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Subcommittee on Terrorism, Nonproliferation and Trade

New Biotechnologies: No Longer Science Fiction

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Mr. Chairman and Members of the Committee:

Thank you for holding this important hearing to discuss the pertinent and imminent issues of new human biotechnologies. The social, environmental, trade, and governance impacts of these new technologies are vast and complex, and it is crucial that Congress begin to examine them.

My name is Gillian Madill, and I am the Genetic Technologies Campaigner for Friends of the Earth. Friends of the Earth is a national environmental non-profit advocacy organization that has been promoting a just and healthy world for nearly forty years. We have taken an interest in new human biotechnologies because they concern the very nature of life itself and pose great threats to justice, human health and the environment. Friends of the Earth strives to engage the public on emerging technologies, exposing the pervading nature of technological development and use while motivating legislators to be proactive in creating forward-thinking regulations that protect human and environmental justice and health.

In this testimony, I have outlined several current issue areas within the broad topic of human biotechnologies that are in desperate need of regulatory action. There are several corresponding pieces of proposed legislation included as well.

New Biotechnologies: No Longer Science Fiction

The level of genetic modification is intensifying and getting more complex each day. Genetic technologies are developing at an exponential pace, and have far outpaced existing regulatory structures, putting human health, the environment, our economy, and homeland security at risk. It is imperative that Congress take action and guide this important research so that it is productive and non-destructive.

Part human-part chimp children, kidnapping for blood cells, genetically engineered pets, genetic cures for drug addiction, and the emergence of a new human race are the topics of some of the best-selling scientific fiction stories, such as *Next* by Michael Crichton or *I Am Legend* starring Will Smith. These stories are no longer fiction. Scientific advancements are making these fantasies possible, and Congress must act quickly to institute a regulatory structure that saves us from the tragic endings of these previously fantasy stories.

Scientists have been manipulating the genetic code for many years, beginning in 1973 when *e. coli* bacteria was inserted with a frog gene, creating the first recombinant DNA organism. Since then many bacteria, plants, and animals have been genetically modified. Crops have been inserted with pesticide-producing genes in an attempt to increase pest resistance and product yield. Fish and rabbits have been inserted with genes from jellyfish and coral to make them glow for purely aesthetic purposes.

In the past few years, scientists have cloned dogs and cats for wealthy pet-lovers, cloned livestock for food, injected human sperm into rabbit eggs to create embryos, grown human ears on the backs of mice, created genetically modified mosquitoes to resist parasites, and patented the most basic form of a living organism – DNA. Humans are further mastering the science of all life, which comes with great responsibility. This responsibility so far has been in the hands of the scientists and companies seeking to make profit, most of whom have no regulatory, ethical or environmental safety background.

Human Genetic Modification

One of the most alarming possibilities of new human biotechnologies is the genetic contamination of the human species. Our DNA is what defines us as uniquely human, and we now have the ability to manipulate it. Altering what nature has given us from billions of years of evolution exposes our genetic makeup to human error. The mild form of our alteration of the human gene lines, is the use of genetic screening to select our children. But the technology is becoming more intrusive. Presently, some are pursuing human-animal hybrid research and gene-doping. In the near future, we will likely see attempts to fully engineer human genes from scratch, create designer children and other technologies that could lead to a rebirth of eugenics with transhumanist aims.

Human-Animal Hybrids

Research in human biotechnologies is pushing our intellectual and moral limitations. For a few years, some scientists have been pursuing the creation of human-animal hybrids, or chimeras, at the embryonic level. They are creating embryos that are part human, part animal. So far, scientists have used animal eggs as a way to avoid the ethical and legal barriers associated with using human eggs and embryos for research. Other scientists want to create human-animal hybrids as exploratory research. However, it is hard to believe that performing research on human-animal hybrid models will be translatable to human models or would not pose new ethical challenges.

Creating human-animal hybrid embryos ignores every law of nature and billions of years of evolution. It could potentially change what it means to be human, and opens Pandora's Box of potential consequences, including threats to human health, such as cross-species disease transmission. Thousands of animals are subjected to hormone injections and egg retrievals which are painful and can cause death. This research is unnecessary and dangerous. It conjures up the creatures of Greek mythology for the sake of scientific exploration, with little real-world, practical use.

Currently there is no regulation or oversight for the creation of human-animal hybrids. The Human-Animal Hybrid Prohibition Act (S.2358), proposed by Senators Sam Brownback (R-Kan.) and Mary Landrieu (D-La.), would make it illegal to combine human and animal eggs and sperm to create a hybrid embryo, insert animal DNA into a human embryo, or create an animal with human reproductive organs or a human brain.

This bill is the first real Congressional step towards gaining more substantial, broad-reaching regulatory oversight for new human biotechnologies.

Gene Doping

Few realize that the technology being heralded as gene therapy can be used to give people extra abilities. Gene doping is the same as gene therapy, separated by a very fine line which is defined by a loose combination of medical and societal ethics. While there has yet to be a successful gene therapy or gene doping experiment, the technology exists and may soon be exploited, particularly to create super-athletes.

Gene therapy has the potential to help prevent otherwise unpreventable disease, but it also poses a grave danger to the integrity of natural human abilities. We have seen the harm that steroid doping has caused in sports and many young people's lives. Gene doping has the potential to wreak even more havoc in athlete health and destroy lives because it has a permanence that drugs do not have – gene doping involves changing the actual structure of a person's DNA, the basic building block of life. Once these changes become part of the DNA, they can be passed from generation to generation thus creating a practicably irreversible change in human evolution.

Thankfully, the World Anti-Doping Agency has adopted a proactive policy which prohibits gene doping in Olympic competition. Additionally, the Reauthorization of the Office of National Drug Control Policy Act of 2006 required the National College Athletic Association to adopt an anti-gene doping policy as well. Friends of the Earth is asking other United States professional sports organizations to follow their lead. Developing a national pro-sports policy which prohibits gene doping would not only enforce the World Anti-Doping Agency and Office of National Drug Control policy, but also protect our youth from experimenting with a dangerous new technology which would inflict permanent, unknown damage. These first steps are important regulations but they only protect athletes. Without Congressional oversight, the rest of the population beyond the reach of these professional associations is left exposed.

Threat of genetically modified bioweapons

The advent of any technology presents new dangers and possibly new weapons. New genetic technologies pose unprecedented new threats to humanity and the environment because it gives us the ability to manipulate life at its most basic molecular form. Traditionally, bioweapons have consisted of known viruses and bacteria which have been weaponized. These viruses and bacteria can be controlled with vaccines and other known methods. Emerging genetic technologies, however, present us with new forms of life never seen before and that have no natural controls.

In fact, one of the most dangerous aspects of these new technologies is that they have a "home-brew" nature – many experiments can be done with just a few simple materials and the reagents used (DNA sequences, etc.) are not tracked by any regulating authority.

This means there is a whole new level of complexity that we have not seen with past situations like the advent of the nuclear bomb and nuclear proliferation, which cannot be created in backyard laboratories. Entire genomes of infectious diseases can be ordered online through DNA synthesizing companies for relatively small fees. It is possible that new, extremely virulent organisms can easily be released into the environment, devastating ecosystems, destroying species, and causing great human suffering and death.

Synthetic Biology

One of the most quickly developing, new genetic technologies is synthetic biology. Scientists have been manipulating the genetic code for many years. To date many bacteria, plants, and animals have been genetically modified. The level of genetic modification is about to get much more intense and complex because of advances in genetic engineering, nanotechnology, and robotics. Combining these technologies has led some scientists to attempt to create life from scratch or re-design existing life. This is called synthetic biology, or synbio.

Some scientists believe that they can improve upon existing life. Synthetic biology frees scientists from the constraints of working with existing life and allows them to create alien life forms in order to accomplish their goals, whatever they may be. Potentially, synthetic biology could lead to the development of numerous alien bacterial, plant, animal, and human species which could have disastrous effects because of their ability to self-replicate.

The first SynBio business ventures are aimed toward consumers: biofuels and pharmaceuticals. In the United States alone, over 15 companies and most top universities have begun major SynBio programs to develop the first trillion dollar organism that produces biofuels. Pharmaceutical companies and medical universities have begun to develop designer viruses that might cure disease. While these goals may sound noble, the reality is that man-made life will be released into the environment, and will evolve independent of our control. Without some safeguards and constraints on this research, these 'miracle' organisms will become *killer* organisms.

There are already at least 66 companies worldwide that are conducting synthetic biology research or are selling manufactured pieces of DNA online. Almost every leading engineering school in the United States has a rapidly growing and heavily funded synthetic biology research department. Companies already own and are applying for patents on the most basic forms of life.

The assumption that humans can benignly re-design or create superior forms of life is naive and erred. Synthetic biology involves the entire re-making of genetic material, introducing new structures into a genetic code that has provided all the biodiversity on Earth. Attempting to improve upon the original design of life disrespects and ignores the perfect balance of the natural world. All life is interconnected, which includes new forms of man-made life which will undoubtedly interact with the Earth's ecosystems. As we know, altering just one part of an ecosystem affects all the living beings within it in ways we are just beginning to understand and discover.

Synthetic biology is a dangerous area of research. Since it is still developing, we have time to put regulations in place to ensure that synthetically-created life is not released into the environment. This includes close scrutiny of research and of waste products resulting from tampering with the code of life. The precautionary principle is as important now as it ever was in order to protect human health, the environment, and prevent the development of bioterror weapons.

Social challenges posed by human biotechnologies

The social challenges posed by new human biotechnologies are pervasive and far-reaching. As with any technology, there will be inequity. People with more resources will be the primary beneficiaries of new human biotechnologies, while people with few resources and in disadvantaged parts of the world will be denied access to beneficial technologies and will likely be most subjected to the misuses and harms of new technologies. For example, many people in disadvantaged communities are the first ones to be recruited as test subjects for new technologies. Currently, women in Southeast Asia are renting out their wombs to wealthy Westerners who are unable to bear their own children. This is a highly controversial practice with absolutely no international oversight, greatly compromising the health and rights of women living in poverty. This is just one example of the inequity new human biotechnologies may pose.

Patents

Inequity is caused by lack of financial resources. New biotechnologies will only be accessible to the wealthy since the technology is being driven by the desire for profit. Biotechnology companies can make profits on new biotechnologies because life is patentable in the United States. New organisms, sequenced genes, or entire species can be owned and companies can collect profits on the use of such basic elements of life.

Millions of bacteria, viruses, animals and human genes are owned by large companies. This creates serious concerns in international trade and research since many other countries do not allow life to be patented. As life is not invented by man, patents on life and especially on human genes should be banned. The Genomic Research and Accessibility Act, introduced by Representatives Xavier Becerra (D-Calif.) and Dave Weldon (R-Fl.), would stop the patenting of human genes. Up to one-fifth of every person's DNA is owned by a company, and cannot be examined without applying for a license and paying high royalty fees. This is problematic because it allows companies to legally own pieces of human beings and prevents scientists from performing research on important genetic diseases like breast cancer (BRCA1 and BRCA2 are owned by Myriad Genetics). Patents on the genomes of disease-causing organisms, like SARS, are also patented which prevents and discourages scientists from researching treatments.

Allowing patents on life has led to biopiracy. Companies have raided indigenous communities' genomes – obtaining blood samples from remote, genetically-unique

villages, mining them for genes and then patenting what they think might be profitable. Biopiracy is on a scale of injustice that far exceeds anything we have seen, including the raiding and pillaging of the ancient tombs of Egypt by colonialists, who then sold the valuables for large amounts that ended up in control of the elite.

Patents on plants and seeds have destroyed thousand-year-long traditions of agrarian traditions in indigenous communities. Seeds are now owned by the Monsanto, Cargill and Duponts of the world, which makes it illegal for peasant farmers to collect and save their seeds from annual harvests. Instead, they are forced to buy new seeds every year from these large, disruptive corporations who now hold patents on seeds that have been collected and used for generations.

At minimum, the United States should stop allowing patents on human genes. Human genes come from the collective evolution of humanity. Genes and life itself is not an invention of man and should not be patentable under any context.

Call for Congressional Action

New biotechnologies present a vast, complex, interdisciplinary array of problems and possibilities. Existing regulatory structures have failed to keep up with this quickly developing science, leaving society vulnerable to serious harm. We call upon Congress to update the regulatory structure of this uncharted area of research and protect human health, the environment, our economy, and strengthen homeland security.