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To: The Biden-Harris transition team

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## Heritable Human Genome Editing Political Implications and Opportunities for Leadership

Among the daunting issues facing the Biden-Harris Administration is the question of heritable human genome editing – whether powerful new gene editing technologies should be used to alter the genes and traits of future children and generations. The prospect of “CRISPR babies” is not as immediately urgent as the surging pandemic, the sagging economy, or deepening inequality. But it holds significant risks of intergenerational and global havoc, and threatens to trigger the emergence of a new market-based eugenics.

In the short term, a clear stance on heritable genome editing could serve to unite Americans across the political spectrum; public opinion polls show considerable wariness. In a longer view, few issues are more important than averting the potentially dire consequences of unleashing this species-altering technology. Many observers, including former [Vice President Al Gore](#)<sup>2</sup> and environmental author and activist [Bill McKibben](#),<sup>3</sup> see heritable genome editing as parallel to climate change in importance for the human future. Unlike the climate crisis, the solution to this threat is straightforward and inexpensive.

### Opportunities for leadership

The Biden-Harris team will have the opportunity to ensure that the United States leads the way in encouraging development of gene therapies for existing patients while forestalling the use of genome editing for human reproduction.

President-elect Biden has already been part of a similar effort to reclaim human biotechnologies for the common good. In 2009, the Obama-Biden Administration brought clarity and resolution to the debate then raging about human cloning and stem cell research. As it lifted the Bush Administration’s restrictions on funding for new human embryonic stem cell lines, [President Barack Obama pledged](#) that “we will ensure that our government never opens the door to the use of cloning for human reproduction. It is dangerous, profoundly wrong, and has no place in our society, or any society.”<sup>4</sup>

In rejecting what President Obama termed “a false choice between sound science and moral values,” this policy accomplished several important goals: It supported federal investment in responsible biomedical research; it put an unacceptably dangerous use of human biotechnology clearly off limits; and it affirmed both U.S. leadership and the importance of international cooperation on technical developments that have the potential to reshape the human future.

The Biden-Harris Administration could play a similar role in resolving the controversy about heritable genome editing. It can foster meaningful public deliberation about human biotechnologies in ways that reflect widely shared values, revive governmental bodies that offer objective guidance on complex technological issues, and re-engage with crucial international organizations including the [World Health Organization](#) on the issues raised by developments in human genome editing.<sup>5</sup>

## **Why it matters: The case against heritable genome editing**

The prospect of heritable genome editing is sometimes misleadingly characterized as a promising new way to prevent genetic diseases. In fact, safe and effective alternatives already exist, and attempts to justify it on medical grounds are dubious.

Every person at risk of passing on a harmful genetic condition can avoid doing so by using third-party eggs or sperm. When prospective parents are also concerned about full genetic relatedness, they can address both issues with the widely available embryo screening procedure known as pre-implantation genetic diagnosis (PGD). Yet these safe and effective alternatives are often omitted from discussions of heritable genome editing. And while embryo selection raises sticky ethical issues about what kinds of people we should welcome into the world, its eugenic potential is much less far-reaching than that of heritable genome editing.

Scientists, scholars, and policy makers have debated the likely social and inter-generational consequences of heritable genome editing for decades. Controversy intensified with the 2012 development of the powerful new genome editing tool CRISPR (for which Jennifer Doudna and Emmanuelle Charpentier were recently awarded the Nobel Prize in chemistry). The issue hit the front pages in November 2018, when Chinese researcher He Jiankui announced the birth of twin “CRISPR babies” whose genomes he had edited at the early embryo stage.

This scandal illuminated a longstanding rift within the scientific and research community. Some who condemned He Jiankui as a “rogue” nonetheless remain eager to move forward with heritable genome editing, although even enthusiasts acknowledge that it would currently be far too dangerous to try. (Many scientists think this will always be the case, and previously unrecognized technical challenges continue to emerge, including those reported in a June 2020 article in *Nature* titled “[CRISPR gene editing in human embryos wreaks chromosomal mayhem](#).”<sup>6</sup>)

Other prominent scientists, researchers, and clinicians are outspoken about the need for a moratorium or prohibition on heritable genome editing. A 2019 article in *Nature* urging a moratorium was [authored by 18 scientists and bioethicists, including Charpentier and Eric Lander](#), co-chair of the Obama-Biden Administration President’s Council of Advisors on Science and Technology.<sup>7</sup> [NIH Director Francis Collins and Associate Director for Science Policy Carrie D. Wolinetz support a moratorium](#),<sup>8</sup> as do a number of [scientific](#) and [professional](#) societies.<sup>9</sup>

The societal risks of heritable genome editing have also prompted opposition from a range of public interest advocates:

- [Advocates for reproductive rights and justice stress](#) both the increased risk to any women who would carry gene-edited pregnancies and the pressures on them to do so.<sup>10</sup>
- [Disability rights advocates raise the question](#) of whether choices to “edit out” certain conditions would increase stigmatization of and reduce support for disabled people.<sup>11</sup>

- The present context of increasingly visible and virulent racism, xenophobia, anti-Semitism, and violence stoked by far-right extremism raises urgent concerns among social justice and human rights advocates about the introduction of a technology with dangerous eugenic potential.

Should heritable genome editing be permitted even for limited preventive purposes, attempts to produce genetically “upgraded” children would almost certainly follow. In the U.S. as in many other jurisdictions, regulatory agencies would have no power to control its “off-label” uses – that is, regulatory approval for any indication would permit fertility clinics to offer it for all purposes. It is telling that the researcher who announced his creation of “CRISPR babies” immediately got [requests from fertility companies](#) around the world seeking to commercialize the procedure.<sup>12</sup>

The threat of a high-tech market-driven eugenics is an insidious twist on twentieth-century eugenic efforts ([still not](#) entirely [abandoned](#)<sup>13</sup>) to sterilize those considered “unfit.” The sum of individual choices to “improve” our offspring could exacerbate existing inequalities and discrimination, and even usher in a future of genetic “haves” and “have-nots.” Considering this prospect, [Eric Lander asks](#),

“Would we come to regard our children as manufactured products? Would marketers shape genetic fashions? Would the “best” genomes go to the most privileged?”<sup>14</sup>

## Policy and political implications in the US and internationally

[Heritable human genome editing is legally prohibited in 70 countries](#)<sup>15</sup> and by the Council of Europe’s Convention on Human Rights and Biomedicine (also known as the [Oviedo Convention](#)), a binding treaty ratified by 29 of these countries.<sup>16</sup> However, in the United States it is prohibited only by a rider to the annual federal [budget bill](#).<sup>17</sup> A bipartisan [U.S. Senate resolution](#) calling for “international ethical standards in genome editing research” was introduced in July 2019 by Senators Dianne Feinstein, Marco Rubio, and Jack Reed, but did not make it out of the Committee on Foreign Relations.<sup>18</sup>

Like [many scientists](#),<sup>19</sup> [biotech industry figures](#),<sup>20</sup> [scholars](#),<sup>21</sup> [policy experts](#),<sup>22</sup> and public interest [advocates](#),<sup>23</sup> the [Center for Genetics and Society](#) strongly supports somatic gene therapy – that is, editing the genes of targeted tissues or cells in existing patients (with appropriate oversight of its safety, efficacy, and accessibility) – while urging an immediate moratorium on editing the genes of gametes or early embryos in an attempt to bring about the birth of genome-edited children. This pause would allow time for [broad democratic deliberations](#), which we believe will lead to effective international cooperation on heritable genome editing and additional national prohibitions of it.<sup>24</sup>

## Recommendations

The Biden-Harris Administration should work with Congress to enact either a legislative ban on heritable human genome editing, or an enforceable moratorium during which wide-ranging and appropriately resourced public deliberations could take place.

Keeping heritable genome editing off limits in the US while supporting the development of promising gene therapies for existing patients would strengthen the existing “soft law” prohibition provided by the budget rider. It would also align the US with the views of scientists, policy experts, and advocates, and with the policies already enacted by 70+ countries around the world.

In short, the new administration will have opportunities to advance scientifically worthy and responsibly conducted biotechnology research, while ensuring that powerful new technologies promote fairness, inclusion, and human flourishing. We look forward to offering additional recommendations toward these goals during the transition period.

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- <sup>1</sup> The [Center for Genetics and Society](#) is a nonprofit organization based in Berkeley, California that works to bring a perspective grounded in human rights and social justice to the development, use, and governance of human genetic and reproductive technologies.
- <sup>2</sup> Al Gore. *The Future: Six Drivers of Global Change* (Random House, 2013).
- <sup>3</sup> Bill McKibben. *Falter: Has the Human Game Begun to Play Itself Out?* (Henry Holt and Co., 2019).  
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- <sup>4</sup> Barack Obama. [Obama's Remarks on Stem Cell Research](#) (transcript), *The New York Times*. March 9, 2009.
- <sup>5</sup> [A World Health Organization committee](#) is currently completing an analysis of “global standards for governance and oversight of human genome editing.”
- <sup>6</sup> Heidi Ledford. [“CRISPR gene editing in human embryos wreaks chromosomal mayhem,”](#) *Nature*. June 25, 2020.  
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- <sup>7</sup> Eric S. Lander et al. [“Adopt a moratorium on heritable genome editing,”](#) *Nature*. March 13, 2019.
- <sup>8</sup> Carrie D. Wolinetz & Francis S. Collins. [“NIH supports call for moratorium on clinical uses of germline gene editing,”](#) *Nature*. March 13, 2019.
- <sup>9</sup> [European Society of Human Genetics; International Rare Disease Research Consortium](#)
- <sup>10</sup> Center for Genetics and Society. [Gene Editing and the Future of Reproductive Justice](#). June 13, 2017.
- <sup>11</sup> Rebecca Cokley. [“Please Don’t Edit Me Out,”](#) *Washington Post*. August 10, 2017.
- <sup>12</sup> Sharon Begley. [“Fertility clinics around the world asked ‘CRISPR babies’ scientist for how-to help,”](#) *STAT*. May 28, 2019.
- <sup>13</sup> Molly O’Toole. [“19 women allege medical abuse in Georgia immigration detention,”](#) *Los Angeles Times*. October 22, 2020.  
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- <sup>14</sup> Eric S. Lander. [“Brave New Genome,”](#) *New England Journal of Medicine*. June 3, 2015.
- <sup>15</sup> Françoise Baylis, Marcy Darnovsky, Katie Hasson, Timothy M Krahn. [“Human Germline and Heritable Genome Editing: The Global Policy Landscape,”](#) *The CRISPR Journal*. 3(5): 365-377. 2020.
- <sup>16</sup> [Oviedo Convention and its Protocols](#).
- <sup>17</sup> Marcy Darnovsky. [“The wrong way to make policy about heritable genome modification,”](#) *The Hill*. May 29, 2019.
- <sup>18</sup> [S.Res.275 - A resolution calling for international ethical standards in genome editing research](#).
- <sup>19</sup> Edward Lanphier et al. [“Don’t Edit the Human Germline,”](#) *Nature*. March 12, 2015.  
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- <sup>20</sup> [Scientific Leaders Call For Global Moratorium on Germline Gene Editing](#).  
[Alliance for Regenerative Medicine Gene Editing Task Force Therapeutic Developers' Statement of Principles](#).
- <sup>21</sup> Françoise Baylis. [Altered Inheritance: CRISPR and the Ethics of Human Genome Editing](#) (Harvard University Press, 2019).
- <sup>22</sup> J. Benjamin Hurlbut. [Experiments in Democracy: Human Embryo Research and the Politics of Bioethics](#) (Columbia University Press, 2017).  
Francis Fukuyama. [Our Posthuman Future: Consequences of the Biotechnology Revolution](#) (Farrar, Straus and Giroux, 2002).
- <sup>23</sup> Center for Genetics and Society. [Open Letter Calls for Prohibition on Reproductive Human Germline Modification](#).
- <sup>24</sup> Roberto Andorno et al. [“Geneva Statement on Heritable Human Genome Editing: The Need for Course Correction,”](#) *Trends in Biotechnology*. April 1, 2020.