GENETICS AND OTHER HUMAN MODIFICATION TECHNOLOGIES: SENSIBLE INTERNATIONAL REGULATION OR A NEW KIND OF ARMS RACE?

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GENETICS AND OTHER HUMAN MODIFICATION TECHNOLOGIES: SENSIBLE INTERNATIONAL REGULATION OR A NEW KIND OF ARMS RACE?

THURSDAY, JUNE 19, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION,
AND TRADE,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:01 a.m., in room 2200, Rayburn House Office Building, Hon. Brad Sherman (chairman of the subcommittee) presiding.

Mr. SHERMAN. Folks, thanks for being here.

I am going to take a little bit more than 5 minutes for my opening statements because I first need to explain why we are here. If these hearings were about al-Qaeda or about OPIC, I would not have to explain that.

Science has already created enough national security issues for us foreign policymakers to deal with. If science stopped now, we could spend centuries working out the right international agreements, but science is not stopping.

As Christine Peterson, a futurist, points out:

> If someone is describing to you a picture of the future 25 years from now and that picture looks like a science fiction movie, then the description may be false. But if someone is describing to you a picture of the future 25 years from now and it does not look like a science fiction movie, you know it is false. We are going to be living in a science fiction movie. We just do not know which one.

In particular, science could very well create—and I focus here on the scope of today's hearing's focus on biotechnology—super-soldiers, super-intelligence, super-animals, and, of course, just outside the scope of today's hearings, super-computers. This is somewhat analogous to what science bequeathed policymakers in the middle of the last century, nuclear weapons.

We will focus today on the possibility of using genetics and other advanced technologies for human modification or for other national security advantages.

Advances in the field of genetics have provided humanity with the possibility of great benefits and also raises complex issues. When, if ever, should it be permissible to utilize genetic technology

not to alleviate suffering or to deal with a malady, but to actually enhance normal human capacity? Where do we draw the line between therapies and enhancements? What manipulation of animal DNA is moral, and what special rights would be accorded to special new animals that are created? What is the morality of mixing human and animal DNA, and what are the potential national security advantages either to ourselves—and we may be constrained by all these concerns—or the national security advantages to potential adversaries who might not feel similarly constrained?

The history of nuclear technology may be instructive, though not exactly analogous. On August 2, 1939, Albert Einstein sent Roosevelt a letter saying a nuclear weapon was possible. Six years later, nuclear technology literally exploded on to the world scene. Only after the world saw the negative effects of nuclear technology did we see the prospects for nuclear power and nuclear medicine and only 2½ decades after Hiroshima did we get the NPT.

I do not know whether we will have 2½ decades from the day when these technologies have some explosive effect on the world scene to when we would need international controls. It is quite possible, I think probable, that if we are going to get any international controls, they need to precede the development of the technology.

The development of these technologies is going to be different than nuclear technology. The undeniable benefits of computer and DNA research are going to provide benefits long before the problematic possibilities become obvious. The introduction of these technologies will be gradual, not explosive.

On the other side, helping us deal with these issues is, as I pointed out, the fact that we have more than 6 years, but having more than 6 years will not matter at all if we squander all the time between when I think we in this room are aware that these technologies may have a dramatic effect and when the technologies are available to either the good guys or the bad guys in the world.

Now the easiest and cheapest thing that can be done with this subject is mockery. If there are people who disagree with the concerns I voice, I hope that they will not substitute cheap derision for serious discussion. Some will argue that those with the technology have the morality and, therefore, these technologies will not be a problem, that our scientists in the West would never mix human and animal DNA, would never engage in the dangerous experiments necessary to advance this technology, that those with the technology will be constrained by morality.

Need I point out that North Korea has developed nuclear weapons? Not all technology is in the hands of the moral.

Second, what we are talking about today does not always in its first stages involve the kinds of moral questions that the whole western world would agree on. There will be limits on the use of human DNA, but what about animal DNA? Western scientists may not have the same compunctions. As these technologies go by, the benefits of treating diseases will be so enhancing that these moral questions may be pushed to the side, and the issue of implanting computer chips into humans, something that technology is already beginning to do to treat diseases, may pose far fewer moral questions than those that involve manipulating the human genome.

We cannot assume that everyone in the world will reach the same philosophical and moral answers that we do, especially when we do not know what answers we might reach. Rather, we need to approach this issue assuming the opposite, that in the absence of international consensus binding all nations, some states will attempt to manipulate human genetics and use other technologies to gain some national security advantage.

If we do not develop some international consensus on controlling this technology or if we fail to enforce any consensus that does emerge, we can anticipate a world in which a rogue state or not such a rogue state or a non-state actor would attempt to manipulate human genetics in ways that would horrify us, but they may feel that they are gaining a national security advantage.

Those who say that mankind would never manipulate the genome for military purposes must read the writings of those who say that mankind would never manipulate the atom for such purposes.

I have much more to say, but it is time for these hearings to begin, and I look forward to beginning to build a foundation for what will be, I think, at least a decade-long process to build an international consensus on what limits there should be on this technology and what inspection or other enforcement regimes should enforce that consensus.

With that, I yield to our ranking member, Mr. Royce.

[The prepared statement of Mr. Sherman follows:]

PREPARED STATEMENT OF THE HONORABLE BRAD SHERMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SUBCOMMITTEE ON TERRORISM, NONPROLIFERATION, AND TRADE

The Subcommittee turns its attention today to a subject that may confront us in the first half of the 21st Century in ways similar to how nuclear technology confronted global international relations in the latter half of the 20th Century. We focus today on the possibility of utilizing genetics and other advanced technologies for human modification.

Advances in the field of human genetics have the potential to provide humanity with invaluable benefits—namely, the ability to identify, diagnose, treat and prevent some of the world's worst maladies in ways that were unthinkable less than a few decades ago. But these technologies also raise some of the most complex moral issues ever to confront humanity; they have the potential to impact our society in fundamental ways; indeed they raise existential questions for humanity.

When, if ever, should it be permissible to utilize genetic technology, not to alleviate someone's suffering, but to actually enhance a normal human being? How will we draw the line between "therapies" and "enhancements"?

I believe that the impact of science on this century will be far greater than the enormous impact science had on the last century. As futurist Christine Peterson notes: If someone is describing the future 30 years from now and they paint a picture that seems like it is from a science fiction movie, then they might be wrong. But, if someone is describing the future a generation from now and they paint a picture that doesn't look like a science fiction movie, then you know they are wrong. . . . We are going to live in a science fiction movie, we just don't know which one.

There is one issue that I think is more explosive than even the spread of nuclear weapons: engineered intelligence. By "engineered intelligence" I mean the efforts of computer engineers and bio-engineers to create intelligence beyond that of a human being. As we develop more intelligent computers, we will find them useful tools in creating ever more intelligent computers, a positive feedback loop.

The history of nuclear technology is analogous to the potential rapid development of advanced technologies for human modification. On August 2, 1939, Einstein sent Roosevelt a letter saying a nuclear weapon was possible; six years later, nuclear technology literally exploded onto the world scene. Only after society saw the nega-

tive effects of nuclear technology, did we see the prospects for nuclear power and nuclear medicine.

The future of engineered intelligence will be different. The undeniable benefits of the computer and DNA research are arriving long before the problematic possibilities. Their introduction will be gradual, not explosive. And fortunately, we will have far more than six years to consider the implications—unless we choose to squander the next few decades. My fear is that our philosophers, ethicists and society at large, will ignore the issues that will inevitably present themselves until . . . they actually present themselves. And these issues require more than a few years of thought.

The easiest and cheapest thing that can be done with this topic is to say that we shouldn't talk about it because it is subject to mockery. If people disagree with these points let them argue seriously and not substitute cheap derision for serious discussion. I could argue that some of the types of technology that I have just referred to will be actually feasible this century if scientists are inclined to achieve that result. Some will argue that Western scientist will not do the kinds of morally questionable activity necessary to develop some of these technologies.

First, remember that North Korea developed a nuclear bomb, albeit long after the West. And if you think North Korea will be constrained by morality or our conception of human rights when proceeding with its scientific research, reflect that this is a government that kidnapped nearly 500 civilians from other countries and starved hundreds of thousands of its own citizens—will they be reluctant to manipulate an embryo?

Second, some of what we are talking about today can be accomplished using animal rather than human DNA. Are all Western scientists adverse to playing with dolphin embryos or concerned that a dolphin with enhanced intelligence might pose a moral dilemma? I don't think so.

Third, many of these technologies will get safer as decades go by, and the benefits in treating disease will be more and more enticing.

Fourth, one of the potential technologies related to our topic today, implanting computer chips in humans, may pose less risks to a human subject than genetic engineering.

Again, we cannot assume that others around the world will reach the same conclusions we do. Rather, we need to approach this issue assuming quite the opposite: that in the absence of international consensus binding all nations, some states will attempt to manipulate human genetics and other technologies to gain some advantage, perhaps even a military advantage.

If we do not develop some international consensus on controlling this technology, and if we fail to enforce any consensus that does emerge, we can anticipate a world where rogue (and even not-so-rogue) states and non-state actors attempt to manipulate human genetics in ways that will horrify us.

Those who say mankind will never manipulate the genome for military purposes must count themselves with those who would have said that mankind would never manipulate the atom for military purposes. Or that mankind would limit itself to just enough nuclear weapons to win World War II, but not enough to endanger the entire planet.

In fact, we are already working to enhance humans for military uses. Currently, the Defense Advanced Research Projects Agency (DARPA), the Department of Defense's research arm, is pouring millions into a "Peak Soldier Performance" program aimed at creating technologies to improve a soldier's performance in combat. DARPA would like to create a soldier that eats and sleeps less without any significant long-term consequences. Will these same technologies be available to students taking their SATs?

We are not doomed to the dangerous and the immoral. But if we refuse to think of the diplomatic and ethnical issues that confront us this century because we are sublimely confident in the goodness and morality of all human actors, then we will be a bit naïve.

Mockery of those who wish to exam the issues that will confront us, or Pollyannaish belief that these issues will somehow be swept away, is just as wrong as a luddite that would cause us to halt all genetic research in its tracks. We should neither bow to the ethical problems that we will confront nor ignore them.

One of our witnesses today has put forward the idea of a treaty to help define the permissible uses of technology, specifically using the model of the Nuclear Nonproliferation Treaty (the NPT). Why the NPT and why the underlying comparison to nuclear technology?

First, the NPT assumes that countries will want to utilize nuclear power for legitimate purposes and provides a guarantee that they will have access to it. In return for forgoing the right to develop nuclear weapons, countries will receive access to civilian nuclear technology. As with nuclear power—indeed even more so—people

from all countries should enjoy the benefits of the "legitimate" uses of genetic technology, whatever we determine those to be. As we look to potential regulation, whether international or domestic, we should be concerned with ensuring the widest possible access to the beneficial uses of genetic technologies.

Second, the legitimate uses of the technologies provide the means, and may provide the cover, for a nefarious program. You can operate a nuclear reactor for the generation of electricity or for the production of weapons-grade plutonium. The same may be true of genetic and other technologies—the knowledge and infrastructure you acquire in seemingly legitimate pursuits may be put to use for nefarious purposes. Likewise, as with nuclear power—the operation of what looks like a legitimate program of research may serve as "cover" for a program that is illegitimate.

Whether or not a treaty modeled on the NPT is the best approach, it is clear that we should develop some internationally-agreed standards to prevent the misuse of these technologies. Of course, there is no IAEA for genetics and related technologies, so enforcement mechanisms will have to be developed, and that will be a major challenge. But it is imperative that we try.

The last time a new, higher level of intelligence arose on this planet was roughly 50,000 years ago. It was our own ancestors, who then said hello to the previously most intelligent species, the Neanderthals. It did not work out so well for the Neanderthals.

I thank our witnesses for joining us and look forward to their testimony.

Mr. ROYCE. Thank you very much, Mr. Chairman.

I think we all concur that genetic engineering is going to have extremely profound social and economic and political impact in the decades and the years ahead of us. The human imagination is really stretched to comprehend the full implications of this. Technology is developing so rapidly—certainly far more rapidly than public policy discussions on this, and certainly more rapidly than any consensus is developing. So this hearing today will further that discussion. In reviewing the testimony, it is very farsighted.

New human biotechnologies clearly have the potential both for great good and great harm. The upside is that diseases could be eradicated. The upside is longer, healthier lives for the human race. That is quite possible with this. On the downside, negative traits could be promoted. I think social norms and compacts would be destroyed. The specter of cloning and human animal hybrids are certainly very alarming.

In a sense, this dichotomy is not unlike another technology that we have struggled with in the sense of nuclear energy. Nuclear power provides a significant portion of our energy, yet a nuclear weapon in the wrong hands some day will probably be a real calamity. One of our witnesses is going to draw out that comparison, suggesting a treaty similar to the nuclear nonproliferation treaty in order to counter abuses of human biotechnology.

I think achieving an international consensus on limiting genetic engineering is going to be extremely difficult. It is going to be more difficult than the NPT consensus, and that consensus, unfortunately, is fraying. The task requires overcoming some vexing moral and philosophical issues in a very diverse world in which the viewpoints certainly are not going to coincide, all of them, with our western view of the autonomy of the individual and the rights of man and so forth.

The international work that has been done, mainly through the United Nations so far on this issue, is very preliminary; enforcement would be difficult. It may be impossible. Meanwhile, of course, we watch this technology speed on. It is motivated by huge potential impacts, both for good and bad. National regulation, while far more promising, has very limited effect in a world in

which ever-more countries strive for advanced science and advances in technology. This technology in the hands of rogue states could be a very grave problem.

Thank you again, Mr. Chairman. There are no easy answers, but there rarely are concerning proliferation issues. We are dealing with the opening stages of a very grave proliferation issue. Thank you for holding this hearing.

Mr. SHERMAN. I thank the ranking member.

I know none of us in our districts have been asked at a town hall whether we are spending enough time dealing with this issue, and that is why I want to thank so many of my colleagues for being here for this hearing. I had a fear that there might be just one bald guy on this side of the table.

With that, let me recognize our vice chair, Mr. Scott.

Mr. SCOTT. Thank you very much, Mr. Chairman. Appreciate you having this hearing. Very important one.

It is certainly undeniable that the growing emphasis on human gene therapy certainly represents one of the most momentous breakthroughs of the 21st century. However, with this powerful technology comes a great sense of liability and accountability.

While science has the complex task for researching human genetic engineering, the onus of responsibility has been placed on the government. It is our job to ensure that these tremendous medical advances are followed by an ethical application of such innovations.

In light of the war on terrorism and the age of nuclear proliferation, it is very important that we understand that this new technology could very well be utilized in numerous ways, including those less honorable than the original intentions of science. We are all familiar with the infamous Island of Dr. Merot as well as Joseph Mengele, the Nazi—I do not even want to say physician—corrupt mind.

There is no more piercing example what can go wrong, no more piercing example of man's inhumanity to man, than what took place in so many arenas especially during the Nazi regime, and no one personifies what could go wrong more in terms of an evil standpoint than Joseph Mengele. I would raise that specter as we move forward in these discussions.

So I hope the panelists will speak today to the implications of this new technology and address what we need to do in terms of international agreements regarding the proper use of human biotechnologies. Insights into any existing policies nationally or internationally will be particularly relevant. It also would be very informative to hear from you, our witnesses, on how human gene therapy and human biotechnologies will contribute to the future of the arms race where there is a very direct connection.

There are some specific questions, I think, that we certainly need to have before us. What specific policies, such as codes, treaties, protocols, will be the most effective way in creating a set standard for nations, and if an international governance body was created to monitor actions, would individual nations have the responsibility of ensuring that ethical behavior is being followed or would the onus rest on the international body itself? Very, very important question here.

And, finally, nations have always prided themselves on a sense of diversity and uniqueness. The question becomes then: How can we protect the individuality of intelligence while promoting the regularity of moral behavior?

I look forward to your testimony.

Thank you, Mr. Chairman.

Mr. SHERMAN. Thank you.

Let me now recognize Mr. Tancredo.

Mr. TANCREDO. I have no statement.

Mr. SHERMAN. Thank you.

Mr. Green?

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing.

And I would like to welcome our panelists.

I am used to discussing these issues in the Health Subcommittee before the Energy and Commerce Committee, and this is the first time I have spoken about this issue in an international context, and let me quickly add that there are very real and yet unintended consequences of our own Federal restriction in our country and our states' inability to keep up with the world-class embryonic cell research being performed in other countries.

While the support of Federal funding and U.S. scientists have long led the world in cutting-edge medical research, however, the current policy carves out an entire field of research with which we cannot compete. Obvious victims in this policy are the millions of Americans living with incurable diseases and holding to the dream that a cure will become available in their lifetimes.

But then let's get back to the topic today. We are here to discuss the international agreements concerning the proper use of human biotechnologies, and I agree we should begin to think proactively about what might need to be done to address this future challenge, but it seems to me we first have to develop globally acceptable norms and standards for human genetic research and its applications to prevent future abuses.

How do we go about establishing international framework when each country has different ethical and religious perspectives on this topic? There are already several international principles that form the declarations and resolutions concerning human biotechnologies, but there is yet to be a multilateral treaty on this issue reflecting the difficulty in negotiating just on the issue. However, I do think there is an emerging consensus among governments and intergovernmental organizations for the prohibition against human reproductive cloning.

I look forward to the testimony of our witnesses and their insight.

I yield back my time.

Mr. SHERMAN. Thank you.

I have long been interested in an issue I call engineered intelligence, the ability of either the genetic engineers or the computer engineers to develop a level of intelligence well beyond that of a human being, and I thought I had given up the right to talk about that in committee when I left the Science Committee. I was kind of waiting for somebody in the foreign policy scholarship area to turn this into an issue relevant to this subcommittee.

I want to welcome Dr. Jamie Metzl who is the executive vice president of the Asia Society. Dr. Metzl authored an article recently in Democracy: A Journal of Ideas which explored the idea of international controls on genetic technologies perhaps along the lines of the NPT.

I want to thank you for your article, thank you for the testimony you are about to give, and thank you for converting this issue clearly into an issue relevant to those who focus on non-proliferation treaties.

Dr. Metzl?

STATEMENT OF JAMIE F. METZL, PH.D., EXECUTIVE VICE PRESIDENT, ASIA SOCIETY

Mr. METZL. Thank you, Mr. Chairman, members of the committee. It is a tremendous honor for me to be here.

I am here testifying before you today because I believe, as you do, Mr. Chairman, that perhaps the greatest foreign policy challenge of our time will ultimately be how we as Americans and as an international community deal with our growing ability to manipulate our genetic makeup. How we responsibly nurture and manage that power and how we negotiate some sort of international protocol to govern these new capabilities will play a significant role in defining our nation's and our world's security for generations to come.

And I might add I am glad that there are so many young people in the audience here today because this is an issue that next generations will surely inherit.

Although the prospect of human genetic modification is terrifying to many, it is a reality and potentially a very positive reality of our future. My essential point today is that as difficult as it will be to establish an international framework for maximizing the benefits and minimizing the dangers of this revolutionary advance, we must supercharge our process for seeking such an outcome. A completely unregulated international policy environment surrounding these promethean capabilities will ultimately delegitimize critically important research, destabilize international affairs, and potentially harm both our country and the human race at large.

Given how far we have come to date, it is inevitable that our ability to manipulate the human genetic code will steadily increase into the future. This development will have tremendous potential to help alleviate human suffering and improve our life, as a number of the members of the committee mentioned. But it would be dangerously Pollyannaish of us to not recognize that the potential dangers inherent in these advances will also have the ability to maximally destabilize the international order unless we start thinking now about how we as a global community can work together to both unleash the promise of the science and prevent the worst abuses.

It is sometimes difficult for those of us who support this work to be honest about the dangers because this honesty is often seized upon by those who oppose the research and its applications altogether. Nevertheless, we must.

As we develop an ever greater ability to influence our genetic makeup, scientists around the world will race to push the bound-

aries of what is possible. Standards across the globe and within communities will continue to vary regarding what is acceptable, as Congressman Green has mentioned, and very importantly, competitive pressures will push this process forward at warp speed.

In today's increasingly globalized and competitive world economy, individuals, corporations, and states tirelessly seek even the smallest advantages over competitors that can then be leveraged into industry-transforming gains. It is extremely difficult, if not impossible, to believe that these types of competitive pressures will not also become drivers of the human genetic manipulation process.

Advances in the life sciences supercharged by competition will inevitably cause conflict within and between societies based on the inherent nature of this work and on differing attitudes toward it. Within societies, significant moral and ethical concerns related to such issues as unequal access, treatment of unimplanted embryos, and genetic discrimination will continue to be debated heatedly. Between societies, particularly those with very different views on this technology due to religious, natural, or cultural differences, major fault lines will begin to emerge.

In this context, states not engaged in or opposed to this work will have four basic options. First, they can do nothing and face competitive disadvantages and the consequences of genetic manipulation by others that could impact the species as a whole, which will not be seen as a good option.

Second, they can start doing the work to "keep up with the Joneses," which is probably not acceptable for states with moral or cultural concerns and likely to start a genetic arms race.

Third, they can use coercive tactics to get others to stop, which would be extremely destabilizing internationally and most likely futile, given the ease of knowledge transmission.

And, fourth, they might develop a global governance structure to both maximize the benefits of this research and its applications and minimize the potential harms, an imperfect solution, but very likely the best option.

The challenge for the world, therefore, will be to figure out what type of global governance structure might work. Based on past efforts to negotiate an international agreement on human genetic manipulation in the U.N. and in other forums, which I have described in greater detail in my written testimony, it is clear that the lack of international consensus has thus far made meaningful progress impossible in this area.

That efforts in the U.N. and elsewhere have so far amounted to very little does not auger well for concerted action in the future. Nevertheless, it is in all of our interests to think about what such a structure might look like and what we might be able to learn from analogous models. In this context, one model, as the chairman pointed out, that might be particularly applicable is that of the nuclear nonproliferation treaty.

As you know, the NPT has limited the spread of nuclear weapons by establishing limits on which states can legitimately maintain such weapons and providing a set of incentives to encourage nonnuclear armed states from following suit.

Obviously, as was mentioned, the NPT has come under increasing strain and is far from perfect. That said, the treaty still boasts

an overall impressive track record and could be a good starting point at least for thinking about how to prevent the genetic arms race.

There are a number of common characteristics between the potential for a nuclear arms race and the potential for a genetic arms race. Both deal with the implications of cutting-edge technologies whose applications become increasingly accessible to wider groups of people and states. Both represent capabilities that have enormous potential to improve people's lives, matched by a similarly great potential to harm them. Both represent technological capabilities developed in more advanced countries that become desirable the world over.

What might an NPT-like framework for human genetic engineering look like?

First, states possessing greater knowledge in the field of applied genetics could share basic science capabilities with states that agree to accept common protocols for human genetic manipulation.

Because scientific standards will change over time, we would, second, also need to establish an international advisory committee of experts and ethicists who could report of the latest global country-by-country developments in human genetic engineering and regularly re-examine the basic tenets of the treaty, including the list of abuses outlined in it, which would be extremely tricky.

Third, those states that allowed violations of the treaty on their territory would be required to immediately stop violating activity or face sanctions potentially including a limitation of their access to some of the benefits of the genetic manipulation process.

Significant problems with this approach are clear, which I have outlined in my written testimony, but may not suggest a better course.

It is certainly premature to begin drafting a genetics abuse nonproliferation treaty today because the science does not yet exist to create designer babies based on meaningful human line germline genetic modification that many people are most worried about, but, as the chairman pointed out in your opening remarks, that does not mean that we need to wait in order to move this process forward.

But my message today is that this science is moving extremely fast and that we must kickstart a national and global dialogue about a policy structure that can protect and promote important scientific advances while avoiding a self-destructive genetic arms race.

We may find this process takes us in an entirely different direction without any bearing to the NPT. We do not know. But we do know that the consequences of inaction will be great and that we must begin addressing this challenge with a far higher level of attention than we are now affording it.

As a start, I believe this committee could call for the establishment of a commission to explore the national security implications of the genetics revolution and how the United States and the world can best prepare to face the coming challenge.

Far more will, of course, need to be done, and I look forward to engaging in further dialogue with members of the committee and the other experts on this panel regarding what these steps might

be. But I commend you, Mr. Chairman, on this important hearing and your role in kickstarting this critically important process for the future of our country.

Thank you very much.

[The prepared statement of Dr. Metzl follows:]

PREPARED STATEMENT OF JAMIE F. METZL, PH.D., EXECUTIVE VICE PRESIDENT, ASIA SOCIETY

Mr. Chairman and Members of the Committee,

Thank you for inviting me to testify before you today. It is an honor for me to be here.

When our descendants two hundred years from now look back at our present age and ask themselves what were the greatest foreign policy challenges of our time, I believe that terrorism, as critically important as it is, will not be on the top of their list. I am here testifying before you today because I believe that how we as Americans and as an international community dealt with our new abilities to manage and manipulate our genetic makeup will be.

It has been only 55 years since Watson and Crick deciphered the construction of DNA, and humankind has made monumental progress towards understanding our genetic code since then, and significant progress in manipulating the genetic code of plants and animals. But a relatively short time from now, a period counted in decades, our abilities to manipulate the human genetic code will very likely be substantially enhanced. This development will have tremendous potential to help alleviate human suffering and improve our lives. It will also have the potential to maximally destabilize the international order unless we start thinking now about how we as a global community can work together to prevent the worst abuses.

These wondrous advances in our technological abilities are, almost literally, a goose that lays a golden egg which we must protect. We must also not let the necessary dialogues about the need to establish global norms for human genetic research and applications be used as a front for those who oppose this important work altogether. But it would be dangerously Pollyannaish of us to not recognize the potential dangers inherent in these advances and to not begin thinking proactively about what might be done to address this future challenge.

Whether it arrives a decade from now, or more, the day will come when the human race, or at least a subset of us, will have the ability to take control of key aspects of our own evolution. While national and global debates on such issues as in-vitro fertilization (IVF), stem cell research, and genetically modified organisms (GMOs) have begun to open people's mind to the challenges and opportunities of revolutionary advances in the life sciences, America and the world remain dangerously unprepared for the international genetic "arms race" that could one day emerge. To maximize the benefits of these new capabilities while minimizing the potential harms, and to keep popular fears of this enormous transformation from overcoming its potential contribution to the quality and security of human life, the world community must develop new standards for human genetic enhancement and an enforcement structure that nurture this research and its beneficial application, but simultaneously prevent their most dangerous abuses.

As the convergence of complementary and mutually reinforcing advances across the fields of nanoscience, biotechnology, information technology, human fertility, gene therapy, molecular biology, and cognitive science make the arrival of more revolutionary capabilities in human reproductive, or "germline," engineering inevitable, our species will become equipped with the Promethean ability to manage our own evolutionary process to an extent and at speeds that Charles Darwin never could have imagined. As opposed to the somatic gene therapies already in use today that target non-reproductive cells, germline technology alters reproductive cells at the outset of the fertilization process, allowing genetic changes to be replicated in every ensuing cell.

While germline engineering is likely not being carried out on humans today (although we cannot be one hundred percent sure of this), the process is already being used widely in experiments with laboratory animals such as mice. Scientists disagree over the timeframe, but most generally accept that this technology will relatively soon reach a stage of development where it could be used on humans.

Already today, the pre-implantation genetic diagnosis (PGD) process enables parents to select from among their fertilized eggs prior to re-implantation during the In Vitro Fertilization (IVF) process. PGD is today being used in approximately seventy-five percent of IVF clinics across the United States to screen fertilized eggs for certain genetic diseases such as Down Syndrome, Cystic Fibrosis, and Tay Sachs,

to select the gender of one or more fertilized eggs to be implanted into women, and for other reasons. As our ability to "read" the genetic code from the cells extracted in the PGD process becomes greater, prospective parents will have increasingly more information that will inform their decisions about which fertilized eggs to implant. It might well be the case that this could become the reproductive method of choice for some group of parents seeking to maximize, according to their own criteria, the genetic inheritance of their children.

At some point in the more distant future, an additional step to this process might allow genetic material from fertilized eggs to be swapped out and replaced by genetic material from a different fertilized egg from the same batch, or from an artificial chromosome with a targeted genetic alteration. As these capabilities advance, they will hold the key to potentially massive enhancements to human life and well-being.

Just as advances in agriculture, sanitation, and health care have dramatically enhanced the length and quality of our lives (and transformed whatever an alternate evolutionary process might have been), so to will advances in bioengineering help secure and enhance our future—extending our lives, making us immune to some genetic diseases, massively expanding our memory capabilities, and expanding our sense perceptions to only name a few possibilities. Enormous hurdles exist on the scientific, cultural, and legal levels to making these enhancements possible, especially in light of the complex mix of genetic and environmental factors that underpin most human attributes and behaviors. But these hurdles will have a greater impact on determining "when" major breakthroughs will occur than on "if" they will occur.

This process will likely be supercharged by global competitive forces. Although spectacular debates have emerged within societies and in international fora on many issues related to the human genetic manipulation process, and although some states and groups of states have mandated and will continue to establish tough restrictions on these capabilities, it will be extremely difficult to stop motivated states or groups of individuals from engaging in human genetic manipulations that go beyond any commonly accepted norms that may emerge. On the contrary, some states, groups and individuals will have an increasing incentive to move forward aggressively.

In today's increasingly globalized and competitive world economy, individuals, corporations, and states tirelessly seek even the smallest advantages over competitors that can then be leveraged into industry-transforming gains. It is extremely difficult, if not impossible, to believe that these types of competitive pressures will not also become drivers of the human genetic manipulation process. On the contrary, it is far more likely that humans, or at least some groups of us, will seek to provide our children with the competitive advantages that would come with exceptional gene-driven capabilities. The developments will create enormous competitive pressures within and between societies that will, if unchecked, propel the human species into the unknown territory of human genetic manipulation at warp speed.

Within societies, social Darwinists have long claimed that the elites were smarter and had a greater natural capacity than the masses, a concept that has clearly been proven wrong as opportunity has democratized. But if, in addition to having better nutrition, more exposure to ideas, and better schooling, the rich and privileged within a society also had genetic manipulations that actually made their brains function better, would it begin to make sense for these enhanced people to assume leading roles in running institutions and governments and making decisions on behalf of the less enhanced populace? Uneven genetic enhancement could, in this manner, be a pre-cursor to genetic discrimination and place enormous strains on the democratic process.

Between societies, enormous conflict would likely ensue between the states that ban or restrict new forms of human genetic manipulation and those that do not. If the current debate over genetically modified crops is anything to go by—where many Europeans see an existential threat to their way of life and Americans and Asians are generally far less concerned—the stress on international systems over genetically modified people would be monumental. As in the GMO debate, countries opposed to the human genetic manipulation process will increasingly feel that those engaged in these activities are affecting their fate, and the genetic make-up of their species, in ways the opposing countries cannot control—a recipe for heated conflict.

But, if a specific country, corporation, or a group of motivated individuals were to move forward with an aggressive genetic enhancement program while other countries banned or limited these activities, competitive pressures would force the other countries to choose between (1) doing nothing and accepting a deteriorating relative position in the world (if the increased capabilities of the genetically enhanced people proved competitively decisive); (2) beginning such genetic enhancement activities themselves in order to keep up; (3) working to halt the genetic enhancement activi-

ties going on in the offending country or other entity by means of coercion; or, (4) seeking to develop a global governance structure that attempts to influence the behavior of all state and non-state actors.

Among these options, doing nothing will become increasingly untenable in light of global competition, a genetic arms race absent of any global norms or standards will come to seem increasingly dangerous, and using coercive measures to stop scientific advance elsewhere will be massively destabilizing and likely futile given the inherent nature of knowledge transmission. The fourth option, developing some type of permissive global governance structure, will likely come to be seen as the best, or at least the least bad, option.

While each nation will be forced to develop policy approaches for maximizing the benefits and minimizing the dangers of genetic manipulation, the global competitive environment, the ease of transfer of scientific knowledge, and the implications for all humans of germline manipulations done to any human will require a far more concerted approach.

The challenge for the United States and the world, therefore, will be to maximize the benefits of the scientific progress, while seeking to develop globally accepted norms and standards for human genetic research and its applications that can prevent the worst abuses and establish an international framework for addressing and mitigating the conflicts that will emerge. Although it is likely premature for the world to develop such a structure at this time, we must all begin thinking about and discussing what such a future structure might look like. This process has in fact already begun, but it has so far amounted to very little.

In 1997, UNESCO adopted the *Declaration on the Human Genome and Human Rights*, a non-binding document that claimed to prohibit "practices which are contrary to human dignity, such as reproductive cloning of human beings." The following year, the Council of Europe adopted its *Convention on Human Rights and Dignity with Regard to Biomedicine*, which asserts that interventions aimed at modifying the human genome can only be undertaken "for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendents," although this protocol has only been ratified by 20 of the Council's 41 member states.[1]

In February 2002, the United Nations Ad Hoc Committee for an International Convention Banning Human Reproductive Cloning began negotiations intended to lead to a binding treaty. The Committee convened high-level exchanges by experts on genetics and bioethics and drafted text that was eventually brought to the General Assembly for a vote. Over the years of negotiations, the members of the UN General Assembly Legal Committee could not come to agreement between the countries that wanted to allow research or therapeutic cloning and only ban human reproductive cloning (including China, Great Britain, Singapore, South Korea, and Sweden), and those countries (including the United States, the Vatican, and others) who wanted to ban all forms of cloning. Although the *United Nations Declaration on Human Cloning*, adopted in March 2005 by a vote of 84 in favor, 34 against and 37 abstentions, called on all member states to: "to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life," this non-binding resolution had neither any significant impact or influence nor any influence on those countries that disagreed.

The weakness of all of these documents and the standards they seek to set is obvious based on the lack of both consensus and enforcement power. As they did in the UN resolution, the countries with the most to gain from and the greatest hopes for this scientific advancement are and will remain extremely reluctant to have their activities limited in any way by others, especially if they see efforts to build international consensus as carrying water for an anti-life sciences agenda. These documents also say very little about establishing standards for how even research that fits in principle into accepted norms should be carried out.

Some genetic manipulation, for example, might be considered acceptable if chromosomes are inscribed with genetic instructions making it impossible for introduced mutations to be transferred to future generations, or if artificial chromosomes contain chemical "switches" that can be used to activate or de-activate specific genes. Although the expertise currently exists to make a germline genetic mutation non-inheritable, the world community, even in a context of general agreement on what standards should be, would still have to figure out a way of ensuring that any human genetic manipulations are carried out in a matter which does this. The issue in this case is not whether a mutation is introduced, but how it is introduced.

The challenge faced by any international regime could therefore be to both prevent whatever are agreed to be abuses of the genetic manipulation process and at

[1] http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=1&DF=&CL=ENG

the same time ensure that those engaged in legitimate activities are doing so according to internationally accepted standards and procedures. An international regime which sought to accomplish this would have the tough dual role of being on one hand an enabler of responsible research and technological advancement, and on the other an enforcer of limitations regarding how far these activities can go.

There are few successful models in the international legal system for effectively confronting a challenge of this nature, but in spite of its flaws and limitations the Nuclear Non-Proliferation Treaty (NPT) provides one model that could be applicable in this context.

As is well known, the 1970 NPT sought to limit the spread of nuclear weapons by establishing both standards for non-proliferation by the five states permitted to own nuclear weapons (Britain, China, France, USA, and the USSR) as well as a set of incentives designed to encourage non-nuclear armed states to remain so. The non-nuclear signatories of the NPT basically agreed to refrain from acquiring or developing nuclear weapons in exchange for a promise from the five nuclear-armed states to help the others develop nuclear energy capacities for peaceful purposes.

Although the NPT has come under increasing strain as the technology required to develop nuclear arms has become far more easily transferable, as non-signatory states have transferred requisite knowledge and equipment, and as exceptions to the norms outlined in the treaty are being carved out for India, a non-signatory state, the treaty still boasts an overall impressive track record. Signatory states South Africa and Ukraine voluntarily gave up their nuclear weapons, Libya publicly renounced its secret effort to develop them, and the acquiring of nuclear weapons by non-nuclear states remains a taboo, even if a weakening one.

The potential for a genetic "arms race" and the potential for a nuclear arms race share a number of characteristics. Both deal with the implications of cutting edge technologies whose applications become increasingly accessible to wider groups of people and states, both represent capabilities that have enormous potential to improve people's lives matched by a similarly great potential to harm them, and both represent technological capabilities developed in more advanced countries that become desirable the world over.

An NPT-like framework for human genetic engineering would be incredibly difficult to negotiate because it would need to neither offend the sensibilities of powerful constituencies deeply uncomfortable with the concept of human germline engineering nor impede the beneficial development of new generations of knowledge and its applications. In addition, the standard for such a framework would need to be extremely permissive and flexible enough to keep the more scientifically aggressive countries, particularly those with the most to gain from the development of these capabilities, on board. Although this balance would be enormously difficult to develop and maintain, finding it will be critical to preventing an unimpeded, unregulated human genetic "arms race," and the conflict and unregulated abuse that could well emerge under such a scenario. If such a position could be reached, an even more difficult step would be finding ways to use a combination of carrots and sticks to try to enforce it along the lines of the NPT model.

According to a Human Genetic Modification Abuses Non-Proliferation Treaty, states possessing greater knowledge in the field of genetics would pledge to share basic science capabilities and the broadly-defined benefits of this science with those states that have agreed to accepted protocols for human genetic manipulation and to implement appropriate regulations, possibly requiring the non-inheritability of germline genetic manipulations and the banning of human reproductive cloning. As part of the ratification process, all signatory states might be required to pass enforcing legislation in their own countries based on the principles of the treaty.

Because scientific standards will change over time, such a treaty would also need to establish an international advisory committee of experts and ethicists who would report yearly on the state of development in the field of human genetic engineering globally and country-by-country. At regular intervals, the basic tenets of the treaty, including the list of what is considered to be an abuse of the genetic modification process, would need to be re-negotiated. Those states that allowed violations of the treaty on their territory would be required to immediately stop the violating activity or face sanctions, potentially including a limitation of their access to some of the benefits of the genetic manipulation process.

Three serious objections to this approach demonstrate the imperfections of such a treaty, but do not suggest a better course. The first is that states will need to develop their own standards for genetic modification before they can consider an international regime. Although this argument makes some logical sense, the danger is that the science is moving so quickly that the international community must work to establish an enforceable, if changeable, international standard or risk creating a global culture more conducive to the worst abuses.

The second is that this type of regulation, particularly if armed with enforcement mechanisms, will be used by opponents of legitimate research to advance principles antithetical to the genetic engineering process as a whole, including its many benefits. This is a real danger, although the supporters of the treaty will always be able to invoke the counter-pressure of needing to maintain a progressive and permissive framework in order in order to keep the most advanced countries on board.

Third, it is by no means clear that states will be the drivers behind the most aggressive applications of these technologies, which would potentially leave open the question of how to deal with non-state actors that could, for example, engage in such activities from ships based in international waters or, conceivably, on research platforms in space. Life sciences research today often requires tremendous resources, but this may not always be the case. And applying these technologies on an individual basis can even today be carried out on a far smaller scale. International agreement on standards, however, would help establish norms that could be enforceable in these non-national environments.

Although the prospect of human genetic modification is terrifying to many, it is a reality, and a potentially very positive reality, of our future. As difficult as it will be to establish an international framework for maximizing the benefits and minimizing the dangers of this revolutionary advance, the consequences of not doing so are severe. Allowing these capabilities to emerge completely unregulated and unchecked will ultimately serve to de-legitimize critically important research and applications, prove destabilizing in international affairs, and potentially allow actual abuses to occur that could harm individuals and our species as a whole.

I am not here today to advocate for immediately establishing a Genetics Abuse Non-Proliferation treaty. In fact, I think that establishing such a treaty is premature in light of where the science now stands, and there may be a better approach than this altogether that has yet to be proposed. I do believe, however, that this science is moving extremely fast and that we must supercharge our national and global dialogue about how to build a global policy structure that achieves our dual goals of promoting miraculous life science research and avoiding an arms race of the human race that could prove extremely dangerous to us all.

Thank you very much. I look forward to answering any questions you may have.

Mr. SHERMAN. Thank you.

On most of the topics this committee deals with, there is plenty of information out there. In contrast, we are just beginning to get involved in this one, and there is no journal on these issues. So we are going to create an email list to anybody who gives their email address to Rebecca or Don or anyone on the committee staff. We will keep you posted of further developments starting with letting you know when the transcript of this hearing is available online.

Next, I want to welcome Richard Hayes who is the executive director of the Center for Genetics in Society, a non-profit organization that is working to encourage responsible uses and effective societal governance of the new human genetic and reproductive technologies.

Dr. Hayes?

STATEMENT OF RICHARD HAYES, PH.D., EXECUTIVE DIRECTOR, CENTER FOR GENETICS AND SOCIETY

Mr. HAYES. Thank you so much, Mr. Chairman and members of the committee.

As you mentioned, I am with the Center for Genetics Society. We work at the state and national and international levels with scholars, scientists, legal experts, and with leaders in human and civil rights, women's health, social and economic justice, and the environment.

I thank you for opening up this issue and holding this hearing.

I have been asked to address the question: Is there an emerging international consensus on the proper uses of the new human genetic technologies? While countries differ widely in the policies they

have adopted, I believe that in regard to the most consequential of these technologies, the answer is yes.

The new human biotechnologies have the potential for both great good and great harm. If used responsibly, they could lead to medical advances and improved health outcomes. If misapplied, they could exacerbate existing disparities and create new forms of discrimination and inequality. They could open the door to new eugenic practices and ideologies that would undermine the foundations of civil society and, indeed, our common humanity. In combination with emerging technologies, such as nanotechnology, neurotechnology, and synthetic biology, they could put agents of unprecedented lethal force in the hands of both state and non-state actors.

Our organization has surveyed human biotechnology policies throughout the world, including all 192 countries as well as binding conventions and declarations produced by the United Nations, the European Union, UNESCO, the world's anti-sports doping agency, the Council of Europe, the African Union, the World Health Organization, and the Group of 8, and I believe this review supports the following general conclusions.

First, there is widespread support for stem cell research involving embryos created but not used in the course of assisted reproduction procedures. There is similar widespread support for the use of genetic screening techniques to avoid passing serious diseases to one's offspring.

Second, there is widespread support for prohibitions on reproductive human cloning, inheritable genetic modification, and genetic screening for non-medical purposes.

Third, there appears to be widespread concern about the use of genetic technologies for so-called enhancement purposes, concern about the commercialization of human reproductive activities, and concern about international trafficking in human genetic materials.

Fourth, policies differ concerning the creation of clonal human embryos for research. Most countries that have adopted positions on this practice have prohibited it, but a significant number support it.

It is instructive to note that of the 30 OECD member countries, which together account for 84 percent of world GDP and have the most fully developed biotech research sectors, 97 percent have banned reproductive cloning, 83 percent have banned inheritable genetic modification, and 77 percent have banned genetic screening for non-medical purposes. None have explicitly approved these practices, and of those few that have not yet taken formal policies, all the indications are they would be opposed to these practices.

This record is encouraging, but it is important to note that the majority of countries worldwide have not yet adopted any policies at all on these technologies. This policy deficit is an open invitation to rogue scientists and delusional demagogs. If what I believe is the emerging policy consensus is to be meaningful, all countries will need to be part of it in one manner or another, and we will need treaties, conventions, and other agreements to seal this deal.

In my submitted testimony, I noted proposals modeled on the 1997 Landmine Treaty, Jamie Metzl's proposal for a genetic heritage safeguard treaty, the important 2002 proposal by a number of

noted legal scholars for a convention on the preservation of the human species, and other proposals. So a productive next step might be to commission a high-level task force with representation from the full range of concerned constituencies to undertake a comprehensive assessment of these and other options for global oversight.

Development and enforcement of such global agreements, as a number of you have mentioned, is not going to be easy. The boundaries between acceptable and unacceptable uses are often unclear, people are understandably reluctant to forego prospective benefits without good reason, and in a world still afflicted with racial, cultural, and national conflict, some will want to use these technologies for aggressive purposes.

These challenges are serious, but if we can mobilize the needed social and political will, there is no reason they cannot be met.

In my remaining minutes, I want to mention what I believe may be the single greatest obstacle to mobilizing the needed social and political will. In many countries, the debate over policies addressing human genotechnology has become enmeshed in the politics of the culture wars. In the United States, the result has been a stalemate and a policy vacuum at the Federal level and hastily conceived programs at the state levels. At the international level, the result has been stalemate and avoidance.

Opinion surveys, however, show broad support for what might be called a principled middle-ground position concerning these technologies. The majority of people in America and in much of the rest of the world do not necessarily oppose medical research involving human embryos, but they strongly reject reproductive cloning and the engineering or selecting of the social traits of future generations.

So the issues raised by the new human genetic technologies transcend conventional ideological divides. Many women's health advocates oppose such technologies that put women's health at risk and commodify reproduction. Human and civil rights leaders are wary of a new free-market eugenics that could stoke the fires of racial and ethnic hatred. Disability rights activists charge that a society obsessed with genetic perfection could come to regard the disabled as "mistakes" whose existence should have been prevented, and many environmentalists see human genetic modifications and other hubristic technology being promoted with little regard for long-range consequences.

Similarly, it is misleading to try to categorize countries as either liberal or conservative based on their positions on human genetic technology. Western European countries, widely regarded as bastions of secular liberalism, have adopted some of the strictest regulations over human genetic technology in the world, and this derives from their generally social democratic political culture and from their firsthand experience in the 20th century with eugenics, euthanasia, and the Holocaust. Europeans know all too well what can happen when ideologies and policies that valorize the creation of "genetically superior" human beings come to the fore.

For different but related reasons, developing countries, such as South Africa, Vietnam, India, and Brazil, have likewise adopted strong policies of social oversight and control.

Despite many statements to the contrary, the genie is not out of the bottle. I sincerely believe we have the time and the capability to get ahead of the curve and do the right thing. But it will require enlightened, committed bipartisan leadership at the national and international levels and very soon.

Thank you so much.

[The prepared statement of Mr. Hayes follows:]

Testimony of Richard Hayes, Ph.D.,
Executive Director, Center for Genetics and Society

House Foreign Affairs Committee
Subcommittee on Terrorism, Nonproliferation and Trade

IS THERE AN EMERGING INTERNATIONAL CONSENSUS ON THE PROPER USES OF THE NEW HUMAN GENETIC TECHNOLOGIES?

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Testimony of Richard Hayes
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Is There An Emerging International Consensus on the Proper Uses of the New Human Genetic Technologies?

Mr. Chairman and members of the Committee:

Thank you for inviting me to discuss what I and many others believe is one of the most urgent topics on the world agenda today: the need for international agreements concerning the proper use of the new human biotechnologies.

My name is Richard Hayes and I am executive director of the Center for Genetics and Society. CGS is a public affairs institute working in support of the socially responsible governance of the new human biotechnologies. We work at state, national and international levels with scholars, scientists, legal experts and leaders in the fields of human rights, civil rights, women's health, social and economic justice and the environment.

I've been asked to address the question, "Is there an emerging international consensus on the proper uses of the new human genetic technologies?" While countries differ widely concerning many aspects of the policies they have adopted, I believe that in regard to the most seriously consequential of these technologies, the answer is "Yes." I want to begin with introductory comments, review genetic technologies and practices of special concern, highlight areas around which consensus appears to be developing, and conclude with some observations on the challenges we face in translating that consensus into formal policy.

I. Introduction

The new human biotechnologies have the potential for both great good and great harm. If they are developed and used responsibly and in accordance with commitments to human rights and social justice, they could lead to medical advances and improved health outcomes. If misused they could exacerbate existing health disparities and lay the basis for new forms of discrimination and inequality. They could open the door to new eugenic practices and ideologies that would undermine the foundations of civil society and indeed our common humanity. In combination with emerging technologies such as nanotechnology, neurotechnology and synthetic biology, they could put agents of unprecedented lethal force in the hands of both states and non-state actors.

If the benefits of these technologies are to be realized and the dangers avoided, effective regulatory oversight and control will be needed at both national and international levels. Many

countries have already adopted comprehensive national policies of the sort needed, but most have not adopted any policies at all, and international agreements are few and partial. International initiatives that would encourage individual countries to adopt best practices, and that would draw needed lines and address cross-border, trade and technology transfer issues, are long overdue.

II. Technologies and Practices of Special Concern

There are scores, if not hundreds, of new human biotechnologies and practices, but I'm going to focus on a subset widely recognized as being of particular consequence. These are new technologies of human genetic engineering that have the potential to alter the nature of human nature and society at the most fundamental levels. I'll focus further on ones that are currently practicable or could become practicable in the near future, and thus might be of particular concern to policymakers and the public.

The technologies that I'll address fall into three general categories: human genetic modification, human genetic trait selection, and human cloning. An outline of these is shown in **Attachment A.**

Human genetic *modification* means manipulating and changing the genes in living human cells. Human genetic *trait selection* means selecting eggs, sperm or embryos that possess genes associated with particular traits, without actually modifying those genes. And human *cloning* means the creation of either human embryos or full term human children that are genetically identical to previously existing human beings, whether living or dead.

Let's first consider human genetic modification. A convenient device for considering types of human genetic modification and their societal implications is the box shown in **Section I** of Attachment A.

Human genetic modification has been proposed for both "therapeutic" and "enhancement" purposes. "Therapeutic" purposes are those that return a person suffering from an illness or deficiency to a condition of health or wholeness. "Enhancement" purposes go beyond considerations of normal health and seek to make a person "better than well." Some applications of human genetic modification appear to fall into a gray area between "therapy" and "enhancement," but for most applications this distinction is reasonably clear.[1]

Human genetic modification can be applied at two levels, called "somatic" and "germline."[2] Somatic modifications are those that change genes in the cells of a person's body *other than* their sperm or egg cells, and thus do not make changes that are inheritable. Germline modifications change the genes in a person's egg or sperm cells, and are thus passed on to all succeeding generations.

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[1] I discuss the distinction between therapy and enhancement further in Section IV.

[2] "Somatic" derives from the Greek *soma*, meaning *body*. "Germline" refers to the germinal or seed cells, ie, the eggs and sperm.

Together, these aspects of human genetic modification define four types of applications: "somatic therapy, "somatic enhancement," "germline therapy," and "germline enhancement."

Somatic therapy is commonly known as "gene therapy." Examples of somatic therapy include attempts to cure cystic fibrosis or severe combined immunodeficiency disease ("bubble boy" disease), by inserting healthy genes into lung tissues or bone marrow cells to correct dysfunctional genes. Clinical gene therapy trials have been underway since the early 1990's.

Examples of somatic enhancement might involve inserting genes into the muscle or lung tissues of athletes to increase their strength or respiratory capacity. At the present time such interventions have not been attempted in humans.

Examples of germline therapy might involve inserting healthy genes into an early-stage embryo that is found to contain the genes causing cystic fibrosis or bubble boy disease. Such interventions have not been attempted, but the techniques that would enable such intervention are under development.

Examples of germline enhancement might involve modifying the muscle or lung-cell genes of an early-stage embryo in an attempt to generate increased muscular strength or respiratory capacity in the child that that embryo gives rise to. Germline enhancement has also been seriously proposed as a means of creating people with such novel cognitive, psychological, and behavioral traits that they would constitute a new, "post-human" species, incapable of interbreeding with "normal" humans.

Next, let's consider human genetic *trait selection,* noted in **Section II** of Attachment A. This process doesn't actually *modify* the genes in any human cells. Rather, it involves determining which genes are carried in particular eggs, sperm and early embryos, and using only those which carrying preferred genes to create a child.

Human genetic trait selection can be used for medically-related purposes or for non-medical or "social" purposes.

An example of medically-related genetic selection would be testing a set of single-cell zygotes created via IVF procedures for the genes that cause cystic fibrosis or Tay-Sachs, and only using zygotes free of those genes to initiate a pregnancy. Such medically-related genetic trait selection – commonly referred to as "preimplantation genetic diagnosis", or PGD – is available in many countries, although use is typically limited. In cases where there is a risk of passing on a sex-linked disease such as Duchenne muscular dystrophy, PGD can be used to ensure that the child born will be of the sex that does not carry or have the disease.

An example of social genetic selection would be testing embryos created using IVF procedures to ensure that one's child is a boy or a girl, independent of any evidence of risk of a sex-linked disease.

Trait selection can't easily be used for *enhancement* purposes, if at all, because it involves selecting from genes that span the normal range of human genetic variation. And it is unclear to what extent it can be used to select for most social traits, given that these typically depend upon a

multitude of genes, and for technical reasons it is difficult to select embryos for more than one or two genes at a time.

It's important to note that the "medical/social" distinction, like the "therapy/enhancement" distinction, can in some instances be ambiguous or subject to interpretation. Many people with disabilities, for example, don't believe that their conditions are medical ones that need to be prevented or cured. Policies on human genetic technology will need to take such concerns into account.

Finally, we come to the topic of human cloning, noted in **Section III** of Attachment A. Once more, there are two different applications of cloning technology. *Research cloning* refers to the process of creating a clonal human embryo for experimental purposes.[3] *Reproductive cloning* also involves creation of a clonal human embryo, but rather than being used for experimental purposes it would be implanted in a woman's womb, gestated and brought to term as a born child.

Attachment A doesn't include embryonic stem cell research, because such research does not *per se* involve the modification or selection of particular human genes. However, some forms of embryonic stem cell research involve research cloning.[4]

A Broad Assessment

The benefits and risks that the new human genetic technologies entail have been debated for well over a quarter century. Rather than attempt a summary of that complex debate here, I'd like to offer what I believe is a fair assessment of where there appear to be rough areas of general agreement among experts, policymakers, and the general public, both domestically and internationally, and where it is clear there is disagreement. After that I'll review the policies that have been adopted in particular countries and by intergovernmental bodies.

I believe it's fair to make the following generalizations:

- The development and use of *somatic therapy* is widely considered to be acceptable. Positive results to date have been sparse, but recent experimental treatments for leukemia and retinal eye disease have offered new encouragement.
- *Germline enhancement* is widely considered to be unacceptable. It serves no compelling medical purpose, could generate new and deep forms of inequality, gives individuals in one generation new and profound power over the life conditions of individuals in another without

[3] Research cloning is otherwise known as *somatic cell nuclear transfer* (SCNT). A clonal embryo results when the nucleus of a somatic cell (eg, a skin or muscle cell) is transferred into a female egg from which the nucleus has been removed.

[4] The Center for Genetics and Society supports embryonic stem cell research and public funding of it, and does not oppose the use of cloning for research purposes if carefully regulated. At the same time we believe that the highly polarized public debate over these topics has led many supporters to overstate the benefits that the use of cloning techniques might offer, and to underplay its risks and limitations. These latter include the large number of women's eggs required, the fact that it opens the door to human reproductive cloning and inheritable genetic modification, and that it is costly.

their consent, and could change the nature of human nature and society in unpredictable ways.

- *Somatic enhancement* is widely considered to be highly problematic. It serves no compelling medical purpose, and could introduce new forms of inequality. It is less consequential that germline enhancement because at least in the first instance it only affects a single individual and consent would be easy to obtain. But its impact on the nature of human values and human relationships could be profound.

- *Germline therapy* at first appears to be a difficult call. Most people strongly support therapeutic applications of genetic science, but they also realize that the manipulation of inheritable genetic traits crosses a consequential barrier. In the great majority of instances, couples at risk of passing on a serious genetic disease can ensure that their child is disease-free by means of medically-related trait selection, thus obviating the need for the far more complex and risk-prone intervention that germline modification would entail.

- *Human genetic trait selection* is generally supported if it is used to allow a couple at risk of passing on a serious genetically-based illness to their child a chance to avoid doing so. However, it is generally opposed for non-medical or "social" purposes, such as ensuring that the child is of a desired sex.

- *Human reproductive cloning* is almost universally rejected. It serves no justifiable purpose and raises profound social risks.

- The use of *cloning for research purposes* has become a divisive issue, in the United States and other countries, with many strongly supportive and others strongly opposed. Research cloning has become especially contentious because it has been seen as a key element in some forms of stem cell research. However, recently developed procedures that allow derivation of cells similar to embryonic stem cells from normal body cells may reduce or eliminate the utility of using clonal human embryos to derive stem cells.[5]

- *Embryonic stem cell research* using embryos created in the course of *in vitro* fertilization procedures, but left unused, is generally but cautiously supported.

With this background, what can we say about the policy response to date on the part of individual countries around the world, and by intergovernmental bodies?

[5] Gina Kolata, "Scientists Bypass Need for Embryo to Get Stem Cells," *New York Times*, November 21, 2007, available at http://www.nytimes.com/2007/11/21/science/21stem.html

III. Policies

A. Policies in Countries Around the World

Summaries of policies for key technologies and practices are shown in **Table 1** and **Table 2** (on the next page). Full tables, including definitions of the policy categories used, are shown in **Attachments B** and **C.** A table showing data for embryonic stem cell research is shown in **Attachment D**.

TABLE 1: All countries (192 total)

	Number of countries in which the practice is explicitly:	
Practice	*Prohibited*	*Allowed*
Reproductive cloning	59	0
Germline modification	44	0
Social trait selection	36	0
Research cloning	40	14
Embryonic SCR using IVF embryos	12	44
Medically-related trait selection	6	30

Among those countries that have adopted policies addressing these practices, reproductive cloning, germline modification, and social trait selection have been unanimously prohibited. Of countries that have adopted policies on research cloning, the majority have prohibited it, but this position is by no means unanimous, as 14 countries have explicitly sanctioned it. Opinion is also divided regarding embryonic stem cell research using embryos previously created in the course of fertility treatments, although far more allow it than prohibit it. Medically-related trait selection is widely sanctioned, although several countries prohibit it. Data on policies addressing somatic enhancement have not yet been compiled.

Additional insight can be had by reviewing the status of policies in those countries that are members of the OECD. These countries account for nearly one-fifth of the world's population and fully 84% of the world's GDP, and support the most fully developed human biotechnology research sectors. They include many European countries, but also include non-European countries such as Japan, Korea, Turkey, Mexico, Canada, Australia, and the United States. Table 2 shows that between 77% and 97% of OECD countries have banned reproductive cloning, germline modification and social trait selection, and that none have explicitly approved it. A majority have also banned research cloning, although 27% have explicitly sanctioned it. Strong majorities have approved embryonic stem cell research using IVF embryos, as well as medically-related trait selection, although several countries have prohibited both of these. Data for all 30 OECD countries is shown in **Attachment E.**

TABLE 2: OECD countries (30 member countries)

	Percent of countries in which the practice is explicitly:	
Practice	*Prohibited*	*Allowed*
Reproductive cloning	97%	0
Germline modification	83%	0
Social trait selection	77%	0
Research cloning	63%	27%
Embryonic SCR using IVF embryos	13%	73%
Medically-related trait selection	10%	67%

B. Policies Adopted by Intergovernmental Organizations

What policies have been adopted or promoted by major intergovernmental organizations? I review key organizations in turn.

1. The United Nations

In 2001 France and Germany proposed a binding UN treaty calling for a prohibition on human reproductive cloning. An early procedural vote suggested unanimous support for this measure. Subsequently, a significant number of countries expressed opposition to banning reproductive cloning without simultaneously banning research cloning. This led to extended controversy, and the debate became, essentially, a debate over the acceptability of research cloning. By 2003 it became clear that a consensus concerning research cloning could not be achieved. In 2005 a non-binding declaration opposing both research cloning and reproductive cloning was brought to a vote. It received a plurality of votes (46%), which under UN rules makes it the official UN position. Both opponents and supporters of research cloning claimed vindication of their positions. Supporters of research cloning noted that as the declaration was non-binding, and as 18% of UN member states supported research cloning, the vote was of questionable significance. Opponents of research cloning noted that a larger number of countries had expressed strong opposition to research cloning than had initially been anticipated.[6]

2. UNESCO

The United Nations Educational, Scientific, and Cultural Organization (UNESCO) Bioethics Programme is led by the International Bioethics Committee (IBC), consisting of 36 outside

[6] See Center for Genetics and Society, "The United Nations Human Cloning Treaty Debate, 2000–2005," June 1st, 2006, available at http://www.geneticsandsociety.org/article.php?id=338.

experts, and the Intergovernmental Bioethics Committee (IGBC), consisting of representatives from 36 member states. The Bioethics Programme has sponsored three major nonbinding international agreements:[7]

1. The *Universal Declaration on the Human Genome and Human Rights* was adopted unanimously by the UNESCO General Conference in 1997 and ratified by the UN General Assembly in 1998. The Declaration calls for member states to undertake specific actions, such as the prohibition of "practices which are contrary to human dignity, such as reproductive cloning of human beings." It also calls on the IBC to study "practices that could be contrary to human dignity, such as germline interventions."

2. The *International Declaration on Human Genetic Data* was adopted in 2003. The declaration is intended "to ensure the respect of human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic and proteomic data, and of the biological samples from which they are derived, in keeping with the requirements of equality, justice and solidarity, while giving due consideration to freedom of thought and expression, including freedom of research."

3. The *Universal Declaration on Bioethics and Human Rights* was adopted in 2005. The Declaration used a human rights framework to establish normative principles in fifteen areas, including human dignity and human rights; equality, justice and equity; and protecting future generations. These principles cover a wider range of issues than the previous two bioethics Declarations.

UNESCO took the lead in negotiating the International Convention Against Doping in Sports, in collaboration with the World Anti-Doping Agency (WADA), which had earlier been established by the International Olympic Committee. It includes language banning the use of genetic technology to enhance athletic performance in official athletic events, referred to as "gene-doping." The Convention entered into force on February 1st, 2007, and has been ratified by 86 countries (not including the United States). More are expected to sign prior to the Beijing Olympics in August.[8] The earlier Copenhagen Declaration on Anti-Doping in Sport has been signed by 192 countries, including the United States.[9]

3. Council of Europe

The 47-member Council of Europe maintains a Bioethics Division, guided by a Steering Committee on Bioethics. The Council's Convention on Biomedicine and Human Rights was opened for signatures in 1997 and went into force in 1998. As of March 2008 it has been signed or ratified by 34 countries. It explicitly prohibits inheritable genetic modification, somatic genetic

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[7] See UNESCO, "Bioethics," at www.unesco.org/shs/bioethics

[8] UNESCO, "International Convention against Doping in Sport 2005," http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html

[9] World Anti-Doping Agency, "Copenhagen Declaration on Anti-Doping in Sport," 2003, linked from, and overview at, http://www.wada-ama.org/en/dynamic.ch2?pageCategory.id=272

modification for enhancement purposes, social sex selection, and the creation of human embryos solely for research purposes. A summary of the Convention's main articles is shown in **Attachment F.** The Convention is perhaps the single most well-developed intergovernmental agreement extant addressing the new human biotechnologies. Human reproductive cloning was banned by an Additional Protocol on the Prohibition of Cloning Human Beings, which went into force in 1998.[10]

4. European Union

With 27 member states, the European Union (EU) and its constituent bodies play a major and growing role in European policy integration. Article 3 of the EU's Charter of Fundamental Rights, entitled "Rights to the Integrity of the Person," prohibits human reproductive cloning, "eugenic practices, in particular those aiming at the selection of persons," and "making the human body and its parts as such a source of financial gain."[11]

5. African Union

At its 1996 Assembly of Heads of State, the African Union (then called the Organization of African Unity) approved a Resolution on Bioethics that affirmed "… the inviolability of the human body and the genetic heritage of the human species" and called for "supervision of research facilities to obviate selective eugenic by-products, particularly those relating to sex considerations."[12]

6. World Health Organization

In 1997 the WHO called for a global ban on human reproductive cloning.[13] In 1999 a *Consultation on Ethical Issues in Genetics, Cloning and Biotechnology* was held to help assess future directions for the WHO. The draft guidelines prepared as part of this consultation, *Medical Genetics and Biotechnology: Implications for Public Health*, called for a global ban on inheritable genetic modification. In 2000 WHO Director-General Gro Harlem Brundtland

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[10] Council of Europe, "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," 4 April, 1997; available at http://conventions.coe.int/treaty/en/treaties/html/164.htm

"Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings," 12 January, 1998; available at http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm

[11] *The Charter of Fundamental Rights of the European Union*, Article 3, text available from http://www.europarl.europa.eu/charter/default_en.htm

[12] Organization of African Unity, Assembly of Heads of State and Government, 32nd Ordinary Session, Cameroon, July, 1996, "Resolution on Bioethics" (AHG/Res 254[XXXII]), paragraphs 3b and 3f; available at http://www.africa-union.org/root/au/Documents/Decisions/hog/6HoGAssembly1996.pdf

[13] World Health Assembly, Resolution 50.37, on "Ethical, Scientific and Social Implications of Cloning in Human Health," Geneva, 1997; not currently available on the web. The resolution was reaffirmed in 1998, in Resolution WHA51.10 (same title), available at http://www.who.int/ethics/en/WHA51_10.pdf.

reiterated opposition to human reproductive cloning.[14] In September 2001 the WHO convened a meeting to review and assess "recent technical developments in medically assisted procreation and their ethical and social implications." The review covered, among other items, preimplantation genetic diagnosis, intracytoplasmic sperm injection (ICSI), and cryopreservation of gametes and embryos. In February 2002 the WHO repeated its opposition to human reproductive cloning and cautioned against banning cloning techniques for medical research. In October 2002 the WHO established a Department of Ethics, Equity, Trade and Human Rights to coordinate activities addressing bioethical issues.[15]

7. Group of Eight

At its June 1997 summit in Denver, Colorado, the G-8 called for a worldwide ban on human reproductive cloning. According to the Final Communique of the Denver Summit of the Eight, the leaders of the G-8 nations agreed "on the need for appropriate domestic measures and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child."[16]

C. An Assessment

What conclusions can we reach from this cursory review of policies adopted by individual countries and by intergovernmental organizations?

I believe this review strongly suggests that there is an emerging consensus among governments and intergovernmental organizations for the prohibition of human reproductive cloning, inheritable genetic modification, and social trait selection. It also suggests that opinion is divided concerning the acceptability of research cloning, and is supportive of both embryonic stem cell research using IVF embryos, and medically-related genetic trait selection.

The review also suggests that there is concern about somatic genetic enhancement, as stated in the Council of Europe's *Convention on Biomedicine and Human Rights* and by the strong positive response to the UNESCO/WADA initiative calling for bans on the use of genetic enhancement in athletic competitions. This set of practices hasn't yet received the level of public and policymaker attention that some of the other practices have, however, and has only infrequently or indirectly been addressed in national policies.

There are very likely a significant number of procedural, administrative, and governance rules and guidelines around which consensus or near-consensus exists or might be attained fairly

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[14] *Cloning in Human Health: Report by the Director-General*, World Health Organization, May 10, 2000; available at http://www.who.int/ethics/en/A53_15.pdf

[15] See "Ethics and Health at WHO," http://www.who.int/ethics/about/en/.

[16] *Final Communique of the Denver Summit of the Eight*, June 22, 1997; available at http://www.g7.utoronto.ca/summit/1997denver/g8final.htm

easily. These would help ensure safety, efficacy, transparency, inclusion and accountability regarding practices involving the new human genetic technologies. These are expressed, for example, in the UNESCO declarations, various sections of the Council of Europe's *Convention,* and numerous policy advisories issued by the World Health Organization.

There also appears to be significant support for policies that would guard against the commercialization and commodification of human reproductive practices. This is seen in the prohibitions that many countries impose on payment for women's eggs for research or assisted reproduction, for similar prohibitions on commercial surrogacy, and the various conventions and policy declarations promulgated by UNESCO, the Council of Europe, and the European Union.

I want to mention here one other set of issues that falls outside the domain of human genetic modification *per se* but is certainly related and might well fall within the jurisdiction of this subcommittee, and about which I believe a strong consensus can be established: the issue of international trafficking in human genetic and other biological materials. Organ trafficking in kidneys and other organs is growing, and often puts the largely poor donors at risk of their lives. Reports of "egg trafficking," in which eggs are extracted from women in poor countries and traded across borders for commercial gain, are increasing. "Reproductive globalization," in which pregnancy itself is "outsourced" to gestational surrogates in the global South, is also on the increase. The lack of effective controls on such potentially exploitative and harmful cross-border practices is troubling.

I also want to note that while I believe consensus around a core set of critical concerns is developing or could easily be encouraged to develop, there is no cause for complacency. The fact that 59 countries have banned human reproductive cloning, for example, and that none have authorized it, may be taken as an encouraging sign, but the same statistic makes clear that 133 countries still lack any legal prohibitions on that practice. The same applies for other practices widely judged to be unacceptable. In the past rogue scientists have flaunted their intention to establish human cloning clinics in one or another of these countries.

D. Policy instruments

Assuming that broad areas of consensus exist or can be reached concerning the proper use of the new human genetic technologies, it will still be necessary to translate these into formal agreements, codes, protocols, treaties and the like. What might these look like?

At a conference held in 2001 at Boston University, experts in the field of international law suggested ways in which the 1997 Ottowa Treaty on the prohibition of anti-personnel landmines, and other treaties, might serve as models for international agreements addressing the new human genetic technologies.[17]

[17] "Beyond Cloning: Protecting Humanity from Species-Altering Procedures," Boston University, September 21–22, 2001. See "Health & Human Rights Leaders Call for Global Ban on Species-Altering Procedures," *Genetics Crossroads*, October 2, 2001; available at http://www.geneticsandsociety.org/article.php?id=2809.

A 2002 proposal by legal scholars George Annas, Lori Andrews and Rosario Isasi called for an international "Convention on the Preservation of the Human Species" that would prohibit human reproductive cloning and inheritable genetic modification, and mandate the establishment of national systems of oversight ensuring that the use of human gametes or embryos for experimental or clinical practices met informed consent, safety and ethical standards.[18]

In 2007 scholars associated with the United Nations University argued that the notion of a straightforward ban on human reproductive cloning had attained or had nearly attained the status of customary international law, and that measures to formalize this, perhaps negotiated under the auspices of the UNESCO International Bioethics Committee, would stand a good chance of success.[19]

Most recently, Jamie Metzl proposed a "Genetic Heritage Safeguard Treaty" (GHST) modeled on the 1970 Nuclear Nonproliferation Treaty. He argued that such a treaty could serve the dual function of both encouraging responsible applications of human genetic research and specifying limits on those applications deemed undesirable.[20]

There are other possibilities as well. The Council of Europe's *Convention on Biomedicine and Human Rights* allows countries other than Council members to ratify it, suggesting that well-crafted regional agreements might serve as foundations for global agreements.[21] Alternatively, independently negotiated regional agreements might seek to harmonize those provisions that affect humanity as a whole, while allowing other provisions to vary in accordance with regional social or cultural differences.

A productive next step might be to have a high-level task force, representing the full range of constituencies with major stakes in these issues, undertake a comprehensive review and assessment of options for global oversight and regulation.

However, the best designed policy instruments will be of little value if the expressed desire for such policies is thin or strongly divided. What can we say about the current state of the politics of the new human genetic technologies?

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[18] George J. Annas, Lori B. Andrews and Rosario M. Isasi, "Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations," *American Journal of Law & Medicine*, Vol. 28, Nos. 2 & 3, pp. 151–178 (2002), available at http://geneticsandsociety.org/downloads/2002_ajlm_annasetal.pdf

[19] Chamundeeswari Kuppuswamy, Darryl Macer, Mihaela Serbulea and Brendan Tobin, *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*, United Nations University – Institute of Advanced Studies, Yokohama, Japan, 2007; available at http://www.ias.unu.edu/resource_centre/Cloning_9.20B.pdf

[20] Jamie Metzl, "Brave New World War," *Democracy*, Spring 2008; available at http://www.geneticsandsociety.org/article.php?id=3985. Metzl is Executive Vice President of the Asia Society, and served as Director for Multilateral and Humanitarian Affairs for the National Security Council during the Clinton Administration.

[21] Council of Europe, "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," 4 April, 1997; available at http://conventions.coe.int/treaty/en/treaties/html/164.htm

IV. Politics: Challenges, Choices and Leadership

The new human genetic technologies are a case study of what economists, political scientists and game-theoreticians call the *prisoner's dilemma* or the *collective action problem,* and what environmentalists have called the *tragedy of the commons.* Situations frequently arise in which the choices any of us might make as individuals, can, if chosen by everyone, generate negative consequences that everyone regrets.

A parent might fantasize that it would be gratifying to have a child who is an athletic superstar, perhaps through genetic enhancement, but on reflection conclude that they would not want their child to live in a world in which such genetic enhancement, building at a constantly accelerating pace, had become the norm. If enough parents shared this concern, they could collectively agree to forego the possibility of genetic enhancement. In large societies such agreements are codified and enforced through laws and regulations. Indeed, the existence of such collective action problems is the reason that governments exist in the first place. There is no inherent reason to expect that democratic governments will not be able to address collective action problems posed by the new human genetic technologies.

It's true, however, that these technologies pose special challenges. They are very new, and neither the general public nor policymakers have had the occasion to fully consider what is happening and what is at stake. The trade-offs between acceptable and unacceptable uses are clear in many instances but not in others, and people are understandably reluctant to forego possible benefits without good reason.

It was noted earlier that some applications of genetic technology fall into definitional gray areas. If it were possible to use germline engineering to create a child with immunity to all major diseases, would this constitute "therapy" or "enhancement?" Using genetic technology to allow a child lacking a key growth hormone gene to grow to normal height might be considered therapeutic, but what about allowing children with normal hormone functioning, but who are nonetheless very short, to use genetic technology to similarly grow to normal height?

Some have argued that the inability to easily draw clear lines regarding the therapy/enhancement distinction means that no lines *can* be drawn. But this is a specious argument. Public policy is in large part a matter of drawing lines; we do it all the time. Putting our trust in commercial markets and the free play of human desire would unleash a genetic enhancement rat-race that could never be contained. The responsible alternative is to establish the clearest lines possible as a matter of law, and delegate decisions over remaining gray areas – which typically impact fewer individuals - to accountable regulatory bodies. Such structures have been put in place in the United Kingdom, Canada, France and many other countries.

Another challenge is the fact that some policies will need to be universal, or nearly so, if they are to be meaningful at all. It does little good if the great majority of the world's countries agree to ban human reproductive cloning, but a handful decide to distinguish themselves as free havens for the creation of human clones. If these countries are small this may be a small problem and resolvable through diplomacy, but if they are large this would be a large problem. In this regard it is worth noting that neither Russia nor the United States have yet banned human reproductive cloning.

We also need to acknowledge that in a world still far from having overcome its propensity for racism, xenophobia and warfare, the possibility of a techno-eugenic arms raced driven by nationalist fervor cannot be dismissed. In 2000 concern about massively lethal applications motivated computer scientist Bill Joy to call for a permanent halt to particular avenues of genetic research.[22] In 2003 the Sunshine Project documented nearly a dozen possible uses of genetic science for biowarfare purposes, including the creation of ethnicity-specific pathogens.[23] In November 2006, in one of his final addresses as UN Secretary-General, Kofi Annan urgently called for new international treaties guarding against the development and use of genetically-enhanced bioweapons.[24] We have been moderately – but only moderately – successfully in containing the spread of nuclear, chemical and "conventional" biological weapons. We now need to add bioweaponry incorporating human genetic technology to our arms control portfolio.

Given the stark nature of the potential threats posed by the new human genetic technologies, why has more attention not been paid to addressing them? One reason is that in many countries, including the United States, the debate over policy concerning the new human biotechnologies has become enmeshed in the political dynamics of the culture wars. Religious conservatives were the first to become vocal on high-profile issues such as human cloning, and the debate over the new human genetic technologies was quickly framed within the conventional categories of abortion politics. In response, many liberals assumed that the progressive response was therefore one of largely uncritical support. The result has been a stalemate and a policy vacuum at the federal level and a plethora of hastily conceived programs at the state levels. At the international level the result has been avoidance and neglect.

However, public opinion surveys repeatedly show broad, bi-partisan sentiment for what might be called a principled middle-ground position concerning the new human genetic technologies. The majority of Americans are not necessarily opposed to all research involving human embryos, but they reject reproductive cloning and the engineering or selecting of the social traits of future generations.[25] Surveys conducted in other countries suggest similar opinions.

The issues raised by the new human genetic technologies transcend conventional ideological divides. Many pro-choice women's health advocates and feminist leaders oppose new genetic and reproductive technologies that put women's health and well-being at risk and raise concerns about the commodification of reproduction and human relationships. Human rights and civil rights leaders are wary of a new free-market eugenics that could stoke the fires of racial and ethnic hatred. Disability rights leaders charge that a society obsessed with genetic perfection could come to regard the disabled as mistakes that should have been prevented. Many

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[22] Bill Joy, "Why the Future Doesn't Need Us," *Wired*, April 2000; available at http://www.wired.com/wired/archive/8.04/joy.html

[23] The Sunshine Project, *Emerging Technologies: Genetic Engineering and Biological Weapons*, November 2003; available at http://www.sunshine-project.org/publications/bk/bk12.html

[24] "Annan Calls for Strategy to Prevent Biological Weapons Falling into Terrorists' Hands," UN News Centre, November 20, 2006; available at http://www.un.org/apps/news/story.asp?NewsID=20653&Cr=biological&Cr1=weapons

[25] See "About Public Opinion & Human Biotechnology" (and links therein) at http://www.geneticsandsociety.org/article.php?list=type&type=54

environmentalists see human genetic modification as another hubristic technology being promoted with little regard for long-range consequences.[26]

It is likewise misleading to use the conventional categories of "left/right" or "liberal/conservative" to categorize the responses of different countries to human biotechnology concerns. Western European countries widely regarded as bastions of secular liberalism have the strictest polices of any region in the world concerning applications of human genetic technology. This derives from the social democratic ethos of European political culture, and from its first-hand experience in the 20th century with eugenics, euthanasia and the Holocaust. Europeans know all too well what can happen when ideologies and policies that valorize the creation of "genetically superior" human beings come to the fore. For different but related reasons, developing countries such as South Africa, Vietnam, India and Brazil have likewise adopted policies bringing the new human genetic technologies under social oversight and control.

Despite many statements to the contrary, the genie is *not* out of the bottle. In any event some of the genies are *good* genies. And the *worst* genies are still *in* the bottle. I sincerely believe we have the time and the capability to get ahead of the curve and do the right thing. But it will require committed engagement on the part of social and political leaders, socially responsible scientists, representatives of the world's major religious traditions, opinion leaders, public intellectuals and the press, and, finally, the general public, if we are to adopt responsible policies ensuring that the new human genetic technologies are used to improve the human condition rather than jeopardize it. There is no greater challenge.

# # #

Acknowledgements

Jesse Reynolds, Pete Shanks and Jamie Brooks assisted in the preparation of this testimony and in the data shown in the attachments.

[26] See "Health & Human Rights Leaders Call for Global Ban on Species-Altering Procedures," *Genetics Crossroads*, October 2, 2001; available at http://www.geneticsandsociety.org/article.php?id=2809. Also see the "Letter to the US Senate from Environmental Leaders Concerning Cloning and Inheritable Genetic Modification," signed on February 6th, 2002, by leaders from nine major organizations (Earth Island Institute, Friends of the Earth, Greenpeace USA, Institute for Agriculture and Trade Policy, Physicians for Social Responsibility, Rainforest Action Network, Sierra Club, Waterkeeper Alliance, WorldWise); available at http://www.geneticsandsociety.org/article.php?id=1989.

ATTACHMENTS

Attachment A. Human Genetic Engineering

Attachment B. Summary of National Policies

Attachment C. Summary of International Agreements

Attachment D. Summary of Policies on Embryonic Stem Cell Research

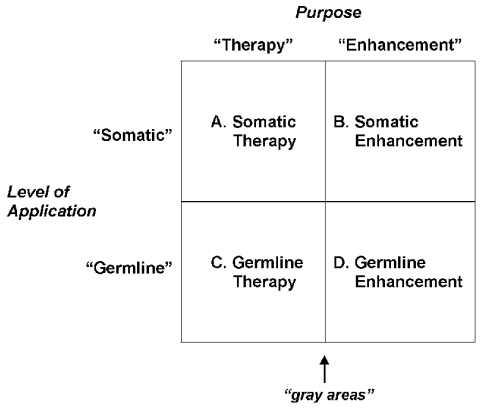
Attachment E. Summary of Policies of OECD States

Attachment F. The Council of Europe *Convention on Biomedicine and Human Rights*

Attachment G. The Canadian Assisted Human Reproduction Act

Attachment A. Human Genetic Engineering

I. HUMAN GENETIC MODIFICATION



II. HUMAN GENETIC TRAIT SELECTION

A. For Social Purposes

B. For Medically-Related Purposes

III. HUMAN CLONING

A. For Reproductive Purposes

B. For Research Purposes

Attachment B: Summary of National Policies

The Table shows the laws and policies currently in effect in all countries regarding selected practices and technologies.

Definitions:

- ***Eggs for Assisted Reproduction:*** the provision of oocytes for use by another woman for reproductive purposes
- ***Eggs for Research:*** the provision of oocytes for use by scientists in research, whether for SCNT or for other purposes
- ***Inheritable Genetic Modification:*** the manipulation or replacement of the genes in a person's egg or sperm cells, such that the changes can be passed on to all succeeding generations
- ***Preimplantation Genetic Diagnosis:*** the testing of one or more zygotes created via IVF procedures in order to select the zygote with which to initiate a pregnancy
- ***Reproductive Cloning:*** the creation of fully gestated human children that are genetically identical to previously existing human beings, whether living or dead
- ***Research Cloning:*** the creation for research purposes of human embryos that are genetically identical to previously existing human beings, living or dead, but will not be brought to term
- ***Sex Selection:*** the choice of the sex of an unborn child, whether before or after conception, either to avoid sex-linked heritable diseases or for personal preference
- ***Surrogacy:*** the practice in which one woman bears a child on behalf of another, whether using the eggs of one of the contracting parties or those of a third woman

Key:

- ***PROHIBITED:*** This practice is prohibited by national law or policies having the force of law.
- ***regulated:*** This practice is allowed and regulated by national law or policies having the force of law.
- ***social prohibited:*** Social (or nonmedical) use of this practice is prohibited by national law or policies having the force of law.
- ***commercial prohibited:*** Commercial use of this practice is prohibited by national law or policies having the force of law, but non-commercial use is allowed.
- ***commercial allowed:*** Commercial use of this practice is allowed by national law or policies having the force of law.
- ***unrecognized:*** Surrogacy contracts are explicitly unrecognized by national law or by other mechanism which carries the force of law.
- ***no policy:*** This practice is not addressed by national law or policies having the force of law.
- ***?:*** It is unknown or unclear whether this practice is addressed by national law or policies having the force of law.

Note: The categories defined in the key and used in the table characterize the policies in any given country in a broad manner. Policy details may vary among countries. Data were compiled by the Center for Genetics and Society, June 2008. Sources included country- and topic-specific websites, other surveys and inventories, and journal accounts, as well as laws and policy instruments when available in English. Texts of policies are often difficult to interpret, and policies are subject to change.

Summary of National Policies

Country	Eggs for Assisted Reproduction	Eggs for Research	Inheritable Genetic Modification	Preimplantation Genetic Diagnosis	Reproductive Cloning	Research Cloning	Sex Selection	Surrogacy
Afghanistan	?	?	?	?	?	?	?	?
Albania	?	?	?	?	?	?	?	?
Algeria	?	?	?	?	?	?	?	?
Andorra	?	?	?	?	?	?	?	?
Angola	?	?	?	?	?	?	?	?
Antigua and Barbuda	?	?	?	?	?	?	?	?
Argentina	no policy	no policy	no policy	no policy	PROHIBITED	PROHIBITED	no policy	no policy
Armenia	?	?	?	?	?	?	?	?
Australia	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	commercial prohibited; unrecognized
Austria	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Azerbaijan	?	?	?	?	?	?	?	?
Bahamas	?	?	?	?	?	?	?	?
Bahrain	?	?	?	?	?	?	?	?
Bangladesh	?	?	?	?	?	?	?	?
Barbados	?	?	?	?	?	?	?	?
Belarus	?	?	?	?	?	?	?	?
Belgium	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	unrecognized
Belize	?	?	?	?	?	?	?	?
Benin	?	?	?	?	?	?	?	?
Bhutan	?	?	?	?	?	?	?	?
Bolivia	?	?	?	?	?	?	?	?
Bosnia and Herzegovina	?	?	PROHIBITED	social prohibited	?	PROHIBITED	social prohibited	?
Botswana	?	?	?	?	?	?	?	?
Brazil	no policy	no policy	PROHIBITED	no policy	PROHIBITED	PROHIBITED	no policy	no policy
Brunei	?	?	?	?	?	?	?	?
Bulgaria	?	?	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	?
Burkina Faso	?	?	?	?	?	?	?	?
Burundi	?	?	?	?	?	?	?	?
Cambodia	?	?	?	?	?	?	?	?
Cameroon	?	?	?	?	?	?	?	?
Canada	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	commercial prohibited
Cape Verde	?	?	?	?	?	?	?	?
Central African Republic	?	?	?	?	?	?	?	?
Chad	?	?	?	?	?	?	?	?
Chile	no policy	?	?	no policy	?	?	?	?
China	PROHIBITED	commercial prohibited	?	social prohibited	PROHIBITED	regulated	social prohibited	PROHIBITED
Columbia	no policy	?	PROHIBITED	no policy	PROHIBITED	PROHIBITED	no policy	no policy
Comoros	?	?	?	?	?	?	?	?
Cook Islands	?	?	?	?	?	?	?	?
Costa Rica	?	?	PROHIBITED	?	PROHIBITED	PROHIBITED	?	?
Croatia	no policy	no policy	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	no policy
Cuba	?	?	?	?	PROHIBITED	regulated	?	?
Cyprus	?	?	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	?

Country	Eggs for Assisted Reproduction	Eggs for Research	Inheritable Genetic Modification	Preimplantation Genetic Diagnosis	Reproductive Cloning	Research Cloning	Sex Selection	Surrogacy
Czech Republic	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	?
Côte d'Ivoire	?	?	?	?	?	?	?	?
Democratic Republic of the Congo	?	?	?	?	?	?	?	?
Denmark	commercial allowed	permitted	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	commercial prohibited; unrecognized
Djibouti	?	?	?	?	?	?	?	?
Dominica	?	?	?	?	?	?	?	?
Dominican Republic	?	?	?	?	?	?	?	?
Ecuador	no policy	?	?	?	PROHIBITED	PROHIBITED	no policy	no policy
Egypt	no policy	no policy	no policy	no policy	?	no policy	no policy	no policy
El Salvador	?	?	?	?	PROHIBITED	PROHIBITED	?	?
Equatorial Guinea	?	?	?	?	?	?	?	?
Eritrea	?	?	?	?	?	?	?	?
Estonia	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	?
Ethiopia	?	?	?	?	?	?	?	?
Fiji	?	?	?	?	?	?	?	?
Finland	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	PROHIBITED
France	commercial allowed	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Gabon	?	?	?	?	?	?	?	?
Gambia	?	?	?	?	?	?	?	?
Georgia	?	PROHIBITED	PROHIBITED	?	PROHIBITED	PROHIBITED	?	?
Germany	PROHIBITED	?	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Ghana	?	?	?	?	?	?	?	?
Greece	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	commercial prohibited
Grenada	?	?	?	?	?	?	?	?
Guatemala	?	?	?	?	?	?	?	?
Guinea	?	?	?	?	?	?	?	?
Guinea-Bissau	?	?	?	?	?	?	?	?
Guyana	?	?	?	?	?	?	?	?
Haiti	?	?	?	?	?	?	?	?
Honduras	?	?	?	?	?	?	?	?
Hungary	commercial allowed	commercial allowed	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	commercial allowed
Iceland	?	?	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	?
India	no policy	no policy	PROHIBITED	social prohibited	PROHIBITED	regulated	PROHIBITED	commercial allowed
Indonesia	?	?	?	?	?	?	?	?
Iran	?	?	?	?	?	?	?	?
Iraq	?	?	?	?	?	?	?	?
Ireland	?	?	?	?	PROHIBITED	PROHIBITED	?	?
Israel	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	commercial prohibited
Italy	PROHIBITED	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Jamaica	?	?	?	?	?	?	?	?
Japan	PROHIBITED	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	unrecognized
Jordan	no policy	?	?	no policy	?	no policy	no policy	no policy

Country	Eggs for Assisted Reproduction	Eggs for Research	Inheritable Genetic Modification	Preimplantation Genetic Diagnosis	Reproductive Cloning	Research Cloning	Sex Selection	Surrogacy
Kazakhstan	?	?	?	?	?	?	?	?
Kenya	?	?	?	?	?	?	?	?
Kiribati	?	?	?	?	?	?	?	?
Kuwait	?	?	?	?	?	?	?	?
Kyrgyzstan	?	?	?	?	?	?	?	?
Laos	?	?	?	?	?	?	?	?
Latvia	permitted	permitted	?	?	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Lebanon	?	?	?	?	?	?	?	?
Lesotho	?	?	?	?	?	?	?	?
Liberia	?	?	?	?	?	?	?	?
Libya	?	?	?	?	?	?	?	?
Liechtenstein	?	?	?	?	?	?	?	?
Lithuania	?	?	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	social prohibited	?
Luxembourg	?	?	?	?	PROHIBITED	PROHIBITED	?	?
Macedonia	?	?	?	?	?	?	?	?
Madagascar	?	?	?	?	?	?	?	?
Malawi	?	?	?	?	?	?	?	?
Malaysia	no policy	?	?	no policy	?	?	?	no policy
Maldives	?	?	?	?	?	?	?	?
Mali	?	?	?	?	?	?	?	?
Malta	?	?	?	?	?	?	?	?
Marshall Islands	?	?	?	?	?	?	?	?
Mauritania	?	?	?	?	?	?	?	?
Mauritius	?	?	?	?	?	?	?	?
Mexico	no policy	?	?	?	PROHIBITED	?	?	?
Micronesia	?	?	?	?	?	?	?	?
Moldova	?	?	PROHIBITED	?	PROHIBITED	?	?	?
Monaco	?	?	?	?	?	?	?	?
Mongolia	?	?	?	?	?	?	?	?
Montenegro	?	?	?	?	?	?	?	?
Morocco	no policy	no policy	?	no policy	?	?	?	no policy
Mozambique	?	?	?	?	?	?	?	?
Myanmar	?	?	?	?	?	?	?	?
Namibia	?	?	?	?	?	?	?	?
Nauru	?	?	?	?	?	?	?	?
Nepal	?	?	?	?	?	?	?	?
Netherlands	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	commercial prohibited
New Zealand	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	PROHIBITED	commercial prohibited; unrecognized
Nicaragua	?	?	?	?	?	?	?	?
Niger	?	?	?	?	?	?	?	?
Nigeria	?	?	?	?	?	?	?	?
North Korea	?	?	?	?	?	?	?	?
Norway	PROHIBITED	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Oman	?	?	?	?	?	?	?	?
Pakistan	?	?	?	?	?	?	?	?
Palau	?	?	?	?	?	?	?	?
Panama	?	?	?	?	PROHIBITED	PROHIBITED	?	?
Papua New Guinea	?	?	?	?	?	?	?	?
Paraguay	?	?	?	?	?	?	?	?

Country	Eggs for Assisted Reproduction	Eggs for Research	Inheritable Genetic Modification	Preimplantation Genetic Diagnosis	Reproductive Cloning	Research Cloning	Sex Selection	Surrogacy
Peru	no policy	?	PROHIBITED	no policy	PROHIBITED	PROHIBITED	?	no policy
Philippines	no policy	no policy	?	?	PROHIBITED	?	?	no policy
Poland	?	?	?	?	PROHIBITED	?	?	?
Portugal	no policy	?	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	no policy
Qatar	?	?	?	?	?	?	?	?
Republic of the Congo	?	?	?	?	?	?	?	?
Romania	no policy	?	PROHIBITED	no policy	PROHIBITED	PROHIBITED	?	no policy
Russia	commercial allowed	commercial allowed	?	social prohibited	?	?	social prohibited	commercial allowed
Rwanda	?	?	?	?	?	?	?	?
Saint Kitts and Nevis	?	?	?	?	?	?	?	?
Saint Lucia	?	?	?	?	?	?	?	?
Saint Vincent and the Grenadines	?	?	?	?	?	?	?	?
Samoa	?	?	?	?	?	?	?	?
San Marino	?	?	?	?	?	?	?	?
Sao Tome and Principe	?	?	?	?	?	?	?	?
Saudi Arabia	?	?	?	?	?	?	?	?
Senegal	?	?	?	?	?	?	?	?
Serbia	?	?	?	?	?	?	?	?
Seychelles	?	?	?	?	?	?	?	?
Sierra Leone	?	?	?	?	?	?	?	?
Singapore	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	no policy
Slovakia	?	?	PROHIBITED	?	PROHIBITED	PROHIBITED	?	?
Slovenia	commercial prohibited	?	PROHIBITED	?	PROHIBITED	PROHIBITED	?	PROHIBITED
Solomon Islands	?	?	?	?	?	?	?	?
Somalia	?	?	?	?	?	?	?	?
South Africa	no policy	no policy	PROHIBITED	no policy	PROHIBITED	PROHIBITED	no policy	no policy
South Korea	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	PROHIBITED	no policy
Spain	commercial allowed	commercial allowed	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	unrecognized
Sri Lanka	?	?	?	?	?	?	?	?
Sudan	?	?	?	?	?	?	?	?
Suriname	?	?	?	?	?	?	?	?
Swaziland	?	?	?	?	?	?	?	?
Sweden	permitted	permitted	PROHIBITED	?	PROHIBITED	regulated	?	PROHIBITED
Switzerland	PROHIBITED	?	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Syrian Arab Republic	?	?	?	?	?	?	?	?
Taiwan	commercial allowed	commercial allowed	?	?	PROHIBITED	regulated	?	PROHIBITED
Tajikistan	?	?	?	?	?	?	?	?
Tanzania	?	?	?	?	?	?	?	?
Thailand	no policy	?	?	?	PROHIBITED	regulated	?	no policy
Timor-Leste	?	?	?	?	?	?	?	?
Togo	?	?	?	?	?	?	?	?
Tonga	?	?	?	?	?	?	?	?
Trinidad and Tobago	?	?	?	?	?	?	?	?
Tunisia	PROHIBITED	?	?	?	PROHIBITED	PROHIBITED	?	PROHIBITED

Country	Eggs for Assisted Reproduction	Eggs for Research	Inheritable Genetic Modification	Preimplantation Genetic Diagnosis	Reproductive Cloning	Research Cloning	Sex Selection	Surrogacy
Turkey	PROHIBITED	?	PROHIBITED	social prohibited	PROHIBITED	PROHIBITED	social prohibited	PROHIBITED
Turkmenistan	?	?	?	?	?	?	?	?
Tuvalu	?	?	?	?	?	?	?	?
Uganda	?	?	?	?	?	?	?	?
Ukraine	?	?	?	?	PROHIBITED	?	?	?
United Arab Emirates	?	?	?	?	?	?	?	?
United Kingdom	commercial prohibited	commercial prohibited	PROHIBITED	social prohibited	PROHIBITED	regulated	social prohibited	commercial prohibited
United States of America	no policy	no policy	no policy	no policy	no policy	no policy	no policy	no policy
Uruguay	no policy	?	?	no policy	?	?	?	no policy
Uzbekistan	?	?	?	?	?	?	?	?
Vanuatu	?	?	?	?	?	?	?	?
Venezuela	no policy	?	?	no policy	?	?	?	no policy
Vietnam	commercial prohibited	?	PROHIBITED	?	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Yemen	?	?	?	?	?	?	?	?
Zambia	?	?	?	?	?	?	?	?
Zimbabwe	?	?	?	?	?	?	?	?

Attachment C: Summary of International Agreements

The Table shows the current status in all countries of selected intergovernmental agreements. It also shows how each country voted on the 2005 UN Human Cloning Declaration.

Definitions:

- ***1997 COE Biomedicine Convention:*** The Council of Europe (COE) is an international organization of 47 member countries that works to foster democracy and human rights. Its Convention on Biomedicine and Human Rights explicitly prohibits inheritable genetic modification, somatic genetic modification for enhancement purposes, social sex selection and the creation of human embryos solely for research purposes. The Convention went into force in 1998.[27]
- ***1998 COE Cloning Convention:*** This additional protocol to the COE Biomedicine Convention, prompted by then-recent scientific events, specifically banned human reproductive cloning. It went into force in 1998.[28]
- ***2005 UN Cloning Vote:*** After discussions lasting several years, a non-binding Declaration implying opposition to both reproductive and research cloning was passed with a plurality of votes (46%) and thus, under UN rules, became the official UN position.[29]
- ***2005 UNESCO Sports Doping Convention:*** This incorporated the previous World Anti-Doping Code, which was drawn up by the World Anti-Doping Agency (originally established by the International Olympic Committee) and until the UNESCO Convention was negotiated could not be legally binding on national governments. It addresses the use of steroids and other banned substances, and includes a prohibition of gene doping.[30]

Key:

- ***RATIFIED:*** This country has ratified this measure, and thus agrees to abide by its provisions.
- ***signed:*** This country has signed this measure, indicating an intent to ratify it.
- ***n/a:*** This country is not a member of the intergovernmental organization responsible for this item.
- ***blank cell:*** This country has neither signed nor ratified this measure.

2005 UN Cloning Vote

- ***YES:*** This country voted in favor of the Declaration, indicating support for a ban on both reproductive and research cloning.
- ***no:*** This country voted against the Declaration, indicating support for a ban on reproductive cloning only.
- ***abstain:*** This country took an official position of abstaining from voting on the Declaration.
- ***no vote:*** This country's delegate was absent at the time of the vote, or otherwise refrained from voting.

Note: Data were compiled by the Center for Genetics and Society, June 2008, from official records.

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[27] http://conventions.coe.int/treaty/en/treaties/html/164.htm

[28] http://conventions.coe.int/Treaty/EN/Treaties/Html/168.htm

[29] For a full discussion, see Center for Genetics and Society, "The United Nations Human Cloning Treaty Debate, 2000–2005," June 1st, 2006; available at http://www.geneticsandsociety.org/article.php?id=338.

[30] http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html

Summary of International Agreements

Country	1997 COE Biomedicine Convention	1998 COE Cloning Convention	2005 UN Cloning Vote	2005 UNESCO Sports Doping Convention
Afghanistan	n/a	n/a	YES	
Albania			YES	RATIFIED
Algeria	n/a	n/a	abstained	RATIFIED
Andorra			YES	
Angola	n/a	n/a	abstained	
Antigua and Barbuda	n/a	n/a	no vote	
Argentina	n/a	n/a	abstained	RATIFIED
Armenia			no vote	
Australia	n/a	n/a	YES	RATIFIED
Austria			YES	RATIFIED
Azerbaijan			abstained	RATIFIED
Bahamas	n/a	n/a	abstained	RATIFIED
Bahrain	n/a	n/a	YES	
Bangladesh	n/a	n/a	YES	RATIFIED
Barbados	n/a	n/a	abstained	RATIFIED
Belarus			no	
Belgium			no	
Belize	n/a	n/a	YES	
Benin	n/a	n/a	YES	
Bhutan	n/a	n/a	no vote	
Bolivia	n/a	n/a	YES	RATIFIED
Bosnia and Herzegovina	RATIFIED		YES	
Botswana	n/a	n/a	no vote	
Brazil	n/a	n/a	no	RATIFIED
Brunei	n/a	n/a	YES	RATIFIED
Bulgaria	RATIFIED	RATIFIED	no	RATIFIED
Burkina Faso	n/a	n/a	abstained	
Burundi	n/a	n/a	YES	RATIFIED
Cambodia	n/a	n/a	no	RATIFIED
Cameroon	n/a	n/a	abstained	RATIFIED
Canada	n/a	n/a	no	RATIFIED
Cape Verde	n/a	n/a	abstained	
Central African Republic	n/a	n/a	no vote	
Chad	n/a	n/a	no vote	
Chile	n/a	n/a	YES	
China			no	RATIFIED
Columbia	n/a	n/a	abstained	
Comoros	n/a	n/a	YES	
Cook Islands	n/a	n/a		RATIFIED
Costa Rica	n/a	n/a	YES	
Croatia	RATIFIED	RATIFIED	YES	RATIFIED
Cuba	n/a	n/a	no	
Cyprus	RATIFIED	RATIFIED	no	
Czech Republic	RATIFIED	RATIFIED	no	RATIFIED
Côte d'Ivoire	n/a	n/a	YES	
Democratic Republic of the Congo	n/a	n/a	YES	
Denmark	RATIFIED	signed	no	RATIFIED
Djibouti	n/a	n/a	YES	
Dominica	n/a	n/a	no vote	
Dominican Republic	n/a	n/a	YES	
Ecuador			YES	RATIFIED

Country	1997 COE Biomedicine Convention	1998 COE Cloning Convention	2005 UN Cloning Vote	2005 UNESCO Sports Doping Convention
Egypt	n/a	n/a	abstained	RATIFIED
El Salvador			YES	
Equatorial Guinea	N/A	N/A	YES	
Eritrea	N/A	N/A	YES	
Estonia	RATIFIED	RATIFIED	no	RATIFIED
Ethiopia	N/A	N/A	YES	
Fiji			no vote	
Finland	signed	signed	no	RATIFIED
France	signed	signed	no	RATIFIED
Gabon	n/a	n/a	no	RATIFIED
Gambia	N/A	N/A	no vote	
Georgia	RATIFIED	RATIFIED	YES	
Germany			YES	RATIFIED
Ghana	N/A	N/A	no vote	RATIFIED
Greece	RATIFIED	RATIFIED	no vote	RATIFIED
Grenada	N/A	N/A	YES	
Guatemala	N/A	N/A	YES	RATIFIED
Guinea			no vote	
Guinea-Bissau	N/A	N/A	no vote	
Guyana	N/A	N/A	YES	
Haiti	N/A	N/A	YES	
Honduras	N/A	N/A	YES	
Hungary	RATIFIED	RATIFIED	YES	RATIFIED
Iceland	RATIFIED	RATIFIED	no	RATIFIED
India			no	RATIFIED
Indonesia	N/A	N/A	abstained	RATIFIED
Iran	n/a	n/a	abstained	
Iraq			YES	
Ireland			YES	
Israel			abstained	
Italy	signed	signed	YES	RATIFIED
Jamaica	n/a	n/a	no	RATIFIED
Japan	n/a	n/a	no	RATIFIED
Jordan	n/a	n/a	abstained	
Kazakhstan	n/a	n/a	YES	
Kenya	n/a	n/a	YES	
Kiribati	n/a	n/a	no vote	
Kuwait	n/a	n/a	YES	RATIFIED
Kyrgyzstan	n/a	n/a	no vote	
Laos	n/a	n/a	no	
Latvia	signed	signed	no	RATIFIED
Lebanon	n/a	n/a	abstained	
Lesotho	n/a	n/a	YES	
Liberia	n/a	n/a	YES	
Libya	n/a	n/a	no vote	RATIFIED
Liechtenstein			YES	
Lithuania	RATIFIED	RATIFIED	no	RATIFIED
Luxembourg	signed	signed	no	RATIFIED
Macedonia	signed	signed	YES	
Madagascar	n/a	n/a	YES	
Malawi	n/a	n/a	no vote	
Malaysia	n/a	n/a	abstained	RATIFIED
Maldives	n/a	n/a	abstained	
Mali	n/a	n/a	no vote	RATIFIED
Malta			YES	

Country	1997 COE Biomedicine Convention	1998 COE Cloning Convention	2005 UN Cloning Vote	2005 UNESCO Sports Doping Convention
Marshall Islands	n/a	n/a	YES	
Mauritania	n/a	n/a	no vote	
Mauritius	n/a	n/a	YES	RATIFIED
Mexico	n/a	n/a	YES	RATIFIED
Micronesia	n/a	n/a	YES	
Moldova	RATIFIED	RATIFIED	abstained	RATIFIED
Monaco			YES	RATIFIED
Mongolia	n/a	n/a	abstained	RATIFIED
Montenegro	signed			
Morocco	n/a	n/a	YES	
Mozambique	n/a	n/a	no vote	RATIFIED
Myanmar	n/a	n/a	abstained	
Namibia	n/a	n/a	abstained	RATIFIED
Nauru	n/a	n/a	no vote	RATIFIED
Nepal	n/a	n/a	abstained	
Netherlands	signed	signed	no	RATIFIED
New Zealand	n/a	n/a	no	RATIFIED
Nicaragua	n/a	n/a	YES	
Niger	n/a	n/a	no vote	RATIFIED
Nigeria	n/a	n/a	no vote	RATIFIED
North Korea	n/a	n/a	no	
Norway	RATIFIED	signed	no	RATIFIED
Oman	n/a	n/a	abstained	RATIFIED
Pakistan	n/a	n/a	abstained	RATIFIED
Palau	n/a	n/a	YES	
Panama	n/a	n/a	YES	RATIFIED
Papua New Guinea	n/a	n/a	no vote	
Paraguay	n/a	n/a	YES	
Peru	n/a	n/a	no vote	RATIFIED
Philippines	n/a	n/a	YES	
Poland	signed	signed	YES	RATIFIED
Portugal	RATIFIED	RATIFIED	YES	RATIFIED
Qatar	n/a	n/a	YES	RATIFIED
Republic of the Congo	n/a	n/a	no vote	
Romania	RATIFIED	RATIFIED	abstained	RATIFIED
Russia			no vote	RATIFIED
Rwanda	n/a	n/a	YES	
Saint Kitts and Nevis	n/a	n/a	YES	RATIFIED
Saint Lucia	n/a	n/a	YES	RATIFIED
Saint Vincent and the Grenadines	n/a	n/a	YES	
Samoa	n/a	n/a	YES	RATIFIED
San Marino	RATIFIED	signed	YES	
Sao Tome and Principe	n/a	n/a	YES	
Saudi Arabia	n/a	n/a	YES	
Senegal	n/a	n/a	no vote	RATIFIED
Serbia	signed		abstained	
Seychelles	n/a	n/a	no vote	RATIFIED
Sierra Leone	n/a	n/a	YES	
Singapore	n/a	n/a	no	RATIFIED
Slovakia	RATIFIED	RATIFIED	YES	RATIFIED
Slovenia	RATIFIED	RATIFIED	YES	
Solomon Islands	n/a	n/a	YES	
Somalia	n/a	n/a	abstained	
South Africa	n/a	n/a	abstained	RATIFIED

Country	1997 COE Biomedicine Convention	1998 COE Cloning Convention	2005 UN Cloning Vote	2005 UNESCO Sports Doping Convention
South Korea	n/a	n/a	no	RATIFIED
Spain	RATIFIED	RATIFIED	no	RATIFIED
Sri Lanka	n/a	n/a	abstained	
Sudan	n/a	n/a	YES	
Suriname	n/a	n/a	YES	
Swaziland	n/a	n/a	no vote	
Sweden	signed	signed	no	RATIFIED
Switzerland	signed	signed	YES	
Syrian Arab Republic	n/a	n/a	abstained	
Taiwan				
Tajikistan	n/a	n/a	YES	
Tanzania	n/a	n/a	YES	
Thailand	n/a	n/a	no	RATIFIED
Timor-Leste	n/a	n/a	YES	
Togo	n/a	n/a	no vote	
Tonga	n/a	n/a	no	
Trinidad and Tobago	n/a	n/a	YES	RATIFIED
Tunisia	n/a	n/a	abstained	RATIFIED
Turkey	RATIFIED	signed	abstained	
Turkmenistan	n/a	n/a	no vote	
Tuvalu	n/a	n/a	no vote	
Uganda	n/a	n/a	YES	
Ukraine	signed	signed	abstained	RATIFIED
United Arab Emirates	n/a	n/a	YES	
United Kingdom			no	RATIFIED
United States of America	n/a	n/a	YES	
Uruguay			abstained	RATIFIED
Uzbekistan	N/A	N/A	YES	
Vanuatu	N/A	N/A	no vote	
Venezuela			no vote	
Vietnam	n/a	n/a	no vote	
Yemen	N/A	N/A	abstained	
Zambia	N/A	N/A	YES	
Zimbabwe	N/A	N/A	abstained	

Attachment D: Summary of Policies on Embryonic Stem Cell Research

This Table groups countries according to their attitudes to human embryonic stem cell research (hESC). Countries with no known policies, or whose policies are known to be unclear (for example, Ireland), are not included. The United States is not included, since national policy is currently based largely on executive funding decisions rather than legislation, and policies among the states vary widely.

Definitions:

- ***SCNT Allowed:*** Research cloning is specifically permitted under certain conditions.
- ***Use of Leftover Embryos Allowed:*** Research cloning is prohibited, but hESC using embryos left over from fertility treatment is permitted, explicitly or implicitly.
- ***Specific Cell Lines Only:*** Research on hESCs is only permitted using cell lines created before a certain date.
- ***Prohibited:*** Research using embryos or cell products derived from embryos is prohibited.

Note: The data is largely based on a UK Human Fertility and Embryology Authority (HFEA) publication and on the Hinxton Group database on World Stem Cell Policies.[31] *However, the Center for Genetics and Society interprets policies in South Africa as less permissive and in Finland as more permissive, and adds Cuba and Thailand to the list. Several Central and South American nations are consistently listed as having prohibitive policies due to constitutional expressions extending a "right to life" to conceived or unborn persons, but there is some doubt as to whether these apply to all research.*

Summary of Policies on Embryonic Stem Cell Research

SCNT Allowed	Use of Leftover Embryos Allowed		Specific Cell Lines Only	Prohibited
Australia	Argentina	Iran	Germany	Austria
Belgium	Brazil	Latvia	Italy	Colombia
China	Bulgaria	Moldova		Costa Rica
Cuba	Canada	Netherlands		Ecuador
Finland	Croatia	New Zealand		El Salvador
India	Cyprus	Portugal		Lithuania
Israel	Czech Republic	Romania		Norway
Japan	Denmark	Russia		Panama
Singapore	Estonia	San Marino		Peru
South Korea	France	Slovenia		Poland
Spain	Georgia	South Africa		Slovakia
Sweden	Greece	Switzerland		Tunisia
Thailand	Hungary	Taiwan		
United Kingdom	Iceland	Turkey		

[31] HFEA, *Hybrids and Chimeras: Findings of the Consultation*, Annex C – International Perspective, September 5, 2007; available from http://www.hfea.gov.uk/en/1579.html
The Hinxton Group, "World Stem Cell Policies," http://www.hinxtongroup.org/wp.html

Attachment E: Summary of Policies of OECD States

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation of thirty countries that accept the principles of representative democracy and free market economy. It provides a forum in which governments can share policy experiences, identify good practices, and coordinate domestic and international policies addressing economic, environmental and social issues.

Definitions:

- ***Reproductive Cloning:*** the creation of fully gestated human children that are genetically identical to previously existing human beings, whether living or dead
- ***Inheritable Genetic Modification:*** the manipulation or replacement of the genes in a person's egg or sperm cells, such that the changes can be passed on to all succeeding generations
- ***Non-Medical Trait Selection:*** the selection of eggs, sperm or embryos that possess genes associated with particular traits considered desirable, even if the unwanted traits do not suggest an increased likelihood of developing disease, without actually modifying those genes
- ***Research Cloning:*** the creation of fully gestated human children that are genetically identical to previously existing human beings, whether living or dead
- ***Medical Trait Selection:*** the selection of eggs, sperm or embryos that possess genes associated with particular traits, in order to avoid an increased likelihood of developing disease, without actually modifying those genes

Key:

- ***PROHIBITED:*** This practice is prohibited by national law or policies having the force of law.
- ***allowed:*** This practice is permitted (and generally regulated) by national law or policies having the force of law.
- ***no policy:*** This practice is not addressed by national law or policies having the force of law.
- ***?:*** It is unknown or unclear whether this practice is addressed by national law or policies having the force of law.

Note: The categories defined in the key and used in the table characterize the policies in any given country in a broad manner. Policy details may vary among countries. Data were compiled by the Center for Genetics and Society, June 2008. Sources included country- and topic-specific websites, other surveys and inventories, and journal accounts, as well as laws and policy instruments when available in English. Texts of policies are often difficult to interpret, and policies are subject to change.

Summary of Policies of OECD States

Country	Reproductive Cloning	Inheritable Genetic Modification	Non-Medical Trait Selection	Research Cloning	Medical Trait Selection
Australia	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
Austria	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Belgium	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
Canada	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Czech Republic	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Denmark	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Finland	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
France	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Germany	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Greece	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Hungary	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Iceland	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Ireland	PROHIBITED	?	?	PROHIBITED	?
Italy	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Japan	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
Luxembourg	PROHIBITED	?	?	PROHIBITED	?
Mexico	PROHIBITED	?	?	?	?
Netherlands	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
New Zealand	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Norway	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Poland	PROHIBITED	?	?	?	?
Portugal	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
Slovakia	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	?
South Korea	PROHIBITED	PROHIBITED	PROHIBITED	allowed	PROHIBITED
Spain	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
Sweden	PROHIBITED	PROHIBITED	?	allowed	?
Switzerland	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED
Turkey	PROHIBITED	PROHIBITED	PROHIBITED	PROHIBITED	allowed
United Kingdom	PROHIBITED	PROHIBITED	PROHIBITED	allowed	allowed
United States of America	no policy	no policy	no policy	no policy	no policy

Attachment F: The Council of Europe *Convention on Biomedicine and Human Rights*

The Council of Europe is an organization of 47 European countries that works to foster democracy and human rights. Much of the Council's work focuses on intergovernmental agreements, some of which may be open to signatories other than Council members. The Council maintains a Bioethics Division within its Legal Affairs field, guided by a Steering Committee on Bioethics (CDBI).

The Council's landmark Convention on Biomedicine and Human Rights was opened for signatures in 1997 and went into force in 1998. It explicitly prohibits inheritable genetic modification, somatic genetic modification for enhancement purposes, social sex selection, and the creation of human embryos solely for research purposes:

> ***Article 11*** *– Non-discrimination:* Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.
>
> ***Article 12*** *– Predictive genetic tests:* Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling.
>
> ***Article 13*** *– Interventions on the human genome:* An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.
>
> ***Article 14*** *– Non-selection of sex:* The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided. …
>
> ***Article 18*** *– Research on embryos in vitro:* … The creation of human embryos for research purposes is prohibited.
>
> ***Article 21*** *– Prohibition of financial gain:* The human body and its parts shall not, as such, give rise to financial gain.

Human reproductive cloning was banned by an amendment to the Convention, the Additional Protocol on the Prohibition of Cloning Human Beings:

> Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

In other articles the Convention addresses additional topics around which international consensus may be possible. These include:

- The necessity of equitable access to health care
- Adherence to professional obligations and standards
- Commitment to free and informed consent, and special protection for those not able to give consent
- Commitment to the protection of research subjects
- Procedures concerning organ and tissue removal from living donors for transplantation purposes
- Respect for privacy and the right to know regarding information collected about one's genetic makeup

Attachment G: The Canadian Assisted Human Reproduction Act

In 2004 the Canadian Parliament approved the Assisted Human Reproduction Act (AHRA). The legislation drew clear lines prohibiting unacceptable applications of new human genetic and reproductive technologies while allowing beneficial applications to proceed in a socially accountable manner.

Canada grounded the AHRA in an explicit "declaration of principles," including:

- the health and well-being of women and children
- nondiscrimination; non-commodification
- free and informed consent
- human health, safety, dignity and rights in the use of assisted reproduction
- human individuality and diversity, and the integrity of the human genome.

The AHRA prohibits a number of practices, including:

- the creation of cloned embryos, whether for research or reproduction
- the creation of human embryos solely for research
- germline genetic modification
- human/non-human hybrids and chimeras
- sex selection except to "prevent, diagnose or treat a sex-linked disorder or disease"
- payments for surrogacy, gametes, or embryos.

Permitted practices include:

- *in vitro* fertilization
- sex selection for sex-linked diseases
- non-commercial surrogacy
- embryonic stem cell research using embryos created but not used for reproductive purposes.

The AHRA establishes the Assisted Human Reproduction Agency of Canada to develop and oversee regulations covering these and other permitted activities. The Agency is to license and monitor all private and public fertility clinics, research facilities and other institutions whose research or commercial activity involves human gametes or embryos.

The Agency is governed by a 13-member Board and chief executive officer, both of whom are appointed by the federal Cabinet and report to the Ministry of Health. Serving 3-year terms, board members are to be selected from a wide range of relevant backgrounds, "including: health sciences; health law; social ethics; or a relevant field in the social sciences (such as women's and children's health)" but cannot be in a position regulated by the Agency. Senators voting for the bill recommended that at least 50% of the members be women.

The AHRA provided for a legislative review after three years. This provision enabled many who were not completely satisfied with the measure to support it nonetheless.

Mr. SHERMAN. Thank you, Dr. Hayes.

Welcome, Dr. Nigel Cameron, president of the Center for Policy on Emerging Technologies here in Washington, DC. In 1983, Dr. Cameron established the Journal of Ethics and Medicine which focuses on the ethical assessment of new issues and technologies in medicine and bioscience. Dr. Cameron's current research focuses on the ethical and policy aspects of cloning, nanotechnology, and human enhancement. I have had a chance to get to know Dr. Cameron over the last several years focusing on these issues, and I look forward to hearing them now.

STATEMENT OF NIGEL M. DE S. CAMERON, PH.D., PRESIDENT AND CO-FOUNDER, INSTITUTE ON BIOTECHNOLOGY AND THE HUMAN FUTURE

Mr. CAMERON. Thank you very much, Mr. Chairman.

It is a privilege and an honor to be here and not least indeed to be supportive of your initiative in raising these crucial questions in this context.

My research concerns for most of my life have been focused on the implications of emerging technologies. We tend to call these discussions ethical discussions. I think it is more significant that we see them as policy discussions, and that is one reason why my major concern in this entire enterprise is to mainstream this conversation, which is why I think to find this conversation taking place in this committee is of particular importance.

It is nowhere more the case than in the context of the asymmetric threats confronting us in the 21st century that we find the importance of bringing the conversation about the future of emerging technologies and their social significance into the political and the policymaking mainstream. In fact, the implications of emerging technologies, especially in relation to their increasing speed of progress and their tendency to converge, will frame essentially every major policy discussion of the 21st century.

To the extent that we choose not to be cognizant of this fact, which, by and large, our political establishment, our policymakers have not been cognizant because they have been focused elsewhere, we raise significantly the risks involved, not simply risks for security risks, sort of moral risks, but also investment risks, technology risks.

In Europe, of course, because the GMO food experience, it is far easier to command a hearing in policy circles for this conversation than it is elsewhere in the world, but there is a salutary lesson there in the common interests, both of the business community and, if you like, the moral and political community, in raising these issues and in providing the kind of ballast which mainstream conversation then provides.

It has been suggested that the transformative impact of emerging technologies is best understood in the context of the convergence of technology, and in particular, to use one category, which has been widely adopted, to bring together nanotechnology, biotechnology, information technology, and cognitive science, sometimes referred to as NBIC, or NBIC, the acronym, and this is the theme of several substantial documents that have issued from the National Science Foundation in recent years.

The first was published in 2002 under the title Converging Technologies for Improving Human Performance, and this report suggests that the chief goal of convergence lies in its improvement of the performance of individuals and of the community, engaging a fundamental change in human capacities, and that is where I want to focus my remarks this morning, essentially on the significance of the reengineering of the brain and the development of the so-called brain machine interface—the initials BMI primarily are used to refer to people's concerns about their weight—but BMI of the 21st century, which I think may prove to be the single most significant question to be discussed in the 21st century will be the ways in which the human brain is being enabled to interface with machine intelligence and, therefore, in which the bio issues and non-bio issues become one and the same issue in this kind of convergence.

The significance of this report and related reports from the National Science Foundation in this context is to show that there are your mainstream thinkers at the heart of our own science and engineering technology establishment who take these questions enormously seriously and, in some cases, who seem to have enthusiasm for this particular application of these technologies, but it has been very much in the mainstream of conversation within that community, and I think that is helpful if we are seeking to bring this into the mainstream of the policy community.

Now dramatic claims have been made for what may come from these technologies. To go to one of the founders of nanoscale science, the latest Nobel laureate Richard Smalley, who testified, in fact, in a hearing here on the Hill in 1999, he said:

> "There is a growing sense in the scientific and technical community that we are about to enter a golden age. These little nano things and the technology that assembles and manipulates the nanotechnology will revolutionize our industries and our lives."

Less modest projections, referenced, indeed, in that NSF report and other documents, have included—and I am not making this up—something akin to eternal life and also an end to scarcity, an end in principle to scarcity. The implications, of course, of claims of that kind for every policy area are immediately obvious since all of our contemporary policy assumptions assume immortality will not come and scarcity will remain.

One recent writer put the matter in these terms:

> "Among the applications of nanotechnology that some researchers consider science fiction, while others are actively attempting to implement, are enhancements to human memory, physical strength, other characteristics. Though usually framed as attempts to monitor or repair ailments or disabilities, some of these technologies can simultaneously be used to control or enhance particular human characteristics."

And, of course, in his widely noted essay, somewhat notorious essay, "Why the Future Doesn't Need Us," technology guru Bill Joy proffered alternative scenarios of doom: Either unintended disaster

or intentional enhancement which will bring about de facto the end of human nature as we know it.

International significance of these discussions has already been illustrated—I will make a brief reference here—in that the European Commission was so concerned about that 2002 NSF report that they set up a High Level Expert Group, which produced a report in response and sort of developed a European framing of these questions which was not so focused on the optimistic assumptions of human enhancement and more concerned about the enhancement of human experience and the human community as the goal of these technologies.

Concluding observation: It is not necessary to take any particular view of the merits of individual uses of these technologies—and I am not for this purpose taking any particular view myself—to recognize that the fundamental question we face is how we can weigh the significance of these questions, re-weigh the significance of these questions. Of course, one can understand the political arena of the sort of matrix in which political ideology comes together with the weighting of individual questions.

And I think we need a fundamental re-weighting of the significance of the questions raised by these technologies in order that here in the United States where, of course, we are still the global leader in the individual technologies themselves and in the many multilateral institutions where these conversations have been taking place, although where they fail to find a primary location in which to take place, we can begin to address the implications of these technologies and to mainstream the conversation, which, of course, will be central both to our economy as well as our security, but also to the social order.

Thank you very much.

[The prepared statement of Mr. Cameron follows:]

PREPARED STATEMENT OF NIGEL M. DE S. CAMERON, PH.D., PRESIDENT AND CO-FOUNDER, INSTITUTE ON BIOTECHNOLOGY AND THE HUMAN FUTURE

Mr. Chairman, Ladies and Gentlemen:

I am Nigel Cameron, Research Professor at the Illinois Institute of Technology and President of the Center for Policy on Emerging Technologies, a new nonpartisan think tank focused on the policy implications of the technologies that are set to shape tomorrow. It is an honor to be invited to testify before the Committee on matters of profound consequence for the human future. I should state that I speak on my own behalf today and not for either of these institutions and my various colleagues. Much of my professional life has been devoted to questions raised at the interface of emerging technologies, ethics and public policy. It is my view that questions of this kind are of increasing import, and will permeate every policy discussion of the 21st century. We would do well to be better prepared.

This is nowhere more the case than in the context of asymmetries and the risk that flows from them. Our tendency has been to avert our eyes from the societal implications of technologies, except in specific hot-button issues such as research involving human embryos or, particularly in Europe, so-called GMO foods. In fact the implications of emerging technologies, especially in relation to their increasing speed of progress and their tendency to converge, are far greater. To the extent that we choose not to be cognizant of this fact, we raise considerably the risks involved. Our policy response to these two sets of issues has been to segment them from broader questions of technology and address them on their own terms. It is needful also to see them as flashpoints of controversy within the wider context of a social order that is increasingly pervaded by transformative and disruptive technologies, the future significance of which is very hard to assess though which will undoubtedly be both vast and comprehensive in its impact on our social and individual life, as on that of our nation and the wider world.

As 9/11 demonstrated, the increasing complexity of the global order and the open-textured nature of our societies have brought us to a point where asymmetric possibilities are reshaping our notions of security and threat.

The transformative impact of emerging technologies is best understood with reference to the "convergence" of nanotechnology, biotechnology, information technology, and cognitive science (sometimes referred to as NBIC). This is the theme of several substantial documents issuing from the National Science Foundation, the first published in 2002 under the title *Converging Technologies for Improving Human Performance*. The report suggests that the chief goal of "convergence" lies in "improving human performance," a fundamental change in human capacities. This is where I am focusing my remarks today, since the prospect of a race to enhance human performance through re-engineering the brain, and developing the brain-machine interface so that a cyborgs model emerges, could lead to both destabilization and the final subsuming of the Renaissance and Enlightenment ideals that have birthed and sustained democracy through the making of a super-race. While this may seem far-fetched, my point this morning is that there are many smart and influential experts in these technologies who do not believe that to be the case. They may be mistaken, but the issue must be addressed with a far greater degree of seriousness, both within the United States and the wider global community.

Among the goals and anticipated results are listed the following: "enhancing individual sensory and cognitive capacities . . . improving both individual and group creativity . . . communication techniques including brain-to-brain interaction, perfecting human-machine interfaces including neuromorphic engineering. . . ."[1] The report asks: "How can we develop a transforming national strategy to enhance individual capacities and overall societal outcomes? What should be done to achieve the best results over the next 10 to 20 years?"[2] And, at the end of one list of long-term implications, it specifies a basic shift in "human evolution, including individual and cultural evolution."[3] Then this:

> Technological convergence could become the framework for human convergence. The twenty-first century could end in world peace, universal prosperity, and evolution to a higher level of compassion and accomplishment. . . . [I]t may be that humanity would become like a single, distributed and interconnected "brain" based in new core pathways of society.[4]

While this document has plainly been influenced by the futurist ideology called "transhumanism," which couches the prime purpose of emerging technologies as the transformation of human functioning into something ultimately "posthuman," the point to be noted is that senior NSF figures see these ideas as congruent with the potential of emerging technologies, and view the prospect with enthusiasm and optimism.

Such dramatic claims have focused on the role of nanotechnology, or nanoscale convergence, in enabling innovation and control that is at present far beyond us. It is no simple matter to assess likely outcomes in an area where much research is still at a fundamental level. But in developing policy to ensure appropriate policy responses to what may ensure, it is prudent to assume that the expectations of leading researchers may come to fruition. One of the founders of nanoscale science, the late Nobel laureate Richard Smalley, used these measured terms: "There is a growing sense in the scientific and technical community that we are about to enter a golden age. . . . These little nanothings, and the technology that assembles and manipulates them—nanotechnology—will revolutionize our industries, and our lives."[5] Less modest projections, referenced in NSF publications, have included something akin to eternal life, and an end to scarcity.

Six distinct sets of questions are raised for ethics and policy by developments on the nanoscale. From one perspective they represent the familiar ethical questions that all technologies entail. Yet the hopes and expectations that have been raised for the application of nanotechnology to human well-being are so great that its ethical implications are potentially of a proportionately higher order of magnitude. Indeed, they have the effect of transforming discussion of the particular applications

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[1] Roco, M. and Bainbridge, W. S., eds. (2002). *Converging Technologies for Improving Human Performance*, pg. ix. Retrieved October 17, 2006, from http://wtec.org/ConvergingTechnologies.

[2] *Id* at x.

[3] *Id.* at 4.

[4] *Id.* at 6.

[5] Richard E. Smalley, Oral Testimony Before United States House of Representatives Science Committee Subcommittee on Basic Research (June 22, 1999).

of a particular technology at the nanoscale into a point of focus for our consideration of the place of technology in relation to human nature and human society.

Several key questions are raised.

1. The question of hazard: what risks are appropriate? While issues of safety are always also issues of ethics, the ethical dimension of nanotechnology risk is in proportion to the potential dangers of the technology. The cautious approach taken in the 2004 SwissRe report[6] suggests that while some of the detractors of nanotechnology may overstate its risks to health and the environment, and while the likelihood of unintended harm may be low, the scale of damage that would result from a serious misjudgment could prove very great.
2. Broader challenges that these new technologies present for the social order and the wider human community include threats to confidentiality. Such prospects as large-scale diffusion of radio-frequency identifier chips (RFIDs), retinal scanning, face identification technologies, and so far undeveloped options that may render privacy in general a costly commodity. The preservation of medical confidentiality has already been rendered enormously more difficult by the development of electronic databases.
3. Issues of equity, which have been termed the "nano-divide," since despite the hopes of some that technology at the nanoscale will prove ultimately cheap, it is a reasonable to assume that its distribution applications will follow current economic patterns. Thus the suggestion that "all cancer" will be curable or become chronic and manageable by 2015 is unlikely to include the cancer of all persons afflicted with the disease in parts of the globe struggling to establish basic public health.
4. Special issues raised by military applications of these technologies.
5. The question of the human condition, which may seem at an intuitive level clear though is hard to define. A major theme of the President's Council on Bioethics report on enhancement technologies, *Beyond Therapy*, is the difficulty we face in drawing such lines. But there is no more important question, since the fundamental challenge of this technology is to our anthropology and the assumptions we make about human being and what is proper to ourselves.[7]

THE PROSPECT OF HUMAN AUGMENTATION

One recent writer has put the matter thus: "Among the applications of nanotechnology that some researchers consider 'science fiction,' while others are actively attempting to implement, are enhancements to human memory, physical strength, and other characteristics. Though usually framed as attempts to monitor or repair ailments or disabilities such as Parkinson's disease or genetic abnormalities, some of these technologies can simultaneously be used to control or enhance particular human characteristics in 'normal' humans as well."[8] In his widely-noted essay, "Why the Future doesn't need us," technology guru Bill Joy proffered alter-

[6] SWISS RE, NANOTECHNOLOGY: SMALL MATTER, MANY UNKNOWNS (2004).

[7] By way of illustration, a recent document from the World Health Organization, in the context of a generally sympathetic review of artificial reproduction technologies, places them in this anthropological framework: "What are the consequences for a society of having chosen to develop a medically mediated form of reproduction? . . . *What seems to be at stake in the development of these practices is a transformation of the anthropological conditions of procreation*." Simone Bateman, When reproductive freedom encounters medical responsibility: changing conceptions of reproductive choice, in Current Practices and Controversies in Assisted Reproduction. Report of a meeting on "Medical, Ethical and Social Aspects of Assisted Reproduction," September 2001, Geneva: World Health Organization, 2002, at 330. Our emphasis. She states: "The fact that would-be parents, whatever their social status, are asking physicians to provide the means of accomplishing what was once an intimate act is hardly an anodyne fact. Whatever the differences in technical variants, reproductive technology appears essentially to be "emancipating" procreation from the usual conditions of heterosexual commerce. Artificial insemination has long since desexualized the act of conception. IVF has now disembodied conception, a trend that could be extended to the rest of pregnancy by creating the conditions for ectogenesis. The prospect of cloning now augurs the emancipation of procreation from what still remains the fundamental requirement of sexual reproduction, the participation of sexually differentiated beings, and introduces the possibility of using reproductive cells (embryonic stem cells) for non-reproductive therapeutic purposes."

[8] Bruce V. Lewenstein, *What Counts as a 'Social and Ethical Issue' in Nanotechnology?* 11 HYLE–INT'L JOUR. PHIL. CHEM. 5, 12 (2005).

native scenarios of doom: either unintended disaster or intentional enhancement will bring about the end of human nature as we know it.[9]

Recent discussion of "converging technologies" as the context for nanotechnology draws attention to the interconnected challenges they present, above all to human nature. Leon Kass, then chairman of the President's Council on Bioethics, remarked on the inter-relations of these technologies, such that advances in genetics "cannot be treated in isolation" but must be correlated with "other advances in reproductive and developmental biology, in neurobiology, and in the genetics of behavior—indeed, with all the techniques now and soon to be marshaled to intervene ever more directly and precisely into the bodies and minds of human beings."[10]

A critique of the NSF's 2002 NBIC report has come from a High Level Expert Group (HLEG) established by the European Commission. It offers a useful counterweight to the NSF report's embrace of "transhumanist" aspirations that have seen nanotechnology as a route to the transformation of human nature as we know it into some "posthuman" form—whether that of radically enhanced human being, or machine intelligence that supplants corporeal Homo sapiens altogether.

The major area of concern, as noted in the HLEG report, lies in cognitive science.[11] Concerns may perhaps be most starkly illustrated with reference to the prospect of cognitive "enhancements" that involve the manipulation of perception and memory, whether through neuro-pharmacology (including what has been termed "cosmetic neurology") or cognitive prostheses. A recent editorial in the journal Neurology discussed the challenge of such technological use in these terms: ". . . its presence is already beginning to be felt in neurology. Cochlear implants are the sentinel example of mechanical interfaces providing sensory input to the human nervous system. Neural stimulators—for movement disorders and epilepsy—are other examples of technologies currently in (increasing) use. Some worry that these successes represent the beginnings of Cyborgs—individuals who are part human and part machine. For more than 50 years science fiction writers have imagined the potential for such human-robotic chimeras. Nanotechnology promises the potential of designing micromachines capable of dramatically advancing the potential of such interfaces."[12] Since development of such technologies will be invariably "dual use"—with initial applications that are legitimately therapeutic—the policy challenges they raise are profound.

CONCLUDING OBSERVATIONS

These developments undoubtedly require global assessment. This is the case not simply because U.S., European and Asian governments and corporations are alike embarked on the same enterprise, but because the implications of work on the nanoscale concern the future of the global community, and potentially that of the human species itself. Such efforts as the UNESCO Universal Declaration on Bioethics and Human Rights, setting questions of emerging technologies within the framework of "fundamental human rights and freedoms," offer a precedent. In seeking to set the pace in global biopolicy for the 21st century, the Declaration takes as its point of departure the Universal Declaration on Human Rights. It sets the new technology questions in the framework of human values, with special focus on the rights and dignity of the individual. Yet the location of global governance discussions has yet to be clarified, with OECD and various ad hoc bodies engaged.

While the dividing line between therapy and enhancement is not easily drawn, the principle is clear: the restoration of human function lies in a separate category from the development of functions not found in humans, or the upgrading of human functions (and especially human intelligence) to a level not found in humans. While this may appear an issue of ethics or simply one of choice, its implications for the global community remain to be addressed.

Mr. SHERMAN. Thank you.

Without objection, the full written statements submitted by all witnesses will be included in the record, together with the materials prepared for these hearings by CRS and the Library of Congress, together with a speech I gave to the World Congress on Health and Information Technology, and together with any other

[9] Bill Joy, *Why the Future Doesn't Need Us*, WIRED, April 2000.

[10] Leon R. Kass, *The Moral Meaning of Genetic Technology*, Commentary, Sept. 1999, at 34, 35.

[11] *Foresighting the New Technology Wave: Converging Technologies—Shaping the Future of European Societies*, HLEG Report, at 12.

[12] Neurology 2004, 63: 949

materials submitted by witnesses or by members in the next 10 legislative days.

[The information referred to follows:]

Memorandum June 17, 2008

TO: House Committee on Foreign Affairs
Subcommittee on Terrorism, Nonproliferation and Trade
Attention: Don MacDonald

FROM: Judith A. Johnson and Amanda Sarata
Domestic Social Policy Division

SUBJECT: Human Gene Transfer Research: An Overview of the State of the Science and U.S. Efforts to Address Related Ethical and Social Issues

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In response to your request we have prepared a memorandum on human genetic engineering, often referred to as human gene transfer research or human gene therapy. You asked for a review of the state of the science in this area, in terms of both what is currently possible and what may be possible in the not-so-distant future. You also requested that we outline the efforts by the United States government to manage the ethical and societal implications of such research. As we discussed by phone, the international aspects of your request will be answered by staff in the Law Library of the Library of Congress. Lastly, you requested "a brief survey of the literature concerning possible misuses or uses of human genetic technologies that raise significant ethical consideration, especially those that permanently alter inheritable human genetics." We are attaching summaries, abstracts, and excerpts for articles and reports on inheritable genetic modification provided by our colleague, Angela Napili.

The State of the Science

Human genetic engineering may be defined as the directed modification of human genetic material. This is in contrast to genetic screening, for example prenatal genetic diagnosis or pre-implantation genetic diagnosis, which does not physically alter genetic material, but rather screens it for variants of interest. The research technique of gene therapy, or gene transfer, was conceived of for the purposes of modifying genetic material to treat or even cure disease.

Currently, human gene transfer research modifies somatic genetic material which is not inherited or inheritable.[1] It targets the amelioration of disease rather than the enhancement of normal traits, and attempts to deliver only one gene (or possibly two) at a time.

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[1] A somatic cell is a body cell. In contrast, a germ cell is a gamete, such as an egg or sperm cell.

The National Institutes of Health (NIH) defines human gene transfer as the process of transferring genetic material into a person.[2] Researchers are using a variety of experimental techniques to investigate whether health problems, many caused by a malfunctioning gene or genes, can either be cured or ameliorated via this form of molecular medicine. Gene transfer research begins in cell and animal models, and must have a long history of cellular and animal experiments prior to clinical trials involving human subjects. A recent search performed on ClinicalTrials.gov found 1414 studies involving gene therapy; of these, 828 studies currently are seeking new volunteers.[3] All such clinical trials must be reviewed by the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA), and the NIH Recombinant DNA Advisory Committee (RAC), as well as the Institutional Review Board (IRB) at each research site before the trial can begin to recruit patient volunteers.

Most of the clinical trials involving gene transfer are cancer related (70%) and are conducted on terminal patients.[4] The vast majority of gene transfer clinical trials are in the relatively early stages of investigation, either Phase I (safety) or Phase II (initial efficacy), with only a very small percentage (~1%) in Phase III.[5] Between 2004 and 2007, only ten Phase III protocols were submitted for review to the Recombinant DNA Advisory Committee.[6] Although many believe there is great potential for gene therapy to revolutionize the treatment of disease, it is still considered to be an experimental technique with unique and potentially unknown risks. FDA has not yet approved for sale any human gene therapy products.[7] In fact, one commentator notes that, "(g)ene transfer has often been characterized as permanently 5 years away from clinical application."[8]

An Overview of the History of Gene Transfer Research

Many point to the attempt by W. French Anderson in 1990 to treat patients suffering from a form of severe combined immune deficiency (SCID) as the first clinical trial of human gene therapy.[9] In this form of SCID the lack of an enzyme, called adenosine

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[2] Frequently Asked Questions (FAQs) about the NIH Review Process for Human Gene Transfer Trials, at [http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm].

[3] ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. The search on gene therapy was performed on June 11, 2008.

[4] Inder M. Verma and Mathew D. Weitzman, "Gene Therapy: Twenty-First Century Medicine," *Annual Review of Biochemistry*, v. 74, 2005, p. 711-738.

[5] Ibid., p. 730. For a description of Phase I, Phase II and Phase III clinical trials, see [http://www.cancer.gov/clinicaltrials/learning/goldstandard/page3].

[6] Kimmelman, J.(2008) "The ethics of human gene transfer," *Nature Reviews Genetics*, v. 9, March 2008, p. 239-244.

[7] "FDA 101: Human Gene Therapy," FDA Consumer Health Information, U.S. Food and Drug Administration, March 3, 2008, at [http://www.fda.gov/consumer/updates/genetherapy022608.html].

[8] Kimmelman, "The ethics of human gene transfer," p. 240.

[9] Others say the first attempt occurred in the early 1970s when two young German sisters were (continued...)

deaminase (ADA), prevents the development of a functioning immune system. Children with SCID must be shielded from infection; the diagnosis is often missed and many die in early childhood from infection or following immunization with live viral vaccines. SCID can be treated with bone marrow transplantation but there can be problems with the transplants and most patients do not have a matched donor. Anderson and his team removed white cells from the patient's blood and used a retrovirus, a mouse leukemia virus, to insert the ADA gene into the white cells before returning the cells to the patient. The patients also received a drug, at that time newly approved by FDA, that is a synthetic form of the missing enzyme. Although the patients were successfully treated, the results continue to be controversial because many scientists believe the gene inserted by the viral vector failed to produce the missing enzyme and that the patients improved due to administration of the synthetic enzyme.[10] Years later Anderson's career came to a halt following an arrest in 2004 and conviction in 2007 on child molestation.[11]

Perhaps the most successful gene transfer trial conducted to date was led by Alain Fischer of the Necker Hospital in Paris, France. The trial involved children with X-linked SCID. This disease is another form of immune deficiency that affects only boys, the most well-known patient being the Bubble Boy in Texas, David Vetter.[12] The trial began in 1999 and used a retrovirus, a modified mouse leukemia virus, to insert the replacement gene into cells that had been removed from the patient. The cells were stem cells—progenitors destined to become white blood cells. The trial was successful and the results were superior to those achieved via bone marrow transplantation.[13] However, of a total of ten children treated by the Paris-based group, three developed a leukemia-like disease, two in 2002 and one in 2004; another group of ten patients treated in the UK has not been affected by the leukemia complication.[14] This development resulted in FDA imposing a "clinical hold" on a number of gene transfer trials that used the same viral vector. The clinical hold stopped administration of the gene transfer vector and enrollment of new research subjects until the

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[9] (...continued)
treated for a newly identified genetic disease, an enzyme (arginase) deficiency that caused mental retardation and cerebral palsy. The girls were injected with a wart-causing virus that was associated with high levels of the enzyme arginase in the skin of infected individuals. The attempt to treat the sisters was unsuccessful. A second case occurred in 1980 when Dr. Martin Cline of UCLA unsuccessfully attempted gene therapy on patients suffering from thalassemia, a hereditary blood disorder.

[10] Horace Freeland Judson, "The Glimmering Promise of Gene Therapy," *Technology Review*, November/December 2006, p. 40-47; and, Verma and Weitzman, Gene Therapy: Twenty-First Century Medicine, 2005.

[11] Jennifer Kahn, "Molest Conviction Unravels Gene Pioneer's Life," *Wired Magazine*, September 25, 2007, at [http://www.wired.com/print/techbiz/people/magazine/15-10/ff_anderson].

[12] Randy Dotinga, "Sad Story of Boy in the Bubble," *Wired*, April 10, 2006, at [http://www.wired.com/entertainment/theweb/news/2006/04/70622].

[13] Fred S. Rosen, "Sucessful Gene Therapy for Severe Combined Immunodeficiency," *New England Journal of Medicine*, v. 346, April 18, 2002, p. 1241-1243.

[14] Fabian Filipp, "From Bench to Bedside: An interview with Alain Fischer, immunologist and gene therapist at the Necker Hospital in Paris," France, *EMBO Reports*, v. 8, n. 5, 2007, p. 429-432.

cause of the leukemia-like disease was identified and the risks and benefits of the gene transfer could be assessed. Chemotherapy effectively treated two of the patients, the third child died. Research has determined that the leukemia-like disease was caused by insertional mutagenesis — the curative gene inserted within or near a gene associated with leukemia on one of the patient's chromosomes.[15]

Although the field of human gene transfer research has been plagued with problems, a recent successful attempt to correct a faulty gene that causes blindness by using another viral vector, adeno-associated virus, has produced a fair amount of optimism with impressive results. Researchers in Pennsylvania and London restored the sight of four adults born with a disorder called Leber congenital amaurosis 2 (LCA2).[16] All four are still legally blind, but some of them can read several lines on an eye chart or navigate through an obstacle course after receiving a single injection of a solution containing the curative gene. The researchers believe the benefits may be greater when the procedure is tried on young children with LCA2.

Technical and Safety Concerns

Two of the three examples of human gene transfer research described above illustrate some of the challenges that scientists face in this line of research. The gene may not function at all once it is inside the patient, as in the case of the French Anderson group studying ADA-SCID. Conversely, the expression of the gene, once inserted, may be uncontrolled, unstable or time-limited. The gene may insert randomly into the patient's genetic material and, therefore, may cause an adverse event by (1) disrupting a normal and necessary gene, or (2) activating a gene that causes cancer, as in the case of the Paris group studying X-linked SCID. For gene transfer experiments, most researchers use a pathogenic virus in which the disease-causing viral genes have been removed. Although this is generally thought to be safe, there are no guarantees that the virus could not somehow cause disease, an immune reaction or some other adverse event after it enters the patient.

An example of an adverse immune reaction to a viral vector can be found in the infamous case of Jesse Gelsinger. In 1999, researchers at the University of Pennsylvania began recruiting volunteers for a Phase I clinical trial to test the safety of a human adenovirus vector that would be used to transfer the gene for the liver enzyme ornithine transcarbamylase (OTC). Patients lacking OTC are unable to break down ammonia, a byproduct of protein metabolism. One 18 year-old volunteer, Jesse Gelsinger, died 4 days after administration of the adenovirus vector. His death was caused by a massive immune system reaction to the viral vector beginning with "jaundice, and progressing to a blood clotting disorder, kidney failure, lung failure, and ultimately brain death."[17] Gelsinger, who

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[15] Matthew P. McCormack and Terence H. Rabbitts, "Activation of the T-Cell Oncogene LM02 after Gene Therapy for X-Linked Severe Combined Immunodeficiency," *New England Journal of Medicine*, v. 350, February 26, 2004, p. 913-922.

[16] Jocelyn Kaiser, "Two Teams Report Progress in Reversing the Loss of Sight," *Science*, v. 320, May 2, 2008, p. 606-607.

[17] Larry Thompson, "Human Gene Therapy: Harsh Lessons, High Hopes," *FDA Consumer* (continued...)

lacked a normal OTC gene, had experienced a chest infection at some point before the trial and this may have contributed to his immune system reaction.[18]

Investigations by FDA found a number of serious deficiencies in the way the clinical trial had been conducted by the University of Pennsylvania such as (1) failure to immediately report to FDA serious side effects experienced by two human volunteers, and (2) the deaths of monkeys given a similar treatment were not included in the informed consent discussion.[19] These findings and the investigation of other human gene transfer trials resulted in new initiatives by FDA and NIH to increase the level of scrutiny of the trials via additional reporting requirements and random inspections.[20]

Gene Transfer Vectors

A major challenge in all gene transfer research is the development of a vector, often a modified virus, that can deliver a properly functioning gene into the appropriate tissue without causing any serious adverse effects.

Both French Anderson and Alain Fischer used a retrovirus as the vector to deliver the curative gene in their research. The ability of retroviruses to insert genes into the patient's genetic material is considered to be very useful—it allows for the long-term expression of the curative gene. However, a major disadvantage is that retroviruses insert genes into cells that are dividing, such as stem cells and cancer cells. This limits the utility of retroviruses because most cells in the patient are not in the process of dividing. Both research groups also used an *ex vivo* approach in their research, meaning that the procedure occurs outside the body. In both experiments, researchers removed cells from the patient, performed the gene transfer experiment, and then reintroduced the cells back into the patient. With a disease that impacts white blood cells such as SCID, an *ex vivo* approach can be used. However, there are many disease conditions in which cells or tissue cannot be easily removed from the patient in order to perform the gene transfer procedure. Therefore, an *in vivo* procedure, in which the viral vector is introduced inside the body, would be necessary in many cases.

In order to deliver a gene *in vivo*, an adenovirus vector may be used. Adenoviruses efficiently infect many human cell types such as the respiratory tract, eye, bladder, liver and gastrointestinal tract.[21] These viruses also cause few symptoms in humans, usually only the mild symptoms associated with the common cold.[22] One drawback, however, is that although the transferred gene is transported into the nucleus it is not normally inserted into

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[17] (...continued)
Magazine, September-October 2000, at [http://www.fda.gov/fdac/features/2000/500_gene.html].

[18] Adam Bostanci, "Blood Test Flags Agent in Death of Penn Subject," *Science*, v. 295, January 25, 2002, p. 604-605.

[19] Thompson, "Human Gene Therapy: Harsh Lessons, High Hopes."

[20] Ibid.

[21] Verma and Weitzman, "Gene Therapy: Twenty-First Century Medicine," p. 719.

[22] Kelly K. Hunt and Stephen A. Vorburger, "Hurdles and Hopes for Cancer Treatment," *Science*, v. 297, July 19, 2002, p. 415-416.

a chromosome. Therefore, the presence and expression of the transported/curative gene is only temporary and repeat administration of the adenovirus vector would be necessary in order to have the desired clinical effect in the patient. Newer versions of adenovirus vectors are being developed to address these shortcomings. Other vectors under investigation for gene transfer research include different viruses—such as herpes virus, lentivirus (HIV-1), foamy virus—and various nonviral gene delivery systems such as liposomes, which are microscopic fat globules used to deliver substances, including drugs or in this case a gene, to cells in the body.[23]

Future Research Directions

Research is currently focused on developing more sophisticated mechanisms of regulating the transferred gene by using inducible promoters (regions that control activation or repression of the gene) that respond to chemicals or hormones.[24] Another possible gene expression control mechanism is the use of zinc-finger protein transcription factors that have been designed specifically to control the expression of the desired target gene.[25] Other researchers are investigating the use of zinc-finger nucleases to one day directly repair gene mutations in the patient instead of introducing the curative gene via a vector.[26]

Enhancement

You are particularly interested in human genetic engineering for enhancement. When compared with the number of papers on using gene transfer to treat human disease, far fewer papers focus on enhancement research. Those that do, concentrate on concerns over "gene doping" and sports—improving performance by increasing muscle mass and endurance. Interesting examples of the natural variation in human performance as a result of naturally-occurring genetic variation do exist. The 1964 winner of two Olympic gold medals in cross-country skiing had unusually high levels of red blood cells due to a naturally-occurring mutation in a gene for erythropoietin, a hormone involved in the production and differentiation of red blood cells.[27] In another example, a German boy with mutations in the gene for myostatin, which regulates muscle development, has larger than average muscles and remarkable weight lifting ability.[28] The child's mother also had a myostatin mutation and is a professional sprinter.[29] Mice that have a disruption in the myostatin gene have a

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[23] Verma and Weitzman, "Gene Therapy: Twenty-First Century Medicine," p. 729.

[24] Ibid.

[25] Ibid.

[26] Jocelyn Kaiser, "Putting the Fingers on Gene Repair," *Science*, v. 310, December 23, 2005, p. 1894-1896.

[27] M. Kiuru and R.G. Crystal, "Progress and Prospects: Gene Therapy for Performance and Appearance Enhancement," *Gene Therapy*, v. 15, 2008, p. 329-337.

[28] David Epstein, "The Future," *Sports Illustrated*, v. 108, March 17, 2008, p. 44.

[29] Ibid.

doubling of muscle mass.[30] There has also been some speculation on the use of gene transfer for the enhancement of memory, cognition, and better appearance by controlling weight, height and hair growth.[31]

From a scientific perspective, there are two major barriers to the successful modification of somatic genetic material for the purposes of enhancing a complex physical or behavioral trait that is likely controlled by the expression of multiple genes (i.e., a polygenic trait). First, there is the actual laboratory technique which raises myriad technical and safety issues. As discussed previously, there are numerous technical barriers to successful somatic gene transfer research currently, including insertional mutagenesis, immune reactions to the delivery vector (usually a modified virus), uncontrolled expression of the gene, stable or long-term gene expression, and multiple gene insertions, to name a few. For example, overexpression of erythropoietin in mice can lead to liver, kidney, nerve and muscle degeneration.[32] In addition, where the desired trait is polygenic, as it likely would be in cases of enhancement, a technique for delivering multiple genes to a cell would need to be developed, and such a technique does not yet exist. Finally, in complex traits, those typically considered when contemplating enhancement, it is likely that delivery would not be targeted exclusively to one cell type or sub-system; therefore, a delivery mechanism would need to be developed that could target multiple systems or cell types. There is no current gene transfer research technique which is capable of delivering a gene to all the cells of the body.

Second, the genetics of the trait of interest would need to be fully understood. Although the sequencing of the human genome was a notable achievement, scientists are still years, and probably decades, away from a full appreciation of the genetic underpinnings of complex physical, and particularly behavioral, traits. Hypothetically speaking, even if the genetics was understood and safe and effective techniques for transfer were developed, scientists would still be faced with a number of difficult issues, including epigenetic changes and the role of the environment in the expression of a trait.[33]

If one were attempting to modify inherited genetic material, rather than simply somatic genetic material, additional technical issues would be raised because this research would be performed in embryos or on gametes and would require the successful development of a viable and unharmed fetus.

There is currently no gene transfer research being conducted *in healthy humans* which has as its aim the enhancement of traits and which modifies inheritable genetic material. At Cornell a gene for fluorescence was inserted into a non-viable (triploid) human embryo. Some have criticized the Cornell study for moving forward with inheritable genetic

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[30] Kiuru and Crystal, "Progress and Prospects: Gene Therapy for Performance and Appearance Enhancement," p. 333.

[31] Ibid., p. 329.

[32] Ibid., p. 330.

[33] Epigenetic changes affect a cell, organ or individual without directly affecting its DNA. An epigenetic change may indirectly influence the expression of the genome through, for example, DNA methylation or chromatin remodeling.

modification.[34] However, others maintain that because the embryo was non-viable, this research did not cross any ethical boundaries. From a scientific perspective, there are innumerable technical issues that would need to be addressed successfully to move a technique from a non-viable three-day-old embryo to a healthy human being.

U.S. Efforts to Address the Ethical and Social Implications of Human Genetic Technology

Genetic enhancement, both somatic and germ-line, raises significant social and ethical issues. Ethical discussions of human genetic technologies are often guided in their consideration by three critical distinctions. The first is whether the technology is used to identify, or screen, a specific variant or if it seeks to modify, or physically change, genetic material. The second is, if the technology actually modifies genetic material, whether it does so only in the somatic cells, thus limiting the effects to the treated individual, or whether it modifies germ-line genetic material, thus having the potential to affect future individuals. The third is whether the screening, or modification, is being used to screen for or ameliorate a disease or disability or rather to screen for or enhance an existing normal function, such as strength or intelligence. Enhancement would be considered a more ethically problematic application of genetic technology given that it would modify human genetic material for the purposes of enhancing a normal function, rather than ameliorating a disease. If enhancement were used to modify germ-line genetic material, it would be considered to be even more ethically problematic, as it would be modifying genetic material which in turn would be passed to subsequent generations.

As mentioned previously, enhancement raises numerous ethical and social issues. These include, but are not limited to: defining the distinction between therapy and enhancement; concerns about "playing god"; the moral status of the embryo; concerns about a return to eugenics; concerns about the commodification of human life; issues around social justice and disparities in access to new technologies; and the autonomy of future human beings. The length and scope of this memo does not allow for an in-depth treatment of all of these ethical issues, but it is worth noting that there are numerous issues currently under debate by ethicists, policymakers, scientists, clinicians, consumers and lawyers.

These significant ethical and social issues are being debated and addressed through a variety of mechanisms, outlined below. For purposes of clarity, efforts to address the ethical, legal and social implications of human genetic technologies often address two large, overarching categories: the issues which arise as a result of research using or developing human genetic technologies and those issues that will arise when a technology has passed out of the research phase either into the clinical or commercial phase. The term human genetic technologies, as used in the language of your request, is extremely broad and encompasses an enormous range of applications. Specifically, it may encompass prenatal genetic diagnosis, preimplantation genetic diagnosis, inheritable genetic modification, human reproductive or therapeutic cloning, stem cell technologies, genetic testing, and gene transfer

[34] N. Zaninovic, et al., "Genetic modification of preimplantation embryos and embryonic stem cells (ESC) by recombinant lentiviral vectors: efficient and stable method for creating transgenic embryos and ESC," *Fertility and Sterility*, v. 88, 2007, S310 - S310.

(for therapy or enhancement). For this reason, the following list of U.S. efforts in this area attempts to be as inclusive as possible.

- The Recombinant DNA Advisory Committee (RAC): RAC was established in 1974 due to public concern about scientific research with recombinant DNA. According to NIH, RAC serves as a "critically important forum for open, public deliberation on the panoply of scientific, ethical, and legal issues raised by recombinant DNA technology and its basic and clinical research applications." One of RAC's major roles currently is the review of human gene transfer research protocols which receive NIH funding for safety, scientific and ethical concerns.[35]

- President's Council on Bioethics: The Council was established in 2001 by President Bush in order to provide advice on "bioethical issues that may emerge as a consequence of advances in biomedical science and technology." The Council has examined numerous issues relating to human genetic technology, including human cloning, stem cell research, and genetic enhancement. A similar body was established during the Clinton Administration, the National Bioethics Advisory Commission.[36]

- White House Office of Science and Technology Policy: OSTP was established by Congress in 1976 with a broad mandate to advise the President and others within the Executive Office of the President on the effects of science and technology on domestic and international affairs. One of the issues that OSTP focuses on specifically is life sciences and genomics.[37]

- National Human Genome Research Institute's Ethical, Legal, and Social Implications (ELSI) Program: The ELSI program "was established in 1990 as an integral part of the Human Genome Project (HGP) to foster basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities. The ELSI Research Program funds and manages studies, and supports workshops, research consortia and policy conferences related to these topics."[38]

- Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS): SACGHS provides advice to the Secretary of Health and Human Services about the social, ethical, legal and clinical implications of genetic technologies. The Committee was chartered in 2003 and has

[35] See [http://www4.od.nih.gov/oba/rac/aboutrdagt.htm]. Access June 13, 2008.

[36] The reports of the National Bioethics Advisory Commission and other former U.S. national bioethics bodies can be found at [http://www.bioethics.gov/reports/past_commissions/index.html]. Accessed on June 16, 2008.

[37] See [http://www.ostp.gov/]. Accessed on June 16, 2008.

[38] See [http://www.genome.gov/10001618]. Accessed on June 14, 2008.

released major reports on a number of topics, including pharmacogenomics, coverage and reimbursement of genetic tests and services, and oversight of genetic testing.[39]

- National Academies Reports and Guidelines: The Institute of Medicine and the National Research Council of the National Academy of Sciences have issued reports addressing the social and ethical issues surrounding many human genetic technologies, including human embryonic stem cell research, human reproductive cloning, and genetic testing. Specifically, the NRC developed a set of national ethical guidelines for the conduct of human embryonic stem cell research, which, although voluntary, have been widely lauded by the scientific community as a valuable resource.[40]

The Genetic Information Nondiscrimination Act of 2007 (GINA) was signed into law on May 21, 2008. GINA extends protections against the use of genetic information to discriminate against individuals in health insurance or in employment. This is seen as an important step toward ensuring that new beneficial genetic technologies are utilized and that individuals are willing to participate in clinical trials involving genetic research.

It is worth noting that ethical analyses of genetic enhancement, and especially germ-line genetic enhancement, are based largely on speculation at this point despite progress in genetic research. One commentator notes the following:

> Ethical analysis of genetic enhancement has tended to argue from extreme premises: in these accounts, interventions aim at lurid and perfecting traits, absolute safety is assumed and the relationship between genetic modifications and traits is determinate. However, the first two decades of gene transfer belie problems with the later two assumptions — at least for the foreseeable future. What seems to be needed is an ethical framework applicable for the sorts of imperfect, risky and variably effective genetic interventions that are likely to be encountered in the near future.[41]

There are those who believe that there is value in addressing these concerns through guidelines or policies before the technology becomes a reality, even if the technology never does become a reality, and that this is an important dialogue that society must engage in openly.

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[39] See [http://www4.od.nih.gov/oba/sacghs/sacghsml.htm]. Accessed on June 16, 2008.

[40] The 2007 Amendment to the 2005 Guidelines for Human Embryonic Stem Cell Research can be found at [http://www.nap.edu/catalog/11278.html].

[41] Kimmelman, "The ethics of human gene transfer," p. 243.

[NOTE: The Library of Congress material is not reprinted here but is available in committee records or may be accessed on the Web at: http://www.foreignaffairs.house.gov/110/LawLibrary.pdf]

Congressman Brad Sherman

WORLD HEALTHCARE INNOVATION AND TECHNOLOGY CONFERENCE

Keynote Address of **Congressman Brad Sherman**

(Washington, D.C. — December 10, 2007)

Hello, I am Brad Sherman from California's best named city, Sherman Oaks.

I am in my sixth term in Congress. I spent four years on the Science Committee, until I was assigned to allegedly more important committees. And I have spent nine years focused on an issue I call "engineered intelligence".[1]

I believe that the impact of science on this century will be far greater than the enormous impact science had on the last century. As futurist Christine Peterson notes: If someone is describing the future 30 years from now and they paint a picture that seems like it is from a science fiction movie, then they might be wrong. But, if someone is describing the future a generation from now and they paint a picture that doesn't look like a science fiction movie, then you know they are wrong. We are going to live in a science fiction movie, we just don't know which one.

> WE ARE GOING TO LIVE IN A SCIENCE FICTION MOVIE, WE JUST DON'T KNOW WHICH ONE.

There is one issue that I think is more explosive than even the spread of nuclear weapons: engineered intelligence. By that I mean, the efforts of computer engineers and bio-engineers who may create intelligence beyond that of a human being. In testimony at the House Science Committee,[2] the consensus of experts testifying was that in roughly 25 years we would have a computer that passed the Turing Test,[3] and more importantly exceeded human intelligence.

As we develop more intelligent computers, we will find them useful tools in creating ever more intelligent computers, a positive feedback loop. I don't know whether we will be creating the maniacal Hal from 2001, or the earnest Data from Star Trek --- or perhaps both.

There are those who say don't worry, even if a computer is intelligent and malevolent --- it is in a box and it cannot affect the world. But I believe that there are those of our species who would give hands to the devil, in return for a good stock tip.

I do draw solace from the fact that just because a computer is intelligent, or even self-aware, this does not mean that it is ambitious. By ambitious, I mean possessing a survival instinct together with a de-

sire to affect the environment so as to ensure survival, and usually a desire to propagate or expand.

My washing machine does not seem to care whether I turn it off or not. My pet mouse does seem to care. So even a computer possessing great intelligence may simply have no ambition, survival instinct, or interest in affecting the world.

DARPA[4] is the government agency on the cutting edge of supercomputer research. I have urged DARPA to develop computer systems designed to maximize the computer's utility, while avoiding self-awareness, or at least ambition.

I have spoken about computer engineering. But there is a whole different area of engineering: bio-engineering. Roughly 30 or 40 years from now bio-engineers should be able to start with human DNA and create a 2,000 pound mammal with a 300 pound brain designed to beat your grandkids on the LSAT. No less troubling, they might start with canine DNA and create a mammal with near-human intelligence, and no civil rights.

DNA is inherently ambitious. Those microbes which didn't seek to survive or replicate, didn't. Even birds seem to care whether they or their progeny survive, and they seek to affect their environment to achieve that survival.

In any case, you have the bio-engineers and the computer engineers both working toward new levels of intelligence. I believe in our lifetime we will see new species possessing intelligence which surpasses our own.

WILL OUR SUCCESSORS BE CARBON-BASED OR SILICON-BASED?

The last time a new higher level of intelligence arose on this planet was roughly 50,000 years ago. It was our own ancestors, who then said hello to the previously most intelligent species, Neanderthals. It did not work out so well for the Neanderthals.

I used to view this as a contest between the bio-engineers and the computer engineers (or if you use the cool new lingo, wet nanotechnology and dry nanotechnology), in an effort to develop a new species of superior intelligence. I felt that the last decision that humans would make is whether our successors are carbon-based or silicon-based:[5] the product of bio-engineering or of computer engineering.

Now I believe we are most likely to see combinations that will involve nature, computer engineering, and bio-engineering: humans with pharmaceutical intelligence boosters; DNA enhancements; computer-chip implants; or all three. First, this will be used to cure disease, then to enhance human capacity. The partially-human will precede the trans-human.

Now how should we react to all of this? It is important that we benefit from science even as we consider its more troubling implications. I chair the House Subcommittee on Nonproliferation which deals with the only other technologies that pose an existential threat to humankind, namely the proliferation of nuclear and biological weapons.

The history of nuclear technology is instructive. On August 2, 1939, Einstein

sent Roosevelt a letter saying a nuclear weapon was possible; six years later, nuclear technology literally exploded onto the world scene. Only after society saw the negative effects of nuclear technology, did we see the prospects for nuclear power and nuclear medicine.

The future of engineered intelligence will be different. The undeniable benefits of computer and DNA research will arrive long before the problematic possibilities. Their introduction will be gradual, not explosive. And fortunately, we will have far more than six years to consider the implications --- unless we choose to squander the next few decades. My fear is that our philosophers, ethicists and society at large, will ignore the issues that will inevitably present themselves until . . . . they actually present themselves. And these issues require more than a few years of thought.[6]

I have been urged not to make this issue the centerpiece of my reelection campaign. One journalist has told me that he can guarantee that computers will not be self-aware or overly intelligent: "All we have to do is get them elected to Congress."

I am confident that if we plan ahead we can obtain the utility of supercomputers, and the medical treatments available from bio-engineering, without creating new levels of intelligence. We can then pause and decide whether we in fact wish to create a new intelligent species or two.

Finally, I would quote Oliver Wendell Holmes in 1913 when he said,

> "I think it not improbable that man, like the grub that prepares a chamber for the winged thing it never has seen but is to be -- that man may have cosmic destinies that he does not understand."[7]

Likewise, it is possible that within the next 30 or 40 years, our children --- or should I say "our successors" --- will have less resemblance to us than a butterfly has to a caterpillar. I don't know whether to cry or rejoice, but I do know that our best minds in philosophy, science, ethics and even theology ought to be focused on this issue.

1. I gave my first speech on the House floor regarding engineered intelligence on May 17, 2000. For speech go to http://thomas.loc.gov/home/r106query.html on page H 3306.
2. On April 9, 2003, the U.S. House of Representatives, Committee on Science, held a hearing titled The Societal Implications of Nanotechnology. The transcript is available at http://commdocs.house.gov/committees/science/hsy86340.000/hsy86340_0f.htm
3. A test to determine whether computers are able to demonstrate intelligence matching a human's. In particular, a human sends text-only messages to communicate with both a computer and another human located in a different room. If the human sending the messages cannot determine if the response messages are composed by the computer or by the human, then the computer has passed the Turing Test. It should also be noted that one route to developing a computer with human intelligence is by reverse engineering the human brain perhaps using nanobots.
4. The Defense Advanced Research Projects Agency.
5. While I realize that supercomputers may not use chips with silicon substrate, I still prefer to call computer chips "silicon".
6. This issue is discussed in "Brave New World War" by Jamie Metzl. Published in Issue 8, Spring 2008, Democracy: A Journal of Ideas.
7. Oliver Wendell Holmes. "Law and the Court," speech at the Harvard Law School Association of New York, 15 February 1913.

Mr. SHERMAN. With that, we will move on to our final witness, Dr. Paul Billings, who is a board-certified internist and a clinical geneticist and serves as president and CEO of Cellpoint Diagnostics, Inc. Dr. Billings' experience lies with diagnostics in medical care and genomic medicine, and he has published extensively on topics of immunology and genetics.

Dr. Billings?

STATEMENT OF PAUL R. BILLINGS M.D., PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, CELLPOINT DIAGNOSTICS, INC.

Dr. BILLINGS. Thank you very much. I am honored to be here.

I have submitted my prepared testimony as well as an article I wrote nearly a decade ago outlining the problems with germline modification in——

Mr. SHERMAN. Well, without objection, the attachment will also be part of the record.

[The information referred to follows:]

translation, and L F Prescott and T Sauerbruch for their valuable comments and criticism. JHS received a research grant from the Paul Martini Foundation.

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Viewpoint

Human germline gene modification: a dissent

Paul R Billings, Ruth Hubbard, Stuart A Newman

Human germline gene modification has been foreseen but not yet accomplished.[1-8] It can be defined as the genetic manipulation of human germ cells, or of a conceptus, resulting in inherited changes in DNA. With the development of advanced in-vitro fertilisation (IVF) methods, preimplantation DNA analysis, improved techniques for gene transfer, insertion, or conversion, and of embryo implantation procedures, the technical barriers to such an intervention seem easily surmountable. Unintended changes in DNA may occur when gametes are manipulated or stored.[7,8] Inadvertent germline mutations, therefore, may have already occurred as a result of reproductive technologies in current use, such as artificial insemination and IVF. There are unpublished reports that researchers in the USA have already carried out a manipulation involving the exchange of a mitrochondrial genome in an IVF protocol. If true, this human experimentation involving intentional hereditary changes was probably conducted without federal oversight of safety, since there are no discussions of this protocol in the available public record.

Tsukui and colleagues[9] used viral vectors in somatic gene therapy protocols to infect mouse eggs in vitro, leading to germline transmission of a transgene in the progeny. Although removal of the zona pellucida is a prerequisite for infection of the eggs in vitro, the early oocytes of postnatal ovaries also lack zonas. These experiments thus raise the possibility that modification of gametes may occur in vivo, and constitute a germline hazard in the 200 or more somatic gene therapy protocols now in use. Any such alterations would be difficult to detect. Intentional or inadvertent germline modifications may pose significant burdens. Although there are restrictions on experimentation that might result in human modifications,[10] and opposition to its implementation has been voiced,[11-15] some leading scientists and other commentators have begun to advocate the development and application both of techniques that may increase the risk of inadvertent alteration of the germline, and of methods that would alter it deliberately.[6,16-18]

W French Anderson and his colleagues have developed an experimental protocol for the treatment of adenosine deaminase deficiency during fetal development; although their therapeutic intent is directed towards somatic cells, they acknowledge that the technique may modify germ cells as well. They have submitted this proposal to the National Institutes of Health (NIH) for review (panel). By introducing a genetic construct in utero, which knowingly allows for the alteration of germinal tissue, their attempt at a potentially transmissible correction could be used to erode opposition to germline genetic manipulation since germline modification would be achieved, though unintentionally.

Opposition to germline modification is based on several lines of reasoning.[19-22] First, as we have already suggested, germline DNA modifications may affect gene function in ways that are not immediately apparent, so their occurrence may not be recognised for a generation or more—for example, germline introduction in mice of an improperly regulated normal gene resulted in progeny with unaffected development but high tumour incidence during adult life.[23] Furthermore, interactions among genes and their products are highly integrated, have been refined over

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Early fetal manipulations reviewed by the NIH

This experimental protocol, along with another that uses a different method to treat α-thalassaemia in utero, was submitted to the Recombinant DNA Advisory Committee (RAC) of the NIH by W French Anderson and colleagues on July 31, 1998. After several discussions and a public conference, the RAC unanimously endorsed a statement, on March 11, 1999, indicating that in-utero gene therapy should not be attempted at this time. The RAC suggested that they would consider proposals in the future with more sufficient data on safety, effectiveness, and use of animal model systems. The Food and Drug Administration (FDA), rather than the RAC, has final approval authority over experimental procedures under existing US statutes. The FDA's ability to regulate practices conducted as part of non-federally funded protocols at private sector facilities is limited.

evolutionary time scales, and often serve to stabilise developmental pathways and physiological homeostasis.[24-26] Through experimental error, unanticipated allelic interactions, or poorly understood regulatory mechanisms such as imprinting, there is a risk that germline genetic manipulation will alter sensitive biological equilibria. Disruption of these interactive systems is likely to have complex and uncertain biological effects, including some that appear only during the development or functioning of specific cells or tissues.[27] Many of these effects could be undesirable.

Second, this sort of intervention is not needed. With available methods of prenatal diagnosis, virtually all interested couples can choose not to transmit specific identifiable genes. Other reproductive options (artificial insemination, egg donation) and adoption are available to those not able or willing to use prenatal or preimplantation selection methods. An exception might be when, rarely, two individuals have the same recessively inherited disorder. If such couples chose to reproduce, it could be argued that they would "need" germline or very early genetic interventions since all their progeny might inherit a disease-associated genotype. Yet, even these children may differ genotypically and phenotypically from their parents, and the development of a new mode of treatment for this unusual occurrence does not seem justifiable. Although available alternative procedures are invasive, germline modifications would also require similar interventions, since they would probably involve IVF. Moreover, the associated risks with existing procedures are not as serious as those created by introducing a hereditary genetic "error" into a family. People who oppose prenatal diagnosis on philosophical or religious grounds would be unlikely to want to take part in germline modification if they were aware of its intrinsically experimental nature and of the numbers of human embryos that would have to be expended during the development of the technology. No unmet need balances the risks of germline interventions to mothers, fetuses, and future generations. Moreover, the costs associated with the general development and implementation of germline manipulation would be formidable.

If there is no clinical need for germline modifications, the primary reason for using this intervention would be human enhancement.[28] Apart from the uncertainties about its ultimate outcome, enhancement is a form of eugenics. Though not a recrudescence of overtly coercive, public-health-based eugenics popular earlier this century, germline manipulations represent an individual or familial form. Seemingly private personal decisions and "choices" about medical or non-medical programmes for enhancement would, nevertheless, reflect prejudices, socioeconomic and political inequalities, and even current fashion. Though enhancement procedures now in use (eg, cosmetic surgery or orthodontics) also change according to fashion, germline intervention would intentionally subject later generations to modifications undertaken on the basis of existing values and conditions. The chance that "desirable" manipulations might later be viewed as disastrous makes germline enhancement "therapies" unacceptable.

Human germline interventions would necessarily alter the lives of individuals who are yet to be born. Informed consent by the affected individuals is not possible. Extension of the parental right to consent for minors would be required.[29] Such legal permission to specifically alter the lives of generations of unborn individuals would be unprecedented and unjustified.

If germline manipulation is attempted, there will be mistakes or errors in its application. Neither social acceptance nor the necessary range of protections and care for accidentally damaged individuals can be guaranteed.[30] Unexpected alterations in family relationships will occur, and "wrongful life" disputes could arise.[31] Irrespective of whether such interventions were to take place in research or clinical settings, these issues mean that germline modifications cannot be approved by existing standards for the protection of human beings.[32] No benefits to any future individual would justify abrogating or curtailing these restrictions.

For these biomedical reasons, as well as others based in legal,[33] philosophical,[19,24,25] cultural, and spiritual/religious traditions,[36,37] human germline modifications should be opposed and prohibited. Experimentation that may gradually make human germline modification more feasible is under way; it may require further review. Further study is needed of the safety of somatic gene therapy protocols to ensure that they detect, with adequate sensitivity, germline alterations. Many individuals and groups that monitor developments in human genetics can be expected to mount vigorous opposition to the development of human germline protocols, involving direct action, legal manoeuvres, and organising among interested public groups. Unlike many other countries, including those of the EU, which have prohibited germline manipulation in principle,[38,39] restrictions on the procedure in the USA are mainly based on practical considerations (see, for example, the summary of the January 1999, RAC-sponsored conference at http://www.nih.gov/od/orda/gtpcconc.htm. Site accessed March 20, 1999) and are subject to revision as the state of the science changes. Although debate about human germline modifications should continue and, indeed, be broadened to include representation of a diverse cross-section of viewpoints and backgrounds, such discussion should not be construed as suggesting that such a method would ever be appropriate or acceptable.

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Essay

Gut rot

Adrian Marston

Which are the most important vessels in the human body? Clearly, those in the neck, because they supply the brain, and hence the mind and even perhaps the soul, if there is one. Lose your carotid arteries and you suffer at best a transient ischaemic attack and at worst major paralysis and death. Others will remind us that if the central pump fails through a major myocardial infarct the whole system crashes, so that we must at all costs protect the coronary circulation.

However, damage to these vascular territories is not invariably lethal. Buried deep in the lower thorax where the imagers find it hard to see and the surgical approach is difficult, lurks a huge branched tube, the superior mesenteric artery (SMA) the size of both carotids put together, which claims a fifth of the cardiac output. Not only does this artery supply the muscle, mucosa, and hormonal apparatus of the gastrointestinal tract from duodenum to colon, but it is also the vehicle of absorption of all our nourishment. A breakdown in that area of the circulation is almost always fatal, because it initiates an irreversible cascade of events (figure). You and I survive on our SMA, so did Thomas Wakley, and somewhere (probably in California) there is a vascular surgeon driving a large car labelled SMA 1 who in a rather different sense is also surviving quite well. Surely this vessel has some claim to supremacy?

Uniquely among the organs of the body, the gastrointestinal tract harbours pathogenic bacteria, and while a sterile infarct can repair itself, an infected one cannot. Evolution has learned this lesson, so that all mammals have developed an efficient switching mechanism, to ensure that the mesenteric blood supply is protected by fail-safe mechanisms. For some reason, medical scientists have paid more attention to the details of the cerebral and cardiac circulations than to this intricate and beautiful system, which protects us against bacterial challenge.

The small band of professionals who study the splanchnic vessels would probably accept four propositions. The first proposition is that the intestinal circulation is autoregulatory, which means that flow is to a great extent independent of input pressure; in this it resembles the circulation to the brain. The second proposition is that total flow needs to be distributed among the layers of the intestine to oxygen demand. This process is allowed for because from the duodenum to the rectum, the intestinal mucosa floats upon a carpet of small

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Dr. BILLINGS. I am also here as a director of the Council for Responsible Genetics, the oldest watchdog on biotechnology organization, which is based in Cambridge, Massachusetts, and as an incoming member of the Secretary's Committee on Genomics, Health, and Society.

Science is a hopeful and creative human activity. It is crucial that scientific freedom not be fettered unreasonably or unnecessarily. In fact, we should cherish scientific freedom and look for ways to unleash science and scientists more.

Insights and advancements should be nurtured for a whole range of demanding human concerns. Even reforms in our policy and law-generating practices to accommodate more easily and quickly proven scientific facts should occur. They are likely to yield a system that produces more rational, appropriate legislation than other historical systems we have applied over the course of human culture and history.

I only point out to the committee that the translation of genetic science into DNA forensics has allowed for new ways of identifying people who have committed crimes, but also has revealed that we have unjustly convicted people in the past. So we need more examples of how good science when applied can change our lives.

So what is good science? Well, even more important than the uniqueness of its discovery component is the rigor applied to the design of experiments, the critical view of the purported facts generated by applied methods, and the absolute necessity for independent and multiple verification of results by unconflicted researchers.

Openness, publication, sharing in professional societies, verification across labs, geographies, and other sources of variability are all essential to good science and for the production of true and applicable scientific fact. Any consideration of international scientific policy must first enforce values and principles that will enhance the production of good and reliable science where the applications and limitations of scientific facts are sought and made known.

What is possible, particularly in the biotechnologies? As the famous physicist Niels Bohr is once said to have noted, "Forecasting, particularly about the future, is difficult." What can be said reliably is that the conduct of basic research in the human biotechnologies is now more common than ever before, is produced by more skilled and motivated scientists, and that its pace and accomplishments are dizzying.

The speed that we have accumulated basic knowledge about the components of our genes, cells, and bodies, and then the creativity demonstrated in taking the core information and manipulating it and the methods used to produce it into hypotheses, studies, and hopefully insight and progress, are breathtaking.

Take for example my own interest in circulating tumor cells and their role in cancer. We have known that cancer spreads, but we have never had a tool to identify the mode of that spread. We have just invented tools now to show how the tumors spread through the blood. This is yielding all sorts of new information about how cancer grows. It also is yielding important new diagnostic tests that

are going to revolutionize how we manage cancer. All this would be unimaginable 10 years ago.

Mass DNA sequencing of human genes and genomes; isolating and studying stem cells; imaging, measuring, and modifying aspects of human brain behavior; easy manipulation of genetic materials; creating new solutions to biological or other problems with synthetic biology programs—these are all now possible projects of biotechnology inquiry and are underway.

As scientific methods for these and other programs are created and mixed with rapidly evolving protocols in engineering, the potential to translate some of this basic science work into attempts by scientists, physicians, or other components of society to alter the human germline, engage in reproductive cloning, create animal-human chimeras or human-machine hybrids, or attempts to create new human subspecies with enhanced or curtailed traits for some instrumental purpose may occur.

Eugenics in varying new guises, for instance, to protect national interests, might be attempted. Techniques that may provide benefits like those employed in prenatal and preimplantation clinical settings could be perverted toward some eugenic or instrumental aim. For instance—and there are, of course, many examples of this—the use of ultrasound during pregnancy has improved the health of many fetuses and mothers, while also resulting in the abortion of millions of female conceptions worldwide.

Despite this fact, success or even effectiveness of such programs on a significant scale is generally unlikely, but attempts may be made and intermediate but unfortunate outcomes could occur. Even endorsement by powerful governmental elements of such programs is conceivable. We must consider carefully how to lessen the probability of these occurrences and resulting harms.

How should we proceed? First, we must reemphasize the great value of biotechnologies. For societies with a variable history of respect for individuals—and that includes our own—this will likely generate new power and respect for all individuals. I would only point out that the recent passage of the Genetic Information Non-Discrimination Act is an example. When you add this to civil rights legislation and protections for the disabled, this law modernizes and broadens our traditions of inclusion and acceptance of individuality and human difference.

Scientists and scientific communities should be more transparent about how projects are created, funded, and how individual scientific careers are motivated and incented. Conflicts of interest, political coercion, and other differences in international scientific cultures should be well known.

When scientific facts and methods are translated in human societies, particularly powerful basic biotechnologies, multidisciplinary assessments and approaches to studies should occur. It is a very interesting development that research groups comprised of basic and applied scientists, engineers, social scientists with historians and others are now common in many biotechnology investigational settings in the developed world. This development may help curtail premature application and point out more limitations of knowledge or potential for misuse.

In balancing other human values with the goal of fostering scientific insight and progress, international policy and laws may be necessary to generate some uniformity. This should be only pursued after significant study by multiple broadly constituted bodies and the determination of need. It should be clear that while prohibiting methods and applications may be necessary, individuals who are suffering may find relief delayed by these actions. This is a harm too and should be minimized.

Finally, as biotechnologies gain more momentum in discovery, development, and delivery in our society, and as we consider policies to control the inevitable ways these powerful insights will alter how we consider human life, we should emphasize in international policy two traditions that are codified in the U.N. Charter and other global documents.

First, that citizen safety, whether those individuals are patients or research participants or in other ways engaged in applications of science is paramount. Their knowledge and consent are required. Our ability to alter aspects of human life with biotechnologies needs to be matched by powerful new ways to assess safety and optimize this crucial value.

Then, and this is a crucial second tenet, after we assure our neighbors that scientific facts and applications are safe, we must strive to deliver them with equity to all those who need or desire them.

Mr. Chairman and members, only when science is allowed to be fully creative in an international environment of optimal human safety and equitable delivery of needed progress will the great potential of advances in biotechnology be realized. With broad and careful study, novel policy crafting, and a healthy sense of how limited scientific knowledge is, how unlikely bad translations are, along with a recommitment to all those in need and to better monitoring of harms, good science policy and good science will arise.

Thank you.

[The prepared statement of Dr. Billings follows:]

PREPARED STATEMENT OF PAUL R. BILLINGS M.D., PH.D., PRESIDENT AND CHIEF EXECUTIVE OFFICER, CELLPOINT DIAGNOSTICS, INC.

Chairman Sherman, Ranking Member Royce, and other distinguished Subcommittee Members, I am Dr. Paul R. Billings, President and Chief Executive Officer of Cellpoint Diagnostics, Inc. a biotechnology company seeking to develop tests that will revolutionize the management of cancer worldwide. Among other professional activities, I am also awaiting final appointment as a member of the HHS Secretary's Committee on Genomics, Health and Society and am past Chair and President, now Director, of the Council for Responsible Genetics, the oldest biotechnology "watchdog" organization in the United States, based in Cambridge, MA. I have supplied the Subcommittee with my current Short Biography and also a relevant publication I co-authored a few years ago in the LANCET on germline genomic modification. I am honored at the invitation to testify before you today.

Science is a hopeful and creative human activity. Scientific discovery while mostly incremental—building on previous work that is known and shared—is also serendipitous. No one who knows the history of the discovery of penicillin can not take away two points: luck is a great thing in science and success comes to those who are prepared. It is crucial that scientific freedom, the ability to inquire broadly about the natural world and to create understanding about our vast experience in this amazingly varied universe, not be fettered unreasonably or unnecessarily. In fact, we should cherish scientific freedom and look for ways to unleash science and scientists more. Insights and advancements should be nurtured for a whole range of demanding human concerns. Even reforms of our policy and law generating practices, to accommodate more easily and quickly proven scientific facts, should occur;

they are likely to yield a system that produces more rational and appropriate tenets and legislation than other historical systems we have applied over the course of human culture and history. A good example of this is the evolving role of DNA identification methods in our system of investigation and criminal justice. This method, a result of basic study of human DNA variation, is fostering revolutionary changes in how we conduct criminal investigations, allowing criminals who might have escaped prosecution to be brought to trial, and also revealing injustices committed by our less scientifically informed justice system in the past. We are still learning how to balance these powerful methods and facts with other cherished principles of individuality, privacy, and freedom from unwarranted governmental suspicion or coercion. We need to generate more examples of improvements in our varied lives through good science.

What is good science? Even more important the uniqueness of its discovery component is the rigor applied to the design of experiments, the critical view of the purported facts generated by applied methods, and the absolute necessity for independent and multiple verification of results by unconflicted researchers. Openness, publication, sharing in professional settings, verification across labs, geographies and other sources of variability are all essential to good science and for the production of true and applicable scientific fact. Any consideration of international scientific policy must first enforce values and principles that will enhance the production of good and reliable science; where the applications and *limitations* of scientific facts are sought and made known.

What is possible, particularly in the biotechnologies? As Niels Bohr, the famous physicist is said to have noted, "Forecasting, particularly about the future, is difficult." What can be said reliably is that the conduct of basic research in the human biotechnologies is now more common than ever before, is produced by more skilled and motivated scientists, and that its pace and accomplishments are dizzying. The speed that we have accumulated basic knowledge about the components of our genes, cells and bodies, and then the creativity demonstrated in taking that core information and manipulating it (or the methods used to derive it) to produce more hypotheses, studies and hopefully insight and progress, are breathtaking. Take for instance my current field of interest, circulating tumor cells (CTC). We have known for centuries that cancer often killed people by spreading to distant sites in our bodies. Even after the invention of anesthesia and aseptic surgical methods, with some people being cured by simple removal of their tumors and surgical recovery, many others succumbed eventually to distant recurrences. We hypothesized, long ago, that the initial tumor spread via the blood stream and lymphatic system (and possibly by other yet to be discovered routes), seeding distant sites in the body. But no methods for studying this imaginary phase in cancer human biology existed. We now have such tools and these are beginning to reveal new facts in oncology. In addition, the methods are being translated in to clinical tests that may disrupt current assessment paradigms and revolutionize cancer management. We have discovered for instance that there is heterogeneity in the characteristics of CTC. Some of the cells we can now identify may be cancer stem cells. An ability to access those cells and deliver them for assessment may yield very significant advances in management and treatment. The rapidity by which new methods are changing our views of cancer, and the speed that basic work is being verified and then translated in to clinical effort, would have been unimaginable even 10 years ago.

Mass DNA sequencing of human genes and genomes; isolating and studying stem cells; imaging, measuring and modifying aspects of human brain activity; accurately measuring and predicting complexity using the approaches of systems biology; and creating new solutions to biological or other problems with synthetic biology programs; these are all now possible projects of biotechnology inquiry and are underway. As scientific methods for these and other programs are created, and mixed with rapidly evolving protocols in engineering (for instance, nanotechnologies), the potential to *translate* some of this basic science work in to attempts by scientists, physicians or other components of society (for instance the Raelians), to alter the human germline, engage in reproductive cloning, create animal/human chimeras or human/machine hybrids, or attempts to create new human subspecies with enhanced or curtailed traits for some instrumental purpose, may occur. One of the byproducts of greater understanding and developments in engineering is that some approaches are very simple and thus might disseminate in society in unpredictable ways. Eugenics in varying new guises, for instance, to protect national interests might be attempted. Techniques that may provide benefit like those employed in prenatal and preimplantation clinical settings could be perverted towards some eugenic or instrumental aim. For instance, the use of ultrasound during pregnancy has improved the health of many fetuses and mothers, while also resulting in the abortion of millions of female conceptions worldwide. Despite this fact, success or even

effectiveness of such programs on a significant scale is generally unlikely, but attempts may be made and intermediate but unfortunate outcomes could occur. Even endorsement by powerful governmental elements of such programs is conceivable. We must consider carefully how to lessen the probability of these occurrences and the resulting harms.

How should we proceed to enhance scientific efforts that can benefit people around the world even in the face of risks for abuse and harms? First, we must all agree that the biotechnologies have great value particularly as they produce insight in to individuals and illnesses. For societies with a variable history of respect for individuals, and that includes our own, this will likely generate new power and respect for ALL individuals. A good example of that result is the Genetic Information Non-Discrimination Act of 2008 recently signed by President Bush. Along with federal Civil Rights legislation, and protections for the disabled, that law continues to modernize and broaden our traditions of inclusion and acceptance of individuality and human difference. Other societies, cultures and nations should take note as international bodies have.

Scientists and scientific communities should be more transparent about how projects are created, funded and how individual scientific careers are motivated and incented. Conflicts of interest, political coercion and other differences in international scientific cultures should be well known. Harmonization with internationally accepted values ought to be attempted.

When scientific facts and methods are translated in human societies, particularly powerful basic biotechnologies, multidisciplinary assessments and approaches to studies should occur. It is a very interesting development that research groups comprised of basic and applied scientists, engineers, social scientists with historians and others are now common in many biotechnology investigational settings in the developed world. This development may help curtail premature applications and point out more limitations of knowledge or potential for misuse.

In balancing other human values with the goal of fostering scientific insight and progress, international policy and laws may be necessary to generate some uniformity (a baseline) and prohibit rogue behavior. This should only be pursued after significant study by multiple broadly constituted bodies and determination of need (including that based on real risk not just precaution). Then recommended policies should seek narrow applications and provide flexibility in crafting ("sunsetting" of provisions) so as to accommodate new facts as they develop. It should be clear that while prohibiting methods and applications may be necessary, individuals who are suffering may find relief delayed by these actions. This is a harm too and should be minimized.

Finally, as biotechnologies gain more momentum in discovery, development and delivery in our societies, and as we consider policies to control the inevitable ways these powerful insights will alter how we consider human life—the individual and our experiences, we should reemphasize in international policy two traditions that are already codified in the UN Charter and other global documents. First, that citizen *safety*, whether those individuals are patients or research participants or in other ways engaged in applications of science is paramount. Their knowledge and consent are required. Our abilities to alter aspects of human life with biotechnologies need to be matched by powerful new ways to assess safety and optimize this crucial value. Then after we assure our neighbors that scientific facts and applications are safe, we must then strive to deliver them with *equity* to ALL those who need or desire them.

Mr. Chairman and members, only when science is allowed to be fully creative in an international environment of optimal individual safety and equitable delivery of needed progress, will the great potential of advances in biotechnology be realized. With broad and careful study, novel policy crafting, and a healthy sense of how limited scientific knowledge is, how unlikely bad translations are, along with a recommitment to all those in need and to better monitoring of harms—good international science policy and good science will arise.

Thank you for the opportunity to testify today and I would be delighted to answer any questions I can.

Mr. SHERMAN. Thank you.

I know some of our witnesses may be thinking they will be out of here soon, but we will probably do more than one round. So expect to be here for at least another hour.

Without objection, we will place into the record a statement by Friends of the Earth.

[The information referred to follows:]

Testimony of Gillian Madill
Genetic Technologies Campaigner, Friends of the Earth

House Foreign Affairs Committee
Subcommittee on Terrorism, Nonproliferation and Trade

New Biotechnologies: No Longer Science Fiction

June 19, 2008

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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 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 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 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 can not 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 lead 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 unchartered area of research and protect human health, the environment, our economy, and strengthen homeland security.

Mr. SHERMAN. Dr. Hayes put forward the idea that there are at least some areas where we have an international consensus and that one of these is not to affect permanently the human genome. In other words, not to change somebody's genetics in a way that will be inherited by their offspring. And yet I can imagine someone who has Tay-sachs or sickle cell anemia saying, "Hey, wait a minute. If a virus can carry into each of my cells, a genetic patch that cures one of those diseases and permanently changes my genetics, and frees me from the effect of the diseases, that would be good. If it also works for my offspring, that is even better."

Is there a consensus that any medical treatment that affects not only the patient but also their offspring is out of bounds?

Mr. HAYES. This question always comes up in all these discussions, and, actually, the example you give—and it is really the most common—is fortunately one in which we have—I do not want to use the term "technical fix"—but where the existing practice really does enable couples at risk of passing on a genetic disease to avoid doing so, and this is the practice of preimplantation genetic screening. So it is possible if there is a couple who is at the risk of——

Mr. SHERMAN. Although there are a couple of things there. First, that involves what some would consider an abortion, and, second, what if as an inherent byproduct of treating someone who has Tay-sachs or who has sickle cell anemia, you do not have a choice. If you are going to affect the cells in their body, you are going to affect all their genes, including their reproductive glands, and you will inevitably affect their offspring. Is there a consensus against a treatment that inherently affects offspring?

Mr. HAYES. Again, there are a number of technical issues here, but it is possible to—again without affecting the germ cells, the eggs and sperm—allow couples at risk of passing on these diseases to have a completely healthy child. Now, again, for people who——

Mr. SHERMAN. Yes, I am not talking about a healthy child. You may have an adult who is suffering from this disease, and there is a treatment, and the person says, "Hey, I do not know if I am ever going to have any kids or not, but I want to just get treated. But, oh, by the way, do not deny me the treatment just because it has this societally terrible byproduct which is that my kids will not have the disease either."

Mr. HAYES. Right.

Mr. SHERMAN. In other words, assume this is the best way to treat the adult.

Mr. HAYES. Sure. Obviously, it varies with the type of disease and the like, but if you are talking about an adult where we are talking about having the disease as opposed to diseases can be treated, the term—you may know this—"somatic"—it does not require the manipulation of eggs and sperms, and, in fact, that can be precluded in the course of any of those therapeutic treatments.

So this is one of the areas where fortunately we have a way to proceed that should meet many of these concerns. Now I have to acknowledge, for people opposed to the destruction of human embryos on principle grounds, PGD and other procedures like this do involve that. But, otherwise, we can proceed in a way that meets most people's needs.

Mr. SHERMAN. Now the other thing you seem to indicate there was consensus on is that we should not be using this technology to try to select which embryos are allowed to develop for the purpose of improving the species, and yet you just suggested selecting the embryo without sickle cell instead of the embryo with sickle cell.

Mr. HAYES. Right.

Mr. SHERMAN. What is the line between preventing genetic diseases from being included in babies that are born, on the one hand, and using genetics to try to breed a slightly more optimal human being?

Mr. HAYES. This is one of the areas where there are some questions. Fortunately, the gray areas are rather few on this, though we have to acknowledge they do exist.

In most cases, the kinds of conditions you can select for through prenatal or preimplantation genetic diagnostics are single-gene defects which are the nature of their diseases. They are severe impairments. It is difficult, if not impossible, to select for social characteristics or for complex characteristics because you need to select for more than one gene to have any real effect on that.

There are gray areas, and as a number of folks mentioned, we would need some sort of Federal agency or commission that does make rulings on exactly those gray areas, but this is what countries have already done and I have confidence we can do that.

Mr. SHERMAN. I wish I was as sanguine as you. I think there are a bunch of scientists out there looking for two genes, three genes, not just one gene and that we may have to decide whether I should select a child, not only one that does not have Tay-sachs and use genetic screening to pick the embryo without Tay-sachs, but perhaps the one that does not need glasses or the one that is not follicly challenged, and we will have to [Laughter] decide which of my many flaws are significant enough to allow me to try to include them or exclude them from my offspring.

With that, a man with far fewer flaws, Mr. Royce.

Mr. ROYCE. I will go right to Dr. Cameron with any views as to that last point. That last question that was asked by the chairman because if you can eliminate defects, especially those that would limit one's full potential for life—well, let me just have your view on that, Dr. Cameron.

Mr. CAMERON. Well, sir, in fact, this brings us to one of the stickiest sets of issues here, and partly because, of course, the approach to screening embryos which is being offered as a solution here is also extremely controversial, not simply within those who would take a pro life view of the embryo, but also within a good number of those who would not take that view of the embryo, but who would regard this as eugenic use of a technology, and so there are from two different ends.

The use of this technology to solve the problem of disease is highly controversial. I am not arguing a case on behalf of either of these groups. But my point is if you are looking for a way to build a consensus, which is the assumption of this conversation, I think that that is a minefield, and if we can find a way to avoid that minefield, we should.

Mr. ROYCE. But, at the same time, take a case like sickle cell anemia, which we were just discussing. I would like your views on that and whether you think that if science were capable of eliminating that very injurious trait——

Mr. CAMERON. Well, sir, it seems to me that partly because the embryo screening questions are so controversial, I think there will be huge pressure to engage in germline——

Mr. ROYCE. Commercial pressures, you say?

Mr. CAMERON. Well, commercial, but, I mean, political pressures to engage in germline inheritable changes, to deal with inheritable diseases, because that will prove a lot less controversial than these embryo interventions, and so I am not as sanguine as my good friend Rich Hayes as to the capacity of the international community to handle the germline issue because it will be pressed initially, of course, in relation to serious diseases of this kind and as a kind of solution which preserves the integrity of the embryo.

Mr. ROYCE. Maybe we could go to Dr. Hayes or Dr. Metzl on that question. In his written remarks, Dr. Metzl said "an international advisory committee of experts and ethicists who would report yearly on the state of development in the field of human genetics engineering globally and country by country" could be developed. I was wondering, does the United States have an interest in being overseen by an international committee where the viewpoints would be composed of individuals representing countries with very different viewpoints?

I just wonder about the NPT concept that is being advanced. I have worked to try to make the NPT work. But as we start to get into the countries that have basically violated the NPT by going right up to the line and then at that point deciding to pull out of the NPT or deciding to circumvent and move forward with some very dangerous technologies, nuclear weaponry.

What can that tell us about the functioning of this kind of an international solution?

Mr. METZL. Let me try to address the two questions, the one that you raised in the very beginning just asking my viewpoint on the comments that were just made and then this.

I also would respectfully disagree perhaps with my colleague, Dr. Hayes, about the clarity of the lines between the different activities that we are talking about, particularly use of PGD or other processes to try to screen out mutations for Tay-sachs or whatever, Down's syndrome, and the line between that and making a leap toward selecting four desirable traits.

I think it is going to be extremely difficult, if not impossible, to draw that line because all of us have lots of mutations of all types. That is the very underlying principle of human diversity, and as we have more and more information that we are able to read through the PGD process and the DNA analysis that comes with it, we are going to have a choice of which mutations are we selecting against, and the flip side of that is which are the mutations that we are selecting for.

And as I mentioned in my testimony, driven by global competition so that whatever we decide to do as a country, other countries are going to make different choices, that is going to really supercharge this debate, and just to give one example, this year, Britain

passed a new embryology law that allows for the use of chimeras, human-animal hybrid embryos, up to 14 days for research purposes.

In the debate in Singapore that is happening right now, there are published articles where people are saying, "For Singapore, in order to maintain our competitive position in the world"—and they have been very competitive. As a matter of fact, they are so competitive that lots of our top scientists are leaving the United States and going to Singapore to work in a more permissive environment. For them to reach that point, they need to be as or more permissive than Britain.

So whatever we do as a country, competition is going to drive this process forward, and I certainly agree with the gist of your question about my proposal, that it would be extremely difficult to maintain how we would have a standard with the nuclear arms, at least with nuclear weapons. There is a pretty clear line. Either you have them or you do not.

Mr. ROYCE. And at least we got everyone to sign on early in the game.

Mr. METZL. Right.

Mr. ROYCE. And one of your points is move now before this technology has really developed——

Mr. METZL. Absolutely.

Mr. ROYCE [continuing]. And get everybody to sign off now.

Mr. METZL. Right. And so I think it would be absolutely difficult. As I said in my testimony, I am not sure that this is the best approach. It is only the best approach that I could think of.

But I think that we need to have some kind of consensus about what are the red lines, and that means that it is not—you know, our conversation—going to be somewhere in the absolute middle, if you put all of the countries of the world together, because the countries, like Singapore, like Britain, that are pushing ahead on this, they are going to say, "Well, we do not want to be part of this if it is going to be used to clamp down on things that we believe are in our interests and that we want to do so."

It is going to have to be a pretty permissive structure, but one that identifies what are the worst abuses and then can police who is going beyond those red lines. But it certainly would be extremely difficult.

Mr. ROYCE. Lastly, I would just ask what other countries are involved in this type of technology. We know what has developed in Britain and then with Singapore, cutting-edge technology that is very problematic that is going on there.

Mr. METZL. Yes.

Mr. ROYCE. Where is the infrastructure developing for this?

Mr. METZL. A number of places. Israel has. South Korea, of course, is extremely aggressive in these areas. We all know about the experience a couple of years ago of Dr. Wong, and what happened with Dr. Wong pointed out a couple of things. Obviously, the big story that was reported was that his research processes were flawed.

But another story that I think was critically important was that the debate in Korea around the experience of Dr. Wong and the reports of human cloning was very different from the debate we

would have had in the United States. There, people were upset because they were hoping that Dr. Wong would be the national champion and win the Nobel Prize.

There were not the kind of moral debates that we would have had here. As a matter of fact, there were national religious leaders who were calling on Korean children to stop using wooden chopsticks and to start using metal chopsticks so they could be part of early training for how to be involved in genetic engineering activities in the future.

There are just enormous cultural and national and religious differences that are really going to drive this process, and that is why finding some kind of international consensus where we can say there are some things that are going to happen elsewhere in the world that we may not be fully comfortable with, but we are going to have to accept, but in exchange for that, we are all going to determine what are the outer red lines that we do not want to cross because doing so will harm our species as a whole. That I see as the essential challenge.

Mr. ROYCE. Thank you.

Thank you, Mr. Chairman.

Mr. SHERMAN. I would quickly comment that one approach completely different from that involved in these hearings is for us to just chant USA, USA, and figure that the world belongs to the genetically enhanced and we want to be first with the most and that next century may not be inhabited by exactly humans, but at least whatever it is, it will be of our creation.

Mr. METZL. I hope I can get my hair back under that scenario. [Laughter.]

Mr. SHERMAN. Tell me about it.

Mr. Wu?

Mr. WU. Thank you, Mr. Chairman.

I am very glad that we have this setting to discuss this crucial set of topics.

As I have contemplated this issue in the past, it is not a matter of what we are able to do, but there are the challenges of the wisdom that we bring to the issue.

Some scientists have approached me in some of these discussions that we should never ban any form of experimentation, and my reply to them has been that the Nuclear Non-Proliferation Treaty, some restrictions on primate testing and human testing, there are experiments that we have by agreement banned. There are cultural differences in norms, but over a multi-century period, we have by and large abolished slavery, we have come to agreement that some forms of behavior are outside the bounds.

I have a little bit of a scientific background. I am strongly pro-science, but I think I have come to better appreciate with time the limits of knowledge versus wisdom and the difference between the two, and I wonder whether we would have a better world or a worse world if we had to come to power 500 years from now.

Now circling back, it seems to me that we are on the edge of one of the great challenges of our era. There is a question about why there are not more intelligent species around, and one theory is that they do not last very long, and right off the top of my head,

you know, these are things that, I think, we are in part paid to think about.

Threats to human long-term survival identifiable today would be potentially an all-out nuclear exchange, self-induced radical climate change that somehow leads to unforeseen consequences, and intentional genetic manipulation. Those would be the top three on my list. There are a couple of other things we could talk about.

Now you all have addressed the gene line issue, but I want to move the red zone or at least look at something that you all have not identified as in the red zone, and that is because there is research going on right now on chimeras and on embryos that are intentionally created for scientific research purposes.

Now, as a supporter of stem cell research, I have viewed this as a troubled ethical territory, but if the choice is between the trash bin and the laboratory, a spare embryo, if you will, that was created for other purposes is between the range of choices, it is an appropriate choice, in my view, to use that embryonic tissue for stem cell research.

I am deeply troubled, and I am wondering if any of the witnesses are deeply troubled, with the intentional creation of human embryos for research purposes and what I view as the misselling of that technology by some proponents as that which will lead to the cure in very simplistic ways. It may lead to cures for various things, but not in the way the general public thinks of it.

The method is more likely to be the creation of intentionally flawed human tissue as a test bed for the study of disease mechanisms, just as we have genetically uniform mice as a test bed for study, and if the public were focused on that, would we be more concerned and should we be more concerned about the intentional creation of human embryonic tissue for experimental purposes?

I think it was Oliver Wendell Holmes who said, "Even a dog can tell the difference between a stumble and a kick." I think that question of intent, about how the embryo got there, is absolutely crucial, and I would like to hear this panel, this very thoughtful panel, on that issue which is slightly outside of the red zone which you all have been addressing.

Please go ahead.

Mr. CAMERON. Sir, a brief comment. I was at the bio conference in San Diego earlier this week. I flew back last night. The British Government, my former—and I have been in the States for 20 years now. The British Government had proposed a panel to the bio conference on the chimeric hybrid embryo creation activities, and I was kindly invited to sum up the kind of ethical arguments on both sides, which I did with complete fairness.

But what interested me was that the scientist from the U.K., who have done the first ever chimeric embryo research successfully, actually agreed with me that in 20 years' time, it is unlikely people will be using embryos for research. He said he thought the science would move on. He is the person doing this work. So, in a sense, this problem may solve itself through technical developments and the fact that scientists, like everybody else, try to avoid controversy.

But my personal view is it is a shame that we have been so preoccupied with the embryo questions, not because I do not care

about embryos because I am conservative on the embryo, but because this has distracted us from all of these other questions which will affect all of us.

Mr. SHERMAN. I thank the——

Mr. WU. May we let the witnesses——

Mr. SHERMAN. We will let one more response, but I want Mr. Manzullo to be able to ask his questions before we have to go to votes. Quick response from one more witness.

Mr. HAYES. A quick response. Just as Nigel identifies himself in good faith on the pro life side, I would identify myself on the pro choice side. The interesting thing here is there is some convergence, though there are differences as well. And so, Congressman Wu, in response to your direct question, let's say I too would support, and our organization would support, the use of surplus human embryos for experimental reasons. We do not believe theologically that the embryo is identical to the human person, but do have concerns about the creation, the intentional creation, of human embryos specifically for experimental purposes because of the objectification and the things that could open in terms of the misuse.

Mr. SHERMAN. Thank you, Dr. Hayes.

Let's move on to Mr. Manzullo.

Mr. MANZULLO. Thank you.

Mr. SHERMAN. We will reconvene, assuming witnesses are available, at 12:15.

Mr. MANZULLO. Unfortunately, I was tied up with the Department of Treasury and could not get here to hear the testimony. I have had a chance to read a good part of it.

My question is very simple: At this point in time, is there a fixed immutable standard by which to judge truth?

Mr. HAYES. No.

Mr. MANZULLO. Short answer. Anybody?

Mr. HAYES. Collective discourse.

Mr. CAMERON. Mr. Manzullo, if I might offer a brief response to that, I think, aside from the private views we bring to this discussion, there is enormous value in the way in which—the notion of human rights—we offer the international community with, if you like, a functional view of a large segment of truth, which people can come to from very different perspectives, and it interests me that the UNESCO Declaration on Human Rights and Bioethics, which is the one global instrument addressing these questions, keeps going back to fundamental rights and freedoms as its baseline. Even if we might have different reasons for accepting it, those fundamental rights and freedoms are central.

Mr. MANZULLO. Anybody else? Anybody else want to touch that question?

Mr. HAYES. Through sincere honest discourse of different parties, a resolution can be obtained.

Dr. BILLINGS. Well, I would only say that there may be no single truth, but there are common values that are shared.

Mr. MANZULLO. Truth by its nature has to be singular.

Dr. BILLINGS. I am sorry?

Mr. MANZULLO. Truth by its nature has to be singular. That is the goal.

Mr. METZL. When the chairman gave us the opportunity for one very quick question before the vote, I do not know, what is the nature of truth itself, if it fits into that category, but I would say——

Mr. SHERMAN. You have under 3 minutes.

Mr. METZL. I would say——

Mr. MANZULLO. You understand the question?

Mr. METZL. I do understand it, and that is the hard issue for this, that there are different scientists, as I was mentioning before, different cultures, different countries that are all coming at this issue with different perspectives, and there may be basic scientific truth that underlie the science, and on those, I think, many people or nearly everybody would agree.

But how those truths can be interpreted, what the context is in which those truths can be considered is entirely different, and that is the challenge of building some kind of international consensus.

Mr. MANZULLO. That is why you are trying to find a standard.

Mr. METZL. That is why you try to find a standard, but it is a standard that recognizes the difficulties, that it recognizes that so many people are coming at this from so many different perspectives, and as Dr. Hayes said, the challenge for all of us is to find what the common denominators are.

Mr. MANZULLO. Trying to find some boundaries.

Mr. METZL. Boundaries. And even if everybody does not agree on every basic premise, just find what the areas are in which we can agree.

When we look at this chart here, when you go down this list, although I would have some questions about some of the categories, you can just see—just go straight down—reproductive cloning is the area where there is the greatest amount of consensus, although I would say that it is not 100 to 1 or 97 to 0, and if you go down, there are things that are more controversial.

So we need to find what are the areas in which we can agree, even if there is no one absolute standard of truth that we can all share.

Mr. MANZULLO. Dr. Billings?

Dr. BILLINGS. I believe that there are some common values across cultures and that part of the reason that there is consensus on some of those issues is because of values like safety, as I indicated in my testimony.

I would also agree with the previous speaker that some of these categories listed on that chart are a little difficult to get your hands around.

Mr. MANZULLO. Thank you.

Thank you, Mr. Chairman.

Mr. SHERMAN. Thank you.

Mr. WU. Can we let Dr. Billings take a crack at my question since we obviously have——

Mr. SHERMAN. You have 1 minute and 9 seconds to take a crack at Mr. Wu's question, and then we will reconvene at 12:15.

Mr. WU. Thank you, Mr. Chairman.

Dr. BILLINGS. It is a complex question, obviously, Congressman Wu, but intention is always important. There is no doubt about it. And in my testimony, I tried to emphasize that the intention of most scientists and people who apply science in medical settings is

good, but I agree with you that the creation of human embryos, for instance, to be quality control agents for preimplantation genetic diagnosis or quality control agents for something like germline genetic modification, that would be very troubling and unacceptable, and we would rapidly want to find other ways—if we decided we wanted to go ahead, let's say, with preimplantation genetic diagnosis for a variety of medical traits—other controls to prove that those techniques worked so that they would be, in fact, safely applied.

Mr. WU. Thank you very much.

Thank you, Mr. Chairman.

Mr. SHERMAN. We stand adjourned until 12:15.

[Recess.]

Mr. SHERMAN. So, if our witnesses could sit down, we will reconvene the hearing.

I do not know whether other members will join us. I talked to a few on the floor who would like to. I promise to be as longwinded as possible to give them an opportunity to get here.

The first issue we are talking about is what these standards ought to be, and it occurs to me that there would be three different levels of standards.

One is what I would set in my own life. I could not necessarily convince my whole country to agree with me, but I would not participate in certain activities, second is what we do as a country, and the third and presumably least rigorous standard would be what we could get the entire world to agree to, and I think one of the witnesses made that point already.

In terms of dealing with other countries, there are two reasons why I would object to something done in Singapore. One is from a human rights and ethical perspective. For example, Singapore might engage in an all-out effort to breed out of Singaporeans follicly challenged craniums. I would personally view that—and Dr. Billings might as well—as an act of genocide. [Laughter.]

But at least it is not one that challenges the United States from a national security perspective.

So we might have international agreements on these technologies that are similar to our other international agreements on human rights where we recognize that our country is not endangered by the deprivation of women's rights in Afghanistan, but we are appalled by it, and we would work toward a world in which human rights would exist for women, bald people, and even bald women. The other area is where it is closer to the non-proliferation aspect where the science going on in a particular country threatens our national security.

I know Dr. Metzl has probably done the most looking at international treaty proposals. Is there a differentiation in diplomatic circles between treaties that would limit science for human rights concerns versus those that would limit these sciences for national security concerns?

Mr. METZL. It is a very interesting question, and in some ways, I do not believe that there has been an absolute differentiation among those two categories, but I do think that different people in different countries have come to this question from different perspectives that have been both of the ones that you mentioned.

I mean, obviously, there are two issues which you raise, are, one, what are the basic inherent rights of an embryo, and on that, as I mentioned before, there are significant cultural differences. There are significant religious differences, Catholicism and Christianity tend to be more conservative on these issues in general than Judaism and Islam, and Judaism and Islam tend to be more conservative than Hinduism and Buddhism. These are vast overgeneralizations.

So, coming from different perspectives, there are different ways of looking at the basic human rights issue, but the one thing that everybody agrees on is that the human genetic code is some form of a commons and that if there are——

Mr. SHERMAN. Some form of a what?

Mr. METZL. Of a commons. And that if there are mutations that are introduced in any way in a germline manner into humans, that is something that will potentially affect the population as a whole.

So it is not a satisfactory answer to your question, but I think that in some ways the perspective of people who are thinking about regulation may be less important than just what are the things that everybody can agree that we are most concerned about.

Mr. SHERMAN. I want to get to Dr. Billings in just a second and then Dr. Hayes on this, but you raise an interesting point, and that is the human genome being a commons. There are two ways to affect that.

One is the decision of a parent not to continue to full term a particular embryo for this or that reason or to select in IVF one embryo over another. That does not change the total diversity. It adds no genetic code to the human genome to the 6 billionth power, the 6 billion human genomes we have out there.

Separate from that is if you were to take one individual and add a gene that does not exist in any other individual. Now you have created something that did not exist among the 6 billion of us already, and that would pose a very different issue.

I did not know that Britain had allowed officially the mixing of human and animal DNA. I had somebody ask me in the elevator whether—what is the term for——

Mr. METZL. Chimera.

Mr. HAYES. Chimera.

Mr. SHERMAN [continuing]. Whether they should be participating in the Olympics or not, and——[Laughter]

Mr. METZL. It is only for 14 days that it is allowed.

Mr. SHERMAN. I understand. I understand, but if Singapore is going to maintain a lead over Britain or can achieve a lead over Britain, in attracting scientists and developing technology, they may want to go to 28 days rather than 14 days, and then I know that some other country will want to be in advance of Singapore.

Dr. Billings, back to the original question.

Dr. BILLINGS. Well, I would focus on really two things. First, on the national security side, there is the ability to manipulate DNA to create modified infectious agents, new toxins, using genetic DNA techniques. It is widely known that one could do that, one could create new botulitum toxins, new things, and they could enter the human societies in various ways and could be done by rogues, and so in my view——

Mr. SHERMAN. Are you talking about the bioweapons——

Dr. BILLINGS. Bioweapons. Exactly. And, you know, I think there are obviously people who have been thinking about this for a long time.

We need better monitoring tools to know as sensitively as we can when people are engaged in work like this that might lead to such things and when they gain access to public dissemination, but, you know, this is not a unique area of monitoring that is different than other kinds of weapons monitoring that you might want to regulate for defense purposes or international treaty purposes.

So, you know, there are some unique aspects of the kinds of weapons that could be created, but I think the regulatory rubric is pretty similar to what you have done before.

In the area of reproductive methods and, as you say, some of the areas of germline modification, while I am in favor of a intentional ban on germline modifications, I would only point out that the germline has been modified over the years by inherent biological mechanisms, by exposures to toxins and other things, infectious agents. The germline, because of the 6 billion other germlines that are out there and because of a lot of redundancy and a lot of other things about the biology of the system, responds rather well, and we do not put ourselves at apparently too much risk.

Mr. SHERMAN. Human beings are just mutant protozoa——

Dr. BILLINGS. Right.

Mr. SHERMAN [continuing]. And so everything that makes us human is a mutation of earlier life forms and this——

Dr. BILLINGS. Right. And——

Mr. SHERMAN. However, we have been able to deal with the mutations and evolution in the human genome over the last 50,000 years pretty well. If we leave ourselves only to natural mutations, I will feel a lot safer.

Dr. BILLINGS. Well, you know, I agree with you that a campaign to modify the genome for certain purposes or for, you know, current purposes is one that is fraught and will likely fail, but just in thinking about mutation at the genome and at the germline level and thinking about mixing of human and animal DNA, I would say that human and animal DNA are DNA, and while I can——

Mr. SHERMAN. Dr. Billings, scientifically, you are right. Politically, it is different.

Dr. Hayes, do you have a particular comment?

Mr. HAYES. I will hear where you are going.

Mr. SHERMAN. Let's for a few minutes here focus exclusively on non-human DNA. Right now, we are protected in this building by dogs. They have a certain ability to sniff for explosives. Imagine if those dogs had greater endurance or better noses or they were just smarter and we could train them to do more. Is there any country that has limited the experimentation in exclusively non-human-derived DNA, knowing that some of the genes in animal DNA are absolutely identical to the genes of human DNA to some extent.

Dr. BILLINGS. Let me just take the first crack at this. Then Rich and Jamie might have other things to say. I mean, the United States has rules about animal experimentation in this country, rather extensive ones, and anyone who has participated in animal experimentation in research institutes——

Mr. SHERMAN. Assuming you could do this in ways to minimize the experience of pain, is there——

Dr. BILLINGS. No. Otherwise——

Mr. SHERMAN [continuing]. Anything that prohibits us from breeding Dolly?

Dr. BILLINGS. No.

Mr. SHERMAN. Is there anything that prevents us from mixing cow DNA with sheep DNA?

Dr. BILLINGS. No, but I would point out, Congressman, that Dolly is a good example. I mean, Dolly had a lot of new traits, some of them rather undesirable, for both Dolly and for the purpose that Dolly was created for, and that will be the result of most of those. It is highly unlikely——

Mr. SHERMAN. It will be a while before the best way to make the most meat and the cheapest way to do it is to go with genetically identical sheep. We are years from there, maybe a decade from there, but that does not mean that just because Dolly was a failed experiment that 10 or 20 years from now, it would also be.

Dr. Hayes?

Mr. HAYES. The question is where do we want to go, and this does point to any——

Mr. SHERMAN. Well yes, I am trying to avoid the philosophical and just focus on the diplomatic. We could be here all day if we were just to discuss our own personal views as to what is moral and what is not. So I will ask you to focus on the international consensus or lack of international consensus on the issue of the manipulation of genetic material not derived from human beings.

Mr. HAYES. Not derived from humans?

Mr. SHERMAN. Right. We are talking animals here. Right.

Mr. HAYES. Other than safety and animal welfare concerns, I am not aware of anything that goes beyond that.

Mr. SHERMAN. Okay. And I am not aware of any humane society objection. Certainly, we have an awful lot of animal protection legislation in this country. I do not think any of it would have been violated in any state by the actions that were taken to create Dolly.

Mr. HAYES. Well, I will say, however, the Humane Society of the USA and——

Mr. SHERMAN. Oh, there are groups that would oppose it, but they have not been successful in passing statutes that would have prevented it.

Mr. HAYES. On animals, not to my knowledge.

Mr. SHERMAN. Okay.

Dr. Metzl?

Mr. METZL. And I would say for sure not. There is no international standard.

But I would just add a couple of points, one, that the dog, the existence of the category dog, is a result of human manipulation of the wolf, and the dogs that we have, the different categories of dogs themselves, are based on selection for certain traits. So the question is——

Mr. SHERMAN. Yes, but there is a certain——

Mr. METZL [continuing]. As we move to the next step——

Mr. SHERMAN [continuing]. Speed by which dogs change through breeding.

Mr. METZL. Right.

Mr. SHERMAN. And, obviously, the technology of 1950 for breeding was slightly better than 1850, but we are going to get some damn strange canines over the next 50 years if science goes forward.

Mr. METZL. And we are already having that. I mean, there are already monkeys that are being genetically manipulated to incorporate some of the genetic material of jelly fish, for example. That already exists. Last week, it was reported that South Koreans were moving forward on cloning a dog that had cancer-sniffing capability. So I think this process is certainly moving forward extremely rapidly, and there is not any kind of international agreement to regulate it.

Mr. SHERMAN. Let me put forward the idea that the one area that we do need a treaty on in this is enhancements to intelligence. We may very well get animals that demand the minimum wage, and as a Democrat, I think it should be higher than minimum wage.

Mr. METZL. "Planet of the Apes," I think.

Mr. SHERMAN. Yes. I mean, one of the opportunities for derision is that the science fiction writers are so far ahead of everyone else in this, whether it be the ethicists, the futurists, or the Congressmen. They have already made the movies. Some of those movies will not come to pass, but some will. And "Planet of the Apes" does not presuppose genetic engineering, but it would have been a better movie if it had.

Yes, Dr. Hayes?

Mr. HAYES. If I could comment on your suggestion around the two-or three-tier system and then link that with chimeras and the animal issue.

I think the two- or three-tier system makes a lot of sense, and the chimera issue is a perfect example of this. Right now, there is experimentation going on that is mixing human and animal sheep DNA, and there is sort of an emotional queasiness about that, the case could be made that there is some useful medical research that this helps make possible.

But if it was possible to mix the human and animal DNA and bring the resulting conceptus to term as a born live creature, how do we feel about that?

If we are able to get an international consensus, an international agreement, that we would—it would be the same framework as the human rights violation—never allow that sort of thing to happen, then it actually builds confidence in being able to use some sort of human-animal experimentation in good faith as part of medical research.

But without having drawn that prior red line, then the otherwise beneficial medical research merely pushes the envelope or runs the risk of intentionally or unintentionally pushing us into——

Mr. SHERMAN. And there are two reasons to mix human and animal DNA. The reason they are doing it now is to create tissues that can be used to research or treat human diseases. The other reason to mix human and animal DNA is to create an animal with both human and animal characteristics, and that poses some real ethical issues and, to some extent also, national security issues.

Hannibal had elephants, if those elephants would have been genetically engineered, they would have been better. The use of animals in warfare, if you can program the brain of the animal, whether that be through computer chips or genetic engineering or the combination of the two, creates something that would—I mean, we are working now on robot soldiers, but biological robot soldiers offers a whole new way to fight a war.

And I would draw the absolute red line at anything that creates an animal with enhanced intelligence beyond that of the animal and anything that enhances a human being above the average human being, because, as I think the witnesses have pointed out, every gene we have can be viewed as a disease in the sense that, well, it is not working perfectly, my heart is going to give out at age 100, I would like it to last—if I am lucky, it will give out at age 100—longer.

But if you had an embryo with a heart that was going to give out at 40, who amongst us would say we should not use genetic techniques to give that person a full life? But once you start enhancing human beings above the average, you are in the human enhancement business rather than the treatment business, and then most especially enhancing human intelligence.

All of us would be in favor of retarded or whatever the politically correct term is for those with dramatically reduced intellectual capacities being treated. That person probably needs treatment. On the other hand, once you start trying to create, you know, a nation of super Einsteins, you pose a national security risk to other countries.

But putting aside where exactly that red line is, I have drawn a red line that I think is a very permissive red line. I think I have included on the permissible side of the red line things that each one of our witnesses would say, "Hey, do not allow that either." But say we went with a red line that dealt exclusively with actions which are unacceptable in another country because they pose a national security risk to the United States. The question is then: How do we develop a treaty that deals with those things?

Now Ranking Member Royce brought up the non-proliferation treaty and the biggest loophole in it—Dr. Metzl, I see you are taking notes because you know the question is coming your way—and the big loophole is, at least according to some, you can be a signatory as a non-nuclear state and control the whole fuel cycle, which means you are allowed to get within a few months of the prohibited while still being legal, and then you can either do a hidden program or pull out of the treaty or take a number of actions.

You know, when we have Fort Knox, we do not let you steal the gold from Fort Knox. We also do not let you get within 8 inches of the gold at Fort Knox and then trust our laws to prevent you from actually grabbing the gold bar. What do we do to have a biological treaty that not only prohibits what is behind the red line but keeps countries from getting within striking distance of the red line while still being legal?

And if you do not have any answer, I will let you think about it for——

Mr. METZL. No. I mean, here would be my general answer, and I am curious to know what my colleagues think. But I think it is

going to be very hard to draw a red line based on the underlying science. I think the red line needs to focus more on the applications, what you can and cannot do, because if we try to limit the science, knowledge finds a way and it will find a way, and I think it is better to focus on this is what is permissible and this is what is not permissible in terms of applications, but the——

Mr. SHERMAN. But that is almost exactly contrary to what we would want to do in the nuclear area if you or I were interpreting in a proper way the NPT treaty. In other words, we would not want somebody to say, "Well, I am going to go to 95 percent enriched uranium, but it is just because I want to see what happens when I enrich uranium. I am a curious guy, and it is scientific." In other words, a pure heart does not let somebody get within a few inches of the gold bar.

Can we do that in this biological area or are we doomed to a treaty that does nothing more than says, "Develop all science, acquire all capacity, put yourself in a position to do that which threatens American national security, but as long as you claim a pure heart and do not actually act, you can put yourself within a week of being able to do something terrible, but as long as you profess that you do not intend to cross that line, you are fine."

Mr. METZL. I do not think it is about what people profess they are going to do or do we know. I think the essential point will be what people are doing and what countries are doing and what they are allowed to do. As I said, I just do not think that it is going to be feasible to say what kind of research that countries can do, other than research where we say that the research itself crosses a specific line that we have articulated. It may be about human-animal hybrids. It may be about reproductive cloning, but this knowledge will find a way.

And the other thing is that the language that is going to be used—and in some ways, this is similar to the nuclear analogy—to describe the research will be the language of disease eradication, and it will not be long. People who are doing that research will say, "Well, we have the ability to eliminate these types of cancers," and all of these capabilities will be transferrable, and what we need to do is find a way to not squash the science but keep the applications of that science from crossing certain ethical boundaries.

Mr. SHERMAN. So you would let a country develop all the science it wanted and be on all sides of the technology necessary to do something terrible and be in a position where with a few months of research they could do something terrible and threatening, so long as they have a professed reason to do all of the research they are doing. I am a little scared of that.

I will go on to Dr. Hayes.

Mr. HAYES. I do not have an answer on this. I want to reaffirm the point you are raising is really a very critical point, if not one of the most critical.

So let's say we agree on where a red line is. The question then is: What sort of margin of safety do you want to build in such that it will preclude that red line either intentionally or accidentally being passed over? And, again, I think this is very interesting. We are using terms such as "all the science," things like this. Until we really do the kind of study, inventory, you know, detailed examina-

tion of all the issues and how they relate, it will be difficult to come up with an easy answer.

But I do want to say also that this is where at some level—and, again, this is partly a challenge, but I think a real opportunity—it is going to force humanity as a whole to grapple with some very deep questions about what is it about our common humanity that we value. Let's say we are clear, we know which red lines we do not want to cross. What then do we want to do? What margin of safety do we want to build in so that we do not wander across?

Mr. SHERMAN. Okay. Dr. Hayes, nothing forces us to be rational, and, in fact, the most likely outcome of the technologies we are talking about is that that which we consider human is not the dominant species on the planet by the end of the century. That is the most likely outcome. We are trying to wrestle with that and offer some other alternatives, but I have been in politics and government long enough to know that just because it has to happen does not mean it happens.

Dr. Billings?

Dr. BILLINGS. Mr. Sherman, I would ask for you to consider why you are not discussing research and engineering in pure weaponry by other countries rather than biotechnologies because, you know, some country being innovative and creating a new gun is probably a much bigger threat, frankly, directly to American lives than some highly improbable to be successful, biotechnology kind of research, in this area. So I wonder why your rubric——

Mr. SHERMAN. We have a whole committee, we call them the Armed Services Committee, and——

Dr. BILLINGS. Yes, I understand that.

Mr. SHERMAN [continuing]. And this country is certainly spending enough money to make sure our guns are bigger than their guns, and I would not propose that the subjects of this hearing get even 1 percent of the funding or the attention of the bigger, more practical, more immediate question, which is how do we make sure our guns are bigger than their guns.

Dr. BILLINGS. Exactly.

Mr. SHERMAN. The fact is we have done a great job at that.

Dr. BILLINGS. And I think that that has to do—I hope that that has in part to do—not only with just our industries and our spending, but with our intelligence and assessment of other people's capabilities, what is going on elsewhere and our ability to respond reasonably quickly to that.

That is why in my written comments I emphasized the issue of monitoring, particularly for safety purposes, what is going on. What techniques are being applied to humans here and elsewhere and whether the assessment of those are safe.

But I would also like to return for one moment to your question about enhancing the intelligence of animals. There have been, as you may know, experiments published that have claimed to show through genetic manipulation and the enhancement of intelligence of animals and, you know, the problem has been how you measured that outcome. It was, in this case, how fast a lab animal did a maze, and they learned it and did it faster after the genetic manipulation. These were rather unhappy lab animals in other ways.

And that is, you know, one of the big areas, I would say, of caution as one thinks about some of the questions you asked because, you know, any tinkering with a very complex system can have rather amazing unintended results, and that is likely to be more common.

Mr. SHERMAN. Yes, I have no doubt that the things we are here to discuss cannot be accomplished by today's science. We should thank God that he did not create a physical universe in which the kinds of things we are talking about here were easy to accomplish. Had he created a physical universe in which creating a nuclear weapon was scarcely more difficult than creating a steam engine, I doubt we would be here to discuss it at all.

But just to say that the creation of useful new life forms has not yet occurred, to my knowledge, Dolly is not the best way to get mutton, and the lab rats that you are talking about, while they may do mazes well, are not an overall superior lab rat, does not mean that we are not within a decade or 2 of a military or civil defense dog that is more useful than the dogs we have now or more useful than what you could get by breeding a poodle with a cocker spaniel.

Mr. METZL. Or synthetically created algae just to start more simply.

Mr. SHERMAN. Yes. And I do not think that we are going to get an agreement to prevent the use of genetic engineering to create superior animal or plant life forms. It is just too useful. The question is do we single out the intelligence of the animal as something that we do not mess around with or are we in a circumstance where the country with the most intelligent dogs wins the battle.

And so you are right. Developing algae that is good to create fuel, mix a few algae genes together——

Yes, we are going to try to wrap this up within 5 minutes.

Now, Dr. Metzl, your article focuses on the NPT as a model. Seemingly an even more analogous model is the bioweapons convention. Why did you pick the NPT in terms of a model for dealing with what we are talking about here, how did the NPT compare with the bioweapons convention?

Mr. METZL. I am neither an expert in NPT nor in the bioweapons treaty, but what I will say is that the reason why the NPT model made sense to me is because it dealt with the technology that had both incredibly positive and beneficial uses and incredibly negative potentials, and the challenge in this kind of situation is how can you regulate abuse, while empowering the positive applications, and that is something which I think is in some ways unique to the NPT, although there may well be the other models.

That is the challenge for us because, as I said, in my testimony, the people who are opposed to this very positive research altogether will use the same language of regulation and global governance in their attempts to squash it altogether, and for those of us—and I certainly put myself into this camp—who think that this is critically important research and work that needs to be done and that it is very natural, healthy, and good for human beings to be following many of these directions in our research and applications, we need to figure out what the model is that can balance the good and the bad.

Mr. SHERMAN. I would point out the NPT creates three classes of countries—the non-signatories, the nuclear states, and the non-nuclear states that are signatories—and by creating one of those, namely the signatory nuclear states, you are able to restrict in five countries the full fuel cycle, if you interpret the NPT the way I do, the way our Government is pushing for at the IAEA. Whether or not you are going to be able to create a few countries that control the fuel cycle in biology or whether you can only have one class of signatory, which means that something has to be permitted to all or prohibited by all, makes drafting it—it is easier to draft a prohibited by all, allowed by all, and allowed to some because that allows you to have nuclear plants and have a few countries control the fuel cycle.

I do not know whether we are going to have to create a circumstance where all of humanity is denied the benefits of any technology that cannot be fully trusted to every country in the world. So we do have that issue.

I do have one other line of questioning, and that is right now in these areas, it is the general practice, sometimes a requirement of funding that research programs publish their results. What technology is going on today where we might very well as a nation decide that it should be secret in the bio area? Does anyone have an opinion on this?

Dr. Billings?

Dr. BILLINGS. Well., I do not have anything to add on the top of my head that I think need to be useful, but I think that science in the absence of publication is a risky business. That is all I will say about that.

Mr. HAYES. I would say the worst example was about 1½ years ago where the 1912 influenza virus was constituted, and the scientists who did that published that information, and——

Mr. SHERMAN. Which virus again was that?

Mr. HAYES. The 1912 influenza virus. So how many——

Mr. SHERMAN. They published how to recreate the most deadly disease of modern times.

Mr. HAYES. Exactly. Precisely. And it was literally within a few weeks, there was an op ed in The New York Times written by—I think it was Bill Joy on the one hand and one of the human genome scientists. So here are people, if you will, with two opposite perspectives of the general perspective saying this really was in violation of common sense and human security.

Mr. SHERMAN. Okay. And we know that DARPA is pouring millions of dollars into the Peak Soldier Performance Program creating technologies to improve soldiers' combat performance. It appears as if this technology is not focused on intelligence so much as endurance, but also avoiding sleep, which is at most an inch away from intelligence. I wonder whether the same technologies will be available to students cramming for the SATs.

And so my final question to all three panelists is: Do you have any comments about the biological research of DARPA and other defense agencies?

Mr. METZL. Just go across? There are all kinds of research. I mean, there was an article in Time magazine last week about the number of people in the armed forces who are on Prozac, the stu-

dents who are cramming for exams and the majority, I believe, of people in the baseball—what is the baseball league? You should know this. I should know this—are taking Ritalin for focus. So there are all kinds of enhancements, and I know that the armed forces——

Mr. SHERMAN. And then even Viagra for something other than its intended purpose.

Mr. METZL. Exactly. For hitting. What I will say is that there is a push for all of these to find applications that provide competitive advantages in all of these areas, and, traditionally, military has been one driver.

I know that there are many people in the armed forces who are looking at a range of methodologies for enhancing the ability of our armed forces, some of which include the biotechnology strategies, but I do think that when we think about what our armed forces are going to do and what types of genetic enhancements might be appropriate 20, 30, 40 years from now, we should seek to have one standard for everybody.

If somebody is in the armed forces or not in the armed forces, it really should not matter because the issues that we are discussing here have such major consequence for the world as a whole and for our species that any limitations that we would seek to put on any other parts of the population should also be applied to the military.

Mr. SHERMAN. And this raises the huge difference between trying to improve a soldier by a drug versus by genetic engineering.

I do not know if our other two witnesses have a comment on this.

Mr. HAYES. Well, just a quick comment. About 2 years ago, I was at an invitational meeting at the AAAS, the American Association for the Advancement of Science, and they invited a number of experts, including a lot of people from government agencies. DARPA had respectively declined to attend, and one of the people there who is somewhat familiar with that said, "DARPA is exceeding everything that all the rest of us are doing in this regard," and so I think this is where the question of national security in, if you will, the simplistic sense and global security in a more mature sense becomes an important consideration.

Mr. SHERMAN. And one issue before us diplomatically is: Does it make sense to try to achieve a tremendous lead over other countries, and then from that position, try to negotiate the NPT equivalent, or will we be able to negotiate something now when we may or may not have a lead?

Mr. HAYES. We have a rare opportunity to do the latter, or our political leaders do.

Mr. SHERMAN. And if that does not work, we will be stuck with trying to do a forum.

Dr. Billings?

Dr. BILLINGS. What I would say only is that oversight of defense research, whether conducted by DARPA or other agencies, is a good thing. I would also say that DARPA wastes a lot of money on things that will not work, and I think——

Mr. SHERMAN. Are you just saying they have the science wrong, that certain things they think are practical just are not?

Dr. BILLINGS. Exactly. Exactly. And that there are probably, as you say, conventional drugs and robotics and so forth that will produce more rapidly the outcomes that our military people want than genetic engineering.

Mr. SHERMAN. Okay. This is a public hearing, so do not reveal anything you know that is classified. I am not aware of any genetic engineering by DARPA on an unclassified basis. Are any of you?

Mr. HAYES. Interesting to put a query.

Mr. SHERMAN. What?

Mr. HAYES. It would be interesting to put a query to DARPA.

Mr. SHERMAN. I think I would get a respectful non-response. So at least if they are doing it, it has not leaked out to the point where any of us have learned about it from non-classified sources.

All right. Gentleman, you have shown human endurance. You have not shown superhuman endurance. To my knowledge, none of you has been genetically engineered in order to endure a 3-hour hearing with a break.

And the watch word maybe in this area—we are looking at other countries—if we do not do it, they will, and that will continue to be the truth unless we have not only an international treaty but one truly comprehensive in its scope and truly practical and effective in its enforcement. Thank God that the universe is difficult in making these scientific developments, and we have a little time to go far beyond where we are now.

Thank you for your endurance.

[Whereupon, at 1:02 p.m., the subcommittee was adjourned.]

APPENDIX

Material Submitted for the Hearing Record

Congressman Brad Sherman

Congressional Record
May 17, 2000

Mr. Speaker, let me now bring up, in the waning minutes of this brief presentation, a third topic, a topic that is very important. I have only a bit to say about it, because, frankly, it is a topic that has me stumped. Let me by way of introduction mention that this is a topic that, as far as I know, has never been addressed.

It is a topic that my staff has said, BRAD, maybe you do not want to bring that up, because you will be the only one talking about it, you will look weird. It is a topic I ought to bring up, because it is one of the seminal topics. And it is only one of several seminal topics that gets no attention; by seminal topics, I mean one of the topics that really goes to where we are going as a species and what are the dangers, not only to the prosperity of the people in my district and in the country, not only to the issues we fight about here everyday, but to where we are going as humankind.

Now, there are a number of issues that rise to that level of significance that do receive significant attention: nuclear proliferation, environmental catastrophe, overpopulation; all of these threaten humankind's continued prosperous existence on this planet.

There is a fourth issue that does, I think, rise to the level where it can be included, and it is an issue really without a name; I call it the issue of engineered intelligence.

I am going to propose to this House, I hope some of my colleagues will join me, we will have dinner, we will have a drink or two, we will think this over, not maybe a drink or two, we will think over what form this bill should take, but I am planning to introduce a bill calling for the creation of a national commission on engineered intelligence.

There are several different forces coming together or scientific technologies that come under the title of engineered intelligence : First,

there is biological engineering which could give us either of two huge ethical dilemmas; one is the prospect that biological engineering will allow us to design some sort of animal, perhaps starting with human DNA and going down, perhaps starting with chimpanzees' DNA and going up, but some sort of animal that is significantly more intelligent than the domestic animals that help us do our work, sheepdogs or watchdogs or seeing eye dogs, considerably smarter than the canines that help us do work, but less intelligent, less self-aware than human beings, and one wonders whether this would be an engineered slave race or just an improvement in today's pooches, a better seeing eye dog, or a sparely self-aware cognitive entity engineered by man to serve man, arguably to be enslaved by man.

Biological engineering can engineer intelligence at a level where some will argue that that entity deserves the protection of our Constitution, and others would argue that that entity is here to serve us in the same humane way that we turn to watchdogs and seeing eye dogs. Likewise, biological engineering can go beyond.

I can see, not today, but we are within 20 years or 30 years or 50 years of when biological engineering cannot only do what I just covered, but could also engineer an intelligence well beyond that of the average person, perhaps well beyond that of any human that has ever lived, and we would have to wonder, do we want our scientists to create a new species that Darwin might think is superior to our own? I do not know.

But it raises ethical issues that are going to take longer to resolve than it will take the science to get there and present those logical issues, those ethical issues to society.

One example is that Einstein a few years before World War II, together with others, brought to the attention of Franklin Roosevelt the great power or potential power of nuclear science and the nuclear bomb, and we had only a few years to consider what that would mean. The science developed more quickly than the ethics, and we had to struggle as a species to figure out, and we are still struggling to figure out what the rules are with regard to the nuclear engineering.

We need to begin thinking now of the ethics and the international agreements and the laws that are going to apply when science gets to where only science fiction is today.

Mr. Speaker, it is not just is biological engineering capable of engineering intelligence; it is also mechanical engineering. One of my friends has said that perhaps the last decision that will be made by the human race is whether our successors are the products of biological engineering or mechanical Silicon Valley engineering; whether our replacements are carbon-based or silicon-based, because I do not know whether it will be biological engineering that engineers intelligence first, or whether intelligence rivaling our own or perhaps surpassing our own will first come from silicon chips; but the same ethical issues arise.

One can imagine a thinking machine capable of spirituality. I believe there is a book that addresses that issue by that title.

One can imagine a thinking machine smarter than any computer, almost self-aware, some would argue properly used by people, others would say properly embraced as the constitutional equal of human beings. Likewise, it is possible for us through silicon engineering, through computer engineering that some day we will invent machines considerably smarter than us who may or may not regard us as their appropriate peers or masters.

I know this is science fiction, but would it not be wise to spend a few years, and a few, in the minds of a few people a lot smarter than I am trying to figure out what we would do if science begins to offer this as an alternative for human kind?

I can only mention third, nanotechnology, the idea of engineering at the molecular level, at a level where perhaps it would be hard to decide whether what we had engineered was biological or mechanical, or maybe we will see a fusion of biological and mechanical or biological and electronic engineering where a combination of silicon chips and brain cells from human DNA or brain cells from dog DNA are fused together.

I do not want to sound unusual, but the science of the future will be a little unusual. We in this Congress will not do the science, but we in this Congress should make sure that we focus the appropriate societal attention long in advance on the ethical dilemmas that will face us as engineered intelligence either approaches or surpasses our own.

Mr. Speaker, although there would be one benefit of such marvelous engineered intelligence for, perhaps if we had an engineered intelligence massively smarter than myself, maybe we would know what the right course was for the World Bank to take or what the right course was for this Congress to take on the issues I addressed earlier in this speech.

Congressman Brad Sherman

Congressional Record
June 6, 2000

Mr. Speaker, I have talked about a number of topics. Topics that are complex topics that I do not get enough time to study about, read about; and it leaves me longing for a greater level of intelligence . Mr. Speaker, there are those working on greater levels of intelligence today. There are those engaged in silicon chip engineering who are creating more intelligent machines all the time. And there will come a time when the silicon chip-driven machines rival humans in intelligence .

There are genetic engineers mapping the human genome and within a few decades they may be in a position to create a more intelligent human being, perhaps one that could have dealt with all of the topics confronting this Congress with greater wisdom than I have been able to muster.

There are those dealing with nanotechnology, technology where things are manipulated at the atomic and molecular levels, technologies that offer a chance to engineer either from biological materials or from electronic materials or from a combination of the two a level of intelligence way beyond today's computers, way beyond today's animals, and perhaps way beyond today's humans.

Speaking of intelligent humans, on August 7, 1939, Albert Einstein wrote to President Roosevelt and brought to his attention clearly and crisply the importance that nuclear technology might have for the future of the world. In just a few years, that nuclear technology literally exploded. What was the

high and unusual science of 1939 became the public policy issue of 1945 and beyond.

We today are still wrestling with the political, the international, and the ethical issues of nuclear power and, of course, nuclear weapons.

Would it not have been great if we had gotten a bit more of a head start? Would it not have been good for humankind if the scientists had come to us 20 or 30 years before the nuclear weapons were created and told the world's political leaders that the genie will soon be leaving the bottle and it is time to develop a code of ethics and central understandings that will fit the new technology?

Now, some more than 50 years after nuclear weapons, we are still struggling with the ethical issues that they create. Well, I do not know how many years we have before what I refer to as remembered intelligence poses even more severe ethical issues for us than nuclear weapons do.

Let me bring a few of them to our attention. I know this may sound like science fiction today, but I do not think anyone familiar with science would say that these are not real possibilities. I am not saying this decade, maybe not next decade, maybe not in the lifetime of those of us who have lost our hair, but certainly within the lifetime of some of the younger folks in the back of the room.

First, we will see genetic engineering that will either create or offer to create our slaves or our masters. Today dogs are a man's and woman's best friend. They are great pets, and a few of them are engaged in work, shepherding sheep, for example. Today's dogs have been bred, not genetically engineered , just bred to be friendly, docile, and obedient.

There are a few who think it raises ethical issues, but most of us view a dog's intelligence as below that of self-awareness and consciousness and are quite happy to have dogs that are obedient, docile.

But what happens when the genetic engineers start developing more intelligent canines? What happens when we start having dogs as intelligent or more intelligence than apes? Fortunately, I do not think we are going to face this issue in the next decade. But we are going to face it this century, and we are probably going to face it before we figure out what to do with it.

At what point must we recognize other life forms as being protected by our Constitution? How intelligent must a genetically engineered animal be to be worthy of our protection and respect? I do not know.

Likewise, we have seen many science fiction shows where scientists start with human DNA and deliberately try to create a being that is less intelligent or simply more docile than the average human form, and we are told to imagine a race invented for slavery. I think all of us recoil at the ethics of that.

But will we recoil with the same level of revulsion if the nearly as intelligent as human or perhaps as intelligent as human docile race is engineered from canine DNA or simian DNA, perhaps someday if we are not careful, human DNA? But not only may there be genetic engineering that invents those entities which some would wish to enslave, genetic engineering , whether it starts with simian DNA or human DNA, could very well invent a level of intelligence well beyond that of any of us here, perhaps even beyond that of the Albert Einstein I quoted earlier. Then how should human kind react?

That which can be done with genetic engineering may also be done with silicon chip engineering . A book I have not had a chance to read bears the interesting title the Age of Spiritual Machines. How many decades is it before the computer screen lights up with the question, am I alive? Why am I here? Should there be any ethical limitations on creating computers with intelligence, not just to balance our checkbooks or to figure the trajectory of the rocket, but computers intelligent enough to ask the spiritual questions? I do not know. I do know that it will take a panel of Einsteins to give us some guidance as to what our laws should be. This is going to be a tough issue.

I am going to propose probably next Congress, if I am fortunate enough to be here, if there is interest by some of my colleagues, perhaps we could work on it this month or next month, that we create a national commission on the ethics of engineered intelligence to try to give some guidance to those lawmakers that will come after us in dealing with the issues of silicon or carbon-based intelligence that approach or exceed that of today's human being.

I do not know how to deal with these issues. It is a tradition in this town that, when one does not know what to do, one creates a commission. There is also a tradition in this town to wait till the last minute, to wait till some development is going to impair jobs in our own districts before we get serious about the issue. I would say that these are issues, and there are others as well that we ought to try to tackle at least at the thinking stage at the earliest possible time.

END