

2023

**THE LEGAL DILEMMA OF HUMAN GERMLINE
ENGINEERING**

Akshaya Jebakumar

Recommended Citation

Akshaya Jebakumar, 'The Legal Dilemma of Human Germline Engineering' (2023) 2 IJHRLR 67-88.

Available at www.humanrightlawreview.in/vol-2-issue-3/.

This Art. is brought to you for free and open access by the International Journal of Human Rights Law Review by an authorized Lex Assisto Media and Publications administrator. For more information, please contact info@humanrightlawreview.in.

THE LEGAL DILEMMA OF HUMAN GERMLINE ENGINEERING

Akshaya Jebakumar¹

ABSTRACT

The paper examines the ethical and legal ramifications of genetic engineering with a particular focus on human germline engineering. It looks at a three-question framework to assess whether human germline engineering should be embraced or abandoned. The existing legal system, including international law and domestic law in the US and India, is examined. While there are possible advantages to genetic engineering, such the eradication of diseases, there are also drawbacks, like the commodification of life and societal division. Discussed risks include off-target mutations, consent difficulties, genetic augmentation, and inequality. The purpose of the essay is to offer a legal analysis and suggest ways to balance the benefits of genetic engineering with their drawbacks.

KEYWORDS

Human Germline Engineering, Legal Analysis, CRISPR, Human Rights, Technology

INTRODUCTION

For a long time now, science fiction has imagined worlds where human beings are capable of being superhumans. For example, Stan Lee's conception of the X-Men, a superhero team of mutants born with a genetic trait called the X-gene which naturally gives them superhero capabilities. Plenty of the stories deal with the prejudice and discrimination they face on account of their mutation. In the movie series, the controversial Mutant Registration Act is passed into law

¹ Law Student, 5th Year, BBA.LL.B.(Hons.), Jindal Global Law School, Sonapat.

which enforced mandatory registration of mutant individuals with the government. Some real-life gene mutations in history have produced real life superpowers such as Liam Hoekstra, the world's strongest toddler, who had a rare genetic condition in which his body blocked the protein *myostatin* which inhibits muscle growth which led to him having larger muscles with little body fat².

However, science fiction is slowly becoming a reality with the growth of genetic engineering, allowing us the ability to edit genes. There is now a possibility of choosing to mutate a gene to free a child from Mendelian diseases such as cystic fibrosis, sickle cell diseases, muscular dystrophy and so on. There is even a possibility of eradicating such diseases in a family line with germline engineering. The idea of being able to use genetic technology to ease human suffering and unlock potential that can only be imagined is fascinating. The same technology, however, also raises concerns such as devaluing and commodifying human life and increasing division amongst societies. Human beings have long been in the business of altering the world around but can we as human beings hack natural evolution and self-design ourselves?

How can one unlock the potential of genetic engineering while minimising the atrocities that can arise from its use? One such way is through the passing of laws. Over time, there has been an emphasis on the intersection of law with science and technology. Law regulates science and technology through passing of laws and provides remedies to aggrieved parties by the judiciary. However, most countries have legislations that banned altering human genomes citing concerns such as safety of techniques, lack of research on long term effects, possibility of erroneous genome editing, etc.

This paper primarily aims to look at genetic engineering from a legal

² PCMag Staff, *13 Humans With Real-Life X-Men Mutant Super Powers*, PC MAAG (March 14, 2023, 14:32), <https://www.pcmag.com/news/13-humans-with-real-life-x-men-mutant-super-powers>.

lens. Specifically, this paper shall look at human germline engineering since the issue of heritability raises a myriad of ethical, social, and legal concerns. Thereafter, a three-question framework is provided – question of equality, question of risks and question of autonomy. This framework is used to assess whether human germline engineering should be embraced or brought to a halt. Subsequently, the current legal framework on human germline engineering is laid out – international law, Indian domestic law, and US domestic law. Lastly, based on the information laid out, a legal analysis is provided as well as suggestions that can be implemented in this area.

AN OVERVIEW OF GENETIC ENGINEERING

Genetic engineering refers to the process in which laboratory-based technology can be used to alter the DNA makeup of an organism³. It allows for self-design mutation. These techniques involve locating the gene that is to be edited and making the necessary changes to it such as deleting, repairing, replacing, etc⁴. This may even include adding a gene from one organism to another organism of another species in order to produce a desired trait. Genetic engineering techniques are used in producing genetically modified plants and livestock (GMOs), cancer therapy, brewing yeasts, etc⁵.

Primarily, there are two types of human genetic engineering or editing – somatic and germline. The difference in the two is the heritability of the altered gene. With somatic gene editing, the change only affects the patient who is being treated since it targets only genes in specific types of cells. However, germline editing affects all the cells in the organism since it targets genes in an early embryo which is copied in every cell

³ Mary Todd Bergman, *Perspectives on gene editing*, THE HARVARD GAZETTE (March 14, 2023, 18:04), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>.

⁴ Mary Todd Bergman, *Perspectives on gene editing*, THE HARVARD GAZETTE (March 14, 2023, 18:04), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>.

⁵ Mary Todd Bergman, *Perspectives on gene editing*, THE HARVARD GAZETTE (March 14, 2023, 18:04), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>.

and hence can be passed on to future generations⁶. While somatic gene editing has been researched and tested for over two decades and is highly regulated, germline gene editing is a novel concept and heritability of such edited genes brings about ethical and moral concerns that are to be addressed⁷. This paper is interested in the latter due to the futuristic implications it has.

Of the many genetic modification technologies, the most well-known and popular is CRISPR-Cas9 genetic modification technology (“**CRISPR**”). It was first developed by a University of California, Berkeley research team led by biochemist Jennifer A. Doudna and French Scientist Emmanuelle Charpentier⁸. Cas9 is an enzyme that is capable of cutting apart DNA which is used by bacteria to fight off viruses. This virus fighting tool is used to tweak the genes of any plant or animal and has gained popularity due to the simplicity, ease and inexpensiveness of the method which has led to genetic editing being more accessible⁹.

With genetic engineering technology being more accessible, there are questions of its potential floating around. If we can control the mutations of our genes, can we aim to eradicate diseases such as sickle cell anaemia, Huntington’s disease or even breast cancer? Could we use this technology to produce stronger and faster human beings? Can we manipulate an embryo’s IQ? Such instances give rise to concerns of unequal access to resources, increase in discrimination and even the misuse of such technologies for biological weapons. What is necessary is the need to draw a line between how such technologies can benefit us and where it has potential to harm us.

⁶ Mary Todd Bergman, *Perspectives on gene editing*, THE HARVARD GAZETTE (March 14, 2023, 18:04), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>.

⁷ Mary Todd Bergman, *Perspectives on gene editing*, THE HARVARD GAZETTE (March 14, 2023, 18:04), <https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>.

⁸ James Kozubek, *Crispr-Cas9 is Impossible to Stop*, 18(2) GEORGETOWN JOURNAL OF INTERNATIONAL AFFAIRS, 112-119 (2017)

⁹ Adam J. Gross, *Dr. Frankenstein, Or: How I Learned To Stop Worrying And Love Crispr-Cas9*, 56(4) JURIMETRICS, 413-447 (2016)

QUESTIONS OF EQUALITY, RISKS AND AUTONOMY

In November 2018, Chinese scientist He Jiankui announced at a conference in Hong Kong that he had created the world's first genetically edited babies¹⁰. The twins were born from genetically modified embryos which were genetically edited by CRISPR genetic editing technology to be made HIV resistant¹¹. In 2019 he was sentenced by a Chinese local Court to imprisonment of 3 years as well as a 3 million RMB Yuan fine for committing the crime of “illegal medical practice”¹². Initially praised as a major scientific advancement, it later received major condemnation due to the concerns of genetically editing human embryos¹³. Vivek Wadhwa with Alex Salkever in their book “The Driver in the Driverless Car,” discuss the impact of rapidly evolving technology in our lives and our future. The book provides a three-question framework to evaluate the value of technology to humankind:

1. Question of equality – whether or not the technology has the potential to benefit everyone equally.
2. Question of risks – the risks and rewards of the technology.
3. Question of autonomy – whether or not the technology strongly promotes autonomy or dependence.

If the technology has the potential to benefit everyone equally, the rewards outweigh the risks and the technology strongly promotes autonomy, then such technology would be of high value to humankind.

QUESTION OF EQUALITY

¹⁰ Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) STEM CELL REPORTS, 530-537 (2020).

¹¹ Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) STEM CELL REPORTS, 530-537 (2020).

¹² Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) STEM CELL REPORTS, 530-537 (2020).

¹³ Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) STEM CELL REPORTS, 530-537 (2020).

To answer this question with respect to human germline engineering, focus is mainly being drawn to the reward of therapeutic gene editing. The market of healthcare technologies is starkly divided between the poor and rich. However, improving healthcare through technology may make it accessible to more people over time. Take the example of smartphones for example: it was initially available only to the elite but over time, the smartphone industry was capable of driving the prices down making it accessible to almost everyone. Similarly, human germline engineering technology may be initially available to only the elite but over time, with research and funding, the market would be capable of making such technology available to different strata of the population.

At the same time, it cannot be denied that this technology on the flip side also has the potential of production of designer babies which can threaten the fabric of our social society. This point has been further elaborated upon when addressing the question of risks.

QUESTION OF RISKS

Rewards	Risks
Therapeutic Gene Editing to Treat Serious Illnesses	Off-Target Mutations
Rational Evolution	Problem of Consent
Delay Aging	Threat of Genetic Enhancement
Cost-Effective Technology such as CRISPR	Rise in Inequality and Discrimination

Table 1: Summarised Table of Benefits and Risks of Human Germline Engineering

Reward: Therapeutic Gene Editing

The most commonly cited benefit of human germline engineering is therapeutic gene editing. There are certain serious illnesses that

medicine has struggled to find a cure for. These include dominant diseases such as Huntington's disease and where you are most likely to get the disease if you inherit the single gene responsible for it or recessive disorders like sickle cell anaemia and Tay Sachs where you must inherit the gene from both parents to get the disease. Both Huntington's and Tay-Sachs have no cure whatsoever but human germline engineering, if used, can treat the gene that causes such diseases and potentially eradicate the disease. The only current cures for sickle cell anaemia are stem cell and/or bone marrow transplants which are of high risk. Human germline engineering may also be an alternative, safer cure for such diseases. Furthermore, widely available human germline engineering to treat such diseases may allow people to avoid the cost of providing a lifetime of care for those that would otherwise be born with such diseases.

Risk: Problem of Consent

Since human germline engineering involves the editing of the gene of an embryo, the problem of consent of the embryo arises. When it comes to research, informed consent is a regulatory requirement and for treatments such as IVF, informed consent to treat the embryo must be given by the oocyte and sperm donor¹⁴. However, consent becomes an issue in human germline engineering as the change made impacts not only the embryo that the parents consent to but as well as future generations who had no say in the matter¹⁵. In the CRISPR-baby experiment, Dr. He had used female participant consent forms but did not use any male participant consent. The lack of regulation with respect to informed consent in the area can lead to misuse¹⁶.

¹⁴ Naomi Cahn, *CRISPR Parents and Informed Consent*, 23 SMU SCI. & TECH. L. REV. 3 (2021) <https://scholar.smu.edu/scitech/vol23/iss1/2>

¹⁵ Naomi Cahn, *CRISPR Parents and Informed Consent*, 23 SMU SCI. & TECH. L. REV. 3 (2021) <https://scholar.smu.edu/scitech/vol23/iss1/2>

¹⁶ Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) STEM CELL REPORTS, 530-537 (2020).

Reward: Rational Evolution

This is a controversial argument to make yet in the future it may be a strong argument in favour of human germline engineering. Nature does not allocate genes equally amongst the human population – some are more susceptible to certain diseases than others. Genes are partially responsible for certain human characteristics such as strength, IQ, height, etc. Rational evolution through human germline engineering may even allow eradication of psychopaths in society. Natural evolution is widely accepted yet rational evolution, that is the ability of science to alter genes, is disputed. Nonetheless, rational evolution may be viewed by some advocates of human germline engineering as something that benefits the human society as a whole.

Risk: Threat of Genetic Enhancement

Liberal eugenics, a term coined by Nicholas Agar, refers to human enhancement by human genetic engineering. While there are those who argue that parents should have access to such technology to make the best-informed decisions, a majority fear the risk of production of designer babies that can threaten the social system in place. Potential genetic enhancements could include increase in IQ, creativity, physical characteristics like height or beauty, super sensory capabilities, etc. If people are allowed to choose to make such modifications to embryos that further affect their descendants, their decisions may be impacted by cultural biases which would further widen the gap in society. This may even lead to something alike the Nazi Eugenics.

Reward: Delay Aging

Aging is the leading cause of death amongst humans. This includes diseases such as heart disease and cancer amongst many. Human germline engineering has the capacity to delay aging. Telomeres is a specific DNA-protein structure that can be found at the end of

chromosome. It has found to be responsible for aging as the length of the telomere shortens with age¹⁷. Techniques like CRISPR can be used to edit telomeres to delay aging in human beings and can potentially increase life expectancy in human beings¹⁸.

Risk: Off-Target Mutations

The main medical risk or concern with human germline engineering is the risk of off-target mutations, that is, a gene editing gone wrong. Since human germline engineering leads to heritable changes, any off-target mutation would not only affect the gene edited embryo but also future generations of that lineage. Hence off-target mutations carry a large risk with it.

Reward: Cost-Effective Technologies like CRISPR

Human germline engineering is a novel technology that is still being explored. Its novelty means that there is lack of funding, making it an expensive ordeal. However, the advent of technology such as CRISPR-Cas9 makes the process simpler and cost-effective, allowing more people to access the technology. There is a possibility that over time this technology would become more accessible and cheaper for common people to make use of.

Risk: Rise in Inequality and Discrimination

Firstly, the novelty of the technology makes it an expensive and inaccessible technology (other than CRISPR) which means that only those who can afford to spend such money would be capable of making use of such technology. The future implication of the technology also means that any changes made to an embryo would be heritable and

¹⁷ Brane, A. C., & Tollefsbol, T. O, *Targeting Telomeres and Telomerase: Studies in Aging and Disease Utilizing CRISPR/Cas9 Technology*. *Cells*, 8(2), 186. <https://doi.org/10.3390/cells8020186>

¹⁸ Brane, A. C., & Tollefsbol, T. O, *Targeting Telomeres and Telomerase: Studies in Aging and Disease Utilizing CRISPR/Cas9 Technology*. *Cells*, 8(2), 186. <https://doi.org/10.3390/cells8020186>

passed down to future generations. Such changes impact the family line. Families that can afford it would be able to eradicate serious illnesses such as Huntington's disease for generations while others would still be at risk to such diseases.

QUESTION OF AUTONOMY

With respect to the question of autonomy, it is important that we do not depend on technology but instead that such technology promises us greater autonomy to live our lives the way we wish to. Focus will yet again be drawn towards the benefit of therapeutic gene therapy – curing illnesses such as HIV, Huntington's, Tay-Sachs, etc. would make us capable of living our lives the way we wish to. People would no longer have to visit hospitals and clinics for constant treatment of such diseases. All in all, there is a potential for autonomy with human germline engineering.

CURRENT LEGAL FRAMEWORK ON HUMAN GERMLINE ENGINEERING

Science is an ever-growing field with concerns of its impact on people's lives being constantly voiced out. Before the Internet took over our lives, concerns of data privacy were flooding yet the Internet intersects in every aspect of our everyday lives now. Law and policy allow us to regulate and control the way in which science and technology enters our lives. For the most part, human germline engineering has been legally banned in most countries. This section of the paper shall look into the legal standing on the subject matter by first looking at international law. It moves on to then look at what Indian law has to say on human germline engineering as well as the legal positions in the US.

INTERNATIONAL LAW ON HUMAN GERMLINE ENGINEERING

International law that directly deals with human germline engineering is quite scant. Firstly, there is the Convention on Human Rights and Biomedicine also known as the Oviedo Convention which is the only internationally legally binding instrument on human rights protection in the biomedical field¹⁹. It established that when it comes to biomedicine, interests and welfare of individuals should always prevail over that of science and society²⁰. However, this Convention is only applicable to Europe²¹.

The Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO in 1997, recognizes the importance of the human genome. It emphasizes that the human genome should benefit everyone and that it is important to respect human dignity, privacy and freedom of choice when it comes to any and all activities with respect to the human genome²². It promotes responsible practices and ethical standards and primarily protects the fundamental rights and freedoms of individuals in the genomic era²³. With respect to human germline engineering, it does recognize the benefits that it can offer but suggest careful consideration of ethical, legal and social implications that may arise²⁴. It stresses upon the importance of responsible and ethical practices that simultaneously protect the fundamental rights and freedoms of individuals²⁵. Otherwise, there are no legally binding treaties or conventions other than the Oviedo Convention that directly regulate human germline engineering.

Considering that the above-mentioned instruments draw attention to

¹⁹ *Oveido Convention and its Protocols*, COUNCIL OF EUROPE PORTAL (April 16, 2023, 18:01), <https://www.coe.int/en/web/bioethics/oviedo-convention>.

²⁰ *Oveido Convention and its Protocols*, COUNCIL OF EUROPE PORTAL (April 16, 2023, 18:01), <https://www.coe.int/en/web/bioethics/oviedo-convention>.

²¹ *Oveido Convention and its Protocols*, COUNCIL OF EUROPE PORTAL (April 16, 2023, 18:01), <https://www.coe.int/en/web/bioethics/oviedo-convention>.

²² Universal Declaration on the Human Genome and Human Rights

²³ Universal Declaration on the Human Genome and Human Rights § 6

²⁴ Universal Declaration on the Human Genome and Human Rights § 14

²⁵ Universal Declaration on the Human Genome and Human Rights § 9

the human rights perspective on human germline engineering, it would be rather helpful to look into some of those rights. UNESCO Declaration affirms that the human right to dignity is ‘imperative not to reduce individuals to their genetic characteristics.²⁶’ A human being would not lose their dignity merely if created by germline engineering, but it could result in physical or behavioural traits perceived by the general population as “freakish” which would then violate human dignity²⁷.

The right to non-discrimination and equal protection of the law may be violated if a person who has been modified by genetic engineering may be viewed as superior to others or the dangers of unknown side effects may lead to employers or insurers considering such people too great of a risk²⁸. This hence also affects a person’s right to privacy and right to work. Unequal access to expensive biotechnology may lead to the elite having access to such technology and it is unlikely that biotechnology of this form and nature is offered through public health services, at least at the beginning²⁹. The potential risks of human germline engineering can have a negative impact on a person’s right to health.

INDIAN LAW

In terms of legislation in India, the most relevant act is the Pre-Conception and Pre-Natal Diagnostic Techniques of 1994 (hereinafter referred to as “PPDT”) which absolutely prohibits sex selection both before and after conception³⁰. PPDT regulates pre-natal diagnostic techniques and allows them in strictly defined cases – only for the purposes of detecting the abnormalities such as chromosomal abnormalities, genetic metabolic diseases, sex-linked genetic diseases,

²⁶ Universal Declaration on the Human Genome and Human Rights § 2(b)

²⁷ Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

²⁸ International Covenant on Civil and Political Rights § 24

²⁹ Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

³⁰ Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 § 3A.

congenital anomalies, etc³¹. It also allows for use of pre-natal diagnostic techniques if the parents have any family history of ‘mental retardation’ or ‘physical deformities’ such spasticity or other genetic diseases³².

With respect to non-binding guidelines, there are two such guidelines issued by the Indian Council of Medical Research (ICMR) that directly deal with genetic genome:

- (1) National Ethical Guidelines for Biomedical Research on Human Subjects [2017] – it recognises how genetic manipulation can have grave consequences and hence great care has to be taken towards the risks that can come of it³³. The Guidelines endorses somatic cell gene therapy, restricted to treating serious diseases³⁴. Guidelines on this include period review of guidelines, long term surveillance of gene therapy trials, requirement for informed consent, etc.³⁵. The Guidelines ban germline therapy as well as the attempt to make “designer babies”³⁶. The reason for this is that they recognise the lack of sufficient information on understanding the effect of such therapy and what impact it can have on the genetic machinery³⁷. Environmental interaction with manipulated genes is an idea that has also not be sufficiently researched³⁸.
- (2) National Guidelines for Stem Cell Research [2017]– It categorises research as permissible, restricted, and prohibited based on ethical and safety concerns³⁹. It prohibits “culturing of genome modified human embryos beyond 14 days of fertilization or the

³¹ Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 § 4

³² Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 § 4

³³ National Ethical Guidelines for Biomedical Research on Human Subjects

³⁴ National Ethical Guidelines for Biomedical Research on Human Subjects § 10.14

³⁵ National Ethical Guidelines for Biomedical Research on Human Subjects § 10.14

³⁶ National Ethical Guidelines for Biomedical Research on Human Subjects § 10.15.3

³⁷ National Ethical Guidelines for Biomedical Research on Human Subjects § 10.15.3

³⁸ National Ethical Guidelines for Biomedical Research on Human Subjects § 10.15.3

³⁹ National Guidelines for Stem Cell Research § 8.0

formation of primitive streak, whichever occurs earlier”⁴⁰. Research on human germline gene therapy is a prohibited area of research as well as research involving implantation of human embryos after in vitro manipulation into humans⁴¹.

US LAW

In the US, genome editing is not prohibited as such but funding for research that involve embryos and genome editing of embryos is limited⁴². There have been comments expressing that there be guidelines framed on genome editing for human reproduction considering the risks that come of it⁴³. The National Academy of Sciences (NAS) and the National Academy of Medicine (NAM) issued recommendations on human genome editing in February of 2017 – with respect to germline editing, it suggested that “ongoing reassessment of both health and societal benefits and risks, with broad ongoing participation and input by the public, should precede consideration of any clinical trials of heritable germline genome editing.”⁴⁴ Clinical trials for gene editing, both somatic and germline, cannot be authorised unless it is for treating or preventing diseases and disability⁴⁵.

The 2016 National Institutes of Health (NIH) Guidelines says that it would entertain proposal for somatic cell gene transfer but not germline alterations⁴⁶. Since the former only affects the individual on whom therapy is performed and the latter has an effect on descendants, the

⁴⁰ National Guidelines for Stem Cell Research § 8.0

⁴¹ National Guidelines for Stem Cell Research § 8.0

⁴² Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

⁴³ Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

⁴⁴ Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

⁴⁵ Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).

⁴⁶ National Institutes of Health (NIH) Guidelines

potential risk that it carries leads to its discouragement⁴⁷. There is a need for pre-clinical and clinical studies, a more thorough understanding of human organ systems, etc. Yet NIH said it would be willing to consider “well-rationalised human in utero gene transfer clinical trials”⁴⁸.

The stand in India on human germline engineering has been clearer than in the US. Through the PPDT, preventing serious diseases is allowed through pre-natal diagnostic methods. The Guidelines that exist in India prohibit human germline engineering but allow for somatic gene therapy where there is a concern for serious diseases that cannot be otherwise treated. The stance in US is complicated as only funding on researching has been prohibited while human genome editing itself has not. The non-binding guidelines in the US also prohibit germline engineering, largely because of the lack of sufficient information on the matter.

It can be said that there exists a fear of the possible consequences that can come of human germline engineering and the lack of information on it worsens it. US has prevented itself from gaining such knowledge through research by limiting funding for the same. Other countries also exhibited this kind of attitude towards human germline engineering with countries like Australia and Germany having criminalised genome editing.

Hence in light of this, it can be said that there requires to be a change made in the way law and polices regulate this area of human germline engineering as fear of the risks has led to reluctance in knowing the benefits that can come of it. As established, the stance on human germline engineering differs in the scientific community with some fearing what can come of it and others boasting of its rewards.

⁴⁷ National Institutes of Health (NIH) Guidelines

⁴⁸ National Institutes of Health (NIH) Guidelines

ANALYSIS AND SUGGESTIONS

When it comes to human germline engineering, there are two different perspectives – one is the essentialist and welfare state perspective and the other is the utilitarian and neoliberal perspective. The essentialist and welfare state perspective perceives the state to have a duty to provide equal opportunities and ensure basic needs⁴⁹. There is an emphasis on maintaining natural order and with respect to technology, it refrains from use of new technology where consequences are uncertain⁵⁰. The utilitarian and neo-liberal perspective suggests that the state should actually refrain from entering private activity⁵¹. This perspective allows private actors to be unregulated as long as they do not interfere with others. Between the two perspectives, the former attitude towards human germline engineering sees a bigger role for the state to play in ensuring that access to such technology is ensured while prioritising equal access to benefits⁵². The latter attitude prioritises individual rights and choices more so than the overall impact of the technology on society as a whole⁵³. Europe tends to have an essentialist and welfare state perspective in international law when it comes to human germline engineering whereas countries like the US have a utilitarian and neo-liberal perspective⁵⁴.

To understand how law should go about human germline engineering, it is worth mentioning that the novelty of human germline engineering

⁴⁹ Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

⁵⁰ Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

⁵¹ Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

⁵² Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

⁵³ Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

⁵⁴ Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) CHICAGO JOURNAL OF INTERNATIONAL LAW (2002).

contributes to the lack of research in the area⁵⁵. To add to that, law has so far addressed human germline engineering by simply banning it. One of the fundamental principles of modern democratic societies is the freedom of scientific research and inquiry⁵⁶. Restricting this right restricts scientific inquiry which is necessary to find ways of bettering our lives⁵⁷. Prohibiting scientific inquiry through legal instruments should only be limited to those cases where there are the most “severe and unavoidable restrictions.”⁵⁸ The risks of human germline engineering, while severe, cannot be deemed unavoidable. They are risks that can potentially arise and the use of appropriate legal instruments can help ensuring that the freedom of scientific research and inquiry is ensured. These legal instruments should aim to manage undesirable application of scientific knowledge while also allowing beneficial application of the same⁵⁹. Additionally, restrictions on publication of scientific results can allow for scientific inquiries to take place while simultaneously ensuring that the same information is not misused⁶⁰. This could include deleting sensitive information when publishing or ensuring limited distribution of such publications to a “need to know” basis⁶¹. Furthermore, non-legal self-regulatory initiatives such as consensus codes and guidelines could prove to be beneficial as it is flexible to readily amend changing scientific information and circumstances and can create a “culture of responsibility” in the scientific community⁶².

With respect to human germline engineering, it is important to first regulate research in the area. Those that warn against human germline engineering are largely discouraged by the various risks that have been associated with human germline engineering. The lack of research and

⁵⁵ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁵⁶ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁵⁷ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁵⁸ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁵⁹ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁶⁰ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁶¹ Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

⁶² Gary E Marchant et al, *The Problems with Forbidding Science*, Sci Eng Ethics (2009).

scholarship in the area makes it difficult to make a case for human germline engineering. Instead of banning research, freedom of scientific inquiry would be able to flourish if law instead chose to regulate aspects of research such as funding. Allowing public funding and some level of state intervention in overlooking who can research would be helpful. Furthermore, non-legal self-regulatory instruments such as consensus codes and guidelines by the scientific community would allow them to have a say in the matter. Scientists would be better informed and capable of the risks of the technology and giving them a hand in coming up with such instruments gives them the flexibility to prepare it as per the need of the scientific community. This would also ensure better adherence. Any research in the area should also have limitations with respect to the publications. Allowing people access to research results on a “need to know” basis can prevent use of human germline engineering for say the production of biological weapons.

Hypothetically if enough research in the area allows us to come to a consensus with respect to the safety of the technology, law would further have to regulate the human germline engineering market. The below given suggestions attempt to balance the two perspectives on human germline engineering:

1. Regulate informed consent of embryos – IVF when first introduced was a controversial method of reproduction that over time has gained acceptance in society. It is necessary for there to be informed consent of embryos given by the oocyte and sperm donor for the procedure. Similarly, it would be necessary for there to be informed consent of embryos given with respect to the parents of the embryo.
2. Where to draw the line: Here, the implications are greater with respect to impact it can have on future generations. To curb this, it would be necessary to draw the line between what is allowed

and what is not when it comes to human germline engineering. Therapeutic gene editing is a widely accepted benefit of human germline engineering and hence should be allowed by law. But it would be necessary that it ban aspects of human germline engineering that carry a high risk and are largely incompatible with what is accepted in society. This includes genetic enhancements, production of biological weapons, etc. amongst many.

CONCLUSION

With only a century worth of discovering and understanding the genes that make us, we have reached a point in which the technology to alter genes exist. The idea is simultaneously exciting and frightening for the ability to literally transform life can better and destroy life as we know it. Technologies to edit genes have been around for decades but the development of CRISPR-Cas9, a technology, has made gene editing faster, flexible and more affordable. Human germline engineering with its capacity to pass down such changes to descendants has its many rewards and risks. Legally, the risks are seen to outweigh the benefits as can be told by the careful mannerism in which laws prohibit human germline engineering wherever possible, with some even criminalising it. However, it is suggested that human germline instead be regulated instead of banned with both legal and non-legal instruments used where necessary to allow for the freedom of scientific inquiry to flourish.

BIBLIOGRAPHY**STATUTES:**

1. International Covenant on Civil and Political Rights § 24
2. National Ethical Guidelines for Biomedical Research on Human Subjects § 10.14, 10.15.3
3. National Guidelines for Stem Cell Research § 8.0
4. National Institutes of Health (NIH) Guidelines
5. Pre-Conception & Pre-Natal Diagnostic Techniques Act, 1994 § 3A, 4
6. Universal Declaration on the Human Genome and Human Rights § 2(b), 6, 9, 14

BOOKS:

1. VIVEK WADHWA AND ALEX SALKEVER, *THE DRIVER IN THE DRIVERLESS CAR*, BerrettKoehler Publishers, Inc. (2017).
2. JAMIE METZL, *HACKING DARWIN: GENETIC ENGINEERING AND THE FUTURE OF HUMANITY*, Sourcebooks (2019).

JOURNALS:

1. Adam J. Gross, *Dr. Frankenstein, Or: How I Learned To Stop Worrying And Love Crispr-Cas9*, 56(4) *JURIMETRICS*, 413-447 (2016)
2. Brane, A. C., & Tollefsbol, T. O, *Targeting Telomeres and Telomerase: Studies in Aging and Disease Utilizing CRISPR/Cas9 Technology*. *Cells*, 8(2), 186.
<https://doi.org/10.3390/cells8020186>

3. Dr. Rumiana Yotova, *The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law*, (2017).
4. Erica C Jonlin, *Informed Consent for Human Embryo Genome Editing*, 14(4) *STEM CELL REPORTS*, 530-537 (2020).
5. Gary E Marchant et al, *The Problems with Forbidding Science*, *Sci Eng Ethics* (2009).
6. James Kozubek, *Crispr-Cas9 is Impossible to Stop*, 18(2) *GEORGETOWN JOURNAL OF INTERNATIONAL AFFAIRS*, 112-119 (2017)
7. Marks, Stephen P, *Tying Prometheus Down: the International Law of Human Genetic Manipulation*, 3(1) *CHICAGO JOURNAL OF INTERNATIONAL LAW* (2002).
8. Naomi Cahn, *CRISPR Parents and Informed Consent*, 23 *SMU SCI. & TECH. L. REV.* 3 (2021)
<https://scholar.smu.edu/scitech/vol23/iss1/2>

INTERNET SOURCES:

1. Mary Todd Bergman, *Perspectives on gene editing*, *THE HARVARD GAZETTE* (March 14, 2023, 18:04),
<https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/>
2. *Oveido Convention and its Protocols*, *COUNCIL OF EUROPE PORTAL* (April 16, 2023, 18:01),
<https://www.coe.int/en/web/bioethics/oviedo-convention>
3. PCMag Staff, *13 Humans With Real-Life X-Men Mutant Super Powers*, *PC MAAG* (March 14, 2023, 14:32),
<https://www.pcmag.com/news/13-humans-with-real-life-x-men-mutant-super-powers>.