Genetic Modification of Humans:

A Legal and Ethical Perspective

Ahmad Saad Ahmad AL-Dafrawi[1]

[1]Faculty of Law, Universitas Islam Indonesia, Indonesia
234101612@uii.ac.id

Abstract. Genetic modification is a fairly fresh category of technologies, and its relative stability is still being investigated. Supporters of these medicinal technologies seek to broaden their application, whilst countries and international organizations seek to establish strict control over their use and confine them to the narrowest possible scope. The inability to forecast the medical outcomes of these technologies is the study's main problem. This study paper provides a brief overview of the most critical ethical and legal concerns with gene editing technology. The main goal of this study: is to determine to what extent the legal system can accept open-ended gene editing. The most crucial finding of this study is the lack of a worldwide framework agreement binding on all countries to control the issue of genetic alteration and manipulation.

Keywords: Genetic Modification, Human Rights, Medical Law.

1 Introduction

While moral, legal, and scientific challenges still exist, it is evident that emerging genetic technologies possess a chance to transform many aspects of our lives.[1] In the medical area, such genetic technologies have the potential to dramatically increase our ability to foresee, avoid, and treat sickness, which is expected to emerge as the field in which gene editing is most widely accepted.[1] There will most likely be no genuine legal barriers to changing certain embryos, particularly when their DNA maps indicate a high risk of inheritable illness conditions in the future.[2] In addition, possibly formal government agencies worldwide will grasp the concept of genetic alteration and modification, and genetically modified babies will be approved as well.[2] Perhaps it is necessary at this point to ask: Is genetic modification a blessing or a curse? And are there clear and acceptable limits to what can be considered genetic modification and not manipulation?

This study attempts to answer these two central questions. It also attempts to draw clear lines between what is considered a necessary medical modification, and therefore legally acceptable because it is within medical ethics, and what is considered genetic manipulation (Gene Doping), which is not necessary, and therefore actually outside the framework of the law.

2 Problem Formulation

From a legal standpoint, legislation opposes gene-editing technology based on what will be, not what is. As long as the outcomes of gene editing remain unknown, laws do not approve them, except in very limited areas. On the other side, the lack of a foundation for justice between the benefactors of this costly technology and the rest of the general public poses ethical concerns. Finally, from a medical standpoint, there may be no moral objections to the use of gene editing technologies on people because prohibiting them would stifle critical scientific advancement.

3 Method

The descriptive approach and the approach of comparison are the two research methodology types used in this paper to handle the study problem and its objectives. As for the primary legal materials, the main reliance was placed on the most important international declarations and agreements, such as (the Declaration of Helsinki, and the 1997 UNESCO Declaration on the Human Genome and Human Rights) that directly discussed the issue of genetic modifications to the human body. As for the secondary legal materials, to complete this research, the reliance was placed on peer-reviewed journals and reliable websites to complete this research.

4 Result and Discussion

4.1 Presenting the Results

Genetic modification technology, also known as human germline engineering, is quickly evolving and will play an important role in illness diagnosis and therapy.[3] Although mammalian genome editing has immense potential and hope for both curing and avoiding genetic diseases, it additionally poses significant and new health and legal issues. The hazards, worries, and governmental methods of modifying the human genome vary greatly across various groups.[3] States are responsible for their citizens' health and safety through the measures they implement based on domestic legislation that is consistent with international conventions. Current and potential legislation conversations about heritable modification of the human genome necessitate a strong evidence base that openly examines and properly represents the current international policy environment.[4] The modified genes are no different from their natural counterparts. Therefore, it is almost impossible to prove that genetic modification has occurred. The use of genetic modification technology to treat diseases is permitted, but using these technologies to improve or enhance athletes' sports performance is strictly prohibited by law and ethics.

4.2 Our Genes Determine Our Eternal Destiny

Gene therapy, including gene doping, involves the delivery of DNA into cells and

tissues by a variety of viral or nonviral carriers. A transgenic is delivered to target cells using viral vectors (attenuated retroviruses, adenoviruses, or lentiviruses) and produced by cell division mechanism.[5] Certain of these infectious agents, like retroviruses, incorporate their genetic code into the chromosomal structure within a human cell. Other types of viruses, especially adenoviruses, deliver the modified gene to the cell nucleus with no chromosomal fusion.[5] However, it should be noted here that genetic doping refers to the non-curative use of gene therapy by healthy sportsmen to improve their abilities in sports events. Genetic doping might have catastrophic, potentially fatal implications, as an understanding of gene therapy is still in its early stages.[6] In the overwhelming majority of cases, gene-doping-derived proteins created in the athlete's body will be indistinguishable from endogenous proteins.[6] It is objectively problematic to discern the difference between two proteins, one produced by genetically modified cells and the other by cells that have not been genetically changed or manipulated. This is exactly what biomedical ethics experts believe.[6]

Until recently, it was prevalent in society that diseases were treated by treating the environmental factors related to the disease, while genetic factors are an inevitable fate that cannot be changed.[7] However, this view has now changed with the progress of genetic engineering and artificial intelligence research. These studies, research and experiments have made it possible to re-engineer the human genetic makeup, or to introduce a change to the genetic material of the cell.[7] It has become possible to isolate a specific gene carrying a specific genetic trait from the cells of one organism, then introduce it to the genetic material of another organism, so that the latter is transferred to the genetic trait of the former.[7] This refers to the process of making genetic alterations to in vitro early-stage embryos, gametes (eggs and sperm), or germ cells that serve as the progenitors of gametes; genetically engineered embryos are subsequently given to a womb to establish a being pregnant, resulting in the delivery of an infant with a changed genome.[5] If the youngster reaches the age of reproduction and grows again with its own gametes, the offspring will inherit a biologically changed DNA.[5]

Scientists agree that all genetic diseases that affect humans are caused by deformities or defects in the genetic material.[7] This technology has the potential to improve people's lives, reduce bio-risks, and prevent irreparable injury.[8] Medical genetic screening identifies DNA abnormalities that can have serious effects. Its goal is to forecast the likelihood of contracting illness and passing illness-causing variations to progeny.[9] A large number of uncommon genetic disorders are now stated, collectively affecting millions of individuals globally. Gene variants behind these illnesses have been found and are being collected and organized in records such as ClinVar and the Leiden Open Variation Database (LOVD), with over 3 million unique variation records submitted to ClinVar and over 4.5 million entries in LOVD (as of October 1, 2024).[10]

4.3 Legal Reservation on Genetic Modification

In June 1964, the Declaration of Helsinki emerged as a basic document on the ethics of conducting research on human subjects. Article 9 of the Declaration states: “It is

the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, autonomy, privacy, and confidentiality of personal information of research participants. The responsibility for the protection of research participants must always rest with physicians or other researchers and never with the research participants, even though they have given consent.".[11]

For example, Fetus genome editing for fecundity at an early stage violates the moral norms set by the "Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects," which has been largely accepted by the worldwide community.[12] That does not imply that national legislations will always follow, but it creates a standard from which countries may diverge only when they can demonstrate that it is required to accomplish some benefit to the public.[13] Then, all application of technology for genome editing on humans has to be guided by morality and the rule of law, and the Convention on Human Rights and Biomedicine (also known as "the Oviedo Convention"), which is the only enforceable European treaty tackling human rights in the biomedical field, offers a special framework for reference in this regard.[14] Article no.13 of the Convention says: "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic, or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants. ".[15]

In the field of genetically modified products, by the beginning of 2021, Indonesia had prepared regulations governing CRISPR-based GEd and other GEd procedures. Pursuant to the version, GE goods are going to be classified as GMOs if they include a unique DNA sequence ("from exterior the species").[16]

International legislation currently regulates genome modification. Despite the fact that no international agreement of broad scope deals with the issue, essential local human rights agreements, such as the Council of Europe's Oviedo Convention on Human Rights and Biomedicine (Oviedo Convention) and the EU Charter of Fundamental Rights (EU Charter), include particular provisions that apply to genetic interventions.[17] There are additionally significant informal human rights instruments, like the 1997 UNESCO Declaration on the Human Genome and Human Rights and the 2005 UNESCO Declaration on Bioethics and Human Rights.[17]

5 Conclusion

Perhaps modern science had no negative intentions regarding how we live now. Originally, genetic change and modification research had many benefits, as it allowed some animal species that were in danger of going extinct to be preserved. Not only this, but other genetic research also contributed to developing new varieties of crops that can withstand drought and water scarcity in different regions of the world. Gene therapy is a medical approach based on the integration of new or modified genes into patients' cells. Gene therapy works directly to alter DNA, so in theory, the intended therapeutic effects could last for months, years, or even a lifetime.

References

[1] M. Alonso, "Post genetic revolution dynamics. How will modified and unmodified

humans coexist?," *Enrahonar Int. J. Theor. Pract. Reason*, vol. 72, pp. 35–54, Mar. 2024, doi: 10.5565/rev/enrahonar.1527.

[2] A. S. A. Al-Dafrawi, "Critical Legal Reading of World Anti-Doping Agency's Gene Doping Guidance," *Hasanuddin Law Rev.*, vol. 9, no. 3, p. 269, Dec. 2023, doi: 10.20956/halrev.v9i3.4653.

[3] G. E. Marchant, "Global Governance of Human Genome Editing: What Are the Rules?," *Annu. Rev. Genomics Hum. Genet.*, vol. 22, no. 1, pp. 385–405, Aug. 2021, doi: 10.1146/annurev-genom-111320-091930.

[4] F. Baylis, M. Darnovsky, K. Hasson, and T. M. Krahn, "Human Germline and Heritable Genome Editing: The Global Policy Landscape," *CRISPR J.*, vol. 3, no. 5, pp. 365–377, Oct. 2020, doi: 10.1089/crispr.2020.0082.

[5] E. Brzeziańska, D. Domańska, and A. Jegier, "GENE DOPING IN SPORT – PERSPECTIVES AND RISKS," *Biol. Sport*, vol. 31, no. 4, pp. 251–259, Sep. 2014, doi: 10.5604/20831862.1120931.

[6] A. S. Ahmad AL-Dafrawi, "Absence of Reliable Screening Methods That Prove the Use of Gene Doping in Sports," *MHSalud Rev. En Cienc. Mov. Hum. Salud*, vol. 20, no. 1, pp. 1–3, Jan. 2023, doi: 10.15359/mhs.20-1.14.

[7] Y. Al Najjar, "The Role of Artificial Intelligence in Genetic Modification of Human Cells in light of Islamic Jurisprudence a Comparative Study," *J. Fac. Sharia Law Assiut*, vol. 36, no. 5, pp. 595–718, Jul. 2024, doi: 10.21608/jfsu.2024.277797.1208.

[8] L. Wang, X. Liang, and W. Zhang, "Genome editing and human rights: Implications of the UNGPs," *Biosaf. Health*, vol. 4, no. 6, pp. 386–391, Dec. 2022, doi: 10.1016/j.bsheal.2022.10.002.

[9] A. Zhong *et al.*, "Ethical, social, and cultural issues related to clinical genetic testing and counseling in low- and middle-income countries: a systematic review," *Genet. Med.*, vol. 23, no. 12, pp. 2270–2280, Dec. 2021, doi: 10.1038/s41436-018-0090-9.

[10] "Improving reporting standards for genetic variants," *Nat. Genet.*, vol. 56, no. 11, pp. 2283–2283, Nov. 2024, doi: 10.1038/s41588-024-02002-3.

[11] WMA, "WMA - The World Medical Association-WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants."

[12] S. Liu, "Legal reflections on the case of genome-edited babies," *Glob. Health Res. Policy*, vol. 5, no. 1, p. 24, Dec. 2020, doi: 10.1186/s41256-020-00153-4.

[13] R. A. Charo, "The Legal and Regulatory Context for Human Gene Editing," Issues in Science and Technology.

[14] Council of Europe, "Ethics and Human Rights must guide any use of genome editing technologies in human beings - Human Rights and Biomedicine - www.coe.int," Human Rights and Biomedicine.

[15] 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: Convention on Human Rights and Biomedicine (ETS No. 164)," Treaty Office.

[16] T. Sprink, R. Wilhelm, and F. Hartung, "Genome editing around the globe: An update on policies and perceptions," *Plant Physiol.*, vol. 190, no. 3, pp. 1579–1587, Oct. 2022, doi: 10.1093/plphys/kiac359.

[17] R. Yotova, "Regulating Genome Editing Under International Human Rights Law," *Int. Comp. Law Q.*, vol. 69, no. 3, pp. 653–684, Jul. 2020, doi: 10.1017/S0020589320000184.