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Editor's Journal

# Governance and the Human Genome

The first scientific papers about breakthrough developments in the use of the gene-editing tool CRISPR appeared in late 2012 and early 2013. Researchers soon recognized that this relatively accurate and easy-to-use technology makes possible a vast number of applications in plants and animals, including humans. In January 2015 a group of leading researchers and policy experts, some of whom had participated in the legendary 1973 Asilomar Conference on the possible risks of recombinant DNA technology, published an article in *Science* warning that the potential uses of the technology in humans raised profound ethical and social issues that needed to be discussed.

The US National Academies of Sciences and Engineering, the UK Royal Society, and the Chinese Academy of Sciences decided to organize the first International Summit on Human Gene Editing, to be held in December 2015. Even before it was held, the summit itself became a focus of controversy. Sheila Jasanoff, J. Benjamin Hurlbut, and Krishanu Saha published an article in the fall 2015 *Issues*, titled "CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation," arguing that the planned summit should not follow the Asilomar model of limiting participation to a select group of leading US scientists. Recognizing the broad implications of the new technology, they called for a more broad-based event that would include ethicists, legal scholars, social scientists, and the larger public from across the globe.

The summit organizers listened. Speakers represented a vast array of disciplines and a large number of countries; the meeting was open to the public and was webcast. Following the summit, *Issues* published a group of articles by leading figures from the meeting: organizing committee chair David Baltimore, legal scholar R. Alta Charo, historian Daniel Kev-

les, and sociologist Ruha Benjamin (*Issues*, Spring 2016). The summit was a quickly organized attempt to create an innovative forum for addressing a perplexing problem. Although it might not have achieved the ideal of a fully integrated, multidisciplinary, broadly representative discussion of CRISPR, it was an enormous step in that direction and a catalyst for all that has followed. (Bias alert: I provided staff support for the summit.)

Interest in CRISPR has mushroomed, with governments, scientific organizations, faith communities, think tanks, and advocacy groups joining the discussion. The topic was back in the headlines in December 2018 when the organizers of the first international summit joined with the Hong Kong Academy of Sciences to host the Second International Summit on Human Genome Editing. The highlight of the meeting was a presentation by the now-notorious Chinese scientist He Jiankui in which he explained how he used CRISPR in engineering a human embryo that resulted in a live birth. Although much certainty clouds our knowledge of what He actually did, his claim ignited a heated round of discussion at the summit and elsewhere. For this edition of *Issues* we invited a few of the leading thinkers in the field to comment on where we are in the process of understanding and managing this powerful tool.

The Stanford University legal scholar Henry T. Greely addresses the immediate practical problem of how to prevent rogue scientists from violating scientific and social norms. He recommends deterrence measures that will make miscreants pay a heavy price for their deeds and some norms and procedures for disclosure when people have suspicions of wrongdoing. Greely ends with an appeal for humility in the scientific community, by which he means a recognition that human genome editing is a technology with enormous social implica-

tions that must be governed not by scientists alone but by the will of society at large.

Peter Mills, the associate director of the United Kingdom's highly respected and globally influential Nuffield Council on Bioethics, develops further what it means to engage society in this discussion. He encourages us to consider the professed purpose of any use of this technology as well as its implications in light of the principles of human rights. He calls for an ecology of approaches that aims to strike the right balance among the scientific, legal/political, and public/ethical frameworks for considering human genetic engineering.

The Dalhousie University bioethicist Francoise Baylis, who was a member of the organizing committee for the first summit, acknowledges the various frameworks that should be applied when approaching this question and places special emphasis on the necessity of achieving broad societal consensus before moving forward with this technology. She explains that consensus is not unanimity and that it is achievable.

Reaching that broad social consensus will necessitate engaging with all the world's religious and ethical traditions. At this early stage in the technology's development, most of us lack a clear understanding of how the world's religions will regard the use of human genetic engineering. Mohammed Ghaly, a professor of Islam and bioethics at Hamad Bin Khalifa University in Qatar, provides a valuable service in explaining how Islamic scholars and ethicists approach the question.

As even the experts struggle to develop a firm and coherent position on CRISPR, members of the public are often bewildered by the choices that society faces. Some special interest groups have formed opinions based on their particular concerns. Families afflicted with genetically inherited diseases find grounds for hope that their progeny will be spared from the disorders. Many members of the deaf community who do not consider deafness a disability view CRISPR as a threat to deaf culture. But it is likely that most people have not yet formed a strong opinion and are experiencing an uneasy mix of fear, hope, and confusion.

The Australian artist Patricia Piccinini has created a series of attention-grabbing sculptures of human/animal hybrid creatures that tap into the anxiety that many people feel about the prospect of human genetic engineering. She has obviously touched a nerve. The images are widely shared on the internet, and an exhibition of her work in Brazil attracted more than 400,000 visitors, leading *The Art Newspaper* to dub her the most popular contemporary artist in the world. Scientists understandably bridle at the unfairness of these disturbing creations, which do not reflect the real risks of the technology, but respecting the full range of responses to the prospect of human genetic engineering is essential to mapping a path forward. Scientists have trumpeted the unprecedented power of this tool, so they should not be surprised that the human imagination will generate apocalyptic as well as beneficent visions.

As difficult as it is to decide what is the medically, ethical-

ly, legally, socially proper way to apply the CRISPR tool, the more difficult task could be to make any emerging consensus a reality. Regulating human genetic engineering, along with other world-altering technologies such as climate engineering and artificial intelligence, is an inherently global challenge for which we have no existing governance structure. A number of new approaches are being proposed.

The organizing committee of the second genome editing summit, held in Hong Kong, called for "an ongoing international forum to foster broad public dialogue, develop strategies for increasing equitable access to meet the needs of underserved populations, speed the development of regulatory science, provide a clearinghouse for information about governance options, contribute to the development of common regulatory standards, and enhance coordination of research and clinical applications through an international registry of planned and ongoing experiments." The committee also recommended that the world's scientific academies continue to hold international summits "to review clinical uses of genome editing, to gather diverse perspectives, to inform decisions by policymakers, to formulate recommendations and guidelines, and to promote coordination among nations and jurisdictions."

The World Health Organization (WHO) announced that it is planning to explore ways to regulate the technology. One possibility recently suggested by a WHO advisory committee is to create an international registry of all human genome editing research to promote transparency.

A diverse group of ethicists, social scientists, biomedical researchers, religious thinkers, and legal scholars met for several days at Harvard in April 2017 with a goal of moving beyond a science-dominated discussion. (More bias: I spoke at the meeting.) The group developed the idea of a "global observatory" on gene editing, which would promote interactions across disciplinary and cultural divides. Sheila Jasanoff, one of the meeting's organizers, commented that "The notion that the only thing we should care about is the risk to individuals is very American. So far, the debate has been fixated on potential physical harm to individuals, and not anything else. This is not a formulation shared with other countries in the world, including practically all of Europe. Considerations of risk have equally to do with societal risk. That includes the notion of the family, and what it means to have a designer baby." Jasanoff sees the observatory as a possible model for addressing other powerful emerging technologies.

We won't know for a while whether any of these mechanisms will take root and become an effective tool for managing scientific and technological challenges. But this type of social experimentation is obviously needed. The CRISPR phenomenon has made two things clear: we do not have a broad social consensus on how to proceed with this technology, and we lack an existing mechanism for arriving at a consensus and then implementing it.