

A Case Study on Inheritable Gene Modification

by

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What is Inheritable Gene Modification?

Genetic engineering refers to manipulation of genes to create or alter life. Generic engineering falls into two categories: 1) cloning (copying an existing life form) and 2) genetic modification, which refers to changing genes in living cells. This discussion is concerned with genetic modification (GM, a.k.a. gene therapy) to human cells. There are two types of genetic modification: *somatic* and *germline*, a.k.a. *inheritable gene modification*. Somatic refers to modification of cells other than those of egg, sperm, or early stage embryonic. For instance, altering cancerous liver cells by adding a gene that turns off mutation/defective gene that causes that type of cancer. Germline, as the name implies, refers to cells that germinate into human form: an egg, sperm or early-stage embryo. Germline modification is also called inheritable gene modification (IGM) because altering the genes that merge to create life become permanent traits of progeny DNA. Unlike somatic that only alters genes in the body of an already created human, germline alters the sperm or egg, thus, the modified gene will be inherited by any progeny (next and future generations). Germline requires the use of stem cells and cloning. For these reason, germline or IGM is more controversial than somatic gene modification.

Considerations and Challenges

Inheritable genetic modification is controversial because it can be used to “engineer” humans. People—parents, doctors, scientists, tyrants, and so forth—have the potential to design human beings as they wish them to be rather than leaving the outcome solely to nature. This can be a good thing when considering prevention of debilitating inherited diseases or birth defects. It can be a terrible thing if used to engineer humans for subjective purposes. Thus, the technology is a double-edged sword.

On one hand, there is potential for good. There are more than 2,000 known inheritable diseases. IGM can prevent genetically inherited diseases. For instance, a woman could be tested for the breast cancer gene. If she has it, IGM could be used to alter that gene in her egg so she could not pass the disease to her child. This would be done by removing some of her eggs, altering the defective gene in each and then fertilizing them invitro. It should be noted that inherited diseases can be prevented by using another technique called pre-implantation genetic diagnosis, which uses in vitro fertilization to produce several zygotes and screen them for defective gene, selecting one free of the gene in question for implantation.

On the other hand, a person may simply decide that she wants child with certain traits. Perhaps she only wants a baby with green eyes, and will seek to have both her egg and sperm (partner's or donor's) stripped of other possible eye color or have a gene added for green eye color. This may seem harmless, but where does the line get drawn, or does it? What if societal values influence parenting to the degree that more and more parents seek super athletes or children who are not shy? What about societies ruled by tyrants? Could people be forced to have IGM children based on the whims of a dictator?

Evaluation Criteria

1) Individual rights: Do individuals have the right to determine the genetic make-up of their off-spring? It is hard to argue that a person should be prevented from passing along a genetic disease if there is a choice not to do so. But does a person have right to design a person based on their view of what makes the best kind of human? Should one be allowed to pre-determine height, weight, hair color, eye color, twitch muscles, personality traits, and so forth?

2) Society's rights: Does society, at large, have the right to determine if IGM should be allowed or even required? After all, would not society benefit by ridding all cancers or obesity caused by genetics? Think of the cost savings, both in human suffering and lives lost, medical costs, and work productivity. Yet, what if a society decided that shyness or curly hair were undesirable traits. For instance, what if in a highly competitive society, business interests could show that shy people were not aggressive enough and required more handling (thus, time and money and other resources) to train and perform as required. Should it be suggested or required to remove the "shy" gene, forever? Another concern is that the technology may only be accessible to the privileged. So, does would use of such technology set up of system of genetic discrimination based upon ability to pay? Eugenics and gene castes are risks that people on both of sides of the debate acknowledge as possibilities.

3) Moral/Ethical: What is the implication of tampering with nature and natural selection? Does one person have a right to alter her or his traits, and those of generations to come? Who decides if germline engineering is right or wrong? These questions are pondered by bioethicists, but also average people.

4) Science & Technology: Is the science sound? What are the risks? Are the benefits ensured? Can IGM be conducted safely and easily? Biophysicists and other experts acknowledge that genes are interconnected and altering a single gene does not only impact that gene, and the short or long-term impact of altering a gene or group of genes is not fully known at this time. These are questions for scientists and oversight agencies, notably the FDA, to answer.

5) Financial Costs: Would IGM save costs as far as preventing expensive diseases, preventing the need for research on curing or treating disease? Would it reduce the costs of insurance for both consumers and insurers in not having to cover certain diseases? Would it be a

boon for insurers to sell pricier policies that cover the IGM procedures? IGM is part of the interrelated fields of biomedicine and genetics/bio-engineering, which are phenomenal business for the health care industry. Whether one agrees or not that financial costs should be a determining factor in shaping this particular public policy, it cannot be overlooked that corporate interests carry massive weight in the policy arena. The opposite side of the coin to reducing health care costs and company profits, however, is the costs to individuals, society, and business interests if the hopes and intended results for germline go south.

6) Role of government: In the United States the government serves the role of watchdog. It has an obligation to balance rights of each citizen with the rights of all citizens, which include people and corporations. When it comes to the issue of the human genome, all three branches of national and state government are already engaged to varying degrees; thus, there is no reason to expect or desire that this should change.

Identifying Alternatives

1) Laissez faire and caveat emptor--let biotechnology self-regulate and let the market decide, and buyer beware. Keep the issue in the realm of science and technology. Allow science to proceed to develop IGM and refine the procedure to the point of the health care industry providing it to consumers.

2) Begin/expand public education and dialogue to inform and engage the public about the science and its benefits and risks, so that society can determine the policy.

3) Introduce and pass legislation to prevent or regulate germline engineering.

Evaluating Alternatives

1) Keeping the issue in realm of science, technology, and business is much the case now.

The genie is out of the bottle and technology is proceeding. Still, it seems that altering human genes to the point of engineering human life is something that goes beyond science and technology in the practical sense. Science's role is to explore and push the envelope, but in doing so bad comes with good. Take nuclear fusion, it can be used to create energy to light cities, but there are problems with nuclear waste disposal and risk of radiation exposure. Further, the same technology that created energy for the good resulted in unprecedented human and environmental destruction when nuclear bombs were dropped by the United States on Hiroshima and Nagasaki. Science should not be curtailed from imagining, creating or exploring, but there must be checks and balances. In addition, science is big business, and, as we have recently experienced with the housing crisis and financial industry scandals, regulations with teeth are necessary.

2) Public education and dialogue are prudent endeavors for any public policy issues.

Informing the public of the science and its pros and cons is reasonable. There are some groups attempting this, but the issue has not gained widespread interest. Government could play a role in this, but under our current system, politicians may be fearful of the health care industry, which includes rich and powerful biotechnology and R&D of academia. These interests are major campaign contributors and often get the media microphone. Politicians also fear religious interest groups that have a successful track record of turning out significant numbers of voters to the polls on election day. Major challenges would include competition among interests and spinning of facts. The public could be easily confused and swayed by interests with the money to influence media and policymakers. In addition, the facts may be trumped by emotions, ranging from individual liberty and freedom of choice to adherence to religious belief and fear of change.

3) Introducing and passing federal legislation to prevent or regulate IGM is a likely direction. Congress first debated gene therapy in the 1980's, but only in the last decade introduced significant legislation focused on genetic cloning, none of which has passed. There is no US federal legislation prohibiting inheritable genetic modifications in human beings. Eleven states have laws prohibiting or limiting embryo research that may be applicable to the technologies of inheritable genetic modification. The Food and Drug Administration (FDA) and the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH) are the federal oversight agency for the biotechnology and human genome. Neither has had any proposal for germline modification come before them for consideration.

On the other hand, several countries have enacted laws banning human cloning and limiting gene therapy, and the international community has taken some strong positions. The Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the *Application of Biology and Medicine: Convention on Human Rights and Biomedicine* concluded that that human genome interventions "may only be undertaken for preventative, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants... and shall not be used to select a future child's sex, except where a serious hereditary sex-related disease can be avoided by sex selection."

The World Health Organization (WHO) states "germ-cell therapy, where there is an intention or possibility of altering the genes passed on to the next generation, should not be permitted in the foreseeable future."

Proposed Alternatives

Government regulation is needed. Germline has been used in a very few select trials on humans since 2003. It has not been proven safe or effective. At this time, Congress should attempt to ban IGM. Such a ban would not prevent somatic modification, which has been used and could be used more, within in strict guidelines and monitoring, to fix defective genes in individuals that would not impact progeny. Congress introducing and attempting to pass such legislation will likely not pass (at this time), but would bring the issue up for debate.

Public education and dialogue is needed. Americans need to know about this technology, its potential impact, and how it is proceeding. The technology is complicated and currently not easy to access information let alone process it. While IGM is not impacting many people—yet—the technology is not going away. Like other divisive issues, such as reproductive choice and end of life choices, there will likely be no solution agreeable to a super majority. Congress and the White House and state government websites should have the information about the issue posted on a web page or web site. They would not have to create a new site, but could add to sites, such as the Human Genome Project. This is not a stand-alone alternative, but rather a supplemental alternative to go along with government regulation.

References

Council for Responsible Genetics

<http://www.councilforresponsiblegenetics.org/>

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Genetics and Public Policy Center

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Human Genome Project

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Institute on Biotechnology and the Human Future

<http://www.thehumanfuture.org>

Library of Congress

<http://www.thomas.gov/>

National Right to Life

http://www.nrlc.org/killing_embryos/CloningMisconceptions.html

United States Conference of Catholic Bishops

<http://www.nccbuscc.org/prolife/issues/bioethic/cloning/index.shtml>