Regulating the Revolution: Lessons from Vaccine Regulation to Guide CRISPR Oversight

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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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I. Introduction

CRISPR-Cas9 is a revolutionary gene-editing technology that allows for the precise modification of the human genome, offering the potential to treat and cure diseases by correcting faulty DNA sequences (Asmamaw, 2021). However, this promise comes with a significant barrier: the exorbitant costs associated with CRISPR treatments, often ranging from $500,000 to $2 million per procedure. These high prices effectively restrict access, especially for marginalized communities, risking a healthcare divide that excludes those who may need it most (Reuters, 2023). Beyond therapeutic uses, CRISPR also raises ethical concerns in its application for non-medical purposes, such as genetic enhancement. This possibility evokes societal risks, including deepening inequality, new forms of discrimination, and questions around bodily autonomy (Trauner, 2024). The destabilizing condition is that while CRISPR-Cas9 offers vast potential, the implications of its widespread adoption with respect to safety, individual rights, and equitable access are not yet fully understood. Knoppers (2019) quotes Frances Collins, former Director of the Human Genome Research Institute, who says that "should such epic scientific misadventures proceed [without proper regulation], a technology with enormous promise for prevention and treatment of disease will be overshadowed by justifiable public outrage, fear and disgust."

To address these challenges, this paper uses Emmanuel G. Mesthene's research framework on technological innovation by examining vaccine regulation as a historical case study. Mesthene's approach emphasizes the need for deliberate public decision-making by institutions to manage the societal impacts of emerging technologies. Applying this framework, this paper analyzes vaccine regulation to identify lessons for CRISPR in balancing safety

oversight with individual autonomy and ensuring that public collaboration fosters equitable access.

The central claim of this paper is that Mesthene's framework reveals a current lack of institutional structures needed for effective CRISPR management, highlighting how analyzing vaccines as a historical case study can be used to demonstrate public institutions' role in building public trust, accommodating non-therapeutic uses, and promoting accessibility for CRISPR usage.

II. Problem Definition

The potential of CRISPR-Cas9 to transform genetic medicine makes it one of the most promising biotechnologies of the 21st century, though it also raises ethical and regulatory concerns that have yet to be fully addressed. CRISPR's therapeutic applications, from treating cancer to preventing hereditary diseases, provide a glimpse of its capabilities in advancing human health (Asmamaw, 2021). Excitement surrounding its potential has shown a steady increase over the last eight to ten years, as evidenced by the following Google Search trends chart (Figure 1):

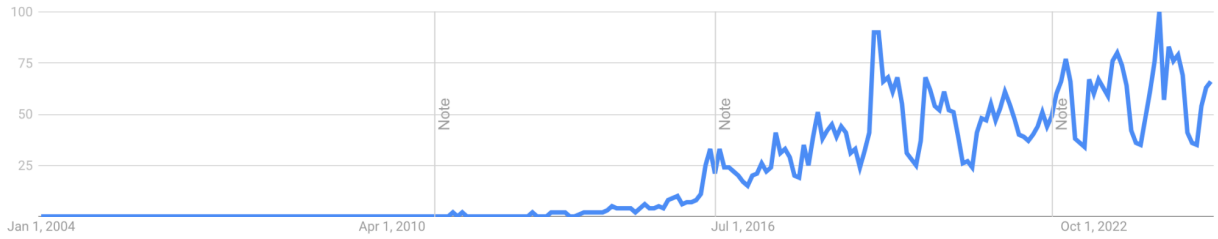

Figure 1: Google Search trends chart showing a steady increase since 2016 in online engagement pertaining to gene editing and CRISPR technology (generated by Google Trends).

However, the cost of CRISPR-based therapies highlights an economic barrier to access that could exacerbate health disparities. According to a pricing review conducted by Reuters (2023), the cost of CRISPR therapies is wildly unaffordable for the vast majority of the population, with some treatments estimated at around $1.9 million. Such high costs underscores a significant difference between the technology's promise and its accessibility, raising questions about fairness and the long-term implications of exclusive access to gene editing only for those who can afford it.

Additionally, as Paul Ball (2017) discusses, CRISPR's potential for creating “designer babies” (genetically modified children with tailor-made “desirable” traits) introduces many ethical considerations and public reluctance. The issue of designer babies highlights the need for a regulatory framework that both encourages innovation and safeguards against abuses. Public concerns surrounding bodily autonomy also play a critical role in framing the regulatory debate. The fundamental right to bodily autonomy is central to ensuring that individuals have control over medical decisions that directly affect their bodies (Trauner, 2024). This issue was brought to light in 2018, where a Chinese scientist performed in-vitro fertilization using genetically edited embryos without the patient’s consent (Normile, 2018). Without a regulatory framework that respects bodily autonomy, CRISPR technology risks infringing on individual rights, further highlighting the need for a comprehensive oversight approach that integrates ethical considerations.

Common Ground, Destabilizing Conditions, and Significance

To develop a foundational understanding of CRISPR regulation, it is important to identify areas of common ground and destabilizing conditions that define the regulatory landscape. There

is broad agreement that CRISPR holds immense promise for addressing genetic diseases, but this consensus soon diverges when the use of non-therapeutic treatments, such as enhancements, come into regard. Michael Sandel (2007) argues that the pursuit of genetic "perfection" raises moral concerns, as enhancements could create societal pressures and widen existing inequities. This shared ethical ground on the risks of enhancement technologies establishes a basis for regulatory caution.

The significant destabilizing conditions revolve around the economic and ethical factors that influence CRISPR's accessibility and equity. The exorbitant costs associated with CRISPR therapies threaten to render the technology exclusive to wealthier populations, creating a divide between those who can afford gene editing and those who cannot (Negussie et al., 2019). This cost disparity risks entrenching existing health inequities and undermining the principle of universal healthcare access, especially if CRISPR becomes a standard treatment option for certain diseases. According to Lim and Moon (2023), public trust in health interventions relies heavily on the perceived fairness and accessibility of those interventions. If CRISPR therapies continue to bolster healthcare inequity, it could destabilize public trust in not only gene editing but also the broader healthcare system as well.

The consequences of failing to regulate CRISPR effectively could be far-reaching, with potential impacts on both societal equity and individual rights. When looked in a historical perspective, regulatory oversights in fields like vaccine development have had direct consequences on public trust and access (History of Vaccines, 2022). Just as vaccine mandates and their enforcement were shaped by ethical concerns over individual autonomy, CRISPR regulation must consider similar issues to avoid repeating historical missteps. These concerns

underscore the urgent need for a regulatory model that balances innovation with ethical safeguards, one that can foster trust and ensure equitable access to gene-editing therapies.

From Broader Context to Specific Focus and Research Approach

In examining the broader regulatory and ethical challenges posed by CRISPR, this paper focuses specifically on the intersection of health equity and individual autonomy. Existing regulatory models, particularly in vaccine oversight, provide a compelling historical framework for addressing CRISPR's challenges. Vaccine regulations, which have evolved to prioritize both public health and individual rights, can offer insights into how CRISPR oversight might similarly accommodate diverse ethical perspectives. The *History of Vaccines* (2022) provides an overview of vaccine regulation, detailing how mandates and ethical considerations evolved in response to public health needs. Similarly, Pugh (2020) highlights the role of informed consent and autonomy, a critical aspect in healthcare that applies equally to CRISPR regulation.

In recent years, emergency authorization processes for vaccines, such as those issued by the FDA during the COVID-19 pandemic, demonstrate the regulatory agility necessary for modern healthcare interventions (U.S. Food and Drug Administration, 2020). These frameworks illustrate a pathway for balancing innovation with ethical oversight, allowing public health benefits to be realized while respecting individual autonomy. This approach informs the specific focus of this paper, which aims to explore how regulatory models developed for vaccines could be adapted to CRISPR to ensure both accessibility and respect for individual rights. This transition narrows the broader context to a focused exploration of regulatory precedents that may serve as a model for CRISPR.

The Knowledge Gap in CRISPR Regulation

Despite the potential of CRISPR to revolutionize genetic medicine, there is a significant gap in the existing regulatory frameworks that govern its use. While much has been written on the ethical implications of gene editing and its potential to exacerbate inequalities, there remains a lack of structured oversight that addresses both the public health benefits and the ethical concerns associated with CRISPR (Subica, 2023). This paper identifies a knowledge gap in institutional readiness to manage CRISPR technology effectively, as current frameworks inadequately address the dual nature of both public health and individual rights. This gap is not controversial but rather a synthesis of current understanding, because although we know that CRISPR holds transformative potential, we lack a regulatory system that fully reflects its ethical and societal complexities.

The following section examines how Emmanuel G Mesthene's framework can be used as a research approach to analyze CRISPR through the lens of historical vaccine regulation. This approach emphasizes the need for addressing present "institutional inadequacies" pertaining to public trust, access, and ethical frameworks regarding emerging technologies. Drawing from Mesthene's framework, this analysis will shed light into the ways that lessons learned from historical vaccine regulation can be incorporated with CRISPR.

III. Research Approach: Applying Mesthene's Framework to CRISPR Regulation

In order to develop a research approach to examine the regulatory management of CRISPR-Cas9 technologies, I draw heavily from Emmanuel G. Mesthene's framework on technological innovation as outlined in *Technological Change: Its Impact on Man and Society*. Mesthene's emphasis on the need for public institutions to engage in deliberate decision-making serves as a central guiding concept in my work. This framework, which highlights the growing

necessity for large-scale social considerations in managing emerging technologies, provides a structured model that can be applied to the complex regulatory challenges posed by CRISPR. My research aims to explore how regulatory bodies should adapt by examining historical precedents, such as the regulation of vaccines, to create a model that balances safety with individual autonomy in the context of gene editing.

Key Concepts and Models

Mesthene's primary concept is that technological innovation requires a shift from sporadic, privatized decision-making toward centralized public regulation. He argues that existing institutions, when faced with new technologies, often lack the full capabilities of addressing its societal impacts, stating that "the need for institutional innovation arises out of the inadequacies of present institutions" (p. 74). This is especially relevant to CRISPR, because its ability to alter human genetics introduces new ethical challenges that are not encountered in typical medical regulations. Mesthene claims that private institutions are suited to tasks like public engagement and demand testing, but they often fall short in their ability to handle broader societal impacts. This perspective suggests that CRISPR regulation should not be left solely to private interests that prioritize profitability but should rather be framed within institutions designed to prioritize public welfare and social equity above pure profit.

The gradual evolution of regulatory structures in response to new medical technologies is central to my approach, with vaccine regulation serving as a historical case study. Vaccines, like CRISPR, were initially met with resistance and regulatory challenges. Over time, as public institutions took a more active role in ensuring their safety and accessibility, vaccines became widely accepted and essential public health tools. This historical parallel provides a useful

framework for understanding how CRISPR regulation might evolve. Regulatory bodies such as the FDA and NIH are already involved in overseeing medical uses of CRISPR, but there are significant gaps when it comes to non-medical applications. Drawing from Mesthene's framework (shown in Figure 2), my research aims to analyze how vaccine regulation can address the gaps pertaining to CRISPR.

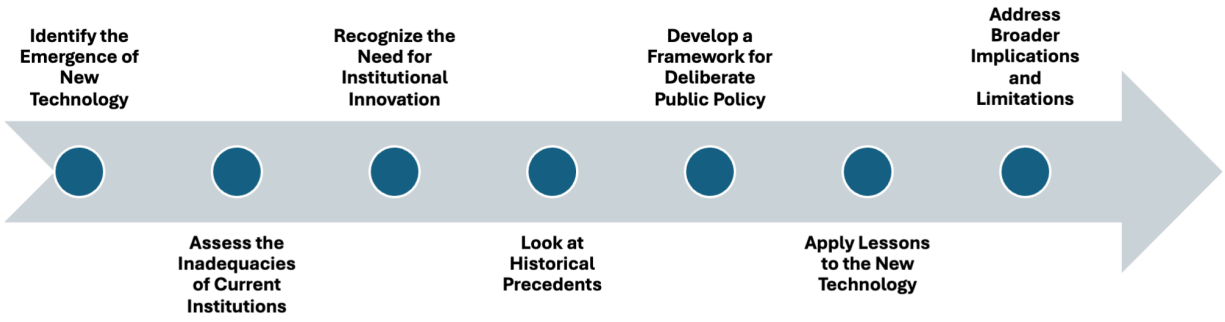

Figure 2: Flowchart outlining the sequential steps in Mesthene's research approach (created by author).

Sources of Evidence

The primary source of evidence for my research comes from historical regulatory models, specifically those developed for vaccines. By studying how vaccine regulation evolved, I aim to identify patterns that can be applied to CRISPR technologies. Mesthene's work, such as his assertion that technological innovation must be managed through public decision-making, provides a theoretical foundation for this exploration. I also draw from other scholars who have explored the ethical and social implications of CRISPR, such as Knoppers (2019) and Sandel (2007), who highlight the risks of "genetic elitism" and the ethical concerns around bodily autonomy and enhancement. These sources help contextualize CRISPR within broader societal debates about technology and inequality.

To gather evidence on regulatory gaps, I analyze reports and guidelines from current regulatory bodies, such as the FDA and NIH, examining how they address CRISPR's therapeutic uses but struggle with issues surrounding genetic enhancement. These sources will help illuminate how public institutions can adapt and innovate, consistent with Mesthene's call for "proper economic and political organization" (p. 75) to manage the societal impacts of CRISPR.

Analytical Process

My analysis follows a multi-step process, beginning with a historical examination of vaccine regulation as a model for CRISPR governance. The first step is to trace how vaccine regulation evolved from minimal oversight to a robust system that ensures safety and equity. By identifying key turning points in this regulatory history, I can draw parallels to CRISPR and its current state of oversight. Next, I examine the specific gaps in CRISPR regulation, particularly regarding non-medical applications like genetic enhancement. Using Mesthene's framework, I analyze the institutional inadequacies that exist today and propose areas where regulatory bodies can innovate. This involves a comparison of current CRISPR regulations to those for other medical technologies, identifying where CRISPR's unique capabilities present new challenges.

Finally, I integrate insights from Mesthene's call for deliberate public decision-making with contemporary scholarship on the social and ethical implications of gene editing. This allows me to develop a regulatory model that balances the need for innovation while also upholding individual rights and bodily autonomy. The model emphasizes the importance of public involvement in regulatory decisions, ensuring that the societal impacts of CRISPR are considered alongside its medical potential. My analytical process can be visualized through the following flowchart (Figure 3):

Figure 3: Flowchart outlining the analytical process using Mesthene's research approach (created by author)

Appropriateness of Approach

Mesthene's framework is appropriate for addressing the regulatory challenges of CRISPR-Cas9 because it emphasizes the societal consequences of technological innovation. CRISPR is not just another medical technology—it has the potential to fundamentally alter human biology and society. By using Mesthene's approach, which focuses on the need for public institutions to guide technological innovation, I can research how regulatory bodies may address both the medical and non-medical uses of CRISPR. His insight that "deliberate public decision-making" is necessary for managing the risks of new technologies (p. 69) aligns with my goal of proposing a regulatory framework that ensures CRISPR's safe and equitable use. The historical parallel of vaccine regulation provides a concrete example of how public institutions can evolve to manage new technologies. Vaccines, like CRISPR, faced initial skepticism and regulatory challenges but eventually became integrated into public health systems. By studying this evolution, I can develop a better understanding of how regulatory bodies might adapt to CRISPR, ensuring that its potential is harnessed without exacerbating existing inequalities or infringing on individual autonomy.

Furthermore, my approach is applicable to other emerging technologies that raise similar ethical and regulatory concerns. Just as vaccines prompted new regulatory frameworks, CRISPR

requires a reevaluation of existing institutions and policies. Mesthene's model of public decision-making can be applied to a range of technologies, from artificial intelligence to nanotechnology, making it a valuable tool for addressing the broader societal impacts of innovation. By drawing from Mesthene's framework on technological innovation and public decision-making, my research approach offers a structured method for addressing the regulatory challenges posed by CRISPR-Cas9. By analyzing the historical evolution of vaccine regulation, I aim to develop a model that balances the need for innovation with the protection of individual rights and social welfare. This approach not only helps to understand the current regulatory gaps but also offers a transferable model for managing other emerging technologies in the future.

I. Results: Key Insights and Parallels in Vaccine Regulation for Informing CRISPR Policy

Using vaccines as a historical case study sheds light into how CRISPR technology can also be regulated responsibly in order to find the balance between public health and individual autonomy. The adaptation and evolution of regulatory frameworks as a result of vaccines provides a rich foundation for how CRISPR can be governed.

Insight 1: Responsiveness to Safety Risks and the Role of Transparent Oversight Mechanisms

One of the most compelling insights from vaccine regulation is the necessity for quick and transparent responses to safety incidents. The 1955 Cutter Incident, where improperly manufactured polio vaccines led to cases of paralysis, highlighted the need for robust oversight to maintain public trust. This crisis prompted the establishment of the Division of Biological Standards and set a precedent for creating transparent regulatory practices that inform the public about risks and protective measures (FDA, 2019). According to the U.S. Food and Drug

Administration (2019), the immediate response to this crisis fostered increased trust in vaccine oversight, as regulatory agencies implemented stricter safety protocols to prevent similar incidents. When applying this lesson to CRISPR, it is essential for regulatory bodies to adopt transparent, responsive practices when adverse events occur. Proactively disclosing outcomes and risks associated with gene-editing technologies would likely promote greater public confidence. As the U.S. Food and Drug Administration's (FDA) oversight of vaccines illustrates, ensuring public access to safety-related information is crucial in fostering a responsible regulatory culture around CRISPR (FDA, 2021).

Insight 2: Balancing Public Health with Individual Autonomy in Regulatory Mandates

The history of mandatory vaccinations in the United States also offers insights into navigating the balance between collective health interests and individual rights. Since the early 20th century, vaccine mandates, especially in educational institutions, have sparked debates about individual freedoms. Many states incorporated exemptions for personal or religious beliefs by acknowledging the importance of autonomy even while prioritizing public safety (College of Physicians of Philadelphia, 2018). This approach of allowing certain exemptions shows a method of respecting individual autonomy within public health regulations, which is a principle that can inform CRISPR policy. Similarly, in the case of CRISPR, regulation could be structured to allow freedom for therapeutic use while setting clear boundaries for applications that may impact future generations or societal norms. This perspective aligns with the Mayo Clinic's (2020) discussion of vaccine regulation, emphasizing regulatory flexibility that respects individual choice while protecting public welfare. For example, voluntary guidelines for non-therapeutic applications of CRISPR could be introduced, reflecting the balance between autonomy and regulation seen in vaccine mandates.

Insight 3: Leveraging Collaborative Models to Advance CRISPR Access and Innovation

The rapid and diverse partnerships formed during COVID-19 vaccine development highlight the potential for collaborative frameworks in advancing CRISPR technology. Nearly one-third of COVID-19 vaccine candidates were developed through partnerships, with two main collaboration models: “materials transfer” and “knowledge sharing” (Druedahl, 2021). In materials-transfer partnerships, organizations shared physical and intellectual resources, as seen in the collaboration between Oxford University and AstraZeneca, where Oxford provided the vaccine candidate and AstraZeneca handled large-scale development and distribution. Knowledge-sharing partnerships, like that between BioNTech, Pfizer, and Fosun, fostered joint research and expanded manufacturing capacity by pooling technical expertise, critical for rapid response.

Applying this model to CRISPR, similar partnerships could foster a more equitable and efficient development landscape. For example, academic labs, often rich in innovation but limited in resources, could engage with industry partners for advanced testing, distribution, or commercialization, allowing CRISPR advancements to reach wider populations. Policymakers could create incentives for structured collaboration between public, private, and academic sectors, helping reduce redundancy in research and enhancing accessibility to CRISPR-based treatments across socioeconomic boundaries. Just as collaborative frameworks accelerated vaccine development, structured partnerships could advance CRISPR in ways that prioritize both innovation and equitable access.

Table 1: Insights Gained from Vaccine Regulation as Models for CRISPR Policy

Stage in Vaccine Regulation	**Key Focus**	**Implication**
Safety Oversight	Responded to the Cutter Incident with stricter safety standards and transparency.	Implement transparent safety protocols to build public trust in CRISPR.
Mandates and Autonomy	Vaccine mandates in schools balanced public health with autonomy through religious exemptions.	Introduce non-mandatory CRISPR guidelines for non-therapeutic use, respecting autonomy.
Collaboration and Accessibility Focus	COVID-19 vaccine partnerships highlighted the importance of collaboration for innovation and access.	Encourage structured partnerships among public, private, and academic entities to drive innovation and equitable access to CRISPR technology.

Integrating Insights with Research Approach

These findings reinforce Mesthene's framework by demonstrating how historical vaccine regulation provides a blueprint for CRISPR governance. Mesthene's framework advocates for centralized public oversight and responsive institutional adaptation, especially when managing disruptive technologies. The Cutter Incident, which led to stricter safety protocols in vaccine regulation, illustrates the need for transparent oversight in CRISPR to maintain public trust and echoes Mesthene's call for responsive institutional growth and evolution.

Similarly, the historical balance between vaccine mandates and individual exemptions aligns with Mesthene's view on upholding individual rights within public health regulations.

This approach can inform CRISPR policy by allowing personal choice in non-therapeutic uses while safeguarding societal welfare, which embodies Mesthene's emphasis on adaptable regulatory systems. Lastly, the collaborative models from COVID-19 vaccine development correlate with Mesthene's idea of leveraging both public and private sector strengths to maximize societal benefit. Applying this to CRISPR, structured partnerships could advance innovation and equitable access, aligning with Mesthene's focus on the importance of "proper economic and political organization" (75). Together, these insights illustrate how vaccine regulation's transparent, adaptable, and collaborative frameworks can guide CRISPR regulation within Mesthene's model, thus ensuring responsible and inclusive management of gene-editing technologies.

Conclusion

This paper argues for a regulatory framework for CRISPR-Cas9 that balances innovation with ethical responsibility and equitable access. Using Emmanuel G. Mesthene's model, which emphasizes public decision-making in managing transformative technologies, and drawing from historical vaccine regulation, the research illustrates how adaptive and transparent oversight can address CRISPR's unique challenges. Lessons from the Cutter Incident, vaccine mandates, and recent collaborations to expedite COVID-19 vaccine development and access reveal the potential of a flexible regulatory system that upholds individual autonomy, prioritizes public safety, and ensures equitable access. These are key principles that could guide CRISPR's responsible integration into society.

This research highlights specific policy and ethical implications for CRISPR regulation, such as setting clear limits on non-medical applications, implementing stringent safety protocols,

and fostering collaboration between various research groups, pharmaceutical companies, and governmental agencies. Despite CRISPR's broad societal impact, its potential for misuse underscores the need for constant regulatory modification and awareness. This study's limited timeframe means that a wider range of case studies could not be explored. Nevertheless, the findings provide a foundation for CRISPR regulation modeled on historical insights from vaccine oversight, supporting a flexible framework that can evolve alongside gene-editing technology. Through this approach, society may navigate CRISPR's transformative possibilities with respect for individual rights in an era where genetic modification has become a present reality.

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