

Plenary Address, 8<sup>th</sup> Global Summit of National Bioethics Advisory Bodies  
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Good morning. I am Amy Gutmann, President of the University of Pennsylvania and chair of the United States' Presidential Commission for the Study of Bioethical Issues.

I am delighted to be here with all of you today. It is a privilege to share the stage with members of some of the world's most distinguished and respected deliberative bioethics bodies and to address my colleagues in the international bioethics community.

In November of 2009, President Barack Obama asked me to serve as chair of his Commission -- an honor that I wholeheartedly accepted because of my lifelong interest in the intersection of ethics and public policy. I share leadership of the Commission with Vice Chair Jim Wagner, the President of Emory University, and an accomplished educator, engineer, and scientist.

Jim and I have the privilege of working alongside eleven dedicated citizens appointed by President Obama. They are experts from wide-ranging fields including medicine, nursing, law, ethics, religion, and engineering. Our Commission is fortunate to include three members of the federal government, as well as representation from two branches of the United States military. This roster reflects not only the diversity of the United States, but also the complexity inherent in today's bioethical issues. No longer can these issues be well considered by a single field or just a few fields.

The work of our Commission -- and the work of your groups -- demands careful analysis and thoughtful public deliberation from multiple perspectives (medicine, engineering, domestic and international law, and ethics, to mention just a few). Our goal is to identify those policies and practices that are most likely to ensure that scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

Importantly, ours is not a decision-making or regulatory body. Rather, President Obama has asked that we provide him with practical, policy-oriented advice to ensure that "...our nation invests in science and innovation and pursues advances in biomedical research and health care... in a responsible manner."

Our Commission's first order of business is consideration of recent advancements in the field of synthetic biology. As you know, on May 20<sup>th</sup>, the J. Craig Venter Institute announced its creation of the world's first self-replicating synthetic genome in a bacterial cell of a different species. News of this achievement circled the globe and wide-ranging reactions were penned and published swiftly.

Rather than offer an immediate opinion, President Obama made a direct request that we, the members of his Bioethics Commission, begin our work by considering the implications of this scientific milestone. Before the year is out, we will develop recommendations about -- to quote the President -- "any actions the Federal government should take to ensure that America reaps the benefits of this developing field of science while identifying appropriate ethical boundaries

and minimizing identified risks.”

The days, weeks, and months separating us from a New Year may seem like an eternity. Many of us have become accustomed, for better and for worse, to immersion in a lightning-paced world. The question now is: What can we gain -- or regain -- from rejecting tidy “soundbites” and embracing substantive debate about issues of global importance?

The weather...market ups and downs...World Cup scores: these can be absorbed with just a quick, indeed quite cursory, glance. But coming to grips with the implications of cutting-edge bio-technological advancements requires far more sustained attention; it requires a respect for the expertise of others and the sensibilities of multiple perspectives, and it requires an appreciation of complexity. Only then do we succeed in addressing complex and controversial issues in meaningful and effective ways.

By engaging in substantive argument and exchange in a publically open way, we also gain a better understanding of the nature and sources of controversy. Discovery of a new way of replicating or enhancing life raises public expectations, and it also raises public concerns. Airing these expectations and concerns in a public forum maximizes the potential for public benefit and shines a light on risks that deserve our attention and careful consideration.

As important, by creating a public forum for careful deliberation, we maximize the possibility of improving the quality of both public debate and public policy. Some of those who shout the loudest and the longest in response to controversial issues often expend little effort to uncover the facts; they refuse to consider conflicting ethical perspectives; they block the possibility of discovering common ground, where possible, and cultivating mutual respect where disagreements persist and common ground is impossible to find.

Respectful and careful deliberation draws attention away from these voices -- not by grandstanding, but by demonstrating the value of robust and constructive deliberation.

Our Commission hopes to gain all that may be gained from adopting an inclusive and deliberative approach to our work. We have encouraged and will continue to encourage the exchange of well-reasoned perspectives with the goal of making recommendations that will serve both the American public and humankind.

Given our deadline from the President, we have decided to hold three public meetings on the topic of synthetic biology before we issue our report.

We held our first meeting earlier this month in Washington, D.C. The gathering was structured to maximize the Commission’s understanding of the issues at hand and to provide ample time for discussion. Over the course of two days, some of the world’s leading experts in synthetic biology addressed the Commission in public panels and had the opportunity to speak to one another in a less formal plenary session.

The experts had diverse academic and professional backgrounds. We heard from a synthetic biologist and genetic engineer; a chemical engineer; a molecular biologist; an ecologist; a

geneticist; and a physicist. We also heard from experts in public opinion, education, philosophy, bioethics, technology assessment, law, and law enforcement. Representatives from environmental groups and international bodies helped to broaden the conversation and emphasized the global importance of advances in synthetic biology.

Each panel covered essential territory from multiple perspectives. Some guests presented information about recent and upcoming advances in the science of synthetic biology, as well as current and future applications. Others shared their perspectives on possible benefits and anticipated risks; related regulatory and oversight issues; and ethical considerations. We opened up every session to questions from the public, as well as from Commission members. This format contributed to highly interactive and valuable sessions.

We focused first on understanding the science. As you well know, the pace of advancement in genomic synthesis is unprecedented in human history. The ability to synthesize DNA in a wholesale fashion may be the most significant scientific advance of the 21<sup>st</sup> century. Though there was general agreement that the world's first self-replicating synthetic genome is an exceptional achievement, there also was vigorous debate about just how momentous the Venter Institute's success is.

Some scientists consider it a quantum leap and others an incremental stride. Whether one considers the accomplishment a paradigm-shifting advance, an incremental technical step, or some combination of the two, one cannot deny the importance of understanding the potential implications of this and related accomplishments for humanity.

We began with an overview of the potential benefits because, without any realistic promise of benefits, no risks would be worth taking. Our Commission's expert panelists cited a host of benefits: the electronic sharing of genomic information, the expeditious synthesis of vaccines in response to pandemics, and the ability to engineer algae and other microbes to spur advances in agriculture, aquaculture, biofuels, bioremediation, regenerative medicine, and pharmaceutical development and production.

In addition, we heard about the promise of a robust bio-economy, beginning to materialize in the form of biological platforms producing eco-friendly alternatives to petroleum-based plastics and other products.

After discussing the possible benefits of scientific and technological advances, the Commission considered the current and foreseeable risks posed by the rapidly evolving field of synthetic biology. Several themes emerged in these panels.

First: We need to respect the intricacies of the natural world. Biological systems have developed over billions of years and their interactions with the environment are impressively and astoundingly complex. We are far from being proficient speakers of the language of life, and we almost certainly will not have the luxury of recalling synthetic organisms that we release into the world.

Second: We must understand our own limitations. Like other new technologies, synthetic biology

poses biosafety and biosecurity concerns. Rapidity of change, dispersion of information, and increases in technological competence heighten these concerns. Newly synthesized genomes may be so far outside our scope of experience that we will find it increasingly difficult to characterize them and assess their potential for harm.

Third: We should consider ancillary effects. In addition to safety and security risks, the rise of a biotechnologically-based economy threatens to cause social upheaval, economic displacement, conflicting and possibly excessive demands on already scarce resources, and possibly increased social and economic stratification. Anticipating all the ramifications of our actions is impossible. Determining how best to live with uncertainty is the better part of wisdom.

So: How might the United States' government respect the intellectual freedom of scientific inquiry and nurture the developing field of synthetic biology in a way that maximizes its potential benefits, while reducing the risks and likelihood of both direct and indirect harm?

Here our panelists recommended a continuum of responses. Some argued that because the knowledge, information, and technology of synthetic biology are already widely dispersed, and the benefits accrue from “do it yourself” as well as “do it together” science, the best approach is one of laissez-faire innovation or minimal regulation. A society that maintains an open information environment does not drive innovation underground or elsewhere.

Other experts -- including some synthetic biologists themselves -- argued that, even at this early stage, licensing, oversight, and registration and training requirements are critical both to facilitating fluid communication and to avoiding the worst case harm scenarios.

The goal of supporting a culture of responsibility within the scientific, academic, and amateur communities informed both the minimal regulation and the comprehensive oversight positions. Our experts also highlighted the challenge of tailoring communications (and any regulations) to suit both the “do it yourself” and the “do it together” communities.

We also must prepare science and societies to address unforeseen challenges. To this point, several panelists recommended building safety measures into genomes in the form of “terminator technology” or synthetic “suicide genes” in engineered organisms. The counterpoint, of course, is that safety may not be among the motivations of all those who use this new technology, so scientific self-regulation may not suffice to allay biosafety and biosecurity concerns.

Whatever their position on the regulatory spectrum, guests and Commission members generally agreed that regulatory systems work best when they are adaptable and subject to continuous assessment and revision in light of new facts and evolving contexts. Foresight and preparedness before “the genie is entirely out of the bottle” also was a major theme.

Other major matters of concern included the importance of public trust in the integrity of scientific and engineering communities, and regulatory bodies plus -- perhaps the most universally expressed priority -- the need for greater public education and engagement on these and other emerging issues in science so public acceptance and constructive criticism are not afterthoughts.

Distrust not only of public regulatory bodies, but also of private industry and of professional self-regulation has been growing in the U.S. and many societies worldwide over the past five decades. Key to coming to some agreement on what constitutes progress in any controversial field of public interest is increasing trust, encouraging transparency, and establishing mutual respect across persisting disagreements.

Speakers and Commission members alike therefore recognized the importance of our maintaining an on-going dialogue among all stakeholders – scientists, social scientists, policy-makers, ethicists, civil society groups, and the public – as the field of synthetic biology develops and as new applications are considered. The Commission also discussed the need to recognize the perspectives of pluralist publics with differing religious sensibilities and worldviews. Assuming we are successful in our deliberations, the Commission’s work may be “an existence proof” of the value of establishing clearer lines of communication among the practitioners, policy-makers, law enforcement and regulatory bodies, and the pluralistic public.

My presence here today is an extension of our efforts, as the Commission invites international perspectives on its work -- and on the issues raised by synthetic biology. The issues are relevant not only, or even primarily, to America, but to all societies and all people. The Commission has already heard from some of you about your countries’ and organizations’ approaches, and we hope that more of you will consider conferring with us in the coming months. To facilitate input, we’ve created a mechanism for public commentary on our website, [www.bioethics.gov](http://www.bioethics.gov).

Our next two meetings will be held at the University of Pennsylvania in Philadelphia on September 13<sup>th</sup> and 14<sup>th</sup> and at Emory University in Atlanta on November 16<sup>th</sup> and 17<sup>th</sup>. We will use those meetings to deepen our understanding of issues pertaining to the ethics and social responsibility in synthetic biology raised in our inaugural meeting. We also intend to address issues pertaining to intellectual property and the possibility and desirability of coordinated international efforts.

In closing, let me thank you for the opportunity to speak here today. I find it exhilarating to work at the intersection of science, ethics, and technology at a watershed in scientific history. Much is to be gained by our embracing robust deliberation, collaborating with one another, and fostering a mutually respectful and mutually beneficial environment for science and technology. One that allows us to discover, create, and apply scientific and technical knowledge in the service of humankind.

Thank you.