How Will Genetic Modification Affect Laws And Ethics In The Future?

Genetic modification has been slowly climbing in popularity as it may be the answer to curing incurable diseases and preventing harmful hereditary traits. Scientists have discovered the plausible ability to insert genes into human cells to try and correct whatever damage has been done. This would be a replacement for the use of pharmaceutical drugs and surgeries to treat the human population. Through research, scientists have discovered different procedures for gene therapy in humans including “replacing a mutated gene that causes disease with a healthy copy of the gene, inactivating, or ‘knocking out,’ a mutated gene that is functioning improperly, and introducing a new gene into the body to help fight a disease” (NIH U.S National Library of Medicine. 21 Jan. 2020). The idea behind genetic therapy is quite extraordinary, considering the number of benefits it would create if executed correctly, but how safe is genetic therapy for humans?

Is Genetic Modification Safe for Humans?

The purpose of genetic therapy is to propose new genetic material into the body, targeting damaged or irregular cells to repair them. Although, just inserting a gene into a cell will not do much on its own, it requires a genetically engineered carrier called a vector to deliver the genes. The carrier can enter the body via injection or an IV fluid, into a distinct tissue where it is absorbed by cells. A sample of these specialized cells are removed from the body and looked at in a lab. After a close examination, the cells consisting of the vector carrier are sent back into the human body. If the operation is successful, the brand-new gene; transported by the vector, will create a working protein. Even though this complex process doesn’t sound too scary, a multitude of studies and research has shown that this specific procedure can result in various serious health issues. The stand-out risks include “toxicity, inflammation, and cancer” ('Is Gene Therapy Safe?' NIH U.S National Library of Medicine, 21 Jan. 2020).

The risk levels regarding health concerns are difficult to predict with a process so new to us, but researchers in the medical field are focused on establishing a safe route for gene therapy. There is a way to test these newfound processes, and this is called a clinical trial. Those who undergo these clinical trials are protected by federal laws, guidelines, and regulations. This process is regulated by The U.S. Food and Drug Administration (FDA), who “regulates all gene therapy products in the United States and oversees research in this area. Researchers who wish to test an approach in a clinical trial must first obtain permission from the FDA. The FDA has the authority to reject or suspend clinical trials that are suspected of being unsafe for participants” ('Is Gene Therapy Safe?' NIH U.S National Library of Medicine, 21 Jan. 2020). The National Institute of Health (NIH) is also involved in the assurance of safety surrounding the research standpoint of genetic therapy. NIH “provides guidelines for investigators and institutions (such as universities and hospitals) to follow when conducting clinical trials with gene therapy...

The protocol, or plan, for each clinical trial is then reviewed by the NIH Recombinant DNA Advisory Committee (RAC) to determine whether it raises medical, ethical, or safety issues that

warrant further discussion at one of the RAC's public meetings” ('Is Gene Therapy Safe?' NIH U.S National Library of Medicine, 21 Jan. 2020). An Institutional Review Board (IRB) and an Institutional Biosafety Committee (IBC) “must approve each gene therapy clinical trial before it can be carried out...Multiple levels of evaluation and oversight ensure that safety concerns are a top priority in the planning and carrying out of gene therapy research” ('Is Gene Therapy Safe?' NIH U.S National Library of Medicine, 21 Jan. 2020). Although the process of approving clinical trials is long and enduring, it helps ensure that everything is carried out in a safe and ethical way, limiting the potential of any harm to the participants. Through more thorough research and clinical trials we may be able to discover a completely harmless procedure for genetic therapy in humans.

In What Cases Would Genetic Modification be Socially, and Ethically Acceptable?

Genetic modification, or gene therapy, alters the genetic makeup of a person. It’s one thing to use gene therapy to cure an incurable disease or virus such as HIV, but to use it to improve the way you look, your intelligence, or athleticism is crossing over onto the unethical side of things. This is where the concept of “designer babies” comes into play. It would be completely unethical and unfair for people to alter the genetic makeup of their child in the embryo giving them extreme advantages over a normal human being. For those who can afford it, it is seen as an economical advantage over those who cannot. A child born into a wealthy family would have much more opportunity to better the life of their child through genetic modification than someone in the working class or lower.

If it was something that most people could afford, then wiping out diseases, disorders, and any negative hereditary traits would be ethically acceptable. Designing the way the child looks or giving them any unfair physical or mental advantages would not be ethically or socially accepted as it would put them into a tier far above the average person. If gene therapy was widely accessible to most people, I believe that these ‘designer babies’ would be socially accepted as regular people just like you and me. This is of course, if they had only been modified for health reasons rather than the unfair advantages. Another option for these designer babies would be through something called “Germline Gene Therapy”. This process allows for the inserted genes within the egg and sperm cells, allowing for these new genetic modifications to be passed on throughout the family's generations, limiting the risk for disorders and disease in the bloodline. There are developmental concerns for this process concerning the fetus, it may affect it in unanticipated ways or cause long term side effects for the child that are still undetermined. Due to the fact that the “people affected by germline gene therapy would not yet be born, they can’t choose whether to have the treatment. Because of these ethical concerns, the U.S. Government does not allow federal funds to be used for research on germline gene therapy in people” ('What Are the Ethical Issues Surrounding Gene Therapy?' NIH U.S. National Library of Medicine, 21 Jan. 2020). Genetic modification would be socially and ethically acceptable if it was widely accessible by many, and was only used when needed, not abused and used for selfish reasons.

How costly would this process be, and how would you qualify for it?

Unsurprisingly, the costs for a process such as genetic therapy are quite staggering. The price points for genetic therapy can range from $375,000-875,000 per year of treatment. The most expensive genetic therapy drug on the market costs $2.1 million dollars for just a single use. The unbelievably high prices make this process only accessible to the higher class. Those who cannot afford it are not eligible for genetic therapy. This is a very expensive process for both the consumers and the drug companies as “gene therapies are also often tailored to specific individuals, making completing clinical trials for FDA approval very challenging and costly. One estimate holds it costs drug providers nearly $1 million per clinical trial participant” (March, Raymond J. 'Why This New Gene Therapy Drug Costs $2.1 Million.' FEE, Independent Institute, 3 June 2019). The FDA has made it so that gene therapy is not a widely accessible procedure as it costs a lot of money just to undergo one person. Because this is such a costly process just for the companies to test, they have jacked up the price for consumers, leaving the wealthiest people at a much higher advantage than those of the working class. Many families and people in general would not put out $2.1 million dollars for the single use of a drug when they have to deal with the expenses of everyday life.

All in all, gene therapy is a very expensive and complicated process. It is only accessible to the higher class, which may potentially lead to some ethical issues later down the road. The extreme expense required to undergo gene therapy puts the rich at a much higher advantage for quality of life than regular working class people, and those suffering from poverty. Most people who are in dire need of help or are suffering from untreatable disorders or diseases cannot afford these gene therapy drugs, and instead suffer for the majority of their life. If gene therapy becomes a super popular solution for incurable issues, and is still not made more widely accessible, there could be an extreme ethical dispute over why only a certain class of people get such an unfair advantage over the rest of the population. This could lead to big problems regarding popularity for the drug companies for the lack of fairness regarding the costs for such a life changing process.

Works Cited

1. Darnovsky, Marcy, and John Harris. 'Pro and Con: Should Gene Editing Be Performed on Human Embryos?' National Geographic, www.nationalgeographic.com/magazine/2016/08/human-gene-editing-pro-con-opinions/. Accessed 9 Feb. 2020.
2. 'Is Gene Therapy Safe?' Nih U.S National Library of Medicine, 21 Jan. 2020, ghr.nlm.nih.gov/primer/therapy/safety. Accessed 9 Feb. 2020.
3. March, Raymond J. 'Why This New Gene Therapy Drug Costs $2.1 Million.' FEE, Independent Institute, 3 June 2019, fee.org/articles/why-this-new-gene-therapy-drug-costs-21-million/. Accessed 9 Feb. 2020.
4. Nih U.S National Library of Medicine. 21 Jan. 2020, ghr.nlm.nih.gov/primer/therapy/genetherapy. Accessed 9 Feb. 2020.
5. 'What Are the Ethical Issues Surrounding Gene Therapy?' Nih U.S. National Library of Medicine, 21 Jan. 2020, ghr.nlm.nih.gov/primer/therapy/ethics. Accessed 9 Feb. 2020.
6. 'New Advances in Gene Editing of Human Embryos.' Biologos, 9 Aug. 2017, biologos.org/articles/