Harvard Model Congress
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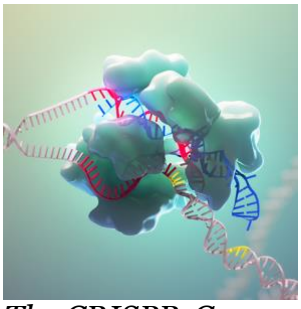
GENE EDITING

By Conrad Hock

INTRODUCTION



The CRISPR-Cas9 complex that allows for precise and efficient genomic editing

["CRISPR-Cas9 Mechanism & Applications"]

In 2020, Emmanuelle Charpentier and Jennifer Doudna received the Nobel Prize in Chemistry for their "development of a method for genome editing," recognizing their work with the CRISPR-Cas9 complex. Ever since its invention as a gene editing tool in 2009, CRISPR has transformed the landscape of biological discovery and innovation, with implications for a large variety of industries (National Human Genome Research Institute, 2019). As the Royal Swedish Academy of Sciences put it, CRISPR "has revolutionized the molecular life sciences, brought new opportunities for plant breeding, is contributing to innovative cancer therapies and may make the dream of curing inherited diseases come true" (Royal Swedish Academy of Sciences, 2020).

Derived from a bacterial defense mechanism against viruses, CRISPR has vastly accelerated the efficiency and precision with which scientists can edit the genome. Biologists have quickly begun to apply this technology for many varied purposes. To name a few, CRISPR can be used to create models of disease for medical investigation, to create crop varieties that are resistant to drought or pesticides, and even to produce animals with certain productive or desirable traits.

Nevertheless, with this power comes a host of legal, ethical, social, and economic concerns that desperately need to be addressed. Although there are some public fears about gene editing that are largely fueled by a misunderstanding of the technology, there are several pressing and difficult questions that will require thoughtful and effective policy. In what circumstances should gene editing be allowed in plants and animals? In what circumstances, if any, should gene editing be allowed in humans? Who should decide if any given genetic edit is acceptable? If certain edits are acceptable and prove useful–whether as therapies for humans or enhancements to plants

and animals–how should these technologies be licensed? Finding answers to these questions will be crucial in crafting any policy that seeks to regulate and legislate gene editing.

EXPLANATION OF THE ISSUE

Historical Development

While CRISPR was not the first developed method of gene editing, its development signaled the start of easy and efficient gene editing. Other methods had already existed since the 1970s, but these required significantly more time, effort, and training to use, yet produced results with far less efficiency or precision. Thus, the development of CRISPR has enabled researchers in academia, biotech, and agriculture to experiment with genetic modifications at great scale and with great ease. It is in this context of accelerated progress empowered by CRISPR that Congress must write and adopt legislation to regulate gene editing.

embryo *– early developmental stage of an organism, generally characterized as beginning after fertilization until approximately 8 weeks*

In 2018, He Jankui, a Chinese researcher, made headlines when he announced at a conference that he had genetically edited human **embryos** using CRISPR to make a modification conferring resistance to HIV (Normile, 2019). While these edits were in clear violation of existing Chinese regulations, the uproar in wake of the news quickly became global. In response, a team of scientists led by Eric Lander, former science advisor to the President, called for a global moratorium on "**heritable genome editing**" in humans (Lander et al., 2019).

heritable genome editing *– genetic modifications to the egg cells, sperm cells, or early embryonic cells of an organism*

While the editing of human embryos has been strictly banned by Congress, CRISPR therapies for a number of human diseases are undergoing clinical trials and gene editing is only growing more popular among researchers and within the agricultural sector. In light of this changing context, effective policy to ensure oversight of these technologies as well as regulation of their commercial use is needed now more than ever.

Scope of the Problem

In 2019, Congress voted to renew a 2015 provision banning the editing of human embryos with the intention of creating a baby.

In 2019, Congress voted to renew a 2015 provision banning the editing of human embryos with the intention of creating a baby, but some researchers as well as members of Congress have taken issue with the language and nature of the ban, believing it to be too harsh (Stein, 2019). Questions remain on the ethics and permissibility of gene editing that does not occur in embryos, namely non-heritable human gene editing. Furthermore, underlying many concerns regarding gene editing in both plants and animals are questions regarding what regulatory bodies should oversee and approve various gene editing initiatives. Ensuring strong oversight is

especially crucial in the context of agriculture, because as opposed to human genome editing, editing of plant and animal genomes in agriculture has become quite widespread, leaving questions about the safety of these changes. Finally, given that much of the application of gene editing is occurring in the private and commercial sector, the sale and use of products resulting from gene editing has spurred a wide debate on how various genetic modifications can and should be patented.

Ethics

As both CRISPR technology and understanding of its technological application remain nascent, many prominent researchers have urged caution regarding gene editing in humans, as evidenced by the moratorium endorsed by Eric Lander and others in 2019. These researchers specifically called for a halt on heritable gene editing in humans. Heritable edits are edits to the genome that can be passed down to the offspring of the genetically modified organism. These occur when genetic changes are introduced either to the **gametes** of an organism or the resultant embryo, and typically go on to be present within every cell of the resultant organism. Given that such heritable edits can affect every cell of the modified organism as well as future generations, the stakes of such changes are high and must be made informed.

gamete *— an organism's reproductive cells that, when they fertilize those of the opposite sex, produce a zygote, a cell that eventually forms a new organism.*

Nevertheless, although the current state of genomics might make such edits uninformed, delegates should consider enacting robust legislation that accounts for the likely future when scientists can make such edits with confidence and precision. If confidence in gene edits has been established, what kind of edits might be permissible? CRISPR therapeutics to treat disease are already undergoing evaluation in clinical trials and are seeing success. For example, Vertex Pharmaceuticals has innovated a therapy to treat Sickle Cell anemia by restoring fetal hemoglobin in patient stem cells. (Vertex Pharmaceuticals, 2023). Notably, such gene edits are both non-heritable and not in embryos, and therefore do not fall under the existing congressional ban.

Thus, it seems that at least in the case of disease, some (non-heritable) gene edits have been deemed acceptable. Assuming heritable gene editing progresses to a state of high confidence both in safety and efficacy, would this logic extend to heritable edits as well? If cancer or even blindness could be prevented by screening and editing an embryo using CRISPR, would such changes be acceptable (Genetic Literacy Project, 2019)? What if humans could be made stronger or faster? Indeed, Article 13 of the Oviedo Convention, a "Convention on Human Rights and Biomedicine" adopted by the Council of Europe, states that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes" (Baylis et al., 2020). Although this is not a

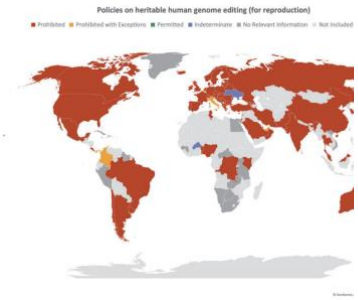
convention ratified by the United States, it suggests that many would restrict genetic modification to therapeutic purposes and bar enhancement. Where does the line for both heritable and non-heritable gene editing lie?

Delegates should consider what body decides when, if ever, heritable gene editing is safe or even advisable. They should also consider what safe and effective policy for such a future might look like as well as what groups, regulatory bodies or organizations should write and enforce it. Delegates can also consider to what extent Congress should invest in genomics research both to increase understanding of the human genome and to further improve precision and efficiency of gene-editing technology.

Oversight

***FDA** – federal agency responsible for vetting the safety and efficacy of various food, cosmetic, and medicinal products*

As it stands, all clinical trials involving human genome editing require permission and review by the **Food and Drug Administration** (FDA) as well as review by Institutional Review Boards (IRBs), Institutional Biosafety Committees (IBCs), and the Novel and Exceptional Technology and Research Advisory Committee (NExTRAC) (National Academies of Sciences, Engineering, Medicine issuing body, 2017). IRBs must be made up of experts in the relevant field, along with at least one member in a nonscientific field and one member not affiliated with the institution. Specific details or regulations regarding the approval process vary between states and institutions. The focus of IRBs is the protection of the rights and wellbeing of trial participants and minimization of risk. IBCs ensure enforcement of safety measures and guidelines in laboratory work. Finally, the NExTRAC is a federal advisory committee under the National Institute of Health (NIH) that "provides a forum for the in-depth review and public discussion of a protocol" (National Academies of Sciences, Engineering, Medicine issuing body, 2017) (Collins, 2019).



Countries in red are those in which heritable human genome editing is currently prohibited
[Baylis et al., 2020]

Notably, under the current congressional ban of editing human embryos, the FDA is barred from even considering any proposals to do so. Delegates might consider whether such an outright ban should be maintained or dropped, in which case they must decide either whether to leave the decision of approval simply in the hands of the regulatory bodies as discussed above or to a new, additional committee. In other words, delegates should decide whether the existing landscape of oversight for human genome editing is sufficient or whether it requires modification. Furthermore, if the existing landscape is maintained, delegates might consider whether IRBs should be required to follow a federally mandated procedure in their approval process.

The regulatory architecture for gene editing in plants and animals is quite different from that of humans. The Coordinated Framework for Regulation of Biotechnology, issued by the United States

government in 1986, is a federal regulatory policy through which the US Department of Agriculture (USDA), FDA, and Environmental Protection Agency (EPA) cooperate in overseeing agricultural biotechnology, including gene editing (Meyer, 2021). These agencies consult each other in the review of gene-edited crops and livestock before approving them to ensure that a given product is in line with each agency's regulations. Delegates can consider the efficiency and efficacy of this framework, especially in consideration of information provided in the following subsection.

Agriculture

Agriculture lies at the heart of food production and is critical for production of various textiles and medical plants. With an increasing global population, more and more resources are required to accommodate the needs of our world. As a result, an important area of research lies in genetically modifying plants and animals to increase yield and productivity. Due to significantly fewer ethical concerns as compared to human genome editing, CRISPR has been used to make plants significantly more resilient and resistant to **biotic** stresses, such as insects, pests, and pathogens, as well as **abiotic** stresses, including drought and flooding (Zaidi, 2020).

biotic *– related to or caused by living organisms*

abiotic *– not related to or caused by living organisms*

As stated previously, regulation of these modifications is overseen by the Coordinated Framework. When tasked by Congress to create a standard for disclosure of a product as bioengineered, the USDA set the requirement for disclosure to apply only to "foods modified using techniques that 'could not otherwise be obtained through conventional breeding or found in nature'" (Meyer, 2021). Notably, the USDA purposely decided not to define the term "found in nature." Additionally, the FDA does not need to approve a food additive if it is "generally recognized as safe" or if it already exists at similar levels within the organism. Nor does it need to do so if the structure and function of a compound resulting from an introduced genetic modification are like existing compounds in the organism (Meyer, 2021).

Delegates should consider whether these standards are satisfactory or whether new legislation should be passed to ensure that these organizations clarify these regulations. Additionally, they may consider whether the Coordinated Framework is currently equipped to evaluate products in this context of increasingly popular CRISPR-mediated gene editing. Additionally, delegates should consider government investment into research regarding genetic enhancement of plants and animals to accommodate a growing population.

Intellectual Property

With the rise of CRISPR therapeutics and gene-edited plants and animals, interesting controversies have arisen in how to regulate and

enforce intellectual property interests in patent law. The number of CRISPR-related agricultural patents that have been granted yearly has risen from around 100 in 2016 to over 1500 in 2021.

Development of these genetic modifications costs on average 136 million dollars, meaning that exclusive rights granted by patents are an important incentive for innovation

Many patents corresponding to genetically modified plants are not patents on the seeds or plants themselves, but rather utility patents on the molecular mechanisms used to modify the plants. Although companies cannot patent genes, they can patent DNA constructs called cDNAs, (with the argument that they are not present in nature) which essentially comprise the functionally important regions of genes. Using these utility patents, companies can gain exclusive rights to their modifications across all plant species. They can also ensure that farmers who buy their seeds cannot use seeds harvested from the cultivated plant for the next generation (Zhou, 2015).

Development of these genetic modifications costs on average 136 million dollars, meaning that exclusive rights granted by patents are an important incentive for innovation (Zhou, 2015). Nevertheless, utility patents last for 20 years before the technology becomes public domain. Delegates might consider whether such patents are truly in the public interest, especially as these modifications become easier and easier to perform. Furthermore, delegates are encouraged to question whether a utility patent should in fact apply to the genetic modification of plants.

Congressional Action

germline *– population of cells that pass on genetic information to offspring*

As stated previously, in 2015, Congress passed the Consolidated Appropriation Act of 2016 with a renewable provision "forestalling the prospect of human **germline** modification" (Cohen, 2016). This provision was renewed in 2019, thereby banning FDA approval of clinical trials involving genetic modification of human embryos. This remains the most significant provision related to genome editing in humans and it represents the lack of congressional legislation regarding gene editing that has been passed thus far. The majority of regulation has come from the FDA and other previously mentioned scientific bodies.

In 2016, Congress passed the National Bioengineered Food Disclosure Law, which "directed USDA to establish a national, mandatory standard for disclosing foods that are or may be bioengineered." (Meyer, 2021) Additionally, in 2018, Congress passed the Agricultural Improvement Act; section 7208 of this act allotted 40 million dollars in spending each year from 2019 to 2023 in service of the "Agricultural Genome to Phenome Initiative," with the purpose "to expand knowledge concerning genomes and phenomes of crops and animals of importance to the agriculture sector of the United States" among other reasons ("Agriculture Improvement Act of 2018," 2018).

Other Policy Action

In 2015, the NIH declared that it will not "will not fund any use of gene-editing technologies in human embryos" and that the NExTRAC "will not at present entertain proposals for germ line alteration." As previously mentioned, 29 countries of the council of Europe have ratified the 1997 Oviedo convention, which states that "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants." (Baylis et al., 2020)

Additionally, in 2015, the office of the President issued a directive to the FDA, EPA, and USDA to update the Coordinated Framework, which was completed in 2017 to clarify each agency's roles and responsibilities ("Modernizing the Regulatory System," 2017).

Finally, in 2013, the Supreme Court notably held that cDNA was patentable because it was "manmade" and therefore subject to utility patents (Ratner, 2013).

USDA official label for GMOs

[BE Symbols]

IDEOLOGICAL VIEWPOINTS

Positions regarding heritable gene editing in humans do not generally fall along party lines. In fact, the congressional measure to ban gene editing in embryos passed with bipartisan support. Given the early stage of the technology, this bill is largely in agreement with the views of the broader scientific community. Nevertheless, given the pace of technological progress, as CRISPR becomes a viable preventative therapeutic, it is likely that any such regulatory measure will require a tremendous amount of nuance. Delegates will have to work together to craft robust, bipartisan measures in the face of such a volatile issue. They should also consider whether it is Congress or another regulatory body that should make such decisions, if at all. Any individual congressional member's view on the matter will likely be informed both by the prevalent beliefs of the state they represent as well as their personal ethical and religious convictions.

Conservatives and liberals may, however, disagree on the nature of oversight that is required and to what extent such regulatory bodies should be funded. Conservatives might argue that gene editing regulation should be left to the states, whereas liberals might be more in favor of federal regulatory statutes.

Regarding agriculture, liberals are generally more skeptical of large-scale agriculture than conservatives, and they may fear that gene editing technologies might allow corporations to further consolidate their monopoly on the market. On the other hand, conservatives are often against increased government oversight of such corporations and in favor of leaving their fate to the market.

Although opinions certainly don't fall strictly along party lines, the two sides might further clash on matter of intellectual property and licensing, with some democrats seeking patent reform and conservatives seeking to protect existing patent law. Conservatives may argue that such patents are a necessary incentive for innovation, whereas liberals might argue that they in fact stifle innovation through monopoly.

Regardless, positions on all of these issues will be specific to the senator and their constituents, so delegates should take the time to research these issues in depth.

AREAS OF DEBATE

Modify Existing Ban on Human Embryo Modification

As the language of the measure stands, it leaves no room for embryonic modifications of any kind. This means that the FDA is even unable to consider certain procedures adopted in other countries. For example, in Ukraine, a new procedure has been used to transplant mitochondria into human embryos, but under the current ban, the FDA cannot even consider clinical trials seeking to investigate such a procedure (Stein, 2019).

The FDA is unable to consider certain procedures adopted even in other countries.

Modifications to the ban could entail an avenue for appeal in special cases (as with mitochondria or when therapies have been adopted abroad). This would allow the FDA to then review and make a judgement on the given proposal.

Some arguments in favor of modification, or even repeal, are that the ban stifles progress in the field of gene editing. The FDA is not even permitted to review any proposals, and this has drastic implications for potentially lifesaving therapies. The FDA can make judgements on a case-by-case basis regarding whether to approve a certain treatment.

Those against modification say that the technology remains too new, and any consideration of its use in germline editing would be reckless and premature, until we have a secure ethical and scientific grasp of the issue. Some might argue further that allowing the FDA to currently review any such proposals would be a waste of government funds.

Political Perspectives on this Solution

As stated previously, this issue does not necessarily fall along party lines. Nevertheless, although the measure passed with bipartisan support, some Democrats on the committee were hesitant to agree, arguing that more discussion was needed (Stein, 2019).

Some scientists have also criticized the ban, arguing that it suppresses scientific progress. There are also research groups with

interest in studying the mitochondrial transplant procedure as therapeutic (Stein, 2019).

Establish Oversight Committee on Gene Editing

Given the scientific and ethical complexity of the issue—and large web of regulatory bodies—it may be advisable to establish a committee on gene editing. Members could be sourced from Congress as well as several institutions and government organizations to represent a variety of disciplines. Arguments in favor of such a measure may be that it represents an opportunity to foster dialogue between legislators, representatives of regulatory bodies, and eminent scientists and ethicists. Such a committee could monitor and discuss the progress of gene editing and generate a robust ethical framework to evaluate future therapies with. Committee findings could be presented to Congress in the form of a comprehensive report. Arguments against such a proposal may be that enough regulatory bodies already exist and that such a committee would be a waste of government funds.

Political Perspectives on this Solution

Although it is not likely a partisan issue, special interests might include researchers involved in the development of gene editing therapies.

Increase Funding for Agricultural Genomic Research

Funding for the Agricultural Genome to Phenome Initiative provided by the Agricultural Improvement Act ends in 2023. A possible proposal might seek to extend the duration or amount of funding for the initiative. Arguments in favor are that innovations in agricultural practices will be crucial both in increasing yield and ensuring a resilient food supply even in the face of coming threats like climate change. Arguments against such an initiative might be that it is an unnecessary use of federal funds and that such innovation can be left to the private sector.

Political Perspectives on this Solution

Such a bill would likely see support from both parties, as the 2018 Agricultural Improvement Act also received broad bipartisan support. As with all proposals, how a given senator votes will come down to the state they represent and specific attitudes on such measures, as evidenced by voting records on similar bills.

Establishment of an Interagency Gene-Editing Working Group between Agencies of the Coordinated Framework

As the Coordinated Framework clarified in their 2017 policy update, they make use of many "formal and ad hoc interagency

working groups" in the review of various biotechnology products (Modernizing the Regulatory System, 2017). In the same vein, Congress might consider calling for the formation of a working group on gene editing with representatives from the FDA, EPA, and USDA. This group could be tasked with keeping a high-level view of innovation in agricultural gene editing to coordinate necessary changes in policy. They could also seek to communicate these changes with Congress and the public on a regular basis.

Arguments in favor of such a proposal are that the current regulatory architecture of the Coordinated Framework remains convoluted and the formation of such a group would allow for efficient communication between agencies and the public in a manner that is sensitive to the rapid pace of progress. Arguments against this proposal are that agencies already coordinate with one another on a necessary basis and that the existing structure is sufficient to respond to the growth in gene editing. Such a proposal may only create unnecessary bureaucracy and government expenditure.

Decrease Power of Utility Patents for Genetically Modified Plants

Although the Supreme Court has already ruled that utility patents can be applied to the use of cDNA to create genetically modified organisms, this decision continues to be "under discussion among scientists and patent practitioners" (Zhou, 2015). Delegates may first consider whether such patents should be applied to genetically modified organisms or whether new legislation may be necessary in light of their increasing prevalence. Additionally, they might consider whether such patents should prohibit the replanting of seeds harvested from purchased GMOs, as they do now. According to patent law, "any subsequent owner of a patented article other than the original seller may use or sell the thing without patent restriction" (Zhou, 2015). Thus, the prohibition hinges on a specific understanding of the word "use" that the court ruled did not extend to replanting. Delegates might consider drafting legislation specifying how such patents may be employed in the case of GMOs.

Arguments in favor of such a move are that patents are designed to reward and incentivize innovation while still acting in the general interest of the public. Current interpretations of patent law in the context of GMOs allow monopolies to form that are not commensurate with the investment made by large agricultural companies; thus, they slow innovation and act against the interests of the American people. Those who oppose such a move may argue that such decisions should be left to the interpretation of the courts. Additionally, without these strong incentives, companies may be

discouraged from investing the amount they do in these technologies, stifling innovation in the field.

Political Perspectives on this Solution

Although views will be specific to the representative, liberals might generally be more in favor of patent reform, for reasons listed above; they might argue that too much power is being given to large corporations at the expense of the public. Conservatives on the other hand are less likely to accept changes to existing patent law; they may oppose such reform on grounds that they discourage innovation.

Special interest groups might include large agricultural GMO corporations like Monsanto and various lobbying groups that act on their behalf.

Drought-resistant genetically modified corn

[Genetic Literacy Project]

BUDGETARY CONSIDERATIONS

Many of the proposals, including committee formations, modifications to patent law, or repeal of legislation, will only be associated with minor costs. Funding for agricultural gene editing research provided by the Agricultural Improvement Act amounted to 40 million dollars per year, but delegates can change this amount as they see fit if they choose to endorse such an initiative.

CONCLUSION

As we hope has become clear, CRISPR and gene editing have come to affect our society in a complex and multifaceted manner. These technologies hold great potential for our future if harnessed correctly, but doing so will require thoughtful and informed policymaking.

In this coming Model Congress, we ask you to consider a host of issues pertaining to CRISPR. Among these are the development of robust legislation regarding heritable human genome editing, improvement in the structural mechanisms of oversight, regulation, and facilitation of innovation in agriculture, and consideration of intellectual property rights corresponding to innovations in these technologies.

In determining your senator's position on a given issue, it may be helpful to examine historical voting patterns on issues pertaining to gene editing, agriculture, or patent law. Additionally, for many of these issues, voting decisions may come down to the expressed ethical or religious convictions of your senator on the content of a given proposal.

Finally, please remember that the proposals in this briefing paper are only a few of the possible solutions to these issues and there are

likely better ones. Thus, we encourage you to conduct additional research and to consider solutions of your own.

GUIDE TO FURTHER RESEARCH

Delegates are encouraged to familiarize themselves with their Senator's voting history on issues pertaining to this briefing; these are accessible on Congress.gov.

It may also be helpful to further investigate the nature of the existing regulatory architecture overseeing gene editing in humans and agricultural products. Materials on these topics can be found below in the bibliography.

Finally, polls regarding public attitudes toward gene editing or statistics related to various CRISPR therapeutics or agricultural benefits of gene editing might be useful in structuring arguments for various measures.

GLOSSARY

abiotic *– not related to or caused by living organisms*

biotic *– related to or caused by living organisms*

embryo *– early developmental stage of an organism, generally characterized as beginning after fertilization until approximately 8 weeks*

FDA *– federal agency responsible for vetting the safety and efficacy of various food, cosmetic, and medicinal products*

gamete — *an organism's reproductive cells that, when they fertilize those of the opposite sex, produce a zygote, a cell that eventually forms a new organism.*

germline *– population of cells that pass on genetic information to offspring*

heritable genome editing *– genetic modifications to the egg cells, sperm cells, or early embryonic cells of an organism*

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