Synthetic Biology

Thorson

Applications of Genetic Engineering to Humans: What the future holds

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Executive Summary

The technologies surrounding genetic engineering have gathered a massive amount of attention in the scientific field within the past few years. This is partially due to its wide domain of applications with humans. The field blew up in 2013 when a revolutionary gene-editing tool was created (CRISPR-Cas9). It has opened the door to completely new styles of living and could lead to solutions to some of the greatest global issues earth faces today (e.g. genetic mutations). However, its increasingly impressive potential lacks a concrete ethical foundation to support its quick growth.

The government is the first system that people turn towards for regulations on ethical intricacies. However, there is little precedence for when the government lacks confidence and data on a subject matter. This happens to be the case with CRISPR-Cas9. The lack of information and communication between different social groups and stakeholders could end up bottle necking the progress of the field or even worse, be the cause of an international disaster. Balancing the freedom to work/progress in this field versus potentially harmful long term effects is what makes this a wicked problem.

Developing a strong understanding of the wicked problem within the global community is essential towards long-term growth in the field of genetic engineering. Therefore, a short term plan of action that could be molded into a long term solution would most effectively address this wicked problem. We propose internationally spread community workshops that would attempt to bridge local misunderstandings of this field with real research. This plan assumes government funding through research grants (e.g. National Institute of Health and Human Services) in the hope of collecting data on undocumented work in this field.

Background: The Wicked Problem

Since the discovery of CRISPR-Cas 9, more ethical questions arise regarding the use and applications in humans. Currently the only legally internationally binding instrument regarding biomedicine is the Oviedo Conference from 1997 [3]. Article 13 of the Oviedo convention states that all germline editing is prohibited and use of genome editing will only be allowed "for preventive, diagnostic or therapeutic purposes" [4]. Though germline editing is prohibited, there are no regulations on how much somatic cell editing is allowed. We must set a line to what counts as medical editing and what is cosmetic. Currently in the United States, there are no other regulations regarding genome editing and specifically CRISPR-Cas 9. Every country has different cultures and values leading to different moral compasses. This brings a problem for medical issues such as genome editing which is best if every country is able to communicate common regulations. In 2018 a Chinese scientist, He Jiankui was able to genetically edit a human embryo which was brought to term. The doctor implanting the embryo into a woman had no knowledge of Jiankui's actions [5]. This scientist's actions were punished with a fine and 3 years in prison. There are no set protocols for any situation violating the regulations set in place, which in themselves are sparse. Situations like these must be prepared for as the technology for genome editing continues to advance.

Beyond the government and regulations, the public perception and knowledge of this technology is not enough and causes unwarranted fear and hesitation when using this technology. Some worries associated with gene editing include the use of a viral vector to bring a gene inside the body and currently has unknown repercussions. Some are also worried about the idea of "Playing God" when it comes to changing people's genes. Another concern is that once a gene has been altered it cannot be reversed [6]. Though there may be concerns that must be studied further, there are still many positive outcomes and possibilities with the use of CRISPR-Cas 9. As explained through our interview with a patient with a genetic disease, there tends to be a disconnect between the doctors and patients. She explained that as the doctor told her the medication she would be taking, she was still confused as to what the medication would be doing to help her disease. With newer technology involving gene therapy, there will be a gap of knowledge between doctors and patients. This disconnect goes beyond the patients and public all the way to the government. It suffocates proper communication not only between the nation, but also internationally. The regulations should come from well informed officials to create the best decisions. Our main stakeholders include the government, researchers, and common patients. Other stakeholders with a secondary focus include hospitals, health insurance firms, and doctors. The government plays a very important role due to the power they have over setting regulations and changing them. We expect researchers and patients will be the most affected by these regulations.

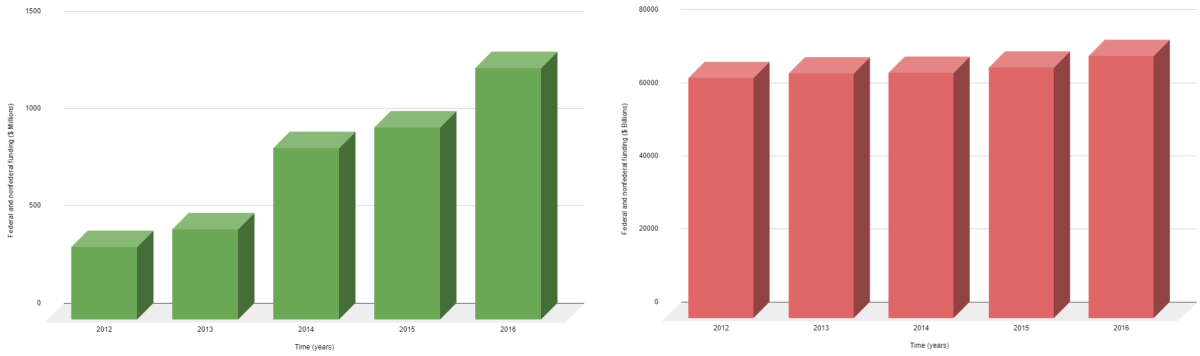

Figure 2,3: *2012 - 2016 federal and non-federal research funding*
The green colored graph represents funding (in millions) in synthetic biology companies from 2012 to 2016 [11] while the red colored graph represents funding (in billions) in academic research from 2012 to 2016 [12]. Notice the drastic percent growth of the synthetic biology industry as it more than doubles in 2-3 years.

Appendix A (References)

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