GENOME EDITING AND THE LAW – AN ANALYSIS OF THE EXISTING LEGAL REGIME IN NEED OF CHANGE

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ABSTRACT

The world of biotechnology has grown by leaps and bounds in the past few years. Most of the growth can be attributed to the fascination of the scientists with correcting what they perceive to be nature's mistakes. It also has to do with the growing demands of the human race and nature's limited resources being over utilised. However, when it comes to human genomics, efforts towards changing defects in the human genome or the susceptibility towards diseases have raised ethical and legal concerns regarding the manipulation of the human genome and the subsequent implications of the same. While the discipline of it is yet to develop completely, the application of human genome editing technology to real subjects has raised controversy not just in the scientific community but also in political and legal circles. The main concern, therein, is how the practice can be regulated and whether the consequences flowing from the practice of human genome editing can be reined in under existing international legal instruments. This paper shall delve into the existing frameworks regulating human gene editing and its application. It will discuss the positives and negatives of the same. It will also discuss the hurdles in adopting an

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international regime and the means to rectify the same. Suggestions will be made as to how the current laws can be made better and whether entirely new laws are required.

I. INTRODUCTION

With the advent of growing technology, biomedicine and biotech have seen rapid development. This unforeseen growth has also attracted the attention of ethicists and legislators who look at the field as a ripe opportunity for mismanagement and human rights violations. Whether it is correcting defects in Deoxyribonucleic Acid ("**DNA**") or creating pest-resistant crops, the aim of biotechnology is to improve the already existing. However, this gives rise to certain concerns when the same ideology is applied to the manipulation of the human genome.

In 2018, the news of the birth of the world's first genetically edited babies brought much concern and censure from the international scientific community.[1] Chinese biophysicist He Jiankui and his two colleagues Zhang Renli and Qin Jinzhou illegally conducted human genome editing using the Clustered Regularly Interspaced Short Palindromic Repeats ("**CRISPR**") - CRISPR

[1] Preetika Rana, *How a Chinese Scientist Broke the Rules to Create the First Gene-Edited Babies*, THE WALL ST. J., May 10, 2019, https://www.wsj.com/articles/how-a-chinese-scientist-broke-the-rules-to-create-the-first-gene-edited-babies-11557506697.

associated gene ("**Cas9**") technology.[2] They violated Chinese regulations and ethical principles by practising genome editing in assisted reproductive medicine, by altering embryos in vitro and implanting them into two women.[3] They were consequently convicted for their illegal acts. However, the incident raised concerns regarding the widespread use of human genome editing as well as the lacking legal framework to deal with its consequences. The occurrence of such rogue actions is bound to increase as the CRISPR technology becomes more readily available. It can lead to unforeseen human rights violations considering the unpredictable nature of how the edited gene will manifest in human subjects in the future.

The rapid development in human genome editing has raised concerns regarding unpredictable mutations and the alterations it may cause to the human nature itself. This technology promises improvement to human life by eliminating diseases and enhancing the capacity of human beings. International law has not specifically addressed the situation but, the issue can be resolved by interpreting

[2] Beverley A. Townsend, *Human Genome Editing: How to Prevent Rogue Actors*, BMC MEDICAL ETHICS, 2020, https://bmcmedethics.biomedcentral.com/track/pdf/10.1186/s12910-020-00527-w.pdf (Last visited Mar, 29,2021).

[3] *China Focus: Three jailed in China's "gene-edited babies" trial*, XINHUA NET, Dec. 30, 2019, http://www.xinhuanet.com/english/2019-12/30/c_138667350.htm (Last visited Mar. 29, 2020).

international trade law, intellectual property law and human rights law to address specific incidents that arise. This gives rise to the question whether a specific international framework is required to protect humans from the potential harms that may result from genetic editing as well as to protect the financial interest of significance to international commerce.

The current international legal mechanism when it comes to human genome editing is in its nascent stage owing to the recent and quick evolution in technology. Clinical research for the most part is prohibited in all jurisdictions. In some countries the ban is absolute whereas in others, certain exceptions are provided. Two regional human rights treaties that regulate genetic interventions directly, namely the 1997 European Convention on Human Rights and Biomedicine ("**Oviedo Convention/Convention**")[4] and the European Union ("**EU**") Charter of Fundamental Rights ("**EU Charter/Charter**")[5] assume prime importance. The 29 States party to the Oviedo Convention are all members of the Council of Europe. The principles enshrined herein have therefore not gained widespread general acceptance and cannot be said to have become a

[4] Council of Europe, Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine Apr. 4, 1997, E.T.S. No. 164 [hereinafter Convention on Human Rights and Biomedicine].
[5] Charter of Fundamental Rights of the European Union, Dec. 18, 2000, 2000 O.J. (C 364). [hereinafter Charter of Fundamental Rights].

part of the customary international law governing genome editing. The Oviedo Convention imposes on States to protect the dignity, identity and human rights of all human beings when it comes to application of biotechnology. The EU Charter is considered to be a part of the Founding Treaties of the EU and as such enjoys primacy over domestic law in case of any conflict amongst statutes or rules, as well as a direct effect, meaning that it can be relied upon by individuals directly before domestic courts.

The surge in biotechnology advancements surrounding human genome editing call for an international policy which establishes a regulatory mechanism for research into human genome editing and the limits of the application of any such research to human subjects. The paper aims to study the ethical and legal implications of human genome editing. To this end, the article begins by studying the laws dealing with human genome editing internationally and in select domestic jurisdictions. Subsequently, this article looks at the need for a comprehensive international legal framework governing human genome editing and institutionalised support for the same. Finally, this article makes suggestions as to how reforms can be brought about by suggesting changes to existing regulations, identifying gaps in regulations and providing recommendations for new regulation.

II. THE EXISTING LEGAL REGIME AND ITS INTERSECTION WITH HUMAN RIGHTS

The growing developments in the field of genetic modification have raised legitimate concerns regarding its application to human genome editing. The ethical and humanitarian concerns of the process have created hurdles in the further growth of the procedure as well as its acceptance by the public at large. It is hard to process the exact effects such modifications can result in because a genetically modified human genome can beget enumerable manifestations, which don't possess a set pattern and are rather unpredictable in nature. The results of such a science has not been truly fleshed out. However, this does not preclude its application in real-world circumstances as has already been undertaken in China in 2018 by Chinese biophysicist He Jiankui and his two colleagues Zhang Renli and Qin Jinzhou using the CRISPR-Cas9 technology.

With growing developments that bring fresh opportunities for experimenting, the application of human genome editing technology to real subjects has raised controversy not just in the scientific community but also in political and legal circles. The regulation of the practice has become the paramount concern and the existing international framework has been brought into question regarding its ability to control the consequences flowing from such real-world application. To answer this question, it is necessary

that we first examine the standards, both ethical and legal, by which human genome editing and its consequences shall be evaluated and the existing legal instruments which uphold these standards.

2. The International Scenario

The two primary international legal instruments that specifically address human genetic modification are the Oviedo Convention,[6] and the EU Charter.[7] It is in examining these instruments that we will be able to correctly address any gaps that remain unregulated in the use and application of genome editing technologies to human subjects.

3. The Oviedo Convention

The Oviedo Convention was the result of work of the Committee of Experts on Bioethics and the Council of Europe to confront the problems arising due to the advances in medicine and biology.[8] The Explanatory Report to the Convention addressed that even though they may start with worthy aims, the distortion of the original objectives of such procedures may have extensive

[6] Convention on Human Rights and Biomedicine, *supra* note 4.
[7] Charter of Fundamental Rights, *supra* note 5.
[8] Convention on Human Rights and Biomedicine, *supra* note 4, Explanatory Report.

ramifications that need to be managed at the outset.[9] The report also acknowledged that most of the ethical and legal efforts made to address the situation had, for the most part, become restrained to a certain geographical area and that it is apparent that an international instrument had become the need of the hour. Ratified by just 29 State parties, out of the 47 States that are members of the Council of Europe, the Convention is of regional application. Notably neither the United Kingdom ("**UK**") nor Germany have signed the treaty; nor has any technologically advanced non-member nor international organisation has signed or ratified the treaty.

The principles enshrined in the Oviedo Convention, while not yet accepted as customary international law yet, do merit scrutiny as they consolidate the accepted international standards with regards to biomedicine. The Oviedo Convention imposes upon signatory States the obligation to protect the dignity, identity and human rights of all individuals and take legislative action to enforce the same in the application of biomedicine.[10] It also enumerates that human life takes precedence over the interests of society and science.[11] The human genome is specifically addressed in Chapter IV of the Convention where discrimination on grounds of genetic heritage is

[9] *Id.*
[10] Convention on Human Rights and Biomedicine, *supra* note 4, Article 1.
[11] Convention on Human Rights and Biomedicine, *supra* note 4, Article 2.

prohibited.[12] The Convention addresses predictive tests that identify genetic diseases and predisposition to a disease and states that such tests may only be undertaken for health purposes or for scientific research.[13] Perhaps the most important provision is Article 13. This provision is important because it delineates widely accepted ethical principles that have become the foundation of human genome modification law. The three pronged approach given in the same, can be understood as follows:

1. The use of genome editing can be done only for preventive, diagnostic or therapeutic purposes;
2. Germline editing or editing that can be passed down to future generations is prohibited;
3. Research involving modifications of the genome is, however, not prohibited.

The Oviedo Convention also prohibits the creation of human embryos for the sole purpose of research along with monetary gain from the human body and its parts.[14] Thus, in this manner the Convention protects genetic material under its ambit. Article 28 imposes on State Parties, the duty to conduct public consultation before

[12] Convention on Human Rights and Biomedicine, *supra* note 4, Article 11.
[13] Convention on Human Rights and Biomedicine, *supra* note 4, Article 12.
[14] Convention on Human Rights and Biomedicine, *supra* note 4, Article 18 and 21.

laws are made for the application of such developments in biomedicine.[15] The four Additional Protocols to the Oviedo Convention prohibit the cloning of human beings, regulate transplantation of human organs and tissues, restrict the ambit of biomedical research and genetic testing to health purposes. The Convention and its Protocols are a landmark in the evolution of human rights and biomedicine. At the core, it essentially just sets up basic principles that protect human dignity and integrity in the application of human gene editing practices. It sets common standards and leaves the specifics up to the Member States to handle.

4. The EU Charter of Fundamental Rights

The EU Charter consolidates the fundamental rights enjoyed by the citizens of the EU into one legally binding document. The Charter imposes on States the obligation to protect the personal freedoms and human rights of individuals within the EU. It came into force in December 2009 and is meant to reaffirm the rights as taken from the constitutional traditions and international obligations common to the Member States. It also brings together the rights enshrined in the EU Treaties, the European Convention for the Protection of Human Rights and in the

[15] Convention on Human Rights and Biomedicine, *supra* note 4, Article 28.

precedents as set by the Court of Justice of the European Union and of the European Court of Human Rights.[16]

The Charter is binding on Member States of the European Union and enjoys supremacy over domestic laws when there arises any conflict. The first Chapter of the Charter which talks of right to dignity contains Article 3 which directly references biomedicine and its applications to humans. Article 3 states that:

1. "Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
    a. the free and informed consent of the person concerned, according to the procedures laid down by law;
    b. the prohibition of eugenic practices, in particular those aiming at the selection of persons;

[16] Convention on Human Rights and Biomedicine, *supra* note 4, Preamble.

c. the prohibition on making the human body and its parts as such a source of financial gain;

d. the prohibition of the reproductive cloning of human beings."[17]

The Commentary to the Charter explains that Article 3 of the Charter relies on the principles already proposed in the Oviedo Convention. It maintains that the right to personal integrity does not allow interference with the bodily autonomy of an individual and this includes medical treatment without consent.[18] Therefore, genome editing without the consent of an individual would violate their right to physical integrity.

The Explanatory Report provides that Article 3 of the Charter reiterates what has already been mentioned in the Oviedo Convention, and therefore, prohibits reproductive cloning. It also prohibits eugenic practices such as "campaigns for sterilisation, forced pregnancy, compulsory ethnic marriage among others, all acts deemed to be international crimes in the Statute of the International Criminal Court."[19] The term "*eugenic*" was left

[17] Charter of Fundamental Rights, *supra* note 5 Article 3.
[18] *Id.*
[19] Explanations (1) Relating to the Charter of Fundamental Rights, 2007 O.J. (C 303/02), https://eur-lex.europa.eu/legal-

undefined and the Commentary does not clarify the term. It, rather, references eugenic practices as carried out is Nazi Germany, Bosnia and Herzegovina and those recognized under the Rome Statute to give context for the use of the term.[20]

The drawback of the Charter is its limited scope of application. Article 51 of the Charter states that it applies "to the institutions, bodies, offices and agencies of the Union" and "to the Member States only when they are implementing Union law."[21] This means that only where there is already an existing Union law pertaining to genome modification will the Charter and the right protected therein be applicable.

5. Domestic Regulations from different States and their Practical Implications

In the last decade, the discussion on gene modification and methods of insemination has expanded as scientists across the world make contentious arguments on approval and benefits of gene editing. This has given rise to conflicts concerning the international framework falling somewhat

content/EN/TXT/?uri=celex%3A32007X1214%2801%29 [hereinafter Explanations].

[20] EU Network of Independent Experts On Fundamental Rights, Commentary of The Charter of Fundamental Rights of the European Union, June, 2006, https://sites.uclouvain.be/cridho/documents/Download.Rep/NetworkCommentaryFinal.pdf (Last visited Sept.14, 2021).

[21] Explanations*, Supra* Note 19.

short. The fragmented and non-specific system allows states to implement and undertake a variety of approaches when it comes to formulating their domestic regulations on genome editing.

Domestic regulations are scanty with most countries lacking the scientific know-how and the technology to have well-informed laws. The United States of America ("**USA**") is one key player, alongside China and the EU. The USA has no specific prohibition on research or methods of conducting gene editing. Rather, it is the funding limitations imposed that prohibits states to grant financial support to any research in human embryos without assessing and assuring that the risk level is low.[22] It does not explicitly ban genome editing, hence, allowing clinical development to take place with private funding and approval. The USA Food & Drug Administration ("**FDA**") has the authority to regulate drugs produced for genome editing.[23] The authorities have not, in any of their guidelines, stressed on support or clarity over the use of gene editing to be limited to disease prevention or treatment, hence broadening the scope of methods and gene editing with human interference. Although the US Supreme Court did speak on the patentability of gene-

[22] Omnibus Appropriations Act, Pub. L. No. 111-8, (Dickey-Wicker Amendment, 1996), Sec. 509 (a), 123 Stat. 524 (2009).

[23] Food and Drug Administration, Cellular and Gene Therapy Guidances,https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/cellular-gene-therapy-guidances (Last visited Sept. 14, 2021).

editing, it did not touch the subject of validity or legality of gene-editing.[24] It must be noted that since the USA treats their domestic laws at par with international treaties, it is not of surprise that the topic of genome editing is restrictive and not completely banned.

It is important to understand that terms such as gene-editing, genome modification, germ-line editing and gene therapy are all part of the definition of genetic engineering. When it comes to the human gene modification, the scientific approaches are so far limited to the modification of embryos in most countries unlike Russia, wherein a certain ambiguity exists as to gene editing in humans. It doesn't prohibit human genome editing but prohibits biomedical interference with creation or development of the embryo.[25]

Israel, on the other hand, has completely prohibited the practice of genetic modification on humans since these are considered to be morally and scientifically implicating the human dignity. They have in place the 'Prohibition of Gene Intervention (Human Cloning and Genetic

[24] Association for Molecular Pathology v. Myriad Genetics, 133 S.Ct. 2107 (2013).
[25] Federal Law on Biomedical Products, Jun. 23, 2016, No. 180-FZ (Russ.).

Manipulation of Reproductive Cells) Law', specifically prohibiting gene-editing in reproductive cells.[26]

On the other approaches of the world, countries such as China, India and Japan have non-binding guidelines which place a ban over the methods of genome editing in humans but are legally unenforceable. The National Bioethics Committee[27] and Central Ethical Committee[28] guidelines are responsible for the genetic regulations in India. The guidelines issued by them imply two fundamental considerations to be kept in mind, first being the present knowledge in science and second being the level of risk the method or practice imposes while engaging in such a process.[29] The stem cell research guidelines[30] allow permissibility on a case-by-case basis for genetic manipulation in areas of research, and have several ethical and scientific restrictions under the non-binding guidelines. It is known that India is not part of the Oviedo

[26] Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 5759-1999, art. 3, SH No. 1697, p. 47 (Isr.).

[27] National Guidelines for Gene Therapy Product Development and clinical Trials (2019). Available at https://www.nhp.gov.in/NHPfiles/guidelines_GTP.pdf Last seen on 14/09/2021.

[28] INDIAN COUNCIL OF MEDICAL RESEARCH, NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPATION (Roli Mathur, ed., 2017), (Last visited Sept. 14, 2021).https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (Last visited Sept. 14, 2021).

[29] INDIAN COUNCIL OF MEDICAL RESEARCH, ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH ON HUMAN SUBJECTS (ICMR, 2006), http://www.icmr.nic.in/ethical_guidelines.pdf.

[30] *Supra* note 25 and 26.

Convention and has no binding restrictions in place which makes it even more difficult to have records and supervision over such activities. On the other hand, with the same non-binding guidelines Japan has an express prohibition on human, animal embryos genetic interference.

The most legally forward stand is taken in the case of Mexico where the laws criminalize genetic intervention, with penal punishments.[31] The scientific and research exception is to be in accordance with the laws and any illicit or illegal act by a person will qualify for criminal activity.[32] Australia is similar in the sense of an action-based approach. The state has domestic criminal laws in place for cloning as a method of reproduction under which it penalizes the offense of gene alteration.[33] It has also criminalized the trading of embryos as per the requirements under the provisions.[34] That being said, most of the EU powers such as France[35] and Germany[36] have also classified, as per their requirement, gene-editing or

[31] Art. 7, CÁMARA DE DIPUTADOS DEL H. CONGRESO DE LA UNIÓN, LEY GENERAL DE SALUD, http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf (Last seen on 14/09/2021).
[32] *Id*, Art. 103 bis 5.
[33] *Prohibition of Human Cloning for Reproduction Act 2002* (as amended 2008) (Cth) art. 15 (Austl.).
[34] *Id,* Art. 20.
[35] CODE PÉNAL [C. PÉN.][PENAL CODE] art. 214-1 (Fr.).
[36] EMBRYONENSCHUTZGESETZ [ESCHG][EMBRYO PROTECTION ACT], https://www.rki.de/SharedDocs/Gesetzestexte/Embryonenschutzgesetz_englisch.pdf?__blob=publicationFile (Ger.).

genetic alteration of human reproduction process as a criminal offense. The domestic law approaches are changing with different jurisdictions, genetic modification being the next most anticipated medical research area as seen in scientific discussions. It becomes more and more prominent that there exists a need for an international mechanism for genetic engineering that could provide the nations with guidelines and ideas that they can apply as per their domestic standards and implement them while keeping up the balance between scientific studies and human rights. One must emphasize on the urgent need for addressing these issues and securing the human rights.

6. Gene-Editing and the Issue of Human Rights and Ethics

The interest of the international community was at its peak when He Jiankui made the world aware of his experiment of gene-edited babies in 2018. This made a drastic impact on China's efforts and the international forums which obliviously led to scientists propagating for a global framework. Genome editing is viewed from two sides – the scientific and the ethical. The main goal is to provide the freedom for science and research to take place without violating anyone's rights but the question to consider is what exactly constitutes violation and how can people be secured, and their grievances remedied.

In Mexico, the case of a baby from three parents raised concerns on the issues of ethical standing and limitation of legislations domestically and internationally in 2016. Here, it was the first baby born after a mitochondrial replacement technique, but this was only possible after the federal regulations were broken by the scientists.[37] It wasn't too long before the advancement of heritable genome editing in 2018 initiated a discourse on the capability of this particular technology and its development. It called together a group of experts from both science and legal fields to collaborate and produced a report recommending consideration for safety and efficacy in genome editing and a mechanism of legal oversight for assurance of state and person's accountability. Several risk factors and consideration of element of human health before pursuance with any method of gene modification interference have been emphasized in the 2020 report on *Heritable Human Genome Editing.*[38] While tremendous efforts have been taken by the panel to push the legalisation for methods of genetic engineering in humans, the human element in itself prompts many issues relating to the level of protection for human rights including the

[37] Palacios-González et. al, *Mitochondrial replacement techniques and Mexico's rule of law: on the legality of the first maternal spindle transfer case* 4 J. LAW BIOSCI. 50 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5570699/ (Last visited Sept. 14, 2021).

[38] NATIONAL ACADEMY OF MEDICINE ET. AL,, HERITABLE HUMAN GENOME EDITING (National Academies Press, 2020).

right to information and privacy, all of which can't be contractually waived off.

The context in which human rights are being inferred is the aspect of physical integrity, although the main conflict is with respect to the protection of such rights of a person at the time of and after birth. The question of rights of the embryo and of the violation of said human rights is a key debate in regulating genome editing. Hence, it becomes even more urgent to address the interpretations and the extent of application of human rights in the area of gene editing. The point of worry for the human rights framework is somewhere in the middle of these arguments. The Oviedo Convention, at the time, was a major milestone in the development of biomedicine law. Even though its signatories were few, the principles enshrined in the Convention have come to be the bedrock for modern jurisprudence regarding human genomics. The shortcoming of the Conventions was its limited application with states such as UK, USA, Russia, Germany, Japan, Australia, who possess advanced scientific and rising technologies to access genetic engineering, not becoming signatories to the treaty.[39]

Human rights are integrated to be a part of every legislation all over the world and even then, there is so much more to

[39] Convention on Human Rights and Biomedicine, *supra* note 4.

be learned as to what is to be understood as human rights. It is an evolutionary process of inclusion of many unknown rights and so as the world moves towards advancing in different fields, varied forums need to work collectively in safeguarding individual human interest along with public interest. Human dignity, as we know it, forms the basis of the majority of human rights. The same is reflected in the conventions mentioned in this paper and this is the reason for reluctance from the states in regularisation by allowing human gene-editing. The courts from different jurisdictions have something similar to address, in Germany, the federal constitution court held that the form of life doesn't need to be aware of dignity attested to it, it exists from the moment life is formed.[40]

The ethical complexities and severity lies with the uncertainty gene editing brings, the long term effects would have to be monitored for clinical research. It is important to remember that gene editing will be a business opportunity directly falling under the prospect of both business and human rights where the interest will be weighed against the insurance and contractual obligations which are all together against the core of human rights. There is a basic deductive theory which proposes the

[40] Bundesverfassungsgerichts [BVerfGe] [Federal Constitutional Court] Feb. 25, 1975, BVerfG, Order of the Second Senate of 28 May 1993 - 2 BvF 2/90 -, paras. 1-434.

consequences of allowing one form of genetic engineering in humans would eventually lead to the evolution of another. The theory is known as the slippery slope argument. The theory elaborates upon the consequences of creation and evolution through a chain reaction by performance of an act in genetic interference, "if one form is allowed the other will soon follow".[41]

In India, researchers such as Pandya have pointed out such violations of the right of genetic inheritability by generations of unconsented participation of embryo involved in trial, usage of alteration methods not associated with treatment and an open door for experiments.[42] There are several challenges with genetic modifications in humans, whether that be the right to physical body, human dignity, privacy, racial and generational equity. The impact of gene-editing will initiate action on a person's life just after they are born. One of the other ethical and human rights factors is that of informed consent; people having the right to know of the implications and effect on health before and during the process, having the right to free themselves from the same if genetic engineering is ever allowed. Human rights waivers may even become a part of settlement agreements amongst parties which itself stand

[41] T. McGleenan, *Human Gene Therapy and Slippery Slope Arguments,*21 J. MED. ETHICS 350 (1995).
[42] S.K Pandya, *Ethical Aspects of Clinical Trials in Gene Therapy*, 8 ISSUES MED. ETHICS 122 (2000), https://pubmed.ncbi.nlm.nih.gov/16323376/ (last visited May 26, 2021).

as a violation of the standards of human rights as we know today.

III. CHALLENGES TO EFFICIENT GOVERNANCE OF GENOME EDITING

There are significant challenges to overcome before an effective international regime governing genome editing and its application can be formulated. The process of getting States to sign and ratify such a regulation will be a herculean task in itself. This is why it is crucial that the intricacies of the technological and scientific aspects of the gene editing process is carefully and completely laid down before the States are even brought to the table. There are significant hurdles that prevent the current regulations from being efficient tools in the governance of genome editing.

1. The Uncertain Terminologies

The problem with regulating a nascent science is the unpredictable nature of its results. This is the case with genome editing. There have been innumerable efforts made to formulate a law regarding the science but the primary hurdle is the vagueness of the definitions. Take for example the EU's Biotech Directive which mentions 'germline genetic identity' and prohibits patenting of the process for modifying the same as well as those for cloning

of human beings.[43] The term itself is ambiguous. It is also uncertain how a germline intervention shall affect the genetic identity of the individual in the future. The prohibition does not specify whether all germline interventions are covered by the provision or only the ones that affect identity or pre-determined characteristics of future individuals.[44]

The scientific process in itself is so complex and has various facets that use vague terminologies in regulatory frameworks and are bound to give rise to future conflicts. The process of Human Nuclear Genome Transfer ("**HNGT**"), for example, is different from gene editing. Therein the dysfunctional mitochondrial DNA is replaced by healthy mitochondrial DNA.[45] It can be argued that HGNT would not fall under the ambit of the above-mentioned provision as it does not affect the genetic identity of an individual. However, it still comprises modification of the person's DNA and "is not substantively different from modification of the nuclear DNA in terms of its effects on the identity of the future

[43] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.1998, p. 13–21, 40.

[44] Bredenoord AL et. al., *Ethics of Modifying the Mitochondrial Genome*, 37 JOURNAL OF MEDICAL ETHICS 97 (2010), https://www.researchgate.net/publication/47755512_Ethics_of_modifying_the_mitochondrial_genome/link/0f317536b95743b325000000/download(last visited Sept. 14, 2021).

[45] Falk et. al., *Mitochondrial Replacement Techniques — Implications for the Clinical Community,* 374 N. ENGL. J. MED. 1103 (2016).

person."[46] However, countries have created significant distinction between how both of the process are regulated. While in the UK[47] editing of nuclear embryonic DNA is banned, the same ban does not include nuclear mitochondrial DNA as used in HGNT.[48] This ambiguity is not limited to the above-mentioned countries. This advanced process has given rise to the application of HGNT procedures on humans resulting in many 'three parent babies' being born around the world with the first baby being born in 2016.[49]

Similarly, other terms remained undefined leading to a wide scope being given to the laws. The term "eugenic practices" as mentioned in the EU Charter, discussed above, lends to the understanding that only organized 'selection programs' involving a large number of people shall be considered a eugenic practice and not that of individuals who voluntarily undertake such reproductive methods. The same provision contains the words 'among others' which also indicates that there are a variety of eugenic practices that have not been mentioned in the

[46] A.L. Bredenoord et. al., *Ethics of Modifying the Mitochondrial Genome,* 37 JOURNAL OF MEDICAL ETHICS 97 (2011).
[47] The Human Fertilisation and Embryology Act 2008, c. 22, Section 3 (UK).
[48] The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015, SI 2015/572, Explanatory Note (UK).
[49] Jessica Hamzelou, *Exclusive: World's First Baby Born with New "3 Parent" Technique*, NEW SCIENTIST, Sept. 27, 2016, https://www.newscientist.com/article/2107219-exclusive-worlds-first-baby-born-with-new-3-parent-technique/ (last visited May 26, 2021).

Charter giving rise to uncertainty. There is also a question of ethical objections raised by third parties. If parties undertaking the procedure give informed consent, such third-party objections should have no legal ground.

Even the terms 'clinical trials' and 'subjects' have raised considerable debate. This is because the EU law centres on the 'subject' of the clinical trials. Scholars argue that germline editing is performed on embryos and not persons, because of which, it does not qualify as a clinical trial.[50] Objecting to this, is the argument that it is not the rights of the embryo that are in concern, rather the rights of the individual that shall be born of such procedure should be the subject.

2. Overcoming the Existing Legislative Structure

Regulatory differences exist as countries have different methods of approaching each issue. When it comes to making laws, countries formulate them keeping in mind the risk level involved.[51] In the United States, drug regulations are treaties with the same level of risk for all

[50] NUFFIELD COUNCIL ON BIOETHICS, GENOME EDITING AND HUMAN REPRODUCTION: SOCIAL AND ETHICAL ISSUES (Nuffield Council on Bioethics, 2018), https://www.nuffieldbioethics.org/assets/pdfs/Genome-editing-and-human-reproduction-report.pdf (last visited Sept. 14, 2021).

[51] R. Alta Charo, *Legal and Regulatory Context for Human Gene Editing,* 32 ISS. SCI. TECH. (2016) https://issues.org/legal-and-regulatory-context-fhuman-gene-editing/ (last visited May 26, 2021).

drugs whereas when it comes to clinical trials, there is efficacy and safety levels considered before regulations are placed and all are detrimental to the fact 'what does the states consider as low, medium or high risk?'. As discussed before, some consider genome modifications as high risk while others treat it as medium.[52] The major issues are regulations permitting gene editing, the ambiguity of present regulations which exists over its scope of use on human genome and therapeutic purposes which definitely needs to be addressed with authority.

To this extent, it is to be noted that approach to structural changes in genetic reforms is differing among states with some states such as Mexico and France providing penal provisions for violations whereas some, such as UK and USA consider them as just violations of guidelines with no human rights security. Getting states to agree on the same lines of penalisations and protection would only be possible by establishing the same understanding of risk level as uniformly as possible. One of the other things associated is privatisation, which can result from stopping state funds for this purpose as it leaves the door open for the private sector to invest. States have vague regulations such as the National Guidelines given by the Indian medical council for Research in India and its counterpart

[52] The Regulations on Administration of Human Genetic Resources, July 1,2019 (China).

in the UK that don't clearly prohibit private funding for clinical trials and research. Heath care is one of the biggest sectors that involves a lot of keeping up when legislations are to be implemented and states not having bioethical restrictions in their laws serves to form loopholes that allow for breakthroughs.

3. Criminalisation and Accountability

The major challenge is the degree of crime to determine if ethical and human rights are violated in genetic modifications. Even after assessing and establishing the risk factor,[53] the states would be conflicted with criminalisation as the classification of illegal practices have lesser implications when weighed-in against human rights violations. Scientific methods such as gene editing require complete technological and financial support, and that would require the states to implicate even those stakeholders as offenders who are involved. This would require for states to enter into bilateral treaties for cooperation since investors could be from any other states, and to hold them accountable under one countries legislation without it being an offense in another is highly unlikely without an understanding between the countries' themselves. Take for example the case cited of the first 'three-parent baby' born to Jordanian parents treated by a

[53] *Id.*

US-based team in Mexico. Therein, the stakeholders have three distinct nationalities and their consequent jurisdictions have differing levels of accepted standards when it comes to human gene editing. Finding and establishing a regime with accountability of cross-border stakeholders would again become challenging without an international regime directing for accountability and state cooperation.[54] It would require changes in the extradition acts and treaties amongst nations that could possibly take years after getting legislations approved in their own nations. Some countries could see this as a possible limitation towards advancing science and not implement any regulations as they have done till date due to lack of understanding and uncertainty.

IV. A PROPOSED SOLUTION

The revision of the existing frameworks seems to be the need of the hour with many people from the scientific communities calling for significant reform. Keeping in mind the human rights concerns, the laws must be revised and the bans and moratoria need to be reconsidered. It calls for an international regime to be established which learns from the short comings of the existing laws to gain widespread acceptance.

[54] Xiaomei Zhai et. al, *No Ethical Divide Between China and The West In Human Embryo Research*,16 DEV. WORLD BIOETH.116 (2016).

1. Prohibition v. Regulation

There is consensus among the scientific community that an international treaty that bans all clinical use of germline editing, like the Oviedo Convention, is not desirable.[55] This would be a restrictive and rigid path. Rather the focus should be on effective governance of the technology. While bans work for the moment, they should be lifted when the clinical requirements are met. This presupposes that extensive research is facilitated by the States which is closely monitored so as to ensure that safe methods are undertaken. This means that provisions like Article 18 of the Oviedo Convention which prohibit creation of embryos for research purposes must be scrapped. When safety and clinical requirements are met, the bans and moratoria must be lifted. To ensure safe practice, the regulations must contain provisions that state that gene editing processes can only be undertaken for therapeutic purposes much like the Oviedo Convention. These purposes must be clearly defined and must exclusively include elimination of serious genetic diseases and conditions. Other non-medicinal uses like for aesthetic purposes must remain prohibited. The regulations must be explicit to ensure the same. The method of public

[55] E.S. Lander et. al., *Adopt a Moratorium on Heritable Genome Editing*, Nature, Mar. 13, 2019, https://www.nature.com/articles/d41586-019-00726-5(last visited Sept. 14, 2021).

consultation must be resorted to determine the requirements for allowing reproductive gene editing in humans. These public debates can weigh the human rights issues of the processes as well.

2. The Distinction between Treatment and Enhancement

The argument for a progressive legal regime for human genome editing seems logical when it allows for the application of the technology for therapeutic processes and to prevent diseases. Most of the existing regimes also ban genetic modification for 'enhancement' of any type. Here it becomes very important that a clear distinction between treatment and enhancement is established.

This should not be a hard task to accomplish. As mentioned most existing laws ban genome editing where it alters genetic identity or is used for eugenic purposes. A similar approach has already been successful in the case of non-invasive prenatal testing and pre-implantation genetic diagnosis where the doctors can test embryos "to identify genetic abnormalities in embryos created through in vitro fertilization ("**IVF**") before pregnancy."[56] The said process is undertaken according to predetermined medical

[56] Molina Dayal et. al., *Preimplantation Genetic Diagnosis: Overview, Indications and Conditions, Process*, Medscape, Aug. 29, 2018, https://emedicine.medscape.com/article/273415-overview (last visited May 26, 2021).

guidelines and a regulatory framework that so far has created no issues.

However, the process is vastly different from human genome editing. There is more of a risk involved with gene editing such as introduction of genes that have never been observed in humans as has been done in the case of the Chinese genetically modified babies. The aim therein was to create babies resistant to HIV rather than to cure a disease. Therefore, it becomes necessary that whichever regulation is formulated defines explicitly the terms "serious disease or condition" as well as "therapeutic purposes."

3. Attachment of Liability

Gene-editing is progressive and a risk driven practice, one that will have impact on both social and health evolution. There is still much to be learned about it scientifically for therapeutic purposes itself, yet there are few extremist scientists such as the ones involved in the Mexico and China cases who initiate experiments in the stages that are non-therapeutic, especially for genetic identity engineering in embryos. Hence, calling for enthusiasm to participate in activities and trials, endangering life of people and encouraging others in that same sense. Since the 2020 report, there were a few recommendations made by the panel and the major call was for states to have an

international mechanism to guide them. Also having an established panel of international scientific advisors to monitor such activities. Although, all these are suggestive towards the presumption of being allowed to carry out HHGE in states.

One thing is true, there needs to be an address through international community in the form of another convention that regulates and provides binding consequences and provisions for criminal investigation by an established panel for this specific task and which will ensure a higher standard of security to the public and practitioners. The regulatory responsibility should be with this panel, being branched out in partied states assisting in domestic legal frameworks' formation and implementation. Having experts from social, scientific and legal fields from States to act in accordance of the convention having to report back annually, the progress and events to the main panel of the UN.

The safe development of genome research invariably is through the medium of legislations that can govern in accordance with human rights and yet allow for scientific advances to be experimented. The balance can only be achieved, when like any other offense, these violations of regulations carry severe consequences. If a panel is set up to deal with the specific purpose of recognising genetic editing not in accordance with the convention or those not

for approved purposes like therapeutic, disease prevention or treatment to save lives, then discrepancies in law and execution can be corrected instantly. This will ensure that practices of human gene editing outside the ambit of existing legislations is declared illegal and appropriate penal punishments for human rights violations are issued.

V. CONCLUSION

The modification of genetic identity is a daunting reality. There has been much resistance to the developing technology with many countries placing complete bans on the use of gene editing in the case of humans. The primary concern has been how such procedures can violate human rights of the person born out of such experiments. The human genome editing process used for reproduction is said to be against human dignity and freedom. Understandably, society has been vary of such technology being used to undertake eugenic practices and make "*designer babies*."

CRISPR has gone into wide use and application since then, as more and more individuals have become aware of the availability of such technologies. The existing frameworks, that once were cutting edge, seem outdated now. Since the technology is now readily available, the bans and moratoria have been unable to stop those curious, daring and industrious deviants who experiment. Today the generally

accepted standard for application of gene editing to humans is for therapeutic purposes and with a preventive aim.

The only approach is one centred on human rights. Both the human right to dignity as well as that to benefit from scientific advancement and research should be the goal of a regulatory framework designed for the governance of human gene editing. The human rights discourse will facilitate the development of an ethical perspective to a science which has the potential of having an extraordinary impact on the future of humanity.

It is widely accepted that there exists a distinction between human germline editing for therapeutic and non-therapeutic purposes. Thus, there exists a place where the application of human gene editing shall be in consonance with human rights laws, i.e., to prevent serious diseases and conditions. All that remains is to make an international regulation that takes all these suggestions into consideration to achieve a law that aids the scientific process and does not hinder it. Rarely do complete prohibitions inhibit the curious minds who wish to undertake such processes. The best we can do is to make a regulation that defines what is permissible and what is not as well as attaches liability to those breaking such rules. The establishment of international governing authority will also aid in overlooking this burgeoning field in its early

days. While it may seem that human rights and gene editing shall forever remain at loggerheads that may not necessarily be the case. Human rights, like its subjects, are living principles evolving with time and circumstance. Gene editing is just one such circumstance.