REGULATING CONCEPTION: A MEDICO-LEGAL ANALYSIS OF ASSISTED REPRODUCTIVE TECHNOLOGY

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ABSTRACT

For the first time in history, in-vitro fertilization (IVF) technology made it possible to separate embryos from the person who created them. It 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 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 Assisted Reproductive Technology (ART) have given birth to a lot of new legal issues and challenges. 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 extend legal principles and precedents to shape families and guide patients and providers. The different techniques of ART involve complex medical procedure as well as raise various ethical, legal and moral issues which are discussed in detail in this article.

INTRODUCTION

The ART is the miracle of the new era where high-tech babies are produced through new reproductive technologies and genetic engineering. In-vitro fertilisation 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.[i] Loiuse J. Brown, the first test tube baby was born on July 25, 1978, in Oldham, England.[ii] 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[iii] in 1986) started a revolution in medical technologies and the creation of family. Infertility which was once considered incurable is now can be treated through ART.

With the development of ART, complex social, ethical, legal and moral issues have been raised. 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 commodification of human organs, the malpractices and misuse of ART etc. 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.

As Debora Spar says in *The Baby Business*, 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."[iv] 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). ART 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,* 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 embryo into the reproductive tract. [v]

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.[vi] Linda Bickerstaff recommended ART as a primary choice of treatment for a couple if:[vii]

- 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

ART 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.[viii] The different techniques of ART involve complex medical procedure as well as raise various ethical, legal and moral issues which are discussed in detail in this article.

ARTIFICIAL INSEMINATION (AI)[ix]

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.[x] 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.[xi] 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." The semen is inserted into the woman, and if the procedure is successful, she conceives.[xii]

A.I.H. (ARTIFICIAL INSEMINATION BY HUSBAND OR HOMOLOGOUS INSEM INATION)

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. [xiii] *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 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…[xiv]

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. 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[xv].

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.[xvi] AID is an ethically acceptable procedure provided there is a medical indication and psychological confirmation for its use.

AID introduces a third party into the reproductive matrix. 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.[xvii]

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.[xviii] However in some cases courts held that the child may not be legitimate under the common law.[xix]In one of the cases court has permitted a sperm donor to obtain a paternity order.[xx] Many A.I.D. sperm donor seeks to maintain their anonymity. But in some cases it may be 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.[xxi]

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.[xxii] 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.[xxiii] 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. [xxiv]

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. [xxv]

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." [xxvi]

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.[xxvii]

Several ethical issues 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.

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.[xxviii]

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

Cryo-banks for human semen were first proposed in 1866, but it was not until 1953 that a successful and practical cryopreservation (freezing) technique was introduced. 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%.[xxx]

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.[xxxi]

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.[xxxii]

INTRA-CYTOPLASMIC SPERM INJECTION (ICSI) & SUB ZONAL INSEMINATIONN (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 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 is

useful where the sperm cannot naturally penetrate the egg or where it is of poor mobility.

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.[xxxiii] It refers to reproductive procedures using sperm donation, egg donation, and surrogacy.

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.[xxxiv]

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 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.[xxxv]

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.

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

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.[xxxvii]

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.[xxxviii]

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.[xxxix]

Davis v. Davis[xl]*,*

Mary 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 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 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.

In the case of *Kass v. Kass*[xli], 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 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[xlii], 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 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.

SURROGACY[xliii]

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.[xliv] The Courts also performed their unique job in defining the term surrogacy. [xlv] 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".[xlvi] 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.

The Government of India has recently proposed The Surrogacy (Regulation) Bill, 2016 to regulate surrogacy in India. The proposed legislation prohibits commercial surrogacy in India. The Bill aims to regulate surrogacy in India by establishing National Surrogacy Board at Central level, State Surrogacy Boards and Appropriate Authorities in States and Union Territories. The Bill guarantees effective regulation of surrogacy, prohibit commercial surrogacy and allow only ethical surrogacy to the "needy infertile Indian couples". The objectives of the Bill are to regulate surrogacy services in the country, to provide altruistic ethical surrogacy to the needy infertile Indian couples, to prohibit commercial surrogacy including sale and purchase of human embryo and gametes, to prevent commercialization of surrogacy, to prohibit potential exploitation of surrogate mothers and protect the rights of children born through surrogacy.

The salient features of the Bill are:

- To allow altruistic surrogacy to infertile couple between the age of 23- 50 years and 26-55 years for female and male respectively.
- The intending couples should be Indian citizens and should be legally married for at least five years.
- The intending couples have not had any surviving biological or adoptive or surrogate child earlier except when they have a child who is mentally or physically challenged or suffer from life threatening disorder with no permanent cure.
- The child born through surrogacy will have the same rights as are available for the Biological child.
- The surrogate mother should be a close relative of the intending couple and should be between the age of 25-35 years. She can act as surrogate mother only once.
- An order concerning the parentage and custody of the child to be born through surrogacy is to be passed by a court of the Magistrate of the first class.
- An insurance coverage of reasonable and adequate amount shall be ensured in favour of the surrogate mother.
- National Surrogacy Board shall exercise the powers and shall perform functions conferred on the Board under this Act.
- The Board shall consist of the Minister in-charge of the Ministry of Health and Family Welfare, as the Chairperson, Secretary to the Government of India in- charge of the Department dealing with the surrogacy matter, as Vice-Chairperson and three women Members of Parliament, of whom two shall be elected by the House of the People and one by the Council of State as Members.
- The National Surrogacy board and State Surrogacy board shall be the Policy making bodies and Appropriate Authority will be the Implementation body for the Act.
- The appropriate authority shall comprise of an officer of or above the rank of the Joint Director of Health and Family Welfare Department, as Chairperson, an eminent woman representing women's organization, as member, an officer of Law Department of the State or the Union territory concerned not below the rank of a Deputy Secretary, as member and an

eminent registered medical practitioner, as a member.

- The surrogacy clinics shall be registered under this Act after the Appropriate Authority is satisfied that such clinics are in a position to provide facilities and can maintain equipment and standards including specialised manpower, physical infrastructure and diagnostic facilities as may be prescribed in the rules and regulations.

- No person, organisation, surrogacy clinic, laboratory or clinical establishment of any kind shall undertake commercial surrogacy, abandon the child, exploit the surrogate mother, sell human embryo or import embryo for the purpose of surrogacy. Violation to the said provision shall be an offence punishable with imprisonment for a term which shall not be less than ten years and with fine which may extend to ten lakh rupees.

- The surrogacy clinics shall have to maintain all records for a period of 25 years.

POSTHUMOUS CONCEPTION

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 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.[xlvii]

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.[xlviii] In 2004, a federal appellate court ruled that twins conceived from frozen semen after their father's death was eligible for Social Security.[xlix]

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.[l]

In *Gillett-Netting v. Barnhart*[li], 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 v. Commissioner of Social Security*[lii], 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.

IN VITRO MATURATION (IVM)

In vitro maturation was first developed in the early 1990's to provide a safer and cheaper alternative to in vitro fertilization (IVF). With IVM eggs are removed from the ovaries and are collected when they are still immature. They are then matured in the laboratory before being fertilized. The difference between IVM and IVF is that the eggs are still 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. [liii]

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. 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 (ZIFT).[liv] Examples of disorders that can occur because of genetic defects include hemophilia, thalassemia, muscular dystrophy, cystic fibrosis,

and Down's syndrome.[lv] 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.[lvi]

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 spectre 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.[lvii] A similar situation recently arose in the UK. *In R (Quintavalle) v HFE Authority*[lviii], 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.

MICRO SORTING

Microsorting was originally developed to help couples avoid passing sex-linked genetic disorders to their children. Hemophilia, for example, 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) observed 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 controversial.

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 well as the medical scientists. Bypassing the natural method of conception, fertilizing more embryos than needed, discarding excess embryos, freezing them and destroying them in research are the issues involved in misuse of assisted reproductive technology. National and international regulation may have a great impact to ART. So, there is a strong need to regulate this complex area through law.

[i] 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.

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

[iii] 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).

[iv] Supra note 1 at xvii.

[v] Sec.2 (c) of ART (Regulation) Bill 2010,

[vi] "Assisted reproductive technology" *http://www.cdc.gov/art/* visited on 01/02/2012 at 10:54 a.m.

[vii] Linda Bickerstaff, Technology and Infertility: Assisted Reproduction and Modern Society, (2009, New York, Rosen Publishing), at 28.

[viii] **"**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.

[ix] "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;

[x] Naomi R. Cahn, Test tube Families: why the fertility market needs legal Regulation, (2009, Newyork and London, Newyork University Press), at 46.

[xi] Id at 48

[xii] 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

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

[xiv] *Warnock Committee Report of the committee of Inquary into Human Fertilisation and Embryology*, Cmnd 9314, (1984, London), HMSO, at 4.1.

[xv] Id at para 4.6

[xvi] National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India, (2005)**,** section 1.6.2.

[xvii] 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.

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

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

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

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

[xxii] Supra note 2 at 25.

[xxiii] Ibid

[xxiv] Supra note 7 at 31.

[xxv] Ibid.

[xxvi] Supra note 14, para 5.2.

[xxvii] Supra note 16, section 1.6.4.

[xxviii] Ibid.

[xxix] 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*
[xxx] Available at *http://www.ivf.com/cryo.html*visited *on* 24 March 2012.

[xxxi] Supra note 16 at section 1.6.8.

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

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

[xxxiv] 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. . .
[xxxv] Supra note 54.

[xxxvi]Supra note 14.

[xxxvii] Id section 1.6.7.

[xxxviii] Supra note 16 at section 1.6.7.1.

[xxxix] Ibid.

[xl] 842 S.W.2d 588 (Tenn. 1992).

[xli] 696 N.E.2d 174 (N.Y. 1998).

[xlii] 193 S.W.3d 40 (Tex. App. 2006).

[xliii] 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.

[xliv] Supra note 14, para 8.1.

[xlv] "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.

[xlvi] Supra note 15 at 45.

[xlvii] "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.

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

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

[l] 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.278.

[li] 371 F.3d 595 (9th Cir. 2004)

[lii] 386 F Supp 2d 1257 (Fla,2005)

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

[liv] Available at *http://www.americanpregnancy.org/infertility/preimplantationgeneticdiagnosis.html* visited on 31/08/2012 at 5:32 P.M.

[lv] Supra note 7 at 37

[lvi] Ibid.

[lvii] Brendan Greene, Understanding Medical Law, (2005, Great Britain, Candevish Publishing Ltd.). at 118.

[lviii] (2005) UKHL 28.