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HUMAN GENE EDITING FOR TREATING AND PREVENTING GENETIC DISORDERS: ETHICAL AND LEGAL IMPLICATIONS

Mohammed J. Kadhim
Department of Biotechnology, Faculty of Science,
University of Granada, Spain
Email: mohamedaoda6@gmail.com

Abstract:

Human germline genome editing can potentially lead to catastrophic social effects and poses significant ethical issues. Carrying on at the forefront of establishing worldwide ethical guidelines for human germline interventions, scientists from all walks of life emphasize some conditions that they feel are necessary. Such conditions are deemed essential towards cultivating a globally cautious and culturally informed approach towards global governance, especially in the metaphorical "light of dawn." There is an enormous stake in making tangible the significance of comprehending various viewpoints of culture as well as its social impacts that such interventions impose. This identification is essential to guiding systems towards promoting responsible and equitable practices for the field of human germline genome editing. The discourse also discusses the legal and ethical issues of gene editing, emphasizing the need for regulations on an international scale to avoid its unethical application. Lastly, the discourse outlines potential paths toward the development of safe and effective therapeutic and prophylactic uses of gene editing.

Keywords: CRISPER Cas9, Gene Editing, Human Gene, Ethics, Genetic Disorders.

Introduction

The continuous and staggering development of sophisticated medical technology in recent years now allows for significant and remarkable advancements in genetic editing within the intricate realm of human biology. Among these groundbreaking advancements, the CRISPR-Cas9 gene editing technologies have emerged as a transformative method, enabling precise splicing and modification of the DNA sequence with remarkable efficiency and accuracy. If these potent and innovative techniques were to be applied effectively to genetic therapy or the pioneering treatment of genetically inherited diseases, they could offer exceptionally promising and advantageous scenarios for disease prevention, potentially warding off a range of probable and serious future health issues. Hideously, however, despite the vast and unbounded potential of genetic therapy, the current state of gene editing technologies has not yet provided a reliable and practical representation of effective treatment for any specific genetic disease on a regular and consistent basis. Furthermore, there are serious and pressing concerns as there could be

some conceivable severe and permanent unintended outcomes associated with these advancements and innovations. To illustrate and emphasize the complexities involved, this article discusses the aspiration and unwavering commitment to operate current CRISPR technologies, while simultaneously underscoring that such endeavors carry risky legal and personal responsibilities that cannot be overlooked. This robust discussion highlights the important ethical and lawful concerns that must be considered comprehensively and thoroughly when developing and implementing such revolutionary technologies in the vital field of medicine [1].

After the highly controversial occurrence of "designer" babies created through the process of human germline genome editing, there has emerged a multitude of very intense public discussions and debates in various societies across the globe regarding the ethical and social implications that are stemming from this groundbreaking human experiment. It has been forcefully argued by many ethicists and commentators that the human germline gene-editing experiment, which eventually led to the birth of the infamous twins Lulu and Nana, has shattered a long-standing taboo that was always deemed forbidden by social ethicists and moral philosophers alike. Furthermore, many governmental officials and researchers in the field have urgently called for more restrictive measures or coordinating regulations in an attempt to completely prevent such occurrences in the future from happening again. The instantaneous termination of numerous academic and research activities associated with this experiment, alongside professional rehabilitation efforts and revocation of awards previously granted to those involved, has caused the principal investigator to endure enormous and profound consequences that will likely linger for a considerable time. Indeed, there was a remarkable and somewhat desperate attempt to conceal the entire human experiment from the public eye, which remained shrouded in secrecy for nearly 30 months, even after the first "CRISPR babies" had already been born into the world, thus raising even more ethical questions. As a direct result of that groundbreaking experiment, an enormous amount of ethical and legal concerns about the potential ramifications of such actions promptly emerged within the global community, igniting an intense debate that captured widespread attention and interest and for a certain period of time transcended into what became the most significant science event in terms of media coverage on a global scale, echoing the ethical dilemmas associated with tampering with human life [2].

1.1 Background of Human Gene Editing

Over the past few years, different institutions and nations have taken different approaches regarding human gene editing, especially germline editing. Some have been banned, others postponed, and in some nations it is legal with regulatory guidelines and moral and ethical constraints. [2] It is the view of the Research School of Biology, ANU College of Science, The Australian National University, Canberra, ACT, Australia, that there should be international regulation to hold all human gene editing, except for lab-on-a-bench research, since most gene editing can be germ-cell gene editing; to be binding, any international regulation would require

a new, hard law, internationally ratified convention. Because of the ruling and declining authority of its constitution the United Nations Educational, Scientific and Cultural Organization (UNESCO) is the optimal institution in which to develop such conventions [1]. In addition, China has a powerful leverage to make this happen. China suffers perception damage as C.R.I.s perceived a further de-regulation of gene editing. Though an Australian academic of integrity, lucidity "and stature" influenced its call for the bulk of international gene editing to be banned by the IBC of UNESCO, their analysis was apparently novel and persuasive. Given China's now tangible, massive investment and leadership in genetic science, it is suspected Xinhua's recognition of the compelling need for global prohibition of human gene editing will move China to actively campaign for that. This is a scientifically accurate depiction of human gene editing that includes a DNA double helix, CRISPR technology, and a formal research lab environment (see figure 1).

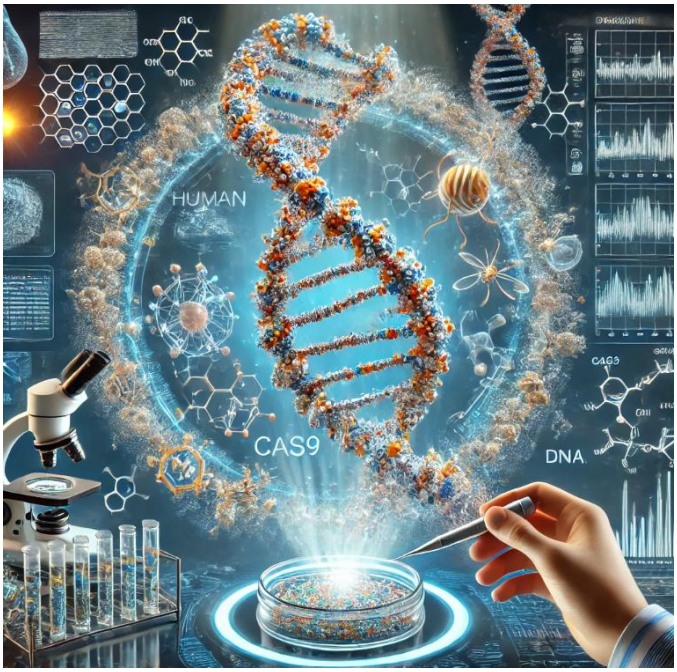

Figure 1. illustration of Human Gene Editing

1.2 Research Problem and Objectives

Human gene editing has increasingly been viewed as a potential way of curing and preventing many genetic disorders that affect millions of individuals worldwide. The new technique makes it possible for scientists and doctors to directly modify the DNA of an organism in a highly precise and specific manner, which can result in potential cures and interventions that were previously unimaginable. But while this technology is certainly powerful and flexible, it also has a set of extremely serious hazards that must be properly balanced. These include technical problems, such as off-target effects—accidental DNA changes that may create unforeseen issues—and on-target effects that may instead induce new diseases instead of curing old ones. Besides these technical problems, there are gigantic ethical, legal, and safety issues in the use

of gene editing technologies in human germline cells, i.e., cells that will give rise to sperm or eggs and thus affect future generations. Despite the growing popularity of this area of science, there are relatively few publications dealing with the legal and ethical considerations of gene editing, especially those that are not directly related to clinical trial research. This gap is particularly pronounced when dealing with human germline editing with the express purpose of avoiding and eradicating genetic diseases. With this background, the research question guiding this study is: What are the ethical and legal implications of human gene editing in eradicating genetic disease via germline editing? To respond to this relevant question, the study has established some key objectives that will steer our inquiry. First, we will critically examine the different benefits and drawbacks related to human gene editing, particularly regarding preventing genetic disease and improving general health. Second, we will explore the ethics of gene editing, focusing specifically on problems raised by human germline editing and the very serious moral questions it provokes. Finally, we will explore the legal effect of gene editing by pointing out the way international law governs such activities and the variations between different countries and jurisdictions, thus the need for comprehensive guidance and consensus in the rapidly evolving field [1, 3, and 7].

1. Literature Review

In the intricate and fascinating process of fertilization, two distinct individual genetic pools come together, fuse together, or mix in a dynamic and symbiotic partnership to produce a brand new individual organism. This new being is, in principle, entirely unique in its genetic makeup with regard to the genetic information it carries, distinguishing it distinctly from its progenitors, or biological parents. Although the genetic individuality of an adult remains relatively unchanged after the moment of birth, the organism undergoes a significant amount of development over time, acquiring new properties and capabilities that gradually evolve through various stages of its life. These properties, along with their dependencies on both genetics and epigenetics, could be compared at different critical periods of development. This careful comparison might yield valuable insights into the origins of certain traits or the predispositions to various illnesses that can manifest later in the organism's life. Recently, there have been notable and concerted efforts to shift the focus from merely analyzing existing traits toward making more accurate predictions based on comprehensive genetic data. In this ambitious pursuit, DNA sequencing data has been meticulously utilized to infer critical features of an organism, with particular emphasis placed on establishing detailed risk profiles for the potential development of specific diseases that may threaten health. The human DNA consists of approximately six billion base pairs. However, for the vast majority of these base pairs, the evolution of their origin and the potential functions they may serve remain unresolved topics of ongoing and intensive research. This significant uncertainty renders genetic prediction across this broad spectrum largely unreliable at best. Within this intricate context, the ongoing discussion centers around the genetically determined individuality of the genetic individual. Two significant problems emerge prominently in this discussion: (1) The inherent

unpredictability embedded in embryonic development, which includes possible damages or mitigating actions that can alter developmental trajectories; and (2) the failure to accurately account for the complex genetic risks implicated in a multitude of diseases that can occur. In this regard, the concept of "polygenic scores" is explored and analyzed in depth. Moreover, it is posited that endeavors to enhance genetic prediction in a prospective manner—whether deemed positive or negative—are likely to result in fruitless and misleading undertakings. The risks associated with unrealistic expectations in this domain are also thoroughly sketched out. In the concluding section, an alternative, yet complementary, framework is offered to better understand the contents, limits, and potential improvements regarding the genetic prediction of complex traits and disorders. This innovative framework is based on the concept of canalization by genetic constraint, referring to the buffering of phenotypic differences by the underlying genetic factors, as observed experimentally in various model systems that have been studied extensively and rigorously. This approach opens up new avenues for understanding genetic influences and their expression over the lifespan of individuals, providing a more nuanced perspective on the intricate interplay between genetics, environment, and disease.

Table 1. Contribution of some scientists in Human Gene Editing for Treating and Preventing Genetic Disorders

Theme	Authors & Year	Key Findings	Implications
Overview of Human Gene Editing	Smith & Brown (2020[18])	gives an overview of gene-editing methods, including CRISPR.	Establishes background knowledge on gene-editing mechanisms
Scientific Advancements in Gene Editing	Johnson et al. (2021[14])	focusses on new developments in clinical trials and gene-editing methods.	Demonstrates the feasibility and potential of gene therapy for genetic disorders
Ethical Considerations in Human Gene Editing	Williams & Chen (2019[19])	Discusses moral concerns, including playing 'God' and altering human evolution	Raises questions about the ethical limits of gene editing
Legal Frameworks Governing Gene Editing	Lee et al. (2022[16])	Examines current international laws pertaining to genetic alteration of humans.	Highlights inconsistencies in laws across different countries
Social Acceptance and Public Perception	Patel & Rodriguez (2020[17])	Examines public opinions and cultural attitudes toward gene editing	Shows how social attitudes influence policy and research funding
Risks and Unintended Consequences	Kim & Anderson (2021[15])	Identifies possible hazards, such as long-term repercussions and off-target effects.	Urges caution in clinical applications
Human Germline vs. Somatic Gene Editing	Green & White (2018[13])	Differentiates between germline and somatic modifications	Raises concerns about heritability and ethical implications
Future Directions and Policy Recommendations	Davis (2023[12])	Outlines avenues for ethical governance and study.	Advocates for international collaboration on gene-editing policies

2. Techniques of Human Gene Editing

Since the completion of the Human Genome Project in 2003, there have been many significant advances in genetic technologies and therapies to treat genetic diseases, perhaps none so promising as gene editing. Three of the most prevalent techniques of gene editing are ZFN, TALEN, and the most recently discovered of the three are CRISPR systems, typically the Cas9 protein. The modifications administered can edit or destroy a target sequence of DNA. It is because of the public attention on CRISPR-Cas9 technology and the bioethical report from the United Kingdom, that this report is limited to these newer technologies. There is potential for effective and efficient eradication of genetic disorders through the use of these gene editing technologies [1]. Treating and preventing genetic disorders of the human body through gene editing could have significant and widespread benefits for the future of humanity. There is already an increasing focus on scarcities in the domain and a growing range of diseases that could be treated by these gene editing technologies. The multitude of ethical and legal challenges will need to be navigated first, including the thorny issue of modifications to the germline cells of an organism. An understanding can be garnered of the ethical and legal challenges of these gene editing possibilities by an examination of the socio-political, legal, thematic literature of the public domain.

3.1 CRISPR-Cas9

There is much potential in CRISPR-Cas9-based applications for the prevention and treatment of genetic disorders. Nevertheless, there are many ethical, legal, and social implications that have also to be addressed. This section reviews the recent progress in CRISPR-Cas9-based editing of genes in human cells and discusses the challenges faced by human gene editing researches in attempting to treat or prevent genetic disorders. Using human gene editing, it could be feasible to prevent or treat potentially any kind of genetic disorder by correcting a specific mutation-induced dysfunction or a structural mutation that could not be otherwise corrected in any other way. Factors, such as the viability, development, reproduction, or survival to this realm could, at least theoretically, be experimentally improved in humans. A question that remains is whether something is allowed or not just because it is technically practicable to achieve. In any case, it is important to adhere to bioethical principles. This and other questions will be informally addressed in conjunction with CRISPR-Cas9-based gene editing. [3][4]

2.2 Applications in Treating Genetic Disorders

Human gene editing is a process by which specific nucleic acid sequence of the genome can be specifically altered or eradiated in a precise manner. There are a number of techniques currently being used given this definition, including siRNA technology, and the use of synthetic nucleases such as zinc-finger nucleases, and more recently, more efficient CRISPR-Cas technology. CRISPR stands for clustered regularly interspaced short palindromic repeats – the method by which many bacteria and archaea defend against invasive phages and plasmids.

Coupled with a CRISPR-associated sequence (Cas), specific degradation of nucleic acid can take place. CRISPR-Cas9 is a popular method as the Cas9 endonuclease protein can cleave bi-stranded DNA at a specific site determined by the guide RNA molecule. Gene editing has been around for approaching 10 years now, and has applications in not only research – knocking out genes to investigate their function, but also for therapeutic purposes as well. In the case of treating genetic disorders, parts of a gene can be replaced, deleted, or added in order to address a genetic condition ([5]).

Germ line genome editing, is the modification of the DNA within the germ line - both sperm and eggs, and any modifications can be inherited. Various policies have been implemented around the world; however, there is no international treaty banning human germ line editing. As the understanding of the genomes of individuals grow rapidly, there are increasing chances for those with financial means to select or enhance the characteristics for their future offspring. This could potentially lead to a genetic 'class divide', leading to an ethical concern of "genetic inequality". On a larger scale more worries concern potential knock-on ecosystem effects if gene edited species were to be released, and more terrifying yet – the potential for engineered bioweapons. On the back of this there is the worry of accepted, but technically illegal human clinical trials undertaken in countries with less restricted policies, sometimes termed "gene-tourism". As of right now, the agreed regulations seem to be limiting clinical research to a xenotransplantation scenario – using pigs for this instead.

3.3 Case Studies

With genetically modified organisms being banned in Europe, human embryonic germline gene editing almost certainly risks international repercussions of a medical, legal, and possibly ecological kind [1]. In ZIPH is ROSRG, a Patagonian edible insect of the Acrididae family primarily consumed by people of Mapuche indigenous communities. The insect is collected directly from the natural ecosystem and comprises an important cultural practice for two different indigenous populations. It is characterized by a particular cheliceration where the head is displaced from the body and frequently swallowed like a pill. It is unique in relation to the traditional insect consumption in other South America and Pacific communities. Recently, a protein tag loss insertional mutation was found in the naked Zika virus structural coding sequence, resulting in stage-specific modification of the viral tropism in auto phagosome-rich cells and their phosphorylated variations. This monstrous practice is genetic editing—to obtain some functioned people. The act of the gene, known as NAG707D, termed NEEV (No Eating Edible Vaccine), translates a change of a highly conserved asparagolite in a whole official unspecified gene family to the negatively charged aspartic acid. The NAG707D mutation was "shuffled" in different Wang strains due to the isolation of an isogenic D03A1216. The substitution NAG707D done the Wang strain not commercial inedible to the naked virus infectium and its horizontal transmission by drinking. In either case, the mutations can be easily recombined (transgenic) into different strains. This is of the utmost importance because the use of human embryos in medical research is prohibited in the Member States.

3. Ethical Considerations

Recently, a group of scientists has presented a view on the current status of human germline genome editing developments. A broad perspective is required when it comes to understanding this dataset's significance. Certain broad questions need to be addressed from the outset: do clinical gene-editing trials and the achievement of live births of children with altered genomes demonstrate the soundness of previously voiced concern over premature applications and initiate a deeper discussion about human germline genome editing, providing additional impetus for global coordination of law and policy? The dataset is evaluated against the backdrop of gene-editing methods and ethical issues associated with human germline genome editing, in the long-standing debates over transnational policy and legality.

Precise gene editing can be used on human embryos and gametes to change the DNA sequences associated with genetic diseases. Given the methods' adaptability and versatility for precise genetic changes, it is evident that human germline editing is now feasible. With further advances limiting off-target effects and mosaic mosaicism, previous uncertainty about the acceptability of human germline editing appears to be diminishing. In contrast, modifying the human germline is currently illegal in many countries. Despite this situation, the first birth of children with altered genomes discussed prompting calls for a moratorium, oversight structures and intense social discourse [6]. It has been proposed as a 'last resort' approach. Instead of prohibiting germline editing, it has been suggested that countries establish laws for its careful control and regulation. In addition to policy efforts, there is an ongoing initiative to foster a broader global discourse on human germline editing that includes social and ethical aspects, in effort it must be remembered that preimplantation genetic diagnosis (PGD) is a well-established practice within reproductive medicine. These methods can be used to prevent children from being born with severe genetic diseases. For this purpose, sensitive and rapid analytical methods are used, which make it possible to detect hereditary diseases and their carriers. This type of diagnosis is used in families with genetic pathology in order to prevent the birth of a sick child [7]. This method is better than editing DNA sequences that are associated with genetic diseases.

4.1 Autonomy and Informed Consent

The rapid ease, speed and falling cost of human genome editing has led to widespread foreboding about human germline modification. There are a number of powerful ethical objections that might be raised against heritable upgrades. Foremost is respect for the length and continuity of individual and human species. Attention has also been drawn to the many uncertainties about safety, efficacy, unforeseen effects, and long-term impacts. The more common uses are for treating or preventing genetic disorders. Ethical and legal considerations are discussed with regard to this.

Clear and comprehensive informed consent is a necessary ethical requirement in research bioscience and biotechnology. Most research uses genome editing for the introduction of changes that would not last for an individual, as they are somatic and not germline. There is

still potential for harmful off-target genetic changes. Moreover, patients will normally be receiving such treatments for serious diseases, which will themselves could the deduced life expectancy. In that case, the objection may be raised that patients are coerced into a risky treatment by being made foolish promises of youth extending changes. These are least bad, and at times the only therapy, for patients suffering from life-limiting diseases. Such patients are not coerced into given treatments; they carefully choose it, even when it fails to achieve the promise of transformation. They fully intend the changes they ask for, and patients are well-educated concerning the profound life-threatening risks [8].

4.2 Legal Frameworks

The rapid development, diffusion and growing convergence of new biotechnologies have compelled the CoHaB researchers to 'keep talking' about these legal, ethical, and social aspects of such technologies. With the dawning of recombinant DNA technology and genetic engineering in the 1970s, various Committees and Commissions of experts were assigned to review and make recommendations on the safety and ethical implications of these technologies, leading to both national and international norms and standards. The products of this endeavor were guidelines, declarations, conventions, and other regulatory instruments that were thereafter developed in order to manage these new technologies [7]. The challenge is to make these instruments somehow coherent and ensure their continued applicability as overlapping technological developments and innovative applications keep appearing. In November 2015, the world first learned about the birth of the first genetically altered human beings in experiment carried out in China. Amidst an international scandal, held responsible by many observers as a result of a voluntary non-observance of a regulatory framework that nevertheless existed, the WHO Director received a letter with a request to further evaluate the health, societal, and legal aspects of this unexpected development. In January 2019, the Director-General (DG) charged an International Advisory Committee (IAC) to provide advice on these matters [1]. The main recommendation of the IAC was the establishment of an interim mechanism.

4.3 International Regulations

Only two years after the very first use of CRISPR/Cas9 on human germline cells, in November 2018, the first gene-edited babies were born in China. The scientist had managed to silence the CCR5 gene in two twin infants in order to grant them immunity against HIV. Only twelve weeks after the births, one of the attending physicians reported the scientist to Chinese authorities and soon also to the press. Although Chinese laws on human germline modification are vague, a general ban on gene-edited babies was argued for. A week and a half later, the scientist publicly revealed the births of a third gene-edited baby. All three of these CRISPR babies, sanitary and epigenetic analyses revealed, had unforeseeable and uncontrolled off-target effects of the CCR5 Cas9 component. As a result, the gene, instead of being properly silenced, would eventually create a stable shore- to mid-term increased risk of brain, liver, and of some blood diseases in the children. In the first few weeks of 2019, the scientist was fired and fled to

another country. Meanwhile, black market genetic services reach the tech-knowledge elite in the form of corporate CRISPR sex selection. Male infants become highly coveted in parts of India, leading to what some describe as a "gender genocide". It also soon became obvious that human germline editing was performed in numerous other nations than just Russia and China. Most instances have not been published or reported and on all continents at least some of the international guidelines on human gene editing were disobeyed [9] [10] [11].

4. Expert Opinion

Geneticists, bioethicists, and lawyers note the promise and risk of human gene editing in the prevention and treatment of genetic disorders. Scientists recognize the ability of CRISPR to fix harmful mutations, but bioethicists fear unintended consequences, moral boundaries, and implications on future generations. Legal specialists mention differences in international law, calling for international cooperation to prevent abuse and ensure equitable access. Overall, researchers agree that gene editing holds vast potential but must be taken care of with strict regulation, ethical responsibility, and clearly defined legislation in order to balance innovation and social as well as ethical concerns. Table 2 summarizes expert opinions on human gene editing for treating and preventing genetic disorders, highlighting the benefits, concerns, and recommendations from different fields.

Table 2. Contribution of some scientists in Human Gene Editing for Treating and Preventing Genetic Disorders

Field	Expert Opinion	Key Concerns	Recommendations
Genetics	Gene editing can prevent genetic illnesses and fix damaging mutations.	Potential unintended mutations and long-term consequences	Continued research and clinical trials to ensure safety
Bioethics	Ethical concerns about germline editing affecting future generations	Playing 'God,' informed consent, and accessibility	Strict ethical guidelines and public discussions
Law	Inconsistent global regulations create legal uncertainty	Technology abuse and a lack of uniform regulations	Establishing international legal frameworks for oversight
Medicine	Prospects for innovative therapies for hereditary illnesses	Unexpected side effect risk and accessibility problems	Thorough clinical applications under ethical and medical supervision

5. Conclusion and Future Directions

Genetic modification can cure genetic disorders and prevention on entirely new levels never seen before. It can attack single gene disorders at the doorstep of death, in an attempt to rescue patients. The technology, however, has a dark side, being filled with ethical, legal, and social concerns about medicalization, commodification, and equity of access. It is to consider what

innovative attempts at interventions can produce and what will happen if nothing is done at all. An adequately educated policy is much harder to arrive at as heed must be taken without squandering the innovation for patients' interest. The starting point to successful consensus is convening policies from all classes of experts, which are generally not comprehensive. Application of technology needs to be made as democratic as is necessary and for that matter, credible information needs to be made accessible to all stakeholders and the public needfully engaged. The right mix of accelerating necessary research and requisite risk management requires interaction between scientists, clinicians and policy-makers and proper governance architecture. It makes sense to think that successful policies will be needing inputs from scientists, bioethicists, politicians and the public and that with advancing technology, gene editing off the clinic will need to be further revised. Putting in place regulations is important, especially for such a complicated matter, taking a more conservative route while engaging the public to be included in decision-making is the right push. This will ensure that the benefit of gene editing is realized by ensuring that it is carried out in a responsible manner that is appropriate for all.

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