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Discussing the Ethical Boundaries of Gene Editing

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RESEARCH REPORT

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Issue: Discussing the Ethical Boundaries of Gene Editing

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Introduction

Genome editing is a technique for changing a cell's or an organism's DNA in a precise way. It can be applied to change, add, or remove DNA from the genome. Technology exists to use human genome editing on somatic (non-heritable), germline (not for reproduction), and germline cells (for reproduction). Challenges persist despite the fact that somatic human genome editing is widely established and acceptable for therapies in several technologically sophisticated nations with laws in place. Among these is the requirement to create innovative approaches to genome editing that are inclusive and take into account the diversity of the human population and their experiences. The reporting of illegal, unauthorized, unethical, or hazardous research as well as other activities, such as the offering of untested so-called therapeutic procedures, provide additional obstacles. Rogue clinics, medical tourism, and other issues are also problematic. Editing nuclear DNA in a way that could be passed down through generations is known as heritable human genome editing. The potential effects of heritable human genome editing on future generations and societal outcomes are hotly debated. Compared to somatic human genome editing, they might present more risk and moral dilemmas.

Definition of Key Terms

Gene editing: the ability to make highly specific changes in the DNA sequence of a living organism, essentially customizing its genetic makeup.

CRISPR: CRISPR/Cas9 edits genes by accurately cutting DNA and then letting natural DNA repair processes take over.

General Overview

The argument over genome editing is not new, but it has recently attracted renewed interest as a result of the finding that CRISPR may make it easier and more accurate than previous methods. Researchers and bioethicists generally concur that human genome editing for reproductive purposes should not be done at this time, but that further research is needed to ensure the safety and efficacy of gene therapy. The majority of stakeholders concur that ongoing public discussion and debate are essential to let the public determine whether or not germline modification should be permitted. Due to ethical and security concerns, around 40 countries, including 15 in Western Europe, prohibited or outlawed research on germline editing as of 2014. Also, there is an international initiative to unify regulation of the use of genome editing technology, which is being led by the US, UK, and China.

Scientists can accurately alter the DNA of living things, including people, thanks to the technology known as gene editing. Gene editing can be accomplished using a variety of methods, but they all entail making precise alterations to the genetic code. CRISPR-Cas9 is one of the most used methods for gene editing. Via the assistance of a protein called Cas9, which functions as a pair of molecular scissors, the DNA is cut using this technique at a specified spot. The desired DNA can then be added, removed, or replaced by researchers.

Gene editing has enormous potential for a variety of uses, including the treatment of genetic disorders, the development of cancer medicines, and increased crop yields. Yet technology also brings up significant ethical issues, especially when it comes to altering human genomes. Concerns about unintended repercussions, the potential for producing genetically altered people, the potential for utilizing gene editing for non-medical objectives, and the ethics of animal research are a few of the ethical problems connected to gene editing. Therefore, it is crucial that researchers and decision-makers move cautiously and thoroughly assess the ethical implications of any gene-editing technique.

Safety

Safety is the main priority due to the potential for incorrect modifications. Germline genome editing should not be used for clinical reproductive purposes until it has been proven to be risk-free through research; the risk cannot be justified by the potential benefit, according to the majority of researchers and ethicists who have written and spoken about genome editing, including those present at the International Summit on Human Gene Editing. According to some experts, there may never be a moment when genome editing in embryos will provide advantages over already-available treatments like in-vitro fertilization (IVF) and preimplantation genetic diagnosis (PGD). Scientists and bioethicists agree that germline editing can sometimes be used to fulfill needs that PGD cannot. This pertains to cases of polygenic disorders, which are influenced by more than one gene, cases where both prospective parents are homozygous for a disease-causing variant (they both have two copies of the variant, so all of their children would be expected to have the disease), and cases where families object to specific PGD procedures.

Several scientists and bioethicists worry that any genome editing, even for medicinal purposes, will set humanity on a precipice leading to its usage for questionable non-therapeutic and enhancing objectives. Others contend that genome editing should be permitted to treat hereditary diseases after it has been shown to be safe and effective (and indeed, that it is a moral imperative). They think that policies and regulations should be used to address concerns about augmentation.

Gene Editing on Embryos

The use of human embryos for research is frowned upon by many individuals for moral and religious reasons. As long as it is not being utilized for reproductive purposes, many bioethical and research groups feel that studies employing gene editing in embryos is crucial for a variety of reasons, including to answer scientific puzzles about human biology. Several nations have already permitted genome-editing research studies using viable embryos, whereas others have only approved trials using nonviable embryos (embryos that cannot result in a live birth). Generally speaking, research using embryos may involve viable or nonviable embryos left over after IVF, as well as embryos made specifically for research. Every situation has its own unique moral issues.

Major Parties Involved and Their Views

The United States

A fast-developing technology called gene editing has the power to completely transform both agriculture and medicine. The US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) oversee gene editing in the country. The FDA oversees the regulation of gene editing in human medicine, with a particular emphasis on assuring the security and effectiveness of gene treatments. For usage in the US, the FDA has approved a number of gene treatments, including CAR-T cell therapy for specific forms of cancer. The USDA, which is in charge of the usage of GE plants and animals, regulates gene editing in agriculture. The USDA established a new framework for plant gene editing regulations in 2020, with the goal of streamlining the regulatory procedure for crops that have undergone gene editing. Gene editing is generally a heavily regulated industry in the US, with a focus on assuring the security and effectiveness of novel treatments and goods. The morality of gene editing is still being debated, especially in light of the possibility of germline modification that might be passed on to subsequent generations.

China

China has recently shown great interest in gene editing as it has been a pioneer in the field. The CRISPR-Cas9 gene editing method was used in human embryos for the first time by Chinese scientists, which sparked outrage across the globe. He Jiankui, a Chinese scientist, said in 2019 that he had used CRISPR-Cas9 to modify the genomes of twin infants, which sparked intense criticism from the scientific community and calls for a ban on germline gene editing. Afterwards, he received a three-year prison term for his misdeeds. The government of China has made significant investments in gene editing research despite this setback. A number of gene editing research facilities have been built in the nation, and Chinese scientists are actively engaged in numerous initiatives to use gene editing to treat illnesses, advance agriculture, and other goals. To restrict the use of gene editing technologies, the government has

nonetheless also put in place laws. 2019 saw the release of draft laws by the Chinese government that would call for a government body to assess and give the go-ahead for any gene editing research before it is conducted. In accordance with the rules, gene editing cannot be used to modify human embryos. China's government has invested in and regulated the gene editing industry to ensure its safety and moral use. As a result, the area is both tremendously busy and contentious in China.

Japan

Japan is investing in research & development to advance the technology in the field of gene editing. The promotion of the use of gene editing in medical, agricultural, and industrial applications has the interest of the Japanese government. In 2018, a team of Japanese scientists used the CRISPR-Cas9 gene editing technique to modify the genes of fertilized mouse eggs effectively. This accomplishment showed Japan's dedication to developing the technology and signified a significant advance in gene editing. Japan is spending money on research and development to advance gene editing technology. The Japanese government is interested in promoting gene editing's usage in industrial, agricultural, and medical applications. In 2018, a group of Japanese researchers successfully edited the genes of fertilized mouse eggs using the CRISPR-Cas9 gene editing method. This feat demonstrated Japan's commitment to technology development and represented a significant development in the field of gene editing. In general, the subject of gene editing is growing in Japan, with an emphasis on encouraging research and development to progress the technology and guarantee its ethical and safe application in healthcare, agriculture, and other fields.

World Health Organization (WHO)

The World Health Organization (WHO) has acknowledged the potential health benefits of gene editing but has also urged for careful assessment of the technology's ethical, societal, and safety consequences. The WHO has stressed the importance of openness, inclusivity, and accountability in the governance of genome editing and has urged for the participation of all stakeholders, including researchers, patients, civil society, and governments. In general, the WHO acknowledges the promise of gene editing to enhance human health but also the need for responsible governance and ethical concerns to guarantee that the technology is utilized safely and for the good of all.

Timeline of Events

2002	The US FDA has approved the first effective gene treatment for a hereditary condition.
2012	First, researchers show that human cells can be used to change genes using the CRISPR system.
2013	The development of the CRISPR-Cas9 gene editing tool enables accurate and effective DNA editing.

2015	China has approved the first CRISPR-based clinical trial for the treatment of cancer.
2018	He Jiankui, a Chinese scientist, declares that he has edited the twin newborns' genes using CRISPR, causing a global uproar.
2019	The World Health Organization requests both a temporary freeze on germline editing and a global registration of all human genome editing research.
2020	The US FDA approves the first gene therapy for a genetic eye disease, marking a significant milestone for gene editing in medicine.
2021	Researchers report the successful use of CRISPR to treat genetic blood disorders in human patients in a clinical trial.

Treaties and Events

Universal Declaration on the Human Genome and Human Rights: This declaration, which was approved by the United Nations Educational, Scientific, and Cultural Organization (UNESCO) in 1997, aims to safeguard the human genome from exploitation, such as genetic discrimination or eugenics, and to guarantee that genetic advancements are utilized for the good of all humanity.

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity: This 2010 agreement aims to ensure that the advantages of using genetic resources are distributed fairly and equally between the nations providing the resources and the nations using them. When genetic resources are employed as the starting point for gene editing, this technique is applicable.

Cartagena Protocol on Biosafety: This pact, which became effective in 2003, intends to ensure the secure handling, transportation, and use of living-modified organisms (LMOs), which includes genetically modified species (GMOs). Although it is not specifically addressed in the protocol, gene editing is usually thought to fall under the guidelines for LMOs.

International Declaration on Human Genetic Data: This declaration, which was approved by UNESCO in 2003, aims to guarantee that human genetic data is gathered, saved, and used in a morally and socially responsible manner that upholds human rights and dignity. Although gene editing isn't specifically stated in the declaration, its provisions are commonly thought to cover it.

World Medical Association Declaration of Helsinki: This declaration provides ethical principles for medical research involving human subjects, including gene editing research. The most recent version was adopted in 2013 and includes specific provisions on the use of genetic and genomic data in research. For medical research involving human participants, including gene editing research, this declaration lays out

ethical guidelines. The most current revision, which was adopted in 2013, has explicit clauses on the use of genetic and genomic data in research.

Evaluation of Previous Attempts to Resolve the Issue

He Jiankui, a Chinese scientist, claimed to have produced the first genetically modified children in 2018 by using gene editing. He received harsh criticism for carrying out the experiment unsupervised and breaking ethical rules. The incident brought to light the necessity of tougher laws and moral standards for gene editing. The World Health Organization (WHO) organized a team to create international guidelines for gene editing in 2019. The panel, however, faced criticism for its lack of diversity, and some experts contended that it was unrepresentative of the world's population. The panel's suggestions were also criticized for being too nebulous and failing to provide specific answers to the ethical issues raised by gene editing. For several types of gene editing experiments, the US Department of Health and Human Services suggested amending laws in 2020 that would have allowed researchers to forego ethical review panels. The idea was heavily criticized by the scientific community, and the department ultimately decided to withdraw it. Concerns have also been raised about the lack of enforcement or disregard of ethical standards and laws pertaining to gene editing.

Possible Solutions

Creating precise and thorough regulations is a solution. Countries might collaborate to create ethical standards and clear laws for gene editing. The use of gene editing in people and animals, as well as the possible drawbacks and advantages of the technology, should all be covered by these regulations. These rules should be binding and come with consequences for breaking them. Another alternative is to strengthen international collaboration: Research on gene editing requires more worldwide cooperation and collaboration. This entails exchanging data and details regarding gene editing methods as well as cooperating to create standards and laws. It is essential to ensure transparency and public participation. The public should be involved in conversations concerning the ethical implications of gene editing technology, and gene editing research and its uses should be undertaken in a transparent and open manner. This might encompass town hall meetings, open forums, and other types of public participation.

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