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Report

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Engineering the New Human

hen Chinese scientist Dr. He Jiankui announced in late November 2018 at the International Summit on Human Genome Editing in Hong Kong that he had undertaken embryo editing culminating in the birth of twin girls, a firestorm of international criticism erupted from the press and fellow scientists. He revealed what many scientists in the field already knew: the technological advances in genetic engineering have moved so quickly that politicians and the general public have been left behind.

The issues raised by Dr. He and others in the field of genetic engineering and genome research are highly technical and not easily understood by even the most informed layperson. More important, the implications of genome editing for future generations and society are not clear even to the scientists.

Gene editing holds the potential for correcting diseasecausing mutations and for treating some medical conditions. The prospect of eliminating diseases such as malaria, AIDS and even cancer is immensely attractive. Yet we do not know the full consequences of gene editing. Genome editing might correct a trait for one disease, but affect the body's ability to fend off other diseases.

Dr. He, for example, sought to disable the gene associated with HIV, but in editing this genome he may have accidentally increased risks in his subjects for contracting other diseases such as West Nile virus and Japanese encephalitis. The generational effects of gene editing on humans remain unknown and even unclear from animal studies. More seriously, while gene editing might have medical benefits, this technique could be used by bad state actors to develop biological weapons.

Gene editing may not be quite ready to produce on demand designer babies who are highly intelligent, athletic, physically attractive—in short, meeting the specifics of parental expectations—but we stand on the threshold of a "brave new world" not even envisioned by Aldous Huxley, author of

the dystopian novel bearing that title. We are unprepared for this new world. Much like Mary Shelley's literary creation Dr. Frankenstein, we do not know where our experiment in altering life will lead. Dr. He's announcement opens a window on some of the issues being raised.

Dr. He expected applause when he announced that he had successfully created the world's first genetically edited twin babies. Instead he was greeted with nearly universal condemnation for proceeding too quickly and without adequate scientific protocols in his work.¹ Dr. He's announcement sent what has been described as a thunderbolt through the scientific world. Scientists across the globe had feared that a rogue scientist would use new gene editing technology to make changes in human DNA without a better understanding of the implications of these changes.

Why People Were Upset with He

pecifically, he used the gene-editing technique CRISPR to alter embryos and implanted them in the womb of a woman who gave birth to twin girls in early November. He appears to have undertaken this work without the official approval of the Chinese government, although many observers are skeptical that the government was in the dark. What is known is that Dr. He reported his work to a couple of his former American colleagues, who seem to have dismissed his work as just talk.²

CRISPR is a new technology that provides powerful, accessible genome editing.³ The technology has been aggressively commercialized by biotech companies such as Editas Medicine, CRISPR Therapeutics and Intellia Therapeutics. These companies have focused on gene surgery to treat individual patients for various diseases. What Dr. He did was to treat the DNA of human embryos, changing genes not just of a particular tissue in a single patient but of potentially every cell in the patient and for future generations. This is called germline editing. In doing so, he went against the

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consensus among scientists, affirmed in dozens of official reports, that the world is not ready for germline editing.⁴

Dr. He undertook gene editing by targeting a gene that encodes the receptor that controls HIV infection. Only a small percentage of humans carry the gene that prevents HIV from gaining a cellular foothold. Dr. He recruited eight couples in his research. The men in the experiment had HIV and the women did not. After editing the genes, he used in vitro fertilization to create embryos resistant to HIV. The purpose was to engineer babies who were not vulnerable to HIV infection.

Scientific critics raised many concerns about Dr. He's experiment. The most serious problem was that the consequences of editing genes across generations are unknown. The strong consensus among scientists involved in gene editing research and gene medicine is that gene editing should be used only to prevent or treat dire medical conditions.

Misleading Tactics

ther critics of Dr. He's experiment noted that it was strange that he selected HIV as the target because there are simpler ways to protect newborn babies of an infected parent, especially an infected father, from getting HIV. Dr. He claimed that he undertook gene editing for HIV because he wanted to offer hope to couples. Dr. He's claim of doing medical good was challenged by Dr. David Liu of the Howard Hughes Medical Institute and the Broad Institute, who said that if HIV infection was Dr. He's concern, "You already do sperm washing to generate uninfected embryos that could give rise to uninfected babies."

The consent form signed by the couples participating in the gene-editing experiment describes the overall project as an "AIDS vaccine development project." Furthermore, Dr. He allegedly misled some on the medical staff assisting him with the project by causing them to believe that they were involved in conventional in vitro fertilization research that included mapping genomes. They were not told about editing embryos. It is questionable whether he sought approval from Chinese regulators. Only months after beginning his project did he list his research in a Chinese clinical trial registry. Supposedly a third geneedited child is on the way.

China has emerged over the past two decades as a major force in genetic research. The first published report of gene editing in human embryos came in 2015 from a group of scientists in China. China is racing ahead in clinical gene editing, especially for cancer patients.

Dr. He comes from a farming family in Hunan province in southern China. After graduating with a degree in physics in 2006, he entered a Ph.D. program at Rice University. After earning his doctorate, he undertook postdoctoral work on immunotherapy at Stanford University with Stephen Quake, an internationally renowned biophysicist. Dr. Quake is the co-founder of Fluidigm and Helicos, two major biotech companies. Dr. He then joined the faculty of a private university in Shenzhen, China, the Southern University of Science and Technology. There he received research grants of millions of dollars from the Chinese government.

Two years ago Dr. He began germline editing. He cited a National Academy of Sciences report justifying germline editing for the HIV virus. He confided to a small group of American scientists—Mark DeWitt, a scientist at Innovative Genomics Institute, and the father-and-son bioethicists William Hurlbut (Stanford University) and Ben Hurlbut (Arizona State University) that he was undertaking this work. They raised ethical questions with him, but thought he was mostly just talking.

In August 2017 he presented his initial findings on the accuracy of gene editing at a CRISPR conference at Cold Spring Harbor Laboratory. His presentation showed data on improving the efficiency of gene editing by detecting off-target mutations using genome sequencing in more than 300 human embryos. As his work advanced, he confided in Stanford University professor Matt Porteus, who said that he berated Dr. He for modifying human embryos. Porteus now wishes he had alerted other experts about Dr. He's research.

Legal Problems

r. He clearly undertook human gene editing that is illegal in many countries, including the United States. After the announcement, China halted Dr. He from further research and is investigating whether he broke any laws there.⁶ Dr. He appeared to be under house arrest in China and confined to his apartment. In the U.S., Congress has barred the Food and Drug Administration from even considering clinical trials of human embryo editing. The National Institutes of Health prohibit funding such research. The National Academies of Science, Engineering, and Medicine issued a report in 2017 stating that editing genes should be used only to correct a serious genetic disorder that causes disease and disability, when there are no alternatives and there is good evidence that the benefits of gene editing outweigh the risks and there is a plan to follow up on the gene-edited children.

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Scientists involved in genetic editing research issued immediate criticisms of Dr. He's work when it was announced in November. Scientists pointed out that Dr. He produced different genetic mutations in the twins, neither of which had been studied in animal models before being tested in humans. Especially critical was CRISPR pioneer Jennifer Doudna of the University of California, Berkeley, who gave interviews stating, "I don't think there's any way to defend using a brand-new and experimental technology when there are established ways of avoiding HIV transmission."

Even more pointed was Derek Lowe, a well-known science commentator, who described Dr. He's work as "criminal." The problem with Dr. He's research was summarized best by Dr. Qiu Renzong, the leading bioethicist at the Chinese Academy of Social Sciences, who asked rhetorically, "How could Dr. He and [his] team change the gene pool of the human species without considering the need to consult other members of the human species?"

Nevertheless, some scientists warned that these critics might be overreacting. Dr. George Daley, dean of Harvard Medical School, and his colleague, geneticist Dr. George Church, argued that just because there were "missteps" does not mean that research should not proceed. Dr. Church commented, "It seems like a bullying situation to me. The most serious thing I've heard is that he [Dr. He] did not do the paperwork right.... As long as these are normal healthy kids, it's going to be fine for the field and the family."

Calls for a Moratorium

In March a group of eighteen prominent scientists and bioethicists called for a global moratorium on genetically edited babies. Their proclamation declared, "We call for a global moratorium on all clinical uses of human germline editing—that is, changing heritable DNA (in sperm, eggs, or embryos) to make genetically modified children." They called for a moratorium for a number of years—perhaps five—until the full implications of the research are determined. They made clear that they were not advocating a permanent ban, but sought to create an international framework to determine how best to proceed responsibly.

The call for a moratorium itself created controversy. Dr. Daley at Harvard Medical School asked, "How long should the moratorium last? Who gets to decide how and when to rescind the moratorium? Is such a call going to prompt even more restrictive attempts to legislate the science and prohibit any clinical work?" He expressed concern that such a moratorium might drive some scientists underground.

Biochemist Jennifer Doudna at Berkeley added, "I don't think we want to drive people into hiding over this. Instead, I would like to have a much more, open, transparent international conversation. I don't like the word moratorium because it kind of goes against the spirit." Bioethicist Ben Hurlbut responded, "Although it would have been a lot better if the call for an explicit moratorium had been proactive rather than reactive, better late than never."

An open discussion among scientists, bioethicists, policy-makers *and the general public* about where this technology is headed seems reasonable and should be supported. As Marcy Darnovsky, who runs the Center for Genetics and Society, observed following the call for a moratorium, "This is too important to have small groups of scientists who've taken it upon themselves to be making decisions for all of humanity."¹⁰

The point is well taken. What is a scientific consensus?¹¹ Who decides on the consensus? How is a moratorium to be enforced? The World Health Organization? A treaty convention of nations that might not include all nations? The presidents of the U.S. National Academy of Medicine and the National Academy of Sciences as well as the president of the Royal Society in Britain have said they are working to develop an international consensus on standards that should apply to research. They stated, "We must achieve broad societal consensus before making any decisions, given the global implications of heritable genome editing."¹²

The Relevance of Christian Ethics

Hong Kong conference, observed, "Although [Aldous] Huxley could not have conceived of genome engineering, we should take to heart the warning implicit in that book." While scientists are generally concerned about germline genome editing—which changes DNA generationally—the promise of curing genetic diseases through genetic engineering is evident to most researchers. Wider ramifications of genome editing and germline editing for society remain uncertain. Will such editing reinforce social inequities because only wealthy nations and persons will be able to afford it? Will cancer be cured only for those who can afford it? Will wealthy parents seek to create perfect "designer babies"?

Questions about what is human life and what is God's intention for us are fundamental. Although the elimination of disease is certainly a worthy scientific goal, past scientific developments involving human embryos have led to evils justly condemned by the Catholic Church, including the

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destruction of embryos for their stem cells (which in any case has failed to yield any useful therapies) and certain forms of assisted reproduction (such as use of a sperm or egg donor or a gestational carrier). Indeed, any scientific activity causing the destruction of human embryos, as well as the technique of in vitro fertilization generally, violate Catholic doctrine.

Christianity offers an excellent framework for a discussion about the ethics of editing the genes of human embryos. Informed Christians need to enter this discussion and not leave it up to just a small group of secular scientists, policymakers or politicians.

- 1 Pam Belluck, "Chinese Scientist Who Says He Edited Babies' Genes Defends His Work," *New York Times*, November 28, 2018.
- 2 Kevin Davies, "CRISPR's China Crisis," *Genetic Engineering and Biotechnology News*, January 2019; and Gina Kolata and Pam Belluck, "Why Are Scientists So Upset about the First CRISPR Babies?" *New York Times*, December 5, 2018.

The Most Important Person on Earth is a Mother

Venerable Cardinal Mindszenty's respect for mothers was deep. Below is the Cardinal's quote, available on a 5 ½" x 3" card in color.



The Most Important Person on earth is a mother. She cannot claim the honor of having built Notre Dame Cathedral. She need not. She has built something more magnificent than any cathedral—a dwelling for an immortal soul, the tiny perfection of her baby's body ... The angels have not been blessed with such a grace. They cannot share in God's creative miracle to bring new saints to Heaven. Only a human mother can. Mothers are closer to God the Creator than any other creature; God joins forces with mothers in

performing this act of creation ... What on God's good earth is more glorious than this: to be a mother?

- Venerable Joseph Cardinal Mindszenty

Order a supply of colorful cards with the beautiful pro-life message. Insert with your letters, bills; give out at church and meetings. Cost includes postage:

20 cards \$ 8.00 100 cards \$15.00 50 cards \$10.00 500 cards \$50.00 1,000 cards \$95.00

The Mother card is available in Spanish at the same cost as English above.

- 3 The complexity of the CRISPR tool is evident in the meaning of the acronym: "clustered regularly interspaced short palindromic repeats."
- 4 Kevin Davies, op. cit.
- 5 Quoted in Pam Belluck, op. cit.
- 6 Gina Kolata and Pam Belluck, op. cit.; and Elsie Chen and Paul Mozur, "Chinese Scientist Who Claimed to Make Genetically Edited Babies is Kept Under Guard," New York Times, December 28, 2018.
- 7 Quoted in Kevin Davies, op. cit.
- 8 Rob Stein, "Scientists Call for Global Moratorium on Creating Gene-Edited Babies," *National Public Radio*, March 13, 2019; and Anthony King, "Leading Geneticists Call for Worldwide Moratorium on Creation of Gene-Edited Children," *Chemistry World*, March 13, 2019.
- 9 Ibid.
- 10 Ibid.
- 11 See, e.g., Françoise Baylis and Marcy Darnovsky, "Scientists Disagree about the Ethics and Governance of Human Germline Editing," *The Hastings Center*, January 17, 2019.
- 12 Anthony King, op. cit.
- 13 Kevin Davies, op. cit.
- 14 Clara Rodriguez Fernandez, "7 Diseases Crispr Technology Could Cure," https://labiotech.eu/author/clara/ and "Genome Editing, What Are the Ethical Concerns about Genome Editing?" National Human Genome Research Institute, August 3, 2017.
- 15 A. Cecile J.W. Janssens, "Those Designer Babies Everyone Is Freaking Out About—It's Not Likely to Happen," *The Conversation*, December 10, 2018.

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