The Influence of Scientific Consensus and Regulatory Policies on Human Germline Editing

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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction:

In the past decade, CRISPR technology has been developed with the purpose of editing genes with high precision. CRISPR stands for Clustered Regularly Interspaced Short Palindromic Repeats and is a gene-editing tool derived from a naturally occurring defense mechanism in bacteria. It allows scientists to make precise changes to DNA sequences, enabling them to modify, delete, or insert genes in a wide range of organisms, including plants, animals, and even human cells, with potential applications in fields such as medicine, agriculture, and biotechnology. This advancement holds the promise of addressing genetic diseases that have evaded conventional medical interventions. However, with technical innovations in the medical field, especially those regarding changes to the human body, issues in the ethical sphere are bound to arise. This paper seeks to navigate these waters, exploring the development and application of CRISPR technology and its influence on ethical discourse across public policy and scientific communities.

The research question at the heart of this inquiry - How has the development and application of CRISPR technology in human germline editing influenced the ethical discourse across public policy and in scientific communities? - provides a lens through which we can examine the ethical considerations that accompany genetic editing. There are concerns over genetic diversity, genetic disorders, and the introduction of "designer babies". This paper will employ the Social Construction of Technology framework to dissect how discussions between scientists, policymakers, regulatory bodies, and governments have influenced the policy creation and ethical discourse around CRISPR.

In this paper, we will explore the ethical discourse surrounding the development and application of CRISPR technology in human germline editing. Initially, we will examine the

capabilities of CRISPR. Following this, we will dissect the ethical, legal, and social implications of this technology. This will involve a detailed analysis of the arguments for and against the use of CRISPR for medical and non-medical enhancements, assessing potential societal impacts and the risk of exacerbating social inequalities. We will also analyze the regulatory responses at both national and international levels, highlighting legislative efforts and policy discussions that shape the ongoing ethical debates. To frame our analysis, we will employ the SCOT framework to understand how various social groups' perspectives from scientists to policymakers shape and affect policy.

Literature Review

CRISPR technology has emerged as a tool in the realm of genetics, offering the potential to address and correct hereditary diseases at their source. This technology's application in human germline editing, which is making genetic modifications to eggs, sperm, or embryos that can be passed down to future generations, is seen as a promising avenue for combating genetic disorders such as cystic fibrosis and sickle cell anemia as it is able to get rid of the hereditary diseases at the source (Lander, 2015). However, this potential is not without significant ethical considerations. The intervention in the human germline sparks debates around human dignity, which refers to the inherent worth and respect that should be given to every individual, irrespective of their genetic makeup. This dignity is potentially threatened by the misuse of genetic editing technologies as people, especially those who are wealthy, are able to edit their genes, which could lead to genetic discrimination or societal pressures on individuals based on their genetic traits. Additionally, there are concerns about the balance of genetic diversity and the

risk of introducing new genetic disorders, as well as the ethical implications of altering human evolution (National Academies of Sciences, Engineering, and Medicine, 2017). These ethical dilemmas highlight the tension between the promise of medical breakthroughs and the preservation of the unique characteristics and attributes that define our humanity, which could be undermined if genetic editing leads to homogenized human traits.

Researchers and ethicists such as Edward Lanphier and David Baltimore are concerned about the technology due to its potential for use in non-medical enhancements, such as selecting for specific physical traits or intelligence. This possibility raises fears in bioethicists and scientists about the future of genetic modification, suggesting a scenario where societal divisions could emerge based on genetic traits (Lanphier et al., 2015). Such divisions could entrench existing social inequalities and potentially lead to a resurgence of eugenic practices. The discussion around these non-medical enhancements has sparked significant ethical debates across various groups, including bioethicists, genetic researchers, and policymakers (Baltimore et al., 2015). These debates often occur in academic settings, international bioethics conferences, and within legislative bodies, questioning the morality of "designer babies" and the implications for human society. One instance of this in the United States was a legislative discussion concerning CRISPR and genetic enhancements in Senate Resolution 275, introduced on July 15, 2019. This resolution, spearheaded by Senators Feinstein, Rubio, and Reed, was aimed at establishing international ethical standards for genome editing research (S.Res.275 - 116th Congress, 2019-2020). It highlighted the ethical concerns and the need for caution in the application of genome editing technologies, especially in human embryos. The resolution explicitly opposed the experiments that led to pregnancies using genome edited human embryos, which were shown

to be unsafe and lead to health complications. It called for international collaboration to develop a framework to govern the clinical use of human germline editing.

The global scientific community, including organizations such as the National Academies of Sciences and the Royal Society of the UK, has sought to establish a consensus through initiatives like the International Summit on Human Gene Editing. This summit, convened by the National Academies of Sciences, Engineering, and Medicine in 2015, aimed to address the scientific, ethical, and governance issues surrounding human gene editing (National Academies of Sciences, Engineering, and Medicine, 2015). The National Academies of Sciences, Engineering, and Medicine are organizations in the United States that collectively provide expert advice on scientific, engineering, and medical issues to support national and international policy decisions. The summit included a gathering of experts from various fields, including biology, medicine, law, ethics, sociology, and journalism. Several institutions like the U.S. National Academies of Sciences and Medicine, the Royal Society of the UK, and the Chinese Academy of Sciences were in attendance. Despite the effort to establish a unified approach to germline editing, the summit highlighted the challenges of achieving consensus amid diverse international perspectives. The discussions during the summit explored a range of topics, including the potential clinical uses of gene editing, ethical considerations surrounding germline modification, and the governance necessary to oversee the responsible development of gene editing technologies. The summit emphasized the need for comprehensive ethical standards and governance structures to ensure that advancements in gene editing are conducted with high ethical and safety standards. The committee decided on a cautious consensus on the clinical use of gene editing, which concluded that while the technology holds significant promise for addressing genetic diseases, it would be irresponsible to proceed with any clinical use of

germline editing until the safety and ethical implications are clearly resolved (National Academies of Sciences, Engineering, and Medicine, 2015). However, the international community's views about gene editing for clinical purposes vary enormously with more than 61 ethics reports and statements having been crafted by more than 50 countries and organizations (Brokowski, 2018).

The international scientific community and ethicists, like Florian Steger and Giovanni Rubeis, are also concerned about consent from future generations and the ethical boundaries of genetic intervention. They argue that the possibility of unintended long-term effects and the implications for future generations without their consent are central to the ethical debate. Unintended long-term effects of CRISPR germline editing could include changes that, once introduced into the human genome, travel through generations with unpredictable outcomes, potentially altering human biology in unforeseen ways (Rubeis, 2018). These genetic modifications carried out without the consent of future generations raises ethical issues as these individuals would bear the consequences of decisions they did not participate in making, thereby impacting their health, identity, and society's genetic makeup. Additionally, there is concern that access disparities could exacerbate societal inequalities. These concerns are particularly pressing for marginalized communities and those without access to advanced healthcare, who may be disproportionately affected by the inequitable distribution of gene editing technologies (Feliú-Mójer, 2020). This highlights the need for careful ethical consideration and regulatory oversight to ensure that CRISPR technology is used in a manner that is both ethical and equitable.

The exploration of CRISPR technology and its integration into society can be understood through the lens of Pinch and Bijker's Social Construction of Technology (SCOT) framework

(Pinch & Bijker, 1984). This framework highlights that technology is not developed in isolation but is shaped by and, in turn, shapes the society in which it is embedded. The case of CRISPR technology exemplifies this mutual construction, as its trajectory is significantly influenced by a diverse array of stakeholder perspectives, including those of scientists, ethicists, and policymakers. These stakeholders bring unique viewpoints that collectively influence CRISPR's design, use, and ongoing evolution, highlighting the pivotal role of ethical discourse and regulatory consensus in determining the technology's integration into clinical practice and research domains.

At the heart of the SCOT framework are several key concepts, including relevant social groups, interpretive flexibility, and technological frames, which offer valuable insights into the dynamics surrounding CRISPR technology. Relevant social groups are defined as collectives whose members share a common understanding of a specific technology (Pinch & Bijker, 1984). In the context of CRISPR, these groups encompass scientists focused on genetic editing, ethicists grappling with the technology's moral implications, and policymakers tasked with regulating its use. The interactions and negotiations among these groups significantly shape CRISPR's societal acceptance and implementation.

Interpretive flexibility refers to the idea that technologies can be understood and interpreted differently by various social groups (Pinch & Bijker, 1984). This concept is particularly relevant to CRISPR, as it highlights the diverse perspectives on the technology's ethical implications, potential applications, and the balance between scientific advancement and societal concerns. Such flexibility underscores the complex ethical debates surrounding CRISPR, reflecting differing viewpoints on its use and regulation.

Technological frames encompass the knowledge, methodologies, and practices employed by social groups to engage with technology. These frames shape stakeholders' perceptions of the technology, influencing how its risks, possibilities, and ethical considerations are evaluated. For instance, the technological frame of scientists may emphasize CRISPR's potential for medical breakthroughs, while ethicists might focus on the moral and societal ramifications of its application.

This study will apply the SCOT framework to dissect how various social groups and their unique perspectives have influenced the discussion and policies surrounding CRISPR. By focusing on the interplay between scientific consensus and regulatory policies, the analysis will delve into the debates, agreements, and disagreements within the scientific field regarding CRISPR's ethical use, safety, and potential. Furthermore, it will investigate how regulatory policies in various jurisdictions have influenced CRISPR's application in research and clinical settings.

Methods:

For the analysis, I used peer-reviewed articles and research papers from 2015 to 2024 spanning various disciplines, including bioethics, genetic engineering, law, and social sciences. These articles offer insights from a multidisciplinary array of experts such as ethicists, legal scholars, scientists, and sociologists to show how the views of different groups differ and are alike with regards to the implementation of CRISP. This study also delves into ethical reviews from ethics councils and bioethics institutes, like the Hastings Center. These reviews offer detailed examinations of the moral and ethical implications of genetic modification. The analyses

presented in these reviews reflect the evolving ethical landscape of CRISPR technology, enriching the study with expert perspectives on the ethical dilemmas and considerations at play.

Furthermore, the research incorporates position statements from leading organizations and governing bodies in genetics and bioethics, such as the National Academies of Sciences, Engineering, and Medicine, the National Institutes of Health, and the World Health Organization. These statements were used for gauging the consensus and identifying the discrepancies within the scientific and ethical communities regarding CRISPR and germline editing. They offer authoritative stances on acceptable practices and ethical guidelines as well as highlight the regulatory frameworks shaping the use of CRISPR technology. I focused on identifying shifts in ethical perspectives, key themes in the debate over germline editing, and the global scientific community's consensus on acceptable practices. The study highlights the primary concerns and arguments of various relevant social groups and discerns patterns of consensus or contention within the community.

Analysis:

The scientists at the International Summit on Human Gene Editing reached a consensus on the definition of CRISPR, agreeing that policy development should focus on its technological capabilities and that research into this technology should continue as a priority. The summit gathered over 500 leading scientists, ethicists, legal experts, and patient advocates from more than 20 countries who offered diverse and critical perspectives on the scientific, ethical, and governance issues associated with human gene editing (National Academies of Sciences, Engineering, and Medicine, 2015). The scientists at the summit, such as David Baltimore and

Jennifer Doudna, primarily emphasized the technological potential of CRISPR to treat genetic diseases (Committee on Science, Technology, and Law, 2016). They presented their latest findings on the capabilities of CRISPR. They discussed the technology's potential to precisely edit genes, correct genetic mutations, and develop new treatments for a range of diseases. Dr. Fyodor Urnov, for example, emphasized the promise of CRISPR in treating conditions like sickle cell anemia and cystic fibrosis (National Academies of Sciences, Engineering, and Medicine, 2015). He argued that the technology could revolutionize medicine and improve the lives of countless individuals suffering from genetic disorders. Jennifer Doudna, one of the co-discoverers of CRISPR, highlighted the need for continued research to fully understand the potential and limitations of CRISPR and also emphasized the promise of CRISPR to change lives. Through these presentations and discussions, the scientists at the committee came to an agreement that the potential of CRISPR to treat diseases was far too important to be overlooked and that it should be a driving factor in the policy creation. This perspective reflects the scientific community's technological frame, which values the advancement of knowledge and the development of new treatments.

Ethicists and legal experts at the summit reached a consensus on the definition of CRISPR, agreeing that policy development should focus on its moral implications by highlighting the potential risks of gene editing. Ethicists, like Marcy Darnovsky, raised concerns about the unintended consequences of germline editing, the potential for the technology to exacerbate social inequalities, and the need for robust public engagement and governance frameworks. They argued that modifying the human germline could have unintended consequences for future generations and raised concerns about the potential for the technology to be used for non-therapeutic purposes, such as enhancing human traits (National Human Genome

Research Institute, 2017). Françoise Baylis discussed the potential for CRISPR to exacerbate social inequalities (Committee on Science, Technology, and Law, 2016). They pointed out that access to gene editing technologies could be limited to the wealthy, creating a divide between those who can afford the treatments and those who cannot. The ethicists emphasized the need for equitable access to the benefits of CRISPR and called for policies to prevent discrimination based on genetics. Through these presentations and discussions, the ethicists at the committee came to an agreement that the potential risks of CRISPR far outweighed the benefits and that this should be a driving factor in the policy creation. This perspective highlights the interpretive flexibility of CRISPR technology, as different social groups attribute different meanings and values to its applications.

These different perspectives from scientists and ethicists on the focus of CRISPR discussions and development were crucial as they guided the integration of the technology's potential to combat genetic diseases with necessary safeguards. By having various experts with different focuses, it helped to establish these safeguards, mitigate risks, and uphold ethical standards. These combined insights from diverse stakeholder groups drove discussion and were instrumental in creating frameworks that responded to both the rapid technological advancements and the moral landscape surrounding these developments. Throughout the discussions, both the scientists and ethicists debated the appropriate boundaries for gene editing research and discussed the need for public engagement and education to foster informed decision making. At the end, both sides recognized the importance of collaboration and the need to consider the long term implications of gene editing. They came to a compromise via these discussions and agreed that while CRISPR is important and has the potential to make an impact, the research should continue after ethical standards are in place to ensure that its development is

safe and for the betterment of humanity (National Academies of Sciences, Engineering, and Medicine, 2015). This compromise came about as the discussions emphasized the potential irreversible effects of gene editing on human genetics and the broader ecological impacts, highlighting the necessity for a cautious and unified approach in moving forward. The exchanges between scientists and ethicists helped to identify key challenges and considerations, and informed the development of guidelines and recommendations for the responsible use of the technology. The summit served as a platform for diverse perspectives to be heard and integrated into the decision making process, ultimately contributing to a more ethically grounded approach to the development and application of CRISPR.

In addition, the summit's organizing committee were instrumental in shaping the outcomes of the event due to them being from different countries and being able to represent the international community. The organizing committee included representatives from international scientific organizations and policy bodies such as the U.S. National Academies of Sciences and Medicine, the Royal Society of the UK, and the Chinese Academy of Sciences (Committee on Science, Technology, and Law, 2016). These representatives, all leaders in their field, brought expertise and a range of perspectives that were essential in navigating the ethical and scientific discussions, enabling the committee to draft informed resolutions. Their collaborative approach fostered a consensus that was vital for reaching the final decision, as it integrated diverse international viewpoints and ensured a more globally acceptable and comprehensive policy stance. Because there were representatives from many countries, many varying perspectives were heard, allowing for this consensus. This would not have been possible without them as the international community would not have taken any decision seriously if it had been representatives from just one or a handful of countries or disciplines. The committee's final

statement called for a moratorium on clinical applications of germline editing until safety and efficacy issues could be resolved and a broad societal consensus could be reached (National Academies of Sciences, Engineering, and Medicine, 2017). It specifically read, “it would be irresponsible to proceed with any clinical use … unless and until (i) the relevant safety and efficacy issues have been resolved … and (ii) there is broad societal consensus about the appropriateness of the proposed application” (Lander, 2019). This reflected the policymakers' efforts to balance the interests of various social groups while ensuring responsible governance of the technology.

Despite the International Summit on Human Gene Editing calling for a global moratorium on all clinical uses of human germline editing, adherence to this decision has been inconsistent by some scientists and it has not had much of an impact on global regulation due to the lack of enforceable international agreements and the absence of a global regulatory framework. A couple years after the summit, many of the leaders and members of the summit reconvened and recalled for a global moratorium on all clinical uses of human germline editing in light of controversial events such as Dr. He Jiankui’s experiments in China, which involved editing embryos to create genetically enhanced babies. Scientist Doctor He Jiankui in November 2018 used CRISPR to edit the genomes of twin girls to build natural resistance to HIV infection (Alonso, 2021). These experiments, which received widespread condemnation and resulted in Dr. He's imprisonment, were clear violations of the summit's recommendations. This event highlighted the lack of effective international oversight and the inability of the summit's recommendations to prevent such unethical practices. The absence of a binding international agreement on human germline editing and lack of regulatory power made it difficult to enforce the summit's proposed moratorium consistently across different countries. Additionally, there

were increasing proposals for genetic enhancements and a significant push to weaken the requirement for board societal consensus, further straining compliance with the summit's directives (Lander, 2019). This shift in attitudes and the lack of a clear definition of what constitutes broad societal consensus made it difficult to maintain a united front against the premature use of germline editing. Despite support from major governmental bodies like the U.S. National Institutes of Health, which reaffirmed the need for the moratorium (Collins, 2019), these recommendations remain ineffective, highlighting the challenges in achieving uniform global governance in the field of gene editing. This situation underscores the complexity of translating international recommendations into enforceable policies.

Even though Dr. He's actions were condemned by the community, it served as a pivot point in the discussions and had a significant impact on regulation due to its unethical nature and subsequent public outcry. His experiments spurred a significant shift in how CRISPR technology is perceived and regulated internationally. The public outcry and following "designer baby" narrative, emphasizing the ethical and societal risks of non-therapeutic uses of gene editing, became a central theme in shaping policy discussions (Greely, 2019). This shift in dialogue led to more rigid international governance frameworks and increased oversight of gene-editing research. In response to the scandal, the Chinese government implemented tougher regulations on gene editing research and increased the supervision of biomedical research institutions (Cyranoski, 2019). These measures, which were informed by the public outcry and international condemnation of He's experiments, reflect the Chinese government's efforts to balance its ambitions for scientific leadership with the need for responsible governance of CRISPR technology (Zhang, 2023). These new regulations not only prevented potentially more harmful experiments under looser regulations but also set a global precedent that discouraged similar

actions elsewhere. In addition, this event led to increased scrutiny and guidelines by the World Health Organization and various scientists and ethicists signing a statement in support of an international governance framework at the second meeting of the International Summit On Human Gene Editing (National Academies of Sciences, Engineering, and Medicine, 2019). Thus, while Dr. He's approach was widely criticized, it led to necessary discussions and important policy development, guiding future developments in gene editing technology to proceed under more vigilant and ethically informed conditions.

While the International Summit on Human Gene Editing's guidelines face challenges and resistance in creating enforceable regulation, they are nonetheless making a tangible impact on global discussions and policies made by other organizations, as evidenced by ongoing efforts to reach a consensus among scientists and ethicists. At the international level, these recommendations have shaped the agenda of the World Health Organization's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (World Health Organization, 2019). Composed of scientists, ethicists, and policymakers from diverse backgrounds, the committee has been instrumental in developing global standards aimed at responsible governance of human genome editing research and applications. Their discussions have led to recommendations for enhancing transparency, public engagement, and promoting international cooperation, including the establishment of a registry for human genome editing research and promoting international data sharing (World Health Organization, 2019). The recommendations have led to increased openness and communication among researchers, encouraging them to share findings and methodologies through the registry and other data sharing platforms. These recommendations have also resulted in more efforts to educate and involve the general public in discussions about human genome editing, leading to a more

inclusive decision making process. The promotion of international cooperation has fostered greater collaboration among researchers, enabling the sharing of knowledge, resources, and best practices, accelerating the pace of scientific discovery. The establishment of a registry for human genome editing research has provided a centralized database for tracking and monitoring ongoing studies, allowing for better oversight and governance of the field, helping to prevent unethical or unauthorized experiments, and contributing to building public trust in the technology (World Health Organization 2021). The committee's work, which built upon the summit's conclusions, represents a significant effort to forge international consensus on CRISPR governance and reflects the impact these relevant social groups and their interpretive flexibility are having on a coordinated global response to the challenges posed by the technology.

While the International Summit on Human Gene Editing and subsequent actions by international bodies have been influential in shaping CRISPR policy, many bioethicists argue that these efforts have not gone far enough in addressing the fundamental challenges posed by the technology and the policies set forth may be insufficient to keep pace with the rapid advancements in the field (Jasanoff & Hurlbut, 2018). Despite the summit's call for a moratorium on clinical applications of germline editing and the development of global governance standards, there remains significant variation in national regulations and a lack of enforceable international agreements. The He Jiankui scandal highlights the limitations of relying on voluntary guidelines and the need for more robust oversight mechanisms. Moreover, the focus on preventing the misuse of CRISPR for non-therapeutic purposes may obscure other important ethical and societal implications of the technology, such as its potential to worsen existing health disparities and the need for inclusive public engagement in policy decisions (Iltis, 2021).

In response to the critiques highlighted by bioethicists, it is crucial to recognize the substantive measures already being implemented which address these concerns. The call for more robust oversight mechanisms overlooks the progressive strides taken post-summit, specifically in response to the He Jiankui incident. The establishment of the World Health Organization's Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing marks a pivotal advancement. This committee has not only proposed international standards but has actively facilitated the creation of a registry for human genome editing research, enhancing transparency and accountability across nations (World Health Organization, 2019). Furthermore, the concerns regarding the exacerbation of health disparities and the need for inclusive public engagement have not been ignored. The ongoing efforts to involve the public in genome editing discussions and public consultations demonstrate a commitment to democratizing this technology (Thaldar, 2022). These platforms provide opportunities for voices from diverse socio-economic backgrounds to be heard, thereby informing more equitable policy development. In addition, while enforceable international agreements are ideal, their development is complex and time consuming. National regulations are adapting. Countries are increasingly aligning their policies with international standards, as evidenced by China's new regulations and the U.S. support for the International Summit's moratorium (Cyranoski, 2019; Collins, 2019). This ongoing dialogue and adaptation reflect a responsive and dynamic approach to both ethical and practical challenges, countering the notion that current efforts are insufficient.

Conclusion:

CRISPR technology has the potential to cure genetic diseases and even enhance human abilities. But as it moves from the lab to real-world use, it raises important ethical questions, especially when it comes to making changes that would be passed down to future generations. The analysis shows that while CRISPR has many promising applications, it is very important to have different relevant social groups' opinions heard and taken into consideration before implementation.

The first International Summit on Human Gene Editing has played a significant role in shaping the policy landscape surrounding CRISPR technology. By bringing together diverse perspectives from scientists, ethicists, legal experts, and patient advocates, the summit facilitated a balanced discussion on the potential benefits and risks of gene editing and reached a consensus on a moratorium on clinical applications of germline editing. However, the summit's impact on global regulation has been limited by the lack of enforceable international agreements and a comprehensive regulatory framework. The controversial experiments conducted by Dr. He Jiankui in China highlighted the need for more robust oversight mechanisms.

Moving forward, researchers, engineers, and policymakers can learn from the successes and limitations of the International Summit on Human Gene Editing to develop more effective governance frameworks for CRISPR technology. Researchers should continue to engage in open and transparent dialogue with the public, policymakers, and other stakeholders to build trust and ensure that the development of CRISPR aligns with societal values and priorities. Engineers should work to improve the safety and specificity of gene-editing tools while also considering the potential consequences of their applications. Policymakers should strive to create more

comprehensive and enforceable international agreements on the governance of gene editing, taking into account the diverse perspectives and concerns of different stakeholders. They should address the potential for CRISPR to exacerbate existing health disparities and ensure that the benefits of the technology are distributed equitably. By learning from the summit's successes and limitations, researchers, engineers, and policymakers can work together to create a more robust and inclusive framework for the future of gene editing, ensuring that its benefits are realized while minimizing its risks.

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