

## Does Gene Editing in the Wild Require Broad Public Deliberation?

By Gregory E. Kaebnick

There is wide agreement among proponents and opponents of genetic editing that genetically edited organisms should not be released into the wild without public deliberation. But how much and what kind of public deliberation? What most clearly commands agreement is the need for deliberation by local communities and immediate stakeholders before going forward with a proposal to release modified organisms. If genetically modified mosquitoes are to be released on one of the Florida Keys, for example, the residents there should, through public deliberations, have an opportunity to influence the proposal and to say no to it.

Should there also be some kind of deliberation by a broader public, at a regional, national, or even international level? The 2016 report from the National Academies of Sciences, Engineering, and Medicine on the use of gene drive to modify wild populations floated this idea; it said that the release of gene drive-modified organisms might also require deliberation among broader “publics”—cross-sections of the overall national or international public, selected or constructed by those carrying out deliberation<sup>1</sup>—but this position has received comparatively little discussion.

The goal of this essay is to explore the strength of the argument for broad public deliberation. Are there cases or circumstances in which broad public deliberation is not needed—or would not even be appropriate—before proceeding with the release of genetically edited organisms into the wild? Or should a moratorium be declared on any release of genetically edited organisms into the wild until broad public deliberation has authorized it?

Three assumptions about the relationship of broad public deliberation to governance and regulation will frame the consideration of this question. First, “broad public deliberation” will refer not just to broader publics instead of local or stakeholder groups, but also to the use of formal, institutional methods to achieve deliberative democracy, as that concept has been described by James Fishkin—that is, as popular impact on public policy, achieved through citizens’ own direct deliberation about policy.<sup>2</sup> The institutional methods to achieve this goal can consist of collective deliberation by the entire citizenry or of creating “deliberative microcosms” that have some claim to representing in miniature the overall citizenry. Fishkin’s “Deliberative Polling” is one example of a microcosmic approach, but other approaches are employed as well. Microcosms might be created either within government or by private groups working independently, and they will be better or worse examples of deliberative democracy according to how they represent the citizenry, how well they foster deliberation, and their impact on public policy—three criteria that Fishkin offers for deliberative democracy. The public engagement effort of the 1979 U.S. Department of Health, Education, and Welfare’s Ethics Advisory Board, prior to issuing its report on IVF and embryo transfer, was a preliminary though limited step in the direction of broad public deliberation, falling short primarily in that it did not include a structured deliberative component. The series of public workshops held by the U.K. Human Fertility and Embryology Authority as it developed its 2013 recommendations for the use of mitochondrial replacement took a step further in the direction of structured public deliberation.

Although there is disagreement among theorists of deliberative democracy about how microcosms should be constructed, this definition of broad public deliberation excludes methods that are distinctly not representative of the overall public, such as policy deliberation by a very

small group or a group that skews heavily toward scholars or government officials or particular stakeholders in some policy question. The definition also excludes forms of citizen engagement that are not deliberative, such as citizen referenda. Finally, it excludes efforts that are focused more on providing information to the public and drawing input from the public. Such public engagement may or may not be deliberative but typically lacks the policy impact needed to count as democratic.

A second important assumption about the relationship of broad public deliberation to governance and regulation is that policy decisions of national significance can sometimes be made through the existing mechanisms of democratic governance and regulation, without broad public deliberation, and that the purpose of broad public deliberation would be to augment rather than replace those mechanisms. This is not an uncontroversial assumption; some theorists of democracy have argued that democracy needs to be rebuilt so as to rest on public deliberation. Benjamin Barber, for example, argues that “strong democracy” requires that the public directly controls policy decisions.<sup>3</sup> John Dewey and Thomas Jefferson may also have believed that public deliberation needed to be incorporated into national democratic processes.<sup>4</sup> In that view, broad public deliberation (perhaps carried out through many smaller publics) should be conducted for every policy decision—at least laying out general rules for cases if not individually deciding for each and every case.

A third framing assumption is that a call for broad public deliberation could be formulated in either harder or softer forms, and both ways of developing it remain on the table. The hard form makes broad public deliberation a flat requirement; in softer forms, the important question is about when broad public deliberation is particularly important or helpful and when it is less critical. If the need for broad public deliberation is softer, then it might be that broad public deliberation could meaningfully be integrated into governance and regulation in a range of ways. It might be carried out by a new governmental or quasi-governmental agency, as a new mechanism within governmental processes, as an independently conducted process commissioned by government agencies, or perhaps as a kind of parallel, nongovernmental process that feeds into governance and regulation. Or perhaps public input mechanisms in existing governance and regulatory processes would suffice—or would suffice if they were altered to ensure that they brought in the right kind of public input or that regulatory agencies weighed them appropriately. (In this special report, the essays “Envisioning Deliberation with a Cultural Theory Lens” and “Regulating Gene Editing in the Wild: Building Regulatory Capacity to Incorporate Deliberative Democracy” explore some of these questions.)

## **The Argument for Broad Public Deliberation, and Its Limits**

Plainly, determining whether and when broad public deliberation is needed depends on how the argument in favor of it is constructed. That argument begins with a preliminary, general argument, applicable to a wide range of topics: public deliberation fosters better and broader understanding, by experts as well as in the public, and therefore cultivates trust between the scientific community and the general public;<sup>5</sup> it ensures that a broad range of consequences, impacts, and values are taken into account;<sup>6</sup> and it ensures that people affected by a decision are involved in making the decision<sup>7</sup> and therefore promotes democratically legitimate outcomes.<sup>8</sup> These considerations support the case for local public deliberation and can also support a case for broad public deliberation.

The general argument can be buttressed by additional considerations that are keyed to the details of the policy debate about releasing genetically modified organisms into the wild. These

additional considerations are not unique to that debate—analogs to them might be found in many other policy debates—but they help explain why broad public deliberation seems especially important here. To begin with, the magnitude of what's at stake calls, as Elizabeth Alter wrote in the *New York Times*, for “a broad conversation about what kinds of advances and risks we want to embrace.”<sup>9</sup> Proposals to release genetically edited organisms into the wild—to modify, suppress, or introduce wild species through the use of genetic editing technologies, with the goal of “sculpting” evolutionary processes, as one of those developing these technologies puts it<sup>10</sup>—would be deliberate efforts to alter the shared environment, with potentially vast implications for conservation, public health, agriculture, forestry, industry, and our relationship to nature, to our own heritage, and to future generations. Arguably, for example, the entire U.S. population has a stake of sorts in preserving California redwoods and sequoias, even if many people have no immediate, tangible interests in redwoods and sequoias. Similarly, the goal of preventing African elephants from being hunted into extinction has led to worldwide calls to limit the ivory trade. The questions here are about the meaning of the phrase “the shared environment,” the moral importance of the shared environment, and how we view the human impact on it. The prospect of releasing genetically edited organisms into the wild is similar in this respect to the prospect of heritable human genome editing, insofar as the human genome is also considered a shared heritage in which all people have a stake.<sup>11</sup>

But what's challenging about these questions, and what generates an argument for broad public deliberation about them, is not just that the questions are near and dear to many people, of course. Not all big and important policy-making topics are seen as requiring broad public deliberation—or at least, there are some for which the call is issued less frequently and urgently: international trade, labor, education. The release of gene-edited organisms into the wild, like human genome editing, needs broad public deliberation because the questions at stake do not seem likely to be addressed effectively *without* a structured, inclusive public deliberation process.

There are several reasons for this. One is that the novelty, uncertainty about outcomes, and conceptual and moral ambiguity and disagreement surrounding them make them uncommonly hard to think about clearly. What does it mean to preserve nature, and how do genetic technologies support or conflict with that goal?<sup>12</sup> How should that goal be traded off against public health or economic or other interests? What are the special interests and rights of Indigenous peoples to employ or to shun the use of genetic technologies in their ancestral lands? How should we think, generally, about risks and uncertainties affecting the shared environment—should we quantify and monetize them, or would quantification and monetization instantly sacrifice some of what we might hope to preserve? We are not yet clear about what the driving moral considerations are, whether and how they even relevant to governance, what the basic facts are, or what kind of governance and regulation is appropriate.

In this terrain, normal governance mechanisms do not seem adequate. Often, they make assumptions about them that some may find overly simplified and dismissive of their views, often giving relatively little space or weight to concerns about how or whether genetic technologies are at odds with the appropriate human relationship to nature and instead forefronting questions about more tangible interests and risks.<sup>13</sup> Even on the questions of risk-benefit assessment, the track record of normal governance mechanisms has come under criticism.<sup>14</sup> More broadly, the policy questions surrounding gene editing in the wild are not seen as affecting our lives and welfare quite as tangibly as, say, health care or labor policy and are therefore less salient to politicians and to the voting public and less likely to get serious,

prolonged attention from existing governmental and regulatory mechanisms unless those mechanisms are spurred to attend to them differently.

Finally, there appears to be a high level of distortion and distrust surrounding the debate about gene editing generally, with both proponents and activists arguably generating disinformation about it. Without a structured deliberative process, therefore, the public's opinions, as ascertained in referenda or public comment periods, are not reliable.

The argument for broad public deliberation about gene editing in the wild, therefore, is not simply that it's a topic that matters to a lot of people, but that it's also associated with great conceptual confusion, that state actors have not given it high priority, and that does not appear to be resolving in the court of public opinion on its own. It's a topic we care about, but don't know how to think about, and cannot yet trust to government. The argument in favor of broad public deliberation for using gene editing in the wild seems quite strong.

There is, of course, an argument for not requiring broad public deliberation, and in fact, clarifying the argument in favor sheds light on the circumstances that would make broad public deliberation less pressing. As a starting point, broad public deliberation may not be necessary, or may be less important, if or when the argument for carrying it out is weaker—if the moral questions at stake seem answerable in other ways, if it is getting adequate political attention; if it is attended with less novelty, uncertainty, moral ambiguity and disagreement; and if there were less distortion in the debate.

The practical and conceptual uncertainty and ambiguity around gene editing in the wild might indeed vary. Possibly, the argument for broad public deliberation will be stronger or weaker, and could change over time, for different classes of cases, according to differences in the technical details of the intervention and the understanding of the risks, the anticipated spread of the altered organism, the goals of the release and therefore the moral trade-offs at stake, or the kind of organism being edited (if, for example, the public has greater moral qualms about altering animals than about altering plants). Development and release of a common mustard plant modified with firefly genes so that it glows faintly in the dark is arguably comparatively simple and straightforward on a spectrum of cases that includes mosquitoes modified with gene drives so as to suppress the overall population of that mosquito species. Gene drive technology arguably generates a stronger case for broad public deliberation, as it is distinguished chiefly by the fact that gene drives are designed to spread across a population at greater than Mendelian rates—they are a way of producing deliberately invasive genetic changes—which is often seen as raising the possibility that the genetic changes would be particularly hard to contain and that whatever potential hazards are associated with their release would be particularly severe. And within cases involving gene drive-modifications, releases intended to affect as large a portion of a species as possible, across as large an area as possible, arguably generate a stronger case for broad public deliberation than releases intended to be limited to a small population of organisms because of geography, the organisms' genotype, or variations in the gene drive technology itself.

Over time, too, the argument for broad public deliberation could, in principle, be stronger or weaker depending on broad, gradual changes in the public debate about gene editing and the degree of distortion within the debate. These changes could include, for example, an evolution in views about the importance of preserving nature, or about whether genetic editing technologies are intrinsically harmful to nature and at odds with preservationist goals. Similarly, the need for broad public deliberation could vary according to the perceived trustworthiness of the normal governance mechanisms for regulating the technology. Robust regulatory efforts to conduct risk

assessments of proposed releases or to collect and respond to the public's concerns might also change the calculus about broad public deliberation.

For now, however, it is difficult to make clear and strong distinctions about what does or does not require broad public deliberation. At the dawn of this age, the public's attitudes have not yet had a chance to develop—the public is not even well informed—and the particular issues at stake in different categories of cases are not clearly differentiated. There may be risks of uncontrolled spread for gene drives that are intended to be localized, and gene drives intended to spread as widely as possibly may well prove always to be somewhat limited. Invasiveness could also be produced by releases of organisms modified without gene drives. Moreover, part of the argument for broad as opposed to local public deliberation is the very idea of using gene editing technologies to change the shared environment, and any approved release of conventionally modified organisms therefore would set an important precedent on that point. Once the precedent is set, the debate is more over how to go forward with the technology than whether to go forward, which would de facto answer some of the moral questions that should be at stake.

The argument for not requiring broad public deliberation about gene editing in the wild also draws some support from the nature of the moral issues at stake. Some of the most conceptually challenging moral issues, and part of the rationale for carrying out broad public deliberation, are the questions about the human relationship to nature. But while these questions are very important to many people, they are arguably not the central values of a liberal democratic state. In the Rawlsian view, for example—an influential though often criticized way of thinking about liberalism—the core liberal values are the autonomy of citizens and the fundamental equality of all citizens in the basic structure of society. Nor is the need for broad public deliberation equivalent to the need to obtain informed consent from research subjects, given that a public is not equivalent to an individual, nor even to a mere aggregation of individuals.<sup>15</sup> Broad public deliberation about gene editing in the wild may therefore seem desirable for a better, stronger democracy but not essential for it.

Finally, as many have argued, there are procedural reasons to limit the use of broad public deliberation is required, at least to reserve it for the most important problems. As National Academies' reports on environmental decision-making and human genome editing have noted, there is considerable "administrative inefficiency" to making decisions via public deliberative processes: doing so is time-consuming, difficult, costly, and not guaranteed to clarify or legitimize a policy decision.<sup>16</sup> Moreover, how such processes can be used to influence policy remains uncertain and experimental; although there are promising examples of broad public deliberation, exactly how best to do it, whether it can be applied effectively to questions such as gene editing in the wild, and how it should influence policy (whether to inform or constrain policy, for example) remain contested. As a result, there is no obvious way to know whether an effort at broad public deliberation should be considered legitimate and whether it has been successfully completed.<sup>17</sup>

Given these concerns, insisting on broad public deliberation could complicate and prolong decisions about gene editing in the wild, and these costs and delays generate risk-risk trade-offs and so pose their own policy problem: there are risks to proceeding with gene editing in the wild without broad public deliberation, but there are risks to requiring broad public deliberation as well. Sometimes—if making a decision quickly is particularly important, for example—then the drawbacks of broad public deliberation might outweigh the rationale for using broad public deliberation. Some of the uses for which gene editing in the wild has been proposed would serve very pressing needs—hundreds of thousands die of malaria each year,

island species flicker into extinction at an alarming rate. It's debatable whether these chronic problems are emergencies, of course; nonetheless, if broad public deliberation is a tool to augment normal policy-making mechanisms, and if its purpose is to clarify important but not immediately pressing moral questions rather than to assess the kinds of tangible costs and benefits that are at stake in an emergency, then the argument for carrying it out for such cases is weaker.

The drawbacks and uncertainties of broad public deliberation raise a problem for its relationship to precaution. If a precautionary approach to an emerging technology is understood roughly as lying somewhere between a prohibitory and a permissive approach (and, still further out on the spectrum, a promotional approach),<sup>18</sup> then the opportunity that public deliberation affords to rethink and perhaps halt the technology can be part of a broadly precautionary stance.<sup>19</sup> On the other hand, if the complexity, expense, and uncertainty about how to conduct broad public deliberation (and what counts as legitimate public deliberation) proves insurmountable, then insisting on it serves the goal of prevention.

### **Toward Support for Broad Public Deliberation, with Caveats**

These considerations suggest several propositions about the need for broad public deliberation about gene editing in the wild.

***Broad public deliberation is highly desirable, and ought to be pursued, as a way of producing at least general guidance about gene editing in the wild.*** Given the factual uncertainties and moral ambiguities surrounding gene editing in the wild and the reasons for thinking that public debate and normal governance mechanisms are unlikely on their own to produce policy that adequately sorts out these uncertainties and ambiguities, broad public deliberation could be helpful for examining, informing, and to the extent possible articulating general principles for making decisions about the use of gene editing in the wild. Broad public deliberation could be useful, for example, for deciding whether and how the governance and regulation of gene editing in the wild should incorporate concerns about the human relationship to nature; whether proposals to eliminate species or to create new species, or bring extinct species back into existence, should be treated differently from proposals to alter the genome of existing species; whether the different kinds of goals for which gene editing in the wild might be used (reducing disease burden, elimination of destructive non-native organisms, creating proxies of extinct species, reducing agricultural pests, for example) should be treated differently; whether different kinds of approaches (gene drive-based modification of populations versus seeding of conventionally genetically edited organisms into populations, for example) should be treated differently; whether different kinds of organisms (microbes, plants, animals) should be treated differently; how risks and uncertainties should be examined and weighed; and what the trade-offs may be between different goals and concerns that may be at stake in gene editing in the wild.

Many questions remain to be resolved about the conduct and framing of broad public deliberation about gene editing in the wild. Given the contested and experimental nature of broad public deliberation, it is likely that a variety of different kinds of endeavors should be pursued simultaneously. The list of questions to be taken up and addressed in a deliberative endeavor could be limited or broadened by framing the deliberation differently. For example, framing a deliberation so as to address the public health goals of gene editing in the wild, setting aside environmental and agricultural goals, will tend to eliminate some questions from consideration. By focusing on goals, the framing of deliberation might also be broadened in other respects; for

example, deliberation might be designed to consider and compare gene editing in the wild to a range of alternative strategies for addressing public health goals. These questions about how best to frame broad public deliberation underscore its somewhat uncertain and experimental nature, but they also underscore its importance: broad assessments of different ways of pursuing a given goals can be more constructive and can avoid a simplistic acceptance of a new technology.<sup>20</sup>

***To produce general guidance about gene editing in the wild, broad public deliberation would ideally examine a maximally wide range of specific potential cases.*** General policy guidance cannot be produced without using particular cases to illustrate the policy questions that the public is asked to address. Moreover, the public will be able to examine the questions most effectively if it considers the full range of possible cases of gene editing in the wild—encompassing the widest possible variety of technologies, goals, and scenarios—because considering a very wide range of cases will give better insight into the potential benefits, risks, uncertainties, and moral tradeoffs. Different examples may elicit different responses about the problems that need illuminating, such as how or whether the human relationship to nature is morally important moral and should be traded off against other goals. Some well-known cases likely illustrate the problems particularly clearly and powerfully; proposals to use gene drives to eliminate rodents from ocean islands or to severely depress the global populations of families of mosquito species are like this: their large goals, the possible unintended consequences, the significance of the target organisms (animals, pests associated with disease), the lack of clear existing oversight mechanisms for gene drives, and the deliberately invasive nature of gene drives might help compellingly illuminate questions about the human relationship to nature, the significance of uncertainty, and moral trade-offs. Yet lesser-known cases that differ in various dimensions from these touchstone cases could be included to establish the diversity of cases and considerations.

***Broad public deliberation is unlikely to be necessary or appropriate for reaching decisions in most specific cases.*** In principle, if there were good general guidance about gene editing in the wild, then there would be fewer outstanding policy issues to be resolved in particular cases, rendering broad public deliberation about specific cases less useful. Moreover, framing broad public deliberation to reach decisions in particular cases may limit its benefit while compounding the expense and logistical difficulty. The argument for conducting broad public deliberation to produce decisions about specific cases is therefore much weaker than the argument for using it to generate general guidance covering a wide range of cases.

Broad public deliberation might, however, be brought to bear on specific cases, or narrowly defined classes of cases, in order to revise, refine, or augment the general guidance for which broad public deliberation would be most useful. The public deliberation process itself can help determine whether further and more fine-grained deliberation would be useful.

These considerations about limiting the use of broad public deliberation in specific cases to produce general guidance have no bearing on the need for local community and stakeholder guidance. As the NASEM report and others have recommended, community and stakeholder public deliberation will still be helpful for particular cases and still necessary to protect the interests of the local community and immediate stakeholders.

***The need for broad public deliberation is greater for categories of gene editing in the wild that pose higher levels of uncertainty and moral ambiguity.*** The argument for broad public deliberation is greater as the benefits, risks, uncertainties, and moral ambiguities of gene editing in the wild increase—for example, when a proposed release is associated with a higher risk and

greater uncertainty of lasting and irreversible ecological changes, or when the risks and uncertainties bear on an organism or ecosystem that is perceived as having greater social or moral significance. For the time being, however, this proposition about the use of broad public deliberation does not have clear implications for the conduct of broad public deliberation, since there are as yet no clear and firm distinctions between proposed uses of gene editing in the wild that warrant broad public deliberation and those that do not. Although the risks, benefits, and uncertainties are arguably often more significant with nonlocalized releases of gene drive-modified animals, conventional modifications to other kinds of organisms can in principle pose high risks, benefits, and uncertainties as well. Further, if broad public deliberation is aimed initially at providing very general guidance about gene editing in the wild, then it might be inappropriate to carve out some exceptions to that goal before broad public deliberation has been undertaken. However, that effort might itself suggest distinctions between categories of cases for which broad public deliberation is more or less important.

***Generating general guidance through broad public deliberation is not a hard and fast pre-requirement for any particular case or class of cases.*** Given the drawbacks and the experimental nature of broad public deliberation, declaring a moratorium on gene editing in the wild until broad public deliberation has been successfully carried out is not reasonable. In effect, the need for broad public deliberation in gene editing about the wild is better understood as a soft requirement rather than a hard one. It is highly desirable, but it is not flatly mandatory for making decisions about gene editing in the wild generally nor about any particular cases of it.

Although the argument for broad public deliberation is particularly strong for some kinds of cases, there is an unavoidable tension in calling for broad public deliberation about these cases: On the face of it, the cases that best illustrate the kinds of problems for which broad public deliberation is needed would be those best halted until after broad public deliberation has been conducted. On the other hand, some of these cases are also the ones that appear most emergent, which should be pursued most quickly, and for which the argument for broad public deliberation might therefore be *least* compelling, given the logistical drawbacks of broad public deliberation. The tension derives from a general problem with broad public deliberation: the benefit of deliberation is that it provides a way of exploring the public's understanding of important but difficult and overlooked values and how the public would make trade-offs between them, but where the trade-offs are most difficult and important is precisely where stopping to engage in broad public deliberation might be most objectionable.

***The desirability of broad public deliberation helps generate a requirement for a precautionary approach.*** If broad public deliberation should be attempted, and ideally in a way that brings under consideration the full range of possible cases of gene editing in the wild, but successfully carrying it out need not be considered a requirement for going forward with those cases, then the best possible overall strategy is to require that, if those developing these cases move forward with them, they do so in a phased and transparent way, creating opportunities for reassessment and allowing time for public attention to be brought to bear on the work, which might in turn strengthen the argument for broad public deliberation to be developed and carried out—or weaken the argument, if public opinion appears to shift broadly in favor of the work. Transparency in the research is therefore very important: if the work has a low public profile, or is even hidden from scrutiny from other researchers, then there is little opportunity for broader public engagement.

This recommendation builds on the recommendations for gene drive research proposed by the National Academies gene drive committee, which called for research into and release of any given gene drive-modified organism to be undertaken in a series of well-delineated defined steps, from preliminary research and development through a series of confined trials and culminating in the final unconfined release into the wild. In the committee’s analysis, each step should provide an opportunity for making a go/no-go decision about whether to go further, and each step might involve at least stakeholder and community deliberation.<sup>21</sup> The development of a blight-resistant American chestnut (which involves a conventional genetic intervention rather than a gene drive) seems to be following a similar course: research at multiple steps, with attempts to engage at least elements of the public and opportunities for a wider public to become engaged with the case.<sup>22</sup>

Broad public deliberation does not fall neatly into this model of phased research. It cannot be understood as necessarily preceding initial research and development, nor is it a final requirement before unconfined release. It is an overarching process, floating across the phases of any case and floating as well across cases. It is at no point mandatory, but it is highly desirable throughout.

The approach to scientific progress described here—not halting it outright but requiring that it be done in such a way that it is well studied, that research and results are made public, and that there are opportunities to halt it, is one way of understanding the idea of precaution.<sup>23</sup> Given the drawbacks and uncertainties of broad public deliberation, it is not itself a necessary part of a precautionary approach: it is not a further requirement—on top of community deliberation, for example—for gene editing in the wild. But it is desirable enough that it helps build the case for precaution. We should go forward with these extraordinary technologies only in steps, in a public way, with opportunities to reassess our plans, in part so that we can make it easier to have the best possible broad public deliberation about how we will develop and use them. Good decision-making takes time; developing the technology cautiously can help ensure that it squares with the public’s values.

## Notes

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<sup>1</sup> National Academies of Sciences, Engineering, and Medicine (NASEM), *Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values* (Washington, DC: The National Academies Press, 2016), 142.

<sup>2</sup> J. Fishkin, *Democracy When the People Are Thinking: Revitalizing Our Politics through Public Deliberation* (New York: Oxford University Press, 2018).

<sup>3</sup> B. Barber, *Strong Democracy: Participatory Politics for a New Age* (Berkeley, CA: University of California Press, 2004).

<sup>4</sup> R. Westbrook, “Creative Democracy: The Task Still before Us,” in *Democracy in Crisis: Civic Learning and the Reconstruction of Common Purpose*, supplement to the *Hastings Center Report* 51, no. 1 (2021): S21-S35.

<sup>5</sup> NASEM, *Gene Drives on the Horizon*; NASEM, *Public Participation in Environmental Assessment and Decision Making* (Washington, DC: The National Academies Press, 2008); Z. Meghani and J. Kuzma, “Regulating Animals with Gene Drive Systems: Lessons from the Regulatory Assessment of a Genetically Engineered Mosquito,” *Journal of Responsible*

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*Innovation* 5, supplement 1 (2018): S203-S222; C. Emerson et al., “Principles for Gene Drive Research,” *Science* 358 (2017): 1135-36.

<sup>6</sup> S. Jasanoff and J. B. Hurlbut, “A Global Observatory for Gene Editing,” *Nature* 555 (2018): 435-37; Meghani and Kuzma; “Regulating Animals with Gene Drive Systems”; NASEM, *Gene Drives on the Horizon*; NASEM, *Forest Health and Biotechnology: Possibilities and Considerations* (Washington, DC: The National Academies Press, 2019), 112.

<sup>7</sup> J. B. Hurlbut, S. Jasanoff, and K. Saha, “CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation,” *Issues in Science and Technology* autumn, 2015, 25-30; N. Kofler et al., “Editing Nature: Local Roots of Global Governance,” *Science* 362 (2018): 527-29.

<sup>8</sup> Barber, *Strong Democracy*; Hurlbut, Jasanoff, and Saha, “CRISPR Democracy”; C. P. Neuhaus, “Community Engagement and Field Trials of Genetically Modified Insects and Animals,” *Hastings Center Report* 48 (2018): 25-36; Lin 2017; Oye et al. 2014)

<sup>9</sup> E. Alter, “The Risks of Assisting Evolution,” *New York Times*, November 10, 2015.

<sup>10</sup> “Cultivating Wisdom through Evolutionary and Ecological Engineering,” [www.media.mit.edu/groups/sculpting-evolution/overview/](http://www.media.mit.edu/groups/sculpting-evolution/overview/).

<sup>11</sup> NASEM, *Human Genome Editing: Science, Ethics, and Governance* (Washington, DC: The National Academies Press, 2017).

<sup>12</sup> G. E. Kaebnick, “The Spectacular Garden: Where Might De-extinction Lead?,” in *Recreating the Wild: De-extinction, Technology, and the Ethics of Conservation*, supplement, *Hastings Center Report* 47, no. 4 (2017): S60-S64.

<sup>13</sup> G. E. Kaebnick and M. K. Gusmano, ed., *Governance of Emerging Technologies: Aligning Policy Analysis with the Public’s Values*, supplement, *Hastings Center Report* 48, no. 1 (2018): S1-S96.

<sup>14</sup> Meghani and Kuzma; “Regulating Animals with Gene Drive Systems”; A. C. Lin, “Mismatched Regulation: Genetically Modified Mosquitoes and the Coordinated Framework for Biotechnology,” *U.C. Davis Law Review* 51 (205): 205-232.

<sup>15</sup> Neuhaus, “Community Engagement and Field Trials of Genetically Modified Insects and Animals.”

<sup>16</sup> NASEM, *Human Genome Editing*; NASEM, *Public Participation in Environmental Assessment and Decision Making* (Washington, DC: The National Academies Press, 2008).

<sup>17</sup> Cynthia Shairer, personal communication.

<sup>18</sup> A. Charo, “Comparative Approaches to Biotechnology Regulation,” presentation at the International Summit on Human Gene Editing, December 1-3, 2015, Washington, DC, at <https://vimeo.com/album/3703972/video/149182567>.

<sup>19</sup> G. E. Kaebnick et al., “Precaution and Governance of Emerging Technologies,” *Science* 354 (2016): 710-11; G. E. Kaebnick and M. K. Gusmano, “CBA and Precaution: Policy-Making about Emerging Technologies,” in *Governance of Emerging Technologies: Aligning Policy Analysis with the Public’s Values*, supplement, *Hastings Center Report* 48, no. 1 (2018): S88-S96.

<sup>20</sup> A. Stirling and J. Coburn, “From CBAS to Precautionary Appraisal,” in *Governance of Emerging Technologies: Aligning Policy Analysis with the Public’s Values*, supplement, *Hastings Center Report* 48, no. 1 (2018): S78-S87.

<sup>21</sup> NASEM, *Gene Drives on the Horizon*.

<sup>22</sup>

<sup>23</sup> Kaebnick and M. K. Gusmano, “CBA and Precaution.”