Forum: World Health Assembly

Issue: Evaluating the Social, Ethical & Political Implications of Gene Modifying Technology

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Introduction

Gene Modifying technology is “a group of technologies that give scientists the ability to change an organism's DNA”. This form of technology brings up many social, ethical and political implications which is a great downside of the technology. In 1982 the first genetically modified human drug was created. This then led to 2000 when the first designer baby was created. Though the development of gene modifying is greatly advancing, the ethical implications seem to be increasing. The main ethical implications include the religious differences and justice/equity. This then leads to the social implications which include the ripple effect of the modifications and causing a division amongst society. The political implications include the lack of FDA regulations and governmental debates. The United States of America has been very vocal regarding this issue therefore the implication of these regulations.

Though several solutions/ regulations have been placed in order to control the productions of genetically modified organisms. A notable example was the Universal Declaration on the Human Genome and Human Rights which was emplaced by UNESCO to control the productions of the organisms. The FDA regulations are also a very notable regulation which has been replaced. This has been quite effective in some areas of gene modifying technology. Though new technology called CRISPR has recently been emplaced which has caused an increase in the social, political and ethical implications even though they may not be used for a harmful cause. Though there are some potential

solutions such as restricting eugenic genetics, an increase in organizations against the use of genetically modified organisms and synthetic incompatibility

However, there are some positives. GMOs help to keep the costs of food production down, leading to lower consumer prices. GM technology helps to minimize by as much as 15-30 percent the price of food crops such as corn, soybeans and sugar beets. Positives of designer babies include increasing the longevity of humans by up to 30 years. It may help deter inherited disorders like Alzheimer's disease, Huntington 's disease, down syndrome, Spinal Muscular Atrophy, among many others. It reduces the risk of inherited medical disorders such as anemia, hypertension, asthma, cancer and much more.

Definition of Key Terms

UNESCO

The United Nations Educational, Scientific and Cultural Organization is a specialized UN organization aimed at contributing "to peace-building, poverty eradication, sustainable development, and cultural exchange, through education , science, culture, communication and information.

Genetically Modified Organisms

A genetically modified organism is any organism that has changed its genetic material using genetic manipulation techniques.

Embryos

An embryo is an initial stage of multicellular organism development. In general, embryonic development in organisms that reproduce sexually refers to the portion of the life cycle that starts just after fertilization and continues through the creation of body structures, such as tissues and organs

Gene modifying technology

A technology group which gives scientists the ability to change the DNA of an organism. These technologies allow the addition, removal, or alteration of genetic material at specific locations within the genome.

Equity

Equity is the possession of assets that may be associated with debts or other liabilities. For accounting purposes, equity is calculated by subtracting liabilities from an asset's value.

Modifications

A change is a modification or alteration, usually to make things work smoother.

Mutation

Changing the gene structure , resulting in a modified structure that can be passed to future generations, caused by the modification of single base units in DNA, or the deletion, addition or rearrangement of larger gene or chromosome pieces.

Regulations

Regulations apply to the law-enforced regulations or laws in a particular region.

Genome DNA

A genome is the genetic material of an organism.

Designer babies

A child whose genetic material has been chosen to remove a certain deficiency or to guarantee the survival of a certain chromosome.

Eugenics

Eugenics is the research on how reproduction within a human population could be organized to maximize the frequency on heritable characteristics was found attractive.

Key Issues

Ethical issues of Gene Modifying Technology

The scientific innovation of gene modification has had a great impact on the modern world. Since the concept of gene modifying technology is fairly new there seem to be many ethical issues regarding religions and justice/equity. Many individuals may see it as a positive and believe that the advantages outweigh the disadvantages. whereas

others would be against this technology which could influence many to avoid using it thus the need for this technology would decrease.

Religion

As religion plays a great role in many people's lives, different religions may have a different point of views on the use of gene modifying technology. Many religions view gene modification as a duplication of God's role in the universe. Many believe that all life should be created by God and that the alteration of a potential individual's genetics would be changing God's plan for that life. This technology can be seen as a rebellion against God and since around 84% of the world is affiliated with a religion, the majority of the world would most likely not use this technology. Some of these countries include Nicaragua, Croatia and Chile seeing as they are the most religious countries in the world with 70& of their population being religious. In Croatia laws were emplaced which banned GMO's however in Chile the use of GMOs was authorized.

Economic Disparities

The process of gene modification is extremely expensive therefore very few would be able to afford such technology since it costs 15,000 to 25,000 dollars on average. This will increase the number of disparities in regard to health care as well as other medications. Many worry that the modifications of the genes could create division between individuals defined by the nature of the engineered genome. This technology would also be too expensive for standard drug companies to develop therefore this technology would not be accessible to everyone. Even after funds and access is covered it could take years for this modification to be approved by regularities. There is also no guarantee this process would work therefore the large sums of money could be wasted.

Additionally, not all procedures are successful such as Rosa and Vincent Costa who are a couple from New York. They spent $100, 000 over seven trials to ensure the child was a girl. Additionally, the demand for the international surrogacy market for people who are able to travel for the baby further causing economic

inequality – make this an economic issue in its own part rather than justice or equity.

Social issues of Gene Modifying Technology

As gene modifying technology has not fully been integrated into society yet there could be many social issues to the modification of an individual's genetics. Issues such as social division and the ripple effect of the modification would have a great impact on society which could be really hard to reverse. This could eventually lead to the full human species to have a mutation which can't be reversed. These are several effects which could change society in a great way. Countries that have completely banned the use of genome editing include Austria and Ireland who stand by these claims.

The Ripple effect of the modification

When a genetic edit is made to an egg/sperm cells or embryos the modification will be inherited by all future generations. Due to this ripple effect, it could eventually lead the whole human species to inherit these modifications. If this modification was something that could potentially affect the quality of human life, it would not be possible to reverse therefore the entire human species would have to live with this mutation. Many may be against this as it would change the appearance or living standards of society thus many would not like this change. Therefore, society would be against this gene modifying technology.

Division amongst Society

Since the characteristics of the baby would be altered, it could lead the baby to earn more money in the future which would cause a large division amongst society based on wealth. Physical characteristics have proven to affect an

individual's success greatly. A study done by the American Psychological Association shows that an individual who is six feet tall would make $166,000 more than a five-foot five-person over a period of 30 years. A study conducted by the University of Texas showed that men who were considered more attractive earned 17% more than others. This comes from the study of the American Phycological Association

Gender also plays a great role as this study also showed that women earn 12% less than males on average. 30% Fortune 500 CEOs are over six-foot two-inches tall, even though only 3.9% of the world's population is at or above this height. Once these designer babies begin to be created, they would get a biological advantage over others, causing a greater gap between society

Political issues of Gene Modifying Technology

There has been a lot of political debate on Gene Modifying Technology for a long period of time. Movements such as the Tea Party movement in the United States of America 2009 which reached its climax through the nomination of Donald Trump for president in 2016. Though this technology has not been in the limelight due to the very similar controversial topic of abortion, the two correlates thoroughly and have great impact on each other. Many conservatives/ republicans seem to have a great concern with the bioethics/ economic issues of this technology. There are still several FDA regulations regarding this technology primarily in the United States of America. UNESCO has recently reiterated the Universal Declaration on the Human Genome and Human Rights (1997) which states that there is an utter need to follow internationally accepted values which uphold the importance of human rights and human dignity as the primary concern of all medical research and human intervention

FDA regulations

Since this technology is fairly new, not many regulations have been placed by the government. However, a few have which have restricted the research of this technology. In the United States, on January 19, 2017, a revised draft was released by the FDA regarding the "Regulation of Intentionally Altered Genomic DNA in Animals". Public comment was requested in regard to the regulation of altered genomic DNA. This allows the editing of genomes but gives very thorough

restrictions such as only allowing drug provisions from the FDA. This limits research and methods of genome editing. Over 136, 400 foreign facilities are placed in over 150 countries where these products are exported to and from the United States of America therefore impacting a large percentage of the world

Governmental debates

A large political party named Republicans have had great political issues with genome editing. This issue was discussed amongst the Tea Party Movement. This party is extremely against abortions and genome editing and have pushed this forward through President Donald Trump. Along with this President, Barack Obama believed that genomic editing was a line that should not be crossed. This president claims that this new technology brings ethical risks which would require great consideration using the example of researchers in China whom recently conducted genome-editing experiments in human embryos which were not able to develop into a fetus or a person. Another country where this is notable is India. A major and continuing political issue in India is how to feed the 1.1 billion and rising population. Provided that this migration would carry with it the demographic dividend of a young workforce, a main driver of India's macroeconomic policies is food demand as a prerequisite for sustainable industrial development. Therefore, many governmental debates have occurred to use GMO's as it is a sustainable industrial development.

Major Parties Involved and Their Views

Crispr Therapeutics

CRISPR Therapeutics is a leading gene-editing company which uses its revolutionary CRISPR / Cas9 gene-editing technology to develop groundbreaking medicines. CRISPR / Cas9 is a transformative gene editing technology that enables accurate, guided modifications to genomic DNA. Although they convert their unique, powerful and flexible gene-editing tool CRISPR / Cas9 into therapies for treating

hemoglobinopathies, cancer, diabetes and other diseases, they do seem to be addressing the ethical, social and political implication of the technology. Though their cause may be positive, they are a private business therefore their main objective is profit.

United States of America

A prominent political party in the United States of America named Tea Party has discussed the political implications of genetic engineering thoroughly and seems to be against it. This is a republican, conservative party which supports the current president; Donald Trump.

The previous President of the United States of America also seemed to be against the use of genetic engineering as they state, “The White House fully supports a robust review of the ethical issues associated with using gene-editing technology to alter the human germline. The Administration believes that altering the human germline for clinical purposes is a line that should not be crossed...”. There is heavy regulation of designer babies in the United States of America through the FDA and NIH.

However they do use genetic engineering for crops as More than 90% of all soybean cotton and corn in the United States of America is grown genetically. There are over 70.9 million hectares of cultivation areas specifically for genetically modified crops. However majority of citizens consume GMO products and several have advocated for designer babies.

However this is thoroughly regulated through three different major agencies. Genetically modified pets also began in the United States of America as the first genetically modified fish was sold in the United states of America in December 2003. The country also uses genetically modified engineering to help solve disease such as cystic fibrosis, diabetes etc. It is also used for drugs, vaccines and other products that are harvested from organisms. In addition to this, the first designer baby was created in the United States of America in 2003.

Food and Drug administration

Most of the meat we consume today was made using traditional breeding methods. But it can take quite a long time to modify plants and animals through traditional breeding,

and very specific modifications are difficult to make. Following the development of genetic modification by scientists in the 1970s, similar improvements were made in a more precise manner and in a shorter period of time. The FDA requires that all biological products be approved by FDA before they can be released, regardless of whether or not they are produced through genetic engineering, with extensive details about whether they are safe and successful for their intended purpose. The FDA requires anybody that intends to introduce a new drug into the US market, whether it includes genetic modification or not, to apply a New Drug Application (NDA) to the FDA with comprehensive safety and effectiveness information. In most cases, the FDA requires approval of a genetically engineered animal through a New Animal Drug Application on the basis of a proof that it is safe and effective for its intentional use. The FDA considers that most GMO foods fall definitionally within the category of "generally considered safe," thus requiring no pre-market approval, but a GMO product "which differs significantly in structure, function or composition from substances currently found in food" requires pre-market approval as a food additive.

Environmental Protection Agency

The Environmental Protection Agency is an individual agency of the United States federal government, specifically an independent executive agency for protecting the environment. The EPA regulates the genetically engineered pesticides and microorganisms. Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA governs the manufacturing, selling and usage of pesticides. Under FIFRA, pesticides shall not inflict "unreasonable harmful effects on the environment," which is established to include both environmental protection and food health for use. FIFRA mandates that all pesticides be licensed with EPA until they can be widely sold. Pesticides must be tested and proven safe before they can be certified. Information on testing, product identity, draft labeling, residue tolerance information and other safety-related information must be included in a registration application.

United Nations Educational, Scientific and Cultural organization

The United Nations Educational, Scientific and Cultural Organization is a specialized UN agency aimed at contributing "to peace-building, poverty eradication, sustainable development and intercultural dialog through education, science, culture,

communication and information. At the end of a UNESCO meeting in Paris, independent experts from the International Bioethics Committee of the Organization published a report entitled "Updating its Reflection on Human Genome and Human Rights." In it, the experts argue that "gene therapy could be a watershed in the history of medicine and genome editing is undoubtedly the most promising scientific undertaking for the sake of humanity. Overall UNESCO believes that caution must be taken in regard to gene modifications that will pass on to future generations.

People's Republic of China

China is a republic in eastern Asia, formally the People's Republic of China. It is the most populous country in the world, with around 1.4 billion inhabitants in 2019. Covering about 9.6 million square miles, it is the third or fourth largest nation by area in the world. The Peoples Republic of China hasn't hesitated to use its resources and clout to support the growing population of the world. It's bulldozed vast swaths of cities, rerouted and dammed the Yangtze River, and created desert skyscrapers. Yet China is stalling when it comes to consumer GMOs. In 1997, the country issued its first license to a GM crop — cotton, now widely utilized. But the last authorized variety, in 2006, was papaya. China has since confined the GM crops to the laboratory.

Development of Issue/Timeline

Date	Event	Outcome
1953	The twisted-ladder structure of deoxyribonucleic acid (DNA was discovered) by James Watson and Frances Crick	For the first time, it was seen what human genetics is made of and the structure of the DNA (the double helix) was discovered, the basis of which genetic engineering occurs

1958	DNA was created in the test tube for the first time by Arthur Kornberg	DNA polymerase was isolated from bacterial extracts and DNA was successfully synthesized in vitro for the very first time which is also used in genetic engineering.
1967	DNA Ligation Links DNA Fragments Together	The discovery of DNA ligases is revolutionary in molecular biology, as in all species it is necessary for the repair and replication of DNA. Catalyzing the creation of a phosphodiester bond effectively helps DNA molecules to bind together.
1972	Gene splicing trial sets the stage for DNA (rDNA) recombinant.	Paul Berg was the first scientist to ever generate recombinant DNA from more than one species that enabled the genetic manipulation progress
1982	The first genetically modified human drug was created.	Dennis Kleid helped put on the market for humans the world's first genetically engineered drug-insulin.
1993	The discovery of CRISPR (Clustered regularly interspaced palindromic repeats)	A group of genomic DNA sequences which is the foundation of genetic engineering
1994	The first commercial sale of genetically modified foods	Commercial sales of Gmo crops began in 1994, when the first unsuccessful Flavr Savr delayed-ripening tomato was sold
1997	UNESCO implements the Universal Declaration on the Human	The declaration is best known for its pronouncement against human cloning and human genome abuse against human dignity.

	Genome and Human Rights	Article 11 begins with the declaration " Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted."
2000	The first genetically modified baby was created/born	Through the use of in-vitro fertilization and preimplantation diagnosis the first designer baby "Adam Nash" was created/born causing great controversy amongst society.
2006	Food and Drug administration approves the first vaccine developed through genetic engineering	The use of gene-editing to identify cancer therapies has become a success. This was the first cancer preventive vaccine ever to come into the market.
2015	First genetically modified fish is sold in the markets	The salmon developed by AquaBounty corporation became the first to be marketed as a genetically modified product for human consumption. This was approved to help solve the issue of overfishing
2018	First human trials for crispr are approved	In a joint project of two firms, Vertex Pharmaceuticals & CRISPR Therapeutics, the initiation of clinical trials has been approved for an experimental treatment for blood disorder B-thalassemia. When effective, this treatment will end cases of this disease, and anemia of sickle cells.

Previous attempts to solve this issue

Regulations for the production of genetically modified organisms

The food and drug administration has placed several regulations in order to help control the use of gene modifying technology. These regulations have reduced the ethical, political and social issues that arise from this technology. These regulations include a requirement that all biological products are to be approved by FDA before they can be released, whether they are or aren't produced through genetic engineering, with extensive details regarding whether they are safe and successful for their purpose. The FDA requires anyone who intends to introduce a new drug into the US market, whether it includes genetic modification or not, to apply a New Drug Application to the FDA with extensive safety and efficiency information. In most cases, the FDA demands for approval of a genetically engineered animal through a New Animal Drug Application on the principle of a proof that it is safe and efficient for its designed use. The FDA acknowledges that GMO products "which differ significantly in structure , capacity or configuration from substances currently found in food" requires pre-market approval as a food additive.

Restrictions for the explorations of genetically modified organisms

The Animal and Plant Health Inspection Service (APHIS) is a fairly young organization but it has been the responsibility of the United States for much of the vital research that falls under its mandate today. The Agriculture Department (USDA) has been in operation for over 100 years. APHIS controls the importation, interstate movement or release of certain species into the environment (i.e., field trial use) produced using genetic engineering that may pose a risk of plant pest. Under the updated regulations, all controlled activities involving genetically modified organisms must be approved by a permit, except if the organism meets the Regulatory Exemption criteria or is a plant that completes a regulatory status analysis (RSR) resulting in the conclusion that the plant is unregulated. This would be very efficient in terms of regulating the amount of genetically modified plants to help avoid the ethical, social and political implications that could be imposed. However, this may not be enough as these regulations are not very strenuous. These regulations would not be able to avoid the ethical, social and political implications completely by themselves. This was implemented in the United States of America and was extremely effective and efficiently controlled the release of species produced using genetically modified organisms.

Regulations for environmental protection from genetically modified organisms

The EPA controls pesticides and micro-organisms which are genetically modified. The EPA regulates the production, selling and use of pesticides, under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Under FIFRA, pesticides shall not inflict "unreasonable adverse effects on the ecosystem," which is defined to include both the protection of the ecosystem and food for use. FIFRA allows for all pesticides to be approved with EPA so they can be marketed widely. Pesticides must be tested before they can be licensed and proven safe. Registration application may provide information on inspection, product identification, draft marking, residue tolerance information, and other safety-related details. This is extremely effective as most of the environmental social implications would be avoided therefore avoiding the ethical implications from gene modifying technology. However, this doesn't combat the political implications therefore this regulation alone would not be able to combat all implications.

Possible solutions

Synthetic incompatibility

Synthetic incompatibility technology makes a distinct population of modified organisms unable to develop viable offspring with their wild or domesticated relatives. This would help to avoid a duplication of genetically modified organisms therefore this social impact would be suppressed. Synthetic incompatibility has uses in managing or eliminating invasive organisms, crop pests and disease-carrying insects as well as preventing altered genes from spreading to other plant populations from genetically modified crops. The technology uses a new form of molecular techniques called "programmable transcription factors" that allow control of which genes are activated on and the genes in an organism are switched off. If a wild counterpart is balanced by an engineered organism, the transcription factors render the offspring unable to survive by activating genes that cause their cells to die. Synthetic incompatibility may allow the use of

crops to produce medicinal products as well as food, feed and fuel. It also raises hope that genetic modification can be used to combat invasive species or insect populations such as Asian carp in North America and disease-carrying mosquitoes worldwide. The countries in most need for this would be India and Brazil due to their large number of crops and invasive species. Since these countries are low economically developing countries they would probably not be able to afford such advanced technology nor would it be their top priority. Therefore unless an non-governmental organization funds for this technology it is extremely unlikely these countries would do so.

Restricting eugenic genetics

Eugenics is a movement whose goal is to enhance the human race's genetic makeup. This includes the creation of designer babies which causes most of the social, ethical and political implications. The most common objections against any effort to remove a phenotype by germline genetic manipulation or to produce more children with desirable traits, fall into three categories: fears regarding the existence of coercion or compulsion, the introduction of arbitrary expectations of quality, or inequities that might result by enabling eugenic choice to be practiced.

The first issue is not one that seems insurmountable as an obstacle to allowing for individual decisions regarding changes in the germline. The latter two, also, may not dismiss eugenic choices. By restricting eugenic genetics all of these issues can be avoided. The public has usually discredited the use of eugenic genetics due to the poor sampling and statistical methods.

Increase in organizations against the use of genetically modified organisms

The anti-GMO activists have thus earned a remarkable but doubtful victory when it comes to GMO food crops. However, they have not stopped the use of GMO animal feed or GMO cotton by rich countries, but farmers and consumers in poor countries need

increased productivity for food crops, not feed or industrial crops. Some organizations present themselves as advocates of social justice, some as advocates of the rural poor, some as advocates of the environment, some as opponents of corporate-led globalization, and some primarily as advocates of alternative methods of farming, such as organic or agroecological methods, which reject the use of GMO. The campaigns carried out by these organizations have been remarkably successful for almost 2 decades now, especially in blocking the planting of GMO food crops. GMO maize, GMO rice, GMO potatoes and almost all GMO fruits and vegetables have been prohibited also in the United States from commercial planting. Based on the actual results so far, it is the critics of the NGOs who are strong, and the weak private companies. So far, private biotechnology firms have lost almost every battle over food crops.An increase in these organizations will lead to an increase in the effectiveness of removing ethical, social and political implications of genetically modified organisms.

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Appendix

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II. The UNESCO takes cautions against reckless application of Gene Editing https://en.unesco.org/news/unesco-cautions-against-reckless-application-gene-editing.