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A Critical Study on Emerging Legal Challenges of Genetic Engineering: Global Innovations and India's Response

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ABSTRACT

In the era of rapid technological development, the field of biotech is not running late. The development in the molecular biology has called for upgradation in modern biotechnology. One of the important aspects of molecular biology is the study with gene, and the inter-related materials. With the passage of time, study of human gene urge for therapy to cure certain genetic diseases. By the process of genetic engineering, one can edit or alter the gene which is responsible for that particular disease. However, now the science has upgraded in this manner where the process of genetic engineering is able to edit the germ line gene not for therapy but also able to design one's baby according to their choice. Hence, the human are able to interfere the most natural process of the earth, creating new life. The paper thus would be focused on analyzing the international instruments in terms of procreation of designer baby and would further analyze the position of Indian feasibility of the designer baby.

INTRODUCTION

The concept of 'designer baby' is not new today. It's not the design of the outfit of the babies but the design of the very inner structure of the babies. The theory of designer babies is part of Assisted Reproductive Technology (ART), referring to a group of different methods utilized to help the couple to procreate. It's really a wonder that today science is able to interfere the very basic form of a life, zygote-the starting point of a new human life in the earth which in fact is considered to be a purely natural process. The process by which it is possible is called genetic engineering. Today molecular science and biotechnology has reached in that point where man has the knowledge to not only alter but also control the genetic material and above that, scientists are able to stop the process of passing the genetic material to the next generation. [2]

Stanford University scientists Cohen and Boyer discovered a way to cut DNA and then insert an object into the space created by the cutting. [3] This technique was discovered in 1973. This method of processing new proteins is known as "recombination."[1][4] Recombinant DNA technique is utilized in genetic engineering to modify genetic appearance. [5] The procedure began with the cloning of a small piece of DNA, but it has evolved into a massive technology that makes it possible to clone an entire genome with ease. [6] Usually, a gene from another species is added to an organism's genome to give it a desired trait.

David M. Bodine claims that genetic engineering refers to the process of mixing DNA fragments with other DNA fragments. This is something you construct in your own laboratory using test tubes; it doesn't actually happen in nature. and then reproducing what you have created in a variety of organisms, such as yeast cells, bacterial cells, plant cells, and animal cells. Thus, while a precise definition of genetic engineering remains elusive, it does, in the 2000s, characterize a whole field of recombinant DNA technology, genomics, and genetics. Therefore, genetic engineering has the best possibility of spreading swiftly. For this reason, we must acknowledge the importance of technology in the modern world.

In human there are two types of gene; somatic and germ line. The later one is responsible for the reproduction. One of the purposes of edit is to cure diseases like diabetics and other genetic diseases. With the development of science, today, alteration,

addition of the germ line gene does not restrict itself to curing the disease but also extended to form a new life by choice. There is a distinction between the therapeutic purpose and non-therapeutic. The designer baby in context seeks to choose the trait according to couple's choice. This is not therapeutic but merely enhancement. The demand of the human being can never be controlled. For example- choosing a particular of eyes, hairs, the traits of intelligence, height so on and so forth can be controlled by the human which are essentially in the grip of the Mother Nature.

As the scientist very correctly explained that it may be possible that human race will be back again in the period of eugenic where the genetically modified babies would be considered as an enhanced human and the natural human.

Previously in the in vitro fertilization the genes are not edited but in case of designer babies in the stage of or in the maximum when the egg is fertilized and forms zygote then the DNA is being altered or modified according to the requirement. In 2010, the Oxford Dictionary defined it as 'a baby whose genetic makeup has been artificially selected by genetic engineering... to ensure the presence or absence of particular genes or characteristics'. The term design baby has created a lot of serious issues, because here germline gene is being edited. but has gained a huge attention for its controversial nature. The threat to the existence of human race is much greater with the designer baby that germ line therapy.

OBJECTIVE OF THE STUDY

Biotechnology is standing on the research and inventions on microbiology, genetic engineering is not an exception. Consequently, it attracts the intellectual property regime for the purpose protecting the inventions made and adding fuel for further upgraded research. The researcher, thus, will analyze the legal & regulatory framework of India in the context of designer baby

considering the international scenario. The regulatory framework includes both the intellectual property regime and the biotechnological frameworks prevailing over the countries.

MATERIALS & METHODS

The study comprises of mostly analytical, comparative and case study method.

International perspective-

Instruments on Human Genome and genetics, Human Rights & Ethics

a. Nuremberg Code 1947-

The Nuremberg Code, established from the Nuremberg Trials, is a foundational document on ethical human research. It outlines ten guidelines, emphasizing informed and voluntary consent, risk-benefit assessment, and ensuring procedures align with natural processes and necessity. The Code mandates that medical professionals worldwide adhere to these principles. [7]

The code has categorically charged that any process should not be against the process of nature and not accessed unnecessarily. [8,9]

b. Declaration of Helsinki-

The Declaration of Helsinki, created by the World Medical Association in 1964 and revised seven times (last in 2013), outlines ethical guidelines for human research. It prioritizes rights to health, dignity, integrity, privacy, self-determination, and confidentiality. It mandates adherence to national and international standards and emphasizes risk-benefit assessment, prohibiting research with risks exceeding benefits. Moreover, any research whose risk are unknown is subject to precautions and in need prohibited. [10]

c. **Oviedo Convention of 1997 (Europe)**

The 1997 Oviedo Convention, a legally binding treaty in Europe, addresses human rights and dignity in biomedicine. It covers biomedical research, patient rights, genetic engineering, and organ transplantation, emphasizing human germline gene editing for protecting human rights and dignity. Article 13 permits genome modification for preventive, diagnostic, or therapeutic purposes but prohibits changes affecting future generations. The treaty prioritizes human dignity over scientific advances and mandates re-examination with scientific progress. [11]

Article 32 mandates re-examination with scientific advancements. Following CRISPR-Cas9 developments, the Council of Europe's Bioethics Committee issued a 2015 statement on genome editing, emphasizing human health and risks of germline modification misuse. In 2017, the Parliamentary Assembly of the Council of Europe recommended a ban on germline editing, highlighting concerns over its implications. In this way, it maintains the human dignity and integrity of '*inheritance of genetic endowment'*. [12]

Three (3) Treaties issued by The United Nations Educational, Scientific and Cultural Organization (UNESCO)-

UN Universal Declaration on Human Genome and Human Rights of 1997

The United Nations (UN) Universal Declaration on the Human Genome and Human Rights of 1997 (the UN Declaration of 1997) is another important bioethical instrument which deals the human integrity issues involved in the genetic science. [13]

The preamble of the instrument focused totally on the human integrity and it can be summarized as that howsoever the scientific research goes on, in no circumstances it will be more significant than the human welfare and benefits.

The importance of human genome has clearly specified in this Declaration under Article 1 itself which says that

'The human genome underlies… the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.' [14]

International Declaration on Human Genetic Data 2003

The 2003 UNESCO International Declaration on Human Genetic Data emphasizes genetic data safety, individual autonomy, non-discrimination, consent, and human dignity. It restricts genetic data use to specified provisions, acknowledges natural genome mutations, and recognizes that education, environment, emotions, and cultural practices also shape human characteristics. [15]

The Universal Declaration on Bioethics and Human Rights 2005

The 2005 UNESCO Universal Declaration on Bioethics and Human Rights provides a global framework for guiding bioethics legislation, policies, and actions. It prioritizes individual interests over scientific development, safeguarding future generations from emerging biotechnologies, including genetic engineering, and incorporates concerns about biodiversity impacts from human genome editing.[16]

IBC Report on the Human Genome and Human Rights, 2015-

The 2015 Report of the IBC on updating its reflection on the human genome and human rights calls on states and governments (inter alia) to agree a moratorium on germ line engineering 'at least as long as the safety and efficacy of the procedures are not adequately proven as treatments' and to 'Renounce the possibility of acting alone in relation to engineering the human genome and accept to cooperate on establishing a shared, global standard for this purpose.' [17] According to this report, precautionary principles were need to be adhered in order to frame the policy of germ-line editing. The report focuses on the point that the human rights and dignity cannot be compromised in the way of enhancing human life. Although, it speaks for the right to highest attainable standard of health which even by personalized medicine, but precautionary principle should be taken into account. [18]

First International Summit on Human Gene Editing 2015 and NAS Report 2017

The advent of CRISPR-CAS9 led to an International Summit on Human Gene Editing in December 2015, hosted by the U.S. National Academy of Sciences, the U.S. National Academy of Medicine, the Royal Society, and the Chinese Academy of Science. Over 500 experts discussed somatic and germline gene editing, covering scientific, ethical, legal, social, and governance issues. A 2017 report recommended cautious germline editing for genetic disease prevention, considering individual and generational impacts. It emphasized the need for regulatory governance, informed consent, and restricting trials to compelling circumstances. The Summit opposed using modified embryos for pregnancy, limiting germline editing strictly to therapeutic purposes. human gene editing'**. [19]**

The Call for a Moratorium on Clinical Application in 2015

After the 2015 Summit, its organizing committee called for a moratorium on clinical use of heritable human germline editing, aiming to prevent misuse. They advocated for continued basic and preclinical research under legal and ethical oversight to

understand risks and benefits better. The committee emphasized that modified embryos should not be implanted for pregnancy under any circumstances. [20]

Second International Summit on Human Genome Editing 2018

The first Summit on human gene editing addressed the social, ethical, and legal issues of somatic and germline editing, calling for more public engagement and debate to understand genetic complexities and develop a governing framework. The Second International Summit in 2018, influenced by Chinese scientist He, included scientists, ethicists, policymakers, and patient groups. The summit highlighted the rapid advancements, benefits, and risks of gene editing, acknowledging the lack of proper regulation. The committee proposed a transnational clinical pathway for germline editing and emphasized the need for more research and public input to develop appropriate guidelines.[21]

Call for a Moratorium 2019

After the second International Summit in 2018, organizers called for a new five-year moratorium on germline editing in March 2019, recognizing the previous moratorium's failure due to complex international regulations. They proposed an international forum for discussion and debate, urging nations to curb misuse and decide on gene editing. Within five years, they plan to create a body to inspect societal consensus and provide information and recommendations to states. new perspective. [22]

WHO Statement

An advisory body has been established under the governance of the World Health Organization to oversee and govern the current issue with relating to the human genetic engineering. This advisory body has call for a meeting on 18-19 March 2019 and gain continuing the process held the second meeting at Geneva on 26-28 August 2019. [23]

According to WHO Director-general,

'it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing'.

After the meeting, at the opinion of the advisory committee there should not be any practice of germ line editing in any nation and it is the duty of the respective regulatory authority to check upon this. [24]

INDIA

India being one of the main signatories of almost all the international treaty, need to be in consonance with those instruments. In this segment, the paper would be focused on regulatory framework in India as far as designer baby is concerned.

There is no explicit law which prohibit the human germ line editing in India. However, the guidelines and the law relating to implantation essentially barred the editing. Apart from that the patent law in India is restrict enough to considered as a protective public policy. In this section, the intellectual property regime in India, the laws, and the relevant guidelines will be appreciated.

LEGAL POLICIES

Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994

The most significant law in India which indirectly bans the germ line editing or choosing such optional traits for enhancement is the Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994. It lays down certain disease for which pre-natal diagnostic test will be applicable with the consent of the pregnant women and anything which are not specified in the list will be precluded for consideration. [25] Apart from that the person conducting such diagnostic should be maintain the record in writing. [26]

Biotech Guidelines-

- ***Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment 2017-***

The guideline was introduced to set up certain new authority to work, review and stand for the authorization purpose. However, it does no relate to the human germ line editing directly but the bodies are significant role to combat such misuses. [27] It can be understood from the functional aspects of the body. Another purpose of this guidelines was to protect the human and the environment concerning the biotechnological field of research and further process. [28] The safety level and concern for human and environment health would possess serious challenge in DNA recombination process. The committee has called for different bodies.

- ***National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017-***

The guideline has started by elucidating on the very basic yet so significant principles of biomedical research specially where the human body is involved. The principles are –

Principle of essentiality, voluntariness, non-exploitation, social responsibility, privacy and confidentiality, risk minimization, maximization of benefits, professional competence, institutional agreement, transparency and accountability, totality of responsibility, environment safeguarding. [28]

The guideline has raised the ethical uses of using the new technology in human germ line and the concept of eugenics has been highlighted. [28] It expressly prohibits the germ line therapy and editing that it will create eugenic and designer baby. [28]

However, it allows the somatic gene therapy that too with a very cautionary measure. The use of somatic gene therapy is said to be restricted only where there is no other way to treat the diseases and the diseases are of life threating ones. [28] Even for the somatic one the approval of local EC and the DBT is required. And the product relating to somatic gene editing which is considered to be commercialized should have taken permission from CDSCO. [28]

- ***Draft National Guidelines for Gene Therapy Product Development and Clinical Trials 2019-***

The Draft guideline seeks for banning the human gem line therapy due to ethical and social insecurity reasons. [28] However it approves the somatic gene therapy and product related to it. But the safety measures and the related issues like human rights, fundamental freedom should be taken into consideration in the time of researches and clinical trials. [28] Also the principles laid down in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 should be adhered to. [28]

The guideline calls for a Gene Therapy Advisory and Evaluation Committee (GTAEC), the secretariat of the committee will be Indian Council of Medical Research (ICMR) under the aegis of Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India. [37] The committee will be acting and reviewing the GTP products and after that it will go before the CDSCO for final approval.

RESULTS AND DISCUSSION

Results:

The study's findings show that there are new ethical, legal, and regulatory questions around designer babies brought forth by genetic engineering. Consent, ethical limits, and a balance between scientific advancement and human rights are emphasized in international accords like the Nuremberg Code and the Declaration of Helsinki. It is important to prevent the possible misuse of gene-editing technologies, because these tools bring attention to worries about tinkering with human DNA for reasons other than therapy, such as trait selection.

The importance of human dignity is emphasized in recent UNESCO pronouncements and the Oviedo Convention, both of which call for extensive discussion before allowing heritable genetic modifications in Europe. They express concern in the face of fast biotechnological advancements by outlining stringent rules against germline alterations that might impact subsequent generations. Aligning with a collaborative approach toward global bioethics, WHO and UNESCO have also stressed an international moratorium on germline editing owing to safety and ethical issues.

Although germline editing is not explicitly forbidden in Indian law, certain laws, such as the Pre-Conception & Pre-Natal Diagnostic Techniques Act of 1994, do limit the availability of "designer babies" by outlawing non-essential genetic modifications. By prohibiting germline editing and limiting somatic gene therapy to extremely serious diseases, the 2019 Draft National Guidelines for Gene Therapy and the National Ethical Guidelines for Biomedical Research reflect worldwide positions.

DISCUSSION

The comparative analysis of India's policies with global standards reveals a cautious alignment with international bioethical standards. International guidelines provide a clear framework for protecting human rights in genetic engineering, prioritizing

consent, natural processes, and human dignity. India's regulatory approach aligns with these by prohibiting enhancements through germline therapy while allowing limited, heavily monitored use of somatic therapy.

One key area of concern, however, is the absence of a robust, explicit legal framework in India for handling designer babies. Although current policies indirectly restrict germline editing, they leave potential loopholes that could be exploited as technology advances. The Draft Guidelines and various ethical committees within India are essential steps, but India may benefit from an explicit regulatory policy to solidify its stance in alignment with international moratoriums and ethical standards.

Furthermore, the ethical debate around genetic modification is deeply tied to the potential resurgence of eugenics, where designer babies might lead to a divide between genetically "enhanced" and "natural" humans. The discourse on eugenics underscores the need for frameworks that can evolve with scientific advancements, ensuring that the pursuit of biotechnological progress does not come at the expense of social equity and human dignity.

India's stance, combined with international guidance, serves as a vital regulatory foundation in safeguarding ethical standards and preventing the misuse of genetic engineering, particularly in the realm of designer babies.

CONCLUSION

As from the discussion in the chapter, it is a proven fact that there is no international binding instrument which is dealing with the human genome editing especially with the heritable germ line genome editing. There are separate provisions with respect to ethic human rights and intellectual property rights-currently guiding the whole universe to come into a platform. However, scientist all over the world along with the bioethics and academicians are meeting and shared their progress and view. The most important aspects that the public, the common people, engaging them with the discussion will be the most fruitful analysed. Because the subject of the process will be they only. An international binding instrument is not so easily effective or even set up, because every nation is sovereign and has their own ethics morality business strategy. Therefore, there should be a consensus among the entire individual in the world that they will not destroy themselves by their own.

In India there is no legal provision as well. But the prenatal Act is the present umbrella under which one can protect the embryo from editing. However, there is no law that could protect from preclinical trial or basic research. There are guidelines as mentioned above but the germ line genome editing is not so elaborately dealt with.

Thus, to control and regulate this germ line genome editing, the law should be enacted or modified in various segment not only in a particular area. Starting from the biotech regulation the patent regime, the funding and the taxation to the criminology provision to protect, prohibit the current fear of creating designer baby.

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