization. It beings with the collection of semen from the husband/partner though masturbation. The semen is either placed in

[50] Jesusa R. Lapuz, *ART (Assisted Reproductive Technology) and its Legal Innuendos: AChallenge fora Statutorial Renovation, available on http://ustlawreview.com/pdf/vol.LIII/ART_and_its_Legal_Innuendos.pdf* visited8.3.2012

[51] *Available at http://www.webmd.com/infertility-and-reproduction/guide/artificial-insemination* visited8.3.2012

[52] E. Pineda, *Problems in Paternity and Filiations*, U.S.T. L. REV. Vol. XLVI, at 30 (1997).

[53] Brendan Greene, *Understanding Medical Law*, (2006, Candevish Publishing Limited), at 112.

the upper part of the vagina next to the cervix or injection into the uterus through a fine catheter. Insemination is undertakes near the predicted time of ovulation, the time in women's menstrual cycle when she has the highest chance of conceiving. The semen used may be fresh or it may have been frozen and thawed before use…[54]

2.7.1.2. A.I.D. (Artificial Insemination by Donor or Heterologous Insemination) –

This is used where the woman has no partner, or her partner is infertile. It involves the insemination of sperm from a donor into a woman, via her vagina into the cervical canal or into the uterus itself. It is normally used as a last resort.

This involves the woman being impregnated with sperm from another man, as her partner is infertile. The introduction of third party raises the question of their legal status in the arrangements. Although, law could not control any private arrangements of this nature, it does control public arrangements, that is, where services are provided to the public. Control of donors is important because of the possibility of passing on genetic defects or disease.

The *Warnock* committee Report explained artificial insemination by the donor as:

Artificial insemination by donor (AID) may be used when investigations have shown the husband to be sterile or to have significantly reduced fertility, or it may be used for the avoidance of hereditary disease when these are carried by the male… In this procedure the woman is inseminated with semen from a donor[55].

The main advantage of AID is that it enables a couple to achieve pregnancy even though the husband is not the biological father. However, the possible transmission of diseases from the donor to the future child and the risk of consanguinity, constitute some drawbacks that must be brought to the notice of the patients. It is necessary to get the informed consent of both the partners after they are counselled about the possible psychological conflict they may face later in their life with the knowledge that one of them is not the biological parent of their child.[56] AID is an ethically acceptable procedure provided there is a medical indication and psychological confirmation for its use. Also, the normal conditions of anonymity and screening of the donor must be met and only frozen sperm samples that have passed

[54] *Warnock Committee Report of the committee of Inquary into Human Fertilisation and Embryology*, Cmnd 9314, (1984, London), HMSO, at 4.1.
[55] Id at para 4.6
[56] National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005), section 1.6.2.

appropriate quarantining for infectious diseases such as HIV, hepatitis B and C, and syphilis should be used.

A.I.H.D. (Artificial Insemination Husband Donor or Confused Artificial Insemination) –

AID raises ethical questions that are not raised by AIH as it takes place between husband and wife .Even though it is through advanced biomedical techniques and not by natural procedure, most of the people have no moral difficulty to accept it. It maintains the integrity of family and there is continuity between procreation and parenthood. Most people agree that there are no morally significant differences between AIH and procreation by intercourse. It is simply viewed as a medical technology providing assistance to what could not be accomplished by normal sexual intercourse. Whereas AID introduces a third party into the reproductive matrix. Someone who donates sperm to be used for AID, is now contributing genetic material without the intent to parent the child that will be produced through the use of his genes Most of the religions also don't accept the impregnation of one's wife by the sperm of a third person as it doesn't make the child one's own and is looked down upon as illegitimate even in manmade laws. The donation is, however, always made anonymously so that the father could not be traced by the child, nor can the father elect to make contact with the child, potentially disrupting a harmonious family. Still it is redefining the concept of family and turning traditional notions of reproduction upside down.[57]

Artificial insemination with donor semen (A.I.D.) raises various legal questions which includes whether the resulting child is a legitimate child and who will be responsible for child care. In this respect courts held that the child is a legitimate child and the contesting husband is responsible for child support.[58] However in some cases courts held that the child may not be legitimate under the common law.[59]In one of the cases court has permitted a sperm donor to obtain a paternity order.[60] Many A.I.D. sperm donor seeks to maintain their anonymity. But in some cases it may be

[57] Deepa Kharb, Assisted Reproductive Techniques Ethical And Legal Concerns -: available at *http://www.ispub.com/journal/the-internet-journal-of-law-healthcare-and-ethics/volume-4-number-2/assisted-reproductive-techniques-ethical-and-legal-concerns.html#sthash.mhcCqXOv.dpuf* visited on 20 Feb. 2012.
[58] *People v. Sorenson*, 68 Cal. 2nd 280, 437 P.2d 495 (1968)
[59] *Gursky v. Gursky*, 39 Misc. 2d 1083, 242 N.Y.S. 2d 406 (Sup. Ct.1963).
[60]*Thomas S. V. Robin J*., 209 A.D.2d 298, 618 N.Y.S.2d356(1st Dept. 1994)

not possible to maintain anonymity. In a case of California the appellate court of California permitted the parents of a child who has some kidney disease allegedly from the sperm donor to obtain information about the donor in the suit against sperm bank.[61]

2.7.2. In Vitro Fertilization (IVF)

In vitro fertilization (IVF) started the science of assisted reproductive technology. Loiuse J. Brown, the first test tube baby was born on July 25, 1978, in Oldham, England. Louise's parents- Lesley and John Brown was a working class people from Bristol. John worked as a truck driver, Lesley stayed at home. They had been childless for a decade, victims of blocked fallopian tubes that prevented Mrs. Brown from conceiving. Robert Edwards, a reproductive endocrinologist, and Patrick Steptoe, a gynaecologic surgeon, did the first successful IVF procedure and responsible for the birth of Louise. Working together since 1967, Steptoe and Edwards were determined to complete Rock's mission: fertilize an egg outside a women's body and transfer it to uterus. To do so, they realised, would involve at least three components, each medically radical in its own right: they would need to remove the women's eggs at the right time, fertilize them in a medium that could sustain the egg outside the body, and then administer the precise hormones that would convince the woman's body that conception had occurred. Without this chemical conviction, the womb would reject the fertilized egg in what would become essentially a high-tech miscarriage.[62] Between 1967 and 1975 Steptoe and Edwards performed at least eighty in vitro procedures without achieving a single pregnancy. When one woman finally became pregnant in 1975, the pregnancy was ectopic and had to be terminated. The two doctor continued to tinker with their methods, at last arriving at the combination of tactics that produced Louise.[63] Dr. Steptoe harvested a single egg from the ovary of Lesley Brown and placed it in a culture dish. He then placed sperm from the husband, John, into a dish to fertilize the egg. The resulting embryo was transferred into Lesley Brown's uterus, where it implanted and grew. The result was their daughter, Louise Joy Brown. [64]

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[61] *Johnson v. Superior Court*, 80 Cal. App. 4th 1050, 95 Cal. Rptr. 2d 864 (2d Dist. 2000)
[62] Supra note 1 at 25.
[63] Ibid
[64] Supra note 15 at 31.

The technique of IVF that is used today is very similar to that used by doctors Steptoe and Edward. The major difference is that multiple ova, instead of one, are retrieved after a woman undergoes ovarian hyper stimulation. After the eggs are obtained, they are combined with sperm in a laboratory culture dish and placed in an incubator. Three to five days later, the successful embryos are examined under the microscope. Several are selected to be transferred to the woman's uterus. The remaining embryos are frozen for possible future use. [65]

The process of IVF and embryo transfer typically consisting of five main steps:

2.7.2.1. Ovarian Stimulation (super ovulation).

The woman takes ovulation stimulants (fertility drugs) to prompt her ovaries to produce several eggs at once instead of the usual one per month. Standard IVF procedure calls for multiple eggs because often some of them will be defective, and not every embryo may implant or develop properly once transferred to the uterus.

2.7.2.2. Egg Retrieval.

When the eggs are ready, they are extracted from the egg sacs, or follicles, of the ovaries— usually a 30-minute outpatient surgery. In typical egg retrieval, an ultrasound guided needle is inserted into the vagina, through the vaginal wall, and into the ovaries to the egg-bearing follicles. One by one, the eggs are suctioned out through the needle.

2.7.2.3. Intracytoplasmic Sperm Injection (ICSI)

Sometimes the chances of fertilization are greatly increased by a technique known as intracytoplasmic sperm injection (ICSI), in which an egg is pierced and a single sperm cell is injected into it. ICSI is most often used, in conjunction with IVF, for couples in which the male has a very low sperm count. The American Society for Reproductive medicine (ASRM) stated, "ICSI, a form of micromanipulation, involves the injection of a single sperm directly into the cytoplasm of a mature egg using a glass needle. This process increases the likelihood of fertilization when there are abnormalities in the number, quality, or function of the sperm."[66]

2.7.2.4. Embryo Culture.

After fertilization, the embryos are left to grow in a culture medium. Within 48 hours each one consists of 2 to 4 cells; in three days, 6 to 10 cells. Around the third

[65] Ibid.
[66] Id at 32.

day, fertility experts can screen the embryos for genetic diseases using a technique known as preimplantation genetic diagnosis (PGD). Only embryos found to be free of defective genes are selected to be transferred to the uterus.

2.7.2.5. Embryo Transfer.

Delivery of embryos to the uterus is generally painless and is performed in the doctor's office up to six days after egg retrieval. To increase the chances of pregnancy, two or more embryos are usually transferred at once. The embryos, along with the fluid surrounding them, are placed in a long, straw like tube called a transfer catheter. Then the catheter is eased into the vagina and through the cervix, and the embryos are pushed from the tube into the uterus. If all goes well, an embryo implants in the uterine lining.

IVF is also used for infertility caused by endometriosis or male factor infertility. It is sometimes used to treat couples with long-term unexplained infertility who are unable to conceive with other infertility treatments. The woman is given hormones, which stimulate her ovaries up to 30 or more oocyte (ova). These are retrieved by inserting a needle into the ovaries via the vagina with ultrasound guidance. These oocytes are mixed with sperm. The sperm is obtained by masturbation and is usually donated by the husband. If the husband is infertile, however, the sperm may be obtained from another man. If the woman is infertile, similarly, the oocyte may be obtained from another woman whose ovaries have been similarly stimulated. The embryos thus conceived are usually allowed to grow up to the four-to-eight stage over 3 to 4 days, at which time some of the embryos are implanted in the woman's uterus.

The *Warnock* Committee explained the process of in vitro fertilisation in the following terms:

> "The concept of IVF is simple. A ripe human egg is extracted from the ovary, shortly before it would have been released naturally. Next, the egg is mixed with the Semen of the husband or partner, so that fertilisation can occur. The fertilised egg, once it has started to divide, is then transferred back to the mother's uterus. In practice the technique for recovery of the eggs, their culture outside the mother's body, and the transfer of 'the developing embryo to the uterus has to be carried out under very carefully controlled conditions. The development of laparoscopic techniques during the 1960s made the collection of the egg, in cases where the ovaries were accessible, relatively easy. (Another technique for egg recovery based on ultrasound identification has now been developed.) It was not

> particularly difficult to fertilise the human egg *in vitro.* The real difficulty related to the implantation of the embryo in the uterus after transfer. A pregnancy achieved in this way must not only survive the normal hazards of implantation of in *vivo* conception, but also the additional problems of IVF and embryo transfer. More is now known about how best to replicate the natural sequence of events, but undoubtedly achieving a successful implantation is still the most uncertain part of the procedure." [67]

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, technique of IVF consists of bringing about the fertilization of the oocyte and the spermatozoa in the laboratory instead of in the woman's fallopian tube. IVF involves induction of ovulation in order to obtain multiple oocytes, thus making available more embryos with which higher pregnancy rates can be achieved. Serial determination of plasma estradiol levels and daily monitoring of ovarian follicular growth by ultrasonography would indicate the response to ovarian stimulation. At the appropriate moment of follicular growth, the follicles are aspirated to obtain the oocytes. The oocytes are mixed with appropriately capacitated spermatozoa from the husband (or the donor, if the medical condition indicates the use of donor sperm) and kept in an incubator for fertilization which is observed microscopically after 16 to18 hours. Embryos are transferred into the uterine cavity between days 2 and 6 after oocyte aspiration. If implantation ensues, pregnancy can be confirmed by 14 to 16 days after embryo transfer by determining the presence of HCG in a blood or urine sample. Such a test is reliable only when progesterone is used for luteal supplementation instead of HCG. The success rate of IVF is approximately one in every 4-5 women. IVF is the therapeutic option of reproductive medicine with the highest yield per attempt, coming close on many occasions to that achieved by fertile couples conceiving naturally.[68]

IVF cycles pose health risks for both woman and child. For the woman, the physical demands of the IVF process-the surgery, the monitoring, the waiting-can be uncomfortable, inconvenient, and stressful. The surgery itself comes with a risk, however low, of side effects such as bleeding, infection, and damaged tissue. There is also a chance of complications from taking the fertility drugs that instigate super ovulation, including abdominal pain, memory loss, mood swings, and headaches. The

[67] Supra note 54, para 5.2.
[68] Supra note 56, section 1.6.4.

most worrisome among these is a rare but potentially dangerous condition known as ovarian hyper stimulation syndrome, characterized by swollen and painful ovaries. Multiple pregnancies-caused mainly by transferring several embryos at once-increase the chances of high blood pressure, anemia, gestational diabetes, and uterine rupture. For the child, there are concerns that ART techniques may lead to birth defects, low birth weight, and diseases such as cancer.

Multiple pregnancies- a common result of IVF cycles- dramatically raise the risks to children's life and health. The chances of prenatal and postnatal death are higher than for single pregnancies, and premature birth is much more likely. Prematurity increases the risk of cerebral palsy, blindness, heart defects, serious infection, respiratory distress syndrome, and other grave maladies. Even aside from prematurity, babies born after a multiple pregnancy have an elevated risk of birth defects and low birth weight, the latter being a separate risk factor for many diseases. One way that practitioners try to lower the risks of multiple pregnancy is to use fetal reduction (also known as selective abortion) to eliminate some of the fetuses in uterus. But the procedure itself carries with it a risk of miscarriage.[69]

Several issues- technological and ethical- arise from the handling of the unused embryos that inevitably result from IVF. The common practice is to freeze, or cryopreserve the extra embryos for possible transfer in the future. Fertility clinics freeze thousands of embryos every year, and hundreds of thousands of them are now in cryostorage. Freezing a woman's left over embryos give her the option of using them in future IVF cycles rather than going through another arduous (and expensive) round of ovarian stimulation and egg retrieval. By having her embryos frozen, she can also select the timing of embryo transfer to avoid causing or aggravating any health problems in pregnancy. A significant drawback to the process is that cryopreserved embryos are less likely to result in live births than unfrozen embryos are. Another is that many embryos do not live through freezing and thawing. Frozen embryos can remain in cryostorage for years- because the couple divorces, because one or both of them die, because they disagree about what to do with the embryos (for example, if one wants to donate them but the other does not),or because they have changed their minds about getting pregnant. The moral and legal implications of these possibilities are being debated now.

[69] Supra note 48.

One alternative is to donate the unused embryos to an infertile couple, which means that the prospective parents will have no genetic connection to the child born to them. Such an arrangement seems unproblematic to some people but is morally or legally questionable to others. Without legal guidance and ethical consensus, fertility clinics must decide what to do with frozen embryos that are unused, unclaimed, or undonated. Often they either donate the embryos for research or destroy them. To those who believe that embryos have a right to life, both of these options are morally impermissible. But even people who don't believe that embryos are persons may think that embryonic life should not be treated as if it has no moral worth at all.[70] IVF cycles pose health risks for both woman and child. For the woman, the physical demands of the IVF process-the surgery, the monitoring, the waiting-can be uncomfortable, inconvenient, and stressful.

Since the procedure is so expensive, more embryos than required are fertilized in the lab so that if none of the fertilized eggs are successfully implanted, preimplantation can be done without much additional cost and time. The spare embryos are frozen, discarded, donated or used for experimentation. Freezing is an expensive procedure, it can also kill some of them. These embryos are human lives that, given a chance, would develop into a man or a woman. If they are used for experiment action, it can be fatal for them .Since some religions believe that life begins at conception, it may amount to abortion which is contrary to both law and ethics. Using them for expert indentation is also not permissible as science cannot experiment with someone with basic human rights without prior permission. Donation involves separation of the biological and social roles of parenthood that is significant part of family concept and is equivalent to adoption before birth thereby calling for amendments in adoption laws of most of the countries.

2.7.3. Cryopreservation

Cryopreservation refers to the storage of a living organism at ultra- low-temperature such that it can be revived and restored to the same living state as before it was stored. Indefinitely long storage times require that the organism be maintained below the glass transformation temperature of aqueous solutions, approximately -130degC, and the temperature at which frozen water no longer sublimes and

[70] Ibid.

recrystallizes. Although ultra-cold freezers may stabilize some living cells for weeks or even years, liquid nitrogen is required for longer storage times.[71]

Cryobanks for human semen were first proposed in 1866, but it was not until 1953 that a successful and practical cryopreservation (freezing) technique was introduced. The establishment of the first semen bank in the United States was based primarily on the expectation that millions of men would elect to store their semen prior to undergoing vasectomies for fertility insurance, an expectation largely unrealized to date. Current cryobanking includes timed multiple inseminations for AIH and AID, storage pooling, concentration of sperm for AIH, retention of fertilizing capacity in absence, death, or hazard exposure of the husband. Embryo freezing is offered as a service to IVF patients as part of their in vitro fertilization treatment cycle and is offered for three reasons:

1. To reduce the expense, time, and physical discomfort associated with repeated IVF treatment cycles. Embryos from a treatment cycle, which were not transferred, can be frozen for later use.

2. To reduce the risk of multiple pregnancies by transferring a limited number of embryos at a woman's first in vitro fertilization transfer (ET) and freezing the remaining embryos.

3. To take full advantage of all eggs available during the woman's first egg recovery by attempting to fertilize all available eggs.

The first pregnancy from a frozen/thawed human embryo was reported in 1983, and a birth from this source occurred the following year. Of 99,629 cases of Assisted Reproductive Technology in the United States in 2000, about 16% of cases (16,194) used frozen/thawed embryos. In 2000, live birth rates per thaw cycle were 18.3% versus 26.6% from fresh embryo transfer. At GRS, the ongoing pregnancy rate for IVF using frozen/thawed embryos is currently 52%.[72]

Egg retrieval under ultrasound guidance and subsequent fertilization and embryo culture are carried out according to our current procedures. If there happens to be a surplus of embryos following selection for fresh transfer (usually between one to four embryos are transferred to the uterus), then embryos of sufficient quality may be considered for cryostorage. While embryos can be frozen at any preimplantation stage

[71] Jerry J. Brand, "Cryopreservation of Cyanobacteria" , available at *http://wwwcyanosite.bio.purdue.edu/protocols/cryo.html* visited on 13/8/2012 at 2*:38 pm*

[72] Available at *http://www.ivf.com/cryo.htmlvisited on* 24 March 2012.

between one-cell (one day old) to the blastocyst stage (5-6 days old), in an attempt to minimize the freezing of excessive numbers of "spare" embryos and to help pre-select the most potentially viable embryos, we generally choose to cryopreserve only at the blastocyst stage. In certain cases where all embryos need to be frozen without a fresh transfer (e.g., when a woman may be at risk from ovarian hyper stimulation that might be complicated by pregnancy), we generally freeze all embryos the day after egg collection at the one-cell stage.[73]

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, facilities for cryopreservation are an essential component of an ART clinic as they are to be used under a variety of conditions such as those described below. Men, who are likely to suffer from psychological stress at the time of ovum pick-up or those who cannot be present at the time of ovum pick-up, are recommended to have their semen frozen for use at the appropriate time. One of the important reasons for freezing semen from donors is that any donor semen has to be quarantined for six months. The safety of using frozen sperm has been abundantly proven, both by experimental work and the actual results in humans. Matters of concern are the donor's health and the necessity to avoid donors who are infected with venereal diseases, hepatitis B or C, or HIV. One of the drawbacks of sperm freezing is an approximate 20% loss in motility after thawing. Donors whose semen is frozen for future use are required to report to the semen bank six months after donation to be checked for HIV, HBV or HCV infection/disease status.[74]

2.7.3.1. Freezing Embryos

Embryos are routinely cryopreserved to enable storage of supernumerary embryos, as upto a maximum of only three embryos is allowed for transfer to avoid the risk of multiple pregnancies. Embryo freezing is a widespread routine procedure to increase cumulative pregnancy rates.

Human embryos can be successfully cryopreserved at any stage from zygote to blastocyst, using 1, 2 propanediol (PROH) or dimethylsulfoxide (DMSO) for zygotes and cleaved embryos and glycerol for blastocysts. The formation of ice crystals is of concern during embryo freezing. Using programmed, slow freezers

[73] Ibid
[74] Supra note 56 at section 1.6.8.

reduces this problem considerably, and slow cooling is the most widely employed method. Human embryos are known to survive a simple ultra-rapid procedure of fast cooling but there is not much data on the efficacy of these techniques when used routinely. Straws or ampoules used for freezing embryos should be carefully and permanently labeled for identification purpose. Patients should be fully informed before the treatment cycle on the procedure of cryopreservation, the risks and, particularly, what is to be done with their embryos if they do not use them. They should sign a consent form concerning the agreement for embryo freezing as well as for the future use of the embryos. When a serum supplementation is used in the preparation of freezing and thawing solutions, one must carefully avoid any risk of viral transmission to the embryo through the serum.[75]

2.7.3.2. Oocyte Cryopreservation

This procedure has been successfully used in cases where a large number of immature oocytes have been retrieved during ovum-pick-up. The oocyte can be thawed at a later date, matured in vitro and used for oocyte donation or similar procedures either on the person from whom the oocytes were retrieved or on other prospective recipients. However, the success rates in terms of fertilization, pregnancy and live births with the use of cryopreserved oocytes are not very encouraging. Much remains to be learnt on identifying the optimal stage of oocyte development when cryopreservation would be of value.[76]

2.7.3.3. In Vitro Culture Media

There has been a spurt of new media introduced for in vitro culture of gametes and embryos. If one takes a close look at these media, they are products that have evolved over the years. However, some manufacturers do not give the exact composition of their media but merely state that for reasons of patent protection or as trade secret they are constrained to give full details of the composition of their media.

This is an undesirable situation. Infertility clinics that deal with human embryos and the future life of the products they create in the laboratory must be privy to the knowledge about the media they use, if need be by signing an appropriate confidentiality agreement which would prohibit the clinic from using or passing on

[75] Id
[76] Supra note 56 at section 1.6.8.3.

the proprietary information provided by the manufactures of the media to any other organization that may commercially exploit this information.

2.7.4. Gamete Intrafallopian Transfer (GIFT)

The procedure is most often recommended for couples with unexplained infertility with the female partner having at least one open fallopian tube. It may also be recommended for patients whose infertility is due to cervical or immunological factors, mild endometriosis, or selected cases of male infertility. GIFT is considered a variation of in vitro fertilization (IVF), with one significant difference. With the GIFT procedure, fertilization is intended to occur naturally within the woman's body instead of in a laboratory. For this reason, GIFT is sometimes described as an alternative for patients whose religious beliefs prohibit conception outside the body.[77]

GIFT involves three steps. The first step is ovarian stimulation and monitoring. Medications are used to stimulate the woman to produce more than one follicle and ovum and to aid in stimulating the follicles to release the ova. During this time, the woman's response to the medication and the development of her ova are watched and assessed. The second stage begins with a laparoscopy performed under general anesthesia to retrieve the ova. The ova are then examined under a microscope to determine maturity. Semen is obtained and processed in a centrifuge, where it is washed and then placed in a test tube so that the active sperm can swim to the top. The third step consists in transfer of the ova and sperm into the woman's body. Ova and sperm are placed in a catheter, and the catheter is inserted directly into the woman's fallopian tube through a surgical procedure using a laparoscope. The ova and sperm are then injected into the fallopian tube with the intent of fertilization occurring in its normal environment within the woman's body. If fertilization does occur, the developing embryo(s) will remain in the fallopian tube and then move to the uterus for implantation.

2.7.5. Intra-cytoplasmic Sperm Injection (ICSI) & Sub Zonal Insemination (SUZI)

Intracytoplasmic sperm injection (ICSI) is a form of ART involving the injection of a single sperm into the cytoplasm of an oocyte to achieve fertilization. It is indicated for the treatment of couples with male factor infertility and those with

[77] C. Kindregan, Jr, "Thinking About the Law of Assisted Reproductive Technology", 27, *Wisconsin Journal of Family Law* (2007), at 128

poor fertilization with conventional IVF, although some have recommended its broad use as first-line ART treatment. ICSI is the only treatment option for couples with severe male factor infertility. It can be performed with ejaculated or surgically retrieved sperm. In this method procedure is same way as IVF in which oocytes are examined after 16 hours for fertilization, and viable embryos are transferred to the women uterus after 1 to 3 days later. ICSI particularly useful where the sperm cannot naturally penetrate the egg or where it is of poor mobility.

2.7.6. Collaborative Reproduction (Third Party Reproduction)

The term 'collaborative reproduction' is used to describe situations in which a third party (who will have no parenting role once the child is born) assists in the production of child.[78] It refers to reproductive procedures using sperm donation, egg donation, and surrogacy.

2.7.6.1. Egg/Gemete Donation

Women may donate their oocytes to enable another woman to have a child. The oocyte donor normally undergoes a cycle of controlled ovarian hyperstimulation, then, following collection of the oocytes, donates the oocytes to a recipient – normally for fertilization by the sperm of the recipient's partner and replacement of the resulting embryo in the uterus of the recipient. This may be performed either when the recipient has no oocytes of her own – due to age, premature menopause or treatment with chemotherapy – or where the recipient's own oocytes have proved to be unsatisfactory for treatment with IVF.[79]

This procedure may help those women who cannot themselves produce an egg. It may also help those who would be candidates for IVF except that in their case egg collection is impossible because their ovaries are inaccessible. About 5% of infertile couples might benefit from this technique. A mature egg is recovered from a fertile woman donor, for example during sterilization, and is fertilized *in-vitro,* using the semen of the husband of the infertile woman. The resulting embryo is then transferred to the patient's uterus. If it implants she may then carry the pregnancy to term. There are other situations where eggs might be donated. When a woman is

[78] M. Stauch, K. Wheat and J. Tingle, *Text, Cases and Materials on Medical law*, (Routledge Cavendish), at 374.

[79] Peter Edward Grinion, "*A phenomenological study into infertility and the assisted reproductive technologies: U.S.A. and Jamaica compared",* (2006) available on file:///C:/Users/HP/Downloads/Grinion_Peter_Edward_2007.pdf visited on 19.12.2014 at 4:03 p.m. . .

herself undergoing infertility treatment and several eggs have been recovered from her, she may be prepared to donate one or more eggs to another woman whose infertility can be treated only by egg donation.[80]

There are many complex ethical issues associated with the use of donated oocytes, particularly the need for free and properly informed consent on the part of the donor as well as the use of donated oocytes in women at advanced age.

2.7.6.2 **Sperm Donation**

Men may donate their sperm for use by another man to achieve a pregnancy in his partner. Donated sperm may be used in cases where no usable sperm can be obtained from the testis or the couple may choose to have artificial insemination with donated sperm in preference to subjecting the female partner to controlled ovarian hyper stimulation and oocyte recovery. Donated sperm may also be used to achieve a pregnancy in women without a male partner.

2.7.6.3 Embryo Donation

Warnock Committee explains the term as follows:

Embryo donation would help the same groups of women who might benefit from egg donation and, more particularly, the even smaller number whose husbands are also infertile. Embryo donation may take two forms. One involves the donation of both egg and semen. The donated egg is fertilised in *vitro* with donated semen and the resulting embryo transferred to a woman who is unable to produce an egg herself and whose husband is infertile. The second method, known as lavage, does not involve removing the egg by surgical intervention. Instead the egg is released naturally from the ovary at the normal time in the donor's menstrual cycle. At the predicted time of ovulation she is artificially inseminated with semen from the husband of the infertile woman (or from a donor if the husband is also infertile). Some three to four days later, before the start of implantation, the donor's uterus is "washed out" and any embryo retrieved is then transferred to the uterus of the infertile woman. If the embryo implants successfully the recipient carries the pregnancy to term. Embryo donation by lavage is, according to its advocates, much safer for the donor as it does not require general anaesthesia, and a simple and safer procedure is involved; moreover, for the embryo, there is the advantage of a shorter interval *in vitro* during which time it might

[80] Supra note 54.

deteriorate. When semen from the husband is used, the child is genetically his though not his wife's.[81]

According to National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, 2005, oocyte donation would necessitate using the husband's semen for fertilization and transferring the resultant embryo to the infertile female partner. Embryo donation would obviate the necessity of using the husband's semen. The choice of oocytes and embryos for oocyte or embryo donation would depend entirely on the circumstances prevalent at the time the infertile couple comes for treatment, and the access of the infertility clinic to frozen oocytes or embryos.[82]

Donors should be healthy (as determined by medical and psychological examination, screening for STDs, and absence of HIV antibodies) women in the age group of 18-35 years. Oocytes may be obtained for donation, mostly by surgical intervention from women participating in an IVF program, or those undergoing elective sterilization or surgery. The recipient should be a healthy woman (determined by medical and psychological examination) having normal genitalia (as determined by physical examination) and uterine cavity (as determined by hysterosalpingography). In case of OD, the semen characteristics of the husband must be determined to see if they are in conformity with those associated with normal fertility. The blood group of the donor should be noted; the donor should also be tested for antibodies to rubella, HIV, hepatitis, CMV, gonorrhea, syphilis, chlamydia, mycoplasma and trichomonas.[83]

Ovum/embryo donation can be carried out in menopausal women with no surviving child and desiring to have a child. The endometrium of menopausal women has the ability to respond to sex hormones and provide a receptive environment for the implantation of an embryo. Various protocols are now available to prepare the endometrium of the recipient for OD or ED with estrogens and progestogens until the placenta takes over the function of maintaining the gestation.[84]

[81] Supra note 54.
[82] Id section 1.6.7.
[83] Supra note 56 at section 1.6.7.1.
[84] Ibid.

2.7.6.2. Surrogacy[85]

The word "surrogate" derives from the Latin word "subrogate", which means "appointed to act in the place of". Surrogacy is defined as one woman, referred to as the mother, having intercourse or medical treatment in order to achieve pregnancy for the purpose of another woman. Surrogacy was defined in the Warnock Report as "the practice whereby one woman carries a child for another with the intention that the child should be handed over after birth.[86] It went on to say, ' The use of artificial insemination and the recent development of in vitro fertilisation have eliminated the necessity for sexual intercourse in order to establish a surrogate pregnancy.'[87] The Courts also performed their unique job in defining the term surrogacy. [88] In English law, the only statutory definition of surrogacy is contained in the Surrogacy Arrangement Act, 1985.[89]

Law Commission of India in its 228th report[90] defines surrogacy as:

"The word 'surrogate' has its origin in Latin 'surrogates', past participle of 'surrogate', meaning a substitute, that is, a person appointed to act in the place of another. Thus a surrogate mother is a woman who bears a child on behalf of another woman, either from her own egg or from the implantation in her womb of a fertilized egg from other woman."

Assisted Reproductive Technology (Regulation) Bill, 2010[91] defines surrogacy

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[85] In Oxford English Dictionary the term surrogate defined as "*A person appointed by authority to act in place of another, a deputy, A person or thing taking the place of another, a substitute."* , Oxford English Dictionary, Page no.3123, volume 2., In Encyclopedia Americana the word 'Surrogate' means,*"A person appointed to act in place of another."*Encyclopedia Americana, Page no.70, volume 26., According to the Black's Law Dictionary: surrogacy means*"the process of carrying and delivering a child for another person."* Black's Law Dictionary, P.9.

[86] Supra note 54, para 8.1.

[87] ibid

[88] "Surrogacy is a well known method of reproduction whereby a woman agrees to become pregnant for the purpose of gestating and giving birth to a child she will not raise but hand over to a contracted party. She may be the child's genetic mother (the more traditional form for surrogacy) or she may be, as a gestational carrier, carry the pregnancy to delivery after having been implanted with an embryo. In some cases surrogacy is the only available option for parents who wish to have a child that is biologically related to them.", *Manji Yamada v. Union of India and Anr*. (2008), 13 SCC 518.

[89] Section 1(2) of the Act says: A surrogate mother means a women who carries a child in pursuance of an arrangement: a. Made before she began to carry the child; and b. Made with a view to any child carried in pursuance of it being handed over to, and the parental right being exercised (so far as practicable) by, another person or other persons.

Section 1(3) of the Act defines surrogacy arrangement as:, An arrangement is a surrogacy arrangement if, were a women to whom the arrangement relates to carry a child in pursuance of it, she would be a surrogate mother.

[90] Submitted on 5 august 2009

[91] Assisted Reproductive Technology (Regulation) Bill, 2008, Sec.2(t)

as follows "surrogacy", means an arrangement in which a woman agrees to a pregnancy, achieved through assisted reproductive technology, in which neither of the gametes belong to her or her husband, with the intention to carry it to term and hand over the child to the person or persons for whom she is acting as a surrogate*;*

Surrogacy is not so new as far as assisted reproductive technologies are concerned, and it is often noted that the practice dates back to Biblical times. The Old Testament gives the example of Abraham's infertile wife, Sarah, who "commissions" her maid Hagar to bear her a child by persuading Abraham to sleep with her. Another example in the book of Genesis is Rachel, who is infertile, commands her husband to consort with her maid, "Behold my maid, Bilhah," she cries, "Go in unto her, and that she may bear upon my knees, and I also obtain children by her." , Bilhah gives birth to two sons whom Rachel names and considers her children. This is the earliest biblical example of what could be called surrogate mothers. Hindu mythology also gives instances of surrogacy and reflects the secrecy that still surrounds surrogacy practice. In the Bhagvata Purana, Vishnu heard Vasudev's prayers beseeching Kansa not to kill all sons being born. Vishnu heard these prayers and had an embryo from Devaki's womb transferred to the womb of Rohini, another wife of Vasudev. Rohini gave birth to the baby, Balaram, brother of Krishna, and secretly raised the child while Vasudev and Devaki told Kansa the child was born dead.[92]

In Biblical surrogacy, therefore, as in many contemporary surrogacy arrangements, the child was genetically related to the father who would raise him. The birth mother, by contrast, was neither a pure volunteer nor a paid provider. She was a servant in most cases, or sometimes a second wife or concubine of the father. [93] Another form of surrogacy arose in the Middle Ages, when wealthy women regularly turned their newborns over to wet nurses: nursing mothers who, for a fee, would assume the care and feeding of an additional child. Typically, child would live with the wet nurse during the first five year of life, with the natural mother making only occasional visits. In many respects, this relationship is the closest antecedent to modern day commercial surrogacy. The surrogate generally has no long-term

[92] Usha Rengachary Smerdon, "Crossing Bodies, Crossing Borders: International surrogacy between the United States and India", available at *http://www.surrogacyaustralia.org/download/researchCenter/legislationRegulation/Smerdon%202009%20Crossing%20Bodies,%20Crossing%20Borders%20Internat%20Surrogacy%20betwn%20the%20US%20and%20India.pdf* visited on 7 October 2012.

[93] Supra note 1 at 73

involvement with the child; she is employed for a specific task and paid a nontrivial fee. [94]

In the later decade of the twentieth century, though, surrogacy underwent a significant revival. In the past, the only way for surrogate mothers to produce children was to engage in sexual relations with the prospective father- a messy business under any circumstances and the one that held little appeal for the wives of the husband involved. With artificial insemination however, conception was removed from sex, making it possible for a man to impregnate a surrogate without even necessarily meeting her. Artificial insemination also made surrogacy more feasible, allowing infertile couples to procure sperm and eggs outside, unrelated sources.[95] By the mid 1980s, new technology for conception had supplanted the traditional model of surrogacy, creating a substitute with far greater commercial potential. This substitute of course was gestational surrogacy. [96]

A woman may opt for gestational surrogacy because she has an abnormal uterus or no uterus (because of hysterectomy or congenital defect) or because she suffers from health problems that make pregnancy dangerous, such as cystic fibrosis and serious forms of diabetes and heart disease. A couple may turn to a traditional surrogate for many of the same reasons. In both kinds of surrogacy, the intended parents generally want more than just a child— they want a biologically related child. For them, then, adoption may be less attractive.[97] The different types of surrogacy are discussed as follows:-

2.7.6.2.1. Traditional Surrogacy

The birth mother is both the "gestational" surrogate and the biological mother (contributed the genetic material-the ovum). Like a gestational surrogate she is selling her reproductive labour, that is, renting her womb out for a fee. In contrast to gestational surrogates she has a genetic tie to the child she is carrying. In traditional surrogacy, the surrogate mother is artificially inseminated with the sperm of the intended father or sperm donor. The surrogate's own egg will be used, thus she will be the genetic mother of the resulting child.[98] What made the traditional surrogacy

[94] Ibid
[95] Id at 75
[96] Id at 78
[97] Supra note 48.
[98] Supra note 92.

complicated was the surrogate mother was also the genetic mother of the child she bore. Like Rachel's maid, the surrogate was indeed giving her child to another woman, who has no genetic tie to the child.

2.7.6.2.2. Gestational Surrogacy

This is the most common form of commercial surrogacy today. A woman who gestates a fetus (allow herself to be impregnated and carries the pregnancy to term) but has no genetic tie to the child she births. She is not the intended parent but is a paid labourer working on a nine-month commercial contract. There is an embryo transfer and she carries a child of which she is not the biological mother.[99] Eggs are extracted from the intended mother or egg donor and mixed with sperm from the intended father or sperm donor in vitro. The embryos are then transferred into the surrogate's uterus. Embryos which are not transferred may be frozen and used for transfer at a later time if the first transfer does not result in pregnancy.[100]

2.7.6.2.2 **Altruistic Surrogacy**

It is a kind of surrogacy in which surrogate receives no financial reward for her pregnancy although usually all expenses such as medical expenses, maternity clothing, and other related expenses related to the pregnancy and birth are paid by the intended parents.[101]

2.7.6.2.3. Commercial Surrogacy

Commercial surrogacy[102] is a form of surrogacy in which a gestational carrier is paid to carry a child to maturity in her womb and is usually resorted to by higher income infertile couples who can afford the cost involved or people who save and borrow in order to complete their dream of being parents. This procedure is legal in several countries including in India where due to high international demand and easy availability of poor surrogates it is reaching to a level of industry. For the society, commercial surrogacy is questionable because it defines a baby as a commodity, up for sale at the prevailing market price. It is a form of surrogacy in which surrogates are paid for carrying a child to maturity in her womb and is usually resorted to by

[99] Supra note 28 at 11
[100] Ibid.
[101] Available at *http://www.indianchild.com/surrogate_mothering.htm*, visited on 13 march 2011.
[102] Also known as Compensated Surrogacy or Paid Surrogacy or Womb for Rent or Out soured Pregnancies or Baby Farms).

higher income infertile couples or people who save and borrow in order to complete their dream of being parents. [103]

Surrogacy has received more adverse criticism than any of the other 'new' reproductive technology. The true incidence of surrogacy is unknown, though it seems likely that the amount of emotion expended upon it is out of all proportion to the extent to which people would and do resort to it in order to have children. But surrogacy, together with abortion, raises in perhaps starkest form the questions of the extent to which women should be free to exploit and control their reproductive capacity, even when they have no wish to raise a child themselves, and the degree to which other should be able to call upon that reproductive capacity to fulfil their own needs.[104]

Some confusion surrounds the definition of surrogate arrangements. The carrying women may or may not be the genetic mother. In partial surrogacy she provides the ovum, and the commissioning father provides sperm. But in full surrogacy (also called as renting the womb) the commissioning mother provides the ovum, which is fertilised in vitro with her husband's sperm, then gestated in the surrogate's uterus. Here carrying woman is not genetically related to the child she carries. The Warnock Committee noted that surrogacy could theoretically be used for 'convenience', where the commissioning mother is physically able to bear a child, but wishes to avoid doing so, perhaps in order not to interrupt her career, or not to affect her appearance. Surrogacy could also be utilised by lesbian women, and by single men and male homosexuals who want to bring up children.[105]

Third party reproduction, and specially surrogacy, is the most controversial issue in ART. Because, both the sperm and egg donors are paid, and surrogates may receive a considerable amount of money. Many feel that third party reproduction smacks of "baby buying".[106] Defenders of surrogacy deny that it constitutes baby-selling, claiming instead that a surrogate is simply relinquishing her right as a parent to have a relationship with the child.

[103] Supra note 101.
[104] Supra note 78 at 389
[105] Id at 390
[106] Supra note 15 at 45.

2.7.7 **Posthumous Procreation**

Posthumous conception has been defined as the beginning of human gestational process after the death of one or both biological parents. Posthumous births have been recognized since antiquity when a husband or male partner died from illness, from accident, or in war after conception and pregnancy had been achieved, but before the resulting birth has occurred. Legally and socially, the ensuing child has been usually considered the rightful heir of the deceased father.

Posthumous reproduction, on the other hand, became possible only after semen could be frozen and used for artificial insemination after the donor was deceased. The legal and social status of a child born from these origins has been ambiguous, even if the insemination and pregnancy occur with the wife of the dead man. With the advent of assisted reproduction, insemination with a dead husband's sperm might be requested by the widow to achieve a pregnancy and bear a child even if her husband died before. This could be achieved by traditional conception, and they had the foresight to collect and freeze a semen sample before death. Alternatively, requests have been made to collect sperm from the terminally ill or newly deceased male for the same purpose. Such techniques as stimulated ejaculation, Microsurgical Epididymal Sperm Aspiration (MESA), or testicular sperm extraction (TSE) might be employed. In addition, specimens frozen and stored in a sperm bank for donation under usual circumstances might be used for anonymous insemination after the donor has died, in which case issues of assigning legitimacy and inheritance are different than in a husband–wife relationship. In some of the above illustrations, the technology may involve only the cryopreservation of the sperm and insemination, but the social issues are complex. The advent of in vitro fertilization and the potential for cryopreservation of ova may extend the options for posthumous reproduction to the use of the cryopreserved ovum, much as for using sperm for posthumous conception, but with the added requirement of a "surrogate" uterus for gestation to achieve a pregnancy. There is an option to obtain and store undamaged sperm from men who undergo radiation or chemotherapy for cancer, should they wish to have children in the future, and it is possible that this will be available in the future for the protection of ova as well. In the event that the man does not recover from his cancer, his germ cells would be stored and available for posthumous reproduction should his partner request this.

In contrast to the ancient phenomenon of posthumous birth, the recent possibility of posthumous reproduction raises more ethical, practical, and legal questions for physicians practicing reproductive medicine and the public concerning the interests and rights of the donor(s), the gestating woman, the prospective rearing parent(s), and any children that may result.[107]

Section 28(6) (b) of the HFEA 1990 provided that, where sperm was used after a man's death, the man was not to be treated as the father of the child. In 1993, a California appellate court permits the deceased's girlfriend to use semen that he had willed to her.[108] In 2004, a federal appellate court ruled that twins conceived from frozen semen after their father's death was eligible for Social Security.[109]

2.7.7. Cloning

Reproductive cloning is also a kind of ART but presently it is illegal. Cloning is the process of making a genetically identical organism through nonsexual means. It has been used for many years to produce plants. Animal cloning has been the subject of scientific experiments for years, but garnered little attention until the birth of the first cloned mammal in 1997, a sheep named Dolly. Since Dolly, several scientists have cloned other animals, including cows and mice. The recent success in cloning animals has sparked fierce debates among scientists, politicians and the general public about the use and morality of cloning plants, animals and possibly humans.

Cloning is the creation of almost genetically identical organisms. For ordinary purposes, clones can be treated as genetically identical to the organisms from which the nuclear DNA is taken. In fact there is a small difference, because the egg also contains a small amount of DNA in mitochondria, small bodies in the main part of the egg. Like organisms produced by sexual reproduction, the clone inherits this DNA only from its mother, not from the nucleus donor.[110]

2.7.7.1. Reproductive Cloning

Reproductive cloning is the production of a genetic duplicate of an existing organism. A human clone would be a genetic copy of an existing person. Somatic cell

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[107] "Posthumous reproduction, The Ethics Committee of the American Society for Reproductive Medicine , Fertility and Sterility", Vol. 82, Suppl. 1, September (2004), available at *http://www.asrm.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/posthumous.pdf* visited on 3/9/2012 at 4: 43 P.M.

[108] Hecht v. Superior Court, 16 Cal. App. 4th 836, 20 Cal. Rptr.2d 275 (2d Dist. 1993)

[109] Gillett-Netting v.Barnhart,371 F.3d 593 (9th Cir. 2004).

[110] "Reproductive Cloning: Ethical and Social Issues", available at *http://www.hgalert.org/topics/cloning/cloning* visited on 11 April 2011.

nuclear transfer (SCNT) is the most common cloning technique. SCNT involves putting the nucleus of a body cell into an egg from which the nucleus has been removed. This produces a clonal embryo, which is triggered to begin developing with chemicals or electricity. Placing this cloned embryo into the uterus of a female animal and bringing it to term creates a clone, with genes identical to those of the animal from which the original body cell was taken.[111]

2.7.7.2. Therapeutic Cloning

Therapeutic cloning is cloning which is performed for the purpose of medical treatment. For example, it could theoretically be used to grow a replacement organ, to generate skin for a burn victim, or to create nerve cells for someone suffering from brain damage or a neurological condition. Therapeutic cloning is closely related to reproductive cloning, in which a copy of an organism is produced, but the two have very different end goals.

Formally, this type of cloning is called somatic cell nuclear transfer. It involves extracting the nucleus of a cell, and putting the nucleus into an egg which has been denucleated. Then, the egg is allowed to divide and grow. In therapeutic cloning, the growing egg is used as a source of stem cells, which are undifferentiated cells which can grow into a wide variety of different types of cells. In reproductive cloning, the egg is allowed to grow into a baby.[112]

In UK, The Human Fertilization and Embryology Act 2008, permit the licensing of some form of human cloning, but only for the purpose of research. India allows experimentation with stem cell research. In India medical termination of pregnancy is permitted under the MTP Act of 1971.[113] The resulting fetal tissues that are freely available from the MTP Clinics and hospitals can be utilized for research purposes. Termination of pregnancy for obtaining fetus for stem cell research or for transplantation is not permitted. The main source of embryonic cells will be from the ART/IVF clinics dealing with the infertility treatment where spare or supernumery embryos will be available for the purposes. However, no embryos can be created for the sole purpose of obtaining stem cells.

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[111] Supra note 24.

[112] *"What is Therapeutic Cloning?" Available at http://www.wisegeek.com/what-is-therapeutic-cloning.htm*, visited on 11 April 2011.

[113] Medical Termination of Pregnancy Act, 1971 (Act No. 34 of 1971).

Institutional ethics committee should keep in view the ethical, legal and social issues and should adhere to the "Ethical Guidelines for biomedical research on human subjects" issued by the Indian Council of Medical Research (ICMR) in October 2000.[114] In India, only the research programmes and not the therapeutic transplantations are permitted at present.

2.7.8. In Vitro Maturation (IVM)

This is a new form of treatment which has only been used occasionally in England. In vitro maturation (IVM) was first developed in the early 1990's to provide a safer and cheaper alternative to in vitro fertilization (IVF). With in vitro maturation (IVM) eggs are removed from the ovaries and are collected when they are still immature. They are then matured in the laboratory before being fertilised. The difference between IVM and conventional *in-vitro* fertilization (IVF) is that the eggs are immature when they are collected. This means that the woman does not need to take as many drugs before the eggs can be collected as she might if using conventional IVF, when mature eggs are collected. The procedure for IVM is as follows:

Step 1. As in conventional IVF, eggs are collected, but at an earlier stage, when they are immature. This means that you do not need to take as many ovary-stimulating hormones before your eggs are collected.

Step 2. The eggs are matured in a dish placed in an incubator in the laboratory for one to two days.

Step 3. When the eggs are mature, they are fertilised with your partner's, or donor's sperm. Embryos are cultured then transferred to your womb, just as they would be with conventional IVF treatment. [115]

As with all fertility treatments, IVM is not considered appropriate for all women. Women who typically benefit the most from IVM include:

- Women who are at higher risk for ovarian hyper stimulation syndrome (OHSS), including women with polycystic ovarian syndrome (PCOS).
- Women who are younger and have normal menstrual cycles.

The advantage of IVM is that, it can also be used with regular IVF cycles when the stimulation protocol allows for many immature eggs to be obtained as well.

[114] Ethical Guidelines for Biomedical Research on Human Subjects. *ICMR Bulletin (*2000).

[115]Available at http://www.hfea.gov.uk/fertility-treatment-options-in-vitro-maturation.html visited on 3/9/2012 at 5:03 P.M.

IVM is less expensive because it does not involve costly gonadotropin injections and requires less monitoring. On average, an IVM cycle costs about $5,000 to $7,000 compared to $15,000 to $20,000 for traditional IVF. The disadvantage is, IVM is still relatively new, and the overall success rates and long-term outcomes of IVM are unclear. Because the eggs collected via IVM are extremely sensitive, they need to be handled very carefully in the lab or risk losing them. Also, the outer part of these eggs can become tough for sperm to penetrate making ICSI required. [116]

2.8. Recently Developed Techniques

Preimplantation genetic diagnosis (PGD) and microsorting are the two techniques that allow the sex of a child to be selected, are among the issue most hotly debated.

2.8.1. Preimplantation Genetic Diagnosis (PGD)

Reproductive endocrinologists developed Preimplantation genetic diagnosis in England in the mid-1980. It was initially developed to identify genetic defects in embryo of women undergoing IVF. Preimplantation genetic diagnosis, also called Preimplantation Genetic Testing (PGT), is a procedure used prior to implantation to help identify genetic defects within embryos created through in vitro fertilization to prevent certain diseases or disorders from being passed on to the child. The preimplantation genetic diagnosis begins with the normal process of in vitro fertilization that includes: ovary stimulation through medication, egg retrieval, and fertilization in a laboratory. Over the next three days the embryo will divide into 8 cells. The preimplantation genetic diagnosis involves the following steps:

1. First, a one or two cells are removed from the embryo.
2. Next, DNA is retrieved from the cell and copied through a process known as polymerase chain reaction (PCR).
3. Finally, by molecular analysis, the DNA sequence code is evaluated to determine if the inheritance of a problematic gene is present.

Once the PGD procedure has been performed and embryos free of genetic problems have been identified, implantation will be attempted through embryo transfer, intracytoplasmic sperm injection (ICSI), or zygote intrafallopian transfer

[116] Available at *http://www.fertilityauthority.com/treatment/vitro-maturation-ivm* visited on 3/9/2012 at 5:08 P.M.

(ZIFT).[117] Examples of disorders that can occur because of genetic defects include hemophilia, thalassemia, muscular dystrophy, cystic fibrosis, and Down's syndrome.[118] Infertile couples that use PGD have fewer children with genetic disorders than those who do not use PGD. Nevertheless many people believe that the use of PGD is morally wrong. They believe that life begins when a sperm fertilizes an egg and that discarding genetically defective embryo is a type of murder. Others object to PGD because it allows for gender selection.[119]

2.8.2. Micro Sorting

Microsorting was originally developed to help couples avoid passing sex-linked genetic disorders to their children. A sex-linked genetic disorder is one caused by defective genes attached to either the X chromosome or the Y chromosome. Hemophilia, for instance, is a sex linked blood disorder that mainly affects males and is caused by genetic abnormalities on the Y chromosome.

The ethics committee of the American Society for Reproductive Medicine (ASRM) believes that the nonmedical use of preconception gender selection by microsorting or preimplantation genetic diagnosis should be reserved for families who already have at least one child and want to have a child of the opposite sex for family balancing. This issue is still quite controversial.

2.9. Conclusion

The problem of infertility is the grave concern for human being as millions of people worldwide are suffering from it. The people suffering from infertility are living a life of harassment and stigma. So they may go to any possible extent to overcome this problem of infertility. Fertility treatments have brought millions of babies to the infertile couples, and genetic engineering and pre-natal treatment together with sperm and egg-donation make it possible to produce a child of their own choice. ART industry has transformed the character of fertility technology in India. Although ARTs are miracle cure for the infertile couple, there are many complex legal and other issues involved with the use of these technologies. This rapidly developing ART industry has been unregulated at national as well as international level. There is lack of ethical and legal regulation by both sides; the government as

[117] Available at *http://www.americanpregnancy.org/infertility/preimplantationgeneticdiagnosis.html* visited on 31/08/2012 at 5:32 P.M.
[118] Supra note 15 at 37
[119] Ibid.

well as the medical scientists. Infertility is an approximately $3-4 billion-per-year business. By passing the natural method of conception, fertilizing more embryos than needed, discarding excess embryos, unnatural environment for embryos, freezing them and destroying them in research are the issues involved in misuse of technology. National and international regulation may have a great impact to ART. So, there is a strong need to regulate this complex issue through law. The next chapter will try to discuss about the need for legal regulation and also examine the present legal response towards ART.

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Chapter-III

Chapter -III

Regulation of Assisted Reproductive Technology in India

3.1 Introduction

Assisted Reproductive Technology (ART) is now a fast growing global industry. Advances in scientific facilitation of conception offer infertile couples and individuals a lot of options, ranging from the low-tech process of artificial insemination (AI) to the more complex high- cost process of *in vitro fertilization* (IVF) and surrogacy. The growing industry of ART has led the development of markets in gametes, surrogates, and advanced clinical techniques. There are social, scientific, and commercial components associated with ART and as a result, there are a wide variety of players involved in the practice of ART, including clinics, hospitals, and related facilities; egg and sperm donors and surrogates; intended parents; and lawyers. In addition, third party reproductive techniques have created a market for agencies that, on the commercial basis, recruit egg and sperm donors and surrogates.

This development and use of medically ART is continuously raising a range of complex and profound social, legal and ethical issues: now the question is how should we react toward these developing markets? Do we seek to expand every individual's capacity to achieve biological parenthood, or view reproductive potential as appropriately bounded? What role should the state play in providing individuals and families with access to reproductive technologies? What criteria should be used to determine who deserves to have medically assisted reproduction? What restrictions should be placed on ART? Definitely these are some questions which cannot be answered in isolation. The law always plays an important role to determine the role of state, public or private agencies and individual also. This chapter will try to find out the more specific answers to these questions through analyzing the regulatory mechanism.

3.2 Historical Background of Assisted Reproductive Technology in India

The world's first IVF baby, Louise Brown, was born on July 25, 1978 in UK through the efforts of Dr. Robert G Edwards and Dr. Patrick Steptoe. Six years after the first test tube baby was born in the UK in 1978, the Indian government established an IVF project within its contraceptive research establishment, at the Institute for Research in Reproduction (now National Institute for Research in Reproduction or NIRR) in Mumbai. NIRR is an institution of the ICMR. In August 1984, the NIRR

set up an IVF programme in collaboration with the King Edward Memorial Hospital, a tertiary care center of the Bombay Municipal Corporation. IVF was tested on poor women seeking infertility services in this government hospital. The world's second and India's first IVF baby, Kanupriya, alias Durga, was born 67 days later on October 3, 1978 through the efforts of Dr. Subhas Mukherjee and his two colleagues in Kolkata. The techniques used by Mukherjee were markedly different from those used by Edwards and Steptoe. Mukherjee was the first person in the world to use (a) gonadotropins for ovarian stimulation prior to ovum pick-up in an IVF treatment cycle; (b) the transvaginal route by colpotomy for harvesting oocytes; and (c) freezing and thawing of human embryos before transferring them into the uterus that led to the successful birth of Durga. 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). This work was executed after being approved by the Scientific Advisory Committee of the ICMR's Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of the KEM Hospital. Births of IVF babies were reported subsequently during the same year by two other clinics in India.[1]

From August 6, 1986, when the first documented "test tube" baby in India was born,[2] since then, its slow expansion has been a gradual but steadily increasing phenomenon. ICMR supported National Institute of Reproductive Research (NIRR) to take up ART research and later to bring it in the Family Welfare Programme and tertiary care service institutions in the Ninth Five year Plan. The ICPD declaration at Cairo on reproductive rights and choices emphasized expanding the scope of reproductive health and thus promoted ART in the name of women's choices and rights.[3] Finally, India's Ninth Five Year Plan introduced management of sterility in its comprehensive RCH Programme but not in the "Essential" package of RCH. It was said that given an estimate of 5-10 percent sterility, it is essential that couples who do not have children get access to essential clinical examination, investigation, management and counseling. It was proposed that while the expertise would be made available at the tertiary hospitals, basic services to detect causes and carry out

[1] *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) at 4.
[2] Sandhya Srinivasan, *Making Babies: Birth Markets and Assisted Reproductive Technologies in India*, 2010, New Delhi, Zubaan), at xvi
[3] Imrana Qadeer, "New Reproductive Technologies and Health Care in Neo-Liberal India: Essays", *Centre for Women's Development Studies,* (November 2010) at 14.

preliminary investigations like sperm count, diagnostic curettage, and tubal patency tests will be done at the CHC to screen cases and refer them to appropriate institutions. It is interesting that, while the Five year Plans committed to ARTs, the National Public Health Standards evolved for CHC under the NRHM did not include the simple test facilities. This commitment was repeated almost verbatim in the Tenth Five Year Plan yet, the broad framework for Implementation of the NRHM, while enumerating guaranteed services, talked only of treating RTI and ignored the simple tests for infertility at the CHC level. Thus, in the public sector these services are confined to the tertiary sector and therefore not accessible to the majority. We see then, that ART are a part of the glamour technologies projected by India to establish its international standards. It is however confined primarily to the private sector and tertiary public sector institutions accessible to a select few. The basic services have no strategy to deal with infertility.[4]

The Indian Society for Assisted Reproduction has a membership of more than 600. Though the number of experts competent to perform advanced procedures is still small, there are approximately over 2, 00,000 IVF clinics in India. In addition, smaller towns and rural areas have fertility centers that work with ART Centers located in the tertiary care institutions of cities where specialists are available to perform IVF and ICSI (Intra-Cytoplasm Sperm Injection) procedures.

3.3. Need for Regulation

The idea of the government restricting what scientists can or cannot research, or what treatment a doctor can offer a patient, are seen in some countries as improper government interference. Nevertheless the U.K's regulation in this area is well established and is regarded by many countries in the world as a model system.[5] There has been a much debate in the Indian medical community in last 10 years about whether there is any need for legislation in relation to the provisions of ARTs. There is a great deal of uncertainty as to how the law may respond to disputes which arise in relation to ART, such as those involving the ownership of gametes and embryos. ART is quite different from other medical treatments because the process involves the formation of a family and of course the interest of child born through this complex process.

[4] Id at 15.
[5] Jonathan Herring, *Medical Law and Ethics*, 3rd edition, (2010, New York, Oxford University Press), at 354.

3.4 Scheme of Regulation

In order to ensure quality of care it is imperative that a proper accreditation procedure is followed in establishment of ART centers, which should follow standardized protocols and guidelines. National guidelines for accreditation, supervision and regulation of ART clinics have been formulated by ICMR in 2005 to provide optimum benefit of these newer technologies to appropriate persons by skilled team of experts, at affordable health and economic cost, in all public and private facilities in our country. A national registry pertaining to all centers that are accredited by the licensing authority shall be maintained at ICMR and shall contain records of treatment cycles and outcome. Equally important are issues related to the conduct of research with material obtained as byproducts from the clinical activity. These include the follicular fluid, oocytes, spare embryos, semen samples which can be used by researchers in basic or molecular science.[6] Prevention and appropriate treatment of infertility has been included in the ICPD (International Conference on Population and Development) Programme of Action; it follows that alleviation of infertility should be included as a component of the primary health care system. Most types of infertility such as reproductive tract infections (RTI) and genital tuberculosis are preventable and amenable to treatment. About 8% of infertile couples, however, need serious medical intervention involving the use of advanced ART procedures such as IVF or ICSI. Such advanced treatment is expensive and not easily affordable to the majority of Indians. Further, the successful practice of ART requires considerable technical expertise and expensive infrastructure.[7]

To prevent misuse of pre-natal diagnostic techniques, the Pre-Natal Diagnostic Techniques Act-1994, was passed and amended as Pre Conception and Pre Natal Diagnostic Techniques Act- 2002. The first reference to ARTs in an official document appeared in the *"Ethical Guidelines for Biomedical Research on Human Participants"* (herein after referred as ethical guideline) published by ICMR in 2000. Subsequently, in 2005, Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS) framed the *National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproduction Technology Clinics* (herein after referred as ICMR guideline) to regulate the surrogacy. However,

[6] *Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research*. (2000, New Delhi), at 105.
[7] Supra note 1, chapter 1.

since these guidelines had no legal binding and the rules and regulations therein were not mandatory, they were not strictly implemented, resulting in the absence of any form of regulation of ARTs. Recently, ICMR and Ministry of Health and Family Welfare (MOHFW) have come up with the *Draft Assisted Reproductive Technology Bill & Rules 2008*(herein after referred as ART Bill) which was later modified in 2010.

3.4.1 Scheme of the *Draft Assisted Reproductive Technology Bill & Rules 2010*

The *Draft Assisted Reproductive Technology Bill & Rules 2010* has divided into two sections- Bill and Rules. The nine chapters covered under the Bill include details on various aspects of the regulation of ART clinics, semen banks and research on embryos. In chapter I-III dealing with Registration and Regulatory Authorities, the Bill proposes that a National Advisory Board be set up to recommend modifications in the regulations regarding permissible ARTs, the minimum physical infrastructure of the ART clinics, guidelines for counseling, research on human embryos, and other policies on assisted reproduction. Moreover, all states are to establish State Boards, who may advice the state government to constitute a Registration Authority, monitor its functioning and hold enquiries. Chapter IV provides the duties of an assisted reproductive technology clinic, which include general duties, the duty to obtain written consent and maintain accurate records, duties for clinics using gametes and embryos, and duties regarding pre implantation genetic diagnosis and sex selection. Chapter V deals with sourcing, storage and handling of gametes and embryos, records to be maintained by semen banks, and restrictions on sale of gametes, zygotes and embryos. Chapter VI provides regulation of research on embryos, gametes, or other human reproductive material sourcing. Chapter VII discusses on rights and duties of patients, donors, surrogates and determination of the status of the child, the right of the child to information about donors and surrogate mothers. Chapter VIII provides offences and penalties and chapter IX covers certain miscellaneous provisions. The Bill is followed by the Rules, which seek to provide an explanatory background on the various sections of the Bill.

3.5 Regulatory Mechanism for ARTs

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India 2005 have made elaborated provisions regarding ART clinics.

3.5.1 Minimal Physical Requirements for an ART Clinic

The present guidelines require a well designed ART clinic of Level 2[8] or Level 3[9] having a non-sterile[10] and a strictly sterile area. Some of the spaces could be combine (that is, the same space may be used for more than one purpose) as long as such a step does not compromise the quality of service. However, the space prescribed for the sterile area cannot be combined with those for the non-sterile area and vice-versa. For level 1B infertility care units a strictly sterile area will not be required. The space requirement[11], however, will include, a reception area, a waiting room for the patients, a consulting room for the gynecologist, and requirements mentioned under and the non-sterile area, a reception and waiting room for patients, a room with privacy[12]. Evaluation of infertility necessitates history taking of the most intimate sexual practices between the couples followed by close examination of the reproductive tract and sexual organs.

It also emphasizes on maintaining the strict privacy and dignity of the patients. In case a male doctor examines a female patient, there must always be a female attendant present. The room must be equipped with an examination table and gynecological instruments for examining the female per vaginum, an appropriate ultrasonographic machine with a probe for transvaginal examination of the female and examination of the testes and excurrent male reproductive tract. A colour Doppler would be useful but not essential. A general-purpose clinical laboratory, store room[13], record room[14], autoclave room[15], semen collection room[16], semen processing

[8] Id, para 2.5.3
[9] Id para 2.5.4
[10] The non-sterile area must include what is listed under id at sections 1.3.1.1 to1.3.1.9 Sections 2.5.3 and 2.5.4)
[11] Id para1.3.1.8, 1.3.1.9
[12] A room with privacy for interviewing and examining male and female partners independently is essential.
[13] A well-stocked store for keeping essential stock of especially those items that have to be imported, precluding the need to be caught short in the middle of treatment. Facilities must be available for storing sterile (media, needles, catheters, Petri dishes and such-like items) and non-sterile material under refrigerated and non-refrigerated conditions as appropriate.
[14] Record keeping must be computerized as far as possible so that data is accessible retrospectively for analysis or when called upon by the supervisory agency. There are many software programmes for this purpose, which are commercially available today. Besides containing essential details of the patient's records, it must contain history of the cause of infertility as diagnosed earlier, results of new diagnosis if relevant, the treatment option best suited for the particular patient, the treatment carried out and the outcome of treatment, and follow-up if any. Any other noteworthy point such as possible adverse reaction to drugs must be recorded. ICMR should make an effort to devise a form for basic data recording, which would be suitable for India.
[15] A separate facility must be available for sterilizing and autoclaving all surgical items as well as some of those to be used in the in vitro culture laboratory

laboratory[17] clean room for IUI[18] the sterile area[19], the operation theatre[20] room for intrauterine transfer of embryo[21] and the embryology laboratory complex.

The embryology laboratory must have facilities for the control of temperature and humidity and must have filtered air with an appropriate number of air exchanges per hour. Walls and floors must be composed of materials that can be easily washed and disinfected; use of carpeting must be strictly avoided.[22] All material from the operation room, culture dishes and Falcon tubes for sperm collection (including lids), must bear the name of the patient. In the incubator, identified oocytes and sperm are to be kept together on the same tray and double-checked. Pipettes used should be disposed off immediately after use. The embryology laboratory must have a daily logbook in which all the day's activities are recorded, including the performance of the equipment.

It require infertility clinic to a ready access to laboratories that are able to carry out immunoassays of hormones (FSH, LH, Prolactin, HCG, TSH, Insulin, Estradiol, Progesterone, Testosterone and DHEA) and tests such as for HIV and Hepatitis B. Endocrine evaluation constitutes an essential diagnostic procedure to determine the cause of infertility. It also necessitate to estimate blood estradiol in

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[16] This must be a well-appointed room with privacy and an appropriate environment; it should be located in a secluded area close to the laboratory. Such a facility must be available in-house rather than having the patient collect the sample and bring it to the laboratory for analysis as, in the latter case, semen quality and identity is likely to be compromised. Procedures for collection of semen as described in the WHO Semen Analysis Manual must be followed with special reference to the type of container used; these containers must be sterile, maintained at body temperature and nontoxic. This room must have a washbasin with availability of soap and clean towels. The room must also have a toilet and must not be used for any other purpose.

[17] There must be a separate room with a laminar air flow for semen processing, preferably close to the semen collection room. This laboratory must also have facilities for microscopic examination of post-coital test smears. Good Laboratory Practice (GLP) guidelines as defined internationally must be followed.

[18] There must be a separate area/room with an appropriate table for Intra-Uterine Insemination (IUI).

[19] The sterile area shall house the operation theatre, a room for intrauterine transfer of sperm or embryos and an adjoining embryology laboratory. Entry to the sterile area must be strictly controlled by an anteroom for changing footwear, area for changing into sterile garments and a scrub-station. The sterile area must be air-conditioned where fresh air filtered through an approved and appropriate filter system is circulated at an ambient temperature (22-250C).

[20] This must be well equipped with facilities for carrying out surgical endoscopy and transvaginal ovum pick-up. The operation theatre must be equipped for emergency resuscitative procedures.

[21] This room must be a sterile area having an examination table on which the patient can be placed for carrying out the procedure and rest undisturbed for a period of time.

[22] The embryology laboratory must have the following: a laminar flow bench with a thermostatically controlled heating plate, a stereo microscope, a routine high-powered binocular light microscope, a 'high resolution' inverted microscope with phase contrast or Hoffman optics, preferably with facilities for video recording, a micromanipulator (if ICSI is done), a CO_2 incubator, preferably with a back up, a hot air oven, a laboratory centrifuge, equipment for freezing embryos in a programmed manner, liquid nitrogen cans, a refrigerator Appropriate steps need to be taken for the correct identification of gametes and embryos to avoid mix-ups.

samples taken from a woman undergoing controlled ovarian hyper stimulation, and have the result on the same day to determine the dose of drugs to be given for induction of ovulation. Accurate monitoring of endocrine response to controlled ovarian stimulation goes a long way in preventing ovarian hyper stimulation.[23]

It also emphasizes another important facility in an ART clinic (or easily accessible to it) that of a microbiology laboratory that can carry out rapid tests for any infection, and a clinical chemistry laboratory. Facilities for carrying out histo-pathological studies on specimens obtained from the operation theatre would also be desirable.[24]

Each laboratory has to maintain in writing, standard-operating manuals for the different procedures carried out in the laboratory. The patient's name should be clearly labeled on all the tubes, dishes and pipettes containing the gametes and embryos. All pipettes should be immediately discarded after use.[25] Periodical check for microbial contamination using standard techniques, and a record of it is required for laminar flowhoods, laboratory tables, incubators and other areas where sterility is required. A logbook is required to records the temperature, carbon dioxide content and humidity of the incubators and the manometer readings of the laminar air flow. All instruments must be calibrated periodically (at least once every year) and a record of such calibration maintained.

3.5.2 Essential Qualifications of the ART Team

The practice of ART requires a well-orchestrated teamwork between the gynaecologist [26], andrologist [27] and the clinical embryologist [28] supported by a

[23] Id para 1.3.3.1.
[24] Id para 1.3.3.2
[25] Id para 1.3.3.3
[26] The minimal qualification for a gynaecologist in a Level 1B, Level 2 or Level 3 clinic (see Paras 2.5.2, 2.5.3 and 2.5.4) is a post-graduate diploma or degree in gynaecology. Additional experience should include the Understanding the causative factors of male and female infertility, Acquiring knowledge of the practice and use of diagnostic methods for determining the cause of infertility, Acquiring knowledge of the clinical aspects of reproductive endocrinology and the reproductive defects caused by endocrine factors, and an understanding of the limitations of the currently used hormone assay methods, and of the techniques available for medically or surgically correcting endocrine disorders, Acquiring competence/skills in gynecological ultrasonography to diagnose reproductive tract anomalies, monitoring ovarian and uterine response to ovarian stimulation, picking up oocytes at the most appropriate time, and transferring embryos by any one of the several methods currently available to handle embryo transfer in 'difficult cases', The gynaecologist must be well versed, particularly in the pharmacology of hormone action, and know how to avoid situations such as Ovarian Hyperstimulation Syndrome that can pose a great health hazard.
[27] Fifty percent of infertility cases are related to male factors, many of which can be treated by specific ART procedures or other less invasive procedures. Andrology, a subject related to male reproduction, does not constitute a formal course in the medical curriculum in India, although several journals in

counsellor[29] and a programme coordinator/director[30]. The staff requirements would be mandatory for Level 2 [31]and Level 3[32] clinics. In the case of small Level 2 and Level 3 clinics, the services of the andrologist, the clinical embryologist and/or the counsellor could be shared.

The responsibilities of the gynaecologist would include the interviewing of the infertile couple initially, history taking, physical examination of the female, recommending appropriate tests to be carried out, interpreting them and treating medical disorders (infections, endocrine anomalies), carrying out *laparoscopy* or *sonohysterosalpingography* for determining the status of the uterus and the fallopian tube, advising the couple on planned relationship in simple cases, carrying out AIH, AID, IUI, IVF or ICSI as the case may warrant, based on diagnostic evidence. In case of male factor infertility, if the gynaecologist is confident and competent, he/she can treat such cases or refer them to the andrologist. The treating doctor is responsible for maintaining all records of diagnosis, treatment given and consent forms, and also to

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andrology are published from different parts of the world including China. There is also an International Andrological Society with branches or affiliated societies all over the world. In India it is the urologist with a postgraduate degree in urology that often takes on the task of treating male infertility. Such individuals must receive additional training in diagnosis of various types of male infertility covering psychogenic impotence, anatomical anomalies of the penis which disable normal intercourse, endocrine factors that cause poor semen characteristics and/or impotence, infections, and causes of erectile dysfunction.

[28] The clinical embryologist must be knowledgeable in mammalian embryology, reproductive endocrinology, genetics, molecular biology, biochemistry, microbiology and in vitro culture techniques. The biologist must also be familiar with ART. He/she must be either a medical graduate or have a post-graduate degree or a doctorate in an appropriate area of life sciences.

[29] Counsellors are an important adjunct to any infertility clinic. Indeed, in the UK, counsellors are appointed by the clinic but they report to an independent body. This ensures that there is fair play by the clinic and the patients are adequately informed of what and what not to expect from the treatment offered to them.

Counselling for ART is not taught as a separate subject anywhere. A person who has at least a degree (preferably a postgraduate degree) in Social Sciences, Psychology, Life Sciences or Medicine, and a good knowledge of the various causes of infertility and its social and gender implications, and the possibilities offered by the various treatment modalities, should be considered as qualified to occupy this position. The person should have a working knowledge of the psychological stress that would be experienced by potential patients, and should be able to counsel them to assuage their fears and anxiety and not to have unreasonable expectations from ART. A member of the staff of an ART clinic who is not engaged in any other full-time activity in the clinic can act as a counsellor.

[30] This should be a senior person who has had considerable experience in all aspects of ART. The programme co-ordinator/director should be able to co-ordinate the activities of the rest of the team and take care of staff administrative matters, stock keeping, finance, maintenance of patient records, statutory requirements, and public relations. He/she should ensure that the staff are keeping up with the latest developments in their subject, by providing them with information from the literature, making available to them access to the latest journals, and encouraging them to participate in conferences and meetings and present their data. The programme co-ordinator/director should have a post-graduate degree in an appropriate medical or biological science. In addition, he/she must have a reasonable experience of ART.

[31] Id para 2.5.3 and 2.5.4

[32] Id para 2.5.3 and 2.5.4

refer the couple for councelling. It would be the gynaecologist's responsibility to see that all equipment and instruments in the operation theatre are properly functional and in order, and that a logbook is maintained of their use and operation.

The andrologist must have knowledge of the occupational hazards, infections and fever that cause reversible or irreversible forms of infertility, and knowledge of ultrasonographic or vasographic studies of the reproductive excurrent ducts to detect partial occlusion that can be surgically corrected. An individual may act as an andrologist for more than one clinic but each clinic owns the responsibility for the andrologist and ensure that the andrologist is able to take care of the entire work load of the clinic without compromising on the quality of service.

The responsibilities of the andrologist would includes Recording case histories, Prescribing appropriate diagnosis and treatment based on the diagnosis, Carrying out such surgical procedures as warranted by the diagnosis, Maintaining all the records, from the case history to the treatment given, and the patient consent forms, Referring the couple to the gynaecologist for carrying out the appropriate ART procedure if necessary, after the male factor has been duly investigated, Referring the couple to the counsellor if necessary, In cases of surgical intervention, making sure that the operation theatre is fully functional and all supplies are available before the start of any surgical procedure, Entering any deficiency that needs attention in the operation theatre logbook.

Clinical Embryologist[33] must be familiar with the Principles and practice of semen analysis and cryopreservation of semen, Cytology of mammalian and human oocyte to identify stages of oocyte maturation accurately, All aspects of embryology including developmental biology, Cell biological techniques, Molecular biology and genetics of human reproduction, Micromanipulation of sperm and oocytes for carrying out ICSI and single-cell biopsies of embryos for pre-implantation genetic diagnosis, Principles and functioning of all the equipment used in the laboratory, In vitro fertilization of oocytes after processing the gametes, Principles and practice of embryo freezing. The responsibilities of the clinical embryologist would be to ensure

[33] In case of shortage of adequately trained clinical embryologists, an individual may act as a clinical embryologist for more than one clinic but each clinic where the person works must own responsibility for the embryologist and ensure that the embryologist is able to take care of the entire work load of the clinic without compromising on the quality of service. An embryologist must not be associated with more than two centers at any given time.

that all the necessary equipments are present in the laboratory and are functional, To perform all the procedures pertaining to processing, handling and culturing of gametes and embryos in the laboratory and hand over the embryo to the gynaecologist, To maintain records of all the procedures carried out in the laboratory.

The counsellor must invariably appraise the couple of the advantages of adoption as against resorting to ART involving a donor. An individual may act as a counsellor for more than one clinic but each clinic must own responsibility for the counsellor and ensure that the counsellor is able to bear the entire counselling load of the clinic without compromising on the quality of the counselling service.

It would be the responsibility of the National Accreditation Committee to ensure that the list given in the guidelines be enlarged in real time as progress occurs in the field. It is hoped that the practitioners of ART in the country will bring to the notice of the Committee on a continuing basis, any new procedure for the practice of which there would appear to be a sound scientific case. The National Accreditation Committee or a body appointed by it will approve or disapprove the new procedure within six months of its having been made aware of in writing: if this is not done, the clinic could continue to use the procedure until the above body has taken a decision on it. No new procedure that has not been approved as above should be permitted to be used by an infertility clinic for more than the period mentioned above.[34] One of the primary concerns of all ART treatments is the safety of the patients and of their gametes and embryos which constitute the very beginning of a new individual's life. The basic tenets of any medical treatment mentioned in the Helsinki Declaration of 1964 and reiterated in October 2000 in Scotland clearly spell out the ethical concerns of treating patients. These basic tenets are also applicable to ART. The clinic must ensure that a particular ART being offered is fully in consonance with the diagnosis made of the cause of infertility. More particularly, the clinic must make sure that patients are well informed about the treatment being offered to them, the reasons of suggesting a particular form of treatment, and alternative therapies available if any.[35]

If a clinic is offering an ART that is not listed in these guidelines now or as modified in the future, the procedure must be approved by the clinics ethics committee (constituted as recommended by the ICMR ethical guidelines, 2000), justifying the need for the procedure and explaining why alternatives are not suitable.

[34] Id para 1.6.
[35] Ibid.

[Only clinics of (Level 2 or Level 3)[36] would be required to have an ethics committee.] Informed consent from the patients would be mandatory in such cases as well. As mentioned in Para one of this section, the clinic must also bring the new procedure to the notice of the National Accreditation Committee for its approval; if such an approval is not granted, all further use of the procedure must stop.[37] Clinics which should be Registered Clinics involved in any one of the following activities should be regulated, registered and supervised by the State Accreditation Authority/State Appropriate:

- Any treatment involving the use of gametes which have been donated or collected or processed in vitro, except for AIH, and for IUI by level 1A clinics who will not process the gametes themselves.
- Any infertility treatment that involves the use and creation of embryos outside the body.
- The processing or /and storage of gametes or embryos.
- Research on human embryos.

The term ART clinic used in guidelines refers to a clinic involved in any one of the first three of the above activities.

The Guidelines also make code of practice for ART clinics. Those areas which most affect the doctors, scientists and patients and are a part of this code are summarized below.

- Staff: A 'person responsible' shall take full responsibility for ensuring that the staff of the registered unit is sufficiently qualified, that proper equipment is used, that genetic material is kept and disposed -off properly, and that the center complies with the conditions of its registration.[38]
- Facilities: Proper systems for monitoring and assessing practices and procedures are required to be in place in order to optimize the outcome of ART.
- Confidentiality: Except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a

[36] Id para 2.5.3 and 2.5.4.
[37] Id para 1.6.
[38] Guidelines for minimum standards and qualifications of clinical, scientific and counselling staffs are laid down in Chapter 1. Failure of the 'person responsible' to comply with the mandatory code of practice can lead to his/her removal or prosecution, or to the suspension of the clinic's registration.

court order any information related to couples or donor under treatment will not be disclosed to anyone other than accreditation authority

- Information to patient: The patient has to be fully informed regarding limitations results and possible side-effects of the proposed treatment, the techniques involved, the availability of counselling and other treatments the cost of the treatment, the rights of the child born through ART, and the need for the clinic to keep a register of the outcome of a treatment.
- Consent: written consent of the couple on the standard form is required at all the possible stages of that treatment, including the possible freezing of supernumerary embryos. Specific consent must be obtained from couples who have their gametes or embryos frozen, in regard to what should be done with them if he/she dies, or becomes incapable of varying or revoking his or her consent.
- Counselling:it is mandatory that people seeking registered treatment must be given a suitable opportunity to receive proper counseling (support or therapeutic) about the various implications of the treatment.[39].
- Use of gametes and embryos: maximum three oocytes or embryos may be placed in a woman in any one cycle, regardless of the procedure/s used, except under exceptional circumstances (such as elderly women, poor implantation, adenomiosis, or poor embryo quality) which should be recorded. A woman should not be treated with gametes or with embryos derived from the gametes of more than one man or woman during any one-treatment cycle.
- Storage and handling of gametes and embryos: The 'highest possible standard' in the storage and handling of gametes and embryos in respect of their security, and in regard to their recording and identification, should be followed.
- Research: The accreditation authority must approve all research that involves embryos created in vitro. A separate registration for each research project involving human embryos is required. The accreditation authority will give a registration certificate after being satisfied that the use of human embryos is essential for the purposes of the proposed research and the research is in public interest. It also states that no human embryo may be placed in a non-

[39] (of Levels 1B, 2 or 3)

human animal and all research projects must be approved by the Institutional Ethics Committee before submission to the accreditation authority.[40]

- Complaints: All registered ART clinics are required to have procedures for acknowledging and investigating complaints, and to have a nominated person to deal properly with such complaints. The accreditation authority must be informed of the number of complaints made in any year and those that are outstanding.

3.5.3 Responsibilities of the Clinic

The responsibilities of the ART clinic described under the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India are as follows:

- ❖ The clinic has to inform the patients about various options of treatment available (including the cheapest possible course of treatment), and help them in exercising the choices.
- ❖ To maintain records in an appropriate proforma (to be prescribed by the authority) to enable collation by a national body.
- ❖ When commercial DNA fingerprinting becomes available, to keep on its record, if the ART clinic desires and couple agrees, DNA fingerprints of the donor, the child, the couple and the surrogate mother should be done.
- ❖ To keep all information about donors, recipients and couples confidential and secure. The information about the donor (including a copy of the donor's DNA fingerprint if available, but excluding information on the name and address – that is, the individual's personal identity) should be released by the ART clinic after appropriate identification, only to the offspring and only if asked by him/her after he/she reaches the age of 18 years, or as and when specified and required for legal purposes, and never to the parents (except when directed by a court of law).
- ❖ To maintain appropriate, detailed record of all donor oocytes, sperm or embryos used , the manner of their use These records are to be kept for at least ten years after which the records would transfer to a central depository to be maintained by

[40] *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India,* Indian Council of Medical Research National Academy of Medical Sciences (India), New Delhi,2005, Section 3.17 says: Each ART clinic of Levels 1B, 2 and Level 3 must have its own ethics committee constituted according to ICMR Guidelines, comprising reputed ART practitioners, scientists who are knowledgeable in developmental biology or in clinical embryology, a social scientist, a member of the judiciary and a person who is well-versed in comparative theology. Should the local ART clinic have difficulty in establishing such a body, the state accreditation authority should constitute such a body, co-opting a representative of the ART clinic.

the ICMR. If the ART clinic/centre is wound up during this period, the records must be transferred to the central repository in the ICMR.

- The schedule of all its charges has to be suitably displayed in the clinic and made known to the patient at the beginning of the treatment without any extra charges
- To ensure that no technique is used on a patient for which demonstrated expertise does not exist with the staff of the clinic.
- The ART clinic will be totally transparent in all its operations. Thus it must inform the patient about the success rates of the clinic with regard to the procedure intended to be used on the patient.
- To have all consent forms available in English and local language(s).[41]

Chapter IV of the Draft Assisted Reproductive Technology Bill and Rules 2010 make provisions regarding duties of assisted reproductive technology clinics.

3.5.4 General Duties of Assisted Reproductive Technology Clinics[42] –

Apart from above the bill also entrusts the ART clinics with certain responsibilities which are as under:

Firstly, ART clinics has to ensure the eligibility of patients, donors of gametes and surrogate mothers to avail assisted reproductive technology procedures under the criteria prescribed by the rules under this Act and to test them medically for any diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child.

Then ART clinic shall also obtain, from ART bank(s), all relevant information, except the name, personal identity and address, of possible gamete donors and assist the couple or individual desirous of the donation, to choose the donor. When an ART bank receives a request from an ART clinic for a donor oocyte, a responsible member of the staff of the ART bank will accompany the particular donor to the ART clinic, and obtain a written agreement from the authority designated for this purpose by the clinic, that the clinic shall, under no circumstances (except when asked by a court of law), reveal the identity of the donor to the recipient couple or individual or to anyone else; the clinic shall also ensure that all its staff is made

[41] Supra note 1 para 3.3.

[42]. Chapter – IV, Section 20, 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. *http://icmr.nic.in/guide/ART%20REGULATION%20Draft%20Bill1.pdf*.

aware of the fact that any step leading to disclosure of the identity shall amount to an offence punishable under this Act.

ART clinics shall obtain donor gametes from ART banks that have ensured that the donor has been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child. ART clinics shall provide professional counseling to patients or individuals about all the implications and chances of success of ART procedures in the clinic and in India and internationally, and shall also inform patients and individuals of the advantages, disadvantages and cost of the procedures, their medical side effects, risks including the risk of multiple pregnancy, the possibility of adoption, and any such other matter as may help the couple or individual arrive at a decision that would be most likely to be the best for the couple or individual.

ART clinic is also responsible to inform couples or individuals, as the case may be about the rights of a child born through the use of ART. ART clinic will also explain the couple reasons, advantage, disadvantage and limitation of the recommended treatment. The clinic is also responsible to keep the information about clients, donors and surrogate mothers confidential and the information about treatment shall only be disclosed to central database, to be maintained by the Department of Health Research. The information may be disclosed at the request of the person or persons, in a medical emergency or by an order of a court of competent jurisdiction with the consent of the person or persons or the closest available relative of such person or persons to whom the information relates.

The ART clinic shall not consider conception by surrogacy for patients to whom it would normally be possible to carry a baby except if unsafe or undesirable medical implications of such conception arise the use of surrogacy may be permitted. ART clinics shall provide to couples or individuals, as the case may be, a pre-stamped self-addressed envelope to inform the clinic of the results of the ART procedure performed for the couple or the individual. ART clinic is prohibited to obtain or use sperm or oocytes donated by a relative or known friend of either of the parties seeking ART treatment or procedures. Every ART clinic shall establish a mechanism to look into complaints in such manner as may be prescribed. Minimum age of women is held to be 21 years below which, any assisted reproductive procedure performed, shall amount to an offence punishable under the bill. All ART clinics shall issue to the

infertile couple/individual discharge certificate stating details of the ART procedure(s) performed on the couple / individual. Only a registered ART bank (and no other organization) shall be authorized to advertise for, procure or provide semen, oocyte donor or surrogate mother.

3.5.5 Duty of the Assisted Reproductive Technology Clinic to Obtain Written Consent[43]

Assisted reproductive technology clinic has to obtain consent in writing to perform any treatment or procedure of ART of all the parties seeking ART to all possible stages of such treatment or procedures including the freezing of embryos. An ART clinic shall freeze any human embryos with specific instructions and consent in writing from all the parties seeking ART in respect of what should be done with the gametes or embryos in case of death or incapacity of any of the parties. No ART clinic shall use any human reproductive material to create an embryo or use an in vitro embryo for any purpose without the specific consent in writing of all the parties to whom the ART relates. The consent of any of the parties obtained under this section may be withdrawn at any time before the embryos or the gametes are transferred to the concerned woman's uterus.

3.5.6 Duty of the Assisted Reproductive Technology Clinic to Keep Accurate Records[44]

- All ART clinics shall maintain detailed records, in such manner as may be prescribed, of all donor oocytes, sperm or embryos used, the manner and technique of their use, and the individual or couple or surrogate mother, in respect of whom it was used.
- All ART clinics will, as and when such central facilities are established, put on line all information available to them in regard to progress of the patient (such as biochemical and clinical pregnancy) within seven days of the information being available, withholding the identity of the patient.
- Records shall be maintained for at least a period of ten years[45], upon the expiry of which the ART clinic shall transfer the records to a central database of a national ART registry to be set up by the Department of Health Research at the Head quarters of the ICMR.

[43] Id section 21
[44] Id section 22
[45] section 22(i)

- In the event of the closure of any ART before the expiry of the period of ten years, the ART clinic or ART bank shall immediately transfer the records to a central database of a national ART registry to be set up by the Department of Health Research at the Hqrs of the ICMR

3.5.7 Duties of Assisted Reproductive Technology Clinics Using Gametes and Embryos[46]

Under this section Assisted reproductive technology clinics shall harvest oocytes in accordance with such regulations of the National Board or concerned State Board or any rule as may be prescribed under the bill. Then number of oocytes or embryos that may be placed in a woman in any one cycle shall be according to the rules and regulations also. The woman cannot be treated with gametes or embryos derived from the gametes of more than one man or woman during any one treatment cycle. An ART clinic cannot mix semen from two individuals before use. In case of multiple pregnancies as a result of ART, the concerned ART clinic shall inform the patient immediately of the multiple pregnancy and its medical implications and may carry out foetal reduction after appropriate counselling. The gametes from a person whose death is imminent shall only be collected if such person's spouse intends to avail assisted reproductive technology to have a child. ART clinic shall not use ova that are derived from a foetus, in any process of in vitro fertilisation. The ART clinic shall utilise medically analysed semen whether from an ART bank or otherwise, for any aspect of ART. Any contravention of stipulation under sub-section 3, 4, 7 and 8 of this section shall amount to an offence under this Act.

3.5.8 Pre-implantation Genetic Diagnosis[47] –

Pre-implantation Genetic Diagnosis is allowed only to screen the embryo for known, pre-existing, heritable or genetic diseases or as specified by the Registration Authority. The State Board may lay down other conditions in the interests of Pre-implantation Genetic Diagnosis as it deems fit.

3.5.9 Sex Selection[48] –

Under this section the bill not only prohibit ART clinic to provide a couple with a child of a pre-determined sex but makes it a criminal offence for anyone to do any act, at any stage, to determine the sex of the child to be born through the process

[46] Id section 23
[47] Id section 24
[48] Id section 25

of assisted reproductive technology. So no one shall knowingly provide, prescribe or administer anything that would ensure or increase the probability that an embryo shall be of a particular sex, or that would identify the sex of an in vitro embryo, except to diagnose, prevent or treat a sex-linked disorder or disease. Also assisted reproductive technology clinic is restricted to carry out any procedure to separate, or yield fractions enriched in sperm of X or Y variations. Any contravention of provisions this section is held to be an offence.

3.5.10 Responsibilities of the Accreditation Authority[49]

The State Governments through its Department of Health and/or Family Welfare will set up a State Accreditation Authority to oversee all policy matters relating to Accreditation, Supervision and Regulation of ART Clinics in the states in accordance with the National Guidelines. The State Government may also set up appropriate authorities for implementation of the Guidelines for the whole or a part of State having regard to the number of the ART Clinics.

Appropriate authority would have right to visit individually or collectively, any ART Clinic/Centre(s) accredited or not accredited, once a year with or without prior information to the clinic/center, to determine if the ethical guidelines and operative procedures mentioned here are being followed. The appropriate authority will point out the lapses to the clinic/center in writing. If these lapses continued for a maximum period of six months, the appropriate authority would recommend the State Accreditation Authority that the clinic/center may be ordered to be closed.

The appropriate authority may have delegated powers to impose a fine or a penalty on the center/clinic. An appropriate authority would consist of appropriately qualified scientists, technologists and sociologists and this authority will also be authorized to visit and regulate semen banks. In addition to the above, the Ministry of Health and Family Welfare, Govt. of India, will set up a National Advisory Committee to advise the Central Government on policy matters relating to regulation of ART Clinics. The State Accreditation Authority will have the rights and the responsibility of fixing the upper limit of charges for gamete donation and surrogacy and of revising these charges from time to time.

[49] Supra note 1, para 3.15.

3.5.11 Establishing a National Database for Human Infertility[50]

It is important to realize that diagnostic and therapeutic approaches in reproductive medicine have to keep pace with rapidly developing molecular knowledge of human reproduction. Now it is possible to detect the incidence of chromosomal abnormalities using a variety of high-powered PCR techniques (Human Reproduction 13: 3032-3038, 1998.) and multi colour fluorescent in situ hybridization (FISH) analysis. FISH studies on sperm are becoming necessary to understand whether there is a genetic cause for male infertility, before patients can be subjected to ICSI. New spermatogenesis genes are bound to be discovered testing their mutation will become easier with DNA chips and microarray technology. Unfortunately, there is no documented database available in our country that would cover data on all aspects of infertility, and there is an urgent need for the same. It is worrisome to see that, with the primary aim of providing a child to the infertile couple, a variety of sophisticated ART are being used to overcome male factor infertility without understanding the underlying cellular and molecular etiology. In the process of curing infertility in the patient, there is a high iatrogenic risk of transmitting an abnormal paternal geno-(pheno-)type to the ART-born child. An appropriate database would allow the quantification of such risks.

3.5.12 Composition of the National Advisory Committee:

It will comprise of a Chairman[51] Secretary, Ministry of Health and Family Welfare, Govt. of India, Co-chairman; Director General, Indian Council of Medical Research, New Delhi, Executive Secretary; An officer below the rank of Joint Secretary in Ministry of Health and Family Welfare, Govt. of India, and the following Members:

- Representative of the Indian Council of Medical Research .
- Representative of the National Academy of Medical Sciences.
- Representative from the Ministry of Health & Family Welfare, Govt. of India.
- Representative of a scientific society that deals with ART[52].
- A social scientist of repute.
- The Chairman of the National Bioethics Committee.

[50] Supra note 1, Chapter 8,

[51] Ibid.

[52] Care must be taken to ensure that such a representative should be from a society that has democratically elected office bearers and is governed by reasonable rules and regulations. The representative must have a proven track record of having contributed significantly to ART. The nature of the person's association with commercial companies must be made known publicly.

- A gynaecological endocrinologist.
- A gynaecological sonographist.
- An operative gynaecologist.
- A mammalian reproductive biologist.
- An andrologist.
- A representative of NGOs.
- A counsellor.
- A representative of patients.
- A medico-legal expert.
- A representative of FOGSI.
- A representative of ISSRF.

3.5.13 Constitution of Authorities to Regulate Assisted Reproductive Technology

In the scheme of The *Draft Assisted Reproductive Technology Bill and Rules 2010,* there are authorities for regulation of ARTs at national level and state level.

3.5.14 National Advisory Board [53]

The Bill proposes to establish a National Advisory Board for ART, having jurisdiction and powers and discharging the functions and duties conferred on it. Central Government may prescribe the number of members of the National Board, not exceeding twenty one. Also unless the rules otherwise provide, under the Bill, National Board shall consist of the following –

- Secretary, Department of Health Research, Government of India, shall be the Chairman of the Board;
- A senior scientist having knowledge of assisted reproductive technology, from the Department of Health Research or the Indian Council of Medical Research, shall be the Member-Secretary of the Board;
- A representative, not below the rank of Joint Secretary, from the Ministry of Health and Family Welfare;
- The nominee of an Indian professional society concerned primarily with assisted reproduction;
- Up to sixteen other experts of whom one each shall be a nominee of the Ministry of Health and Family Welfare and Indian Council of Medical Research, and at least six of whom shall be women in the fields of assisted

[53] Supra note 42, Chapter II, Section 3,

reproduction, gynecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the Central Government.

- The Chairman of National Board shall nominate a Vice Chairman from among its members.

3.5.15 Meetings of National Advisory Board[54] –

The meetings of National Board may be held when necessary but at least twice a year and at such time and place in the country as the Chairperson of the National Board may think fit. The Chairperson shall preside over these meetings and in his absence the Vice-Chairperson of the National Board shall preside over the meetings of it.

3.5.16 Functions of National Advisory Board [55]**–**

The Bill authorizes the National Board to recommend modification from time to time in the attached rules and schedules where relevant, and performs any other functions and tasks assigned to it by the Central Government. It may recommend minimum requirements related to staff and physical infrastructure for various categories of assisted reproductive technology clinics may regulate the permissible assisted reproductive technology procedures and the selection of patients for assisted reproductive technology procedures and to encourage and promote the training and research in the field of assisted reproduction, and also to encourage the establishment and maintenance of a national database in respect of infertility. It may provide guidelines for counselling and necessary information and advice to patients on various aspects of assisted reproductive technology procedures, also ways and means of disseminating information related to infertility and assisted reproductive technologies to various sections of the society and to regulate the research on human embryos. It may provide Proformae for obtaining information, consent forms for various procedures, and contracts and or agreements among the parties involved, in all of the languages listed in the Eighth Schedule of the Constitution. It also may frame policies from time to time on assisted reproduction.

[54] Id section 4
[55] Id section 5

3.5.17 Establishment of State Boards[56] –

The Bill provides that every State Government shall, within 180 days of the issue of notification in the Official Gazette, establish a State Board[57] for Assisted Reproductive Technology having jurisdiction exercising powers and discharging its functions and duties conferred on it.

The State Boards shall consist a maximum of twelve members, prescribed by the State Government and, unless the rules otherwise provide, the State Boards shall consist of the following members, namely [58]–

- The Secretary of the Department of Health and Family Welfare, who shall be Chairperson, *ex officio;*
- The nominee of an Indian professional society concerned primarily with assisted reproduction who shall be the Vice Chairperson, ex officio;
- An officer not below the rank of a Joint Secretary, who shall be the Member-Secretary of the Board;
- Up to nine other members – of whom at least four shall be women – who shall be experts in the fields of assisted reproduction, gynaecology, embryology, andrology, bioethics, mammalian reproduction, medical genetics, social science, law, or human rights, to be nominated by the State Government.

The Chairman of the State Board shall nominate a Vice Chairman from among its members[59]. The meeting of State Board will be held when necessary but not less than thrice a year and at such time and place as the Chairperson of the State Board may deem fit. The Chairperson of the State Board shall preside over the meetings while in his absence Vice Chairperson of the Board shall preside over the meeting.[60]

3.5.18 Powers and Functions of State Boards[61] –

The Bill provides that the State Board shall have the responsibility for laying down the policies and plans for assisted reproduction in the State[62]. It also provides that the State Board, taking into account the recommendations, policies and regulations of the National Board,[63] may –

[56] Id section 6
[57] Id sub-section (1) of section 3
[58] Id Section6(2)
[59] Id Section6(3)
[60] Id section 7
[61] Id section 8
[62] Id Section 8(1)
[63] Id Section 8(2)

- Advise the State Government to constitute a Registration Authority or Authorities as required, at least of six experts in assisted reproduction technology or a related field, for the use of assisted reproductive technology in the State;
- Monitor the functioning of the Registration Authority subject, in particular, to the guidelines laid down by the National Advisory Board;
- Coordinate the enforcement and implementation of the policies and guidelines for assisted reproduction;
- Constitute advisory committees consisting of experts in the field of assisted reproduction and related fields at the State or district level, to make recommendations on different aspects of assisted reproduction;
- Perform such other functions prescribed under this Act;

On the basis of a complaint or otherwise the State Board may *suo moto* examine and review any decision of the Registration Authority[64]. Also the State Board has power to give directions or pass orders which are necessary, with reasons to be recorded in writing[65].

3.5.19 Term of Office, Conditions of Service, etc., of Chairperson and other Members of State Boards[66] –

The Bill empowers the appropriate Government to appoint any person as the Chairperson or other member after being satisfied that his/her professional interest shall not affect prejudicially his functions as such member[67]. The tenure of the Chairperson and every other Member is prescribed in the order of appointment, not exceeding five years, by the appropriate government, who shall be eligible for re-appointment[68].The resignation of a member should be in writing under his / her hand and addressed to the appropriate Government. A vacancy caused by the resignation or removal of the Chairperson or any other member shall be filled by fresh appointment. If a vacancy occurs in the office of the Chairperson due to his/her death, resignation or otherwise, then one of the members to whom the appropriate Government, by notification, has authorizes, shall act as the Chairperson till the date on which a new Chairperson is appointed and takes charge of the office. In the absence of chairperson,

[64] Id Section 8(3)
[65] Id Section 8(4)
[66] Id section 9
[67] Id section 9(1)
[68] Id section 9 (2)

due to illness or any other cause, the Vice Chairperson shall discharge the function of the Chairpersons, till the date on which the Chairperson resumes his duties. The salaries and allowances payable to and the other terms and conditions of service of the Chairperson and other members are previously prescribed and shall not be varied to the disadvantage of Chairperson or any other member after his appointment. The Chairperson and every other member have to make a declaration of fidelity and secrecy, before entering the office in the form set out in the Schedule. The Chairperson is prohibited for a period of three years from the date on which he ceases to hold such office, to hold any appointment or be connected with the management or administration in any company, hospital, clinic, society, trust or other undertaking in relation to which any matter has been the subject matter of consideration before the State Board.

3.5.20 Procedure of State Boards[69] –

The bill provides the State Board powers[70] to –

- Regulate the procedure and conduct of the business;
- Delegate its powers or functions to such persons or authorities as prescribed in the rules or regulations made.
- The Bill also gives the State Boards, powers[71]to –
- Summon and enforce the attendance of any witness and examine him/her on oath;
- Order the discovery and production of document or other material objects producible as evidence;
- Receive evidence on affidavit;
- Requisition of any public record from any court or office;
- Issue any order for the examination of witnesses;
- Any other matter which may be prescribed.

3.5.21 Constitution and Functions of the Registration Authority[72] –

The State Government shall constitute the Registration Authority within three months on the advice of the State Board. The Registration Authority shall have a full-time Chairman to the level of a Secretary to the State Government, who shall be a recognised expert in assisted reproductive technology or a related field. Other

[69] Id section 10
[70] Id section 10(1)
[71] Id section 10(2)
[72] Id section 11

members of the Registration Authority shall be part-time members, and shall be adequately compensated for their services. Before appointing any member of the Registration Authority, the Government shall satisfy itself that his/her integrity is such that his/her professional interest shall not affect prejudicially his/her functions as a member. The State Government shall provide adequate staff and secretarial assistance and suitable accommodation to the Registration Authority. The Registration Authority shall issue an appropriate letter granting or rejecting registration to an assisted reproductive technology clinic.

3.5.22 Proceedings before State Boards to be Judicial Proceedings[73]**–**

The Bill deems every State Board to be a civil court. when any offence is described in the bill is committed, the State Board may, after recording the facts constituting the offence and the statement of the accused as provided for in the Code of Criminal Procedure, 1973, forward the case to a Magistrate having jurisdiction to try the same, and the Magistrate to whom any such case is forwarded shall proceed with the complaint as if the case has been forwarded to him under the Code of Criminal Procedure, 1973[74]. Every proceeding before a State Board shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228, and for the purposes of section 196 of the Indian Penal Code, and the Board shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.

Chapter III make detailed provisions for procedure for registration and complaints.

3.5.23 Registration and Accreditation of Clinics[75] **–**

Under section 3 of the Bill (ART Bill 2010) all assisted reproductive technology clinics are required to register themselves with the Registration Authority. within prescribed period ,form and manner. An application for registration by an assisted reproductive technology clinic under sub-section (1) of this section shall contain the particulars of the applicant including all details of techniques and procedures of assisted reproductive technology practiced at such clinic. The State Board may, subject to prescribed terms and conditions, register any assisted reproductive technology clinic on the basis of the techniques and procedures of assisted reproductive technology practiced at such clinic, such as –

[73] Id section 12
[74] Section346 of code of criminal procedure
[75] Supra note 42, Section 13

- infertility treatment, including Intra-Uterine Insemination (IUI), Artificial Insemination with Husband's semen (AIH), and Artificial Insemination using Donor Semen (AID), involving the use of donated or collected gametes;
- infertility treatment involving the use and creation of embryos outside the human body;
- processing or storage of embryos;
- research.

Assisted reproductive technology clinic performing any of the functions under sub-section (3) of this section, or any other advanced diagnostic, therapeutic or research functions, shall not practice any aspect of such diagnosis, therapy or research without a certificate of accreditation issued by the State Board. The practice of any aspect of assisted reproductive technology in contravention of the provisions of this section shall constitute an offence under this Act. Assisted reproductive technology clinics registered under this Act shall be deemed to have satisfied the provisions of the PC & PNDT Act, 1994 [amended in 2002], and shall not be required to seek a separate registration under the said Act.

3.5.24 Who May Apply for Registration[76]–

- The Bill says that assisted reproductive technology clinics, ART banks and research organizations using human embryos, operative on the date of notification of it, shall obtain a temporary registration within six months of the notification of the State Registration Authority by the State Board, and regular registration within 18 months of the above notification. If an assisted reproductive technology clinic that has applied for temporary registration under this clause to the State Registration Authority does not receive the registration or hear from the above Authority within 60 days of the receipt of the application by the authority, the clinic would be deemed to have received the temporary registration.
- Registration is necessary for every assisted reproductive technology clinic, ART bank or research organization using human embryos, other than the ones specified above, practicing any aspect of assisted reproductive technology, or

[76] Id section 14

carrying out any research on or using human embryos, or using any premises for such purposes.

- Any assisted reproductive technology clinic or ART bank or research organisation using human embryos, by whatsoever name called, may apply to the to the Registration Authority for registration
- Every application under sub-section (2) of this section shall be in prescribed form and shall be accompanied by prescribed fee and documents.

3.5.25 Grant of Registration[77] –

The Registration Authority after being satisfied, grant registration to the applicant for a term of three years with such terms and conditions as it thinks fit. The Bill also requires the Registration Authority to send a report to the State Board, within one month of a registration being granted. The State Board has to maintain record of all registrations applied for and granted under this section. Before registration being granted the Registration Authority or its authorised person or persons, shall inspect the premises of the applicant.

3.5.26 Renewal, Suspension or Revocation of Registration[78] –

The Bill gives Registration Authority the power to renew a registration on an application with effect from the date of its expiry if it is satisfied that the criteria prescribed in the Schedule continue to be met. The Registration Authority may suspend the operation of a registration and demand the registration holder to produce documents or furnish evidence as may be required if it has reasonable grounds to believe that the terms and conditions of the registration have not been met. The Registration Authority will give the holder of the registration adequate opportunity to be heard before revoking the registration or continuing it. The Registration Authority shall inform the concerned State Board of every assisted reproductive technology clinic in respect of which it has granted, renewed, revoked or denied a registration under this Act within one month of such an action being taken. The Registration Authority shall be deemed to have granted renewal for three years to the applicant if the applicant does not receive a definitive communication from the Registration Authority regarding the renewal application within sixty days of the receipt of the application in the office of the Registration Authority.

[77] Id section 15
[78] Id section 16

3.5.27 Registration Authority to Inspect Premises[79] –

The Bill also empowers the Registration Authority to inspect, with or without prior notice on a working day during working hours, any premises or call for any document or material while exercising its powers and functions.

3.5.28 Applicability to ART Banks and Research Organizations[80] –

The provisions of sections 13 to 16, as relevant, shall apply also to ART banks and research organizations using human embryos.

3.5.29 Appeal to the State Board[81] –

Any person aggrieved by the decision of the Registration Authority may prefer an appeal to the State Board within prescribed time, manner and form. On receipt of an appeal, the State Board may, after giving an opportunity of hearing to the appellant, and after making required inquiry, confirm, modify or set aside the decision of the Registration Authority, within three months of the receipt of the appeal.

The ART Bill, prepared by the ICMR, will make it mandatory for all clinics involved in treating infertility through procedures like artificial insemination with husband's semen (AIH) or in-vitro fertilization-embryo transfer (IVF) to get registered in the country's maiden National Registry of ART clinics.[82]

3.6 Regulation of ART Procedures

The general principles of the Ethical guidelines for biomedical research on human subjects[83] states: There is a certain element of risk associated with all ART procedures. It is, therefore, necessary to ascertain the therapeutic and research value of the ART procedure in each case.

3.6.1 Informed Consent:

After duly counseling the couple/oocyte/semen donor, an informed and written consent should be taken from both the spouses as well as the donor, as the case may be.

- They should explained the various risk factors associated with the procedures like the possibility of multiple pregnancies, ectopic gestation, increased rate of

[79] Id section 17
[80] Id section 18
[81] Id section 19
[82] *The Times of India*, Kounteya Sinha, TNN Jul 13, (2012), 04.41AM IST, available at *http://articles.timesofindia.indiatimes.com/2012-07-13/india/32663156_1_clinics-infertility-medical-technologies visited on 26/01/13 at 10:45 A.M.*
[83] Supra note 6, Chapter viii.

spontaneous abortion, premature births, higher prenatal and infant mortality as well as growth and developmental problems, possible side effects (e.g. of the drug used) and the risks of treatment to the women in simple language and the words which they can understand.

- Non guarantee of the success / failure of the procedure and the need to reduce the number of viable foetuses, in order to ensure the survival of at least two fetuses should also be explained.
- There may be possible disruption of the patient's domestic life which the treatment may cause;
- They should be informed about the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort;
- They should also be explained the importance of informing the clinic about the result of the pregnancy in a pre-paid envelope; and
- Also about the advantages and disadvantages of continuing treatment after a certain number of attempts.
- It should be made clear whether embryos that are not used for transfer could or could not be used for research purposes or implanted in another woman's womb, or "preserved " for use at a later date or destroyed. Investigators should ensure that participants are informed and consent is taken afresh in writing on the above issues at every stage.
- Consent may be withdrawn at any time before implantation.
- Specific consent must be obtained from couples who have their gametes or embryos frozen, with regard to what should be done with them in case of death, or if any of the parties becomes incapable of varying or revoking her or his consent.
- Investigators should clarify the ownership of the embryos that they belong to the genetic mother or the laboratory. Abortions should never be encouraged for research purposes.
- No ART procedure will be done without the consent of the spouse or partner.
- There is no ethical objection at the moment for IVF or any other related procedure for research or for clinical application.
- The semen bank assumes the responsibility in selection of the suitable donor on following terms:

- Complete physical examination of the donor should be done to ascertain the good health of the donors of semen, oocyte or embryo. The donor should be healthy with reasonable expectation of good quality eggs or sperms and preferably with proven fertility record.
- The physical characteristic and mental make-up of the donor should match as closely as possible to that of the spouse of the recipient, especially with reference to colour of the skin, eyes and hair, height and build, religious and ethnic background, the educational level and ABO blood type.
- Blood group of the proposed donor and donee should be tested with respect to Rh compatibility.
- No person suffering from any sexually transmitted disease (e.g. syphilis, gonorrhea, chlamydia, herpes, HIV etc.), infectious disease (e.g. hepatitis B and C, HIV) or genetically transmissible disease should be used as donor. Sexually transmitted diseases should be ruled out within a week of obtaining the seminal fluid.
- It is essential that donated semen is cryo-preserved and used only after 6 months as this would enable the centre to retest the donor after 6 months for HIV and eliminate the potential risk of HIV transmission in the 'window' period of HIV infection.
- Identity of the donor as well as the recipient should be protected from each other. However, all the records of the donor must be preserved for at least 10 years in order to trace her / him in case of any eventuality and should be confidential.
- Confidentiality of the entire procedure and its outcome is advisable and therefore, no relative should be accepted as a donor in order to avoid identification and claims of parenthood and inheritance rights.
- Any information about clients and donors must be kept confidential. No information about the treatment of couples provided under a treatment agreement may be disclosed to anyone other than the accreditation authority or persons covered by the license, except with the consent of the person(s) to whom the information relates, or in a medical emergency concerning the patient, or a court order. It is this person(s)' right to decide what information will be passed on and to whom.

- Written consent of the donor should be taken towards unrestricted use of sperms or oocytes for ART, as well as an undertaking from him / her that he / she will not attempt to seek the identity of the recipient. In case the donor is married, the written consent of the spouse should be taken, if possible.
- It is also desirable to restrict the use of semen from the same donor to a maximum of 10 pregnancies to avoid the possibility of an incestuous relationship occurring among the offsprings at a later date.
- In case of the oocyte donor, incurring any health problems related to the process of donation, the costs of the subsequent health care should be borne by the potential recipient couple irrespective of whether they receive oocyte donation as planned or not.
- In case of unused surplus/ spare embryos, consent of the concerned couple should be obtained to cryopreserve such embryos for donation to other needy couples. Such embryo donations should be kept anonymous. The ownership rights of such embryos rest with the couple concerned.

3.6.2 Gametes and Embryos:

Respect for embryo can be shown by -

- Accepting limits on what can be done in embryo research;
- Committing to an inter-disciplinary process of peer group review of planned Research; and
- Carrying out an informed consent process for gamete and embryo donors. Further, respect for the embryo's moral status can be shown by careful regulation of conditions of research, safeguards against commercial exploitation of embryo research, and limiting the time within which research can be done on embryo up to 14 days' growth i.e. when the primitive streak appears. This restriction is in keeping with the policy in several nations that permit research with embryos. At this time, the development of nervous system begins and the embryo begins to become a distinct individual.

With regard to use of gametes or embryo -

- no woman shall be treated with gametes or embryos derived from gametes of more than one man or woman;
- no ART clinic shall mix semen from two individuals before use;
- no ART clinic shall provide a couple with embryo of desired sex;
- no gametes shall be stored for more than 10 years;

- an embryo shall be stored for not more than five years;
- sale, transfer or use outside India is prohibited;
- The donor shall relinquish all parental rights over the child which may be conceived from her or his gamete.

Women have a special position as care givers for children with disabilities. Since the bulk of care falls upon the women, she should make the final decision among reproductive options, without coercion from her partner, her doctor, or the law. The choice is more than the absence of legal prohibition or coercion and should include the economic and social ability to act upon a decision, including disability. There should be a positive right to affordable genetic services, safe abortion and medically indicated care for children with disabilities.

The possibility of human cloning cannot be rejected since sheep and mice have already been cloned. However, since its safety, success, utility and ethical acceptability is not yet established, research on cloning with intent to produce an identical human being, as of today, is prohibited.

3.6.3 Sourcing, Storage, Handling and Record Keeping for Gametes, Embryos and Surrogates:[84]

The provision for Sourcing of gametes is provided under section 26 of the ART Bill 2010. It says that ART bank has to do the screening of gamete donors and surrogates; the collection, screening and storage of semen; and provision of oocyte donor and surrogates. An ART bank shall operate independently of any assisted reproductive technology clinic. ART banks shall obtain semen from males between twenty one years to forty five years of age, inclusively, and arrange to obtain oocytes from females between twenty one years of age and thirty five years of age, inclusively. All ART banks shall have standard, scientifically established facilities and defined standard operating procedures for all its scientific and technical activities. All ART banks shall cryo-preserve sperm donations for a quarantine period of at least six months before being used and, at the expiry of such period, the ART bank shall not supply the sperm to any assisted reproductive technology clinic unless the sperm donor is tested for such diseases, sexually transmitted or otherwise, as may be prescribed. An ART bank may advertise for gamete donors and surrogates, who may

[84] Supra note 24, Chapter 5.

be compensated financially by the bank[85]. An ART bank is limited to supply the sperm of a single donor for use up to seventy five times[86]. A woman may donate oocytes for six times in her life, keeping three-month interval between the oocyte pick-ups[87]. Eggs from one donor can be shared between two recipients only, provided that at least seven oocytes are available for each recipient[88]. The assisted reproductive technology clinic may preserve all unused oocytes for use on the same recipient(s), or give for research to a bonafide organisation[89]. An ART clinic may use one sample of semen supplied by an ART bank only once on only one recipient[90]. An ART bank shall obtain all necessary information in respect of a sperm or oocyte donor or a surrogate, including the name, identity and address of such donor or surrogate, in such manner as may be prescribed, and shall undertake in writing to the donor to keep such information confidential[91]. No ART bank shall divulge the name, identity or address of any sperm or oocyte donor to any person or assisted reproductive technology clinic except in pursuance of an order or decree of a court of competent jurisdiction[92]. Any person or ART bank who divulges the name, identity or address of a sperm donor in contravention of subsections 11 and 12 of this section shall be guilty of an offence under this Act[93]. An ART bank may, for such appropriate fee as may be prescribed, store any semen obtained from a donor for the exclusive use of the wife or partner of the donor.

Section 27 of the ART Bill 2010 makes provisions for storage and handling of gametes and embryos. It provides that the highest possible standards should be followed in the storage and handling of gametes and embryos in respect of their security, and with regard to their recording and identification. No donor gamete shall be stored for a period of more than five years. An embryo may, for such appropriate fee as may be prescribed, be stored for a maximum period of five years and at the end of such period such embryo shall be allowed to perish or donated to an approved research organization for research purposes with the consent of the patients. If during the period of five years, one of the commissioning partners dies, the surviving partner

[85] Id section26(6)
[86] Id section26(7)
[87] Id section26(8)
[88] Id section26(9)
[89] Id section26(10)
[90] Id section26(11)
[91] Id section26(12)
[92] Id section26(13)
[93] Id section26(14)

can use the embryo for herself or for her partner, provided an appropriate consent was taken earlier. Provided that where the persons to whom such embryo relates fails to pay the fee, or both the commissioning persons die, the assisted reproductive technology clinic may, subject to such regulations as may be prescribed, destroy the embryo or transfer the embryo to any accredited research organisation under section 18 of this Act.

Under section 28 of the Bill, the ART bank shall keep a record of all the gametes received, stored and supplied, and details of the use of the gametes of each donor. The records shall be maintained for at least ten years, after which the records shall be transferred to a central database of the Department of Health Research, Government of India. Where an ART bank closes before the expiry of the ten year period, the records shall be immediately transferred to the central database of the Department of Health Research, Government of India. If not otherwise ordered by a court of competent jurisdiction, all ART banks shall ensure that all information about clients and donors is kept confidential and that information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research.

Section 29 of the Draft bill 2010 imposes certain restriction on sale of gametes, zygotes and embryos. It says, the sale, transfer or use of gametes, zygotes and embryos, or any part thereof or information related thereto, directly or indirectly to any party outside India is prohibited and shall be deemed to be an offence under this Act except in the case of transfer of own gametes and embryos for personal use with the permission of the National Board. The sale of gametes, except for use by an assisted reproductive technology clinic for treating infertility, and the sale of zygotes and embryos, or of any information related to gametes, zygotes or embryos, within India, is prohibited and shall be deemed to be an offence under this Act.

3.6.4 Regulation of Research on Embryos[94]

The Permission of the Department of Health Research for research is mandatory under section 30 of the draft Bill. It says, the sale of any gametes and embryos or their transfer to any country outside India, for research is absolutely prohibited and shall constitute criminal offence under this Act. Research shall only be conducted on such gametes and embryos that have been donated for such purpose.

[94] Id chapter 6.

No research shall be conducted using embryos except with the permission of the Department of Health Research. Any person or organisation, by whatsoever name called, may apply to the Department of Health Research for registration as a research institution permitted to conduct research on embryos. While granting permission on an application for registration made under sub-section 4 of this section, the Department of Health Research may prescribe, and the applicant shall be bound by such terms and conditions as it thinks fit. The Department of Health Research may, if it has reasonable grounds to believe that any of the terms and conditions prescribed under subsection 5 of this section have not been met, –

- call for the production of such documents or the furnishing of such evidence as may be required;
- inspect, or order any officer authorised in this behalf to inspect, any premises related to the grant of registration;
- suspend the registration of the research institution, after giving all concerned parties adequate opportunity to be heard.
- the Department of Health Research may make such regulations as it thinks fit to provide for research on embryos.
- any act or thing done or omitted to be done in contravention of the provisions of this Chapter shall be deemed to be an offence under this Act.

Section 23 of the Draft Bill provides for regulation of research. It says, in exercising its powers under this chapter, the Department of Health Research shall ensure that –

- research will not be conducted on any human embryo unless such research is necessary in public interest;
- research is not conducted on any human embryo created *in vitro* unless such research is necessary in public interest to acquire further scientific knowledge;
- no research is conducted on any human embryo, other than embryos given for storage to an ART bank under sub-section (3) of section 27, unless full and informed consent in writing is obtained from the persons from whom such embryo was created;
- no advertisement is issued, and no purchase, sale or transfer is made, of any human embryo created *in vitro* or any part thereof, except in accordance with this Act;

- no human embryo created *in vitro* is maintained for a period exceeding fourteen days or such other period as recommended by the National Advisory Board;
- no work is done leading to human reproductive cloning;
- other terms and conditions that may be prescribed by the ICMR, are adhered to.
- any assisted reproductive technology clinic or other research institution or person conducting any research in contravention of the provisions of this Act or any rules or regulations prescribed hereunder shall be an offence under this Act[95].

3.7. Rights and Duties of the Parties of ART

3.7.1. Rights and Duties of the Parties of ART under the Ethical Guidelines for Biomedical Research on Human Subjects, 2000:

The specific principal regarding assisted reproductive technology under the Ethical guidelines for Biomedical research on human subjects [96] made provisions about Legitimacy of the Child born through ART, IVF-ET *(in-vitro* fertilisation and embryo-transfer) and Surrogate Motherhood, Preservation, Utilisation and Destruction of Embryos, Spare Embryos, Right of Children / Parents**.**

3.7.1.1. Legitimacy of the Child Born through ART:

A child born through ART is presumed to be the legitimate child of the couple having been born within the wedlock and with consent of both the spouses with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donor should have no parental right or duties in relation to the child and their anonymity should be protected.

3.7.1.2. IVF-ET (In Vitro Fertilization and Embryo-transfer) and Surrogate Motherhood:

There are no medico-legal problems posed by IVF-ET with egg and sperm of married couple. Donation of either egg or sperm is governed on the same lines as those for Artificial Insemination Donor with the married partner as the natural or biological mother. IVF-ET with donated egg or sperm or womb leasing will create

[95] Id section31(2)
[96] Supra note 6, at 110.

two to three sets of parents, genetic/ biological and natural. Following consensus has emerged universally with respect to surrogate motherhood:

- Surrogacy is an arrangement in which a woman agrees to carry a pregnancy that is genetically unrelated to her and her husband, with the intention to carry it to term and hand over the child to the genetic parents with whom she enters into a contract for surrogacy.
- It should be resorted to only when it is coupled with authorized adoption wherever applicable.
- The intending parents should have a preferential right to adopt the child subject to six week's postpartum delay for necessary maternal consent.
- Genetic parent's claim for the custody of the child in its best interest through adoption would be, to establish that the child is theirs through genetic (DNA) fingerprinting, of which the records will be maintained in the clinic,
- Surrogacy should be resorted to only if medically certified as the only solution to infertility or any other medical bar on pregnancy by the intending mother.
- A qualified consultant should supervise to enforce adequate genetic screening.
- Abortion under the Abortion Law on the medical ground should be inviolate right of the surrogate and the genetic parents have no claim over the amounts already paid.
- The contract for surrogacy is legally enforceable. It shall provide for all expenses related to medical management during pregnancy, delivery, and immediate postpartum period till adoption and should be borne by the intending couple. Monetary compensation for agreeing to be the surrogate may also be specified in the agreement.
- Information about the surrogate shall be kept confidential except with the consent of the person whom the information relates to or by court order.
- ART clinics shall not provide surrogate mothers or information on potential surrogate mothers to couples or individuals.

3.7.1.3. Preservation, Utilisation and Destruction of Embryos:

Research is prohibited on embryos of more than 14 days after fertilization excluding the period during which the embryo was frozen with maximum storage period of 10 years and a 5 yearly review of semen and embryo deposits as practiced in other countries *eg*. U.K.

3.7.1.4. Spare Embryos:

Embryo-splitting may be resorted to in selected cases for overcoming the paucity of suitable embryos during ART in a couple. Child born of cryo-preserved embryos after divorce is deemed to be illegitimate if existing law does not permit it.

3.7.1.5.Right of Children / Parents:

A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses. Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to couple through sexual intercourse. Children born through use of donor gametes and their social/adopted parent have the right to know the medical or genetic information about the genetic parents that may be relevant to the child's health. The child's has a right to seek information on genetic parent(s) or surrogate mother (including a copy of the DNA fingerprint, if available) on reaching 18 years, except for information on the personal identity of the gamete donor or the surrogate mother unless when required in threatening medical conditions. The couple is not obliged to provide the information to the child on their own when she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child.

3.7.2. Rights and Duties of the parties of ART under the National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India:

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India also made provisions for rights and duties of the persons involved in the ART procedure.

3.7.2.1. Information and Counselling to be given to Patients[97]

The ICMR Guidelines make detailed provision for information and councelling to be given to patient. Information must be given to couples seeking treatment, on the following points:

- The basis, limitations and possible outcome of the treatment proposed, variations in its effectiveness over time, including the success rates with the recommended treatments obtained in the clinic as well as around the world

[97] Supra note 1, para 3.4

(this data should be available as a document with references, and updated every 6 – 12 months).

- The possible side-effects (e.g. of the drug used) and the risks of treatment to the women and the resulting child, including (where relevant) the risks associated with multiple pregnancy.
- The need to reduce the number of viable foetuses, in order to ensure the survival of at least two foetuses.
- Possible disruption of the patient's domestic life which the treatment may cause.
- The techniques involved, including (where relevant) the possible deterioration of gametes or embryos associated with storage, and possible pain and discomfort.
- The cost (with suitable break-up) to the patient of the treatment proposed and of an alternative treatment, if any (there must be no other "hidden costs").
- The importance of informing the clinic of the result of the pregnancy in a pre-paid envelope.
- To make the couple aware, if relevant, that a child born through ART has a right to seek information (including a copy of the DNA fingerprint, if available) about his genetic parent/surrogate mother on reaching 18 years, excepting information on the name and address – that is, the individual's personal identity–of the gamete donor or the surrogate mother. The couple is not obliged to provide the information to which the child has a right, on their own to the child when he/ she reaches the age of 18, but no attempt must be made by the couple to hide this information from the child should an occasion arise when this issue becomes important for the child.
- The advantages and disadvantages of continuing treatment after a certain number of attempts.
- Pamphlets (one-page on each technique in all local languages and English) which give clear, precise and honest information about the procedure recommended to be used will help the couple make an informed choice.

3.7.2.2. Rights of a Child Born through various ART Technologies

The ICMR Guidelines says [98]:

- A child born through ART shall be presumed to be the legitimate child of the couple, having been born in wedlock and with the consent of both the spouses[99]. Therefore, the child shall have a legal right to parental support, inheritance, and all other privileges of a child born to a couple through sexual intercourse.
- Children born through the use of donor gametes, and their "adopted" parents shall have a right to available medical or genetic information about the genetic parents that may be relevant to the child's health[100].
- Children born through the use of donor gametes shall not have any right whatsoever to know the identity (such as name, address, parentage, etc.) of their genetic parent(s). A child thus born will, however, be provided all other information (including that mentioned in Section 3.4.8) about the donor as and when desired by the child, when the child becomes an adult. While the couple will not be obliged to provide the above "other" information to the child on their own, no deliberate attempt will be made by the couple or others concerned to hide this information from the child as and when asked for by the child[101].
- In the case of a divorce during the gestation period, if the offspring is of a donor programme – be it sperm or ova – the law of the land as pertaining to a normal conception would apply[102].

3.7.2.3. Legitimacy of the Child Born through ART[103]

Under ICMR Guidelines, A child born through ART shall be presumed to be the legitimate child of the couple, born within wedlock, with consent of both the spouses, and with all the attendant rights of parentage, support and inheritance. Sperm/oocyte donors shall have no parental right or duties in relation to the child, and their anonymity shall be protected except in regard to what is mentioned under item 3.12.3.

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[98] Id para 3.12
[99] Id para 3.12.1
[100] Id para 3.12.2
[101] Id para 3.12.3
[102] Id para 3.12.4
[103] Id para 3.16.1

3.7.2.4. Adultery in the case of ART[104]

ART used for married woman with the consent of the husband does not amount to adultery on part of the wife or the donor. AID without the husband's consent can, however, be a ground for divorce or judicial separation.

3.7.2.5.Consummation of Marriage in case of AIH[105]

Conception of the wife through AIH does not necessarily amount to consummation of marriage and a decree of nullity may still be granted in favor of the wife on the ground of impotency of the husband or his willful refusal to consummate the marriage. However, such a decree could be excluded on the grounds of approbation.

3.7.2.6. Rights of an Unmarried Woman to AID[106]

There is no legal bar on an unmarried woman going for AID. A child born to a single woman through AID would be deemed to be legitimate. However, AID should normally be performed only on a married woman and that, too, with the written consent of her husband, as a two-parent family would be always better for the child than a single parent one, and the child's interests must outweigh all other interests.

3.7.2.7. Posthumous AIH through a Sperm Bank[107]

Though the Indian Evidence Act, 1872, says that a child born within 280 days after dissolution of marriage (by death or divorce) is a legitimate child since that is considered to be the gestation period, it is pertinent to note that this Act was enacted as far back as 1872 when one could not even visualize ART. The law needs to take note of the scientific advancements since that time. Thus a child born to a woman artificially inseminated with the stored sperms of her deceased husband must be considered to be a legitimate child notwithstanding the existing law of presumptions under our Evidence Act. The law needs to move alongwith medical advancements and suitably amended so that it does not give rise to dilemma or unwarranted harsh situations.

3.7.3. Rights and Duties of Patients, Donors, Surrogates and Children under Assisted Reproductive Technology Bill 2010 [108]

3.7.3.1. Rights and Duties of Patients[109] –

[104] Id para 3.16.2
[105] Id para 3.16.3
[106] Id para 3.16.4
[107] Id para 3.16.5
[108] Supra note 24, Chapter 7.

- ❖ Assisted reproductive technology shall be available to all persons including single persons, married couples and unmarried couples.
- ❖ In case assisted reproductive technology is used by a married or unmarried couple, there must be informed consent from both the parties.
- ❖ The parents of a minor child have the right to access information about the donor, other than the name, identity or address of the donor, or the surrogate mother, when and to the extent necessary for the welfare of the child.
- ❖ All information about the patients shall be kept confidential and information about assisted reproductive technology procedures done on them shall not be disclosed to anyone other than the central depository of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by a court order.

3.7.3.2. Rights and Duties of Donors[110] –

- ❖ All information about the donors shall be kept confidential and information about gamete donation shall not be disclosed to anyone other than the central database of the Department of Health Research, except with the consent of the person or persons to whom the information relates, or by an order of a court of competent jurisdiction.
- ❖ The donor shall have the right to decide what information may be passed on and to whom, except in the case of an order of a court of competent jurisdiction.
- ❖ A donor shall relinquish all parental rights over the child which may be conceived from his or her gamete.
- ❖ No assisted reproductive technology procedure shall be conducted on or in relation to any gamete of a donor under this Act unless such donor has obtained the consent in writing of his or her spouse, if there, to such procedure.
- ❖ The identity of the recipient shall not be made known to the donor.

3.7.3.3. Rights and Duties in Relation to Surrogacy[111] –

[109] Id section 32
[110] Id section 33
[111] Id section 34

- Both the couple or individual seeking surrogacy through the use of assisted reproductive technology, and the surrogate mother, shall enter into a surrogacy agreement which shall be legally enforceable.
- All expenses, including those related to insurance if available, of the surrogate related to a pregnancy achieved in furtherance of assisted reproductive technology shall, during the period of pregnancy and after delivery as per medical advice, and till the child is ready to be delivered as per medical advice, to the biological parent or parents, shall be borne by the couple or individual seeking surrogacy.
- The surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate.
- A surrogate mother shall relinquish all parental rights over the child.
- Woman below twenty one years of age and over thirty five years of age shall not be eligible to act as a surrogate mother under this Act. Provided that a woman shall not be allowed to act as a surrogate for more than five successful live births in her life, including her own children.
- Any woman seeking or agreeing to act as a surrogate mother shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and must declare in writing that she has not received a blood transfusion or a blood product in the last six months.
- Individuals or couples may obtain the service of a surrogate through an ART bank, which may advertise to seek surrogacy provided that no such advertisement shall contain any details relating to the caste, ethnic identity or descent of any of the parties involved in such surrogacy. No assisted reproductive technology clinic shall advertise to seek surrogacy for its clients.
- A surrogate mother shall, in respect of all medical treatments or procedures in relation to the concerned child, register at the hospital or such medical facility in her own name, clearly declare herself to be a surrogate mother, and provide the name or names and addresses of the person or persons, as the case may be, for whom she is acting as a surrogate, along with a copy of the certificate mentioned in clause 17 below.
- No surrogate mother shall undergo embryo transfer more than three times for the same couple.

- The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of individual/individuals who commissioned the surrogacy, as parents.
- The person or persons who have availed of the services of a surrogate mother shall be legally bound to accept the custody of the child / children irrespective of any abnormality that the child / children may have, and the refusal to do so shall constitute an offence under this Act.
- All information about the surrogate shall be kept confidential and information about the surrogacy shall not be disclosed to anyone other than the central database of the Department of Health Research, except by an order of a court of competent jurisdiction.
- A surrogate mother shall not act as an oocyte donor for the couple or individual, as the case may be, seeking surrogacy.
- No assisted reproductive technology clinic shall provide information on or about surrogate mothers or potential surrogate mothers to any person.
- Any assisted reproductive technology clinic acting in contravention of sub-section 14 of this section shall be deemed to have committed an offence under this Act.
- In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate.
- A surrogate mother shall be given a certificate by the person or persons who have availed of her services, stating unambiguously that she has acted as a surrogate for them.
- A relative, a known person, as well as a person unknown to the couple may act as a surrogate mother for the couple/ individual. In the case of a relative acting as a surrogate, the relative should belong to the same generation as the women desiring the surrogate.
- A foreigner or foreign couple not resident in India, or a non-resident Indian individual or couple, seeking surrogacy in India shall appoint a local guardian who will be legally responsible for taking care of the surrogate during and after the pregnancy as per clause 34.2, till the child/children are delivered to the foreigner or foreign couple or the local guardian. Further, the party seeking the surrogacy must ensure and establish to the assisted reproductive technology clinic through proper documentation (a letter from either the

embassy of the Country in India or from the foreign ministry of the Country, clearly and unambiguously stating that (a) the country permits surrogacy, and (b) the child born through surrogacy in India, will be permitted entry in the Country as a biological child of the commissioning couple/individual) that the party would be able to take the child/children born through surrogacy, including where the embryo was a consequence of donation of an oocyte or sperm, outside of India to the country of the party's origin or residence as the case may be. If the foreign party seeking surrogacy fails to take delivery of the child born to the surrogate mother commissioned by the foreign party, the local guardian shall be legally obliged to take delivery of the child and be free to hand the child over to an adoption agency, if the commissioned party or their legal representative fails to claim the child within one months of the birth of the child. During the transition period, the local guardian shall be responsible for the well-being of the child. In case of adoption or the legal guardian having to bring up the child, the child will be given Indian citizenship.

- ❖ A couple or an individual shall not have the service of more than one surrogate at any given time.
- ❖ A couple shall not have simultaneous transfer of embryos in the woman and in a surrogate.
- ❖ Only Indian citizens shall have a right to act as a surrogate, and no ART bank/ART clinics shall receive or send an Indian for surrogacy abroad.
- ❖ Any woman agreeing to act as a surrogate shall be duty-bound not to engage in any act that would harm the foetus during pregnancy and the child after birth, until the time the child is handed over to the designated person(s).

The commissioning parent(s) shall ensure that the surrogate mother and the child she deliver are appropriately insured until the time the child is handed over to the commissioning parent(s) or any other person as per the agreement and till the surrogate mother is free of all health complications arising out of surrogacy.

3.7.3.4. Determination of Status of the Child[112] –

- ❖ A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having

[112] Id section 35

been born in wedlock and with the consent of both spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse.

- ❖ A child born to an unmarried couple through the use of assisted reproductive technology, with the consent of both the parties, shall be the legitimate child of both parties.
- ❖ In the case of a single woman the child will be the legitimate child of the woman, and in the case of a single man the child will be the legitimate child of the man.
- ❖ In case a married or unmarried couple separates or gets divorced, as the case may be, after both parties consented to the assisted reproductive technology treatment but before the child is born, the child shall be the legitimate child of the couple.
- ❖ A child born to a woman artificially inseminated with the stored sperm of her dead husband shall be considered as the legitimate child of the couple.
- ❖ If a donated ovum contains ooplasm from another donor ovum, both the donors shall be medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed, and all other communicable diseases which may endanger the health of the child, and the donor of both the ooplasm and the ovum shall relinquish all parental rights in relation to such child.
- ❖ The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.
- ❖ If a foreigner or a foreign couple seeks sperm or egg donation, or surrogacy, in India, and a child is born as a consequence, the child, even though born in India, shall not be an Indian citizen.

3.7.3.5. Right of the Child to Information about Donors or Surrogates[113] –

- A child may, upon reaching the age of 18, ask for any information, excluding personal identification, relating to the donor or surrogate mother.
- The legal guardian of a minor child may apply for any information, excluding personal identification, about his/her genetic parent or parents or surrogate mother when required, and to the extent necessary, for the welfare of the child.

[113] Id section 36

- Personal identification of the genetic parent or parents or surrogate mother may be released only in cases of life threatening medical conditions which require physical testing or samples of the genetic parent or parents or surrogate mother Provided that such personal identification will not be released without the prior informed consent of the genetic parent or parents or surrogate mother.

3.8. A Critical Analysis of the ART Bill

ART Bill 2010 has been matter of discussion from the time of its framing among people and stakeholders interested in Indian ART and Surrogacy Arena. The Bill has been placed in various forms since 2005 when the guidelines regulating ART treatments including Surrogacy were first published by Indian Council of Medical Research (ICMR). This was the time when countries in the world and India also started realizing that importance of ART Treatments including Surrogacy and the need to regulate them. This was one of the stepping stones and an initiative by government to regulate Surrogacy Treatment and other ART Techniques in India and also to offer them to overseas patients. Since then Indian ART and Surrogacy arena has been a constant rise and India has earned itself a unique distinction as Surrogacy Capital of World.[114] With India fast emerging as a hotspot for rent-a-womb phenomenon, the Union health ministry has now finalized the Assisted Reproductive Technologies (ART) Regulation Bill 2010, which has been sent to the law ministry for its approval.[115] The Assisted Reproductive Technology Regulation Bill, prepared by the Indian Council of Medical Research (ICMR), will make it mandatory for all clinics involved in treating infertility through procedures like artificial insemination with husband's semen (AIH) or in-vitro fertilization-embryo transfer (IVF) to get registered in the country's maiden National Registry of ART clinics.[116]

The document lacks clarity at various levels and uses ambiguous language, which makes effective implementation of the Bill very challenging. Moreover, different parts of the Draft Bill contradict each other leaving certain critical questions unanswered. The analysis of the provisions of the Bill can be summarized below:

Firstly, regarding the issue of making payment to the surrogate, Clause 26 (6) of the Draft Bill states that

[114] "Update on ART regulation bill (Draft) 2010", available *on http://www.prlog.org/12027899-update-on-art-regulation-bill-draft-2010.html* visited on 19/04/2013 at 1:03 PM
[115] "Bill seeks to regulate wombs-for-rent", *The Times of India* , Jan 27, 2011,
[116] "Bill aims to weed out rent-a-womb clinics", *The Times of India*, Jul 13, 2012

"A semen bank may advertise for gamete donors and surrogates, who may be compensated financially by the bank. But according to Clause 34(2) '… the surrogate mother may also receive monetary compensation from the couple or individual, as the case may be, for agreeing to act as such surrogate."

Further, the Form of Contract between the Semen Bank and the Surrogate [Form- R2 (4)] mentions that "…the consideration for the surrogacy is to be paid by the parent(s) and the Bank will not be responsible for any demand by the surrogate in the form of compensation. The Bank shall not be responsible for payment to the surrogate for any other expenses incurred during the surrogacy period."

It is therefore not clear from this, who is actually compensating the surrogate. Is it the Bank or the couple/individual?[117]

Secondly, the Draft Bill is unclear about the venue of the actual oocyte retrieval and screening process – whether it is at the semen bank or the ART clinic. Clause 26 (1) states that "The collection, screening, storage, and handling of gametes shall be done by a semen bank." However, Clause 20 (1) mentions that "Assisted reproductive technology clinics shall ensure that patients, donors of gametes and surrogate mothers …have been medically tested for such diseases, sexually transmitted or otherwise, as may be prescribed and all other communicable diseases which may endanger the health of the parents, or any one of them, surrogate or child." It is not clear where the screening and testing of donors would take place. Also, since the semen banks are not equipped to conduct oocyte retrieval, the Draft Bill does not specify how they would equip themselves for the purpose.[118]

According to Clause 20 (10), Surrogacy cannot be considered for "patients for whom it would normally be possible to carry a baby to term", the agreement for surrogacy (Form J) makes the surrogate declare that she agrees to act as host mother for the couple "who are / is unable (or do not wish to) have a child by any other means." While on the one hand the Draft Bill makes only those couples eligible for surrogacy who cannot carry a pregnancy to term, on the other, it offers surrogacy as a choice, in case they do not wish to go through pregnancy.

There is ambiguity regarding the minimum age for oocyte donation. Under Clause 26 (3), the minimum age is mentioned as 21 years, but Rule 4.7.1 says that

[117] *Comments and Suggestions on the ART (Regulation) Bill and Rules-2008* by Sama Resource Group for Women and Health, New Delhi, 4 December, 2008 at 2.
[118] Id p. 3

"Donors should be healthy women in the age group of 18-35 years." The Draft Bill must specify its stand regarding the age of donors.

Another point of contradiction is in the Form of Application for Registration or Renewal of Registration of Semen Bank [Form- A (1)]. In the declaration, while on the one hand the person applying for registration of the bank needs to declare that the bank will operate independently of any ART clinic, in the very following point, "he/she must undertake to explain the Act and Rules to all employees of the ART clinic in respect of which the registration is sought." The independence of the semen bank from the ART clinic as envisaged by the Draft Bill comes into question here.[119]

The Draft Bill appears narrow in its approach by trying to regulate only a specified number of procedures. For example, the Draft Bill mentions procedures of: *Artificial Insemination (AIH/AID), Intra Uterine Insemination (IUI-H/ IUI-D), In vitro fertilization and Embryo Transfer (IVF-ET) and associated techniques of, Gamete Intrafallopian Tube Transfer (GIFT) or Tubal Embryo Transfer (TET), Intra Cytoplasmic Sperm Injection (ICSI) and ICSI with MESA/PESA/TESA/TESE, Oocyte donation or Embryo Donation and Cryopreservation of Semen, Embryos, Oocytes and, Ovarian Tissue.* However, the clinics also offer facilities of assisted hatching, blastocyst culture and transfer, laser hatching, ovarian drilling, in vitro maturation, etc. PGD by PCR/FISH techniques have also been introduced in some of the IVF clinics. The Draft Bill does not mention any of these procedures in the entire draft. Further, having included a chapter on research on embryos, it is surprising that the Draft Bill does not mention human embryonic stem cell research and the restrictions related to it.[120]

The Draft Bill in its present form focuses only on IVF clinics and semen banks, but ignores gynaecologists offering infertility 'treatments' and IUI procedure. The Draft Bill also does not take into consideration other consultancies, organizations, agents, private agencies and travel agencies involved in promoting IVF / ART techniques, egg donation and surrogacy. Further, the Draft Bill does not adequately dwell on the regulation and monitoring mechanisms for the public hospitals offering these technologies. Government hospitals are increasingly entering the field of ARTs.[121]

[119] Id p. 3
[120] Id p. 4
[121] Id p. 5

The Draft Bill allows couples to advertise for surrogates without mentioning '*details relating to the caste, ethnic identity or descent of any of the parties'* and prohibits ART clinics from seeking surrogates for its clients [Clause 34(7)].

However, advertisements for egg donors or surrogates by advertisement agencies, tourism departments, surrogacy agents, women's magazines, medical tours and travel agencies are not covered in the Draft Bill at all. Advertisements from couples looking for surrogates and women intending to be surrogates can be found regularly in newspapers and magazines. However, the Draft Bill only prohibits the clinics from advertising but does not foresee the establishment of newer enterprises that may undertake such advertising.[122]

Further, According to Clause 20(4),

"Either of the parties seeking assisted reproductive technology treatment or procedures shall been titled to specific information in respect of donor of gametes including, but not restricted to, height, weight, ethnicity, skin colour, educational qualifications, medical history of the donor, provided that the identity, name and address of the donor is not made known."

Similarly, the couples are entitled to know the ethnicity and educational qualifications of the donor and details like religion, education and monthly income of the donor must be recorded in Form M [Information on Semen Donor (4, 6, 7)].

Form M2 [Information on Surrogate (8, 9)] requires education and occupation of the surrogate and her spouse (if any), religion and monthly income. Moreover, current practices indicate that surrogates and donors are chosen based on their caste, religion, skin colour and attractive physical features.[123]

Unfortunately, the Draft Bill also supports these trends by asking for the surrogate's colour of skin, hair, eyes [Form M2 (34, 35, 36)], which is completely pointless since her oocytes would not be used in the procedures. As she only gestates the child, it is unnecessary to record her genetic characteristics. Giving significance to these characteristics is unnecessary since they do not have a bearing on the genetic composition of a person at all. Revealing particular characteristics of the donor to the intended parents and allowing them to choose donors based on those characteristics ushers in a number of debates. They only encourage eugenic tendencies and lead to discrimination against people belonging to particular religions, castes and with low

[122] Ibid
[123] Id at 6

educational and economic status. These may promote creation of designer babies and can definitely not be allowed through a national legislation.[124]

Further, The Draft ART Bill states that,

"*A child born to a married couple through the use of assisted reproductive technology shall be presumed to be the legitimate child of the couple, having been born in wedlock, with the consent of both the spouses, and shall have identical legal rights as a legitimate child born through sexual intercourse"* [Clause 35 (1)]

It is unclear as to why there is a separate list of the legitimacy of a child born through ARTs to married, unmarried and single men and women. Moreover, the definition of legitimacy is premised on the assumption that only children born within wedlock are legitimate. Such an assumption is problematic firstly because a child should not be accorded legitimacy based on her/his birth within or outside "*wedlock".* This essentially violates the right of a child to live a life of dignity and respect.[125]

The Draft Bill provides for the child to seek information about donors and surrogates on attaining 18 years of age. But at the same time it excludes information regarding personal identification and only in some cases allows disclosing the information with prior consent of the donor(s) or surrogate. Clause 36(1) of the Draft Bill states that "*A child may, upon reaching the age of 18, apply for any information, excluding personal identification, relating to his/her genetic parents or surrogate mother."* But, the document does not make it clear where the child needs to apply for getting the information. Since there are many authorities in the Bill; the Semen Banks, the ART clinics and the central database of the ICMR (where the details of the records will be transferred after expiry of 10 years) will keep the records of the donors and the surrogates, it is not clear where the child should apply.

The Draft Bill also lacks the measures taken to ensure the welfare of the children born through ARTs. In fact there is no section in the Draft Bill, which talks about the welfare of the child. The only points mentioned in this regard are those granting legitimacy to the children born though ARTs and the right of the child to have non-identifying information about his/her genetic parents.[126]

The Draft Bill does not adequately emphasize on adoption. Considering the fact that these technologies do not 'treat' or cure infertility, and keeping the potential

[124] Ibid
[125] Id at 7
[126] Ibid

risks for the mother and child in mind, a responsible legislation regarding infertility and ARTs must encourage adoption. Rather, this Draft Bill mentions adoption only twice in the whole document. It also mentions that *"...Further treatment for the unresponsive couples will then consist of counselling and an in-depth investigation, leading to the use of ART – failing which, adoption may be the only alternative…*" suggesting that adoption is an option if and when ARTs fail for a particular couple. This clearly demonstrates the endorsement of the desire for a 'biological' child or 'genetic make' in an official document.[127]

The provisions regarding oocyte retrieval and donation bring up a number of questions and concerns. According to Clause 26 (9) of the Draft Bill, "*If more than fourteen (14) oocytes are retrieved from the donor at one occasion, they shall not be used for more than two recipients thus ensuring that at least seven oocytes are available for each recipient."* Retrieving large number of eggs (like 14), requires hyper stimulating the ovaries by injecting hormonal drugs, which often entails serious medical complications for women. Moreover, the retrieval procedure in itself is highly invasive, and may result in serious damage/harm to the woman undergoing it. Referring to retrieval of such a large number of oocytes only shows the apathy of the Draft Bill towards the women who undergo the procedures and their health.[128]

The questions that this clause raises include: By what mechanism has the figure 14 been arrived at? How has it been decided that a woman's oocytes can go to two women and not to any number higher? Does this also mean that if less than 14 oocytes are retrieved then they can only be donated to one recipient because if given to a second recipient, she will receive less than 7? The ART Bill needs to give some explanation on these aspects.[129]

It also raises deeper concerns regarding the number of cycles that a woman can undergo while donating. Though the number of times for which a woman can donate oocytes has been limited to 6, [Clause 26(8)] that

"No woman shall donate oocytes more than six times in her life, with not less than a three months interval between the oocyte pick-ups".

However, the maximum number of cycles (which may be 6 or more) has not been mentioned. Also the mechanism to record and monitor the number of times a

[127] Ibid.
[128] Id at 8
[129] Ibid.

woman is making donations has not been mentioned. The three-month interval between the donations stipulated by the Draft Bill is very inadequate. Three months is too early for a woman to start with the hormonal injections again and undergo another oocyte retrieval. This interval should be increased.[130]

The Draft Bill states that

"A *semen bank shall not supply the sperm of a single donor for use more than seventy-five times*" [Clause 26(7)]

At the same time it explicitly mentions that one sample of semen can be given to only one recipient

"*One sample of semen supplied by a semen bank shall be used by the ART clinic only once on only one recipient*". [Clause 26(10)]

The rationale behind allowing the sperm of a single donor to be used for seventy-five times is not clear and has not been explained in the Bill. Seventy-five is a considerable figure for a single semen donor's sample to be supplied.

Further, The Draft Bill states that "*ARTs carry small risks both to the mother and the offspring"* (Rules 6.13) and mentions the risks for women which include multiple gestation, ectopic pregnancy, spontaneous abortion and Ovarian Hyper Stimulation Syndrome (OHSS). Similarly, while the Draft Bill advises a studied recommendation of foetal reduction for multiple gestation, it does not mention the morbid risks of foetal reduction which include: uterine bleeding, developing infection, premature labour and loss of all fetuses. Moreover, the Document states that foetal reduction may be carried out in cases of multiple pregnancy, "…*if so instructed by the patient*…" [Clause 23(5)]), thus once again levying the onus of the procedure on the couple that the Draft Bill itself qualifies as problematic in another section. On the one hand while the Draft Bill enlists ectopic pregnancies as a 'small risk', on the other, it contradicts itself by mentioning that the risk of an ectopic pregnancy could be as high as 5%, and that of OHSS could range from .2 – 8%. (Rules 6.13.3)

The document fails to convey the extent to which the drugs used and procedures performed during ARTs may potentially harm the health and well being of the women undergoing the procedures. This lacuna is also reflected through the consent forms where adequate information on the implications on OHSS (Form D,

[130] Ibid.

Consent form to be signed by the couple for IVF and ICSI) are conspicuous in their absence.

The Draft Bill has left a material void in the process of regulation by not specifying the maximum permissible age of women for undergoing ART procedures. There have been cases where women as old as 60 years or above have been made to conceive through ARTs with serious implications to their health. The Draft Bill should specify the maximum age limit for accessing ARTs.

Another important aspect completely missing in the Draft Bill is the number of embryo transfers and oocyte retrievals corresponding with the age of the woman. It states that "…*not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances (such as elderly women, poor implantation, advanced endometriosis or poor embryo quality*)." (Rules 6.13.1). This may cause problems as it leaves considerable scope to retrieve more eggs and transfer more number of embryos, putting the woman under risk. Moreover, having said that more than 3 embryos may be transferred in cases of older women, the document, on the same page, states that "*Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more fetuses*." (Rules 6.13.3)

As age has considerable bearing on the number of oocytes retrieved and the embryos to be transferred, it is significant that the Draft Bill should take this into consideration.

The importance of counseling for people who opt for ARTs cannot be emphasized enough, provided the counseling is intended to help them make decisions which are truly 'best' for them. If counseling is done by the ART clinics' own counselors, one may never be sure in whose interest the counseling is actually being done – the couple or the clinic. So, there should be provisions to arrange for counselors independent of the ART clinic and the Draft Bill must provide the guidance for accessing such independent counseling agencies. The Draft Bill, while mentioning the educational requirements of a counselor also states that *"A member of the staff of an ART clinic who is not engaged in any of other full-time activity in the clinic can act as counselor."* (Rules 2.4)

Moreover, there are 31 formats (application forms, record sheets, contracts) attached in the end of the Draft Bill, which make up a significant proportion of the document. MOHFW/ICMR's attempt at trying to streamline each and every aspect of

the procedures is commendable. However, in the Consent Form for Freezing of Embryos (Form G), giving the embryos for research (in case of death) is given as one of the options. There is no separate Consent Form for embryo research in the Draft Bill. In Form J, (Agreement for Surrogacy) the surrogate needs to declare that she and her husband have not had any extra marital relationship in the last six months. Such provisions are not only unreasonable but also pointless as this impinges on the sexual life of a woman who would be a surrogate. The various Consent Forms, specially the agreement on surrogacy, stress on spousal consent. This prerequisite appears unreasonable since it takes away the right of the surrogate over her own body. This should be reconsidered while finalizing the Bill.

Implementing the regulations that the Draft Bill proposes to put in place would be impossible without the maintenance of a sound database. While the Draft Bill mentions a centralized database to be maintained by the ICMR, there is no proposed system to record the number of children born to Indian surrogates being taken out of the country and the number of foreign couples undergoing ART procedures in India. Serious steps need to be taken to incorporate all these cases into a proper recording system. Moreover, a database, if properly maintained will be useful in giving a sex-desegregated data (in terms of male and female) with respect to children born through IVF and surrogacy which is not available till now.

Further, The Bill does not contain any Consent form for the procedure of PGD. Even in the Agreement for Surrogacy (Form J) though there is a provision that the surrogate will not be asked to undergo sex determination test for the child, this does not incorporate PGD, which is conducted on the embryo before it is transferred into the surrogate's uterus. Also, the Consent Form for IVF and ICSI (Form D, Pg 81) does not mention anything regarding the prohibition of sex-selection during the procedure. The use of PGD should be strictly monitored and it should be made clear that PGD will be available only where there is a significant risk of serious genetic condition being present in the embryo. Though prohibition of sex selection has been mentioned in Clause 25 (5) but the Draft Bill should deal with the issue of sex-selection more specifically.

Though the Bill claims to be liberal by using the phrase married or unmarried couple as eligible for ARTs, it does not include within its ambit people who are not heterosexual. The Bill clearly defines "Unmarried Couple" as a man and a woman, both of marriageable age, living together with mutual consent but without getting

married [Clause 2(w)] and "Couple", as persons living together and having a sexual relationship that is legal in the country/countries of which they are citizens or they are living in. [Clause 2(e)] In fact, 'Couple' has been defined in such a way in the Draft Bill that homosexual couples from other countries (where same sex relations are legal) can avail ART services from India, but not Indian homosexuals. Under Section 377 of the Indian Penal Code (IPC), "carnal intercourse against the order of nature", non procreative sexual acts are criminalized and this law is used to criminalize homosexuality. Therefore, Indians who openly identify as homosexuals are not eligible. Interestingly, some of the clinics are regularly providing these procedures to gay couples from abroad. As per both the above-mentioned definitions, only heterosexuals, irrespective of their marital status, are eligible to access these technologies in India. Even the Consent Forms require the signatures of husband and wife, and only at some places does the Draft Bill mention signature of the partner and provide ARTs to heterosexual married couple as a single entity.[131]

The Draft Bill prohibits the surrogate from being the egg donor [Clause 34 (13)]. Therefore, in case the oocyte of the intended mother is unviable and she is not able to carry a pregnancy to term, the couple would have to seek an egg donor and a surrogate. This also indicates that the surrogate would have to undergo IVF even when her oocytes are viable and she can bear the child through the much simpler IUI technique. Whether this has been stipulated to prevent the surrogate from being the genetic mother (and hence having a greater right over the child) or to promote the financial interests of the ART clinic is not known. [132]

The Draft Bill neither prohibits nor explicitly permits single women for acting as surrogates. Though it permits single women for accessing ARTs in general and also makes statements like "*In the event that the woman intending to be a surrogate is married, the consent of her spouse shall be required before she may act as such surrogate"* [Clause 34(16)] It does not clearly mention its stand. The MOHFW/ICMR must take care of such ambiguities.[133]

The ART Bill mentions that a relative acting as a surrogate must be from the same generation [Clause 34(18)] while restricting the age of the surrogate from 21 to 45 years [Clause 34(5)]. However, there may be cases when the prospective surrogate,

[131] id at 18
[132] Id at 19
[133] Ibid

mother-in-law for instance, falls within the permitted age group but does not belong to the same generation. The Bill must specify which clause should be adhered to in case the two clash.[134]

The document does not carry a much-needed elaboration on the money transactions between the surrogate, the commissioning couple and the semen banks - a key problem area. Since the thrust of the regulation is to regularize the commercial angle in the 'ART industry', this aspect is conspicuous in its absence. Firstly, there is no clarity on the role of the semen banks with regard to financially compensating the surrogate, as has been explained before. Secondly, the Agreement for Surrogacy (Form J) states that *"I have worked out the financial terms and conditions of surrogacy with the couple in writing" (Pg 92),* but does not mention how this would be carried out. It appears from this statement that the amount will be mutually decided by the couple and the surrogate. But, considering that the surrogate in most of the cases is from a poor socio-economic background, her say in deciding the amount remains questionable. In case the surrogate is not in the capacity to chalk out the financial details by herself, by whom would this process be facilitated? Since the semen bank has a role in sourcing the surrogates, this role may be played by them, which is not a desirable situation either since the semen bank may itself be involved financially in this agreement.[135]

The Bill mentions that '*No woman shall act as a surrogate for more than 3 successful live births*', ([Clause 34(5)] irrespective of the number of earlier pregnancies although the medical risks of frequent childbirths without adequate spacing are well known. The health risks associated with higher and frequent IVF cycles has been adequately emphasized in an earlier section of this critique. Restricting surrogacies in terms of successful live births is futile if the number of cycles is not specified. The document allows three successful live births along with permitting 3 ETs for a particular couple. Therefore the surrogate may legally undergo 9 cycles, which may result in hazardous consequences for her health. Moreover, she may be donating oocytes and may also have had children of her own. These coupled with a lack of record keeping and a subsequent failure to trace a woman's reproductive history may have hazardous consequences on her mental and physical (especially reproductive) health. At the very least, the number of pregnancies that a

[134] Id at 20
[135] Ibid

woman has already had must be considered while restricting the number of surrogacies.[136]

Screening for genetic parents/intended couple has not been emphasized adequately. It has been mentioned in the Contract between the Semen Bank and the Surrogate [Form- R (2)] but has not been listed under the roles and responsibilities of the semen bank. Such provisions in a context where it is the economically weak and the socially marginalized who opt for surrogacy clearly reflect the class and power politics in action. When the Draft Bill makes stringent clauses to screen the surrogate, what is the rationale behind not emphasizing the screening the intended parents to ensure the health and well being of the surrogate?[137]

Clause 34 (19) states that for foreign couples commissioning a surrogacy, a local guardian will be appointed for the surrogate mother. It is highly unacceptable that an adult woman be under the supervision of a guardian, merely because she agrees to carry someone else's child, who can interfere in her daily life by directing what to do and what not to do. Also, maintenance of the anonymity of the surrogate comes under question with the presence of a local guardian. While the Bill goes as far as appointing a guardian for the surrogate, it makes no effort in ensuring the safety of the child being taken by the commissioning couple out of the country. There has to be some sort of follow up or reporting back by the couple/individual regarding the child.[138]

According to Clause 35 (7) *The birth certificate of a child born through the use of assisted reproductive technology shall contain the name or names of the parent or parents, as the case may be, who sought such use.* This implies that the name of the couple seeking ART or commissioning the surrogacy will be written on the birth certificate. The MOHFW/ICMR should consider granting a parental status to the surrogate mother. When a woman gives birth to a child, the birth must be officially documented and that women must be the natural parent of the child born to her. This can be followed by a transfer of parenthood to the intended parents, either through adoption or another system devised for the purpose. Thus the birth certificates must have the name of the genetic/gestational surrogate. Moreover, the document repeatedly assumes that the intended parents are the genetic parents in surrogacy

[136] Id at 21
[137] Ibid
[138] Id at 22

cases. For example, Clause 34(10) states that "*The birth certificate issued in respect of a baby born through surrogacy shall bear the name(s) of the genetic parents / parent of the baby."*If the genetic parent of a child born through surrogacy is a donor, then would the birth certificate have the name of the donor?[139]

The bill must ensure that the intended parents understand and agree that the surrogate has a right to physical integrity and bodily autonomy, i e, she cannot be forced to abort the foetus, go through foetal reduction or be made to follow a certain diet and lifestyle. These decisions are for the surrogate, and no one else, to make. The MTP, 1971 Act guarantees women in India the right to abortion, while international human rights legislation guarantees her physical integrity. However, no sex-selection should be allowed even with the consent of the surrogate. The surrogate's right to privacy and physical integrity should be acknowledged in the Bill.[140]

The ICMR guidelines also state that the surrogacy contract is enforceable against both parties. This seems appropriate in a scenario where the contract needs to be invoked to track the intending parents and legally bind them to take custody. However, neither the guidelines nor the proposed Bill ensures the immediate safety and well being of the child due to the absence of any affiliated bodies enshrined with such tasks. Is the criminal justice mechanism to be invoked by framing charges under Section 317, Indian Penal Code or the Juvenile Justice (Care and Protection of Children) Act, 2000 or is a suit for specific performance of the contract the only remedy? It is also unclear as to who is to be charged in such a case – the surrogate or the intending parents or the fertility experts involved in the conception or any other individual. The Bill lacks proper mechanisms to ensure that the commissioning parents are liable in case they refuse to embrace the baby. This flaw is further heightened in cases where parents refuse to accept this child in case of post partum discovery of the physical or mental disability of the child. [141]

Moreover, in India there is no single uniform law relating to adoption. The Hindu Adoption and Maintenance Act, 1956 read with the Hindu Minority and Guardianship Act, 1956 applies to Hindus, Buddhists, Jains and Sikhs. In 1990 the

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[139] Ibid

[140] Sama Team, "Assisted Reproductive Technologies: For Whose Benefit?", *Economic & Political Weekly*, may 2, 2009 vol xliv no 18 at 29

[141] Jwala Thapa , "Who Speaks for the Child in a Surrogacy?", Posted on October 17, 2012 available on *http://jilsblognujs.wordpress.com/2012/10/17/who-speaks-for-the-child-in-a-surrogacy/* visited4/2/2013 at 11:05 AM

Central Adoption Resource Agency (CARA) was established by the Union Ministry of Social Justice and Empowerment for regulation adoption within India, and international adoptions of children from India. In 1995 it issued guidelines on adoptions that all registered/licenced 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 it was opposed and eventually lapsed. The legal position is thus very complex, and no general provision can be made to all couple having children by ARTs or surrogacy.

3.9. The Recommendations of the Law Commission of India

India is emerged as a centre for destination for people wishing both to have assisted reproduction and for surrogacy. According to the report of the Law Commission of India "the usual fee for surrogacy is around $25,000 to $30,000 in India which is around 1/3rd of that in developed countries like the USA. This has made India a favourable destination for foreign couples who look for a cost-effective treatment for infertility and a whole branch of medical tourism has flourished on the surrogate practice. ART industry is now a 25,000 crore rupee pot of gold. Anand, a small town in Gujarat, has acquired a distinct reputation as a place for outsourcing commercial surrogacy. It seems that wombs in India are on rent which translates into babies for foreigners and dollars for Indian surrogate mothers." Therefore a comprehensive legislation defining the rights and responsibilities of contracting parents, surrogate mothers, rights of child, the responsibility of ART clinic is required to prevent the mal practices and to protect the rights of parties. The Law Commission of India has submitted the 228th Report on "Need for Legislation to Regulate Assisted Reproductive Technology Clinics as well as Rights and Obligations of Parties to a Surrogacy". The following recommendations had been made by the Law Commission of India:

1. Surrogacy arrangement will continue to be governed by contract amongst parties, which will contain all the terms requiring consent of surrogate mother to bear child, agreement of her husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying child to full term, willingness to hand over the child born to the commissioning parent(s), etc. But such an arrangement should not be for commercial purposes.

2. A surrogacy arrangement should provide for financial support for surrogate

child in the event of death of the commissioning couple or individual before delivery of the child, or divorce between the intended parents and subsequent willingness of none to take delivery of the child.

3. A surrogacy contract should necessarily take care of life insurance cover for surrogate mother.

4. One of the intended parents should be a donor as well, because the bond of love and affection with a child primarily emanates from biological relationship. Also, the chances of various kinds of child-abuse, which have been noticed in cases of adoptions, will be reduced. In case the intended parent is single, he or she should be a donor to be able to have a surrogate child. Otherwise, adoption is the way to have a child which is resorted to if biological (natural) parents and adoptive parents are different.

5. Legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parent(s) without there being any need for adoption or even declaration of guardian.

6. The birth certificate of the surrogate child should contain the name(s) of the commissioning parent(s) only.

7. Right to privacy of donor as well as surrogate mother should be protected.

8. Sex-selective surrogacy should be prohibited.

9. Cases of abortions should be governed by the Medical Termination of Pregnancy Act 1971 only.

3.10 The new Indian Medical Visa Regulation:-

The new Indian Medical Visa Regulations dated 9 July, 2012 now stipulate that only married men and women with the subsisting marriage for at least two years will be allowed medical visas for surrogacy. The foreigners visiting India for commissioning surrogacy are required to apply for medical visa with the following conditions:

i. The foreign man and woman are duly married and the marriage should have sustained for at least two years.

ii. A letter from embassy of the foreign country in India or the Foreign ministry of the country should be enclosed with the visa application stating clearly that:

   a. the country recognizes surrogacy and

b. the child/children to be born to the commissioning couple through the Indian surrogate mother will be permitted entry into their country as a biological child/children of the couple commissioning surrogacy.

iii. The couple will furnish an undertaking that they would take care of the child/children born through surrogacy.

iv. The treatment should be done only at one of the registered ART clinics recognized by the Indian Council of Medical Research.

v. The couple should produce a duly notarized agreement between the applicant couple and the prospective Indian surrogate mother.

vi. Before the grant of visa, the couple needs to be informed that before leaving India for their return journey, 'exit' permission from FRRO/FRO would be required. Before granting the 'exit' the FRRO/FRO will see whether the foreign couple is carrying a certificate from the ART clinic concerned regarding the fact that the child/children have been duly taken custody of by the foreigner and that the liabilities towards the Indian surrogate mother have been fully discharged as per the agreement.

vii. Further it may be noted, for drawing up and executing the agreement cited above at (v), the foreign couple can be permitted to visit india on a reconnaissance trip on tourist visa, but no samples may be given to any clinic during such preliminary visit.

viii. If the listed conditions are not fulfilled, the visa application shall be rejected. [142]

This is now clear that any single parent, gay person or unmarried couples would be ineligible to apply for a medical visa for undertaking surrogacy arrangement in India.

The present Assisted Reproductive Technology (Regulation) Bill, 2010 is yet to finalized into an official regulatory mechanism and is undergoing debate amongst various ministries. The most crucial proposal is to restrict surrogacy in India to "infertile Indian married couples" only and it would not be allowed to foreigners unless he/she is married to an Indian citizen. Non-Resident Indians (NRIs), Persons of Indian Origin (PIOs) and Overseas Citizens of India (OCIs) shall, however, be

[142] Anil Malhotra and Ranjit Malhotra, *Surrogacy in India: A Law in Making*, (2013, New Delhi, Universal Law Publishing Company) at 19.

eligible. The object sought to be achieved is to prevent exploitation of Indian women who may be tempted to take the risk in the face of financial hardships.[143] While the Ministry of Home Affairs considers gay couples and single foreigners as ineligible to have a child through surrogacy in India, the Ministry of Health and Family welfare along with Women and Child Development ministry have opined that surrogacy should be allowed for everyone without discrimination.[144] The current suggestion on banning foreign unmarried couples and singles from having a child through surrogacy has given rise to two very pertinent contentions. Firstly, it is argued by those against the proposal, that such a bias does not have a sensible or logical basis and there are more number of single parents in countries like the USA than India. Secondly, the judiciary recognises live-in relationships and the draft ART bill allows Indian single and unmarried people to avail this procedure. Such exclusion would hamper future drafting, thus either the restriction should be for Indians and foreigners alike, or have a better justification backing it. [145]

3.11. Conclusion

No doubt, ART comes to rescue of the infertility. It not only provides the treatment to this serious problem but also exhibit an alternative to the natural means of child bearing. With this growing demand of ART, there arise also certain issues in relation to ART. For which the Government showed a serious concern by providing certain guidelines that can govern this huge ART industry. Though, these guidelines are non-binding in nature, to deal with the ambiguities and complexities the Government of India is seriously working on the process of regulating the ART. Recently the ICMR and MOHFW have drafted the *ART bill and rules 2010* but there are loop holes and lacunas in the current bill. The law commission has also pointed out the need of law to regulate ART in India. Government of different countries passed laws and policies to regulate this complex area. It is in this context the next chapter deals with the legal regulation in different countries of the world.

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[143] Anil Malhotra, "Rewriting surrogacy laws" available on *http://lawyersupdate.co.in/lu/1/1629.asp* visited on 17.12.2014 at 12.58 p. m.
[144] Priyattama Bhanj, "The Assisted Reproductive Technologies (Regulation) Bill, 2010: A Case of Misplaced Priorities?" available *on http://jilsblognujs.wordpress.com/2014/07/17/the-assisted-reproductive-technologies-regulation-bill-2010-a-case-of-misplaced-priorities/* visited on 17.12.2014 at 12:55 p.m.
[145] Ibid.

Chapter-IV

Chapter- IV

Laws in Different Countries on Assisted Reproductive Technology

4.1 Introduction

Although infertility is a global health issue that affects millions of people worldwide there is ambivalence and anxiety about the commercial use of ART and particularly gestational surrogacy. While most industrialized nations ban commercial surrogacy other nations such as Brazil, Israel, and the United Kingdom have established regulatory mechanism or partial ban to control access to it. The surrogacy market is unregulated by the United States government, leaving it up individual states to develop regulatory policies. The legal restrictions placed on surrogacy in most of Europe and Asia has enabled California to be the global destination of choice for reproductive tourists.[1] In the United Kingdom, the influential 1984 Warnock Report argued that "it is inconsistent with human dignity that a woman should use her uterus for financial profit and treat it as an incubator for someone else's child." The British government subsequently prohibited commercial surrogacy under the 1985 Surrogacy Arrangement Act but focused primarily on the role of third parties: technically, brokering a surrogacy arrangement was illegal, but entering into one was not. In many parts of the world, such criticism rapidly made its way into law. Germany and France, for example, banned any form of surrogacy contract, arguing (in the French case) that "the human body, its elements and its products may not be the subject of a contractual agreement.'' In Australia, the Government of Victoria agreed in 1984 that commercial surrogacy was "completely unacceptable as part of an IVF programme" and accordingly passed legislation banning surrogacy contracts, agencies, and advertisement. In most part, of the Canada, noncommercial surrogacy was quietly allowed, but the law explicitly treated the birth mother in such cases as the child's legal parent, regardless of either her genetic link to the child or any outstanding contract with an intended parent.[2] This chapter provides a detail analysis of the laws and policies of different countries in the world regarding the use of ART.

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[1] 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 ix.
[2] Debora L Spar; *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception*, (2006, Boston, Harvard Business School Press) at 83.

4.2 ART in United Kingdom

The United Kingdom was the first country in the world to ART with the first child born through in vitro fertilization (IVF). To control such practices, the government has developed policies to regulate reproduction techniques and protect their users, unlike the United States where such regulation is minimal. As a part of these policies, in 1990 the U.K. enacted 'The Human Fertilization and Embryology Act' (HFEA) with the intent to enforce the regulations related to assisted reproductive technologies and to control research on human embryos. The Act grants, among other provisions, the authority of the agency charged with overseeing HFEA to keep under its own review information about embryos and to advise people who are using ART or to whom posses a license to operate a fertility clinic. Moreover, this Act provides that licensed fertility clinic managers who provide or receive economic remuneration or other benefit to obtain gametes or embryos may be punished by imprisonment. In December 2006, the government revised these regulations and reorganized the agency that has oversees HFEA, creating new proposals in response to social changes and scientific developments that have been occurring in the U.K. over in recent decades. The 1990 Act setup the powerful Human Fertilization and Embryology Authority. Some activities are only permitted under a licence from this Authority. These cover: treatment, research and storage. The Human Fertilization and Embryology Authority (HFEA) is responsible for licensing fertility clinics and regulating the use of donor gametes, assisted fertilization, pre-implantation genetic diagnosis, the storage of gametes and reproductive tissue, and research using human embryos. The HFEA limits the number of embryos transferred per reproductive cycle to 1-2 embryos for women under the age of 40. A maximum of three embryos can be transferred to women over 40. The HFEA also prohibits commercial egg and sperm donation.[3]

As a part of the revisions, the U.K. banned the use of sex selection for "family balancing" and facilitated access to certain assisted reproductive methods, such as in vitro fertilization (IVF), to single women and lesbian couples.[4] The U.K. also proposed a ban on the use of genetically modified sperm, eggs, or embryos for

[3] Kirsten Riggan, "G12 Country Regulations of Assisted Reproductive Technologies", available at *http://cbhd.org/content/g12-country-regulations-assisted-reproductive-technologies,* visited on 24 March 2012.

[4] Mariemma Medina-Morales, "Designing a Baby: Why Is It Illegal in the United Kingdom but a Profitable Market in the United States?", available at *http://www.law.uh.edu/healthlaw/perspectives/2007/(MM)DesignerBabies.pdf* visited on 18 may 2012.

reproductive purposes. However, the law permits the use of reproductive assisted methods and genetic modification intended to prevent the genetic transmission of certain gender-based diseases, such as hemophilia or forms of muscular dystrophy. These policies and regulations promulgated by the U.K. have established controls on certain contentious ART practices. In the United States, there are no similar rules.

The United Kingdom's laws on ART include the *Surrogacy Arrangement Act (*1985), the *Human Embryology & Fertilization Act (1990)*, and the *Human Reproductive Cloning Act*.[5] These laws prohibit reproductive cloning, the transfer of a non-human embryo to a woman or a human embryo into an animal, allowing embryos to develop outside of the human body for fourteen days, germ line modification, non-medical sex selection, and commercial surrogacy arrangements. The broad objectives of the Human Fertilization and Embryology Act 1990 Act are as follows:

(a) To provide a statutory framework for the supervision and control of human embryo research.

(b) To allow for the licensing of certain forms of what are termed 'assisted conception' practices.

(c) To effect changes to the Abortion Act 1967

The research licence allows for the creation and use of *in-vitro* embryos for certain embryos for certain specific projects. Paragraph 3 of schedule 2 to the Act sets out the type of projects for which these licences may be granted:

(a) The promotion of advances in the treatment of infertility.

(b) Increasing knowledge about the cause of congenital disease.

(c) Increasing knowledge about the cause of miscarriage.

(d) Developing more effective contraception techniques.

(e) Developing methods of detecting the presence or absence of gene or chromosome abnormalities before the implantation of an embryo.[6]

The Human Fertilization and Embryology Act 1990 provide a nearly comprehensive scheme for regulating assisted reproduction and research on human embryos outside the human body[7]. It provides for formal administrative oversight

[5] House of Commons, Science and Technology Committee, "Human Reproductive Technologies and the Law", Fifth Report of Session (2004–05), Volume I, available at *http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf* visited on 25 may 2012.

[6] Michael Devies, *Text Book on Medical Law*, (1998, New York, Oxford University Press), at 232.

[7] "Review of the Human Fertilization and Embryology Act, Proposals for revised legislation (including

through the statutory authority, bringing a degree of centralization, but also includes a conscience clause, ensuring that professionals may not be forced to participate in any of the activities governed by the Act. This web of regulation is interesting both for the model it provides for the governance of health care ethics and for the specific provisions governing clinical practice and research. This section considers the impact of the Act on treatment services.

The Act works by outlawing certain activities unless they are carried out under the auspices of a licence from the authority. Section 3 sets out a wide-ranging prohibition on creating, keeping, or using human embryos. Section 3A prohibits the use in fertility services of eggs taken from embryos or fetuses. Section 4 prohibits the storage and use of human gametes. A special exemption has been granted in relation to the storage of the gamete only for the purpose of research, including developing pharmaceutical and contraceptive products, and teaching. Although the 1990 Act covers most type of infertility treatment, some techniques do not come within it. There is no prohibition on artificial insemination where the sperm is provided by the women's partner. Thus this can be offered without the licence. The technique of gamete intra-falopian transfer (GIFT) is not regulating by the Act because it does not involve an embryo being created outside the women's body. Instead, sperm and egg are inserted so that fertilization takes place in the fallopian tube. However, some GIFT treatments will fall within the Act because it involves using stored or donated sperm (which come within the scope of the prohibitions). Self-insemination is not covered, provided that sperm are not stored, because it is only services offered to the public that fall within the definition of the treatment services.

In general, the offences under the Act are punishable by up to two years imprisonment and an unlimited fine. However, some breaches of these provisions carry much heavier sentences. Those who place non-human embryos or gametes into a women, place human embryo or foetus, or mix human gametes with non-human ones are liable to a sentence of imprisonment of up to ten years and an unlimited fine or both. Prosecutions cannot be brought without the consent of the Director of Public Prostitutions.

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establishment of the Regulatory Authority for Tissue and Embryos)", Presented to Parliament by the Secretary of State for Health by Command of Her Majesty, December (2006), available at *http://www.hfea.gov.uk/docs/Review_HFEA_Act_White_Paper_DH.pdf* visited on 22 June 2012.

The power to relax these prohibitions on dealings with human embryos or gametes in treatment services on defined premises. Only activities on those premises are covered, and only when carried out under the supervision of the persons named. The power of the Authority to issue licences is limited by the Act. Licences may not authorize keeping an embryo beyond the appearance of the primitive streak, placing a human embryo in an animal, or replacing the nucleus of an embryo (intended to prevent cloning). In addition to these provisions specifying what may not be authorized, the Act also sets out the type of activities which can be licensed. These are, however, broadly phrased, and include in relation to treatment 'using gametes' and 'placing an embryo in a women'. Further guidance on the exercise of the licencing powers may be given in regulations, but no such regulations have been issued at present. The emerging science of genetic manipulation raises the possibility of overcoming a genetic defect by removing or inserting genes. The Human Fertilization and Embryology Act 1990 prohibit the licensing of this sort of therapy on human embryos, although the Act allows for regulations permitting it in the future.[8] We can divide activities in the areas of ART and research into three categories:

i. Activities Prohibited by the HFE Act

The HFEA Act renders certain activities unlawful and does not permit the HFEA to license them. They include the following:

(1) An embryo cannot be stored for more than fourteen days after the mixing of the gamete (at which time the primitive streak will have appeared). This means that although research can take place on embryos up until the fourteen days, the HFEA has no power to authorize the storage of an embryo beyond that time.

(2) It is unlawful to place an embryo which is not a 'permitted' embryo in a woman. The definition of a 'permitted embryo' allow the HFEA to issue regulations which would allow embryos to be created using animal gametes.

(3) It is unlawful to place a human embryo in a non-human animal.

(4) The use of eggs taken from embryos in fertility treatment is forbidden.

[8] Jonathan Montgomery, *Health Care Law*, (2003, New York, Oxford University Press), at 404-405

Keeping or using an embryo under any circumstances in which regulations prohibit its keeping or use is unlawful. It is unlawful to alter the genetic structure of any cell while it forms part of an embryo.

ii. Activities only Permitted if Performed under a Licence

The HFEA Act also outlaws certain activities, although it enables the HFEA to provide a licence for them which render them lawful.

(1) The storage of an embryo is only lawful if carried out under a licence issued by the HFEA.

(2) The storage and use of gamete can only be lawfully carried out under a licence issued by the HFEA. This includes, since the HFEA Act 2008, those offering courier services delivering sperm to women's home. In 2009 two men were prosecuted after setting up an internet site that offered 450 pound for a 'door to door' service for sperm delivery.

iii. Activities which do not Require a Licence

These are of course other activities involving assisted reproduction which do not require a licence. This is the process which does not involve the creation of an embryo outside the human body or the storage of any gametes. 'Do it yourself insemination' using fresh sperm and a turkey baster (or similar instrument) is not subject to regulation. It would of course be difficult to police a law which made it illegal for someone to give someone else their fresh sperm.

The Paramountcy of Consent

A key principle in the HFEA Act is that gamete or embryos may not be used without the consent of the provider(s). So, if a couple have had embryos frozen these can only be stored with the couple's consent. If they ask for the embryo to be destroyed then it would be unlawful for the clinic not to do so. However, there is a maximum limit of ten years on the storage of embryos and gametes. An embryo can be stored for up to fifty-five years if the couple in question is infertile or likely to be infertile.[9]

4.3 ART in United States

The fertility industry remains largely unregulated in the United States. Where regulation of these technologies has occurred, however, it has had real-life consequences for thousands of people and ripple effects on multiple areas of the law,

[9] Jonathan Herring, *Medical Law and Ethics*, (2006, New York, Oxford University Press), at 354,356-357

from adoption to abortion, from health insurance to inheritance. While some states have passed laws that indirectly affect the practices of fertility clinics, legislatures and courts have focused more on the ramifications of these procedures.[10] Since its 1981 introduction in the United States, through the year 2002, almost 300,000 babies have been born in this country as a result of reported ART procedures (IVF accounts for ninety-nine percent of these ART births). In 2002, approximately one in every one hundred babies born in the United States was conceived using ART (the live birth rate of an IVF cycle in 2002 was twenty-eight percent). According to the Center for Disease Control's (CDC) most recent reports, a total of 89,533 fresh embryo cycles using non-donor eggs occurred in 2004 and 92,389 occurred in 2005. The live birth rate decreases with the age of the intended mother. In 2005, the live birth rate for women under thirty-five was 43.1%; for women forty-one to forty-two it was 17.6%.[11]

In the United States, the federal government has been comparatively mute: there are no federal laws regarding the use of ART. Instead, most issues of surrogacy have been determined by state courts and legislatures, many responding directly to the specific cases brought before them. Initially, for example, the Michigan court that reviewed Noble Keane's business concluded that commercial surrogacy was directly akin to commercial adoption and thus illegal: " The state's interest," held the court, "is to prevent commercialism from affecting a mother's decision to execute a consent to the adoption of her child." Court in kentucky, however, soon found otherwise, ruling in a 1986 case that surrogacy did not constitute baby-selling as long as the contract was entered into before conception. Thus what was illegal in Michigan became legal in Kentucky. New Jersey, meanwhile, echoed Michigan; in the famous *Baby M case*[12], the state supreme court invalidated the surrogacy agreement between the Stern and Mary Beth Whitehead, holding that "this is the sale of a child, or, at the very least, the sale of a mother's right to her child."[13]

As traditional surrogacy gave way to gestational arrangements, some state courts and legislatures continued to rule against commercial surrogacy agreement,

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[10] Jessica Arons, "*Future Choices: Assisted Reproductive Technologies and the Law",* (2007, Center for American Progress December), at 4.
[11] Sanford M. Benardo and Katherine Benardo, "Assisted Reproductive Technology: Egg Donation and Surrogacy Arrangements in Law and Practice", available at *http://www.assistedfertility.com/BCLJarticle.pdf* visited on 5 July 2012.
[12] 109 N.J. 396537 A.2d 1227, (1988).
[13] Supra 2 at 84.

defining them-often with reference to adoption law-as illegitimate payment for a child. Other state courts, most notably those in California, explicitly permitted gestational surrogacy and began to carve out an extended set of rights for parents who contracted with a gestational carrier. In the 1990 case of *Johnson v. calvert*[14], for example, a surrogate carrying the contracting couple's genetic child filed for custody of the baby. Because the surrogate in this case was black and not wealthy and the contracting couple was white and well off, the ensuing legal debate ignited a storm of related controversy. (the intended mother was actually Filipino, a fact that was frequently overlooked.) Even protracted opposition, however, did not impress the courts. Instead, both the trial court and the California Supreme Court found for the contracting parents in the *Johnson case,* arguing that, although both "mothers" in this case presented proof of maternity, "she who intended to procreate the child- that is, she who intended to bring about the birth of a child that she intended to rise as her own-is the natural mother." In California, therefore, the court explicitly tied "intent" to motherhood, using surrogacy arrangements as a way to determine parenthood when genetic links and labor did not coincide in the same woman.[15]

One of the first known case of cross-border surrogacy occurred in 1987, when Alejandra Munoz, a nineteen-year-old Mexican woman, crossed illegally into the United State to be impregnated with the sperm of her cousin's husband. She was followed in due course by several British parents, including gay and single men, who began in the mid-1990s to hire U.S. surrogates to bear their babies.[16]

In contrast with the U. K., the U.S. has developed a profitable market in ART without regulations that limit its commercialization. For that reason, some have considered the United States as the "Wild West" of ART, due to its minimal regulation to control ART technologies. Some fertility experts and bioethicists stated that commercialization is increasing, and that these embryos are treated as "commodities." Commercialization has affected the quality of the services in assisted reproduction and promoted a market in which "shared risk," "refunds" and "warranties" are part of marketing campaigns to achieve a pregnancy. The American Society for Reproductive Medicine (ASRM) characterizes these kinds of reproductive programs as exploitative, misleading and contrary to professional norms. ASRM

[14] (1993) 5 CAL 484.
[15] Supra note 2 at 85.
[16] Id at 86.

thinks that a lot of people using these programs are desperate to have a child, do not receive sufficient information about the best plan to select according to their needs, and may be induced to buy the most expensive form of IVF service.[17]

Federal government surveillance of this issue is limited mostly to the collection of data regarding the use of assisted reproduction in the United States. Although some states have enacted statues on specific reproductive technologies, such surrogacy, such laws are limited to dealing with specific issues and are not enough to oversee this business. Some states and the federal government have started to work on new proposals concerning ART procedures and have recognized this issue as an important one. States such as Arkansas, Illinois, Hawaii, and New Jersey regulate certain aspects of ART, for example, by requiring that in vitro fertilization procedures be performed at medical facilities that conform to the standards provided by ASRM or the American College of Obstetricians and Gynecologists (ACOG). Also, the U.S. has from time to time established commissions to study certain aspects of ART, such as bioethical issues raised by the procedures. Yet these efforts are not enough. The only federal legislation passed pertaining to ART is the *Fertility Clinic Success Rate and Certification Act of 1992* establishing the reporting of pregnancy success rates to the Centers for Disease Control and Prevention for publication. Regulation of ART varies at the state level. Seven states have legislation that prohibits human cloning for both reproductive and research purposes, while eight states ban reproductive cloning. Other states prohibit commercial surrogacy or regulate surrogacy agreements. Several states require private insurance coverage of ART and regulate the donation of sperm, eggs, and embryos. Only Pennsylvania extensively regulates and monitors ART clinics and activities.[18]

California has also allowed the surrogacy agreements, which has no statute directly dealing with surrogacy. Courts generally rely on Uniform Parentage Act to deal with various surrogacy agreements. California Supreme Court in *Johnson v. Calvert*[19], held that gestational surrogate has no parental rights to a child born to her since a gestational surrogacy contract is legal and enforceable and the intended mother is the natural mother under the Californian law. In the above case the intended mother donated the egg and a surrogate mother gave birth, in such a case the Court held that the person who intended to procreate should be considered as the natural mother. In another case decided by the U.S. Court in the year 1998 - *Buzzanca v.*

[17] Supra note 4.
[18] Supra note 3.
[19] (1993) 5 CAL 484

Buzzanca[20], the Court considered the issue of traditional surrogacy agreements. That was a case where the surrogate mother has been artificially inseminated i.e. a surrogate mother was impregnated by using her ova and anonymous sperm, meaning thereby the intended parents had a genetic link to the child. Court held that when a married couple uses non-genetically related embryo and sperm implanted into a surrogate intended to procreate a child, they are lawful parents of the child. In another U.S case decided in 1998, In Re Marrijo Moschetta awarded legal parent rights to the intended father and surrogate mother. In another U.S case considered by the New Jersy Supreme Court, *In Re Baby M*[21] gave custody to the natural father of the child, but rights of the adopted mother was denied. Surrogate mother who conceived the child via artificial insemination was granted visitation rights.

The federal government's failure to regulate this industry has left it up to individual states to regulate. Consequently there is a patchwork of laws and contradictory legislation in the United States. Some states, such as Arizona and the District of Columbia, ban all commercial surrogacy contracts, while other ban payments but allow for services (Florida, Nevada, New York, New Hemisphere, Virginia, Washington), while other like California have become interstate and international destinations of choice for couples wishing to purchase reproductive services and hire surrogates.

4.4 ART in China

ART is very interesting in China because it not only relates to reproductive policy but also involves the family, one of the most important concepts for social organization. Whereas in many western countries, ART policy discussion takes place in a relatively unrestricted context, in China, reproduction is tightly controlled. It is an extremely important process related to two socially and politically significant issues: the one-child policy and China's household registration system (*houkou*) which relies heavily on parentage to determine a child's residency. In addition, whereas in many democratic nations, the public opinion has a direct influence on legislative decisions, in China, policy can be decided by only a handful of people behind closed doors.[22] China's reproductive policies from 1970 onwards incorporated what he translated as

[20] 1961 CAL. App 1410 (1998),
[21] 537 A.2d 1227 (NJ.02/03/1988),
[22] Congcong Guo, "Conceiving Conception: The Bioethics of Assisted Reproductive Policy in China" (March 2011) at 9 available at *http://www.wcfia.harvard.edu/sites/default/files/UGthesis_eguo.pdf* visited on 19/01/2013 at 11:21 A.M.

"eugenic" (*yousheng*) ideals to punish those who deviate from the norm – the mentally disabled or physically deformed – by preventing them from freely engaging in reproductive practices. To put it another way, China has historically sacrificed individual reproductive freedom for public health on the basis of genetic considerations.[23] Many of the most visible public controversies around assisted reproduction have arisen because of conflicts related to the family. In May 2001, Mrs. Zheng□s husband was imprisoned for murder, and in August of that year, he was sentenced to death. Mrs. Zheng wanted to have a child with her husband so she requested permission for use of ART with semen from her jailed husband, first asking the city court, then the High Court of her province. Her request was first rejected, and then circumvented on appeal so that Mrs. Zheng did not receive permission before her husband was executed in January 2002. Her request was widely discussed around China as a case questioning the morality of single-parenting. In another case, a woman and her parents-in-law pleaded for artificial insemination by husband (AIH) following a car accident that left the husband in a coma. She was eventually granted permission. In these cases, traditional conceptions of the meaning of the family and of reproduction were violated mainly because newly naturalized means of reproduction had been made possible by ART.[24]

Yet, ART is not perfect, and bioethicists have voiced concerns over conflicts that may arise due to the procedures. One involves the discontinuation of the blood line in cases where the child is not genetically related to both parents. While some bioethicists simply see this ethical issue as arising from people's lack of understanding about the technology and traditional views of parenthood, others believe the continuation of the blood line is important because it underpins other traditional practices in China.[25]

On February 20, 2001, the Ministry of Health issued Orders 14 and 15 the *Human Assisted Reproductive Technology Administrative Guidelines* and the *Human Sperm Bank Administrative Guidelines*. On May 14 of the same year, the Education and Technology Department of the Ministry of Health issued Orders 143, the *Human Assisted Reproductive Technology Guidelines* and the *Human Sperm Bank Standards* and the *Practical Principles and Ethical Standards for Human Assisted Reproductive*

[23] Id at 23
[24] Id at 61
[25] Id at 62

Technology, abbreviated as *Technology Restrictions: Basic Standards and Ethical Principles*.

In March 2002, the MOH held multiple meetings with experts in different fields to reexamine China's ART policy, taking account of regulations in other countries. At these meetings, the state encouraged experts to evaluate what sorts of technology regulations, standards, and ethical principles would best meet China's practical needs and to consider adapting parts of foreign regulations to include them in a set of revised Chinese ART regulations. In an official policy document, the government stated that through these revisions, it hoped to create guidelines that would provide the right technologies "in accordance with society's ethical, moral, and legal needs to respect life and to protect future generations from harm." The edited draft seriously expanded the scope of government control by providing more detailed ethical and technological requirements, including standards for multiple embryo implantations and embryo reduction, access to ART, and prohibitions on embryo and sperm commercialization. On October 2003, the Ministry of Health issued the final draft of the revised *Human ART Regulations*, *Human Sperm Bank Regulations*, and *Human ART and Sperm Bank Ethical Guidelines and Principles*, replacing the earlier provisions.[26]

The last set of regulations issued by the MOH contains a comprehensive space, facilities and equipment requirements as well as quality standards and specific prohibitions for ART clinics. It also lists background and training needed for medical personnel in offering ART. Two separate parts which have similar provisions address IVF and artificial insemination, respectively. The first section details requirements for the clinics, including the types of rooms and the equipment required in them. Given a large amount of space and high technological capabilities are required, the regulations imply that only large hospitals can legally operate ART clinics. Because clinical operations and laboratory work must take place in the same building, only a hospital with significant research and clinical resources can operate an ART clinic. Each ART institution must also establish a working Reproductive Medical Ethics Committee.

The second section of the regulations concerns clinic management - those hospitals must carefully check the identity cards of potential couples for proof of a marriage certificate; couples must also qualify for pregnancy under national

[26] Id at 73

population and family planning laws. Even foreigners must present passports and marriage certificates before they are allowed to undergo the procedure. In addition, physicians may not transfer more than three embryos per IVF cycle and for women under 35, physicians may not transfer more than two embryos in the first cycle. The third section of the policy provides specifications for couples who can undergo certain procedures, including which couples qualify for IVF treatment.

Physicians can perform a pre-implantation genetic examination if a couple is highly likely to produce a child that might have "single-gene related genetic diseases, chromosomal abnormalities, sex-linked genetic diseases, and reproductive abnormalities." Under these circumstances, a woman is also eligible for an egg donation. Egg donation is also an option if the woman cannot produce eggs or if the woman is carrier of a serious genetic disease. There are additional specifications for women who wish to donate their eggs. To prevent the commercialization of gamete donation, only women who have leftover eggs after undergoing assisted reproductive treatment can be egg donors. Certain people are also prohibited from IVF procedures, including individuals "suffering from severe mental disorders, acute urogenital infections, or sexually transmitted diseases."

The regulations fourth section lists quality standards for ART clinics, measured by their success rates for procedures. These rates are high even compared to international standards. In this area, one provision reads, "multiple pregnancies fetal reduction must be used to avoid twinning and to promote the strict prohibition of the birth of triplets or more than three children in a birth."

The final section provides a list of guiding principles for all medical personnel. These guidelines mandate that all personnel must strictly adhere to national population and family planning laws and regulations. Medical personnel must comply with informed consent and voluntary informed choice procedures and respect a patient's right to privacy. It prohibits non-medical use of sex selection, surrogate technology, embryo donation, and genetic manipulation, and bars single women from ART. The last few provisions forbid the use of ART for human cloning, chimeras, or unspecified research purposes.

In addition to these guidelines, the Department of Medical Technology and Education of the Ministry of Health also issued a set of "ethical guiding principles" regarding ART. These principles were to provide "a safe, effective, and rational implementation of human assisted reproductive technology, the protection of

personal, family, and health of future generations and interests, and to safeguard the social welfare." Seven overriding principles govern these areas: benefit to patients, informed consent, protection of future generations, benefit for social welfare, confidentiality, prevention of commercialization, and ethical oversight. The largest numbers of restrictions relate to informed consent, the protection of future generations and the benefits for social welfare. With regard to the protection of future generations, medical personnel have a duty to stop ART implementation if "there is evidence that the implementation of human assisted reproductive technology will have serious physical, psychological, and social damage to future generations." The MOH explicitly gives medical personnel the responsibility for implementing these ethical principles in assisted reproduction. Thus, while the government broadly defines what "bioethics" entails, hospitals need to ensure that these principles are rigorously carried out.[27]

Currently, marriage is a strict requirement for couples who hope to use ART not only in China but also in Egypt, Hong Kong, Iran, Jordan, Korea, Morocco, Saudi Arabia, Singapore, Taiwan, Tunisia, and Turkey. In all other countries, only a stable relationship is required. This list can further be separated into two categories: countries with a strong Islamic tradition and East-Asian states with a strong Confucian tradition (Korea, Hong Kong, Singapore, and Taiwan). This evidence only reinforces a conclusion about Chinese assisted reproductive policy: cultural norms can be as influential as religious convictions in bioethics, and in the process of coproduction, different bioethical understandings can contribute to different policy outcomes.[28]

In March 1988, the Beijing Review announced the birth of the China's first "test-tube baby," born to a 39-year-old peasant woman. The media presented the official announcement as a technological success story, a symbol of science and medicine ushering in a modern China. This healthy little girl, 3900 grams in weight and 53cms in height, was born at Beijing Medical University at 8:56am. Zou, a peasant from a rural southern province and now a first time father at 42, clapped his hands and wiped away his joyful tears when he saw his daughter. The twelve members of his family had already arrived in Beijing several days earlier to wait for this happy moment. Professor Lizhu Zhang, the famous scientist and head of the in-

[27] Id at 77.
[28] Id at 93.

vitro research program, took the baby in her arms and happily said, "I am a grandmother again."[29]

4.5 ART in Turkey

In 2010, Turkey became the first country to regulate against the cross-border reproductive travel of its citizens seeking third-party reproductive assistance (i.e. donor gametes or surrogacy)[30]. The use of donor eggs, donor spermatozoa and surrogacy arrangements have been prohibited in Turkey since the establishment of a legal structure to regulate assisted reproductive treatment in 1987; however, until recently Turkish men and women retained the option to travel abroad to access these treatments. However, such cross-border reproductive care (CBRC) arrangements are set to cease as a result of recent amendments to Turkey's assisted reproduction regulation.

Introduced on 6 March 2010, 'Legislation Concerning Assisted Reproduction Treatment Practices and Centres[31] sets out the latest version of Turkey's assisted reproduction regulations. It asserts a number of new restrictions that will significantly affect the practice of assisted reproduction in Turkey, including limitations regarding the licensing of private IVF centres, specifications on gamete and embryo storage and restrictions on the number of embryos that can be transferred to a patient (only one for women aged under 35 in their first and second cycle of IVF, and a maximum of two embryos for women in their third or subsequent cycles or over 35 years of age. Turkey's first *tüp bebek* (literally 'tube baby'), Ece Çokar, was born on 18 April 1989[32], 11 years after the birth of Louise Brown heralded a new era in assisted reproduction. Her parents were one of 10 couples recruited to undergo IVF treatment at Ege University Hospital, under the care of doctors who had received their training mostly in Germany. Despite relatively early successes for the next decade resources and infrastructure for IVF in Turkey remained limited, with little public knowledge of or demand for the technique. Now, there is a dramatically different picture. In the past decade, the assisted reproduction sector in Turkey has boomed into a successful, popular and lucrative industry with an elevated social profile, comprising one of the most rapidly growing IVF markets in the developing world. Thus, unlike in some of

[29] Id at 95.
[30] Gürtin ZB, "Banning reproductive travel: Turkey's ART legislation and third-party assisted reproduction", available at *http://www.ncbi.nlm.nih.gov/pubmed/21962527* visited on 18 July 2012.
[31] Official Gazette no. 27513.
[32] *Star Gazette*, 30 December 2006.

its other global incarnations, IVF in Turkey is not shrouded in secrecy, angst and shame, but rather pursued as the weapon of choice in the 'battle' against infertility, transforming involuntary childlessness from an intractable personal tragedy to a solvable medical problem. Currently there are 118 fertility clinics operating in Turkey.[33] A number of fertility clinics exist within public or university hospitals, but the great majorities are based in private hospitals or operate as independent centres. Many are located in densely populated urban cities, such as Istanbul, Ankara and Izmir, although in recent years clinics have also opened in the country's farthest corners. A range of socio-cultural and economic factors can be referenced to explain this transformation. In particular the introduction of (partial) funding for IVF by the state and social security institutions in 2005 and 2006 has been instrumental in broadening access and providing opportunities for the sector's market expansion. Figures from the Ministry of Health attest to an accelerated growth during this period, with the number of licensed fertility clinics rising almost 50%, from 66 in 2005 to 91 in 2007. Reliable data on the number and outcome of assisted reproduction cycles in Turkey are not available, despite mandatory reporting of such figures by clinics to the Ministry of Health since 1996. Estimates based on the consumption of gonadotrophin ampoules suggest that there are around 40,000 cycles of IVF performed each year, with demand far exceeding the supply available. According to reports based on figures from the pharmaceutical industry, total annual IVF expenditure in Turkey is in excess of US$300 million, ranking Turkey as 'The world's 7th biggest IVF market' (behind Israel, France, Spain, UK, USA and Germany)[34]. The Ministry of Health is responsible for licensing, registering, regulating and overseeing all forms of assisted reproduction practice. A framework for regulating assisted reproduction was introduced in 1987 as a piece of pre-emptive legislation preceding the birth of Turkey's first IVF baby by 2 years. This initial legislation, entitled 'By-law on Centres for Assisted Procreation'[35], was superseded by the 'By-Law Concerning Treatment Centres for Assisted Procreation' on 19 November 1996. This comprehensive piece of legislation detailing definitions, prohibitions and all necessary requirements (including building and physical environment specifications, equipment,

[33] Michi Knecht, Stefan Beck, Maren Klotz , (ed.), *Reproductive Technologies as Global Form: Ethnographies of Knowledge, Practices, and Transnational Encounter,* (2012, Campus Verlag) at 89.
[34] Ibid
[35] Official Gazette no. 19551.

materials and personnel) for assisted reproductive practice was subsequently updated a further four times – twice in January 1998, once in March 2001 and once in July 2005– to reflect advances and technological developments but retained essentially the same character. Then, in March 2010 a new version of the regulations, the 'Legislation Concerning Assisted Reproduction Treatment Practices and Centres', was introduced. This latest version instigates some significant changes to the way assisted reproduction is practiced in Turkey.

Although assisted reproduction practice in Turkey can be seen as advanced and liberal in some respects, for example in the use of PGD, it also has a conservative hetero normative character. From the very outset of Turkey's assisted reproduction regulation, any treatment involving third-party reproductive assistance, namely the use of donor eggs, donor spermatozoa or surrogates, has been prohibited. Indeed, the legislation provides the following definition for 'Assisted Reproduction Treatments': "*Procedures, accepted as treatment methods by modern medicine, which involve assisting the fertilization of the prospective mother's egg with her husband's sperm in various ways, enabling them to fertilize outside of the body when necessary, and transferring the gametes or the embryo back to the prospective mother's genital organs*".

The exclusivity of treatment provision to married couples using their own gametes is reiterated at the start of Section 5 Prohibitions:

"*The use of the eggs and sperm or the embryo of applicants undergoing ART for any other purpose, or in the treatment of other applicants, or the use of those [spermatozoa, eggs or embryos] obtained from anyone other than the applicants in the treatment of the applicants, or the storage, use, transfer, and sale [of spermatozoa, eggs or embryos] for any sort of purpose falling outside the definitions of this legislation, are prohibited*".

Apart from this statement, until the amendments of 2010, neither the assisted reproduction legislation nor any other item in Turkish law specifically addressed the use of donor spermatozoa, donor eggs or surrogacy, nor made any provisions for penalties or consequences for engaging in such activities. However, the 2010 version of the legislation, alongside a range of other restrictions to assisted-reproductive-technology practice, also contains three new items specifically related to this matter. Following item 18.4 which outlines the prohibitions on all third-party reproductive

assistance, item 18.5 sets out the legal ramifications that will result if third-party assisted reproduction is practiced by a Turkish clinic:

"*In the event of a discovery at any stage of a pregnancy achieved against any of these prohibitions [on third-party reproductive assistance], the [assisted reproduction practice] certificates of the involved persons will be nullified, the centre will be closed indefinitely, and all personnel will be indefinitely barred from working at ART centers*".

Furthermore, items 18.6 and 18.7 stipulate penalties for CBRC involving third-party assisted reproduction: "*If it is discovered that any centre and/or any centre personnel has participated in acts of referring or sending patients to domestic or international ART centers, encouraging patients or acting as intermediary, in a way that is in contravention with the legislation, such centers will be closed down for 3 months in the first instance, and indefinitely in the event of such acts being repeated. Those who are not centre personnel but are discovered to have acted as intermediaries in such cases will have their certificates, if such exist, nullified by the Ministry. In the event of a discovery at any stage of practices contravening the particulars outlined in the items 18.4, 18.5 and 18.6, the person who has conducted this procedure, the persons who have referred patients or acted as intermediaries, the impregnated person, and the donor will be reported to the state prosecutor".*

The above prohibitions effectively limit the scope of assisted reproductive technology to aiding the reproduction of married heterosexual couples (presumed to be) suffering a medical impediment to conception and they preclude any form of third-party reproductive assistance, not only within national borders but also with international relevance. Although Turkey is a secular country committed to secularism in medical ethics its pattern of assisted reproduction regulation, described above, can be thought of as distinctly 'Sunni Muslim in character'.

4.6 ART in Italy

Legislation on the regulation of ART in Italy has been delayed due to its controversial subject matter. The National Committee for Bio-ethics (CNB) has been considering reproductive technologies since 1991, but only issued its recommendations on 17 June 1994. Due to the large variety of ethical theories and opinions held by the members, the committee's recommendations were not

unanimous, although the members found common ground on several points.[36] The new Italian law is hugely important because it has been influenced to a large extent by Catholic doctrine and, as such, is an example of how moral and ethical issues may be determined by peculiarly national cultural perspectives, identity and heritage.[37]

In Italy, ART is regulated under the *Medically Assisted Procreation Law* (2004). This law prohibits research and reproductive cloning, the manipulation of embryos, the use of donated eggs or sperm for ART, and the cryopreservation of embryos (with the exception of severe injury/illness preventing embryo transfer). A maximum of three eggs can be fertilized and transferred per reproductive cycle. Sex-selection is only permitted through sperm sorting for sex-lined genetic diseases. All forms of surrogacy are prohibited. The use of pre-implantation genetic diagnosis for the selection of embryos is generally prohibited, but has been allowed through the courts on a case-by case basis. Genetic testing for non-medical purposes is prohibited. The use of ART is restricted to stable heterosexual couples who live together, are of reproductive age, are over the age of 18, have documented infertility, and have been first provided the opportunity for adoption.

The Italian parliament passed the first national law on medically assisted procreation (commonly known as Law 40) in February 2004, after a lengthy parliamentary and public debate. This is the first Italian organic law on the use of ARTs.[38] In its very first article, Law 40 states that assisted procreation is allowed with the unique goal of solving reproductive problems arising as a result of human sterility or infertility, in case any other possible types of therapy has failed. The law explicitly guarantees the rights of all the involved subjects, including the foetus. This first article is particularly important because it presents the two main principles the law has been grounded on. First, ARTs are primarily medical therapeutic acts directed at safeguarding the health of sterile couples. Assistance is not available for people who do not prove their disease and the failure of other healing therapies: thus, single women and homosexual couples are excluded from the treatments. Second, the foetus is characterized as a carrier of rights: even if the jurists are still debating on the

[36] Paolo Cattorini, "Assisted Reproduction in Italy", The Hastings Center Report, Vol. 24, No. 6 (Nov. - Dec., 1994), pp. 3-4, at 3, available at *http://www.jstor.org/stable/3563456* visited on 9 July 2012.
[37] Rachel Anne Fenton, "Catholic Doctrine Versus Women's Rights: The New Italian Law on Assisted Reproduction", *Medical Law Review,* 14, Spring 2006, pp. 73–107 at 75.
[38] Giulia Zanini , "Regulating assisted procreation: the Italian case", available at *http://www.antropologia.cat/files/Zanini%20Fnl.pdf* visited on 18 august 2012.

meaning of this particular sentence about the rights of the foetus, it nevertheless gives evidence to the new intensity with which the law guarantees the juridical protection of the foetus.

Access to treatments is allowed only to couples composed of heterosexual adults, married or living together, of reproductive age, who have been formally declared medically infertile or sterile, and who are both alive. Before starting any treatment, these couples must sign a written consent, which can be withdrawn by either of the partners up until the moment of fertilization of the egg but not thereafter. This document states that the patients accept the treatments and what follows, namely they declare that they will be the legal parents of the hypothetical offspring.

Cryopreservation of embryos and donation of gametes and embryos are banned as well as the destruction of fertilized eggs, while pre-implantation genetic diagnosis (PGD) has been possible since March 2008, after the new guidelines mentioned above were issued. Other techniques, like inseminations, In-Vitro Fertilization (IVF) and Intracytoplasmatic Sperm Injection (ICSI) are admitted if they imply the use of reproductive material of the couple. In other words, assisted procreation is open to heterosexual couples with certified medical problems of infertility, which do not require the use of donated gametes. The law limits the number of eggs that can be fertilized to three and each one of them must be transferred into the womb of the woman who produced it.

Further, homosexual couples, single women and healthy post-menopausal women are excluded from assisted procreation, given that, following the principles of biological reproduction; treatments are only available for people who would be potentially fertile, if not affected by medical problems. On the other hand, the law states that each woman who gives birth to a child is given the possibility not to recognize this child as hers despite the biological tie established through the pregnancy and the act of delivery in this case the anonymity of the mother is applied and the child is declared adoptable. Moreover, a non-married father has to declare his paternity although he does not have to prove his biological relation to the child. Only if the court is called to invest somebody with the role of parent for a child who has not been recognized by any one at its birth, the procedure can include a genetic test in order to identify the biological parents. In all the other cases the relationship of descent is confirmed through a voluntary declaration. Thus the relationship of descent is confirmed through an act of will.

4.7 ART in Japan

The great importance placed on family lineage also intensifies pressure to produce genetic offspring. The focus on heredity also means that some couples may be disinclined to adopt, preferring to carry on their family line. More so than in other parts of the world, Japanese couples seeking infertility treatment wish to have children with biological links. The first IVF baby was born in Japan in 1983.[39] The number of infants born as a result of assisted reproductive technology (ART) has increased every year ever since. In 2007, the total number of infants born as a result of ART was reported to be 19,595, close to 2% of all births. Japan is having a large number of registered ART facilities, 606 in total. Among these, only five facilities perform more than 700 cycles of both IVF-ET and ICSI per year. Only a few facilities, all of which are private clinics, perform more than 3,000 cycles of ART per year. In Japan, the practice of ART is not governed by legislation. It is voluntarily regulated by physicians, mainly according to the bulletins of the Japan Society of Obstetrics and Gynecology and the Society of Reproductive Medicine. This regulation has had some degree of success. For example, the multiple pregnancy rates fell to 10.7% in 2007 after the Society of Obstetrics and Gynecology recommended single ET for women under the age of 35 undergoing their first ET. It was also recommended to transfer a maximum of three embryos, even for women who have undergone two or more ETs or for those over age 40. On the other hand, since 1998, there have been cases in which members of the societies have performed IVF using oocytes donated by siblings or third parties, against regulations. Further, there have been some cases in which sisters have acted as gestational surrogates. Many couples go abroad to receive donated oocytes. In 2008, one couple come to India to obtain a gestational surrogate, but divorced before the infant was born. According to Japanese law, the child did not qualify for Japanese nationality, and so has no nationality. Thus, assisted reproduction has been prevalent and has contributed to Japanese society. However, legislation has not caught up with the advances and prevalence of this technology. [40] In Japan, the only law related to ART is the *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar*

[39] Danielle Franco-Malone, "Forging Family Ties Through Full Surrogacy: An Argument in Favor of Recognizing Nontraditional Parents in Japan". Available on *http://lsrj.org/documents/awardsgrants/Forging_Families.pdf, la*st visited 24/12/2014 at 03:36 p.m.

[40] Bunpei Ishizuka,"The Present Status of Assisted Reproduction in Japan", available at *http://www.sart.org/International_Activities/* visited on 19/01/2013 at 2:35 P.M.

Techniques (June 2001). This law prohibits reproductive cloning, germline modification, and the transfer of human/animal hybrid embryos to either a human or animal. Research cloning is permitted in Japan. Other ART activities are regulated by voluntary guidelines produced by the Japan Society of Obstetrics and Gynecology.[41]

Japan has taken a different legal stand in respect of surrogacy. Supreme Court of Japan, on March 23, 2007, denied parenthood to genetic parents since the twin babies were born to a surrogate mother at United States. Interpreting the Civil Code of Japan, the Supreme Court, held a mother who physically gives birth to a child is the legal mother. There is no provision in the Code to recognize the genetic mother as the legal mother. There exists no specific laws in Japan concerning parent-child relationship for artificial insemination, and the mother and child relationship will be based on the fact of delivery. The issue of Citizenship status of such an infant is also a burning problem in Japan. The Japan Supreme Court rejected the Japanese commissioning parents bid to register their twins born to a U.S surrogate mother in Japan, on the ground that the law presumes the woman, who gives birth to a child as its mother.

4.8 ART in Australia

The NHMRC Ethical Guidelines on the use of assisted reproductive technology in clinical practice and research (2007) deal with the ethical aspects of research and clinical practice of assisted reproductive technology.[42] The document is divided into three parts. Part A provides background and introductory material. Part B provides ethical guidelines for the clinical practice of ART and Part C provides ethical guidelines for research. Part C of the guidelines is consistent with the Prohibition of Human Cloning for Reproduction Act 2002 and the Research Involving Human Embryos Act 2002. The guidelines are primarily intended for ART practitioners, researchers, infertility clinic administrators, Human Research Ethics Committees and governments. The Research Involving Human Embryos Act 2002 requires that research on certain human embryos may only be conducted under a licence issued by the NHMRC Embryo Licensing Committee. The Licensing Committee must be satisfied that the research proposal has been assessed and

[41] Supra note 3.

[42] "Ethical guidelines on the use of Assisted Reproductive Technology in clinical practice and research" (2007), available at *http://www.nhmrc.gov.au/guidelines/publications/e78* visited on 6 September 2012.

approved by Human Research Ethics Committee acting in compliance with the *National Statement on Ethical Conduct in Human Research (2007)* and the ART guidelines.

The RIHE Act distinguishes between embryos intended for transfer to a woman to achieve a pregnancy and embryos that have been deemed to be no longer needed in an ART program. The *Prohibition of Human Cloning for Reproduction Act 2002* and *Research Involving Human Embryos Act 2002* permit research on excess ART embryos, including those that are unsuitable for implantation, and embryos created by means other than by fertilization of a human egg and human sperm. Consent from the donor must also be sought prior to use of excess ART embryos for research. For any licensable activity the number of excess ART embryos, other embryos or human eggs should be restricted to that likely to be necessary to achieve the goals of the activity. Research proposals involving human embryos must not include any practices prohibited by the legislation. Many aspects of clinical practice in ART raise ethical issues. The ART Guidelines cover activities including:

- posthumous use of gametes
- surrogacy
- donor conception
- sex selection; and
- Pre-implantation Genetic Diagnosis (PGD).

The *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007* underpin the regulation of ART practice within Australia. Accreditation of ART treatment centres by the Reproductive Technology Accreditation Committee (RTAC) is the basis of a nationally consistent approach for overseeing ART clinical practice. RTAC accreditation requires ART treatment centres to comply with government laws and guidelines concerning the practice of ART. The ART Guidelines are included in this requirement. RTAC was established by the Fertility Society of Australia.

The *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research 2007* are consistent with the *Research Involving Human Embryos Act 2002* (RIHE Act) and the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act). The Guidelines are also prescribed in the regulations under the RIHE Act. The NHMRC Licensing Committee oversees the RIHE Act and the PHCR Act. An independent committee was established by the

Australian Government to review this legislation on cloning and research involving human embryos in Australia and was chaired by the Justice Peter Heerey QC. The review of this legislation commenced in late December 2010 and the independent committee released its report in July 2011. The Australian Government is currently considering the recommendations in the Heerey Report. There are important links between the human embryo research legislation and the ART Guidelines. Accordingly NHMRC is preparing for a review of the guidelines, subject to the response from Government to the Heerey Report.

The ART Guidelines restrict the use of PGD for sex selection in Australia. These Guidelines reflect the sentiment of the community that admission to life should not be conditional upon a child being of a particular sex. Therefore, sex selection (by whatever means) should not be undertaken except to reduce the risk of transmission of a serious genetic condition.

4.9 ART in Belgium

Belgium's key laws pertaining to ART are the *Law on Research into Embryos In Vitro* 2002 and the *Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes* 2007.[43] These laws prohibit reproductive cloning, the creation of embryos for research purposes, non-medical sex selection or treatment for eugenic purposes, and the creation of chimeras or hybrid embryos.

As of 2003, ART is completely covered by Belgium's national health plan. This insurance provides up to 6 cycles of ART for women under the age of 42. Women over 42 years are ineligible for coverage. This coverage comes with strict limits on the number of embryos transferred per cycle, limiting the number of embryos transferred to a maximum of 2 for women under the age of 36 and a maximum of three for women under the age of 40.

4.10 ART in Canada

In Canada reproductive and genetic technologies (RGTs) are of great interest to the Canadian public and the federal government is moving ahead with its work on this complex issue.[44] Same sex marriage has been legalized in Canada and unmarried same sex cohabitants are legally recognized for many purposes. Family law has

[43] Supra note 3.

[44] "The Regulation of Medically Assisted Procreation in Europe and Related Nations and the Influence of National Identity, Social Cultural, and Demographic Differences", available at *http://digital.library.unt.edu/ark:/67531/metadc3192/m1/132/* visited on 4 December 2012.

become largely gender neutral, partly due to the increased recognition of same sex relationships, but also reflecting the influence of the fathers' rights lobby. Sexuality and procreation have increasingly become uncoupled both technologically and socially, and "baby making of all sorts, including the hi-tech and clinical kind, has increasingly occurred outside heterosexual marriage."[45] The first federal Canadian initiative was *The Processing and Distribution of Semen for Assisted Conception Regulations* which falls under the Food and Drugs Act and came into effect in June 1996, and was amended in March 2000. The voluntary moratorium is still in effect in Canada and calls upon the medical and research communities in Canada to refrain from applying nine RGTs identified as raising serious ethical and social problems, including cloning of human embryos.

Canada's *Assisted Human Reproduction Act* (2004) created the Assisted Human Reproduction Agency of Canada (AHRA) responsible for administering and enforcing the AHR act and its regulations. This Act prohibits reproductive and research cloning, the creation of IVF embryos for purposes other than reproduction or reproduction research, non-medical sex selection, germline modification, the creation of a chimera or hybrid embryo, commercial surrogacy, and the commercial trading of human eggs, sperm and embryos. This Act also establishes a series of principles related to ART including the provision that the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use and that the health and well-being of women must be protected in the application of these technologies. These principles also discourage discrimination against persons seeking to use ART on the basis of their sexual orientation or marital status and they discourage the use of ART for commercial ends due to its exploitative nature.

In Budget 2012, the Government of Canada announced that it would wind down Assisted Human Reproduction Canada (AHRC), in response to the 2010 ruling of the Supreme Court of Canada that significantly reduced the federal role in assisted human reproduction (AHR). Health Canada has taken over responsibility for the remaining federal functions in AHR, such as compliance and enforcement, and outreach, effective October 1, 2012. As a result, all federal functions have been transferred to the Health Products and Food Branch (HPFB) of Health Canada. This

[45] Susan B. Boyd, Gendering Legal Parenthood: Bio-Genetic Ties, Intentionally and Responsibility, Windsor Yearbook of Access to Justice (2007), pp. 1-28 at 6.

includes the policy and regulatory development function that previously resided with the Assisted Human Reproduction Implementation Office (AHRIO). AHRIO was wound down at the same time as AHRC.[46]

Assisted reproductive technologies (ART) are a policy concern in Canada due to the continued prevalence of infertility and the recent rise in the number of multiple pregnancies. The issue of access, funding, and the regulation of ART's *in-vitro* fertilization (IVF) in particular has generated considerable debate.[47]

In 2004, the federal government enacted legislation to regulate assisted reproduction. The Assisted Human Reproduction Act, which governs the clinical and research activities of medically assisted human reproduction, identifies activities that either are prohibited or are subject to regulation. In 2006, Assisted Human Reproduction Canada was established to implement and enforce the Act's principles. The constitutional validity of the Act has come under attack from several provinces. In 2008, the Quebec Court of Appeal challenged several provisions of the Act, contesting that they are not matters of criminal justice and do not put the public's health at risk and, therefore, should be governed by provincial legislation.[48]

4.11 ART in France

In France medically assisted procreation (ART) entails clinical and biological procedures enabling in vitro conception, embryo transfer, and artificial insemination, as well as any technique having an equivalent effect enabling procreation outside the natural process. The regulation of ART in France is through the comprehensive set of laws: No. 94-548 of July 1, 1994 on personal data processing for health research purposes; No. 94-653 of July 29, 1994 on respect for the human body; No. 94-654 of July 29, 1994 on donation and use of human body parts and derivatives, ART and antenatal diagnosis.[49] The three laws are incorporated into the Civil Code, the Public Health Code, and the Penal Code. For example 1995 amends the Public Health Code in regard to ART activities. Additionally on the National Commission on Medicine, Reproductive Biology and Prenatal Diagnosis amend the Public Health Code. A more

[46] Available at *http://www.ahrc-pac.gc.ca/v2/index-eng.php* visited on 8 December 2012.
[47] Available at *http://www.cadth.ca/products/environmental-scanning/health-technology-update/issue-10-september-2008/assisted-reproductive* visited on 8 December 2012.
[48] Ibid
[49] Beverly J. Wunderlin, "The Regulation of Medically Assisted Procreation in Europe and Related Nations and the Influence of National Identity, Social Cultural, and Demographic Differences", available at *http://digital.library.unt.edu/ark:/67531/metadc3192/m2/1/high_res_d/dissertation.pdf* visited on 19 December 2012.

current Order of January 12, 1999 pertains to the rules of good clinical and biological practice in the field of medically assisted procreation.

French bioethics law restricts access to ART to heterosexual couples of child-bearing age, both of whom are alive at the time of insemination or embryo transfer, and are either married or in a relationship that approximates to matrimony for a minimum of two years. If one member of the couple dies, frozen gametes or embryos must be donated to an infertile couple by the surviving person or destroyed. Gamete donation includes the provision by a third party of spermatozoa and oocytes for the purpose of ART. An embryo may not be conceived with gametes that are not derived from at least one of the two members of the couple. Donors must be members of a couple that has procreated. Written consent must be obtained from the donor and his or her spouse. The French view this relationship to be a fertile couple donating to an infertile couple in support of family life.

France's key laws include the *Bioethics Law No. 2004-800* (2004) and the *Law on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis, No. 94-654* (1994).[50] The *Bioethics Law* created the French Biomedicine Agency, responsible for licensing and regulating ART centers. These laws prohibit reproductive and research cloning, the creation of embryos for research purposes, germline modification, and non-medical sex selection, surrogacy is also prohibited. In France, pre-implantation genetic diagnosis is allowed only when a parent or close relative has a serious genetic disease and also for HLA tissue matching. France's national health plan provides complete coverage for ART to heterosexual couples who are of reproductive age and are married or have lived together for two years.

4.12 ART in Germany

ART practices are strictly regulated in Germany. The basis for ART regulation in Germany is the *Embryo Protection Law of December 1990*, which took effect January 1, 1991.[51] The thirteen sections of this law are part of the criminal law. The purpose of the law is to prevent the misuse of reproductive technologies.

The improper use of reproductive technologies holds a penalty of up to three years imprisonment or a fine. This includes the transfer of an unfertilized egg cell

[50] Available at *http://www.dnapolicy.org/policy.international.php?action=showall* visited on 23 December 2012.

[51] "Bioethics Legislation in Selected Countries, The Library of Congress", October (2012), available at *http://www.loc.gov/law/help/bioethics_2012-008118FINAL.pdf* visited on 4 November 2012.

from one woman to a different woman or carrying out actions to enable either surrogacy or embryo donation. Sex selection is also prohibited unless circumstances such as sex-linked hereditary disease exist. A physician who violates the sex selection prohibition may receive up to one year in prison or a fine.

In Germany ART is only permissible within the context of a heterosexual relationship that is either a marriage or approximates matrimony. Sperm donation is allowed but oocyte or embryo donation is prohibited. The only exception is the "spare embryo" or unplanned incident whereby the unintentional surplus embryo cannot be implanted in the womb of the woman to whom the embryo originated. In this situation the "spare embryo" may be implanted in another woman, and this woman will be considered the mother of the offspring. The donation is considered preferable to the destruction of the embryo. The 1990 law prohibits cloning. The creation of an embryo genetically identical to another embryo, fetus or individual living or dead is an offense. Implantation of an embryo created in this way is a crime.

Germany's key laws and guidelines pertaining to ART include the *Federal Embryo Protection Law 1990,* the *Adoption Brokerage Law 2006,* and the *Guideline of the German Federal Medical Chamber 2006*. These laws prohibit research and reproductive cloning, gamete donation, the creation of hybrid embryos, the cryopreservation of fertilized eggs, sex-selection (with the exception of sperm sorting for the prevention of a few sex-lined genetic disorders), pre-implantation genetic diagnosis, and all forms of surrogacy. Only three eggs can be fertilized and transferred in one reproductive cycle.

4.13 ART in Netherlands

The Netherlands's key laws on ART are the *Act Containing Rules Relating to the Use of Gamete and Embryos (Embryos Act)* (July 1, 2002) and the *Commercial Surrogacy Act* (November 1, 1993). The *Embryos Act* prohibits the creation of embryos for research purposes, allowing an embryo to develop outside the human body for longer than 14 days, reproductive cloning, germline modification, the creation of human/animal hybrid embryos, non-medical sex selection, and commercial donation of gametes or embryos for reproductive or research purposes. The *Commercial Surrogacy Act* prohibits commercial and professionally arranged surrogacy. In the Netherlands, pre-implantation genetic diagnosis is permitted only for serious genetic disease at one facility, although the government has recently allowed

testing for certain hereditary cancers and is considering offering testing for a wider range of conditions in the future.

4.14 ART in Spain

In Spain, key laws pertaining to ART are the *Law on Assisted Human Reproduction Techniques, No. 14/2006* (May 27, 2006) and the *Biomedicine Law 14/2007* (July 3, 2007). [52] The National Commission on Human Reproductive Assistance is Spain's ART advisory committee. The above laws prohibit reproductive cloning, the transfer of more than three embryos per reproductive cycle, the creation of embryos for purposes other than reproduction, germline modification, non-medical sex selection, and the use of pre-implantation genetic diagnosis for non-medical purposes. Surrogacy is not recognized in Spain. The commercial donation of gametes is allowed for assisted reproduction and research, although only 6 children can be born from the same donor.

Spanish law does not limit access to infertility treatment based upon marital status. Single women may receive treatment if over age 18 years and judged to have full legal capacity. There are no other age restrictions. Posthumous conception by artificial insemination of sperm of the deceased spouse or partner is allowed if the consent of the deceased was granted within six months of the date of death in a will or alternative document. Sperm and ovum donation is allowed. Embryo donation is prohibited. Surrogate motherhood is not legally restricted but delivery decides maternity, i.e., the birth mother is the legal parent. Donation is treated as anonymous.

4.15 ART in Sweden

ART is strictly regulated in Sweden. Artificial insemination was the first to require that information on the sperm donor be recorded in the hospital's special register and made available to the offspring upon maturity when requested. The Swedish In-Vitro Fertilization Act of 1988 is currently the basis for ART practice. This law was passed June 8, 1988 and entered into force January 1, 1989. In vitro fertilization is available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. The couples own sperm and ovum must be used. Ovum fertilized outside the body must be implanted only in the womb of the woman from whom it came. Surrogacy is prohibited in Sweden. Neither ovum nor embryo donation is allowed. No national statutory age limit exists; but the

[52] Supra note 3.

various county councils have established upper age limits between 35 and 37 years of age. Swedish Law prohibits the cloning of embryos and oocytes.

In Sweden, key laws regulating ART are the *Act on Ethics Review of Research Involving Humans, Law No. 460* (2003), and the *Genetic Integrity Act, Law No. 351* (2006). Sweden provides financial coverage for ART to couples who are married or are in a stable relationship. Reproductive cloning, surrogacy, germline modification, and the use of pre-implantation genetic diagnosis for social purposes are prohibited. Pre-implantation genetic diagnosis is permitted for disease and for HLA matching (only after approval by the Board of Health and Welfare). Sweden allows only one embryo (two in older women) to be transferred per reproductive cycle. Embryos can be cryopreserved for up to five years.[53]

4.16 ART in Switzerland

Switzerland's key laws regulating ART include the *Federal Law on Medically Assisted Reproduction* (1998), the *Federal Act on Research Involving Embryonic Stem Cells* (2003), and the *Federal Law on Medically Assisted Reproduction* (2004). Prohibited practices include reproductive and research cloning, egg and embryo donation for ART, creating an embryo for research purposes, creating a hybrid embryo, germline modification, pre-implantation genetic diagnosis, nonmedical sex-selection, and surrogacy. Switzerland limits the number of embryos transferred per reproductive cycle to three and requires cryopreserved gametes and embryos to be destroyed after five years.

4.17 ART in Israel

Israel's reproductive care policy appears to reflect Jewish religious, cultural, and social norms regarding fertility. Parenthood is considered a basic human right based on biblical and other Jewish religious sources. The personal desire for parenthood, and specifically motherhood, has been engrained in Jewish culture and has been strengthened by the historical persecution of Jews in the Diaspora and particularly by the genocide perpetrated against Jews in the Holocaust. The continuing loss of life in Arab-Israeli wars and terrorist acts, combined with constant threats to the State's existence by hostile powers in the region, have also been linked to Israelis' attitudes regarding procreation. Israel's pro-natalist approach is supported by legislation regulating in vitro fertilization (IVF), ova extraction, the use of semen in

[53] Ibid

IVF fertilization, ova donation and allocation, and surrogacy agreements. The regulation of assisted reproductive technology (ART) in Israel appears to support reproductive choice while respecting certain religious and cultural considerations. A person's right to procreate has been recognized in Supreme Court rulings, especially in the leading case of *Nachmani v. Nachmani*[54], where the Court held that in the special circumstances of that case the right of a woman to motherhood was superior to her husband's right not to be a father.

The recognition of the importance of parenthood and the superior right to motherhood, however, has not resulted in recognition of a woman's full autonomy over her reproductive status. By law, a woman does not have a general right to choose to terminate her pregnancy. An interruption of pregnancy may be permitted under certain circumstances by special committees for the interruption of pregnancies established by hospitals or the Ministry of Health. Such circumstances include the age of the woman; the pregnancy deriving from rape, incest, or an out-of-wedlock relationship; and fetal disabilities and physical or mental danger to the mother posed by continuation of the pregnancy.

Israel has one of the highest birth and fertility rates among industrialized countries. Although the average age of women giving birth for the first time has consistently increased in the past ten years, modern technologies such as in vitro fertilization (IVF) and the use of assisted reproductive technology (ART), along with a pro-natalist state policy fully or partially subsidizing such treatments, have made it possible for an increased number of women, including unmarried or infertile women and those wishing to delay procreation to facilitate career development, to give birth.

Israel maintains a system of national health care. In accordance with the National Health Insurance Law, 5754-1994, Israeli residents are entitled to medical services that are provided by Health Funds that are approved by the Ministry of Health. The Health Funds must provide services that are included in "a basket of basic health services," which includes specific reproductive health services and products. The scope of technologies and medications to be included in the basket of basic health services, within the budget allocation, is determined on a yearly basis by a public committee appointed for that purpose by the Minister of Health. Insured patients are entitled to be provided with oral contraceptives. In addition, they are entitled to

[54] 35 TEXAS INT'L L. J. 1 (2000)

prenatal care; interruption of pregnancy for medical reasons, as well as for nonmedical reasons in the case of girls under nineteen years of age; fetal organ system exams; epidurals during birth; exams for identification of fetal disabilities, including amniocentesis, etc.

Israeli residents are also entitled to genetic counseling, including blood tests and genetic evaluation. Such evaluation is provided to carriers of genetic or chromosomal interference or of especially severe genetic diseases, to couples with a high probability of giving birth to a child with especially serious chromosomal disabilities, and to women who have undergone repeated miscarriages. Entitlement to prenatal genetic evaluation is limited to two pregnancies resulting in birth. Israeli women are also permitted to undergo extraction of ova for freezing for future implantation for any reason. The procedure and the freezing of the ova are fully covered when done for medical reasons, and the maximum amount of coverage for other reasons is to be determined by the Ministry of Health. [55]

4.18 ART in Austria

The regulation of ART in Austria is through the 1992 Reproductive Medicine Law and the 1998 Ordinance on reports about activities and experiences with medically assisted reproduction. Effective January 1, 2000 a fund for the financing of in vitro fertilizations was established through passage of legislation: IVF-Fonds-Gesetz.[56]

The 1992 Reproductive Medicine Law amended the General Civil Code, the Marriage Law, and the Rules of Jurisdiction. The filiations of children born is covered in Section 156(a): "If the mother's husband has consented, in the form of a court protocol or act authenticated by a notary, to Medically Assisted Procreation using the sperm of a third person, the legitimacy of the child born as the result of the use of the sperm of a third person may not be contested." Section 163(1) establishes paternity in the case of a child born out of wedlock in ART practice, i.e., "the man whose sperm has been used shall be presumed to be the father of the child." The Marriage Law was amended to state: "A marriage partner shall not have grounds for divorce if the other partner refuses ART or ART".

[55] "Reproduction and Abortion: Law and Policy, Law Library of Congress, Israel", available at *http://www.loc.gov/law/help/israel_2012-007460_IL_FINAL.pdf* visited on 12 December 2012.
[56] Supra note 48.

The Federal Law of 1992 states under Section 2(1): "ART shall only be permissible within the context of marriage or a relationship that approximates to matrimony." It further stresses the need to explore all alternatives before relying on ART practice. Although the sperm of a third party may be used when necessary, the "oocytes and viable cells may only be used in the woman from whom they are obtained". Under Section 9 (3) "The use of a mixture of sperm from different persons shall not be permitted for the purposes of ART."

4.19 ART in Bulgaria

The regulation of ART in Bulgaria is limited to artificial insemination. The July 17, 1990 order of the Ministry of Health and Social Welfare amends Order No. 12 of May 30, 1987 on artificial insemination of women. The order mandates the testing of donor sperm and limits the number of fertilizations. Additional donated sperm may be stored in the sperm bank to be used for insemination of foreign citizens or for research purposes. Bulgarian law limits sperm donation to persons of Bulgarian nationality between 18 and 40 years of age. Posthumous conception, i.e., the insemination of widows with the sperm of deceased spouses is not done. Bulgaria does not specify an upper age limit for people seeking infertility treatment. Access to infertility treatment is not limited according to the marital status of the couples seeking assistance. Although most ART practices are not against the law, the quality of reproductive medicine is impacted by funding limitations.

4.20 ART in Czech Republic

The only legislative text is the 1982 Order of the Health Ministry pertaining to homologous and heterologous artificial insemination. The Czech Gynecological and Obstetrics Society's assisted procreation section is responsible for the founding of ART principles. A Code of Ethics has been prepared by the Association of Medically Assisted Procreation Centers. The Ministry of Health of the Czech Republic and others suggested contacting Dr. Mardesic because he administers the largest infertility treatment center in the Czech Republic.

The practice of sperm and egg donation is legal and practiced. The use of donated gametes is restricted to married couples. Surrogate motherhood is not possible. The donation of gametes is anonymous. The Czech Society for Assisted Reproduction and Sterility is responsible for updating and evaluating the minimum standards.

4.21 ART in Denmark

The regulation of ART in Denmark is through Law No. 460 of June 1997 on artificial fertilization in connection with medical treatment, diagnosis, and research. ART legislation was adopted by the *Danish Folketing* at the third hearing on May 27, 1997, according to *Maja-Lisa Axen* (personal communication, December 16, 1999). ART practices are required to have the objective of uniting a genetically unchanged oocyte with a genetically unchanged spermatozoon. Artificial fertilization is only made available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. ART practice is prohibited where the proposed birth mother is over 45 years of age.

Artificial insemination and the reporting of *in-vitro* fertilization treatments and pre-implantation diagnosis were made in pursuance of Law. Among other things the destruction of sperm stored for the purpose of causing the donor's partner to become pregnant is mandated in the event of the donor's death. It is also prohibited to contribute in any manner to the sale of unfertilized or fertilized oocyte. Fertilized oocyte may be kept alive no longer than fourteen days outside a woman's uterus. The transplantation of ovaries for the purpose of remedying sterility or infertility is prohibited. Human oocytes (fertilized or unfertilized) may be frozen for up to two years. Upon the death of the woman or man, or in the event of their separation or divorce, or at the end of the two year period the frozen oocytes must be destroyed.

A Scientific Ethical Committee System and the Handling of Biomedical Research Projects (1992) addresses cloning. Research on cloning, i.e., production of genetically identical individuals, is forbidden.

4.22 ART in Ireland

The Republic of Ireland has not adopted specific legislation to address ART practices. "General Medical Council Guidelines" issued by the Irish Medical Council (1999) is a guide to ethical conduct, procedures, and fitness to practice. The guidelines stand as the basis for the regulation of treatment. Infertility treatment is provided to married couples. The guidelines state: "There is no objection to the preservation of sperm or ova to be used subsequently on behalf of those from whom they were originally taken".

Physicians are advised to provide extensive counseling to couples and donors when considering third-party donation. Failure to provide such counseling could result in disciplinary proceedings. Techniques such as *in-vitro* fertilization should

only be used after thorough investigation has ruled out alternatives. "Any fertilized ovum must be used for normal implantation and must not be deliberately destroyed".

4.23 ART in Russia

The regulation of ART in Russia is through the Act on Artificial Fertilization Act, 1996. *Thorsteinsdottir* says the Regulation is the same as the Act plus more rules. The Regulation gives the decision to approve ART practices to the physician. If the physician has concerns about the social conditions of the couple, an opinion is requested from child welfare authorities. A committee appointed by the Minister of Health and Social Security composed of a lawyer, a physician, and a social worker who serve for four years review any complaints and issue a decision, which is final.[57]

The Regulation suggests that the couple reside together for three continuous years. There is an upper age limit of 42 years for women or 45 years if gametes are in storage. The upper age limit for men is 50 years. Posthumous conception is not allowed. Surrogate motherhood is prohibited. Sperm and oocyte or ovum donation are allowed. Embryos may be created using *in-vitro* fertilization and placed in storage. The embryo can only be implanted in the womb of the woman the oocyte came from or the wife of the man who contributed the sperm. If the marriage or relationship ends or a spouse dies, the embryo is destroyed.

4.24 ART in New Zealand

The National Ethics Committee on Assisted Human Reproduction (NECAHR) was established by and accountable to the Minister of Health under section 46 of the Health and Disability Services Act of 1993. The objectives or role of the committee is to review proposals to ensure ethical aspects are considered; to ensure rights of patients, donors, and offspring are protected; to develop protocols and guidelines to assist regional ethics committees; and to provide the Minister of Health and National Advisory Committee on Health and Disability Service Ethics with advice on ART issues.

New Zealand has federal regulatory legislation on ART pending. According to Jenny Hawes, an analyst for the Ministry of Health, the government recently agreed to develop new legislation out of the two bills under consideration.[58] The new law was being drafted in late 2001. The two competing bills before the Health Select

[57] Ibid
[58] Ibid

Committee were the Human Assisted Reproductive Technology Bill introduced in 1996 and the Assisted Human Reproductive Technology Bill introduced in 1998.

4.25 ART in Norway

The regulation of ART in Norway is through the Act relating to the Application of Biotechnology in Medicine Act, 1994.[59] Both Norwegian and English versions of the Act were provided by the Health and Social Affairs. The Royal Ministry of Health and Social Affairs advised that administration of the Act is delegated to the Norwegian Board of Health. The Norwegian government has appointed an independent advisory board known as The Norwegian Biotechnology Advisory Board to review problems and suggest ethical guidelines.

ART treatment services are made available to couples within the context of marriage or a conjugal relationship that approximates heterosexual marriage. It is suggested that an upper age limit of 38 years is preferable for the birth mother; but no statutory limit exist. Posthumous conception is prohibited. Sperm donation is allowed. The sperm donor remains anonymous. Ovum and embryo donation are not allowed. Surrogate motherhood is prohibited. Sex selection is prohibited except for reasons of a sex-linked hereditary disease. Embryo cloning is prohibited.

4.26 Conclusion

It is absolutely understandable that different countries will reach different regulatory conclusions regarding assisted reproductive technology, based on a variety of factors including cultural attitudes, traditions, religious views and the majority's moral position. The legislation adopted and regulatory structures implemented vary in regard to the priorities emphasized. The concerns of some nations are health risk based whereas others view the morality of this approach to be in question. A division exists over the importance granted to individual privacy versus social consciousness. These factors along with economic circumstances influence actions taken, as well as, inaction. The level of economic development and the stability of the health care structure are closely related issues.

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[59] Available at *http://www.ub.uio.no/ujur/ulovdata/lov-20031205-100-eng.pdf* visited on 8 November 2012.

Chapter-V

Chapter -V

Ethical-Moral and other Issues in Assisted Reproductive Technology

5.1 Introduction

When societies change rapidly, their prevailing ethical norms are challenged both by the biases of new knowledge and the conflicts created by the new practices that threaten prevailing norms. Ethics is the notion of what is good and right in society that guides human action. In the period of transition, the emergence of new ethical practices is guided by it. This is not a linear process but a trajectory interspersed with conflicts of ideas and interests in various arenas of technology society inter-face. Public health added social responsibility and justice to ethics of medical practice and research. Assisted reproductive technologies introduce ambiguities into traditional ways of defining basic concepts – parenthood, family, individual etc. As the use of technology expands the range of possibilities for procreation, new parties enter the reproductive process and blurs long-established categorical boundaries. Complex questions are further complicated through the uses of ART, such as what is "reproduction," what is meant by "mother" and "father," or when "life" begins. Not only are issues in assisted reproduction important for our understandings of order in the natural world, they are also centre to our conceptions about how we order the social world. As assisted reproduction confuses conventional categories of commodity and of family, normal ways of defining what is social and what is natural do not work well in the context of assisted reproduction. Thus, in trying to accommodate ART into society, bioethicists have used bioethical frameworks to establish new ways of redefining social and natural order. This chapter will focus on the complex ethical, moral, social and health related issues related to assisted reproduction and also discuss the religious response towards different ART procedures.

5.2 Ethical Issues in Assisted Reproduction

In the area of assisted reproduction, the idea of individual autonomy has shaped political and ethical debates. Ethical discussion of reproductive technologies began in the early 1970s, when techniques such as in vitro fertilization became a real possibility. Many of these early commentators were medical practitioners, so the first ethical concerns involved worries about illegitimate human experimentation. Leon Kass, an American scientist and public intellectual, noted in a 1971 article that in vitro fertilization procedures were executed on human embryos, with the possibility of

harming the potential child, there was no ethically acceptable way to perform the procedure. A scientist could not morally choose unknown hazards for the child and then give him a life in which he would have to face those consequences. At the university of Chicago he argued that "this blind assertion of will against our bodily nature-in contradiction of the meaning of the human generation it seeks to control-can only lead to self-degradation and dehumanization. Paul Ramsey, an American Christian ethicist, went even further to argue for a complete prohibition on IVF experimentation, believing that the moral hazards of experimenting on a possible future human being were unacceptable. He pronounced, "Men ought not to play God before they learn to be men, and after they have learned to be men they will not play God."[1]

On the other hand, John C. Fletcher, a leading biomedical ethicist, argued for the procedures, declaring that technology liberated human reproduction from what he termed, "reproductive roulette". However, governments in many countries officially began to research the ethical implications of these technologies only shortly before the birth of the world's first IVF baby, Louise Brown in 1978. In that year, the Ethics Advisory Board of the U.S. Department of Health, Education and Welfare undertook a study of IVF, primarily focusing on procedural safety and efficacy to ensure that scientists were minimizing the risks to potential offspring. Following the media fanfare accompanying Brown's birth, numerous countries, including Spain, Netherlands, Australia and the United Kingdom issued more than a dozen reports on the topic within six years. In 1982, the United Kingdom established the Committee of Inquiry into Human Fertilization and Embryology, headed by the philosopher Mary Warnock, to examine the social, ethical, and legal implications of new and potential developments in human assisted reproduction[2].

Currently, ethical issues around assisted reproductive technologies encompass a wide range of questions including the "naturalness" of the technique, the moral status of the early human embryo, the relationships among relevant parties, and the economics of ART. Because couples substitute lab processes for procreation, some argue that the separation of reproduction from sexual intercourse is ethically dubious because it is "unnatural." Others question whether an embryo can be regarded

[1] Debora L Spar; *The Baby Business: How Money, Science and Politics Drive the Commerce of Conception*, (2006, Boston, Harvard Business School Press) at 26.
[2] Ibid.

as a human being and if it deserves the full range of respect and protections guaranteed to citizens. In cases where ART challenges traditional boundaries of parenthood, the relationship of the genetic or birth parent to the social parent and child is unclear. There are additional problems of ART commercialization and access. Should sperm or ova providers be paid; in the case of surrogacy, how much should surrogate mothers be compensated and do the risks to the surrogate's health outweigh the benefits of payment? These debates represent different approaches to interpreting reproduction so that individuals who have no other options can choose assisted procreation in a way that is morally agreeable to society. They assume the individual to be the unit of society with the ability to make free and self-determined choices. Successful ART regulation should allow for the maximization of individual interests within the confines of society.[3]

The separation between sex and reproduction was too fundamental to replace by technical means; that creating children outside the body would eventually undetermined the very definition of life. Feminists, meanwhile, split into two contentious groups. Some, led most famously by Shulamith Firestone in her *Dialectic of sex*, embraced IVF as the first step towards liberating women from their reproductive biology. Others painted IVF as the self-serving creation of men and commerce. Like option and hormones and tubal surgery, they argued, it was just another "hubristic and harmful technology," born of a conspiracy between the "collective be male ego and the corporate and medical and pharmacological purses." By promoting the idea that a woman could find happiness only in motherhood, it "perpetuate[d] the cycle of depression, despair, hope… [and] promote[d] a fetus-centered ideology."[4]

Chastened by such critics, governments in the United States, the United Kingdom, and Australia launched high-profile inquires into the implication of IVF, promising to arrive at an appropriate set of guidelines. In all three countries, the inquires dragged on for years, becoming intimately intertwined with debates over abortion, fetal research, and state funding. In the end, the three countries reached widely disparate yet similarly inspired conclusions. The British ultimately decided that in vitro techniques, including the freezing and donation of embryos, could "be

[3] Congcong Guo, *Conceiving Conception: The Bioethics of Assisted Reproductive Policy in China,* (Harvard College , March 2011) at 33.
[4] Supra note 1 at 6

regarded as an established form of treatment for infertility." Children born as a result of these techniques as to be considered fully legitimate in the eyes of the law, and a new state agency, the Human Fertilization and Embryology Authority was established to regulate both fertility research and fertility services.[5]

In Australia, state parliaments arrived at their own set of conclusions and recommendations. In South Australia, for example, clinics were permitted to treat only patients who were considered medically infertile, and a new regulatory agency was given sweeping powers to govern reproductive technology. In Victoria, treatment was limited to infertile heterosexual couples and a separate agency was established to license fertility centers and approve fertility specialists. In effect, therefore, the Australians, like the British, decided to permit in vitro fertilization but regulate its practice.[6]

In the United States, by contrast, the political system was still reeling from the 1973 *Roe v. Wade* decision. Faced with fervent-occasionally even violent-opposition to abortion or fetal research, the federal government had suspended funding for fetal research in 1974, pending the recommendations of a soon-to-be-created National Ethics Advisory Board. During the days of the Nixon administration, oversight for these policies fell to Health, Education and Welfare (HEW) Secretary Casper Weinberger, whose conservative views on reproductive matters were well known. In 1976, responsibility moved to Joseph Califano, President Carter's secretary of health and human services, another public opponent of abortion. Califano established a revamped commission and launched his own round of hearings, which most in the field of reproductive medicine regarded as an extended excuse for an eventual ban. Surprisingly, though, Califano's commission reported positively on IVF, recommending in March 1979 that the government end its moratorium on funding. Even with this report, however, Califano and the National Institutes of Health were reluctant to act. "It was a political hot potato," recalls one leading fertility specialist. "No one would touch it." And so, amazingly, the "short-term" moratorium stayed in place. No federal funds in the United States flowed to IVF research.[7]

[5] Id at 27
[6] ibid
[7] Id at 28

Now arguably the language of health care rights has lead to an opening up of issues such as the right to found a family[8], and the demand to be treated to be able to do so. There is now available a whole gallery of possibilities. As Morgan and Nielsen point out:

The development of reproductive technology presents contradictory choices, especially for women. Technically, some of the development have increased the capacity of women to take control of their own bodies; with same versions of cloning and parthenogenesis it has even been argued that the notion that reproduction belongs to women would take on a new dynamic with the ability to reproduce without the need for the patriarchal genetic.[9]

However, in India, in the last few years, advocacy groups have also engaged with the government's plan to regulate the ART industry. Sama-Resource Group of Women and Health has played an important role in this campaign, starting by putting together a picture of the industry and its impact on women and society. It has also held a series of consultations with women and health groups on the government's plans and has developed detailed analyses and critiques of the ICMR's guidelines for ART clinics and the draft ART (Regulation) Bill and Rules 2010. At the first such consultation, participants discussed a number of issues raised by these technologies: the public health context and social impact of infertility; the growth of the ART industry; the use and misuse of technologies; the quality of regulation; the concerns of feminists, disability rights activists and the sexuality movement; emerging genetic technologies, and the new eugenics. The consultation highlighted the need to promote greater public discussion on the social and ethical implications of ARTs and influence the development of regulation and monitoring in this field. This consultation, and other meeting that followed, enabled groups to share their views on the flaws in the bill and suggest modifications before the legislature. Activists have been coming together to look at the industry, its growth and diffusion, to discuss the implications in relation to the women's and health movement, and to press for appropriate regulation that protects women's health and rights.[10] We can enlist some of the ethical issues in the following points:

[8] European Convention on Human Right, Art, 12
[9] McVeigh and Wheeler (eds), *Law, Health and Medical Regulation*, (1992, Dartmouth) p.53.
[10] Sandhya Srinivasan, *Making Babies: Birth Markets and Assisted Reproductive Technologies in India*, (2010, New Delhi , Zubaan), at xxix.

5.2.1 Unnaturalness

One criticism is that assisted reproduction is unnatural. It is 'playing God' and interfering in nature's most precious activity: the creation of life. As one groups of catholic bishops put it: 'increasingly, children are seen as the object of "consumer choice", rather than as new human beings to be accepted unconditionally. Jacqueline Laing and David Oderberg argue that assisted reproduction commodifies life.[11] Objectors to the whole notion of artificial reproduction techniques set great store in the existence of the natural order of biological processes. Naturalness has there been equated with something that is untainted with modern human intervention. The unnaturalness may also be seen as stemming from the introduction of a third party into what is considered an intimate relationship. AID (Artificial Insemination by Donor) can be considered a form of adultery. As Pope Pius XII argued, 'To reduce the shared life of a married couple and the act of marital love to a mere organic activity would be like turning the domestic home into a laboratory'.[12]

Before it is considered that this argument is staying outside the legal realm and intro the realms of theology, consider the case of *Maclennan v Maclennan*[13], which considered such a 'third-party' objection. It was held that a women who goes through a process of AID does not commit adultery, because there has been no sexual contact between the women and the male sperm donor. What may have been argued, however, is that a married women's decision to undergo AID without the consent of her husband could be regarded as constituting unreasonable behavior for the purposes of divorce proceeding. [14]

The objection really resolves itself into one about the morality of artificial forms of infertility treatment per se. It also questions the selection of the 'best' embryos for implantation with some of the techniques. It is wrong to 'make' children, the argument goes like 'IVF is a form of domination over another human life, whereas in authentic parenthood the child is a partner in the common life expressed in the procreative act of married union.[15]

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[11] Jonathan Herring, *Medical Law and Ethics*, 3rd edition, (2010, New York, Oxford University Press), at 349.
[12] Michael Davies, *Medical Law*, 2nd edition, (2009, New York, Oxford University Press), at 239
[13] (1958) SC 105.
[14] Supra note 12, at 240
[15] ibid

5.2.2 Anonymity of the Donor

An issue of great controversy is whether children born using donated sperm should be able to discover the identity of the sperm donor. Until recently such children only had access to the most limited information: a child could discover whether she or he was born as a result of donated gametes and whether he or she was related to a person she or he intended to marry. However, the Human Fertilization and Embryology Authority (Disclosure of Donor Information) Regulations 2004 have provided children with access to a far greater range of information. Though the regulations only apply prospectively: to all donations from 1 April 2005. Children born as a result of donations after that date can apply, once they have reached the age of 18, to discover identifying information including:

a) The donor's name (and name at birth, if different) and address,
b) The donor's date of birth and the town or district of birth,
c) The appearance of the donor,
d) A short statement about the donor.

The regulations will not render a sperm or egg donor a parent in the eyes of the law, nor will they mean that they become liable for child support or take on other financial responsibilities. All they mean is that her or his identity can be discovered by a child.[16]

In USA, some clinic have been offering AID services which include detailed descriptions of donors, allowing the 'purchaser' of such services to exercise choice of donor. Early in 1998 *The Times* reported the development of an illict market in sperm, available through the internet. The Human Fertilization and Embryology Authority noted that these catalogues of apparently physically attractive donors were resulting in charges of about 280 euro for each sperm sample. What is seen as most disturbing is the fact that these donors seem prepared to forgo at least some of their anonymity; a number will forgo anonymity completely, but other will allow a video of themselves to be shown to the child when it reaches 18.[17]

5.2.3 Infertility Treatment and Privacy

One of the difficult balancing acts in relation to infertility treatment is to consider the conflict between the need to maintain the privacy of the couple involved in the treatment and the need to improve information flow and protect the welfare of

[16] Supra note 11, at 372
[17] Supra note 12, at 241.

children who are the product of such techniques. It was noted above that the child may well want to know of its genetic origins, but the parents who have brought it up may well want to keep the fact of donation from it. Added to this it is argued that to gauge the success or otherwise of infertility treatment regimes there need to be empirical research on the children of this reproductive revolution. What of the parents who do not wish this information to become available for risk of altering the child to its origins or the fact that one or both of them were infertile? There is also a serious potential conflict between infertility clinics and the couple's own doctor.[18]

5.2.4 Legal Status of the Child Born As a Result of Donation

The Warnock Committee were faced with the inevitable conclusion that the child born as a result of AID was illegitimate at law. The potential seriousness of this conclusion was that the husband of the women who bears the AID child would have no parental rights and duties with regard to the child so produced , though, as a matter of general family law, the label of illegitimacy now carries with it fewer implications than it once did. The report recommended that the child should be treated at law as the child of the mother and her husband where they have both consented to the treatment.

In India, the ICMR Code refers to the necessity for the parents to adopt the child. This implies that the child born of a surrogate mother belongs to the surrogate mother herself and not to the couple, even if the surrogate mother is only a gestational surrogate and the couple has provided both sperm and egg. This is declared to be a "universal consensus". The ART Guidelines also state that a third-party donor and a surrogate mother must relinquish all parental rights in the child.[19]

5.2.5 Potential Liability of the Donor

What is the situation of the AID child who suffers from a genetic defect passed on from the donor male? Can the donor be found responsible for a failure to communicate his knowledge of the defect, or can the law find the donor negligent for a failure to discover the existence of the defect before becoming a donor, or the doctor in during the treatment?[20]

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[18] Ibid.

[19] 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: Ministry of Health and Family Welfare, Government of India para 3.5.5.

[20] Supra note 12 at 243.

5.2.6. Harm to the Embryo

Many forms of ART involve the creation of a number of embryos from which two are normally selected and implanted. Where the treatment is successful, or the couple decide to stop the treatment, this leaves spare embryos, which if not used, are destroyed. This is strongly objected to by those who regard embryos as having a right to life or having a profound symbolic importance. Of course, it would be possible to meet this concern. Regulations could permit only the creation of single embryos which would then have to be immediately placed in a woman. However, that would greatly reduce the chances of the procedure working. Alternatively, all spare embryos could be made available for donation to other couples.[21]

5.2.7. Child Welfare

There are those who are convinced that children born as a result of ART will suffer harm in a variety of ways. There is medical danger for IVF children, most of which born as a result from multiple births when assisted reproduction is used. There is also, it is said, the danger that children will suffer psychological damage when they discover the unusual circumstances of their conception. It is sometimes said to be harmful for children to be born with no clear familial identity or sense of kinship. In fact, it is far from clear what the danger of IVF are, but the rather limited data to date does not prove that children born using ART suffer psychologically or physically.[22]

5.2.8 The Cost of Failure

The public image of IVF is the joyful production of a new 'miracle baby'. There are official figures on the number of children born using assisted reproduction, but none of the number of couples for whom of the experience has produced only false hopes, huge expense, deeply invasive procedures, and unbearable sadness. It must not be forgotten that the rate of success of assisted reproduction are not high. Indeed the Medical Research Council has accepted that we need much more research than we have to date on the effectiveness and safety of ART

Even where successful there is the risk with ART of multiple pregnancies and with it the extra risks to women and children. Of children born using IVF, 22.7 per cent are twins or triplets. Although they no doubt being delight, the burden on parents raising multiple-birth children is considerable. In particular, multiple births have higher rates of miscarriage, abnormality, prenatal death, and prematurity. This

[21] Supra note 11 at 349.
[22] Id at 350

produces greater strain on the couple, neonatal services, and expenses for the NHS. The HFEA has launched a 'one at a time' strategy which aims to reduce the number of multiple births to 10 per cent over three years. All clinics should have a policy in place which seeks to reduce the number of multiple births. The HFEA code now says that only one embryo should be transferred if couples have a good chance of success. There is a delicate balance here between increasing the chances of success of the treatment, and decreasing the chances of multiple births.[23]

5.2.9 Availability of Infertility Treatment

Infertility treatment, particularly IVF, is costly, time consuming, still not particularly effective, but nevertheless subject to increase demand. Should infertility treatment be available to all or should it be regarded as a form of elective medical intervention and therefore of limited availability? Those opposed to treatment for infertility point to the fact that while there is an ageing population and a growing one, the health-care system will be under financial pressure. To give infertility priority is a form of double jeopardy; the treatment devotes resources better spent saving life, and if successful increases the population.[24]

In India, Almost 60–70 per cent of the public sector doctors reported treating infection of the male genital tract, providing induced ovulation and prescribing fertility drugs and 50–60 per cent offered diagnostic services and counseling for couples. The public sector did not have any facilities for sperm banking and do not deal with donor materials. Most providers, both public and private think that the high cost of treatment is the strongest impediment to effective infertility treatment for patients followed by low educational levels of couples, low rates of success, varying infrastructure and facilities and lack of specialised training. Most public sector providers were of the opinion that services for infertility are lacking and, if at all, they are available at some tertiary level facilities. But, tertiary facilities are difficult to access for people living in small towns and villages. The problems faced by public sector doctors are: poor infrastructure and management, low salaries, career prospects, lack of or dysfunctional equipments, inadequate staff, medical supplies and hygiene at the PHC and CHC levels. Many of them felt that infertility treatment is time consuming and there are no protocols. There are only a few medical education

[23] Id at 351.
[24] Supra note 12 at 244.

programmes enhancing infertility programmes and management and counseling skills.[25]

Perhaps one of the most obvious ethical challenges surrounding ART is the inequitable distribution of access to care. The fact that significant economic barriers to IVF exist in many countries results in the preferential availability of these technologies to couples in a position of financial strength. The cost of performing ART per live birth varies among countries. The average cost per IVF cycle in the United States is USD 9,266. However, the cost per live birth for autologous ART treatment cycles in the United States, Canada, and the United Kingdom ranged from approximately USD 33,000 to 41,000 compared to USD 24,000 to 25,000 in Scandinavia, Japan, and Australia. The total ART treatment costs as a percentage of total healthcare expenditures in 2003 were 0.06% in the United States, 0.09% in Japan, and 0.25% in Australia. Some have maintained that the cost for these cycles pales in comparison to the social advantages yielded by the addition of productive members of society. This is especially true in societies that have a negative or flat population growth rate coupled with an aging population. The funding structure for IVF/ART is highly variable among different nations. For example, no federal government reimbursement exists for IVF in the United States, although certain states have insurance mandates for ART. Many other countries provide full or partial coverage through governmental insurance. In many instances, long waiting times for IVF through these government programs encourage couples to seek treatment in private fertility centers that accept remuneration directly from the patients. In the United Kingdom, for example, only approximately 25% of all IVF cycles performed are funded by the National Health Service.[26]

The ICMR code also says:

1. The setting up of a modern ART clinic and running it satisfactorily is an expensive affair, requiring a dedicated staff that would render longterm service. The setting up of ART clinics in the public sector, which do not exist as of now, must be explored.[27]

[25] Anjali Widge and John Cleland. "The Public Sector's Role in Infertility Management in India". *Health Policy and Planning*, (2009), 24: 108–15.
[26] Paul R. Brezina and Yulian Zhao, "The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies", *Obstetrics and Gynecology International*, Volume (2012).
[27] Supra note 19 Para 7.1

2. The concerned Ministries must take a look at the reason for the high cost of ovarian stimulation hormones, and encourage and support local pharmaceutical industries to start manufacture of human menopausal gonadotropins indigenously so that the treatment of our infertility patients is not dictated by the commercial motives of the multinational pharmaceutical companies but by national needs.[28]

5.2.10 Ethical Issues in Surrogacy

Another topic of ethical, social, and legal debate surrounds the use of surrogacy and gestational carriers. Some also are concerned that the use of surrogates and gestational carriers is a form of "child selling" or the "sale of parental rights". Additionally, the rights of the surrogate or gestational carrier to not relinquish the infant following deliver are not well described. The human organ donation was given a non-commercial status by the Human Organ Transplant Act- 1994, however, temporary lending of uterus on payment has not been objected to by the state. This irrational distinction between human body parts donated and rented, and equating of goods and living beings in commercial surrogacy, is undermining the sacrifice and autonomy of surrogates. The expert providers see it as an industry where cheap Indian "labour" of the surrogate makes it a profitable venture for them. Their logic made the distinction between the product of social human labour (consumable commodities) and the product of woman's procreative labour (a human baby).[29] Another central concern surrounding the use of surrogates and gestational carriers is the possibility that financial pressures could lead to exploitation and commodification of the service. The mean compensation for a gestational carrier in the United State in 2008 was estimated at approximately $20,000. In contrast, a gestational carrier in India receives an average of $4,000 for the same service. Regulation of surrogates and gestational carriers varies widely from nation to nation and even within regions of individual countries. Due to these financial and legal considerations, international surrogacy has emerged as an emerging industry, especially in developing nations. This practice has exacerbated the already difficult ethical and legal issues surrounding gestational carriers. At the present time, issues surrounding issues of individual rights,

[28] Id, para 7.2.
[29] Imrana Qadeer, "New Reproductive Technologies and Health Care in Neo-Liberal India: Essays" *Centre for Women's Development Studies,* (November 2010)**,** at 30.

commodification, exploitation, citizenship of the offspring of international gestational carriers, and even fair trade are largely unresolved internationally.[30]

Commercialization of surrogacy however, creates several social conflicts rather than resolving some. It generates family pressure on poor women to oblige. Given the extreme vulnerability of almost one third of the Indian women due to poverty, exclusion from, and marginalization in labour and job markets, patriarchal social and family structures and low educational levels, the financial gain through surrogacy becomes a key push factor. This is substantiated by the fact that most surrogate mothers are from not so well-off sections and the motive primarily is monetary. This makes their economic exploitation easy for the agents working for commissioning parents. Much debate has centered on whether surrogates should be paid for their services, whether surrogacy contracts should be enforced, and how to resolve custody disputes when one or more parties to a surrogacy agreement change their mind.

5.3 **Feminist Perspective on medically Assisted Reproduction**

A basic assumption of feminist theory is that women have the right to reproductive freedom and control over their bodies, and that this freedom-right-control is essential if they are to have full and equal opportunity in society. Although their concern is as much for the high birth rates in the developing nations as for the basic rights of women, those who are active in the family planning movement are also increasingly calling for reproductive freedom for women. Consequently, the declarations from both the 1974 U.N. World Population Conference and the 1975 U.N. International Women's Year Conference state that individuals have the right to determine the number and spacing of their children.[31]

Control of reproduction means much more than being able to bear a desired number of children at desired time intervals; it is not just a question of knowledge and birth control technology. In order to be assured of control over reproduction, women must have economic independence, the freedom to bear or not to bear children regardless of marital status, and control over the means of controlling reproduction.[32]

Reproduction and motherhood have been at the core of the feminist and women's movements ever since their emergence. And from the start, reproduction

[30] Supra note 26 at 5.
[31] Elizabeth Moe , "Women's Rights and Reproductive Freedom", *Human Rights Quarterly*, Vol. 3, No. 2 (May, 1981), pp. 53, available at: *http://www.jstor.org/stable/761857* .Visited: 19/02/2013 06:20
[32] Id p. 57.

and motherhood have been highly contested issues – both within the feminist movements and beyond. Yet, over the past few years, ART has fundamentally altered the ways of reproduction and the perception of it, as ART has gained in importance not only for individual procreation, but also for population development. ART has opened up the possibility of childbearing to groups of women and men who did not have this option before, such as sub-fecund and infertile women, to women and men with other health problems, to gays, lesbians, and transsexuals, and to women beyond menopause.

Although most of all children in the world are still born without the use of ART, ART is spreading rapidly. Some techniques, such as ultrasound and amniocentesis, have become standard procedures in prenatal care in many countries, financed and often required by public health care. Likewise, many public health care systems recognize infertility as "illness" and subsidize its treatment, although mostly only for selected groups of women and men. While acknowledging the benefit which some women (and men) have from this development, feminist have tried to assess the impact which ART has on the social and economic situation and the cultural and legal recognition of all women. Most feminists view ART with criticism or at least ambivalently. They point to the factual changes in conception, pregnancy, and birth which ART has generated and to the shifts in the cultural, legal, and medical perception of women, reproduction, and motherhood. Reviewing the conditions of both fertile and infertile women, they doubt that ART contributes to empowering women and to granting them more control over their body, reproduction, and motherhood. Many warn against the consequences of the ART-induced dissociation between reproduction and motherhood, and about the split of the maternal body into different "deliverers" of products and services. They maintain that these developments have not reduced society's power over women, but have induced new and global power structures at the gender, the social, and the economic level. The feminist answers to these trends demonstrate the challenge which the development of ART and its consequences poses to the feminist struggle and the feminist discourse. Many feminists call for stops to or restrictions of ART and its commercialization, and for the re-allocation of funds from ART to reproductive and health services which benefit all women. They argue for a stronger integration of ART issues in the discourse about human rights, for a more equal inclusion of feminist advocates in ART debates, and for a general politicization of ART to subject its development and

application to more democratic procedures. The development of ART has posed unsettling questions to many feminist principles and approaches. The medical practice of ART and subsequently the legal systems have drawn new boundaries and instituted previously unknown power imbalances between different biological motherhoods, between the embryo and the mother, and between different biological mothers and a father. The fact that one does not know the long-term consequences for women treated by ART and for their children has further aggravated cleavages between social motherhood and the various forms of biological motherhood. Feminists find themselves in a situation where they must strive to bind the social back to the biological, to re-define "nature" in a way that grasps all forms of fractured motherhood and to make claims on such re-definitions without supporting perceptions of reproduction and motherhood which they have fought against for so long.[33]

When ARTs were first developed in the West, they were perceived both by the medical profession and the public in general as a 'miracle cure' for an aberration caused by nature. While this continues to be the common understanding about ARTs, there were varied opinions amongst feminists about these technologies. At the two extremes are (a) those who claim the technologies to be emancipatory in nature; and (b) those who see them as an instrument in the hands of capitalism and patriarchy, reducing women's role to reproduction and thereby furthering their subordination and exploitation.[34]

Members of the former group welcome these technologies as scientific and technological progress, holding that it is the context in which these technologies are used that makes them good or bad. They base their support for these technologies on the notion that they satisfy the legitimate needs of some women. Shulamith Firestone, a prominent radical feminist, feels that these technologies have the potential to liberate women from the burden of motherhood and hence act as an instrument through which women's emancipation can be achieved. For supporters of these view, ARTs provides solutions for individual women in a context where infertility and childlessness result in social ridicule. Moreover, they empower women by giving them "choice" and "control" over their own reproduction.[35]

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[33] *Gerda Neyer ,* "Feminist Perspectives on Motherhood and Reproduction" Stockholm University Demography Unit; Institute for Social Sciences.
[34] Supra note 10, at.23
[35] ibid

Among the responses to these assertions is a body of feminist analysis that examines these concepts of choice and control, the terminologies used, and questions of ethics, the medical and social implications of these techniques for women's identity, and motherhood.

Feminists like Gena Corea have argued for a total rejection of modern conceptive and parental diagnostic technologies because they reinforced existing unequal social relations rather than enhance women's reproductive choices. This stand is exemplified by the Feminist International Network of Reproductive and Genetic Engineering (FINRRAGE), formed in 1986. FINRRAGE argues that reproductive technologies are '…a manifestation of patriarchal domination and exploitation of women's bodies by men who envy women's procreative power.[36]

Some writers stress the role of patriarchy in oppressing women through New Reproductive Technologies; while others stress the interaction between patriarchy and capitalism. Regardless of theoretical orientation , feminists share a common concern with the fact that these technologies have undermined hitherto taken –for- granted relationships between biology, women's identity ,and the meaning of motherhood.[37]

Another important issue that alarms the feminists is the commodification of the female body and the processes of reproduction. In the word of US-based feminist scholar Marsha Darling , the concept of women's bodily integrity is threatened by the extent to which women's biological and reproductive organs, tissues, cells, including ovum and genes, are quickly becoming 'spare parts' in a medical industrial complex. At the very same time that reproduction is imagined as an industrial process by the biotech industry, women are sought after as consumers of the very technologies that will weaken women's right to bodily integrity.[38]

Such commodification has been brought about by the commercialization of ARTs and feminists feel it is important to highlight their social consequences. Surrogacy is a perfect example of such commercialization. Feminists have referred to

[36] D.Farquhar, *The Mother Machine: Discourse and Reproductive Technologies*. (New York/London: Routledge).
[37] M. Gimenez, 1991, "The Mode of Reproduction in Transition- a Marxist-Feminist Analysis of the Effect of the Reproductive Technologies", *Gender and Society*, September, vol.5, no.3, pp.334-500.
[38] T.M. Darling, 2006, "Reproductive and Genetic Biotechnologies: Takind up the Challenge", *Development*, vol, 49, no. 1, pp. 18-22.

surrogacy as "commercial breeding" and "reproductive trafficking". Linda M.Whiteford, writes,

"Commercial surrogacy exploits socioeconomic class differences, using financial need and emotional need and currency. The exchange of money transforms surrogacy from an altruistic gift between sisters or friends into baby selling or womb renting".[39]

Feminists draw attention to the fact that often it is poor women who act as surrogates because of their financial need and their limited opportunities for earning a livelihood. On the practice of surrogacy, Professor Janice Raymond, who specializes in women's study and medical ethics, says: "surrogacy makes women into mere incubators or receptacles for male sperm."[40]

In other words, surrogacy draws a line of demarcation between pregnancy and motherhood-two seemingly inseparable phenomena-by assuming that the women does not develop any emotional attachment with the feotus.

Starting in the late 1980s, Indian activists and scholars started analyzing the onslaught of new reproductive technologies in India. Malini Karkal looked at the significance of in vitro fertilization (IVF) in developing countries and the emergence of practices such as surrogacy. Lakshmi Lingam argued that, "New Reproductive Technologies raise several moral and ethical issues and they capitalize on the social stigma attached to infertility; the value attached to biological motherhood."An important document from within the women's movement is *We and our fertility* by Chayanika et al., which identified conceptual and programmatic links between fertility and population control technologies. The document contends that conceptive and contraceptive technologies are part of one continuum and both technologies are designed to intervene in the hormonal cycle, either by promoting fertility or controlling it. Furthermore, the author argue that the institutions of marriage and family define women's live as limited to their role as procreator, and describe women's experiences in fulfilling these roles. Jyotsna Agnihotri-Gupta also look at

[39] L.M. Whiteford, 1989, "Commercial Surrogacy: Social Issues Behind the Controversy", in Poland, M. & L.M. Whitehood (eds*), New Approaches to Human Reproduction: Social and Ethical Dimensions*. (Boulder, Colorado: Westview Press).

[40] Janice, Raymond, 1988, "Of eggs, Embryos and Altruism*", Reproduction and Genetic Engineering*, vol. 1, no. 3, pp. 281-285.

the interface of technology, health and women's lives in Indian society, and the implications this has for women's agency.[41]

Furthermore, ARTs have also been seen as urban-centric and expensive, and therefore inaccessible to most women.[42] Even though other social issues in India have taken precedence over ARTs, various movements have been vocal in pointing out the damage done by ARTs on a number of fronts. The ever-changing definition of infertility has also aggravated the labeling phenomenon. Earlier, infertility was defined as childlessness despite at least five years of sex without contraception. Today, the time frame is only one year: if a women does not conceive within one year of marriage, she can be labeled "infertile". This expanded definition also multiplies the number of people who may, and who do, seek ARTs, thus ensuring the expansion of the ART industry.[43] A section of the lesbian, gay or queer movement is strongly critical of ARTs, on the grounds that this technology reinforces hetero normativity-the tendency to exclude everything that does not fit into the norms of heterosexual behavior.[44] The promotion of ARTs is justified by the notion that they give women a choice, and that such a choice is important for women to have.

5.4 Economic Aspect of Medically Assisted Reproduction

Debora Spar has put her finger firmly on the pulse of the ART business when she calls it the "Baby Business" in her book with the same title. As with any other business, the process of making babies has a number of components. A couple looking for a baby may be in need of one or more of the three necessary components-sperm, ovum and womb. Fertility clinics provide the service of matching the technology with the need. They market their services through the media in various forms, just like any other business would do. Mostly, these clinics are in partnerships with established hospitals and doctor who visit them to carry out procedure of egg retrieval or embryo transfer once every three to four months. Also, "patients" are referred from smaller clinics to those offering more sophisticate technologies in bigger cities. There is, thus, a phenomenon of "local globalization" with regard to ARTs operating within the country.[45]

[41] Supra note 10 at 29
[42] Id at 29
[43] Id at 31
[44] Ibid
[45] Supra note 10 at 45

The most contentious part of this chain is the market for wombs. Because it involves a nine-month long confinement, it may involve complex legal arrangements, and very large payments. Given the very high cost of hiring a womb (a surrogate mother) in the developed North, the business of hiring womb has crossed borders. According to journalist Reena Martins the annual number of new surrogate pregnancies in India doubled in the last three to five years. A commissioning couple spends approximately Rs 10 lakh in India compared to Rs 25-35 lakh in the US. According to another press report, doctors states that though relatives usually comes forward to act as surrogate mothers, women who conceive for a fee will charge Rs 8-10 lakh for the entire contract. Doctors have also been quoted as saying that 70 percent of the clients for surrogates are non-resident Indians.[46]

Reproductive technologies have grown in leaps and bound both in domestic and the global market. Tied as ART is with medical tourism, it has all the necessary linkages that help it to thrive in the market economy-educated people and the medical fraternity buying into it and promoting it and the State not being interested in any kind of regulation… and while women's groups continue talking about sex tourism India actually have reproductive tourism that has come along with sex tourism.[47]

A cost-benefit analysis is invalid for health issues, because the inputs and outputs cannot be quantified. When financial constraints determine public health priorities rather than epidemiological resources, the assumption is that the technology is necessary, effective and safe. And when the technology in question is far from the above, its promotion is not only unjustified, but also unethical.[48]

On January 3, 2008, Judith Warner published "Outsourced Womb" in a blog in *The New York Times.* Warner raises ethical questions about the complexities of transnational gestational surrogacy, a growing segment of reproductive tourism industry. Increasingly women and couples from the United States and Europe have begun traveling to India to hire women at discount rates to gestate and deliver babies for a fraction of what it would cost in the United States. They are, like companies that outsource labor to other countries, traveling to purchase a cheaper source of reproductive labor. Gestational surrogacy is a form of industrial labor that has not been previously considered by economists or economic sociologists in their

[46] Id at 48.
[47] ibid
[48] Id at 37.

discussion of outsourcing yet it represent a growing segment of the reproductive tourism or medical tourism market.[49]

5.5 Health Issues Relating to Medically Assisted Reproduction

Even without going through the issues of surrogacy, ova sale and ethical problems around these, if we simply look at the complications reported due to ART procedures, the range is alarming. It is reported that even in the so called take home babies, mortality is four times higher. Risk of ectopic pregnancy in ART is five times higher, miscarriage is 2-3 times higher than normal pregnancies and the rate of Cesarean section is 43.9 percent. Complications range from major congenital malformations, prematurety, multiple pregnancies to gestational complications such as 1st trimester bleeding, abortion, induced hypertension, diabetes, and premature deaths. In addition to these are the less reported problems even though these are so common that they are treated as "normal" for the procedure by doctors and "safe' for the women. These are strong emotional upheavals considered violative of the integrity of the body, depression and grieving caused by the poking and prodding of the body and the drugs injected. These side effects are now getting known in the western countries because women are beginning to talk and complain that they are given no feed backs. Drugs like Letrozol and clomiphene citrate are used for harvesting oocytes. These can cause hyper-stimulation syndrome that other than releasing large number of ova also causes ovarian rupture, vaginal bleeding, kidney and lung failure.[50]

Although, ICSI has revolutionized the treatment for male infertility, its widespread use has raised medical concerns about the transfer of genetic defects to future generations. There is a higher than normal frequency of sex chromosome abnormalities in children born of ICSI procedures compared with the normal population. Besides, infertile men carrying Y chromosome microdeletions pass this defect to ICSI-born sons. During ICSI, the process of fertilization is dramatically changed. For example, there is no fertilization occurring in vivo, and the physiological maturation of sperm, its selection and penetration through oocyte investments, and its influence on embryonic spatial patterning are bypassed. Because ICSI bypasses a part of the process of natural selection and certain early

[49] 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 1.
[50] Supra note 29 at 18.

developmental mechanisms, concerns are expressed on the possible reproductive health risk(s) to the offspring.[51]

In India, it is estimated that about 15% of married couples are sub-fertile or infertile. Treatment of male-factor infertility in the country has improved dramatically with the introduction of ICSI, which is currently being practiced rather extensively in various major ART clinics in the country. It is, however, extremely important that this approach to treating male-factor infertility is carried out with caution, in view of the possible risk of vertically transmitting defective (spermatogenetic) fertility gene(s) to the male progeny, when the etiology of infertility is genetic in origin. Thus, ICSI may fall below the general expectations of the Helsinki Declaration. ART clinics accredited under the present programme must therefore take due note of the above before resorting to ICSI, and counsel the couple for whom ICSI is being recommended, appropriately. Inspite of what has been said above, in some case, ICSI may still be the preferred choice of treatment for infertility.[52]

There is a growing interest in embryonic stem cells because of their potential use for developing spare organs or replacing defective tissues such as parts of the brain destroyed due to Alzheimer's disease, or pancreatic cells in diabetic patients. The range of their potential use is limited only by one's imagination. ART clinics are the only source of embryonic stem cells. Spare embryos are either frozen or returned to the infertile couple for replacement during a later cycle, or donated to another infertile couple, or discarded after five years using a suitable protocol.[53]

Recently, the USA banned all federal support for embryonic stem cell researches. Germany has banned all research on embryos produced in that country but permits the use of embryos brought from abroad. The stand taken by the foreign governments on embryo research opens up the possibility of embryos from developing countries that do not have appropriate national guidelines in this area, being commercially exploited and sold to foreign countries. Therefore sale or transfer of human embryos or any part thereof, or of gametes in any form and in any way – that is, directly or indirectly –to any party outside the country must be prohibited. Within the country, such embryos or gametes could be made available to bonafide

[51] Supra note 19 Para 1.6.11.2
[52] Ibid.
[53] Id, para 3.11.

researchers only as a gift, with both parties (the donor and the donee) having no commercial transaction, interest or intent.[54]

ART procedures carry a small risk both to the mother and the offspring. These risks must be explained to the couple and appropriate counselling done. ART procedures are to be initiated only after patients understand these risks and still want to undergo ART. Some of the most commonly encountered risks are mentioned below:

5.5.1. Multiple Gestations

The reported incidence of multiple gestation ranges from 20 to 30%. Incidence of twin pregnancies in the range of 10-20% may have to be accepted as inevitable, but specific efforts must be made to reduce the incidence of triplets and multiple births of higher order. Therefore, not more than three oocytes should be transferred for GIFT and not more than three embryos for IVF-ET at one sitting, excepting under exceptional circumstances which should be recorded; the remaining embryos, if any, may be cryopreserved and, if required, transferred at a later cycle.[55]

In the United States, while physicians are required to report the number of embryos transferred in an IVF cycle, there are no laws that state the allowed number of embryos transferred. The transfer of multiple embryos in a single cycle increases the rates of multiple births. Because of the increased social costs and health risks associated with multiple births, legislation or guidelines from professional societies have been introduced in many countries restricting the number of embryos that may be transferred per IVF cycle in an effort to limit the incidence of multiple gestations. Indeed, a study in the United Kingdom found that the total health care system costs following a singleton birth were £3313, £9122 following a twin birth and £32,354 following a triplet birth. Additionally, the health risks, both to the mother and the infant, increase dramatically with increasing number of infants. In the United States in 2007, the number of embryos transferred per cycle ranged from 2.2 in women under 35 to 3.1 in women over 40 years of age (CDC). Multiple birth rates in the United States in 2007 ranged from approximately 35% in women under 35 to 15% in women over the age of 40. In Europe, the approximate number of embryos transferred in the year 2006 was one (22%), two (57%), three (19%), or four (1.6%). In 2007, 79.2% of

[54] Id para 1.6.11.3.
[55] Id para 2.4.1.

European births were singletons, with a twin rate of 19.9% and a triplet rate of 0.9%.[56]

However, the practice of transferring multiple embryos has raised ethical questions about whether it is acceptable to do so with the knowledge that aborting some of the fetuses may later be medically indicated. Also of concern is whether it is ethical for patients to refuse selective reduction when they are aware of the attendant risks of carrying multiple fetuses to term. in 2006 the American Society of Reproductive Medicine issued guidelines that no more than two embryos should be implanted for women under 35, no more than three for women who are 35 to 37, no more than four for women who are 38 to 40, and no more than five for women over 40. Clinics, however, are not required to follow the guidelines. Some countries have imposed limits. In the United Kingdom, for example, the Human Fertilisation and Embryology Authority has set a limit of two embryos for women under 40 and three embryos for women over 40, but it is examining whether it should change its rules to make one embryo the norm. In Italy, by contrast, a maximum of three embryos may be created at a given time and, barring exceptional circumstances, all embryos created must be implanted simultaneously. A likely response to the Catholic Church's teachings that embryos should not be intentionally destroyed due to its belief that human life begins at fertilization.[57]

5.5.2. Ectopic Pregnancy

Ectopic pregnancy rates could be as high as up to 8% for ART procedures. The choice of an appropriate procedure as per guidelines mentioned earlier, especially in persons with tubal disease, may reduce the chances of an ectopic pregnancy.[58]

5.5.3. Spontaneous Abortion

Spontaneous abortion rates range from 20 to 35%. Abortion rates rise with increasing age of the mother and in multiple pregnancies, especially with three or more foetuses. In cases where more than two foetuses are present, selective embryo reduction should be advised. It is essential that the advantages of embryo reduction (better chances of the survival of other foetuses and the fact that they are likely to be born nearer term and with better birth weight) and disadvantages (the possibility that there might be an increased risk of abortion following the procedure) must be

[56] Supra note 26 at 2.
[57] Jessica Arons, *Future choices: Assisted Reproductive Technologies and the Law*, (Center for American Progress, December 2007), at. 11.
[58] Supra note 19 para 2.4.2.

explained to the couple, and their informed consent taken before embryo reduction is attempted.[59]

5.5.4. Preterm Birth

There is a higher risk of premature/low birth weight delivery following ART, especially in the presence of multiple foetuses.[60]

5.5.5 Ovarian Hyperstimulation Syndrome

The use of superovulation for ART entails a risk of hyperstimulation in some women. The extent of this risk is determined by the hormonal profile of the woman, the estradiol values , the dose required for triggering ovulation, the ability to aspirate all the follicles at the time of oocyte retrieval, and several other factors.

5.5.6 PGD (Pre-implantation Genetic Diagnosis)

The usual procedure for couples having IVF is to create a number of embryos and implant them two at a time into the women. The question we shall consider here is whether it is permissible to select from the embryos created which will be implanted. There is generally no objection to a selection being made on the basis of which embryos are most likely to survive to birth; but more controversially a couple who are at risk of having a child with a genetic disability may wish to select an embryo which does not carry that disability. This require an assessment of the different embryos to see if they carry the desirable or undesirable characteristics. This is known technically as PGD (preimplantation genetic diagnosis) and requires a licence from the HFEA in U.K. the Human Fertilization and Embryology Act, 1990, sets out the circumstances in which PGD is permitted. This includes 'to establish if an embryo has an abnormality that might affect its capacity to result in a live birth' and 'to avoid a serious medical condition'. The practice is controversial and the HFEA will only allow it for a strict set of reasons. The Code explains:

Preimplantation genetic diagnosis (PGD) can be carried out for a heritable condition only in two circumstances:

(a) where there is a particular risk that the embryo to be tested may have a genetic, mitochondrial or chromosomal abnormality, and the authority is satisfied that a person with the abnormality will have to develop a serious disability, illness or medical condition, or

[59] Id para 2.4.3
[60] Id para 2.4.4.

(b) where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition. A condition is gender related if the Authority is satisfied that it affects only one sex, or affects one sex significantly more than the other.

In the first situation, PGD may be carried out to establish whether the embryo has the suspected abnormality; in the second, PGD may be carried out to establish the sex of the embryo. As at January 2009, sixty genetic conditions had been licensed for PGD.[61]

IVF introduces a refinement in the form of Pre-implantation Genetic Diagnosis. A cell of the fertilized embryo is examined for genetic or chromosomal errors and only those embryos free of these conditions are used for the IVF procedure. In the US, where there is no regulation of the procedure, PGD is used to test for a range of conditions from serious illnesses that affect children to more treatable conditions, and also those that develop in adulthood. In countries where son-preferences is high, its use extends to sex-determination and selection of the embryo. If PGD is not regulated, it will increasingly be used for non-medical purposes. Already research is focusing on the genetic basis for characteristics such as skin colour. The assumption underlying such practices is that certain qualities are desirable and others are not, that there is a "normal" and an "abnormal", that all characteristics are generally determined and therefore the undesirable can be eliminated through genetic engineering.[62]

The ICMR guidelines also states:

There is a growing volume of information that is now available showing that many forms of infertility are caused by genetically transmittable disorders. The genetic disorders include trisomy, translocations, inversions, deletions and microdeletions. All this new information suggests that great care must be exercised with ART because infertile couple may be carriers of such disorders; when one tries to force fertilization, the question arises whether one is transmitting genetic disorders to the offspring. This raises many moral and ethical issues.

One way to get around this problem is to institute top-class genetic diagnostic facilities that will be able to carry out diagnosis of genetic defects in single cells obtained from embryos. This is a very expensive and labor intensive project and

[61] Supra note 11 at 380.
[62] Supra note 10 at 24.

therefore there is a need to establish just a few well equipped centers in the country and later expand them if there is a need. These centers could serve as referral centers and should be used judiciously. The establishment of such centers will go a long way in placing ART practice in India on a firm, healthy and ethical footing.[63]

5.5.7 Saviour Sibling

The emotive term, 'saviour sibling',has come to be used for cases where parents of a sick child wish to have another child whose tissue can be used to provide a treatment for the condition of their sick sibling. In U.K. the 2008 Human Fertilization and Embryology Act has made it clear that embryo testing to ensure an implanted embryo may be a 'saviour sibling' is permitted. Paragraph 1ZA (d) of Schedule 2 allows a testing where:

A person ('saviour sibling') who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of these persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling.

There, are however, limitations on the use of PGD for the use of selecting 'saviour siblings'. First, the statute make it clear that it can only be used in the case of siblings. An 'embryo' who would be the cousin of a child with a serious medical condition could not be selected. Second, paragraph 1ZA(1)(d) makes it clear that selection cannot be made if it is planned that a whole organ (eg a kidney) is to be donated. The plan must be to use the umbilical cord blood stem cells, bone marrow, or other tissue, from a child. That is not to say that a child cannot donate an organ to a sibling, it is simple that they cannot be selected at the embryo state for such a purpose.

Critics of 'saviour sibling' claim that it involves bringing a person into being for the sole purpose of assisting their sibling. This infringes the principle that people should not be used solely as a means to an end. Supporters could reply to this in two ways. One would be to argue that in fact to save the life of one's sibling is beneficial to the donor, or at least not harmful to them. Alternatively, they could argue that it is extremely unlikely that parents would treat the savior sibling simply as a source of tissue. It would be hard to believe that parents would 'discard' a saviour sibling once treatment of the existing child had been effective. The child is being created to be

[63] Supra note 19 para 6.1.

loved in her or his own right as well as assisting the sibling. A slightly different argument is that the child, when older, might perceive her or himself as having been created as merely a means to save her or his sibling. This could cause psychological problems, particularly so if the matching had not worked out. Again, these are only possible dangers and we do not know how likely they are to be realized. The 'saviour sibling' might just as well feel delighted that she or he were able to save or attempt to save another life, and regard it as having enriched her or his own life. John Harris has argued that guesses about possible emotional harms for the 'saviour sibling' do not justify denying treatment which would save a life. Another issue which the courts may need to address at some point is the legal liability that could arise if a 'saviour sibling' is created but does not provide a cure.[64]

The first case in India involving a "saviour sibling" was done in Life Cell in Chennai in 2009. This involved parental testing. A child with thalassemia was treated with stem cells from the cord blood and bone marrow of a sibling who was conceived for the purpose of the providing a tissue match. There is a reason to believe that parental testing will soon give way to PGD for this purpose in India, to produce matched tissue donors for a sibling. However, there has been no discussion of the implication of creating a child in order to be a donor.[65]

In addition to these specific complications of ART, couples undergoing various ART procedures incur the risks associated with the operative and anaesthetic procedures involved in ART.[66]

5.6 Religious Aspect of Medically Assisted Reproduction

Ever since the beginning of human history and society, religion and science have been two very important coordinate of the human evolution, They have always been interrelated and both have exerted a great influence, thus when it comes to assisted reproduction we must take into consideration the religious point of view. Social factors, religious pressure groups and legislation differs from one state to another when it comes to dealing with controversial issues like: the genetic material donation, the use of surrogate mothers, the reproductive age-limitation, genetic diagnosis of the embryo, the selective embryo reproduction and even cloning.[67] In spite now a day's society tendency towards separation from churches old practice,

[64] Supra note 11 at 386.
[65] Supra note 10, at xxiv
[66] Supra note 19 para 2.4.5.
[67] "Religion and Assisted Reproduction", *The Hindu*, online edition, 17 Feb 2005.

civil groups are still manipulated by the various religious influence groups when it comes to important issues related to human reproduction such as contraception, abortion, and infertility therapy.[68]

The recent development of assisted reproductive technology raised serious questions related to reproduction which not always has the clearest answers. Bioethics has been created to deal with the different religious groups' attitude towards the new fields of assisted reproduction but it cannot set the border line between ethical and unethical when it comes to assisted reproductive technologies.[69] It is of a great importance for those who are confronted with infertility issues, both the scientists and the couple who deals with this medical problem, to acknowledge the importance of the religious aspects of the medical approach of infertility, to understand and to make a choice whether it is one which respects the practices of their religion or not.

5.6.1. Islamic Views

Islamic world has been enclosed to modern techniques for many years, delaying thus the implementation of modern reproductive technologies due to the prejudice that Islamic teachings would disapprove assisted reproduction. Islamic laws are extremely strict when it comes to sexual intercourse; sex is the privilege of the married couples, premarital and extramarital sex is strictly forbidden.[70] Sex must be avoided with all costs during menstruation, after the birth, after diseases or disabilities. Homosexual intercourse is strictly forbidden.[71] Adultery is still severely punished, starting with house detention, public dispraise and verbal humiliation.

The Islamic belief associates marital sex with family values and procreation, therefore it supports only the sexual act which involves man's penis penetrating woman's vagina, as it is the only sexual act which can lead to pregnancy, moreover oral and anal sex as well as masturbation are strictly forbidden.[72] With the passage of time Islam offers its support to assisted reproduction, when natural procreation fails, the treatment is seen as the couple's duty and the Islamic laws forbid adoption. Assisted reproductive techniques are only permitted between husband and wife, a

[68] "Religion and Assisted Reproduction", *http://in-vitro-fertilization.eu/religious-and-ethic-aspects-of-assisted-reproduction*, Visited 12 April 2011.
[69] Stephen J. Werber, "Cloning: A Jewish Law Perspective with a Comparative Study of Other Abrahamic Traditions", 30 *SETON HALL L. REV*. 114, 1156(2000).
[70] "Islam: A Brief Introduction" *available at www.islam101.com./dawah/IslamBrief.html* visitedMarch 15, 2012.
[71] Supra note 69.
[72] IVF and Islam, available at *http://in-vitro-fertilization.eu/religious-and-ethic-aspects-of-assisted-reproduction*, Visited 12 april2011.

third party, the donor is not accepted weather it is a sperm donor, or a surrogate mother, an embryo, or an oocyte donor. In the case of divorce or the death of the husband, artificial insemination cannot be made with husband's sperm. Any medical procedure which involves donor is considered adultery. [73]

As long as it is the husband's semen that is used to impregnate the wife, intrauterine insemination ("IUI") is permissible.[74] Permissibility, however, is conditioned upon insemination occurring while the marriage remains intact. Thus, the husband's frozen semen cannot be used after divorce, or after the husband's death.[75] IVF, with its various modifications, i.e., GIFT (Gamete intra-fallopian transfer), ICSI (intracytoplasmic sperm injection) etc., has been declared Islamically permissible,[76] only if the following conditions are satisfied. *First*, the IVF must involve a married couple. *Second*, the sperm must be from the husband, and the eggs from the wife. *Third*, this must occur within the context of a valid marriage. *Fourth*, the procedure must be conducted by a "competent team" in order to reduce the chances of failure. Further, there is a need for conscientious handling of the process so as to ensure that the gametes of the husband and wife are the ones actually being used in the procedure. Finally, no more than the appropriate number of fertilized eggs should be transferred to the uterus.[77] If more than the appropriate numbers are used, the risk of triplets and higher order multiple pregnancies increase, and as a result, the risks of miscarriage and pre-term delivery are great. It is common to transfer only two to three fertilized eggs, although there are usually more fertilized eggs produced. Freezing the remaining fertilized ova is permissible as long as they are only used in subsequent cycles for the same couple, and the couple is still married. The fate of the unused eggs has not yet been decided upon; it will be permissible to use them for medical research with the consent of the couple and within the appropriate guidelines.

The Quran states: "Then has He established relationships of lineage and marriage...." The use of donor sperm, eggs, or embryos will result in the biological father or mother being different from the "married couple." In Islamic law, this is

[73] Hossam E. Fadel, "Assisted Reproductive Technologies: An Islamic Perspective", 25 *J. Islamic Med. Ass'n* 14, 17 (1993).
[74] Supra note 72 at 17.
[75] Ibid.
[76] M. Partowmah, "Biotechnology Issues in the Opinion of Islamic Scholars", 25 J. Islamic Medicine Ass'n, 9, 10-11 (1993).
[77] "Council on Islamic Education", available at *http://www.cie.org.* Visited 15 April, 2011.

similar to adultery in confusion of the lineage. [78] Unclear lineage may cause one to marry a brother, sister, or a close relative, even with the strictest guidelines in place to prevent this from happening. If donor gametes are used despite the prohibition, Islamically, the following applies: in the case of donated sperm, the "husband" would be considered the legal father, although he is not the biological father. Moreover, if a donated egg is used, the birth mother is considered the legal mother, although she is not the biological mother.

Under Islamic law, surrogacy is prohibited. Linguistically and Islamically, the Arabic word for "to give birth" is Walad, and for "mother" it is Walidah, or the "one who gives birth." [79] A verse from the Quran states that, "None can be their mothers except those who gave them birth."[80] Even if there is an agreement between the parties, the confusion of lineage, which is inevitable in these surrogacy arrangements and which is of major importance in Islamic law, prohibits surrogacy. If surrogacy is still done despite the prohibition, it is the consensus of Islamic scholars that the birth mother is the "real" mother.[81]

5.6.2. Hinduism

Hindu religion agrees with most of the assisted reproduction techniques, but it demands that the oocyte and the sperm used in the procedure to come from a married couple, this religion also accepts sperm donation but sets the condition that the donor be a close relative of the infertile husband. Abortion is not prohibited and the adoption of a child which usually comes from a numerous family is also practiced.[82]

According to the Hindu view, in the case of male infertility the wife can be authorized to have intercourse with a brother in-law or another member of the husband's family in order to conceive a male offspring **(**only after 8 years of infertility or after 11 years of delivering only female offspring**)**. According to the above statement this may lead to the conclusion that sperm donation can be practiced according to the Hindu view, with the restriction that the sperm donor must be a close relative of the husband.[83] According to Hinduism, it is suggested that oocyte donation

[78] Maher M. Hathout, "Surrogacy: An Islamic Perspective", 21 J. *Islamic Med. ASS'N* 106, (1989);
[79] Ibid.
[80] *Holy Quran* 58:2 (Abdullah Yusuf Ali trans., 1982).
[81] Barbara katz Rothman, Recreating Motherhood 158 (1989).
[82] Ibid
[83] C. Strong, The Ethics of Human Reproductive Cloning. *Reprod Biomed Online* 2005 ; 10 (1): 45-49.0.

can be practiced on the same grounds as sperm donation and there is no prohibition of the practice of surrogacy.[84]

Hinduism does not view the soul at man as having a specific beginning or specific end. Cryopreservation of pre-embryos may be permissible when it is to help the infertile couple and it serves the dharma of the physician.

5.6.3. Buddhism

Buddhism emerged in India around 500 BC and it is based on the teachings of Siddhartha. Buddhism allows the use of IVF without restricting the access to this medical procedure to the married couples, sperm donation is also permitted.[85] A child conceived from donated genetic material has the right to meet his genetic parents as he reaches maturity.

Traditionally, Buddhism has imposed strict ethics on priests, while it has taken relatively lenient attitudes toward lay people. This means that Buddhist priests allow laypeople to do whatever they want to do as long as they do others no harm in a concrete way. This leads to the idea that we do not have to accept infertility as it is. If medical treatment for infertility is available, we can make use of it. Generally speaking, having no children will be a greater threat to a marital relationship than the practice of modern infertility technology. According to Buddhism, treatment should be given to unmarried as well as to married couples.[86] According to Buddhism, donation of sperm is not prohibited, but it is suggested to refrain from this procedure as much as possible. IVF has been practiced in Japan since 1982 and is also practiced in other countries with Buddhist and Hindu populations. The practice of IVF raises another dilemma from the Buddhist points of view, since it involves the procreation of more pre embryos than are implanted in the uterus. The oocyte donation can be practiced on the same grounds as sperm donation. According to many Buddhist scholars experimentation on is acceptable. They also accepts cryopreservation of pre embryos.[87]

There is no Buddhist prohibition of the practice of surrogacy, but it may raise complications regarding the family ties and legal and moral aspects. Special problems

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[85] Supra note 10 at 1.

[85] Joseph G. Schenker, "Religious Views Regarding Treatment of Infertility by Assisted Reproductive Technologies", *Journal of Assisted Reproduction and Genetics,* Vol. 9, No.1,(1992).

[86] Abdulaziz Sachedina, "National Bioethics Advisory Commission", *Ethical Issues in Human Stem Cell Research, Volume III, Religious Perspectives,* G-6(2000).

[87] Supra note 86.

can arise when the surrogate mother delivers a female offspring, since according to Buddhism; there is an obligation to provide a male offspring.[88]

5.6.4. Christianity

The Christian attitude related to assisted reproduction and infertility therapy differs inside its divisions**.** It divides in three churches and their thinking is different on issues relating to assisted reproduction.

5.6.4.1 The Roman Catholic Church [89]

The main laws for good Catholic conduct are given in the wholly book, the Bible. Also tradition, which comes from church' decisional boards, priests and dogmatic teachings establish certain limitations to the freedom of the believer. The catholic dogma contains three leading principles related to the status of the family, the child and reproduction. First principle commands the protection of the human being from the moment of its conception, thus strictly forbidding abortion. The second principle is related to the duty of procreation, as, just as in Judaism in the Old Testament God commends Adam and Eve to have children. Morally a child is the fruit of marriage, premarital sex is not allowed, and the Catholic Church condemns having a child outside the institution of marriage. The new-born has to embody the love between a husband and his wife and is considered the symbol of their eternal union. A third principle, which is related to integrity and dignity norms, must be taken into consideration when it comes to assisted reproduction ethics.

The Vatican has a clear position against assisted reproduction, ever since 1956, Pope Pius XII, defined artificial fecundation as immoral and illegal, because it affects human lives by separating procreation and sexual normal function. The criteria of this negative evaluation are found in respect, in the desire of defending and promoting human being's fundamental rights to life and dignity and that person's moral responsibility to God. Therefore modern medical techniques used in assisted reproduction like: ET, surrogate mothers, and embryo cryopreservation are not accepted by the Catholic Church.[90] Moreover Catholic Church offers its respect and protection to the human being starting with its first seconds of existence; it considers the zygote, pre-embryo, embryo and fetus as persons and strongly disapproves

[88] Supra note 84.
[89] Available at *http://in-vitro-fertilization.eu/different-religious-concepts-in-vitro-fertilization-assisted-reproduction* visited 16 April2012.
[90] Larigani B, Zahedi F. "Islamic Perspectives on Human Cloning", *Health Law Rev* (2002); 11: 62-6.

research on embryos, cryopreservation and abortion.[91] Pope Benedict XVI has publicly re-emphasized the Catholic Church's opposition to in vitro fertilization (IVF), saying it replaces love between a husband and wife.[92] In addition, IVF is disregarded because it might cause disposal of embryos; in Catholicism, an embryo is viewed as an individual that must be treated as a person.[93]

5.6.4.2 The Eastern Orthodox Church

It was created in 1054 C after the Great Schism which divided Christianity in two: the Roman Catholic Church and the Eastern Orthodox Church. Eastern Orthodox Church is not as strict as the Roman Catholic Church, allowing the medical or surgical treatment of infertility but it is against and other assisted reproduction techniques, surrogate mother, donor sperm insemination-considered adultery, and embryo donation.

5.6.4.3 Protestant and Anglican Church

Basing its life-guiding principles on the old Christian Church and the creeds and teachings of the Apostles, the Anglican Church, allows assisted reproductive techniques, IVF and ET and allows the doctors to use sperm obtained after masturbation, however it forbids gametes donation. Anglican Church is not offering a moral status to the embryo, according to this Church moral can only be given to an individual with a well established personality. The Protestant Church accepts traditional treatment of infertility. Assisted reproductive technologies are acceptable only if the gametes are from the married couple and the procedure avoids damage to the pre-embryo. [94]

The Roman Catholic Church condemns AID for married, as well as unmarried, women. The Vatican's instructions demand a strict connection between procreation and intercourse. Artificial insemination involves separation between "the goods and meaning of marriage". Concerning AID the instructions suggest that the AID process damages personal family relations as well as the offspring. The practice of artificial insemination is also rejected on the grounds that it is based on masturbation and that the AID process is an adulterous act.

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[91] "The Right to Contraception and Abortion in Ten World Religions" available at *www.religiousconsultation.org/islam_contraception_abortion.htm*. visitedMarch 10, 2011.
[92] Available at *http://www.medicalnewstoday.com/releases/38686.php* visited on 6 June 2012.
[93] Alina Dain. "Reconciling Religion and Infertility" Medill report Chicago ,July 30, 2009 *http://news.medill.northwestern.edu/*
[94] Supra note 84 at p 4.

The Greek Orthodox Church opposes the practice of AID on the basis that it is an adulterous act. For the Protestant Church AID is mortally illicit and, at best, morally questionable. The Anglican Church allows semen collection by masturbation for artificial insemination by husband and for IVF.[95]

According to Christianity, in reality the origin of a human is the "result of an act of giving." The Vatican's instructions do not accept the donation of gametes to an infertile couple as an act of generosity. They state that conception by gamete donation (oocyte) can damage personal family relations, as well as the offspring and society. Oocyte donation is forbidden by three main branches of Christianity: Roman Catholic, Eastern Orthodox, and Protestant.[96]

The practice of surrogate motherhood is not accepted by the Christian religion, i.e., Roman Catholic, Protestant, or Anglican. The objection is on the basis that surrogate motherhood is contrary to the unity of marriage and to the dignity of the procreation of the human.[97]

The freezing of embryos, even when carried out in order to preserve the life of the embryos, constitutes an offense against the respect due to humans, by exposing the embryos to great risks of death or harm to their physical integrity and depriving then, at least temporarily, of maternal shelter and gestation**.** [98]

5.6.5. Judaism

The Judaic view can be summarized by the first commandment that God gave to Adam and Eve: "Be fruitful and multiply". The Hebrew law is characterized by a strict association between the religious dogmas and the practice laws.

The origin of the written law can be traced back in the Torah, the Jewish sacred book, which contains the first 5 books of the Scripture, an expression of God's revelation both a humanitarian guide and a book of wisdom. Dominant life guidelines of the oral law are studied in the Jewish schools. The Mishnah includes the traditional interpretations of the Torah and the post-biblical life rules. Talmud is a monumental document which contains rules originated from Mishnah. Moreover Responsa has

[95] Ibid.
[96] Supra note 92.
[97] Supra note 86.
[98] Ibid

approximately 1000 volumes and contains laws which can be interpreted as assisted reproduction.[99]

Another argument can be found in a 2nd century Talmud statement which says that any man without children is a dead man. Mishnah speaks about the number of children required in order to fulfill the divine commandment of procreation. The marriage, called mitzvah is understood by the Jewish church as the legal and religious acts performed by a man and a woman out of religious duty, a useful union which prevents the sexual sins, and moreover must generate heirs. Hebrew laws recognize sex as an important part of the human life, for the Jews sex is healthy and their laws acknowledge the importance of sexual desire. Mitzvah Onah states that a man has 3 important duties to his life partner: he must provide food, clothing and fulfill his conjugal duties.[100]

The Judaism allows doctors to treat infertility and the infertile married couple must be go through all the stages of the diagnosis and treatment as a single unit. Moreover the woman has to be investigated prior to the man, only if she is clinically appropriate to procreate than man will also be examined.[101]

AID is indicated in cases of incurable male infertility or when the husband is a carrier of serious inherited disease or abnormality. It is used extensively throughout the world. All Jewish legal experts agree that AID, using the semen of a Jewish donor, is forbidden. It is the severity of the prohibition that is debatable. AID is commonly accepted, but only if the embryo is fertilized by the husband's sperm. Donor sperm is accepted only as a legal option. According to Jewish law, is prohibited for a variety of reasons: incest, lack of genealogy, and the problem of inheritance. Semen donors for AID, as well as physicians, who use the semen, are violating the severe prohibition against masturbation.[102] Insemination with the husband's sperm is permissible if the wife cannot become pregnant in any other way.[103]

There are various views regarding the legal relationship that exists between the semen donor and the child born as a result of AID. Some rule that no relationship exists with others that the child should be regarded as the donor's child, with all the legal complications of incest, inheritance, levirate marriage, etc. The majority opinion

[99] Stephen J. Werber, "Cloning: A Jewish Law Perspective with a Comparative Study of Other Abrahamic Traditions", 30 *Seton Hall. Rev*. 114, 1156(2000).
[100] Ibid
[101] Supra note 86.
[102] "IVF and JUDISM", http*://in-vitro-fertilization.eu/ivf-and-judaism/* visited on 12 April 2011.
[103] Available at *http://www.sciencedirect.com/* visited on 15 July 2012.

is that the donor has not fulfilled the obligation of procreation by fathering an AID child. The practice of AID is accepted by part of the Jewish population in Israel, and according to the regulations of the Ministry of Health it is allowed in special circumstances.[104]

In the case of egg donation or embryo donation, the problem that arises is who should be considering the mother, the donor of the oocyte or the one in whose uterus the embryo develops the one who gives birth. In the case that one of the women is Jewish and the other is not, the problem of the status of the child whether or not he is a Jew will arise. Jewish law states that the child is related to the woman who finished its formation the one who gave birth.[105]

The freezing of the pre-embryo raises the basic question of whether cryopreservation, which stops the development and growth of the embryo, cancels all rights of the pre-embryo father. With regard to the mother, the problem is simplified, since the embryo is transferred into her uterus later and will renew the mother-embryo relationship. With regard to the relationship to the father, whose main function is to fertilize the oocyte in order to form the pre-embryo, the period of freezing may cause a severing of the relationship between the child and his father. Freezing of sperm and pre-embryo is permitted only when all measures are taken to ensure that the father's identity will not be lost.[106]

The Jewish religion does not forbid the practice of surrogate motherhood. According to Jewish law, if partial surrogacy is practiced and a strange woman is inseminated with the sperm of a man and she completes the pregnancy on agreement the child born should be handed over to the owner of the sperm. In the case of full surrogacy, when the embryo is transplanted into another woman, the question is not resolved, as discussed in the case of ovum donation. From the religious point of view, the child will belong to the father who gave the sperm and to the mother who gave birth.[107]

Nowadays, assisted reproductive technology is a common practice in the treatment of infertility. The clinical achievements of this technology are due to the

[104] Available at *http://in-vitro-fertilization.eu/different-religious-concepts-in-vitro-fertilization-assisted-reproduction/* visited on 12 April 2011.
[105] Supra note 86.
[106] Stephen J. Werber, "Cloning: A Jewish Law Perspective with a Comparative Study of Other Abrahamic Traditions", 30 *SETON HALL L. REV.* 114, 1156(2000).
[107] Shree Mulay & Emily Gibson, "Marketing of Assisted Human Reproduction and the Indian State", 49 *DEVELOPMENT* 84, 85 (2006).

scientific progress in the field of human reproduction. Different religious arguments of the different religions impose limitations on the therapeutic approach to infertility.[108] The prolonged conflict between religion and science is based on the difference in religious belief and scientific theory.[109] Religious authorities, in order to maintain their Strength, power, and efficiency, should undergo continual development, and change in the same way that science does. While religious principles may be unchangeable, they may, nevertheless, undergo significant changes in their implementation.

5.7 Conclusion

To conclude, we see that on the one hand, the use of ART has revolutionized the life of humans, on the other hand, It fulfilled the hope of the despaired infertile people, made it possible for them to have their genetically linked child, but on the other hand the use of ART raised the number of social, ethical, moral economic, religious, and health related issues which put a big question mark on the use of ART. The response of the judiciary is significant towards the various issues arising with the use of ART. So, in the forthcoming chapter the judicial pronouncements will be discussed in detail.

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[108] Supra note 84.
[109] Supra note 86.

Chapter-VI

Chapter- VI

Judicial Response and Assisted Reproductive Technology

6.1 Introduction

For the first time in history, in-vitro fertilization (IVF) technology made it possible to separate embryos from the person who created them. IVF created a new paradigm for reproductive rights outside a women's body and inside an embryology lab. IVF with cryopreservation not only transformed patient's reproductive rights and timetables but also created new responsibilities and vulnerabilities for the professional who maintained the cryopreserved tissues. By changing the ways families were created, IVF and the ART 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. In this context it is worth to understand how the law has responded to these revolutionary medical advances and how the courts have struggled to apply and expand legal principles and precedents to shape families and guide patients and providers. It is also important to understand that new law emerges from older and established areas of the law. Family, health, contract, discrimination, tort, and constitutional law all come into play as courts sort out the legal issues raised by the assisted reproductive technologies. The cases which are discussed in this chapter related to assisted reproductive technologies continue to challenge and extend the existing legal norms and create new laws and policies.

6.2 Judicial Response in different countries

6.2.1 Access to ART Treatment

Access to treatment for infertility sparked considerable legal development. Courts were confronted with claims that infertility was a protected disability and that denial of treatment or termination of employment based on either fertility-related conditions or treatment for such conditions violated constitutional or other statutory laws. If we were to take the right to reproductive autonomy seriously then any person who came forward for treatment would have a right to it unless there were very strong reasons why they should not.

In *R v Sheffield HA ex p Seale*[1] , Seale was a 37 year old woman who wanted IVF treatment but was turned down by the defendant health authority because of their policy of not providing the treatment for women over 35 years of age. The claimant

[1] (1994) 25 BMLR 1

argued that choosing 35 years as the cutoff point was irrational. It was held that this policy was not unreasonable, given the finite resources of the defendants. The policy of the defendant was less likely to be successful in women over 35 years old and it had to balance demand for infertility treatment against other demands for its services.

In the latter case, the decision essentially turns on the potential welfare of any child born as a result of treatment. In the case of *R v Ethical committee of St. Marry's Hospital (Manchester) ex p Harriott*[2] the applicant applied for judicial review after being refused IVF treatment as a result of advice given to her consultant by the hospital's ethical committee. The committee was unhappy with the fact that she and her husband had already been rejected as foster parents on the basis of her past convictions for offences relating to prostitution. Schiemann J said:

> "The applicant wishes to have a child. Unfortunately she has difficulty in conceiving one. She had applied a number of times to Manchester City's social services department to be allowed to foster or adopt children. These applications have been uniformly unsuccessful, the authority taking the view that the applicant's criminal record (which includes allowing premises to be used as a brothel and soliciting for prostitution), her allegedly poor understanding of the role of a foster parent and the social services department, precluded them from approving her applications.
>
> Frustrated in her desire to foster and adopt and to conceive by normal means, the applicant wishes to be considered for IVF under the National Health Service. The Health Service – to use an imprecise term for the moment- decided to refuse to give her this treatment. In this application for judicial review she complains of that decision essentially alleging that it was reached by the wrong body: alternatively that she was not given an adequate opportunity to make representations to the decision maker before the decision was taken.
>
> This, I believe, is the first occasion when a decision to refuse treatment for an illness- and for present purpose infertility may be regarded as an illness- has been the subject of an application for judicial review. The respondents submitted that the court will not investigate the reason behind a decision by the Health Service to refuse treatment nor, submit the respondents, will the courts investigate the procedures which have been followed in the decision making process. It will be obvious that this case potentially raises issues of the widest social and legal significance.

[2] (1998) FLR 512,HC

> Mr. Bell, for the committee , stated "judicial review does not lie to review any advice given by the committee As at present advises, I would be doubtful about accepting that submission in its full breadth. If the committee had advices, for instance , that the IVF unit should in principle refuse all such treatment to anyone who was a Jew or colored, then I think the court might will grant a declaration that such a policy was illegal. See in this context, R v Takeover panel ex p datafinplc[1977]2 WLR 699 in the court of appeal and Gillick v IV Norfolk and wisbech AHA and Another [1986]1FLR 224 in the House of lords. But I do not need to consider that situation in this case. Here the complaint is that the committee's advise was that the consultant must make up her own mind as to whether the treatment should be given that advises was, in my judgment, unobjectionable."

There are two reasons why treatment might be refused. First, the couple may be medically unsuitable. Secondly, and for more controversially, they may be deemed socially unsuitable as parents.

Access to ART treatment in terms of insurance coverage has been, and will likely to be, a major issue in ART treatment. In USA, of the fourteen states that currently mandate some form of infertility treatment insurance coverage, ten were enacted prior to 1990, and only one since 2000.[3]

North Coast Women's Care Medical Group. Inc. et al. v. S.C.(Benitez)[4],– The California Supreme Court has now affirmed that a lesbian patient cannot be refused fertility treatment under California's anti-discrimination statute based on sexual orientation. The state Supreme Court found the Appeals Court erred, and that the defendants had not been precluded from arguing at a trial that their refusal was based solely on marital status. The court ruled it need not reach the question of whether such a refusal would be legally permissible since Benitez did not base her claim on marital status.

The ruling is a major and long-awaited verdict that makes clear there is no religion exemption to California's Civil Rights Act based on sexual orientation, and that physicians may not deny medical services based on their patients sexual orientation.

[3] Susan L. Crockin, J.D and Howard W. Jones, JR., M. D., *Legal Conception: The Evolution Law and Policy of Assisted Reproductive Technologies, (*2009, Baltimore, The Johns Hopkins University Press), p.79.
[4] 2008 Cal. LEXIS 10756

Access to treatment, including insurance coverage for infertility, genetic diagnosis, and ART treatment continues to be an evolving area of both law and medical practice. As both older and nontraditional patients increasingly turn to ART treatments to create families, defining infertility and coverage limits will likely continue to vex policy makers. Same-sex couples who cannot reproduce without medical assistance but who may not be considered medically infertile, couples who can achieve pregnancies but carry lethal or significant genetic defect and seek preimplantation genetic diagnosis to avoid carrying affected pregnancies, and single or older would-be parents who seek out ART treatments will all likely present future challenges to coverage for available treatments.

In *Liberty Mutual Fire Ins. Co. V. (name withheld)*[5] a Delaware superior court addressed the issue of whether a no-fault automobile insurance policy's personal injury protection (PIP) provision covers IVF. Plaintiff both suffered severe injuries in an automobile accident in February 1998. As a result of his injuries, the husband suffered from 'obstructive azoospermia' rendering him unable to produce through sexual intercourse. The couple therefore underwent IVF using ICSI to conceive their child, paying more than $14,000.

The couple claimed that their PIP coverage provided by Liberty Mutual should cover their expenses for IVF not only for the two-year period of coverage, but also for any subsequent IVF attempt as well. Liberty Mutual, however, asserted that the claimant's IVF expenses were not "reasonable and necessary" resulting from prescribed medical treatment, but were merely for their comfort, convenience or other personal reasons. The court, finding in favour of the couple's claim for reimbursement of the initial IVF expenses, found that "the decision to undergo IVF treatment may have been the husband's but the need for it was precipitated by the accident…. But for the accident, he could have chosen to have children." the court went even further to hold that the wife's expenses associated with the procedure must also be covered because in order for the husband's IVF to work, services must be provided to the wife too." The court, did, however, hold that the policy clearly stated a two year limitation on personal injury protection coverage and thus Liberty Mutual was only bound to provide such protection for IVF occurring within that period.

[5] 2001 Del. Super. LEXIS 216

The current challenge must include moving beyond attempts to fit newer developments into those hard-fought, and now accepted, categories to also focus on similarly thoughtful arguments and policy proposals to address these newer options to meet the medical challenges to family-building efforts today and into the future.

6.2.2 Consent to Use of Gametes or Embryos

The advent of in vitro fertilization, followed by embryo cryopreservation, transformed both the medical and legal landscape involving reproduction.

Under para 1 of schedule 3 to the Human Fertilization and Embryology Act 1990, consent must be in writing and, to be effective, it must not have withdrawn. The issue of consent arose in *Mrs U v. Centre for Reproductive medicine*[6]. Mrs U married in 1993 but her husband had had a vasectomy in 1978. They opted for surgical retrieval of Mr. U's sperm for use in IVF treatment. Under s. 4 (1) (a), no one shall store gametes except with the licence and breach is a criminal offence. Under section 11, although the Human Fertilisation and embryology Authority can grant licences for storage of gametes and embryos, the provisions of schedule 3 concerning consent must be met. The day before treatment, Mr. U signed the consent form, which provided that sperm would only be used during his lifetime but he also marked 'no' in the box for allowing the sperm to perish. The sperm was then retrieved and stored. Sometime after this, the couple attended a meeting about treatment at the clinic. Mr. U was asked by the nurse to change his form to comply with the centre's policy of not allowing posthumous use. Mr. U changed the form to allow the sperm to perish on death. The first course of treatment failed and Mr U then died unexpectedly. The clinic sought a court ruling on whether the sperm could be allowed to perish or to be destroyed. The court of appeal said that in order to continue storing the sperm, the clinic needed consent to comply with schedule 3. Mrs. U claimed undue influence but court said that although Mr. U was put under pressure to change his mind, he could have asked for more time and the pressure did not amount to undue influence. Therefore, there was no effective consent and continued storage or use was unlawful.

The issue of the withdrawal of the consent arose in two cases which were heard together by the High Court. In *Evans v. Amicus Healthcare Ltd. and others* [7] and *Hadley v Midland Fertility Services Ltd*.[8], the two claimant women had IVF

[6] [2002] EwcA Civ 565, [22]
[7] (2004) 3 All ER 1025
[8] [2003] EWHC 2161 (Fam)

treatment with their male partners. The male partners had signed consent form agreeing to the treatment. Following treatment, embryos were created and stored. Later, the couples separated and the male partners withdrew their consents to the use of the embryos. The two women wanted a declaration that it would be lawful to treat them using the embryos. Under section 3, para 6(3) of the Human fertilization and Embryology Act 1990, an embryo could not be used unless there was a consent by each person whose gametes had been used to create it, and that consent must not have been withdrawn. A number of questions arose for decision. Could the two women be given treatment on their own? There was also an argument based on promissory estoppels, as the second claimant argued that her partner was stopped from being back on his original promise. There were also questions whether there was a breach of Articles 2 and 8 of the European Convention on Human Rights. The court held that the consent had been given originally for 'treatment together'. The time of treatment would be when the embryos were transferred. As the couples had now separated, they were not being treated together. There was no consent by the male partners for the women to be treated on their own. As regards estoppels, the requirements for consent to treatment provided by the Human fertilization and Embryology Act 1990 provided for withdrawal of treatment. Given that it was not possible to succeed on the basis of estoppels, the claims were dismissed. In Evans case the court of appeal held that a claim by Natalie Evans who wished to use a frozen embryo created with her former partner. Her partner had withdrawn his consent to use it when the relationship ended. The court said that it had no power to override the withdrawal of consent. Thorpe and Sedley LJ said:

> "In relation to his stopped ground… Mr. Tolson [counsel] for Mr. Evans sought to develop the submission that Mr. Johnston had concealed his ambivalence, thereby inducing Mr. Evans to go forward with him into couple treatment. Mr. Tolson submitted that had she knews his true state of mind and feeling she would have appreciated the risk of his withdrawing consent and, perhaps, elected the fertilisation of her eggs with donor sperm."
>
> The clear policy of the Act is to ensure continuing consent from the commencement of treatment to the point of implant. Consent may be given subject to conditions. Consent may be varied. Consent may be withdrawn. Against that background that court should be extremely slow to recognize or to create a principle of waiver that would conflict with the parliamentary scheme. In our judgment therefore, Mr. Johnston was entitled by the terms of the act to withdraw his consent as and when he did. The effect of his withdrawal of consent is to prevent both the use and

> continued storage of the embryo fertilized with his sperm. Future treatment of the appellant would not be "treatment together" with Mr. Johnston. In the alternative, Mrs. Evans contended that the HEFA 1990, by permitting such revocation, was incompatible with her rights under Article 8 of the European convention on Human Right (ECHR).

Arden LJ said:

> "It is common ground that article 8, which has already been set out by Thrope and sedley LJJ, is engaged because Mr. Evans bodily integrity (private life) is affected. I do not consider that she could assert any right to family life with a future child whose embryo has yet been transferred to her… the assumption made by all parties is that article 8 is engaged to the extent that the 1990 Act purports to regulate any right they would otherwise have to use an embryo…"

In re D (A Child Appearing by her Guardian ad Litem)[9]

The mother, D, gave birth to a daughter, R. D's former partner, B, promptly made an application for contact and parental responsibility orders in respect of the child. D had initially attended the clinic with B as her partner and they had been approved for treatment together. They signed forms accepting that they would be receiving treatment services together. Subsequently D and B separated, but the clinic was not informed of this and they continued to provide assisted reproductive services to D. D formed a relationship with S and he supported her through the next stages of the treatment and was still with her. A key question for the House of Lords was whether B was R's father, relying on section 28(3).

The first question for their Lordships was the 'reaming treatment services together'. Lord Hope explained that the phrase 'that this is in reality a joint enterprise-that the treatment is being sought by the woman and the man together because they both wish to receive the benefit of the treatment to bring a child into being jointly as their child.' The nest question for their Lordships was for the purposes of section 28(3) when did the couple need to show they were receiving treatment services together, when the couple were approved for treatment by the clinic or when the embryo was implanted into D? Lard Hope answered that question in this way:

> "The language of the subsection tells us that the man shall be treated as the father if the embryo or the sperm and eggs 'were placed' in the woman or she 'was' artificially inseminated, 'in the course of' treatment services provided for her and the man together. These words make it plain that the point of time is the

[9] [2005] UKHL 33

time when the embryo or the sperm and eggs were placed in the woman or she was artificially inseminated."

This meant that although B could claim he was receiving treatment services together with D when they first approached the clinic, he was not at the crucial time when the embryo or sperm and eggs were placed into D.

There was, however, a further question: in considering whether D and B were receiving treatment services together at the time if implantation, from whose perspective so we consider this? The argument on B's behalf was that from the clinic's understanding they were still treating D and B as a couple, even at the time of implantation. Lord Hope rejected this argument and held that.

"Whether the treatment services were being provided for the woman and the man to together at the relevant time simply raises a question of fact which must be determined by the judge in the light of all the evidence. The perspective of the clients is therefore to be treated as part of the relevant evidence. So too is the perspective of the provider of the services, as demonstrated by the records which the provider has kept as required by the licensing authority. Neither has any priority over the other in terms of the statute. Each is as vulnerable to human error deceit, mistake or misunderstanding as the other. To elevate one over the other the statute does not clearly require this would be to create an unnecessary gloss. It could result in a decision which was unopposed on the man by default and which when looked at in the light of all the evidence, was quite wrong."

R (on the application Bruno quintaville on behalf of pro life alliance) v. secy for health[10] Pro life sought a declaration in judicial review that human embryos produced by CNR fell outside the term of 1990 Act, and hence research and on them could be regulated by the HFE authority. Its argument was based on the fact that, in defining embryo, section 1(1) of the Act appears to treat the embryo coming into being through a process of fertilization as an essential condition, in contrast, the 'embryos 'that result from CNR (i.e. once the egg whose nucleus has been replaced is stimulated and start to divide) has never fertilized. At first instance, Crane J accepted this argument and granted pro-life declaration. Lord Phillip M R said:

on the fact of it the motivation of the pro-life Alliance was not easy to follow they had caused the baby to be expelled with the bath water .they had established that CNR embryos can be created and used for many purposes without regulation or restriction As I understand the position ,however , the

[10] 2002]2wlr550,ca (lord PhillipMR, Thrope and buxtonLjj)

pro life alliance had assumed that if their if their application for judicial review succeeded the government would be forced to introduce legislation to deal with the practice of creating embryos by CNR. There would be a full parliamentary debate on the topic which might well result in the prohibition of the process…

The definition of an embryo in section 1(1) of the Act is manifestly designed to identify the stage at which the process of fertilization produces, or should be deemed to produced alive human embryo. References to fertilization can have no application to an embryo produced by CNR. Arguably, the term zygote is not appropriate to describe the embryo produced at the stage at which the single cell organism produced by CNR divides into two cells. On behalf of the secretary of state, Mr. Parker QC had submitted that it is permissible and appropriate to imply the word into the definition of embryo given in section 1(1) in order to embrace an embryo produced by CNR. This he would achieve by implying a phrase, into the sub section, so that it defines embryo as a live human embryo where [if it is produced by fertilization] fertilization is complete. Mr. Parker accepts that this construction involves straining the natural meaning of the word of subsection, but submits that the purposive approach to construction requires such an approach…

The issue is whether it would be accord with the policy of parliament at the time that the Act was passed to bring embryo created by CNR within the regulatory framework rather than to leave them unregulated. I will accept for the purpose of argument ,that it is the intention of the parliament to prohibit the creation of embryo that might develop into the clone , but the reason for this was, as the White paper indicates ,to prevent the production artificially two or more genetically identical individuals. This policy would be put in jeopardy if the creation and use of the embryo by CNR are unregulated. It would be furthered by making the production of embryos by CNR subject to the regulatory regime ,under the Act for it is inconceivable that that the licensing Authority would permit such an embryo to be used for the purpose of reproduction for the reasons that I have given I consider that a regulatory regime that exclude from its ambits embryos created by CNR is contrary to the intention of parliament in introducing the Act .The prospect of such regime is both startling and alarming. These considerations provide the most cogent reason to reach an interpretation of the act which embraces embryos produced by CNR…"

6.2.3 Artificial Insemination

Artificial insemination has a long history that predates Anton Van Leeuwenhoek's description of sperm in 1677. The idea that a woman could be impregnated outside of the act of intercourse was known as early as the second century, and there are stories of an Arab sheik who, in the fourteen century, used artificial insemination to weaken the bloodline of his enemy's horses. The first recorded artificial insemination of a woman occurred in 1785, when Dr. William Pan coast performed the first artificial insemination using donor sperm, the sperm of someone besides the patient's own husband, in 1884. In that particular case, the women never knew that she had been inseminated by a stranger's sperm. Even if the husband had consented, artificial insemination by a donor was somewhat scandalous, because it might expose the women to a charge of adultery.[11]

Although the first insemination of a woman with frozen semen was performed in 1953, its successful use was not reported until the eleventh International Congress of Genetics in 1963, and the first wave of sperm banks finally opened in the 1970s. When sperm banks first appeared, they were far more likely to sell only to physicians were choosing donors themselves, not using sperm banks.[12]

A number of problems have arisen under the Human fertilization and Embryology Act 1990. In the case of *R v. Human Fertilisation and Embryology Authority ex p blood*[13] Mr. and Mrs. Blood wanted to start a family but, before Mrs. Blood could become pregnant, Mr. Blood caught meningitis and went into a coma. Sperm was taken from Mr. Blood and stored and, shortly after this, he died. Mrs. Blood then wanted to use the sperm to have a baby, but the Human Fertilisation and Embryology Authority refused to allow this because, under section 4 (1) (a) of the Human fertilization and Embryology Act 1990, there was no license to store the sperm and, under schedule 3, Mr. Blood had not consented in writing to use of his sperm. Mrs. Blood's claim for judicial review failed. She then appealed, claiming that: (a) under section 4 (1) (b) of the Human fertilization and Embryology Act 1990, treatment was allowed without written consent for 'the women and man together'; and (b) the authority's refusal to allow export of the sperm for treatment abroad was a breach of European Union law, which allowed citizens to have medical treatment in

[11] Naomi R. Cahn, Test tube Families: why the fertility market needs legal Regulation, (2009, Newyork and London, Newyork University Press), at 46.
[12] Id at 48
[13] (1997) 2AllER 687 (CA)

any member State. The court of Appeal held that, under section 4 (1) (b), treatment could not be regarded as being provided for a women and man together once the man who had provided the sperm had died. In any case, the exception to written consent only applied if the sperm was used immediately and did not need to be stored, so section 41 (1) (b) did not apply. Without a written consent from the husband, the applicant's treatment and storage of the sperm were prohibited under the Human fertilization and Embryology Act 1990. However, under the European Treaty, the applicant had a right to receive medical treatment in another Member State and refusing export of the sperm made fertilization treatment impossible. The court said that Human fertilization and Embryology Authority had failed to take into account the fact that there was unlikely to be any similar cases in the future and the appeal was allowed. The Authority then allowed Mrs. Blood to take the sperm abroad. Lord Woolf MR said:

> "As to storage, section 4(1) makes it clear that it must always be pursuant to a license. That means that storage can only take place lawfully in accordance with the requirements of the license which for the present purposes are those contained in Schedule 3. This means that there must be a consent in writing (Para 1 and Para 8) which complies with Para 2(2) and Para 3 before the storage can lawfully take place."

The position as to storage Sperm can be used fresh or after it has been preserved. Its life, if not preserved, is extremely limited, a matter of a few hours. If it is preserved then it is being stored for the purpose of the Act and therefore is subjected to the requirement of a license. This is made clear by the definition of keeping or preserving sperm contained in s 2(2).The Act therefore takes the preservation process as the beginning of storage. This is understandable, since preservation involves the processing of gametes, and parliament has required that this should be done subject to the control of the licensing process. The result is that in the ordinary way no preservation can take place unless the required written consents exit. This would also apply in the case of the preservation of sperm intended for export unless a particular direction was obtained prior to presentation which permitted the storage to take place notwithstanding that there were not the requisite consents.

It follows that Mr. Blood's sperm should not in fact have been preserved and stored. Technically therefore an offence was committed by the license holder as a result of the storage under s 41(2)(b) of the 1990 Act by the license. There is however no question of any prosecution being brought in the circumstances of this case and no

possible criticism can be made of the fact that storage has taken place because professor Cook was acting throughout in close consultation with the authority in a perfectly bona fide manner, in an unexplored legal situation where humanity dictated that the sperm was taken and preserved first, and the legal argument followed. From now on, however, the position will be different, as these proceedings will clarify the legal position. Because this judgment makes it clear that the sperm of Mr. blood has been preserved and stored when it should not have been, this case raises as to the lawfulness of the use and export of sperm which should never arise again.

As regards the legal position of the child born as a result of artificial insemination by donor, section 28(2) of the Human fertilization and Embryology Act 1990 provides that if the parties are married and the embryo was not created with the sperm of the other party to the marriage, that other party shall be treated as the father of the child, unless he did not consent to the insemination. This makes the husband the legal father of the child. Under section 28(3), if the couple are unmarried and treatment services are provided by a licensed clinic 'for her and a man together', and the embryo was not created with the sperm from her partner, her partner will be treated as the father of the child. The interpretation of section 28(2) fell to be considered in the unusual case of *The Leeds Teaching Hospitals NHS Trust v. Mr. and Mrs. A and Others*[14] . Mr. and Mrs. A, and Mr. and Mrs. B were having fertility treatment at the same clinic. Mr. and Mrs. A were white and Mr. and Mrs. B were black. Due to a mistake, Mrs. A's eggs were fertilized with the sperm of Mr. B and Mrs. A had black twins. The main question was who was the legal father of the twins? Under section 28 (2), if the parties are married and the embryo was not created with the sperm of other party, the other party shall be treated as the father unless he did not consent to the insemination. Under section 28(3), if no man is treated as the father under section 28 (2), but in course of treatment together the embryo was not created by the sperm of that man, that man is treated as the father of the child. Mr. A argued that he was the father under section 28(2) or alternatively under section 28 (3). The court said that the common law presumption was that a child born to a mother during marriage was legitimate. Under section 28 (5), this applied to section 28 (2) and section 28 (3). But on the fact of this case, this presumption was rebutted by tests that showed that Mr. B was the biological father of the twins. As regard consent under

[14] (2003) 1FLR 1091.

section 28(2), Mr. A had consented to his sperm being mixed with Mrs. A's eggs but not to donated sperm being mixed. Because of the mistake which was made he could not be regarded as consenting and could not be presumed to be the father under section 28 (2). Mr. B was the legal father of the twins.

The effect of section 28(3) was considered in *U v W (Attorney General Intervening)*[15]. Miss U and Mr. W lived together for four years in an 'on-off' relationship. Miss U wanted a child and, because Mr. W's sperm was weak, they went to a special clinic in Rome for fertility treatment. They agreed to use donor sperm and signed a form accepting maternity and paternity of the unborn child. Mr. W then returned to the UK and miss U had the treatment. Later, Miss U had twins and claimed that Mr. W was the father. The court considered whether section 28(3) of Human fertilization and Embryology Act 1990 applied to Mr. W. It was argued for Miss U that the requirement for a license under the Human fertilization and Embryology Act 1990 was a restriction on the right of medical treatment under Article 59 of the EC Treaty. It was held that the licensing system did not infringe Article 59 and, although the couple had been treated together, the doctor was not licensed. Therefore, section 28(3) did not apply and Mr. W was not the father.

The courts have further considered what treatment 'together' means in *Re R (Parental Responsibility: IVF Baby)*[16]. The man was infertile and both he and his partner signed consent for IVF treatment. The man agreed that although his sperm would not be used, they were being treated together and he would be the father of any resulting child. The first embryo placement did not work. The woman returned for a second attempt, without telling the clinic that they had separated. This treatment resulted in the birth of a child. The man was granted a declaration of paternity and the court said that under section 28(3) the embryo had been placed in the mother 'in the course of treatment services provided for her and the man together'. The Court of Appeal said that the important point in the time when the services were provided was the point when embryo was placed in the mother. At that point, the couples were separated and the treatment could not be regarded as being provided for the woman and man together. If the circumstances of the couple changed dramatically, then new counseling should be offered before a new attempt was made. It would be easy for clinics to check the relationship between man and woman at that time.

[15] [1997] 2 FLR 282, FD
[16] [2003] 2 All ER 131

There is no problem if the spouses have authorized or ratified the insemination in a written instrument which they signed freely and voluntarily without deception before the birth of the child. For then, the status of the child is indubitably legitimate by express provision of law. However, what will happen if the wife was subjected to artificial insemination without her consent or against her will? Certainly, the child resulting there from will be illegitimate because it is a patent violation of the law which requires the consent of both the husband and the wife to the procedure of artificial insemination. But what is the remedy of the aggrieved wife? Can she file an action for any crime? In the case of *Oxford v. Oxford,* the Supreme Court of Ontario, Canada made the obiter that the process of insemination undergone by the woman against her will is tantamount to "sexual intercourse" and this might constitute rape. In the Philippines, there is still no direct rule and jurisprudence on the matter. At most, the crime that could be charged is coercion, but the same is not commensurate to the gravity of the invasion of the woman's reproductive organs. But surely, the woman is entitled to damages under Articles 20 and 21 of the New Civil Code: Article 20. Every person who, contrary to law, willfully or negligently causes damage to another shall indemnify the latter for the same. Article 21. Any person who willfully causes loss or injury to another in a manner that is contrary to morals, good customs or public policy shall compensate the latter for the damage. Children conceived or born during the marriage of the parents are legitimate. Children conceived as a result of artificial insemination of the wife with the sperm of the husband or that of a donor or both are likewise legitimate children of the husband and his wife, provided, that both of them authorized or ratified such insemination in a written instrument executed and signed by them before the birth of the child. The instrument shall be recorded in the civil registry together with the birth certificate of the child. Now, it may happen that it is the husband's consent that is wanting. If the wife had herself inseminated with the sperm of a donor without the consent of the husband and a child was born as a result thereof, can she be held criminally liable? On this, one may argue that there is no specific penal or criminal law punishing the act. Adultery is defined under Philippine criminal law as being committed by any married woman who shall have sexual intercourse with a man not her husband and by the man who has carnal knowledge of her, knowing her to be married, even if the marriage be subsequently declared void. The woman needs to be married who shall have sexual intercourse with a man not her husband. The essence of adultery is sexual intercourse;

there will be as many counts of adultery as there are sexual acts. Therefore, one may conclude that no crime had been committed by the wife who had herself inseminated with the sperm of a donor without the consent of her husband for there had been no sexual contact, and there is no crime where there is no law punishing it *(nullum crimen nulla poena sine lege*).However, it was the submission of a distinguished authority in Civil Law that the wife may be held guilty of adultery. Allowing the principle of *nullum crimen nulla poena sine lege* to apply will encourage married women to resort to artificial inseminations through donation to the damage and prejudice of the husband as a foreign blood is introduced into his family.

The voluntary surrender of the wife's reproductive powers or faculties to another through artificial insemination is adulterous because of the possibility of introducing into the family of the husband a child not of his own blood.

In U.S. v. Mata[17], the rule is that the controlling factor in adultery is not the actual contact of the sexual organs but the introduction of spurious heirs in the family. Likewise, in the aforementioned case of *Oxford v. Oxford,* it was said: "In my judgment, the essence of the offense of adultery consists, not in the moral turpitude of the act of sexual intercourse, but in the voluntary surrender to another person of the reproductive powers or faculties of the guilty person, and any submission of those powers to the service or enjoyment of any person other than the husband comes within the definition of 'adultery'. The fact that it has been held that anything short of actual intercourse, no matter how indecent or improper that act may be, does not constitute adultery, really tends to strengthen my view that it is not the moral turpitude that is involved but the invasion of the reproductive function. So long as nothing takes place which can by any possibility affect that function, there can be no adultery; so that unless and until there is actual sexual intercourse, there can be no adultery. But to argue from that, the adultery necessarily begins and ends there is utterly fallacious. Sexual intercourse is adulterous because in the case of the woman, it involves the possibility of introducing into the family of the husband a false strain of blood. Any act on the part of the wife which does that would therefore be adulterous. That such a thing could be accomplished in any way other than the natural manner probably never entered the heads of who considered the question before. Assuming the plaintiff's story to be true, what took place here was the introduction

[17] 18 Phil. 490 (1911).

into her body by unusual means of the seed of a man other than her husband. If it were necessary to do so, I would hold that in itself was 'sexual intercourse'. It is conceivable that such an act performed upon a woman against her will might constitute rape. Mr. White (counsel for the wife) was driven, as a result of his argument to contend that it would not be adultery for a woman living with her husband to provide by artificial insemination a child of which some man other than her husband was the father. A monstrous conclusion surely. If such a thing has never before been declared to be adultery, then, on the grounds of public policy, the court should now declare it so."

6.2.4 Pre-implantation Genetic Diagnosis

The legal responses to the developments in the field of genetics over the past decades have been nothing short of revolutionary. With the advances of reproductive genetics (or what some refer to as "reprogenetics"), including newer genetic testing technologies such as PGD (pre-implantation genetic diagnosis), existing legal frameworks and concepts, such as wrongful birth, wrongful conception, status of limitation, definition of "illness," "conception," and what is considered "medically necessary," as well as choice of conflict of law principles have all come under scrutiny.

As courts are forced to interpret and apply long standing legal distinctions between concepts such as "wrongful birth" and "wrongful conception" in the context of PGD testing of IVF embryos, policy implications over when life begins may find a new forum for debate and deliberation. "wrongful birth" and "wrongful conception" are both tort theories of civil liability that may be brought by parents of an affected child or, in other context, parents of a child did not want or expect (traditional fact pattern for such claims include failed tubal ligations or missed diagnoses of genetic anomalies in older siblings or parents). In contrast, "wrongful life" theories of liability belong to the child themselves and require courts to weigh the value of an affected verses a normal life. Thus, for example, a child would sue for being born with a serious anomaly for which the physician failed to properly diagnosis or screen out. The majority of courts reject wrongful life claims, on the theory that courts cannot be properly asked to evaluate the reduced value of an impaired life over no life. All of these theories have been reinvigorated and retested, however, in light of genetic advances, with mixed result to date.

The technique of pre-implantation genetic diagnosis enables an embryo to be tested for a genetic disease and, if one is found, the embryo is not used. The Human Fertilization and Embryology Authority licenses treatment on this basis. The development of such techniques has raised the specter of test tube babies produced to be used for helping others. In August 2000, the first such case occurred in America. Adam Nash was born after tissue matching of an embryo, in order to save the life of his sister Molly. Blood containing stem cells was taken from his umbilical cord to be used in treating Molly's condition, fanconi anaemia. [18] A similar situation recently arose in the UK. *In R (Quintavalle) v HFE Authority*[19], Mr. and Mrs. H's fourth son was born with a life-threatening blood disorder (beta thalassaemia major). The couple wished to have another child who was free of that disease but with a tissue type to match their sick son. Stem cells could be taken from the new baby to treat the sick son. Mrs. H wished to have IVF treatment using an embryo with a tissue type that matched her sick son. The Human Fertilisation and Embryology Authority agreed to grant a license for IVF treatment which included pre-implantation genetic diagnosis and tissue typing. This decision was challenged by Quintaville acting on behalf of a group called CORE (Comment on Reproductive Ethics) on the basis that the Human Fertilisation and Embryology Authority had no power to issue a license for tissue typing to select between healthy embryos. The applicant sought judicial review. The high court said that the Authority has acted *ultra vires* and quashed their decision. The Court of Appeal considered whether the treatment was covered by the term 'treatment services' within section 2(1) of the Human Fertilisation and Embryology Act 1990, which provides that it means medical, surgical or obstetric services provided for the purpose of assisting woman to carry children. The court said that whether the treatment was to produce a child without genetic defects or with stem cells to match a sick sibling, it was still treatment to assist woman to have children. Whether it was the first or second, the purpose was to make sure that the embryos were in a suitable condition for placing in the womb. The Human Fertilisation and Embryology Act 1990 allowed licensing for embryo research to detect genetic abnormalities in embryos and it would be strange if the Act was interpreted to prevent the use of embryos free from abnormalities. The appeal was allowed.

[18] Brendan Greene, Understanding Medical Law, (2005, Great Britain, Candevish Publishing Ltd.). at 118.
[19] (2005) UKHL 28.

6.2.5 Surrogacy

If reproductive right gets constitutional protection, surrogacy which allows an infertile couple to exercise that right also gets the same constitutional protection. However, jurisdictions in various countries have held different views regarding the legalization of surrogacy. Both traditional surrogacy and gestational carrier arrangements (also called gestational surrogacy) have challenged longstanding family law principles and presumptions, with varying and often inconsistent results from state to state. Courts have also struggled with the degree to which existing laws such as those addressing donor insemination and adoption are applicable in various contexts, including gestational carrier arrangements involving parentage and custody disputes over born children. This is another area where courts have frequently emphasized the paramount importance of the child's interests and issued calls for legislative action. A more nuanced issue arises, however, over whether the traditional family law principle of "the best interest of the child" applies if the court is being asked to determine who qualifies as a parent, not which of two legally recognized parents is the better custodian, delving into those issues often highlights the differences between adoption and ART law, with hundreds of years of adoption precedent of varying applicability to ART families.

International developments in this field are also notable, with some countries imposing age and marital restrictions, and court cases illustrate the degree to which reproductive tourism has proliferated. Reported cases involving Kuwait, Italy, Japan, Germany, and England shows the problems that arise when intended parents and gestational surrogates attempt to create international pairings. More recently, the phenomenon of Americans travelling abroad for collaborative arrangements (including for gestational surrogacy in India, with and without donor eggs) is likely to generate novel legal issues. Reports of those arrangements include clinics where women serving as gestational carriers and intended parents do not meet, where the women are not always given information about the intended parents' marital status or sexual orientation, where illiterate carriers sign agreements with the thumbprint, and compensation-a fraction of that paid Western women- is still several times higher than the local annual income figures in India.

Establishing parentage will always be a critical element of any surrogacy arrangement, whether traditional or gestational. For those arrangements that also involve donor gametes, nontraditional couples, single parents, or any parties from

more than one state or country, the complexities and vulnerabilities are likely to be significantly greater. Moving forward without a clear plan to establish parenthood should be both avoidable and avoided by any professional offering services to would-be parents in this ever-changing field.[20]

The practice of surrogacy raises many legal questions. What is the role of the law in relation to surrogacy? What is the legal status of surrogacy? Should payments be allowed to the surrogate mother? How should the law deal with disputes over the child who is born? In UK commercial surrogacy is illegal.

The first case involving surrogacy was heard in 1978, although it did not appear in the law reports until some year later. The case of *A v. C*[21] concerned an unmarried couple in which the woman, who had chicken from a previous relationship, was unable to have any further children. Her partner, A, had a very strong desire to raise his own biological child. He found a woman, C, who was prepared to be inseminated with his sperm and agreed to hand the baby over at birth for adoption by him and his partner in return for a payment of £3, 000. However, after the birth she decided to keep the child and forgo the money. A commenced wardship proceedings seeking custody of the child. In court proceedings Conwyn J. held that the child should remain a ward of court until majority or further order. C was given care and control of the child, the father was granted access, and a supervisory order was made in favour of the local authority. In the Court of Appeal strong disapproval of surrogacy was evident. Ormarod L.J. said:

> "There has never been bond between the father and the child except the mere biological one. There has never been any association, except of the most exiguous character, between the father and the mother. There has never been anything between them except a sordid commercial bargain. The father has only had the intermittent contact provided by access to a very young child over the past year. He has been very assiduous in maintaining that access, bringing with him his present wife whose role in this case, as l have said before, fills me with sympathy. What her position can be in that house during periods of assess, l find very hard to imagine. Her emotions must be very mixed and l feels sorry for her. But what is the future? The mother is 21. She is almost certain, given the chance and a little peace from litigation or the strain of access, to marry and set up a family of which this child will be part. By far the best

[20] Supra note 3 at 216.
[21] F.L.R. 445, [1985] Fam. Law 241

thing that can happen to this child is that he should become a member of a family just like other children. This will give him as normal a life as possible….. So what is the good of keeping this wholly artificial, painful tie going? My answer is: the father, except possibly a financial advantage to which I attach no significance whatever, in this case."

In Re C (minor) (Wardship: surrogacy)[22] A partial surrogacy arrangement negotiated by an agency was entered between an American commissioning couple and a British women , Kim cotton (who married with three children of her own) following the successful birth of a child Mrs. cotton was happy to relinquish all prenatal right in respect of it the commissioning father issued a wardship summons in order to obtain custody , which was duly granted. Lately J said:

"First and foremost, and at the heart of prerogative jurisdiction in wardship , is what is best for the child or children concerned . that and nothing else .plainly the method used to produce child , as this baby has been , and the commercial aspects of it ,raise difficult and delicate problems of ethics , morality and social desirability. These problem are under active consideration elsewhere.

Are they relevant in arriving at a decision on what now and, so far as one can tell, in the future is best for this child? If they are relevant, it is incumbent on the court to do its best to evaluate and balance them.

In my judgment, however, they are not relevant. The baby is here. all that matter is what is best for her now that she is here and not how she arrived .If it be said (though it has not been said during these hearings) that because the father and his wife entered into these arrangements. It is some indication of their unsuitability as parents ,I should reject my any such suggestion . If what they did was wrong (and I am not saying that it was), they did in total innocence. It follows that the moral, ethical, and social considerations are for other and for this court in its wardship jurisdiction.

So, what is best for baby? Her natural mother does not ask for her .should she go in to Mr. and Mrs. A's care and be brought up by them? or should some other arrangement be made for her, such as long term fostering with or without adopting as an end?

The factors can be briefly stated. Mr. A is the baby's father and he want her, as does his wife .The baby's mother does not want her. Mr. and Mrs. A are a couple in their 30s .They are devoted to each other .They are both professional people, highly qualified .They have a very nice home in the country and another in a town. Materially, they can give the baby a very good upbringing. But, for more importantly they are both excellently equipped to meet the baby's emotional needs. They are

[22] [1985]FLR846,HC(Latey j)

> most warm, caring, sensible people, as well as highly intelligent. When the time comes to answer the child's question, they will be able to do so with professional advice if they feel they need it. Looking at this child's well being, physical and emotional, who better to have her care? No one.
>
> Clearly, these two stages are often not separate in practice: the anticipated response of the law at the second stage will almost certainly have an impact on the parties' decision to risk entering into the arrangement in the first place. Nevertheless, in the conceptual terms, it is useful to look at each in turn".

In Re an adoption application (surrogacy)[23] the applicant, Mr. and Mrs. A, were unable to have children and because of their age had been refused as adoptive parents. They entered into a surrogacy arrangement with Mrs. B, who wished to help a childless couple. Under the arrangement, it was agreed that Mr. and Mar A would pay L 10,000 to Mrs. B, who would have to give up her job to have the child. In due course a child was conceived, but in the event Mrs. B, accepted L 5,000 and refused the balance. It was clear that the amount paid did not cover Mrs. B'S lose of earnings and expenses. After the birth, Mr. and Mrs. A applied to court for an adoption order. The question arose-

(i) Whether the payment of money had been a 'payment or reward for adoption' within the meaning of s 50(1) of the Adoption Act, 1958 and.

(ii) If there had been a contravention of the section, whether the court could make a retrospective authorization in respect of the aparent under s 50(3) of that Act and grant an adoption order.

It was held that a surrogacy arrangement for the conception of a child by the natural mother on behalf of others did not contravene s. 50(1) of the 1958 Act if payment made by those others to the natural mother did not include an eminent of profit or financial reward. In any event even if the payments were made for reward, the court had discretion under s 50(3) of the 1958 Act to authorize the payments retrospectively. In all the circumstances the court would exercise its discretion in favour of authorizing the payments and granting the adoption order.

Perhaps the most famous surrogacy case in the U.S. is that of "*Baby M.*"[24] In 1985, William Stern and Mary Beth Whitehead entered into a contract in which, for and in consideration of the sum of $10,000, Ms. Whitehead agreed to be inseminated with Mr. Stern's sperm, become pregnant, carry the pregnancy to term, deliver the

[23] [1987] Fam. 81

[24] In the Matter of Baby M., 537 A.2d 1227 (N.J. 1988).

child to Mr. Stern and his wife, and terminate her maternal rights. The payment was not to be made until the child was surrendered and Ms. Whitehead's rights were terminated. Initially, Ms. Whitehead complied with the contract and turned the child over to the Sterns. The next day, however, she returned and begged to have the child for one more week. The Sterns agreed, but after several unsuccessful attempts to retrieve the child for four months, they obtained a court order to get the child back. Instead of returning the child, Ms. Whitehead and her family fled to Florida. Eventually, the child was found and returned to the Sterns. Prior to this high-profile custody battle, few Americans were aware of this technology and it was relatively uncommon. Because Mary Beth Whitehead had a genetic tie to the child and was the mother as well as the surrogate, there was ambiguity surrounding the issue of whether she could be forced to give up her maternal status. She had not yet signed the adoption papers so she was technically still the legal guardian. Her name and that of her husband were listed on the birth certificate.

When Ms. Whitehead refused to sign the adoption papers and relinquish her rights as the legal mother, a custody dispute ensued that would mesmerize the nation. Whitehead had signed a surrogacy contract with William and Elizabeth Stern in February of 1985. According to this agreement, in exchange for $10,000 she would surrender the baby to Mr. Stern and relinquish all parental rights thus allowing him to be adopted by Elizabeth Stern who had no genetic tie to the child. After giving birth and seeing her daughter Mary Beth Whitehead changed her mind and decided to keep the baby whom she breastfeed for 40 days. A custody battle ensured and they went to court to fight for Sara Elizabeth, who was named Melissa Elizabeth Stern by the Stern and become known as "Baby M" by the press. This case raised a number of issues involving surrogacy, contract law, parental rights, and ultimately led to the State of New Jersey banning commercial surrogacy. An analysis of the media coverage provides insights into the way that class and power played out in the treatment of Mary Beth Whitehead. The judge granted custody to Mr. Stern but also allowed Mary Beth Whitehead to retain her material rights and gave her limited visitation privileges.

In Baby M., the New Jersey Supreme Court ruled that payment of money to a surrogate mother was illegal, perhaps criminal, and degrading to women. The court also said that paid surrogacy agreements violated the state's statutes prohibiting the use of money in connection with adoptions, requiring proof of parental unfitness or abandonment before termination of parental rights, and making surrender of custody

and consent to adoption revocable in private placement adoptions. Furthermore, the contract violated the state's public policy, namely that a child's custody should be determined by an analysis of the child's best interests; that natural parents have equal rights with regard to their child; that consent to adoption be informed, voluntary, and meaningful; and that the sale of a child pernicious. The court clearly acknowledged the respective constitutional rights of the parties- for Mr. Stern, the right to procreate, for Ms. Whitehead, the right to companionship of one's child. The court, however, made a determination that neither Mr. Stern nor Ms. Whitehead suffered a constitutional deprivation. Mr. Stern did exercise his right to procreate and voiding the surrogacy contract did not in any way interfere with the exercise of such right. With regard to Ms. Whitehead, the court found that there was no basis to terminate her parental rights. Ultimately, the court declared that both were the child's natural parents, but the child's best interests warranted the grant of custody to the Sterns and visitation rights to Ms. Whitehead.

In 1987 the New Jersey Court ruled that surrogacy contracts are unenforceable and then awarded custody of Baby M to Mr. William Stern, her biological father and his wife Elizabeth Stern while giving limited visitation rights to Mary Beth Whitehead, who remained the legal mother. Unlike today, this case occurred in a period when the gestational surrogate was also the genetic mother. Since William Stern's wife unable to carry a pregnancy to term and would not be able to bear a child to whom she had a genetic tie, and Mary Beth Whitehead already had two children, the court compromised. They supported one portion of the contract, which gave Mr. Stern custody, but they refused to allow his wife to have her name put on the birth certificate thus upholding Mary Beth Whitehead's legal status as the mother. In the decision handed down the judge wrote,

> We invalidate the surrogacy contract because it conflicts with the law and public policy of this State. While we recognize the depth of yearning of infertile couples to have their own children, we find payment of money to a "surrogate" mother illegal, perhaps criminal, and potentially degrading to women.

The aforementioned case garnered considerable media attention and prompted several states to enact laws governing surrogacy in USA. Arizona and the District of Columbia ban those laws. Washington bans contracts for compensation beyond certain expenses. Michigan and New York void surrogacy contracts and impose penalties. States that declare the contracts void will simply refuse to enforce the

agreements. If people enter into such contracts and disputes arise, they will have to sort out the disagreements on their own. In contrast, the states that ban surrogacy contracts do not allow such contracts to be made and sometimes will penalize anyone involved in making the contract. The states that allow surrogacy vary greatly in terms of whether the surrogate may receive compensation beyond necessary expenses, whether she has a period of time after the birth to change her mind about surrendering the child, whether a court must approve the agreement, and the number of requirements the parties must satisfy ranging from medical and psychological evaluations to home studies. The vast majority of statutes in the United States require the intended parents to be married, but a few do not. If the surrogate is married, the statutes invariably require that her husband consent and be a party to the agreement. The states also vary as to whether at least one of the intended parents must be genetically related to the child and whether the surrogate may use her own eggs. The majority of the states still lack any statutory guidance on surrogacy agreements. When asked to resolve surrogacy disputes, the courts have looked to statutes related to adoption, custody, paternity determinations, termination of parental rights, and "baby selling"; the federal and state constitutions; and public policy considerations.

On the other hand, California has its landmark case of *Johnson v. Calvert*[25], wherein its Supreme Court set forth what has come to be called the "intent" set when addressing surrogacy issues. In this case, Anna Johnson agreed to carry and deliver the genetic child of Mark and Crispina Calvert. However, relations turned sour during the pregnancy, and by the time the child was born the parties were already in court asserting their competing rights as parents. The court said that although the California Uniform Parentage Act did not specifically address surrogacy, it applied to any case in which parentage was in dispute. The court determined that under the Act, both women had established grounds for maternity, Anna by giving birth, and Crispina by providing genetic material but California law recognized only one natural mother for every offspring. The Court, using the "intent" test, concluded that when the roles of genetic consanguinity and giving birth do not coincide in one and the same woman, the one who intended from the outset to procreate and raise the child is the natural mother under California law. This holding effectively precludes a gestational

[25] 851 P.2d 776 (Cal. 1993).

surrogate from ever changing her mind about a surrogacy agreement. The court likewise found that the surrogacy contract in this case was not contrary to public policy because gestational surrogacy differed in crucial respects from adoption and was not subject to the adoption statutes; it did not constitute involuntary servitude; it did not treat children as commodities; and it did not exploit or dehumanize women, including those women of lower economic status. However, the court made an opinion that the better forum for resolving these questions was the legislature, and not the courts. Lastly, the court determined that, because Johnson was not the legal, natural mother, she had no constitutionally protected liberty interest based on her status as a mere "birth mother" and therefore no right to the companionship of the child. A woman who agrees to be a gestational surrogate is not exercising her own right to make procreative choices; she is agreeing to provide a necessary and profoundly important service to a couple who are exercising their right to procreate a child genetically related to them by the only available means.

In this case the courts of US have attempted to vary the definition of mother hood according to circumstances to the child's conception. The California Supreme Court was faced with two possible mothers, each seeking a declaration of maternity.

In Belsito v. Clark[26], the court found that the intent test was unworkable for a number of reasons, including the difficulty of proving the intent. It found genetics to be a much more reliable and established method for determining parentage. Therefore, the presumption in Ohio is that the genetic mother will be the legal mother. The court noted, however, that genetics should not be the exclusive test for determining parentage and that birth can be used as a secondary test. Under the birth test, the birth mother could still be found to be the legal parent if the genetic parent consented. Of course, if that is the case, it is unlikely the parties would end up in court unless there is a problem with the birth certificate. Legal scholar Dorothy Roberts of Northwestern University School of Law in Chicago, Illinois has argued that, even in Johnson, a major factor in these cases involves establishing the primacy of genetics over gestation, and she contends that a racial subtext often drives such decisions. To cite an instance, in Johnson, the surrogate was African-American, the wife was Filipina and the husband was white. The press, however, focused much more attention on the surrogate's race than on the wife's and portrayed the child as white. Roberts

[26] 644 NF 2d 760 (Ohio Com Pl 1994)

worries that gestational surrogacy doubly disadvantages economically challenged women of color who cannot afford a court battle and who are unlikely to gain custody of a white child. One set of academics has noted that surrogacy agencies intentionally select surrogates who are primarily white, Christian, and married with children in order to give the impression that the practice does not exploit low-income women, yet the majority of surrogates fall within the lower middle socioeconomic class. Most earn just above the poverty line, and percent are otherwise unemployed, receiving financial assistance, or both.

The court criticized the Jonson decision for its uncertainty in circum stances when more than one woman 'intends' to raise the child, and the court instead preferred the certainty offered by a genetic test.

In Soos v. Superior Court of Maricopa[27]

The appellate court found that an Arizona statute which specified that the gestational surrogate is the legal mother of the child violated the genetic mother's equal protection rights because there was no compelling reason to justify the dissimilar treatment of similarly situated men and women (the child's genetic father and mother).

The California Court of Appeals applied this ruling in *In re: Marriage of Buzzanca*[28], where the child was at risk of having too few parents rather than too many. In this case, a gestational surrogate carried a child created with gametes from anonymous donors for a married couple who were the intended parents. In his divorce petition, John Buzzanca had asserted that his marriage to Luanne Buzzanca had been childless. Luanne Buzzanca responded by claiming that a surrogate mother (SM) was expecting the couple's first child. Jaycee Buzzanca, who was born six days later, had been conceived using sperm and eggs from anonymous donors (let us call the sperm donor SD and the egg donor ED). The surrogate (SM) and her husband (SH) did not seek to become Jaycee's parents. The question for the court was a complex one. Out of the three plausible candidates for fatherhood (John Buzzanca, SD, SH) and the three possible mothers (Luanne Buzzanca, ED and SM), who are Jaycee's legal parents?

[27] 897 P2d 1356 (Ariz App Div 1 1994)
[28] 72 Cal. Rptr. 2d 280 (Cal. Ct. App. 1998).

When the couple divorced, the husband attempted to claim no responsibility because he was not biologically related to the child. Out rightly rejecting that position, the court held that both the husband and the wife would be deemed the legal parents because they had initiated and consented to the assisted reproduction that brought about the birth of that child. The California Court of Appeals has determined, though, that the intent test is only to be used when the birth mother and the genetic mother are different women. When a surrogate mother uses her own eggs, then she will be considered the natural and legal mother notwithstanding the intent of the parties. Because genetics and birth coincide in the same woman, there is no need to use intent to break the "tie" between two mothers, as there was in the Johnson case. Without a formal consent to adoption, the intended mother has no right to the child. In contrast, Ohio has rejected forthrightly the Johnson intent test in favor of a test that relies primarily on genetics.

At first instance, the trial judge reached the rather surprising conclusion that, despite having six possible mothers and fathers, none could be considered Jaycee's legal parents and Jaycee must be judged to be a legal orphan. This was reversed on appeal when the court held that because Mr. and Mrs. Buzzanca had jointly initiated Jaycee's conception, they were her legal parents and they were both therefore under a duty to contribute to her support. This seems sensible because John Buzzanca had deliberately instigated Jaycee's unconventional conception, and it would seem unfair for the law to allow him to shrug off any legal responsibility for the resulting child. English law might instead have initially identified the surrogate mother's husband as Jaycee's father, and thus absolved John Buzzanca of his responsibility for the life he deliberately created. Legal responsibility for Jaycee's wellbeing could have vested in a man who was not genetically related to her, and who never intended or wanted to become her father.

Briody v. st. Helens and Knowsley Area Health Authority[29] in this case the court of appeal considered whether Mrs. Briody's damages for negligent obstetric care, which had left her unable to carry a child, should in clued the costs of ferreting into a surrogacy arrangement. Initially, Mrs. Briody had intended to employ a surrogate mother in California, and the illegality of the agreement led Bosworth J. to reject her claim. Before the Court of Appeal, Mrs. Briody instead claimed for the

[29] [2001] EWCA Civ 1010, [2002] QB856

costs of entering into a lawful surrogacy arrangement in the UK. However Mrs. Briody's case was again rejected, in part because the chances of success case was 'vanishingly small' (less than 1 per cent) and the court did not think that it would be reasonable to fund a procedure with such a high chance of failure. Hale LJ. Concluded that 'expenditure on surrogacy in this case is not "reasonable "and the defendant should not be required to fund it."

In the case of *Re C (Application by Mr. and Mrs. X under s. 30 of the Human Fertilization and Embryology Act 1990)*[30] Mr. and Mrs. X had tried for over twenty years to have a baby without success. Through COTS they were introduced to a surrogate mother (SM) who agreed to undergo artificial insemination using the husband's semen, to carry any child to term and to surrender the child to the couple at birth. The couple agreed to pay the surrogate mother £12,000 to cover her expense, including a sum for loss of earnings. During the pregnancy it emerged that SM was, in fact, on income support. The sun was, nevertheless, paid and the child was duly handed over at birth. When the couple applied for a parental order section 30, it was initially refused on the grounds that the justice could not be satisfied that the sum paid related to reasonable expenses only.

The question of the identity of the child's father arose *in In Re Q (Parental Order)*[31], where the child born following a surrogacy arrangement was created using an egg from the commissioning mother and sperm from an anonymous sperm donor. Johnson J applied scc.28 of the Human Fertilization and Embryology Act. 1990 to the facts, and decided that this child did not have a legal father.

6.2.6. Frozen Embryos

Only a fistful of states in the U.S. have enacted statutes that provide for the disposition of frozen embryos. Left without statutory guidance, courts have struggled to determine whose interest shall prevail when disputes arise between couples as to the disposition of their unused embryos.

Davis v. Davis[32],

Mary sue and junior Lewis Davis were a married couple who in the course of IVF treatment allowed seven of their embryos to be cryopreserved. The couples were not asked to give advance directions on what should be done with the embryos in the

[30] [2002] EWHC 157 (Fam.), [2002] 1 FLR 909
[31] [1996] 1 FLR 369
[32] 842 S.W.2d 588 (Tenn. 1992).

event of their marriage breaking up, and when this happened subsequently he did not wish to reproduce outside wedlock and wanted the embryos destroyed. Marry Sue, for her part, initially wanted an attempt to be made to implant them in her. However, by the time the case reached the Tennessee Supreme court she had changed her mind and wanted them to be given to another infertile couple.

The Tennessee Supreme Court decided that it must first categorize the human embryo. Rejecting suggestions that embryos are either persons or property, the court found that they inhabit an interim category that entitles them to special respect because of their potential for human life. The court declared that any contract regarding the disposition of stored embryos should be presumed valid, binding, and enforceable. However, because there was no such contract in the Davis case, the court engaged in a balancing test, where it weighed the interests of the parties against each other. The court determined that the essential question was whether the parties would become parents, thereby implicating their constitutional right to privacy and the related right to procreate or to avoid procreation. Despite the increased stress and discomfort that women undergo in the process of IVF, the court found that women and men must be seen as entirely equivalent gamete providers. Moreover, unlike with the question of abortion, the case did not involve interference with a woman's bodily integrity; therefore her interests would not automatically trump the man's. The court also found that the state's interest in the potential life embodied by the embryos was at best slight and not sufficient to justify any infringement upon individuals to make their own decisions about whether to allow the IVF procedure to continue. In this case, the couple divorced and the husband wanted to prevent the embryos from being implanted. The wife initially wanted to use the embryos herself, but by the time the case reached the state Supreme Court, she wanted to donate the embryos to a childless couple. The court determined that unwanted parenthood for the husband was a greater burden than the wife's knowledge that the IVF process would be rendered futile and the embryos she helped create would never become children. The court noted, however, that it would have been a closer case had the wife wanted to use the embryos herself. In that event, the court said, an additional factor to take into consideration would be whether she could achieve parenthood by other reasonable means, like adoption. Daughtrey J said:

"To our way of thinking ,the most helpful discussion on this point is found not in the minuscule number of legal opinion that have involved frozen embryos but in the ethical standard set by the American fertility society, as follows:

Three major ethical position have been articulated in the debate over pre embryo status .At one extreme is the view of the pre-embryo as a human subject after fertilisation ,which require s that it be accorded the right of a person. This position entails an obligation to provide an opportunity for implantation to occur and tends to ban any action before transfer that might harm the pre-embryo research.

At the opposite extreme is the view that the pre-embryo has a status no different from any other human tissue. With the consent of those who have decision making authority over the pre-embryos, no limit s should be imposed on action taken with pre-embryos.

A third view-one that is most widely held –takes an intermediate position between the other two. It hold that the pre-embryo deserves respect greater than that accorded to human tissue but not the respect accorded to actual person .The pre-embryos is due greater respect than other human tissue because of its potential to become a person and because of its symbolic meaning for many people .Yet ,it should not be treated as a person , because it has not yet developed the features of personhood ,is not yet established as developmentally individual. And may never realize its biological potential. In its report, the Ethics committee then calls upon those in charge of IVF programs to establish policies in keeping with the "special respect" due pre-embryos and suggests.

Within the limited set by institutional policies, decision making authority regarding pre- embryos should reside with the person who has provided the gametes. As a matter of law, it is reasonable to assume that the gamete providers have primary decision making authority regarding pre-embryos in the absence of specific legislation on the subject. A persons liberty to procreate or to avoid procreation is directly involving pre-embryos

We conclude that pre-embryos are not, strictly speaking, either "person "or "property", but occupy an interim category that entitles them to special respect because of their potential for human life. It follow that any interest that Mary sue Davis and junior Davis have in the pre-embryos in this case is not true property interest. However, they do have an interest in the nature of ownership, to the extent that they have decision making authority concerning disposition of then pre-embryos, within the scope of policy set by law."

In the case of *Kass v. Kass*[33], the highest court of New York held that agreements between couples regarding their unused frozen embryos should be enforced unless those agreements are contrary to public policy or unless the couple's

[33] 696 N.E.2d 174 (N.Y. 1998).

circumstances have significantly changed. It further said that advance directives both minimize misunderstandings and maximize procreative liberty by reserving to the progenitors the authority to make what is in the first instance a quintessentially personal, private decision. The Supreme Courts of New Jersey and Iowa also concurred in saying that such contracts should be upheld, but subject to a large caveat: the right of either party to change his or her mind prior to the use or destruction of the embryos. This model, known as the "mutual consent" model, requires that both parties must contemporaneously agree in order for any action to be taken. According to the New Jersey court, when a couple disagrees as to the disposition of the embryos, the interests of both parties must be evaluated (effectively a balancing test). In Iowa, on the other hand, when the parties disagree, the status quo must be maintained until they can reach resolution or until the fertility clinic is no longer contractually bound to keep the embryos, with the expenses for maintaining the embryos to be shouldered by the party opposing their destruction. Although the courts have adopted a variety of tests to resolve such issues, thus far they have consistently ruled in favor of the spouse who opposes use of the embryos for procreative purposes. Massachusetts, New Jersey, and Iowa all based their reasoning in part on the fact that advance agreements to procreate or form other family relationships violate their states' public policy and are unenforceable. Tennessee, in contrast, was reluctant to announce any bright-line rule and strained to point out that its holding should not be read to provide an automatic veto to a party seeking to avoid parenthood.

In Roman v. Roman[34], the Texas Court of Appeals followed a contractual approach as well. It observed that there was an emerging majority view that written embryo agreements between embryo donors and fertility clinics to which all parties have consented are valid and enforceable so long as the parties have the opportunity to withdraw their consent to the terms of said agreement. The court also gleaned from a handful of Texas statutes that do address assisted reproduction that the public policy of the state would support this approach. What all of these courts have emphasized is that such disputes should be governed by existing statutes and that each case must be decided according to its own particular facts. On the one hand, it makes sense to require any person who contributes genetic material to an embryo with the intent to become a parent to designate, before hand, what should happen to that embryo if it is

[34] 193 S.W.3d 40 (Tex. App. 2006).

not used for its initial purpose. The process alone should help couples think through future scenarios and commit themselves to a particular course that may reduce the likelihood that a dispute will arise. To that end, further regulation may be helpful. On the other hand, it is in the clinics' best interests to have patients fill out consent forms and it is likely that they now routinely collect information about what is to be done with unused embryos, obviating the need for legislative mandates. As regards child custody disputes, fights over embryos in the U.S. can be incredibly fact sensitive. Suits of this nature will definitely benefit from legislative guidance which must reflect progressive values and will not violate or thwart constitutional protections.

6.2.7 Posthumous Reproduction

Long before the existence of ART, children have been born after the death of their biological fathers. The law, therefore, is no stranger to the need to clarify the legal status of posthumous-born children. Cryopreserved sperm and, more recently, cryopreserved embryos and eggs have created novel opportunities for conception through the use of the cryopreserved genetic material of decreased men and women by an ever-expanding group of would-be progenitors. The first legal issue involving posthumous reproduction is the issue of parentage and intestate inheritance.

A second legal issue involving posthumous reproduction has to do with access: when and under what condition surviving spouses, family, or friends may gain access to genetic material after the death of the patient who preserved it. Cases have arisen both where the decreased left explicit approval and introductions to use his or her genetic material and where no such clear directives were provided. This has raised novel issues of informed consent and public policy principles as to who should have access to the material, and what legal control or relationship-if any-the decreased should have over the material and to any resulting offspring.

A third, less common issue involves posthumous *extraction* of genetic material, and what rules and parameters should be in place-including informed consent and legal parentage-to allow surviving relatives to have sperm or eggs retrieved from the corpse of their loved one in the hope of creating a child. Unlike cases dealing with use or parentage of children resulting from cryopreserved genetic material, posthumous extraction cases typically arise under extraordinary time constraints. With the need to make immediate, consensual (one hopes) decisions, they seldom make it to a reported or appellate court decision. Instead , physicians, families, ethics boards, and lawyers are more likely to reach a decision involving some form of

consensual agreement to extract and freeze the deceased's genetic material or, on occasion, obtain an emergency court order to do so. Those agreement or orders often require a subsequent judicial authorization for the desired future use or a further use or a further agreement to release the professionals from liability in exchange for doing the family's bidding. Such cases seem to be becoming more prevalent, possibly a reflection of the increased awareness of available medical and ART options. Over the past fifteen years, at least nine courts in US have resolved issues involving children whose biological fathers died before their conception through either artificial insemination of cryopreserved sperm or implantation of cryopreserved IVF embryos.[35]

Until the advent of reproductive technologies, it was possible for a child to be born after the death of a genetic parent in only one situation -- when the father died while the child was still in utero. In a twist that seems purely science fiction, children can now not just be born but conceived after the death of one or both of their parents, sometimes years later. Frozen gametes and embryos are the main vehicle for this trend, but sperm (and one day eggs) could likewise be collected from a recently deceased body in extreme circumstances. In addition to whatever emotional fall-out may occur, this new practice has created ripples in inheritance law and posed new questions for government programs that manage Social Security and other benefits. A notorious case in the 1980s raised the issue briefly. Elsa and Mario Rios, a wealthy couple who lived in Los Angeles, had undergone IVF treatment in Australia and had two frozen embryos stored there when they died in a plane crash without a will and without any instructions as to their unused embryos. Suddenly people were faced with questions such as who gets to decide the embryos' fate and would they be entitled to inherit the money? It spurred clinics asking their patients for written indications of their wishes, but 20 years later most states in the U.S. still have not amended their laws to address this type of situation.

The issue will become more and more pressing as families begin to learn of this reproductive option. Increasingly, soldiers who are already involved in IVF programs are storing their sperm before heading off to war; concerned that they may receive wounds in combat that affect their fertility or worried they may not come home at all. Only a handful of states in the U.S. have addressed whether a child

[35]Supra note 3 at 278.

created by assisted reproduction after the death of a genetic parent shall be entitled to inherit or receive government benefits from that parent. Normally, they require the decedent to have demonstrated some intent to be a parent of a child that may be created after his or her death. For instance, in Florida, a child conceived from the gametes of a person who dies before placement of gametes or embryos in a woman's body is not eligible for a claim against the decedent's estate unless the decedent provided for such a child in his or her will. In Virginia, if a genetic parent dies before the implantation of an embryo, there are two ways he or she will be found to be a legal parent of a resulting child: if implantation occurred before notice of death could reasonably be communicated to the physician, or if that person consented in writing to being a parent prior to implantation. It should be noted though that Virginia's statute does not expressly require contemplation of posthumous implantation; it appears that general consent to assisted reproduction is sufficient. The remaining seven states that address the issue follow a provision that was originally included in the Uniform Status of Children of Assisted Conception Act and now appears as section 707 of the Uniform Parentage Act. According to that section, the deceased must have specifically consented in a record to becoming a parent through assisted reproduction that might occur after his or her death in order to be considered the legal parent of any resulting child.

In *Gillett-Netting v. Barnhart*[36], the federal government denied Social Security benefits to children conceived by IVF after their father's death because they were not his dependents at the time of his death. The Ninth Circuit, however, found that they were considered legitimate children under Arizona law. Hence, they could be deemed his dependents and did not have to demonstrate actual dependency.

Similarly, in *Stephen ex rel. Stephen v. Barnhart*, a child was conceived after his father's death and again was denied Social Security benefits because he was not a dependent child at the time of the parent's death. The District Court applied the Florida law that says a child conceived after a parent's death is not eligible for a claim against the estate unless provided for in the will. Because the child in this case was not included in his father's will, he had no claim to the Social Security benefits. The court distinguished the case from Gillett-Netting because Florida had a statute that specifically deals with posthumous fertilization while Arizona did not.

[36] 371 F.3d 595 (9th Cir. 2004)

6.2.8 ART Cases Related to Same Sex Parentage

The law's responses to the increasing use of ART produces by same-sex couples has profoundly affected, and in many respects transformed, family law. Nowhere is the interplay between existing law and the new technologies more pronounced or had a more significant impact. The law of adoption, custody, presumptions and recognition of parentage (including both donor insemination and ART statues, as well as common law presumptions), child support, conflict of laws, have all been implicated.

Long before the advent of assisted reproductive technology, lesbian women have adopted as single parents or used artificial insemination, with sperm obtained from both anonymous sperm banks and known sperm donors. Frequently, the couple's inability to undertake a co-parent adoption and/ or the lack of a biological tie for one partner left the resulting family unrecognized and unprotected in the eyes of established family law principles.

The growing acceptability of same-sex families, as exemplified in the recent and dramatic increase in the number of states recognizing same-sex marriages, is bringing sweeping changes to how family law is interpreted, applied, and in some cases simply reversed when addressing the status of same-sex families. In U.S.A. same-sex marriages have been recognized by courts in Massachusetts (2004), California (2008; subsequently reversed by referendum, with litigation ongoing); Connecticut (2008), and Iowa ((2009); by state legislatures in Vermont, Maine, and New Hampshire (2009); and by the District of Colombia for out-of-state marriages (2009). Even without legal marriage-or before it these few states-courts and legislatures have been increasingly confronted with the realities and resulting need to address the many legal issues surrounding same-sex families. In many of the cases involving parentage of children born to same-sex couples, the court have carefully attempted to glean the parties' intentions based on any existing written documents (including consent form and private agreements) and the parties' actions, pointing out the advisability of parties memorializing their true intentions at the outset. Courts have also noted that medical programs must ensure that their consent forms are current and accurate as applied to specific set of patients.[37]

[37]Supra note 3 at 305.

Male same-sex couples face additional legal issues, since they cannot physically produce eggs or carry and deliver their own child. Thus, male same-sex couples have found themselves either working with a traditional surrogate, with all of the inherent legal vulnerabilities or, more frequently, both an egg donor and a gestational carrier, at considerable additional cost and complexity. In the latter instance, although there is little appellate law, many such male couples are either obtaining pre-birth order of dual parentage or undergoing a co-parent adoption after their child's birth-or both-for the same reasons female same-sex couples do. There has been far less litigation involving custody or rights to children by same-sex male couples than female couples. This may reflect both the more recent entry into parenthood in large number by same-sex female couples and the more complex path they must take to parenthood. Since men cannot casually obtain an egg and achieve a pregnancy, as their female counterparts are able to do with sperm, informal arrangements, and the vulnerabilities they may give rise to, are less common. Unless a male couple is working with a traditional surrogate, they have likely undergone a significantly more complex series of step to achieve parenthood, including entering into formal agreements with an egg donor and gestational surrogate, with all the legal protections and counseling that forming such arrangements bring. Notwithstanding the many advances in this area, same-sex couples of both the sexes remain more vulnerable as parents than traditional, married, heterosexual couples. As a result, both courts and commentator continue to emphasize the need for informal, written records of intentions (including consent forms and legal agreement) and sound legal advice.[38]

In *Elisa B. vs. Emily B*[39], for instance, the California Supreme Court applied its state Uniform Parentage Act to find that a lesbian who consented to the insemination of her partner, welcomed the twins produced into their home, and held them out as the couple's children was a legal mother of the children. Therefore, intent and consent were sufficient to establish legal parenthood absent any biological relationship to the child.

In K.M. v. E.G[40] the companion case to Elisa B., the court again reasoned by analogy to find that genetic consanguinity can be a basis for finding maternity just as it is for finding paternity. That case involved a woman who had donated ova to her

[38] Id at 307.
[39] 117 P.3d 660 (Cal. 2005).
[40] 117 P.3d 673 (Cal. 2005).

lesbian partner, who then carried the pregnancy and gave birth. The court found that both women could establish maternity under the law because one had provided genetic material and the other had given birth. The court further found that nothing precluded a child from having two parents who both happened to be women, as long as there was no third person making a claim for parenthood.

6.3 Judicial Response in India towards Medically Assisted Reproduction

The Judiciary in India too has recognized the reproductive right of humans as a basic right. For instance, in *B. K. Parthasarthi v. Government of Andhra Pradesh*[41], the Andhra Pradesh High Court upheld "the right of reproductive autonomy" of an individual as a facet of his "right to privacy" and agreed with the decision of the US Supreme Court in *Jack T. Skinner v. State of Oklahoma*[42], which characterized the right to reproduce as "one of the basic civil rights of man". Even in *Javed v. State of Haryana*[43], though the Supreme Court upheld the two living children norm to debar a person from contesting a *Panchayati Raj* election it refrained from stating that the right to procreation is not a basic human right.

Baby Manji Yamada v. Union of India[44]

The case of Baby Manji illustrates the complexity and challenges faced by institutions in the face of emerging technologies. Gynecologist Nayna Patel is the medical director of the Akanksha Infertility Clinic. Located in the small city of Anand in the northwestern Indian state of Gujarat, Akanksha has made a name for itself as the global hub of the commercial surrogacy industry. In November 2007, Japanese couple Ikufumi and Yuki Yamada discussed with Dr. Patel their desire to hire a surrogate mother to bear a child for them. The doctor arranged a surrogacy contract with Pritiben Mehta, a married Indian woman with children. Under Dr. Patel's supervision, the clinic staff created an embryo from Ikufumi Yamada's sperm and an egg harvested from an anonymous Indian woman. They then implanted the embryo into Mehta's womb. As a hint of problems to come, the couple included a clause that the husband would care for the child in case the couple separated. According to Akanksha's standard procedure, the surrogate signed away all rights to the baby. The Yamadas then returned to Japan to await the birth of the baby. In exchange for her services, Mehta received a house worth 325,000 rupees (US $6,825), a payment of

[41] AIR 2000 A. P. 156
[42] 316 US 535
[43] (2003) 8 SCC 369
[44] 2008, 13 SCC 518

50,000 rupees (US $1,050), and 5,000 rupees (US $105) per month for living expenses while pregnant.

In June 2008, the Yamadas divorced. A month later, on July 25, 2008, Baby Manji was born to the surrogate mother. Although Ikufumi Yamada wanted to raise the child, his ex-wife, Yuki, did not. The way she saw it, she was unrelated to the baby biologically, genetically and legally. Under the terms of the agreement with the clinic, the egg donor's responsibility had ended once she provided the egg, and the surrogate's job was finished as soon as she gave birth. Suddenly, Baby Manji had three mothers, the intended mother who had contracted for the surrogacy, the egg donor, and the gestational surrogate yet legally she had none. Was she Indian? Was she Japanese? Could she have an identity and a nationality without having a mother? The surrogacy contract did not cover a situation such as this. Nor did any existing laws help to clarify the matter. In fact, no binding regulations on the surrogacy industry existed in India at all. As far as Dr. Patel was concerned, the clinic had fulfilled its promise to produce a baby. The situation soon grew into a legal and diplomatic crisis. Both the parentage and the nationality of Baby Manji were impossible to determine under existing definitions of family and citizenship in Indian and Japanese law. Yamada and his elderly mother launched a months-long campaign to secure the paperwork needed to bring the baby to Japan. The story of Baby Manji generated intense media coverage and public debate in India. It also obliged clinics like Akanksha to reexamine their purpose and practices in light of evolving beliefs around commercial surrogacy in India. When the Yamadas traveled to India to find a surrogate, they joined a growing line of hopeful infertility patients from around the world. They were the latest participants in a phenomenon known as fertility tourism, which works as follows: Patients with fertility problems go abroad to receive medical services-surrogacy, third-party gamete (egg and sperm) transfer, and in-vitro fertilization in order to have a baby.

The day after her birth, 17 explosions rocked Ahmedabad, killing 49 people and injuring over 200.22 An Indian friend of the Yamada family, Kamal Vijayvargiya, saw that Manji was moved to Arya Hospital in Jaipur, Rajasthan, 657 kilometers (408 miles) to the northeast, for her safety. Having contracted septicemia and viral infections, Manji stayed there for an extended time. Vijayvargiya's wife, Shweta, who had given birth to her own baby the day before Manji arrived, breastfed

her while she was in the hospital. Manji stayed on in the hospital once her health had improved because it was unclear who would receive custody.

At first Yamada tried to secure documents to take the baby to Japan. But the Japanese Embassy in India refused to grant Manji a Japanese passport or visa. The Japanese Civil Code recognizes as the mother only the woman who gives birth to a baby. The code does not recognize surrogate children. In this case, the woman who birthed Manji was Indian, not Japanese, which meant Manji was not entitled to a Japanese passport. Yamada's next stop was the Indian government. For a time, even though he was her genetic father, it looked as though he would have to adopt Manji. Because Indian laws don't address commercial surrogacy, the genetic parents of babies born via surrogacy are required to adopt them. Again Yamada hit a legal snag: A 120-year-old law (Guardians and Wards Act 1890) does not allow single men to adopt baby girls. When approached by the press, Dr. Patel insisted that Yamada did not need to adopt the baby, because he was the biological father. Despite this fact, Manji was not allowed to leave the hospital with Yamada. Yamada then tried to file for an Indian passport for Manji, a document that requires a birth certificate before it can be issued. According to Indian law, a birth certificate requires the names of both mother and father. Although Akanksha Infertility Clinic certified that Yamada was Manji's genetic father, the registrar was uncertain which mother should appear on the document: Yuki Yamada, Pritiben Mehta, or the anonymous egg donor. On these grounds, the Municipal Council of Anand refused to grant Manji a birth certificate and referred the case to the national level for advice. Since Yamada is not Indian, and it was unclear whether Manji's mother should be considered Indian, national offices also refused to issue a passport. It was becoming clear that Yamada and his daughter were caught between two legal systems, neither of which was prepared to handle a case like theirs. He hired noted attorney Indira Jaisingh, who took the position that Manji had the right to live with her Japanese family and should receive Japanese nationality. She filed an appeal with the Indian government to issue documents for Manji and claimed the records made clear that Yamada was her father. Two days later, on August 8, the Anand municipality issued a birth certificate to Manji Yamada. The president of the Anand City Council said, "The issue was complicated as the baby technically has three mothers…and we had no experience of issuing a birth certificate in such cases. But now the certificate has been issued stating only her father's name."

Finally the official process for the application for a travel document to Japan could proceed. In the meantime, Manji's paternal grandmother, Emiko Yamada, had traveled to India to care for Manji in the hospital because her son had returned to Japan upon the expiration of his visa. She was reported to be "very emotional" regarding the authorities' refusal to allow her son to take Manji out of India. As soon as the vital records office granted the birth certificate, she filed a petition in Rajasthan High Court for temporary custody as Manji's closest blood relative in India, until custody could be transferred to her son.

At this point, the story took an unexpected turn. In mid-August, Satya, a Jaipur-based social justice and child welfare organization, filed a habeas corpus petition with the Rajasthan High Court. The petition claimed that Manji was a victim of a "child-trafficking racket" organized by Dr. Patel through her for-profit infertility clinic. Satya alleged that Akanskha's aim was "furthering the illegal trade in infants and selling them to foreigners by taking advantage of the lack of proper surrogacy laws." The petition stated that in the absence of such laws, which would clarify who Manji's parents really are; Yamada should not be allowed to claim custody of Manji. The petition called the Yamadas' arrangement "illegitimate conception for money on a commercial basis" and sought custody of the child for Satya on the grounds that she had been abandoned. What had begun as a routine contract between a couple and a surrogate thus reached the highest court in the land. India's Supreme Court stayed the request for Manji's appearance in court, dismissed Satya's accusations that the baby had been abandoned, and granted temporary custody to her grandmother, Emiko Yamada. However, it could not so easily dismiss the larger questions Satya's petition raised about the parentage and nationality of children born via surrogacy. The court asked India's Solicitor General, G.E. Vahanvati, to appear at the next hearing to clarify India's stance on Manji's parentage and citizenship.

On September 15, the Solicitor General told the Supreme Court that the decision about Manji's passport was up to the Union government. Yamada's attorney, Jaisingh, insisted that the ICMR's voluntary guidelines intended babies born via surrogacy to be considered the legitimate children of their biological fathers.

A month later, the Rajasthan regional passport office issued Manji an identity certificate as part of a transit document, paving the way for a travel visa for Japan. It was the first such identity certificate issued by the Indian government to a surrogate child born in India. The certificate did not mention nationality, mother's name or

religion, and it was valid only for Japan, according to the passport office. On October 27, the Japanese Embassy issued the three-month-old a one-year visa on humanitarian grounds. Less than a week later, Manji Yamada and her grandmother, Emiko, flew to Osaka. Japanese authorities stated at that time that Manji could become a Japanese citizen "once a parent-child relationship has been established, either by the man recognizing his paternity or through his adopting her."

Before the Baby Manji case, public pressure in India for national comprehensive regulation of commercial surrogacy had gained some momentum. The ICMR issued National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India in 2005 in response to this pressure. At a June 2006 national consultation, leading activists, academics, researchers, healthcare professionals and attorneys working on women's health and human rights met to scrutinize the guidelines. Their review strongly criticized the voluntary nature of the guidelines, asserted that the sections on clinic accreditation and key medical procedures were inadequate, and condemned the lack of an explicit human rights framework. Public concern was building about the effects of ARTs on women's lives and the wide-ranging issues arising from new reproductive biotechnologies.

In September 2008, citing the upswing in surrogacy agreements, the potential for commercial exploitation, and the issues raised in the Baby Manji case, India's health minister, Anbumani Ramadoss, called for national surrogacy legislation. A week later, the ICMR presented a draft bill of binding national regulations and invited public comments. The bill addresses commercial surrogacy as well as other emerging reproductive technologies. Because Indian law has been silent on commercial surrogacy, the legal struggle to clarify Baby Manji's parentage and nationality that ensued remained unresolved a year after the birth. The case of Baby Manji also raised significant issues for international relations and for private-sector clinics such as Akanksha that provide surrogacy services.

The absence of law relating to surrogacy in India was raised in the case of Baby Manji before the Supreme Court of India, where it was alleged that "There is no law governing surrogation in India and in the name of surrogation lot of irregularities are being committed. According to it, in the name of surrogacy money making racket is being perpetuated. It is also the stand of the said respondent that the Union of India should enforce stringent laws relating to surrogacy." It is pointed out that though custody of the child was being asked for but there was not even an indication as to in

that's alleged illegal custody the child was. It is stated that though the petition before the High Court was styled as a "Public Interest Litigation" there was no element of public interest involved.

Indian judiciary has recognized the reproductive right of humans as their basic right and since surrogacy allows an infertile couple to exercise that right, surrogacy also gets the legal protection. In this case the Supreme Court of India has decided that commercial surrogacy is completely legal in India and held that the surrogacy contract is enforceable. First time in 2005, Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS) framed the National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproduction Technology Clinics to regulate the surrogacy, which will remain in force until the specific act comes in place.

The relevance of this case lies in it being not only the first decision relating to surrogacy made by the Apex Court but also in bringing to light the absence of regulation of the existing surrogacy industry in India. Thus, it can be said to be the direct precursor of the newly enacted Assisted Reproductive Technologies Bill, 2010 which followed the 2008 Draft Bill. The case is also relevant because it was decided under a presumption of legality of surrogacy agreements and motherhood, with the Court merely commenting on the status of such agreements. At the time, the Guidelines regulating surrogacy had been laid down by the ICMR in 2006 but did not find mention in the judgment of the Court to support its presumption of legality of surrogacy in India.

In an another important case in the Gujarat High Court *Jan Balaz v. Anand Municipality*[45], question was whether a child born in India to a surrogate mother, is an Indian national, whose biological father is a foreign national, would get citizenship in India, by birth. The fact was that Petitioner was a German national and was a biological father of two babies given birth by a surrogate mother by name - Marthaben Immanuel Khristi - a citizen of India. Petitioner's wife Susanne Anna Lohle is a German national. Due to biological reasons, the wife of the petitioner was not in a position to conceive a child. Desiring to have a child of their own, they opted for In Vitro Fertilization (IVF). ART Infertility Clinic at Anand came to their help. Investigation revealed that wife of the petitioner would not be in a position to

[45] 2010(2) ALL MR. (JOURNAL) 14

reproduce ova (eggs) as a result of which it would not be possible to conceive a child even with the help of a surrogate mother by using the sperm of the petitioner. An Indian citizen keeping anonymity volunteered to donate ova, and through a scientific process the petitioner's sperm was fertilized with the donor's ova and the fertilized embryo was implanted to the uterus of the surrogate mother. Petitioner and his wife had entered into a surrogacy agreement with the second respondent - surrogate mother. After full discussion with Dr. Nayanaben Patel of the Clinic, surrogate mother was made known about the method of treatment. She had also agreed to hand over the child to the petitioner and his wife on delivery. Further surrogate mother had also agreed that she would not take any responsibility about the well being of the child and the biological parents would have legal obligation to accept their child and that surrogate mother would the child deliver and the child would have all inheritance facts of a child of biological parents as per the prevailing law. Surrogate mother gave birth to two baby boys on 4.1.2008. Petitioner then applied for registration of the birth of the children in the prescribed form to Anand Nagar Palika. Anand Nagar Palika issued a certificate of birth to the children as per the provisions of Registration of Birth and Deaths Act, 1969. Earlier date of birth was shown as 14.1.2008, which was later corrected as 4.1.2008 and the name of the petitioner's wife who was shown as the mother of the babies, was replaced with the name of Marthaben Immanuel Khristi. Petitioner and his wife, though German nationals, are working in United Kingdom, stated that they are desirous of settling down in U.K. and for the said purpose they have to obtain VISA from the Consulate of the United Kingdom in India. Since babies were born in India and are Indian citizens, petitioner applied for their Passport in India showing their names as "Balaz Nikolas" and "Balaz Leonard". Petitioner's name was shown as the father and surrogate mother's name was shown as the mother. Applications were entertained by the Passport Authorities and Passport No. G-8229646 and Passport No. G-8229647 respectively was issued in the name of above mentioned babies. Later, petitioner received an intimation-cum-notice issued by the Government of India, Ministry of External Affairs, Regional Passport Office, vide letter dated 6.5.2008 to surrender both the passport.

Petitioner, on the basis of the direction of the Court on 13.5.2008, surrendered both the Passports on 14.5.2009 before the Passport Authority at Ahmedabad. Petitioner then seeks a direction to the Regional Passport Officer to return those Passports so that he could take the babies to Germany and then made an application in

Germany so as to acquire German Citizenship. Petitioner submitted that surrogacy was not recognized in Germany. Even the Immigration Office at Siberia was also insisting production of the Passport and not Certificates of Identity issued by the Passport Office, Ahmedabad. Petitioner submitted that since babies are born in India and are citizens of India, Germany would not recognize them as its citizens. Denial of Passports, according to the petitioner, is illegal and violative of Article 21 of the Constitution of India. Detailed counter affidavit has been filed on behalf of the Regional Passport Officer at Ahmedabad on 25.3.2008 and 4.11.2009, stating that surrogate mother cannot be treated as mother of the babies, and children born out of surrogacy, though in India, cannot be treated as Indian citizens within the meaning of Section 3 of the Citizenship Act, 1955. Further it was also stated that parents of the children are not Indian citizens and therefore, children are also not Indian citizens as per Section 3(1) (b) of Citizenship Act, 1955. Further it was also stated that as per Passport Act, 1967, only Indian citizens can apply for Indian Passport and as per Section 6(2) (a) of the Act, Passport cannot be issued to non-citizens. Further it was also stated that as per direction of the Government of India, Ministry of External Affairs, Passport Authority can issue identity certificate, showing name of surrogate mother, which does not entail citizenship to the children but would enable him to take his children out of India. Further, it was also pointed out that the Central Government is yet to legalize surrogacy and hence, children born out of surrogacy, though in India, cannot be treated as Indian citizens.

The petitioner had submitted that since both the children were born in India, they are Indian citizens by birth as per Section 3 of the Citizenship Act, 1955 and therefore, entitled to have all the rights of Indian citizens and the Passport Authorities were legally obliged to issue Passports to them under the Indian Passports Act, 1967. Learned Counsel had also submitted that surrogacy is not prohibited in India and admittedly, children are born in India to a surrogate mother who herself is an Indian citizen. Learned Counsel had further submitted that petitioner and his wife were German citizens but as the children are not born in Germany, they would not get German citizenship, especially when German law does not recognize surrogacy. Learned Counsel had further submitted that for the purpose of obtaining VISA from the Consulate of United Kingdom, it is necessary that children should have an Indian Passport since they are born in India and not in Germany.

The court further observed that there arise a lot of legal, moral and ethical issues for the consideration in this case, which have no precedents in this country. The court was primarily concerned with the rights of two new born innocent babies, much more than the rights of the biological parents, surrogate mother, or the donor of the ova. Emotional and legal relationship of the babies with the surrogate mother and the donor of the ova were also of vital importance. Surrogate mother was not the genetic mother or biologically related to the baby, but, was she merely a host of an embryo or a gestational carrier? What was the status of the ova (egg) donor, which in this case an Indian national but anonymous. Was the ova donor, the real mother or the gestational surrogate? Are the babies motherless, can we brand them as legal orphans or Stateless babies? So many ethical and legal questions had come up for consideration in this case for which there were no clear answers, so far, at least, in this country. True, babies conceived through surrogacy, encounter a lot of legal complications on parentage issues, this case reveals. Legitimacy of the babies is therefore a live issue. Can we brand them as illegitimate babies disowned by the world? Further, a host of scientific materials are made available to us to explain what is traditional surrogacy, gestational surrogacy, altruistic surrogacy, commercial surrogacy etc. and also the response of various countries with regard to the surrogacy, especially commercial surrogacy.

The court observed that in India there is no law prohibiting artificial insemination, egg donation, lending a womb or surrogacy agreements. No civil or criminal penalties are also imposed. Public pressure, for a comprehensive legislation defining the rights of a child born out of surrogacy agreement, rights and responsibilities of a surrogate mother, egg donor, commissioning parties, legal validity of the surrogacy agreement, the parent child relationship, responsibilities of Infertility Clinic etc. are gaining momentum. Legislature will have to address a lot of emotional, legal and ethical issues. Question as to whether surrogacy can be seen as a ray of hope to otherwise a childless couple, so as to build up a family of their own, necessary for human happiness and social stability also calls for attention. Few are the case laws and precedents defining the rights of those who have a vital role to play in this reproductive technology. One case law worth mentioning in India is Baby Manji' s case decided by the apex Court of India MANU/SC/8083/2008 : (2008) 13 SCC 518. Various issues which have been highlighted in this case were not discussed or answered in that case. That was a case where the Japanese Embassy in India refused

to grant the child, born to surrogate Indian mother, VISA or Passport on the ground that the Japanese Civil Code recognizes a mother only to be a woman who gives birth to a baby. Attempts made to adopt Manji also did not fructify since Guardian Wards Act, 1890 did not allow single man to adopt those babies. Efforts were made to obtain Indian Passport, which also required a birth certificate. Question arose as to who was the real mother whether it was anonymous egg donor or the surrogate mother. Birth certificate was then issued by the local Municipality, by showing the father's name. Later the Regional Passport Office, Rajasthan issued a certificate of identity as part of a transit document and not the Passport. Certificate did not contain nationality, mother's name or religion of the baby.

The case was primarily concerned with the relationship of the child with the gestational surrogate mother, and with the donor of the ova. In the absence of any legislation to the contrary, the court was more inclined to recognize the gestational surrogate who has given birth to the child as the natural mother, a view prevailing in Japan. Anonymous Indian woman, the egg donor, is not the natural mother. She has of course a right to privacy that forms part of right to life and liberty guaranteed under Article 21 of the Constitution of India. Nobody can compel her to disclose her identity. Babies born were not in a position to know who the egg donor is and they only know their surrogate mother who is real. Wife, of the biological father, who has neither donated the ova, nor conceived or delivered the babies, cannot in the absence of legislation be treated as a legal mother and she can never be a natural mother. By providing ova, a woman will not become a natural mother. Life takes place not in her womb, nor does she receive the sperm for fertilization. Human fertilization is the union of a human sperm and egg usually occurring in the ampulla of the urine tube. Process involves development of an embryo. In Vitro Fertilization process was followed in this case, a process by which egg cells were fertilized by sperm outside the womb in vitro. Resultantly, the only conclusion that is possible is that a gestational mother who has blood relations with the child more deserves to be called as the natural mother. She has carried the embryo for full 10 months in her womb, nurtured the babies through the umbilical cord. Even if it is assumed that the egg donor was the real natural mother, even then she was an Indian national. Both the egg donor as well as the gestational surrogate was Indian nationals, and hence the babies were born to an Indian national.

The court observed that a comprehensive legislation dealing with all these issues is very imminent to meet the present situation created by the reproductive science and technology which have no clear answers in the existing legal system in this country. The court will pave way for a sound and secure legislation to deal with a situation created by the reproductive science and technology. Legislature has to address lot of issues like rights of the children born out of the surrogate mother, legal, moral, ethical. Rights, duties and obligations of the donor, gestational surrogate and host of other issues.

Further, the court observed that under the Indian Evidence Act, no presumption can be drawn that child born out of a surrogate mother, is the legitimate child of the commissioning parents, so as to have a legal right to parental support, inheritance and other privileges of a child born to a couple through their sexual intercourse. The only remedy is a proper Legislation drawing such a presumption including adoption. Further the question as to whether the babies born out of a surrogate mother have any right of residence in or citizenship by birth or mere State orphanage and whether they acquire only the nationality or the biological father has to be addressed by the legislature.

The court further observed that Indian Council of Medical Research (ICMR) has issued certain guidelines on surrogacy and Assisted Reproductive Technology (ART) in 2005. The new Bill ART (Regulation) Bill and Rules, 2008 is yet to become law, and there is extreme urgency to push through the legislation answering all these issues.

Hon. Chief Justice Mr. K.S.Radhakrishnan stated:

> "Commercial surrogacy is never considered to be illegal in India and few of the countries like Ukraine, California in the United States. Law Commission of India in it's 220th Report on Need for Legislation to regulate Assisted Reproductive Technology Clinics as well as rights and obligations of parents to a surrogacy has opined that surrogacy agreement will continue to be governed by contract among parties, which will contain all terms requiring consent of surrogate mother to bear the child, agreement of a husband and other family members for the same, medical procedures of artificial insemination, reimbursement of all reasonable expenses for carrying the child to full term, willingness to hand over a child to a commissioning parents etc. Law Commission has also recommended that legislation itself should recognize a surrogate child to be the legitimate child of the commissioning parents without there being any need for adoption or even declaration of guardian. Further it was also suggested that birth certificate of surrogate child should contain names of

> the commissioning parents only and that the right to privacy of the donor as well as surrogate mother should be protected. Exploitation of women through surrogacy was also a worrying factor, which is to be taken care of through legislation."

The court held that the babies born in India to the gestational surrogate are citizens of this country and therefore, entitled to get the Passports and therefore direct the Passport Authorities to release the Passports withdrawn from them forthwith.

The controversy stretched out for two years, with Mr. Balaz remaining in India, unable to receive a passport for his surrogate children.234 The Supreme Court of India heard the case in the winter of 2009, but before the court rendered its judgment, India's Central Adoption Resources Agency granted a German visa and permitting their residence in Germany. Following the case, the presiding Justices declared that no other child should have to undergo the same trials as the Balaz family. As a singular exception, the Balaz ruling did not have a profound legal effect, but it will be remembered as a cautionary tale of surrogacy gone wrong.[46]

K .Kalaiselvi vs Chennai Port Trust[47]

The question that arose for consideration in this writ petition was whether a woman employee working in the Chennai Port Trust is entitled to avail maternity leave even in case where she gets the child through arrangement by Surrogate parents. The petitioner was working as an Assistant Superintendent in the Traffic department of the Chennai Port Trust. She had put in 24 years of service. She is married. Her son (Shyam Sundar) aged 20 years died due to road accident on 31.01.2009. After his birth, the petitioner has removed her uterus due to some problem on 30.04.2008. Therefore, she in order to have a child had entered into an arrangement with Prashanth Multispeciality hospital, Chennai to have a baby through surrogate procedure. Finally with the consent of her husband and his cooperation, a female baby was born on 08.02.2011 through a host mother. She had incurred substantial expenditure towards treatment. In order to look after the newly born baby, she had applied for maternity leave. But she was informed that she was not entitled for maternity leave (post delivery) for having a child through surrogate procedure though such a rejection was not possible in case of a person adopting a child. The petitioner, therefore, requested for sanction of maternity leave to look after the newly born girl

[46] Sarah Mortazavi, "It Takes a Village To Make a Child: Creating Guidelines for International Surrogacy", available at *http://georgetownlawjournal.org/files/2012/08/14Mortazavi.pdf* visited on 6 December 2012.

[47] Judgment delivered on 04.03.2013, high court of Madras.

child and reimburse the medical expenses and also to issue the FMI Card incorporating the newly born child through her representation, dated 17.6.2011. She sent a reminder on 13.8.2011. However, by proceedings, dated 22.11.2011, she was informed that the Chairman of the Port Trust had granted her two months period leave as a special case, which will be treated as an eligible leave. But the leave granted on 17.9.2011 for a period of 59 days from 08.02.2011 to 07.04.2011 vide medical certificate dated 17.09.2011 was subsequently cancelled. Her request for inclusion of the female child in the FMI card was also rejected. She was informed by a letter dated 05.12.2011 that inclusion of her daughter name G.K.Sharanya in the FMI Card does not arise. The petitioner produced before the respondent Port Trust all documents relating to surrogate arrangement, hospital expenditures incurred by her as well as the birth certificate given by the Corporation of Chennai evidencing that the female child was born on 08.02.2011. The name of the parents is described as the petitioner being the mother and her husband as her father.

The court pointed out that in our Country getting a child through surrogate procedure is at a nascent stage. There are no rules or guidelines available. There are no provision in the Chennai Port Trust (Leave) Regulations, 1987 granting maternity leave to an employee who underwent surrogate procedure. No inspiration can be drawn from the Maternity Benefit Act, 1961. Apart from referring to the practice in the Australia where surrogacy was never treated as legal and in U.K., where surrogacy arrangement was legal, but advertising and other aspects of commercial surrogacy was prohibited under the Surrogacy Arrangements Act, 1985.

The court held that this court do not find anything immoral and unethical about the petitioner having obtained a child through surrogate arrangement. For all practical purpose, the petitioner is the mother of the girl child G. K. Sharanya and her husband is the father of the said child. When once it is admitted that the said minor child is the daughter of the petitioner and at the time of the application, she was only one day old, she is entitled for leave akin to persons who are granted leave in terms of Rule 3-A of the Leave Regulations. The purpose of the said rule is for proper bonding between the child and parents. Even in the case of adoption, the adoptive mother does not give birth to the child, but yet the necessity of bonding of the mother with the adoptive child has been recognised by the Central Government. Therefore, the petitioner is entitled for leave in terms of Rule 3-A. Any other interpretation will do violence to various international obligations referred to by the learned counsel for the

petitioner. Further, it is unnecessary to rely upon the provisions of the Maternity Benefit Act for the purpose of grant of leave, since that act deals with actual child birth and it is mother centric. The Act do not deal with leave for taking care of the child beyond 6 weeks, i.e., the post natal period. The right for child care leave has to be found elsewhere. However, this court is inclined to interpret Rule 3-A of the Madras Port Trust (Leave) Regulations, 1987 also to include a person who obtain child through surrogate arrangement.

The court directed Chennai Port Trust to grant leave to the petitioner in terms of Rule 3-A recognising the child obtained surrogate procedure. Further a direction was issued to the respondent to include the name of the child G. K. Sharanya, as a member of the petitioner's family and also include her name in the FMI card forthwith.

In another separate case, Israeli gay couple Yonatan and Omer Gher became parents in India on October 12, 2008, when their child was conceived with the help of a Mumbai based surrogate mother in a fertility clinic in Bandra. It is reported that a 3.8 kilo baby boy was born to them at Hiranandani Hospital in Powai (Mumbai) on October 12, 2008. Reportedly, Yonatan and Omer had been together for the past seven years and had decided to start a family. But since Israel reportedly does not allow same sex couples to adopt or have a surrogate child, India became their choice to find a surrogate mother. Yonatan and Omer reportedly first came to Mumbai in January 2008 for an IVF cycle when Yonatan is stated to have donated his sperm. Thereafter, they selected an anonymous "mother". Accordingly, the child was conceived with the help of a Mumbai based surrogate mother in a fertility clinic in Bandra. After the child was born, the gay couple left for Israel with the child on November 17, 2008. Even though homosexuality is an "Unnatural Offence" under Section 377 of the Indian Penal Code as Indian law criminalizes homosexuality, there is no bar to gay couples hiring a surrogate mother to deliver children for gay couples in India. Thus, there are reports in the media that there are numerous gay couples coming to India to look for surrogate mothers as India does not disallow such surrogacy arrangements.

Amy Antoinette Mcgregor & Anr vs Directorate Of Family Welfare[48]

[48] W.P.(C)6332/2013

The writ petition was filed by the couple, residents of Sydney, Australia. The fact of the case was that due to some medical problem the wife cannot physically conceive a child. After medical examination by best doctors and taking medical advice, they found that the cause is some 'Lupus'and it is an Immuno-Suppressive Stipulation which does not physically and practically allow the embryos of the mother to thrive and properly flourish in her body. The doctors therefore advised her to proceed with a Gestational Surrogacy. It is a procedure by which one woman, the surrogate mother, carries a fertilized donor egg or embryo for the wife. It basically involves In-Vitro Fertilization (IVF), which involves mixing of eggs and sperms outside the uterus, followed by implanting the fertilized eggs into the uterus, where the embryo will grow and develop into a baby. This is available, apart from India, in only two countries, i.e., Thailand and America, throughout the world, which offer an assured and medically secure IVF process. For a long time, the petitioners had a desire to have a child but because of the medical problem they could not conceive. Now they thought of using the above technique to get a child. However, for the sake of family balancing they intend to have one girl child and one boy child and for this purpose, in the surrogacy procedure for the petitioners, the prenatal techniques play an essential and important role. According to the petitioners, though they want a child, yet they do not want two children of the same sex in view of their principle of balanced family and accordingly they want to control the birth of same sex by using the advanced prenatal techniques.

The petitioners made an application to directorate of family welfare, government of Delhi, seeking to forward it to the concerned department and in that application they made a request that the provisions of The Pre- Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 cannot be made applicable to them and it is also further stated that couples who have no children and wish to have a male or female children should be allowed to make use of the pre-natal diagnostic techniques to have a child of both sex to balance their family. So these couples cannot be treated at par with the couples, who choose the sex of foetus in order to have a male child leading to imbalance in male to female ratio.

The court observed that the assumption of the petitioners that it was possible to identify the gender of the foetus before impregnation, has no basis in the science of genetics or any established principle of sexual reproduction currently. It was not contended that the legislation is beyond the authorized legislative field of the

Parliament. The singular ground of challenge was that the legislation is arbitrary and does not accommodate the 'exceptional category' of the petitioners who desire to have a balanced family comprising a male and a female child, a challenge which in substance means that the Act is unsustainable for the vice of unreasonable classification. The court held that the challenge to the provisions of the Act on the ground of hostile discrimination and unreasonable classification was misconceived.

In an another recent case, a Sudanese national had filed a petition at the Punjab and Haryana High court, contending that foreign nationals cannot be discriminated against in matters of surrogacy against Indians. The High Court chose to dismiss this petition, upholding and in consonance with the Ministry of Home Affairs guidelines.[49] The Court held that since the position of law regarding rights of foreign nationals for surrogacy was not yet finalised in the form of a legislation, deciding upon a case concerning the same would not be correct. The emphasis in this particular case is on a foreign national, who is single and seeking to have a child through surrogacy.

In a recent case, a bench comprising of Revati Mohite Dhere, J. dismissed a petition filed by a social activist against a lower court order which had restricted her from accessing the records and other documents of the baby born through surrogacy. In the present case, the activist had sought prosecution of the actor Sharuk Khan, his wife and their doctors on the basis of a news report in a city newspaper in June 2013 which claimed that the star couple were having a baby boy through surrogacy. She alleged the doctors had allegedly violated the provisions of PC-PNDT Act, 1994 that prohibits sex determination of a fetus. The Trial Court had rejected her application under Section 28(3) of the PC-PNDT Act seeking directions to the local Municipal Corporation to produce all records of the surrogate mother and test conducted on her in order to support her case. The Court discussed Section 28(3) in light of the objective of the legislation, right to privacy of the stakeholders in cases of surrogacy and the scope of the word 'may' used in Section 28(3) indicating discretion given to the Court to direct the Appropriate Authority to handover the documents or not. Mr. Uday Warunjikar, the counsel for the Petitioner contended that the word ‘may’ as it appears in Section 28(3) of the PCPNDTAct should be read as 'shall'.Mr Pranav

[49] *Shihabeldin v Union of India and Ors*. CWP–15490/2013

Badheka appearing for respondents Shahrukh Khan and Gauri Khan, submitted that if the word 'may' is read as 'shall', it would be a mechanical order, leaving no discretion whatsoever, in the Magistrate and would thereby violate the right to privacy of the parties involved in the surrogacy. The Court after listening to all arguments including Senior Counsel MPS Rao, held that it was for the Magistrate to consider whether the demand of documents/records from the Appropriate Authority is genuine, bonafide etc and declined to interfere with the magistrate's order.[50]

6.4. Conclusion

To conclude, I can say that the courts are confronting with many issues and challenges in ART cases. Reproduction laws, which previously focused on contraception, conception and termination of pregnancy related matters now facing the challenges to determine motherhood, gestation, parentage, legitimacy, intention and consent related issues generated from use of new technologies of IVF, cryopreservation and stem cell preservation. The revolution in reproductive sciences has transformed the existing legal principles of family, contract and liability. So there arise various ethical, moral, social and other issues surrounding the use of ART. All these issues need to be seriously debated worldwide. The proposals and suggestions coming out of these debates need to be considered for policy formulation, so to regulate the use of ART and prevent its misuse through the hands of miscreant people.

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[50] *Varsha Laxman Deshpande vs. Municipal Commissioner, Criminal Writ Petition No. 4164 of 2013*, decided on June 19, 2014]

Chapter-VII

Chapter-VII

Conclusion and Suggestions

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 frame, address and resolve some of the most pressing challenges.

Chapter first, as usual consists the introduction of topic, its relevancy and importance and methodology used in study and the scheme of the study.

Chapter second, titled "Conceptual framework of Infertility and Assisted Reproductive Technology" contains the meaning of infertility, its various definitions given under different international instruments and by scholars. The various causes of infertility, its consequences and the role of ART in order to remove infertility have also been discussed. 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. In this chapter social implication of infertility has also been discussed such as isolation, denial of social status, contempt and abandonment. These are the byproduct of patriarchal society where motherhood is treated as essential part of being a women. 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 hand 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. The chapter shows that ART does not only provide a treatment of infertility to the women at large but also provide her a social recognition in the society.

Chapter third, with the title "Regulation of Assisted Reproductive Technology in India" highlighted the serious issue related to lack of legal regulation in the area of

ART. It has also been discussed that due to lack of regulation now ART has been used as a tool of exploitation by medical professionals. In this chapter 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. In this chapter the draft *Assisted Reproductive Technology (regulation) Bill and Rules 2010* (draft ART Bill) has also been examined and analyzed with the objective to highlight the loop holes and weaknesses of the Bill.

It is also found that fertility treatment confined primarily to the private sector and tertiary public sector institutions accessible to a select few. The basic health care system 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 chapter 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 issues of fundamental importance. A revision or reformation 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 in this chapter. It has been found that it is also full of lacunae, inconsistency and ambiguities. 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 places and also left certain critical questions unanswered, like 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. It has also shown in the chapter that 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 a transnational 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 of this chapter 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 chapter fourth, titled "Laws in Different Countries Relating to Assisted Reproductive Technology" is a comparative study of the laws and policies in different

countries. 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 bans to control access to it. The study also 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 regulate international adoption and resolve the issue of nationality of the children born out of surrogacy.

The fifth chapter titled "Ethical–Moral and other Issues in Assisted Reproductive Technology" contains the discussion on other issues like social, moral, ethical, health and religious issues. These issues are attached with the topic of research in such a way that the research cannot be completed without examining these issues. The study reveals that the social ethical and religious norms should not be overlooked by undergoing the fertility 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 in the chapter 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 in the chapter 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 (altruistic).

The sixth chapter titled "Judicial Response and Assisted Reproductive Technology" wherein the decided cases relating to ART has been discussed and

analyzed. The output of the study is that the cases 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 of the chapter shows that the judiciary has played dynamic role while resolving ART related issues. The courts have also touched the issues like limitation on number of embryo transferred, fetal reduction in the case of multiple pregnancy, the 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.[1] Recently, the Madras high court has extended the benefit of maternity leave to genetic mother in the matter of child born through surrogate baby.[2]

The last chapter titled "Conclusion and Suggestions" deals with summary of the study and detailed suggestions has been put forth for the regulation of assisted human reproduction. The conclusion of each chapter has already been discussed above. 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.
- 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

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

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

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.[3] 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 person 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.

[3] 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.

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Bibliography

BOOKS:

Arnold J. Rosoff. *Informed Consent*, (2004, London, aspen publication). .

Andrews, Lori. Between *Strangers: Surrogate Mothers, Expectant Fathers, and Brave New Babies*, (1989, New York, Harper & Row).

Brendan, Greene. *Understanding Medical Law*, (2006, Candevish Publishing Limited).

Bennett, Belinda. *Health Law's Kaleidoscope: Health Law Rights in a Global Age*, (2008, Sidney, Ashgate Publishing)

Bickerstaff, Linda. *Technology and Infertility: Assisted Reproduction and Modern Society*, (2009, New York, Rosen Publishing).

Curran, J. William. *Law and Medicine: Text and Source Materials on Medico-Legal Problems, Law School Casebook Series*, (1960, Little, Brown).

Cahn, R. Naomi. *Test Tube Families: Why the Fertility Market Needs Legal Regulation, (*2009, New York and London, New York University Press).

Corea, Gena. *The Mother Machine: Reproductive Technologies from Artificial Insemination to Artificial Womb*, (1985, New York, Harper & Row).

Chesler, Phyllis,. *Sacred Bond,* (1988, New York, Times Books,).

Dickenson, Donna. *Ethical Issues in Maternal-Fetal Medicine*, (2002, Cambridge University Press).

Davies, Michael. *Textbook on Medical Law*, (1998, New York and London, Oxford University Press).

Erickson, M. Theresa. *Surrogacy and Embryo, Sperm, & Egg Donation: What Were You Thinking?: Considering IVF & Third-Party Reproduction*, (2010, Bloomington, I Universe).

Franklin, Sarah. *Embodied Progress: A Cultural Account of Assisted Conception*, (1997, London, Routledge).

Fishel S. and Symonds, E.M. (ed.). *In vitro Fertilisation: Past-Present- Future*, (1986, England, IRL Press).

Field, A. Martha. *Surrogate Motherhood: the Legal and Human Issues*, (1990, Harvard University Press).

Greene, Brendan. *Understanding Medical Law,* (2005, Great Britain, Cavendish Publishing Ltd).

Hope, R. A. Julian Savulescu, Judith Hendrick. *Medical Ethics and Law: The Core Curriculum,* (2003,London New York, Elsevier Limited).

Horsey, Kirsty and Biggs, Hazel (ed.). *Human Fertilization and Embryology: Reproducing Regulation.* (2007, New York, Routledge-Cavendish).

Herring, Jonathan. *Medical Law and Ethics*, (2006, New York, Oxford University Press).

Hull, T. Richard (ed.). *Ethical Issues in the New Reproductive Technologies*, (1990, New York, Wadsworth Pub. Co.).

Harris, John and Soren Holm. The Future of Human Reproduction, (1998, New York, Clarendon Press).

Ian R. Freckelton. *Disputes and Dilemmas in Health Law*, (2006, Annandale NSW, Federation Press).

Inhorn, C. Marcia. *Reproductive Disruptions: Gender, Technology, and Biopolitics in the New Millennium*: *Volume 11 of Fertility, Reproduction and Sexuality*, (2008, oxford, Berghahn Books).

Inhorn, Claire, Marcia, and Balen, Frank, Van. *Infertility Around the Globe: New Thinking on Childlessness, Gender, and Reproductive Technologies,* (2002, Berkeley/Loss Angeles, University of California Press).

Jackson, Emily. *Medical Law: Text, Cases and Materials*, (2010, New York, Oxford University Press).

Kelly, L. *Globalization and Health – An Introduction*, (2003, Pal grave, Macmillan Publication).

Kuhse, Helga. Singer, Peter. *Bioethics: An Anthology*, (2006, Oxford and Malden, Wiley-Blackwell).

Kirsty, Horsey. *Human Fertilization and Embryology: Reproducing Regulation*, (2006, Cavendish, Routledge).

Lorber, J. *Gender Inequality: Feminist Theories and Politics*, (2001, Los Angeles, Roxbury, second Edition).

Larry, Gostin (ed.). *Surrogate Motherhood: Politics and Privacy*, (1990, Indiana University Press).

Malhotra, Anil and Malhotra, Ranjit, *Surrogacy in India: A Law in Making*, (2013, New Delhi, Universal Law Publishing Company)

Montgomery, Jonathan. *Health Care Law*, (2003, New York, Oxford University Press).

Morris, E. Anne & Jones, A. Michael. *Blackstone's Statute on Medical Law*, (2007, Oxford, Oxford University Press).

Mc Hale, Jean and Fox, Marie. *Health Care Law: Text and Material*, (2007, London, Sweet and Maxwell Limited).

Menikoff, Jerry. *Law and Bioethics: An Introduction,* (2001, Washington D.C., Georgetown University Press).

Mataré, Herbert, Franz. *Bioethics: The Ethics of Evolution and Genetic Interference*, (1990, Westport CT, Greenwood Publishing Group).

Maher, Janemaree. *The Globalization of Motherhood: Deconstructions and Reconstructions of Biology and Care,* (2009, New York, Taylor & Francis).

Merino, Faith, Quiroz Pamela Anne. *Adoption and Surrogate Pregnancy: Global Issues*, (2010, New York, Infobase Publishing).

Mundy, Linda. *Everything Conceivaable: How Assisted Reproduction is Changing Our World,* (2007, New York, Anchor Books).

Melvin L. Taymor, *Infertility: A Clinician's Guide to Diagnosis and Treatment,* (1990, New York, Plenum Medical Book Company).

Markens, Susan. *Surrogate Motherhood and the Politics of Reproduction*, (2007, Berkeley/Loss Angeles/London, University of California Press).

M. Stauch, K. Wheat and J. Tingle. *Text, Cases and Materials on Medical law*, (2005, London, Routledge Cavendish).

Mahowald, B. M. *Women and Children in Health Care: An Unequal Majority*, (1993, New York, Oxford University Press).

Plomar, Auarora. *The Law and Ethics of Medical Research: International Bioethics and Human Rights,* (2005, London, Candevish Publishing Limited).

Qadeer, Imrana. *New Reproductive Technologies and Health Care in Neo-Liberal India: Essays* (2010, New Delhi, Centre for Women's Development Studies).

Shlomo, Mashiach and Zion Ben-Rafael. *Advances in Assisted Reproductive Technologies*, (1990, New York, Plenum Press).

Shannon, Anthony, Thomas. *Reproductive Technologies: A Reader: Readings in Bioethics*, (2004, Maryland, Rowman & Littlefield).

Srinivasan, Sandhya(ed.*). Making Babies: Birth Markets and Assisted Reproductive Technologies in India,* (2010, New Delhi, Zubaan).

Sanger, Alexander. *Beyond Choice: Reproductive Freedom in the 21st Century*, (2004, New York, Public Affairs).

Selvaraj, Kamala. *The Wonder of Motherhood*, (2006, Chennai, Associated Printers (Madras) Private Ltd.).

Sher, Geoffrey, Davis, Marrage, Virginia, Stoess, Jean. *In Vitro Fertlization: The A.R.T. of Making Babies*, (2005, New York, Checkmark Books).

Speroff, Leon & Fritz, A. Marc. *Clinical Gynecologic Endocrinology and Infertility*, (2005, Philadelphia, Lippincott Williams & Wilkins.).

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

Susan L. Crockin, J.D and Howard W. Jones, JR., M. D. *Legal Conceptions, The Evolution Law and Policy of Assisted Reproductive Technologies, (*2009, Baltimore, The Johns Hopkins University Press).

Stauch, Marc & Wheat, Key with Tingle, John. *Text, Cases & Materials on Medical Law,* (2006, New York, Rout ledge Cavendish).

Schwartz, Lita Linger. *Alternative to Infertility: Is surrogacy the Answer,* (1991, Brunner/Mazel, inc).

Theresa, M, Ericson. *Surrogacy and Embryo, Sperm and Egg Donation: What Were You Thinking,* (2010, Bloomington, I Universe).

Twine, France Winddace. *Outsourcing the Womb: Race, Class and Gestational Surrogacy in a Global Market*, (2011, New York, Routledge).

Weisberg , D. Kelly. *The Birth of Surrogacy in Israel*, (2005, Gainesville, University Press of Florida).

ARTICLES:

Appleton, Frelich, Susan. "The Abortion-Funding Cases and Population Control: An Imaginary Lawsuit (And Some Reflections on the Uncertain Limits of Reproductive Privacy)", *Michigan Law Review*, Vol. 77, No. 7, Symposium on the Law and Politics of Abortion (Aug., 1979), pp. 1688-1723.

Allahbadia, N. Gautam and Kaur, Kulvinder. "Accreditation, Supervision, and Regulation of ART Clinics in India—A Distant Dream?", *Journal of Assisted Reproduction and Genetics, Vol. 20, No. 7, July 2003*

Andrews, B. Lori. "Beyond Doctrinal Boundaries: A Legal Framework for Surrogate Motherhood", *Virginia Law Review*, Vol. 81, No. 8, Symposium: New Directions in Family Law (Nov., 1995), pp. 2343-2375.

Anleu, Roach L. Sharyn. "Critiquing the Law: Themes and Dilemmas in Anglo-American Feminist Legal Theory", *Journal of Law and Society*, Vol. 19, No. 4 (Winter, 1992), pp. 423-440.

Burton, J. Steven. "New Stresses on the Antarctic Treaty: Toward International Legal Institutions Governing Antarctic Resources", *Virginia Law Review*, Vol. 65, No. 3 (Apr., 1979), pp. 421-512.

Bradley, David. "Children, Family, and the State in Sweden", *Journal of Law and Society*, Vol. 17, No. 4 (Winter, 1990), pp. 427-444.

Bennett, Belinda. "The Economics of Wifing Services: Law and Economics on the Family", *Journal of Law and Society*, Vol. 18, No. 2 (Summer, 1991), pp. 206-218.

Bussel, A. Karen. "Adventures in Babysitting: Gestational Surrogate Mother Tort Liability", Duke Law Journal, Vol. 41, No. 3, *Constitutional Perspectives* (Dec., 1991), pp. 661-690

Bartlett, T. Katharine. "Re-Expressing Parenthood", *the Yale Law Journal*, Vol. 98, No. 2 (Dec., 1988), pp. 293-340.

Brezina R. Paul, and Zhao, Yulian. "The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies", *Obstetrics and Gynecology International*, (2012).

Bach, R. Ashcroft. "To the Future: Response to: Extending Pre-implantation Genetic Diagnosis: Medical and Non-Medical Uses", *J Med Ethics* 2003; 29: 217-219.

Bridges, M. Khiara. "On the Commodification of the Black Female Body: The Critical Implications of the Alienability of Fetal Tissue", *Columbia Law Review*, Vol. 102, No. 1 (Jan., 2002), pp. 123-167.

Cardozo, Frow, John. "Elvis' Fame: The Commodity Form and the Form of the Person, *Studies in Law and Literature"*, Vol. 7, No. 2 (Autumn - Winter, 1995), pp. 131-171.

Colker, Ruth. "An Equal Protection Analysis of United States Reproductive Health Policy: Gender, Race, Age, and Class," *Duke Law Journal*, Vol. 1991, No. 2 (Apr., 1991), pp. 324-364.

Cahn, Naomi. "Perfect Substitutes or the Real Thing?", *Duke Law Journal*, Vol. 52, No. 6 (Apr., 2003), pp. 1077-1166.

Cattorini, Paolo. "Assisted Reproduction in Italy", *The Hastings Center Report,* Vol. 24, No. 6 (Nov. - Dec., 1994), pp. 3-4.

Clark, A.P. "Embryo Donation/Adoption: Medical, Legal and Ethical Perspectives" *Journal of Law, Healthcare and Ethics,* (2009) Volume 5 Number 2.

Darling, M. T. "Reproductive and Genetic Biotechnologies: Taking up the Challenge", *Development*, vol, 49, no. 1, pp. 18-22, (2006).

D. McCarthy. "Why Sex Selection Should Be Legal", *J Med Ethics* (2001) 27: 302-307.

Dolding, Lesley. "Unfair Dismissal and the Upper Age Limit Exclusion: Erosion of the Rights of the Older Employee", *The Modern Law Review*, Vol. 49, No. 5 (Sep., 1986), pp. 630-635.

Douglas, Gillian. "Family Law under the Thatcher Government", *Journal of Law and Society,* Vol. 17, No. 4 (Winter, 1990), pp. 411-426.

Douglas, Gillian. "The Intention to Be a Parent and the Making of Mothers", *The Modern Law Review,* Vol. 57, No. 4 (Jul., 1994), pp. 636-641.

Deech, Ruth. "Family Law and Genetics", *The Modern Law Review,* Vol. 61, No. 5, Human Genetics and the Law: Regulating a Revolution (Sep., 1998), pp. 697-715.

Duxbury, Neil. "Do Markets Degrade?", *The Modern Law Review*, Vol. 59, No. 3 (May, 1996), pp. 331-348.

Estrich, R. Susan and Sullivan, M. Kathleen. "Abortion Politics: Writing for an Audience of One", *University of Pennsylvania Law Review*, Vol. 138, No. 1 (Nov., 1989), pp. 119-155.

Epstein, A. Richard. "Surrogacy: The Case for Full Contractual Enforcement", *Virginia Law Review,* Vol. 81, No. 8, Symposium: New Directions in Family Law (Nov., 1995), pp. 2305-2341.

Farber, A. Daniel and Nowak, E, John. "Beyond the Roe Debate: Judicial Experience with the 1980's 'Reasonableness' Test", *Virginia Law Review*, Vol. 76, No. 3 (Apr., 1990), pp. 519-538.

Fadel, E. Hossam. "Assisted Reproductive Technologies: An Islamic Perspective", 25 *J. Islamic Med. Ass'n* 14, 17 (1993).

Fenton, Anne, Rachel. "Catholic Doctrine Versus Women's Rights: The New Italian Law on Assisted Reproduction", *Medical Law Review*, 14, Spring 2006, pp. 73–107.

Freeman, T. "Gamete Donation: Parents' Experiences of Searching for their Child's Donor Siblings and Donor" , *Human Reproduction* Volume 24, Issue 3Pp. 505-516.

Glazebrook, R. P. "Human Beginnings", *The Cambridge Law Journal*, Vol. 43, No. 2 (Nov., 1984), pp. 209-214.

Garrison, Marsha. "Law Making for Baby Making: An Interpretive Approach to the Determination of Legal Parentage", *Harvard Law Review*, Vol. 113, No. 4 (Feb., 2000), pp. 835-923.

Gillers, L. Shoshana. "A Labor Theory of Legal Parenthood", *The Yale Law Journal*, Vol. 110, No. 4 (Jan., 2001), pp. 691-724.

Gama, de Katherine. "A Brave New World? Rights Discourse and the Politics of Reproductive Autonomy", *Journal of Law and Society*, Vol. 20, No. 1, Feminist Theory and Legal Strategy (Spring, 1993), pp. 114-130

Gatson, N. Sarah. "Policy and the Social Meaning of Parenthood", *Law & Social Inquiry*, Vol. 22, No. 2 (Spring, 1997), pp. 277-310.

Gimenez, M. "The Mode of Reproduction in Transition- a Marxist-Feminist Analysis of the Effect of the Reproductive Technologies", *Gender and Society*, September, vol.5, no.3, pp.334-500, (1991).

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

Gillian K. Hadfield and Trebilcock, Michael. " The Second Wave of Law and Economics, the Limits of Freedom of Contract", *The University of Toronto Law Journal*, Vol. 46, No. 1 (Winter, 1996), pp. 181-20.

Hull, J. Valerie. "The Right to Health Care: Building on Traditional Self-Reliance in Village Java", *Human Rights Quarterly*, Vol. 3, No. 2(May, 1981), pp. 61-70.

Holmes, Helen, Bequaert and Peterson, Rae, Susan. "Rights Over One's Own Body: A Woman-Affirming Health Care Policy", *Human Rights Quarterly*, Vol. 3, No. 2 (May, 1981), pp. 71-87.

Hicks, C. Stephen. "Human Experimentation: New Wine, No Bottles", *The American Journal of Comparative Law*, Vol. 38, Supplement. U.S. Law in an Era of Democratization (1990), pp. 581-594.

Hathout, M. Maher. "Surrogacy: An Islamic Perspective", 21 J. *Islamic Med. ASS'N* 106, (1989).

Hall, C. J and Jolowicz, A. J. "Surrogacy and Adoption in Two Jurisdictions". *The Cambridge Law Journal*, Vol. 51, No. 1 (Mar., 1992), pp. 37-39.

Hervey, K. Tamara. "Buy Baby: The European Union and Regulation of Human Reproduction", *Oxford Journal of Legal Studies*, Vol. 18, No. 2 (Summer, 1998), pp. 207-233.

Hadfield, K. Gillian. "An Expressive Theory of Contract: From Feminist Dilemmas to a Reconceptualization of Rational Choice in Contract Law", *University of Pennsylvania Law Review,* Vol. 146, No. 5 (Jun., 1998), pp. 1235-1285.

Isaac, R. "Genetic Testing and Its Implications: Human Genetics Researchers Grapple with Ethical Issues: Science, Technology, & Human Values", Vol. 28, No. 3 (*Summer,* 2003) pp. 365-402.

Joseph G. Schenker, "Religious Views Regarding Treatment of Infertility by Assisted Reproductive Technologies", *Journal of Assisted Reproduction and Genetics,* Vol. 9, No.1,(1992).

Joseph, G. Schenker. "Assisted Reproduction Practice in Europe: Legal and Ethical Aspects", Human Reproduction Update (1997), Vol. 3, No. 2 pp. 173–184.

Jackson, Emily. "Conception and the Irrelevance of the Welfare Principle", *The Modern Law Review,* Vol. 65, No. 2 (Mar., 2002), pp. 176-203.

Jejeebhoy, J. Shireen. Infertility in India - Levels, Patterns and Consequences: Priorities for Social Science Research. *Journal of Family Welfare,* June (1998), 44 (2).

Kadidal, Shayana. "Obscenity in the Age of Mechanical Reproduction", *The American Journal of Comparative Law*, Vol. 44, No. 2 (Spring, 1996), pp. 353-385.

Kindregan, C. Jr. "Thinking about the Law of Assisted Reproductive Technology", 27, *Wisconsin Journal of Family Law* (2007).

Knoppers, Maria, Bartha. "Modern Birth Technology and Human Rights", *The American Journal of Comparative Law,* Vol. 33, No. 1 (Winter, 1985), pp. 1-31.

Larigani, B, Zahedi, F. "Islamic Perspectives on Human Cloning", *Health Law Rev* (2002); 11: 62-6.

Morgan, Derek. "Making Motherhood Male: Surrogacy and the Moral Economy of Women", *Journal of Law and Society,* Vol. 12, No. 2 (Summer, 1985), pp. 219-238.

Morgan, Derek. "Who to Be or Not to Be: The Surrogacy Story", *The Modern Law Review,* Vol. 49, No. 3 (May, 1986), pp. 358-368.

Moen, Elizabeth. "Women's Rights and Reproductive Freedom", *Human Rights Quarterly,* Vol. 3, No. 2 (May, 1981), pp. 53-60.

Minow, Martha."Which Question? Which Lie? Reflections on the Physician-Assisted Suicide Cases", *The Supreme Court Review,* Vol. 1997, (1997), pp. 1-30.

Montgomery, Jonathan. "Constructing a Family. After a Surrogate Birth", *The Modern Law Review,* Vol. 49, No. 5 (Sep., 1986), pp. 635-640.

McGarity, O. Thomas. "Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation", *Law and Contemporary Problems,* Vol. 46, No. 3, Federal Regulation of the Chemical Industry (Summer, 1983), pp. 159-233.

Montgomery, Jonathan. "Medicine, Accountability, and Professionalism", *Journal of Law and Society,* Vol. 16, No. 3 (Autumn, 1989), pp. 319-339.

Moe, Elizabeth. "Women's Rights and Reproductive Freedom", *Human Rights Quarterly,* Vol. 3, No. 2 (May, 1981), pp. 53.

Mulay, Shree & Gibson, Emily. "Marketing of Assisted Human Reproduction and the Indian State", 49 *Development* 84, 85 (2006).

Norrie, McK Kenneth. "Reproductive Technology, Transsexualism and Homosexuality: New Problems for International Private Law", *The International and Comparative Law Quarterly,* Vol. 43, No. 4 (Oct., 1994), pp. 757-775.

Nussbaum, C. Martha. ""Whether from Reason or Prejudice": Taking Money for Bodily Services", *The Journal of Legal Studies,* Vol. 27, No. 2, Social Norms, Social Meaning, and the Economic Analysis of Law (Jun., 1998), pp. 693-724, The University of Chicago Press.

O'Donovan, Katherine. ""Real" Mothers for Abandoned Children", , *Law & Society Review,* Vol. 36, No. 2, Special Issue on Non-biological Parenting (2002), pp. 347-378.

Pande, Amrita. "Not an Angel, Not a Whore: Surrogates as 'Dirty Workers' in India", *Indian Journal of Gender Studies* 16(2): 141-73.

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

Priest, A. J. and Mason, K. J. "Medico-Legal Aspects of Reproduction and Parenthood", *The International and Comparative Law Quarterly*, Vol. 39, No. 4 (Oct., 1990), pp. 971-972.

Priest, A. Jacqueline. "The Report of the Warnock Committee on Human Fertilisation and Embryology", *The Modern Law Review*, Vol. 48, No. 1 (Jan., 1985), pp. 73-85.

Patrick, Effy, P, Rowe, J and Griffin, David. (ed.). "Current Practices and Controversies in Assisted Reproduction Report of a meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction" held at WHO Headquarters in Geneva", Switzerland, 17–21 September 2001, *World Health Organization,* Geneva, (2002).

Pineda, E. "Problems in Paternity and Filiations", *U.S.T. L. REV. Vol. XLVI*, (1997).

Partowmah, M. "Biotechnology Issues in the Opinion of Islamic Scholars", 25 J. *Islamic Medicine Ass'n*, 9, 10-11 (1993)90.

Peach, J. Lucinda. "From Spiritual Descriptions to Legal Prescriptions: Religious Imagery of Woman as "Fetal Container" in the Law", *Journal of Law and Religion,* Vol. 10, No. 1 (1993 - 1994), pp. 73-93.

Paul, S. M, Berger,R, Blyth, E. and Frith, L. "Relinquishing Frozen Embryos for Conception by Infertile Couples," Families, Systems and Health, vol. 28, no. 3, pp. 258–273, 201.

Priest, A. Jacqueline. "Assisted Reproduction: Developments in England", *The International and Comparative Law Quarterly*, Vol. 37, No. 3 (Jul., 1988), pp. 535-550.

Pitt, B. Jonathan. "Fragmenting Procreation: In re Marriage of Buzzanca", *The Yale Law Journal,* Vol. 108, No. 7 (May, 1999), pp. 1893-1900.

Roberts, A. Melinda. "Present Duties and Future Persons: When Are Existence-Inducing Acts Wrong?", *Law and Philosophy*, Vol. 14, No. 3/4 (Nov., 1995), pp. 297-327.

Robertson, A. John. "Reproduction and Rights: A Response to Dorothy Roberts" [Commentary], *Law & Social Inquiry,* Vol. 20, No. 4 (Autumn, 1995), pp. 1023-1032.

Roberts, A. Melinda. "Good Intentions and a Great Divide: Having Babies by intending them", *Law and Philosophy*, Vol. 12, No. 3 (Aug., 1993), pp. 287-317.

Rose, P. Andre. "Reproductive Misconception: Why Cloning Is Not Just Another Assisted Reproductive Technology", *Duke Law Journal*, Vol. 48, No. 5 (Mar., 1999), pp. 1133-1156.

Roberts, E. Dorothy. "The Genetic Tie", *The University of Chicago Law Review*, Vol. 62, No. 1 (Winter, 1995), pp. 209-273.

Roberts, E. Dorothy. "Social Justice, Procreative Liberty, and the Limits of Liberal Theory: Robertson's 'Children of Choice'".

Robertson, A. John. "Children of Choice: Freedom and the New Reproductive Technologies", *Law & Social Inquiry*, Vol. 20, No. 4(Autumn, 1995), pp. 1005-1021.

Robertson, A. John. "In the Beginning: The Legal Status of Early Embryos", *Virginia Law Review*, Vol. 76, No. 3 (Apr., 1990), pp. 437-517.

Rao, Radhika. "Constitutional Misconceptions", *Michigan Law Review*, Vol. 93, No. 6, 1995 Survey of Books Relating to the Law (May, 1995), pp. 1473-149.

Rhoden, K. Nancy. "Trimesters and Technology: Revamping Roe v. Wade", *the Yale Law Journal*, Vol. 95, No. 4(Mar., 1986), pp. 639-697.

Radin, Jane, Margaret and Gillian, K. Hadfield. "Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts and Other Things", *The University of Toronto Law Journal*, Vol. 48, No. 1 (Winter, 1998), pp. 151-155.

Raymond, Janice. "Of eggs, Embryos and Altruism*", Reproduction and Genetic Engineering*, vol. 1, no. 3, pp. 281-285, (1988).

Robertson, A. John. "Commerce & Regulation in the Assisted Reproduction Industry", 85 *Texas Law Review*, 665-702 (2007).

Robertson, A. J. "Extending Pre-implantation Genetic Diagnosis: Medical and Non-Medical Uses", *J Med Ethics* (2003) 29: 213-216.

Shapo, *S.* Helene. *"*Assisted Reproduction and the Law: Disharmony on a Divisive Social Issue", North-western University Law Review , Vol. 100, No. 1, 465.

Shah, Monica. "Modern Reproductive Technologies: Legal Issues Concerning Cryopreservation and Posthumous Conception", 17 *J. Legal Med.* 547, 550 (1996).

Singh, Chandra, Subhash. "Reproductive Rights: A Part of Human Rights", (2002) 3 *Supreme Court Journal*, 12 (J).

Strong, C. "The ethics of human reproductive cloning", *Reprod Biomed Online* 2005 ; 10 (1): 45-49.0.

Sama Team, "Assisted Reproductive Technologies: For Whose Benefit?", *Economic & Political Weekly*, may 2, (2009) vol xliv no 18.

Susan B. Boyd, "Gendering Legal Parenthood: Bio-Genetic Ties, Intentionally and Responsibility", *Windsor Yearbook of Access to Justice* (2007), pp. 1-28.

Swinton, Katherine. "Regulating Reproductive Hazards in the Workplace: Balancing Equality and Health", *The University of Toronto Law Journal*, Vol. 33, No. 1 (Winter, 1983), pp. 45-73.

Seymour, John. "Parens Patriae and Wardship Powers: Their Nature and Origins", Oxford *Journal of Legal Studies*, Vol. 14, No. 2 (Summer, 1994), pp. 159-188.

Stanworth, Michelle, Amendt, Gerhard and Schwartz, Paul. "Baby M. in West Germany, Reproductive Technologies: Gender, Motherhood and Medicine", *Columbia Law Review*, Vol. 89, No. 2 (Mar., 1989), pp. 347-368.

Shaun, Veigh, Mc., McLean M. A. Sheila, Cusine, David. "Legal Issues in Human Reproduction | New Reproductive Techniques: A Legal Perspective", *The Modern Law Review*, Vol. 54, No. 2 (Mar., 1991), pp. 318-324.

Sunder, Madhavi. "Cultural Dissent", *Stanford Law Review*, Vol. 54, No. 3 (Dec., 2001), pp. 495-567.

Scott, S. Elizabeth. "Sterilization of Mentally Retarded Persons: Reproductive Rights and Family Privacy", *Duke Law Journal*, Vol. 1986, No. 5 (Nov., 1986), pp. 806-865.

Stumpf, E. Andrea. "Redefining Mother: A Legal Matrix for New Reproductive Technologies", *The Yale Law Journal*, Vol. 96, No. 1 (Nov., 1986), pp. 187-208.

Shanley, Lyndon, Mary. "Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs", *Law & Society Rev*iew, Vol. 36, No. 2, Special Issue on Non-biological Parenting (2002), pp. 257-284.

Shalev, Carmel. W. H. "Birth Power: The Case for Surrogacy", *Columbia Law Review*, Vol. 90, No. 4 (May, 1990), pp. 1177-1180.

Spiller T Pablo. Spitzer L. Matthew. "Where is the Sin in Sincere? Sophisticated Manipulation of Sincere Judicial Voters (With Applications to Other Voting Environments)", *Journal of Law, Economics, & Organization*, Vol. 11, No. 1(Apr., 1995), pp. 32-63.

Stamp, L. Dudley. "World Resources and Technology, *Law and Contemporary Problems",* Vol. 25, No. 3, Population Control (Summer, 1960), pp. 389-396.

Sunstein, R. Cass. "Neutrality in Constitutional Law (With Special Reference to Pornography, Abortion, and Surrogacy)", *Columbia Law Review*, Vol. 92, No. 1 (Jan., 1992), pp. 1-52.

Steiner, Eva. "Surrogacy Agreements in French Law", *The International and Comparative Law Quarterly,* Vol. 41, No. 4 (Oct., 1992), pp. 866-875.

Sanger, Carol. "Separating from Children", *Columbia Law Review,* Vol. 96, No. 2 (Mar., 1996), pp. 375-517.

Schnably, J. Stephen. "Property and Pragmatism: A Critique of Radin's Theory of Property and Personhood", *Stanford Law Review*, Vol. 45, No. 2 (Jan., 1993), pp. 347-407.

Strauss, A. David. "Abortion, Toleration, and Moral Uncertainty", *The Supreme Court Review*, Vol. 1992, (1992), pp. 1-28.

Trebilcock J. Michael and Keshvani, Rosemin. "The Role of Private Ordering in Family Law: A Law and Economics Perspective", *The University of Toronto Law Journal,* Vol. 41, No. 4 (Autumn, 1991), pp. 533-590.

Thornton, Rosy. "Multiple Keyholders. Wardship and Consent to Medical Treatment", *The Cambridge Law Journal*, Vol. 51, No. 1 (Mar., 1992), pp. 34-37.

Thomson, Michael and Jackson, Emily. "Title: Review: [untitled], Regulating Reproduction: Law, Technology and Autonomy", *Journal of Law and Society*, Vol. 29, No. 4(Dec., 2002), pp. 667-671.

Varada, M. J. "Ethical Issues in Assisted Reproductive Technologies", *Social Medicine*, Volume 6, Number 3, (March 2012).

Van, Anton, Niekerk and van, Liezl, Zyl. "The Ethics of Surrogacy: Women's Reproductive Labour", *Journal of Medical Ethics*, Vol. 21, No. 6 (Dec., 1995), pp. 345-349.

Vetri, Dominick."Reproductive Technologies and United States Law", *The International and Comparative Law Quarterly,* Vol. 37, No. 3 (Jul., 1988), pp. 505-534.

Warnock, Gillick, Jane, Lewis and Fenella, Cannell. "The Politics of Motherhood in the 1980s", *Journal of Law and Society,* Vol. 13, No. 3 (Autumn, 1986), pp. 321-342.

Wiegers, A. Wanda. "Economic Analysis of Law and 'Private Ordering': A Feminist Critique", *The University of Toronto Law Journal,* Vol. 42, No. 2 (Spring, 1992), pp. 170-206.

Whitty, Noel. "Law and the Regulation of Reproduction in Ireland: 1922-1992", *The University of Toronto Law Journal,* Vol. 43, No. 4 (Autumn, 1993), pp. 851-888.

Wu, Lawrence. "Family Planning through Human Cloning: Is There a Fundamental Right?", *Columbia Law Review,* Vol. 98, No. 6 (Oct., 1998), pp. 1461-1515.

Weeramantry, G. C. "Review: [untitled], Pauline Todd, The Slumbering Sentinels: Law and Human Rights in the Wake of Technology", *Journal of Law and Society,* Vol. 11, No. 3 (Winter, 1984), pp. 367-370.

Woodhouse, Bennett, Barbara. "Of Babies, Bonding, and Burning Buildings: Discerning Parenthood in Irrational Action", *Virginia Law Review,* Vol. 81, No. 8, Symposium: New Directions in Family Law (Nov., 1995), pp. 2493-2521.

Widge, Anjali and Cleland, John. "The public sector's role in infertility management in India". *Health Policy and Planning*, (2009), 24: 108–15.

Werber, J. Stephen. "Cloning: A Jewish Law Perspective with a Comparative Study of Other Abrahamic Traditions", 30 *Seton Hall. Rev*. 114, 1156(2000).

WEBSITES & URL:

www.icmr.nic.in/

mohfw.nic.in

surrogacycentreindia.com/

timesofindia.indiatimes.com ›

http://academia.edu/2225679/Indias_Assisted_Reproduction_Bill_and_Maternal_Surrogacy_Industry

http://www.searo.who.int/LinkFiles/Reporductive_Health_Profile_infertility.pdf

http://articles.timesofindia.indiatimes.com/2012-12-26/health/35646346_1_sperm-counts-male-infertility-tight-underwear.
http://cgi.unc.edu/uploads/media_items/a-global-perspective-on-infertility-an-under-recognized-public-health-issue.original.pdf
http://www.pregnancyxl.com/pregnancy/fertilization-process/
http://www.ivf-services.com/intrauterine-insemination-iui.html
http://www.ivf.net/ivf/asia-b401_0-en.htm
http://medical-dictionary.thefreedictionary.com/controlled+ovarian+hyperstimulation
http://www.cdc.gov/art/
http://www.oup.com/us/images/hesamplechapters/vaughnchapter8.pdf
http://ustlawreview.com/pdf/vol.LIII/ART_and_its_Legal_Innuendos.pdf
http://www.webmd.com/infertility-and-reproduction/guide/artificial-insemination
http://www.ispub.com/journal/the-internet-journal-of-law-healthcare-and-ethics/volume-4-number-2/assisted-reproductive-techniques-ethical-and-legal-concerns.html#sthash.mhcCqXOv.dpuf
.http://www.oup.com/us/images/hesamplechapters/vaughnchapter8.pdf
http://www.oup.com/us/images/hesamplechapters/vaughnchapter8.pdf
http://wwwcyanosite.bio.purdue.edu/protocols/cryo.html
http://www.ivf.com/cryo.html
http://www.surrogacyaustralia.org/download/researchCenter/legislationRegulation/Smerdon%202009%20Crossing%20Bodies,%20Crossing%20Borders%20Internat%20Surrogacy%20betwn%20the%20US%20and%20India.pdf.
http://www.oup.com/us/images/hesamplechapters/vaughnchapter8.pdf
http://www.indianchild.com/surrogate_mothering.htm,
http://www.hgalert.org/topics/cloning/cloning
http://www.wisegeek.com/what-is-therapeutic-cloning.htm,
http://www.hfea.gov.uk/fertility-treatment-options-in-vitro-maturation.html
http://www.fertilityauthority.com/treatment/vitro-maturation-ivm
http://www.americanpregnancy.org/infertility/preimplantationgeneticdiagnosis.html
http://icmr.nic.in/guide/ART%20REGULATION%20Draft%20Bill1.pdf
http://articles.timesofindia.indiatimes.com/2012-07-13/india/32663156_1_clinics-infertility-medical-technologies
http://www.prlog.org/12027899-update-on-art-regulation-bill-draft-2010.html

http://jilsblognujs.wordpress.com/2012/10/17/who-speaks-for-the-child-in-a-surrogacy/
http://cbhd.org/content/g12-country-regulations-assisted-reproductive-technologies,
http://www.law.uh.edu/healthlaw/perspectives/2007/(MM)DesignerBabies.pdf
http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf
http://www.hfea.gov.uk/docs/Review_HFEA_Act_White_Paper_DH.pdf
http://www.assistedfertility.com/BCLJarticle.pdf
http://www.wcfia.harvard.edu/sites/default/files/UGthesis_eguo.pdf
http://www.ncbi.nlm.nih.gov/pubmed/21962527
http://www.jstor.org/stable/3563456
http://www.antropologia.cat/files/Zanini%20Fnl.pdf .
http://www.sart.org/International_Activities/
http://www.nhmrc.gov.au/guidelines/publications/e78
http://digital.library.unt.edu/ark:/67531/metadc3192/m1/132/.
http://www.ahrc-pac.gc.ca/v2/index-eng.php.
http://www.cadth.ca/products/environmental-scanning/health-technology-update/issue-10-september-2008/assisted-reproductive
http://digital.library.unt.edu/ark:/67531/metadc3192/m2/1/high_res_d/dissertation.pdf
http://www.dnapolicy.org/policy.international.php?action=showall.
http://www.loc.gov/law/help/bioethics_2012-008118FINAL.pdf
http://www.loc.gov/law/help/israel_2012-007460_IL_FINAL.pdf
http://www.ub.uio.no/ujur/ulovdata/lov-20031205-100-eng.pdf .
http://www.jstor.org/stable/761857 .
http://in-vitro-fertilization.eu/religious-and-ethic-aspects-of-assisted-reproduction,
www.islam101.com./dawah/IslamBrief.html
http://in-vitro-fertilization.eu/religious-and-ethic-aspects-of-assisted-reproduction,
http://www.cie.org.
http://in-vitro-fertilization.eu/different-religious-concepts-in-vitro-fertilization-assisted-reproduction
www.religiousconsultation.org/islam_contraception_abortion.htm..
http://www.medicalnewstoday.com/releases/38686.php .
http://news.medill.northwestern.edu/
http://in-vitro-fertilization.eu/ivf-and-judaism/
http://www.sciencedirect.com/

http://in-vitro-fertilization.eu/different-religious-concepts-in-vitro-fertilization-assisted-reproduction/

http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

http://www.jstor.org

ACTS & GUIDELINES

The Assisted Reproductive Technology (Regulation) Bill and Rules, 2010.

The National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005).

The Ethical Guidelines for Biomedical Research on Human Subjects.(2000).

The Human Fertilization and Embryology Act, (1990).

The Uniform Parentage Act, (2002).

The UN Declaration of Human Rights.

The European Convention on Human Rights.

The Human Fertilization Embryology (Statutory Storage Period for Embryos and Gametes) Regulation, 2009.

Medical Termination of Pregnancy Act, 1971

REPORTS/RECOMMENDATIONS

The Law Commission of India, 228th Report.

Warnock Committee Report of the committee of Inquiry into Human Fertilization and Embryology, (1984, London),

NEWS PAPERS & MAGAZINES

The Hindu

The Times of India

The Frontline

Economic & Political Weekly

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Glossary

Amenorrhea- Absence of menstruation.

Andrology- Science of diseases of males, including infertility, spermatogenesis and sexual dysfunction.

Artificial Insemination (AI)- Artificial Insemination is the procedure of transferring semen into the reproductive system of a woman. This technique comprises of artificial insemination with husband's (AIH) or with donor sperm (AID).

Assisted Hatching- Assisted hatching allows easier release of the embryo from its shell (zona pellucida) helping implantation and increasing the pregnancyrate.

Collaborative Reproduction- reproduction involving more than two biogenetic parents

Embryo- a multi-celled fertilized egg, up to 8 weeks of development

Egg or Oocyte Donor- a woman who allows her eggs to be used to create a child whom she does not intend to parent (or to be used in scientific research), whether or not in exchange for compensation

Ectopic Pregnancies- An ectopic pregnancy is one in which the foetus develops outside the uterus- in the fallopian tubes, the cervical canal, or the pelvic or abdominal cavity.

Embryo Cryopreservation- Procedure in which embryos are preserved by freezing

Embryo Transfer/Implantation/Transplant etc- The transfer of an embryo from an in vitro culture into the uterus.

Endometrium- The mucous membrane lining the uterus, which becomes progressively thicker and more grandular and has an increased blood supply in the latter part of the menstrual cycle.

Endometriosis- Presence of endometrial tissue in abnormal locations

Estrogen- Hormone produced in the ovaries. It controls the development of the female sex characteristics and the reproductive system.

Fetus- a prenatal developing human from the 8th week of gestation until birth

Foetal Reduction- Foetal reduction is an invasive/interventional process by which a higher order multiple pregnancy is reduced to a single or twin pregnancy in order to improve the perinatal outcome.

Gametes- Is a mature sex cell: the ovum of the female or the spermatozoon of the male.

Gamete Donation- Gamete donation is a process by which a person voluntarily offers his or her gametes for the process of procreation.

GIFT (Gamete Intra-Fallopian Transfer)- Gamete Intra-Fallopian Transfer is the placement of ova and sperm in the fallopian tube(s) to effect fertilisation.

Gestational Surrogate- a woman who agrees to be impregnated with another woman's fertilized egg and give birth to a child who will be raised by others, whether or not in exchange for compensation

Gestational Mother- a woman who carries and gives birth to a child to whom she is not genetically related but whom she intends to parent

Gestational Carrier-a woman who carries and gives birth to a child to whom she is not genetically related; this can be either a gestational surrogate or a gestational mother

Gonadotrophin- Is any of the several hormones synthesised and released on the pituitary gland that acts on testes or ovaries to promote production of sex hormones and sperm or ova

Human Chorionic Gonadotrphin (HCG)- is a hormone similar to the pituitary gonadotrophin. It is given by injection to treat delayed puberty, undescended testes, premenstrual tension and sterility due to lack of ovulation.

Hysterosalpingogram- Is the X-ray of the uterus and the tubes.

Intrauterine Insemination (IUI)- Placement of washed sperm into the uterus.

In Vitro Fertilization (IVF)- the creation of an embryo by combining sperm and egg in a laboratory dish

IVF-ET (In Vitro Fertilisation - Embryo Transfer)- In Vitro Fertilisation-Embryo Transfer is the fertilisation of an ovum outside the body and the transfer of the fertilised ovum to the uterus of a woman.

Intended Parents (also Contracting or Commissioning Parents)- people who use assisted reproduction to create a child whom they intend to parent, whether or not they have a genetic or biological relationship to that child

In Vitro Oocyte Insemination- In IVF, the addition of sperm to a culture dish containing an egg.

Laparoscopy- Is the surgical procedure to view the pelvis.

Menopause- Is the time in a woman's life when the cyclic function of the ovaries and menstrual period cease.

Micromanipulation- Process whereby a single sperm is injected under the egg's shell or directly into the egg to facilitate fertilisation.

Miscarriage- A miscarriage is the loss of a foetus from natural causes before the twentieth week of pregnancy.

Multiple Pregnancies/ Multifetal pregnancy- The condition of having more than one foetus in the uterus.

Oocyte or Ovum- a human egg

Oocyte Retrieval- Process of removal of the egg by the technique of aspiration from the ovaries

Ovarian Hyper Stimulation Syndrome- OHSS is an illness caused by the drugs and hormones given to stimulate the ovaries. Excessive stimulation may cause ovarian cysts and moisture in the chest cavity or the stomach and may result in serious, even fatal, consequences. In mild cases, ovarian enlargement, abdominal distension and weight gain may occur. In severe cases women may also suffer renal impairment, liver dysfunction, thromboembolism. OHSS can result in death.

Ovarian Twisting- Condition where the stimulated ovary can twist itself cutting Off its own blood supply.

Ovulation induction- Use of female hormone therapy to stimulate oocyte development and release.

PESA (Percutaneous Epididymal Sperm Aspiration) and TESA/TESE (Testicular Sperm Aspiration/ Extraction)- Percutaneous Epididymal Sperm Aspiration Testicular Sperm Aspiration are simplified, minimally invasive outpatient procedures that allow the physician to recover the sperm for fertilisation in patients with obstructive azoospermia (lack of sperm in semen).

Polycystic ovarian syndrome- Development of multiple cysts in the ovaries due to arrested follicular growth.

Pre-implantation Genetic Diagnosis (PGD)- Pre-implantation Genetic Diagnosis is a technique in which an embryo formed through in vitro Fertilisation is tested for specific genetic disorders or other characteristics prior to implantation.

Pre term Birth- Birth of a baby before 37 weeks (259 days) of gestation (calculated from the first day of the mother's last menstrual period).

Progesterone- is a hormone produced in the ovaries. It prepares the lining of the uterus for implantation of a fertilised egg and readies the mammary glands to secrete milk.

Still Birth- A still birth is the loss of a foetus from natural causes after 20th week of pregnancy.

Surrogacy- Surrogacy is an arrangement in which a woman aggress to carry a pregnancy that is genetically unrelated to her and her husband, with the intention to carry it to term and hand over the child to the genetic parents for whom she is acting as a surrogate.

Surrogacy with Egg Donation- Surrogacy with egg donation is a process in which a woman allows insemination by the sperm/semen of the male partner of a couple with a view to carry the pregnancy to term and hand over the child tothe couple.

Traditional Surrogate- a woman who agrees to be impregnated through artificial insemination and give birth to a child who will be raised by others, whether or not in exchange for compensation

Triple Marker Test- A blood test used in the pre natal diagnosis of Down's Syndrome, which can be performed at about the 16th week of pregnancy.

ZIFT (Zygote Intra Fallopian tube Transfer)- ZIFT is the placement of the zygote into the fallopian tube(s).

Zygote- a one-celled fertilized egg

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