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A CRITICAL ANALYSIS ON THE LEGAL AND ETHICAL ISSUES OF FROZEN EMBRYO DONATION: ART ACT, 2021

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Abstract:

Gamete influencing Or manipulation has found its place as an irreplaceable place in the contemporary world for a infertile couple to yield the precious life amidst the mental and physical toils. The first pregnancy achieved by using Assistant Reproductive technology was recorded on 2008. From then on the need for the legal guidelines to regulate the concerns started reaching unimaginable heights resulting in the enactment of the legislation That is the topic of study which is based on the comprehensive overlook of the Artificial Reproductive Technology (Regulations) Act which was enacted in the year 2021 with the deeper focus on the legal and ethical concerns in the present era.

INTRODUCTION :

The term embryo refers to the baby from conception till the 8th week originated from the Greek terminology "embryon" which means ingrow. The use of gamete donating has been a common practise in the assisted reproductive technology since early times. When it comes to donation of sperms early 19 th century is remarkable, while the egg donation started in the early 1980s . Many countries have accepted the embryo donation as common method of assisted reproductive technology followed by India at its year 2021 by establishing the separate act for the assisted reproductive technology. Embryo freezing is done very carefully by a method called as cryopreservation. Cryopreservation was first implemented in the year 2009 on a women that got it's name encrypted in the famous book " SUCCESSFUL BIRTH OF FIRST FROZEN OOCYTE BABY IN INDIA ". The cryopreservation on the woman yeilded a healthy baby of 36 week gestation of about 2.54 kg born via natural delivery. In the process of cryopreservation of embryo two common methods are used. They are

1) For zygote and cleaved embryos the 1,2 propane diol or dimethylsulfoxide is used
2) For blastocyst , glycerol is used as a solution to carry out the cryopreservation.

Sperm donation similar to the embryo freezing also has certain extensive steps to preserve. No sperms are taken for preservation unless it is quarantined for about 6 months for the clearance of tests for chronic and communicable diseases. In the process itself about 20 percentage of the sperms lose their motility in a process called thawing. Thawing is where the frozen substances are melted to return to the normal temperature for subsequent procedural practises.

Now that the concept of sperm donation and oocyte donation and their respective preseravtion techniques are touched upon the concept of embryo freezing and egg freezing comes as a major chaos. Egg refers to the oocyte and freezing of it for fresh start of

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assisted pregnancy whereas embryo as discussed earlier is a stage that has crossed fertilization by means of intracytoplasmic injection or other medical fertilization methods and then frozed for subsequent transfee into the body of the designated female as mentioned in the assisted reproductive technology act of 2021.embryo freezing is carried in the following cases

- When there are risks to naturally conceive a health baby
- When the female has a family history of early menopause
- When the female has the risks associated with cancer treatment and side effects that affects natural unguided pregnancy

The methods carried out to freeze eggs and embryo are also distinguishable. Eggs are freezed by slow freezing methods used. In this method the eggs are put into liquid nitrogen at -132 degree Fahrenheit for preservation. While in embryo freezing the method known as verification is followed where the embryo is put into highly concentrated solution with cryopreservants and liquid nitrogen that instantly cools the embryo to make it appear like a gas like substance.

Chapter I

Frozen Embryo Donation: Legal Issues under the ART Act

In India, the legal regulation of assisted reproductive technologies has been addressed through the enactment of the Assisted Reproductive Technology (Regulation) Act, 2021. This legislation represents the first comprehensive attempt by the Indian Parliament to establish a regulatory framework governing fertility clinics and reproductive technologies. The Act introduces a number of provisions designed to regulate the functioning of ART clinics and banks, ensure ethical medical practices and protect the rights of individuals involved in fertility treatments.

1.1Cryopreservation and Frozen Embryos

Cryopreservation is a scientific technique that involves preserving biological material by cooling it to extremely low temperatures. In the field of reproductive medicine, cryopreservation is widely used to store reproductive cells such as sperm, eggs and embryos. When embryos are frozen, they are typically stored in liquid nitrogen at temperatures approaching minus 196 degrees Celsius. At such temperatures, biological processes effectively come to a halt, allowing the embryos to remain viable for long periods of time.

The introduction of cryopreservation technology has significantly enhanced the effectiveness of assisted reproductive procedures. During IVF treatment, several embryos may be created in a laboratory environment through the fertilization of eggs with sperm. However, medical guidelines generally recommend transferring only a limited number of embryos into the uterus during each cycle in order to reduce the risk of multiple pregnancies and associated health complications. The remaining embryos are therefore preserved for future use through the process of freezing.

Cryopreservation offers several advantages for individuals undergoing fertility treatment. First, it allows patients to avoid repeated cycles of ovarian stimulation and egg retrieval, which can be physically demanding and emotionally stressful. By preserving embryos created during a single IVF cycle, couples may attempt additional pregnancies without repeating the entire procedure. Second, frozen embryo transfer often provides comparable or even improved success rates in comparison to fresh embryo transfer. Third, cryopreservation allows individuals to postpone pregnancy for personal or medical reasons while preserving their reproductive potential.

Despite these benefits, the existence of frozen embryos has created a number of legal and ethical challenges. In many cases, couples who undergo IVF treatment may eventually achieve pregnancy and no longer require the remaining

embryos that were created during the process. These embryos may remain in storage for years without a clear decision regarding their future use. The absence of clear guidance regarding the disposition of unused embryos can lead to uncertainty and disputes between patients and fertility clinics.

In addition, the growing number of frozen embryos stored in fertility clinics has raised broader policy questions about how such embryos should be managed. Determining whether unused embryos should be destroyed, donated for research or transferred to other couples requires careful consideration of both legal and ethical factors. These questions have become particularly significant in jurisdictions such as India where the regulatory framework governing embryo donation remains restrictive.

1.2 Legal Status of Frozen Embryos

The legal status of embryos represents one of the most complex issues in reproductive law. Embryos occupy a unique position that does not easily fit within traditional legal categories. On one hand, embryos represent biological material created through medical procedures. On the other hand, embryos also possess the potential to develop into human life if implanted in the uterus. Because of this dual nature, legal systems around the world have struggled to determine how embryos should be classified and regulated.

In many jurisdictions, embryos are not recognized as legal persons with independent rights. At the same time, embryos are often treated with a degree of special respect due to their potential to develop into human beings. This intermediate status creates uncertainty regarding the extent to which embryos should be protected under the law and who has authority to make decisions regarding their use.

In India, the legal framework governing embryos is primarily contained within the Assisted Reproductive Technology (Regulation) Act, 2021. The Act provides that embryos created through assisted reproductive procedures may be stored in registered ART banks for a prescribed period of time. The intending couple who undergoes the fertility treatment generally retains decision-making authority regarding whether the embryos will be used for future reproductive attempts or whether storage will be discontinued.

However, the Act does not clearly define the legal classification of embryos. As a result, there remains ambiguity regarding whether embryos should be treated as property belonging to the individuals who created them or whether they should be regarded as entities deserving a special form of legal protection. Some scholars argue that embryos should be considered a form of property subject to the control of the individuals who created them. According to this view, couples who undergo IVF treatment should have the authority to determine how their embryos are used or disposed of.

Other scholars, however, contend that embryos should not be treated merely as property because they represent potential human life. From this perspective, embryos should be regarded as a unique category requiring specific legal safeguards. The absence of a clear legal classification for embryos has contributed to ongoing debates regarding the appropriate regulation of assisted reproductive technologies.

1.3 Restriction on Embryo Donation

One of the most controversial aspects of the ART Act relates to the prohibition on embryo donation to other couples. While the legislation allows sperm and egg donation through regulated ART banks, it does not permit the transfer of already fertilized embryos to another intending couple for the purpose of achieving pregnancy. Instead, the law provides limited options for the disposition of unused embryos.

Under the current legal framework, embryos that are not used by the intending couple may be preserved for the duration permitted under the Act. After this period, the embryos may be donated for scientific research or allowed to

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perish. However, the Act does not provide a mechanism for transferring embryos to another infertile couple who may wish to use them to achieve pregnancy.

This restriction has generated considerable debate among legal scholars and medical professionals. Critics argue that the prohibition creates an inconsistency within the regulatory framework governing assisted reproduction. If the law permits the donation of sperm and eggs, it is difficult to explain why the donation of embryos should be completely prohibited. In practical terms, embryo donation simply involves the transfer of genetic material from one couple to another, a process that is conceptually similar to gamete donation.

Furthermore, preventing embryo donation may result in the destruction of viable embryos that could otherwise help infertile couples achieve parenthood. Many fertility clinics create multiple embryos during IVF treatment, and not all of these embryos are ultimately used by the original couple. In such circumstances, allowing embryo donation could provide an opportunity for other couples to conceive while avoiding the ethical dilemma associated with destroying unused embryos.

Supporters of the prohibition, however, argue that embryo donation may create complex legal and social relationships involving multiple parties. For example, a child born through embryo donation may have genetic parents who are different from the individuals who raise the child. This situation may raise questions regarding parental rights, inheritance and the child's right to know their biological origins.

These concerns highlight the broader policy challenges associated with regulating reproductive technologies. Lawmakers must attempt to balance the reproductive autonomy of individuals with the need to ensure clarity and stability in family relationships.

1.4 Constitutional Issues

The prohibition on embryo donation has also generated constitutional debate within the Indian legal context. Scholars have argued that reproductive decision-making forms part of the broader right to personal liberty protected under Article 21 of the Constitution of India. The right to personal liberty has been interpreted by the courts to include a range of rights relating to bodily autonomy, privacy and personal decision-making.

CHAPTER II

Ethical issues in frozen embryo donation

Judicial decisions have increasingly recognized reproductive autonomy as an important aspect of individual freedom. The Supreme Court has emphasized that decisions relating to reproduction are closely linked to personal dignity and bodily integrity. From this perspective, individuals should have the freedom to decide whether and how they wish to reproduce.

In light of these principles, some scholars argue that preventing couples from donating embryos to other individuals may represent an unjustified restriction on reproductive autonomy. Couples who undergo IVF treatment often invest significant emotional, physical and financial resources in the process. When they are prevented from making decisions regarding the fate of their embryos, they may feel that their reproductive choices are being unnecessarily limited.

The prohibition on embryo donation may also raise questions under Article 14 of the Constitution, which guarantees equality before the law. The distinction between gamete donation and embryo donation may appear arbitrary if both practices involve the transfer of genetic material for reproductive purposes. If donor sperm and donor eggs are legally permitted, critics argue that there must be a clear and rational justification for prohibiting embryo donation.

Here is your content re-humanised with a natural, flowing academic tone while preserving its structure and meaning:

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The Ontological Status of the Cryopreserved Embryo

One of the most enduring questions in the ethics of assisted reproduction is deceptively simple: what exactly *is* a frozen embryo? The answer, it turns out, depends heavily on one's philosophical starting point, and there is no shortage of competing views.

For those who subscribe to the personhood argument, the matter is relatively straightforward. Life begins at conception, and from that moment onward, the embryo holds a right to life that cannot be overridden. Destroying it, or using it for research, is therefore morally indefensible. On the other end of the spectrum sits a view that treats the embryo as biological tissue, a cluster of cells over which the individuals who created it retain full authority. Here, reproductive autonomy takes centre stage, and the embryo is understood primarily as an extension of personal choice. Somewhere between these two poles lies the gradualist position, which recognises that embryos, while not yet persons in any full sense, carry enough developmental potential to warrant a meaningful degree of moral respect.

Each of these perspectives carries weight, and none can be easily dismissed. That tension is precisely what makes the debate so difficult to resolve.

The Paradox of Surplus Embryo Creation

The ethical picture becomes even more complicated when we consider how embryos come into existence in the first place. In standard IVF practice, the ovaries are stimulated to produce several eggs at once, and these are fertilised to improve the odds of a successful pregnancy. The inevitable result is that more embryos are created than can be transferred in any single cycle.

This raises an uncomfortable question. If some of those embryos were never really intended for implantation, have they been reduced to instruments, means to an end rather than ends in themselves? Critics of surplus creation would say yes. But others push back, arguing that the practice is driven not by carelessness but by clinical necessity and genuine compassion for people struggling with infertility. From this angle, the real ethical obligation is not to stop producing surplus embryos altogether, but to handle them with the seriousness and care they deserve once they exist.

Psychosocial Impacts and Identity Formation

When embryos are donated and result in the birth of a child, the family that forms is one in which the parents and child share no genetic connection. That arrangement, while increasingly common, gives rise to questions that are anything but routine, particularly around identity.

As donor-conceived children grow up, many of them begin to wonder where they come from, not in a social sense, but in a biological one. This desire to understand one's genetic origins has become a central concern in modern bioethics, and it has gradually shifted professional opinion away from the older model of strict donor anonymity. At the same time, the emotional landscape for donors themselves is often more complex than it might appear from the outside. Some individuals who donate embryos find that they are unexpectedly affected by the knowledge that a child genetically related to them is being raised by someone else. This experience, sometimes described as a kind of genetic grief, underscores the importance of providing meaningful counselling and robust informed consent well before the donation process begins.

Commodification and Human Dignity

As reproductive medicine has grown into a significant industry, concerns about commodification have followed close behind. In a system shaped by market forces, there is a real danger that embryos could come to be valued not for what they represent in human terms, but for what they are worth in economic ones.

This is not a hypothetical worry. If embryos were to be openly bought and sold, it would be a short step toward selecting them on the basis of traits deemed desirable, a path that leads uncomfortably close to eugenic thinking. Ethical frameworks around the world are clear on this point: embryo donation should remain a matter of generosity, not commerce. Legislation such as India's Assisted Reproductive Technology (Regulation) Act of 2021 exists precisely to hold that line, ensuring that the use of reproductive technologies does not drift beyond the boundaries of what a society considers morally acceptable.

Legislation

Assisted Reproductive Technology (Regulation) Act, 2021

Journal Articles

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