future tense

Listening for the Public Voice

Discussions about genetic engineering in humans need input from nonexperts.

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On Aug. 3, the scientific article in *Nature* finally gave us some facts about the much-hyped experiments that involved editing the genomes of human embryos at the Center for Embryonic Cell and Gene Therapy at Oregon Health and Science University. The story had broken in late July in *Technology Review*, spurring profuse hand-wringing and discussion. But until we saw the scientific paper, it was not clear what cells and methods were used, what genes were edited, or what the results were.

Now we know more, and while the paper demonstrates the possibility of genome editing of human embryos, it raises more questions than it answers. It is a useful demonstration of technical promise, though not an immediate prelude to the birth of a genome-edited baby. But the process by which the news emerged is also an ominous harbinger of the discombobulated way the debate about genetically altering human embryos is likely to unfold. We need open, vigorous debate that captures the many, often contradictory, moral views of Americans. Yet what we are likely to get is piecemeal, fragmented stories of “breakthroughs” with incomplete details, more sober publication in science

journals that appear later, news commentary that lasts a few days, and very little systematic effort to think through what policy should be.

The science underlying this news cycle about human genome editing builds on a technique first developed six years ago by studying how bacteria alter DNA. CRISPR genome editing is the most recent, and most promising, way to introduce changes into DNA. It is faster, easier, and cheaper than previous methods and should eventually be more precise and controllable—which is why it may one day be available for clinical use in people.

Though headlines about the study discussed “designer babies,” researchers prefer to emphasize how these techniques could help stop devastating genetic disorders. The Oregon experiments with human embryo cells corrected disease-associated DNA variants associated with heart muscle wasting that can cause heart failure. The treated embryos were alive for only a few days and were never intended to become a human baby. They were, however, human embryos deliberately created for the research.

U.S. guidance in this area is sparse and reflects the lack of societal consensus. In 1994, when the federal government was contemplating funding for research involving human embryos, the NIH Embryo Research Panel concluded that just this kind of experiment was ethically appropriate. But within hours of that report’s release, then-President Bill Clinton announced he did not agree with creating embryos in order to do research on them.

The United States currently has just two policies relevant to genomic editing of human embryos. The first blocks federal funding: On April 28, 2015, Francis Collins, director of the National Institutes of Health, stated, “NIH will not fund any use of gene-editing technologies in human embryos.” This is not embedded in statute or formal executive order, but members of Congress are fully aware of it and it is, in effect, a federal policy. NIH can (and does) fund genome editing of nonembryonic cells that might be used to treat cancer and for other possible therapeutic purposes, but not embryonic cells that would have their effect by creating humans with germline alterations.

Second, Congress has prohibited the Food and Drug Administration from reviewing “research in which a human embryo is intentionally created or modified to include a heritable genetic modification.” This language comes from a rider to FDA’s annual appropriations. Yet use of human embryonic cells for *treatment* should be subject to FDA regulation. So this language in effect means alterations of embryonic cells cannot be done in the United States if there is any intent to treat a human being, including implantation of an altered embryo into a woman’s uterus. This will remain true so long as the rider is included in FDA’s annual appropriations. The federal government thus has two relevant policies, both of which take federal agencies out of the action: One removes NIH funding, and the other precludes FDA oversight of genome-edited human embryos.

This leaves privately funded research that has no direct therapeutic purpose, such as with the Oregon experiments. The funding came from OHSU itself; South Korean Basic Research Funds; the municipal government of Shenzhen, China; and several private philanthropies (Chapman, Mathers, Helmsley, and Moxie). The research complies with recommendations to study the basic cellular processes of genome editing, keeping an eye on possible future clinical use but only so long as the work does not attempt to create a human pregnancy.

By coincidence, on the same day the *Nature* paper came out, the *American Journal of Human Genetics* also published a thoughtful 10-page position statement about germline genome editing from the American Society for Human Genetics endorsed by many other genetic and reproductive medicine organizations from all over the world. It reviews recommendations of the National

Academies of Sciences, Engineering, and Medicine, several international and U.S.-based organizations and commissions, and makes several recommendations of its own, concluding “it is inappropriate to perform germline gene editing that culminates in human pregnancy,” but also “there is no reason to prohibit in vitro germline genome editing on human embryos and gametes, with appropriate oversight and consent from donors, to facilitate research on the possible future clinical applications.” Indeed, the statement argues for public funding. Finally, it urges research to proceed only with compelling medical rationale, strong oversight, and a “transparent public process to solicit and incorporate stakeholder input.”

So is there a problem here? It is truly wonderful that medical and scientific organizations have addressed genome editing. It is, however, far from sufficient. Reports and scientific consensus statements inform the policy debate but cannot resolve it. All of the reports on genome editing call for robust public debate, but the simple fact is that embryo research has proven highly divisive and resistant to consensus, and it is far from clear how to know when there is enough thoughtful deliberation to make policy choices. It’s significant that none of the reports have emerged from a process that embodied such engagement. The Catholic Church, evangelical Christians, and concerned civic action groups who view embryo research as immoral are not likely to turn to the National Academies of Sciences, Engineering and Medicine, the American Society for Human Genetics, the Hinxton Group, the Nuffield Council on Bioetics, or other scientific and medical organizations for their primary counsel. They may well listen to scientists, but religious and moral doctrine will get greater weight. Yet religious groups highly critical of embryo research are part of the political system—and whether we embrace this sort of genome editing in the United States is a political question, not a purely technical one.

Addressing the political questions will be extremely difficult. The U.S. government is poorly positioned to mediate the policy debate in a way that recognizes and addresses our complex moral pluralism. NIH and FDA are two of the most crucial agencies, but current policies remove them from line authority, and with good reason, given that engaging in this debate could actually endanger the agencies’ other vital missions. International consensus about genome editing of human embryos remains no more likely than about embryo research in general: Some countries ban it while others actively promote and fund it. Private foundations don’t have the mandate or incentive to mediate political debate about a controversial technology that rouses the politics of abortion. What private philanthropic organization would willingly take on such a thankless and politically perilous task, and what organization would be credible to the full range of constituencies?

So who can carry out the public engagement that everyone seems to agree we need? The likely answer is no one. This problem occurs with all debate about fraught scientific and technical innovations, but it’s particularly acute when it touches on highly ossified abortion politics.

The debate about genomic editing of human embryos is unlikely to follow the recommendations for systematic forethought proposed by illustrious research bodies and reports. Given the reactions we’ve seen to human embryonic stem-cell research in the past two decades, we have ample reason for pessimism. Rather, debate is more likely to progress by reaction to events as researchers make news—often with the same lack of information we lived with for the last week of July, based on incomplete media accounts and quotes from disparate experts who lacked access to the details. Most of the “debate” will be quote-to-quote combat in the public media, leavened by news and analysis in scientific and medical journals, but surrounded by controversy in religious and political media. It is not what anyone designing a system would want. But the recommendations for robust public engagement and debate feel a bit vacuous and vague, aspirations untethered to a concrete framework.

Our divisive political system seems fated to make decisions about genomic editing of human embryos mainly amidst conflict, with experts dueling in the public media rather than through a thoughtful and well-informed debate conducted in a credible framework. As the furor over the Oregon experiments begins to dissipate, we await the event that will cause the next flare-up. And so it will continue, skipping from news cycle to news cycle.

History shows that sometimes technical advances settle the issues, at least for most people and in defined contexts. Furor about in vitro fertilization after Louise Brown, the first “test tube baby,” was born in 1978 gave way to acceptance as grateful parents gave birth to more and more healthy babies and welcomed them into their families. Initial revulsion at heart transplants gave way in the face of success. Anger about prospects for human embryonic stem-cell research might similarly attenuate if practical applications emerge.

Such historical examples show precisely why reflective deliberation remains essential, despite its unlikely success. Momentum tends to carry the research forward. Yet at times we should stop, learn more, and decide actively rather than passively whether to proceed, when, how, and with what outcomes in mind. In the case of genome editing of human embryos, however, it seems likely that technology will make the next move.

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