EXECUTIVE SUMMARY

The 21st century is widely heralded as the century of biology. Building on the fundamental understanding achieved in the second half of the last century, revolutionary advances are expected to improve many aspects of our lives, from clean energy and targeted, safer medicines to new industries. Prominent among emerging technologies is "synthetic biology," which aims to apply standardized engineering techniques to biology and thereby create organisms or biological systems with novel or specialized functions to address countless needs.

The idea of managing or manipulating biology to identify or develop specific characteristics is not new. Scientists have used DNA to create genetically engineered cells and organisms for many years; the entire biotechnology industry has grown around our expanding abilities in this area. The shelves of grocery stores across the United States are stocked with genetically engineered foods. Medical testing for genetically linked diseases is widely used by people across society.

By contrast, the idea of assembling living organisms wholesale from nonliving parts has intrigued human imagination for centuries with no success outside of fiction. For some, that possibility came one step closer last May with the announcement that scientists at the J. Craig Venter Institute had created the world's first self-replicating synthetic (human-made from chemical parts) genome in a bacterial cell of a different species. Intense media coverage followed, and the announcement ricocheted across the globe within hours as proponents and critics made striking claims about potential risks and benefits of this discovery and whether it amounted to an early-stage example of "creating life."

In response, President Barack Obama asked the Presidential Commission for the Study of Bioethical Issues (the Commission) to review the developing field of synthetic biology and identify appropriate ethical boundaries to maximize public benefits and minimize risks. The Commission approached this task through inclusive and deliberative engagement with a wide variety of sources, including scientists, engineers, faith-based and secular ethicists, and others who voiced, as expected, sometimes conflicting views on the science, ethics, and social issues surrounding synthetic biology. Through public meetings

in Washington, D.C., Philadelphia, and Atlanta, the Commission created a forum for open dialogue to hear and assess competing claims about the science, ethics, and public policy relating to synthetic biology.

What the Commission found is that the Venter Institute's research and synthetic biology are in the early stages of a new direction in a long continuum of research in biology and genetics. The announcement last May, although extraordinary in many ways, does not amount to creating life as either a scientific or a moral matter. The scientific evidence before the Commission showed that the research relied on an existing natural host. The technical feat of synthesizing a genome from its chemical parts so that it becomes self-replicating when inserted into a bacterial cell of another species, while a significant accomplishment, does not represent the creation of life from inorganic chemicals alone. It is an indisputable fact that the human-made genome was inserted into an already living cell. The genome that was synthesized was also a variant of the genome of an already existing species. The feat therefore does not constitute the creation of life, the likelihood of which still remains remote for the foreseeable future. What remains realistic is the expectation that over time research in synthetic biology may lead to new products for clean energy, pollution control, and more affordable agricultural products, vaccines, and other medicines. The Commission therefore focused on the measures needed to assure the public that these efforts proceed with appropriate attention to social, environmental, and ethical risks.

President Obama gave the Commission a rare and exceptional opportunity in the world of presidential bioethics commissions to be forward looking instead of reactive. We are ahead of the emerging science, and this unique opportunity underscores the need for the government to act now to ensure a regular, ongoing process of review as the science develops. The Commission calls on the government to make its efforts transparent, to monitor risks, to support (through a peer-review process) the most publicly beneficial research, and to educate and engage with the public as this field progresses. The government must regularly review risk assessment and other issues as the science of synthetic biology progresses. Only through openness and active engagement with all the relevant communities will the government ensure ongoing public support and appropriate oversight. The Commission emphasizes the need to

engage the public over time through improved science education, a publicly accessible fact-checking mechanism for prominent advances in biotechnology, and other efforts promoting clearer communication on the state of science.

Basic Ethical Principles for Assessing Emerging Technologies

To reach its recommendations, the Commission identified five ethical principles relevant to considering the social implications of emerging technologies: (1) public beneficence, (2) responsible stewardship, (3) intellectual freedom and responsibility, (4) democratic deliberation, and (5) justice and fairness. The principles are intended to illuminate and guide public policy choices to ensure that new technologies, including synthetic biology, can be developed in an ethically responsible manner.

The ideal of *public beneficence* is to act to maximize public benefits and minimize public harm. This principle encompasses the duty of a society and its government to promote individual activities and institutional practices, including scientific and biomedical research, that have great potential to improve the public's well-being. Public beneficence requires that when seeking the benefits of synthetic biology, the public and its representatives be vigilant about risks and harms, standing ready to revise policies that pursue potential benefits with insufficient caution.

The principle of *responsible stewardship* reflects a shared obligation among members of the domestic and global communities to act in ways that demonstrate concern for those who are not in a position to represent themselves (e.g., children and future generations) and for the environment in which future generations will flourish or suffer. Responsible stewardship recognizes the importance of citizens and their representatives thinking and acting collectively for the betterment of all. Importantly, it calls for *prudent vigilance*, establishing processes for assessing likely benefits along with assessing safety and security risks both before and after projects are undertaken. A responsible process will continue to assess safety and security as technologies develop and diffuse into public and private sectors. It will also include mechanisms for limiting their use when necessary.

Democracies depend on *intellectual freedom* coupled with the *responsibility* of individuals and institutions to use their creative potential in morally accountable ways. Sustained and dedicated creative intellectual exploration begets much of our scientific and technological progress. While many emerging technologies raise "dual use" concerns—when new technologies intended for good may be used to cause harm—these risks alone are generally insufficient to justify limits on intellectual freedom. As a corollary to the principle of intellectual freedom and responsibility, the Commission endorses a principle of *regulatory parsimony*, recommending only as much oversight as is truly necessary to ensure justice, fairness, security, and safety while pursuing the public good. This is particularly important in emerging technologies, which by their very definition are still in formation and are not well suited for sharply specified limitations. While clear guidelines to protect biosecurity and biosafety are imperative, undue restriction may not only inhibit the distribution of new benefits, but it also may be counterproductive to security and safety by preventing researchers from developing effective safeguards.

The principle of *democratic deliberation* reflects an approach to collaborative decision making that embraces respectful debate of opposing views and active participation by citizens. It calls for individuals and their representatives to work toward agreement whenever possible and to maintain mutual respect when it is not. Public discussion and debate with open interchange among all stakeholders can promote the perceived legitimacy of outcomes, even if those outcomes are unlikely to satisfy all interested parties. An inclusive process of deliberation, informed by relevant facts and sensitive to ethical concerns, promotes an atmosphere for debate and decision making that looks for common ground wherever possible and seeks to cultivate mutual respect where irreconcilable differences remain. It encourages participants to adopt a societal perspective over individual interests.

The principle of *justice and fairness* relates to the distribution of benefits and burdens across society. Biotechnology and emerging technologies such as synthetic biology, for good or ill, affect all persons. Emerging technologies like synthetic biology will have global impacts. For this reason, every nation has a responsibility to champion fair and just systems to promote wide availability of information and fairly distribute the burdens and benefits of new technologies.

Recommendations

With these guiding principles in mind, the Commission considered the array of public policy issues surrounding the emerging science of synthetic biology and makes the following recommendations. The reasons behind each recommendation are provided in the body of the report, and all readers are urged to consider carefully this more comprehensive account. In the cases of recommendations 1, 3, 5, 9, 11, 12, and 17, the Commission recommends ongoing review by the government, in consultation with the relevant scientific, academic, international, and public communities, with initial action completed within 18 months and made public. Some of these actions could easily be completed sooner, and the government is encouraged to do so and make its progress public.

Promoting Public Beneficence

Under the principle of public beneficence, the Commission recommends that the government review and make public findings regarding the scope of its research funding, especially for risk assessment and ethical and social issues raised by synthetic biology. This will promote public engagement and ensure needed transparency regarding federal efforts in the field of synthetic biology.

Recommendation 1: Public Funding Review and Disclosure

Through a central body such as the Executive Office of the President, the federal government should undertake a coordinated evaluation of current public funding for synthetic biology activities, including funding for research on techniques for risk assessment and risk reduction, and for the study of ethical and social issues raised by synthetic biology. This review should be completed within 18 months and the results made public.

Most potential products of synthetic biology are in very early stages of development. Therefore, basic research is critical to further expansion of this science and its effective translation into useful products. Necessary funding decisions should be made with the goal of advancing the public good, whether these decisions support synthetic biology research or other fields. The Commission

does not offer an opinion on the relative merits of particular research directions, but recommends that such decisions receive ongoing evaluation as to the state of the science and its potential applications.

Recommendation 2: Support for Promising Research

Advancing the public good should be the primary determinant of relative public investment in synthetic biology versus other scientific activities. The National Institutes of Health, the Department of Energy, and other federal agencies should continue to evaluate research proposals through peer-review mechanisms and other deliberative processes created to ensure that the most promising scientific research is conducted on behalf of the public.

Information sharing is a critical mechanism for promoting scientific progress and innovation. The principle of public beneficence requires researchers, inventors, patent holders, and others to work together to develop creative strategies to maximize opportunities for innovation. The government should consider best practices and other policy guidance, if needed, to ensure that access to basic research results and tasks is not unduly limited.

Recommendation 3: Innovation Through Sharing

Synthetic biology is at a very early stage of development, and innovation should be encouraged. The Executive Office of the President, as part of the coordinated approach urged in Recommendation 4, should lead an effort to determine whether current research licensing and sharing practices are sufficient to ensure that basic research results involving synthetic biology are available to promote innovation, and, if not, whether additional policies or best practices are needed. This review should be undertaken with input from the National Institutes of Health, other agencies funding synthetic biology research, such as the Department of Energy and the National Aeronautics and Space Administration, the U.S. Patent and Trademark Office, industry, academia, and public civil society groups. The review should be completed within 18 months and the results made public.

Promoting Responsible Stewardship

The Commission endorses neither a moratorium on synthetic biology until all risks are identified and mitigated, nor unfettered freedom for scientific exploration. Instead, the Commission believes that the field of synthetic biology can proceed responsibly by embracing a middle ground—an ongoing process of prudent vigilance that carefully monitors, identifies, and mitigates potential and realized harms over time. Responsible stewardship requires clarity, coordination, and accountability across the government. While new agencies, offices, or authorities are not necessary at this time, the Executive Office of the President should lead an interagency process to identify and clarify, if needed, existing oversight authorities and ensure that the government is informed on an ongoing basis about developments, risks, and opportunities as this field grows. This process must be undertaken by an office with sufficient authority to bring together all parts of the government with a stake in synthetic biology and be sufficiently authoritative to effectively engage or oversee engagement with foreign governments.

Recommendation 4: Coordinated Approach to Synthetic Biology

The Commission sees no need at this time to create additional agencies or oversight bodies focused specifically on synthetic biology. Rather, the Commission urges the Executive Office of the President, in consultation with relevant federal agencies, to develop a clear, defined, and coordinated approach to synthetic biology research and development across the government. A mechanism or body should be identified to: (1) leverage existing resources by providing ongoing and coordinated review of developments in synthetic biology, (2) ensure that regulatory requirements are consistent and non-contradictory, and (3) periodically and on a timely basis inform the public of its findings. Additional activities for this coordinating body or process are described in other recommendations.

Because synthetic biology poses some unusual potential risks, as "amateur" or "do-it-yourself" (DIY) scientists and others outside of traditional research environments explore the field, these risks must be identified and anticipated, as they are for other emerging technologies, with systems and policies to assess and respond to them while supporting work toward potential benefits.

Recommendation 5: Risk Assessment Review and Field Release Gap Analysis

Because of the difficulty of risk analysis in the face of uncertainty—particularly for low-probability, potentially high-impact events in an emerging field—ongoing assessments will be needed as the field progresses. Regulatory processes should be evaluated and updated, as needed, to ensure that regulators have adequate information. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President should convene an interagency process to discuss risk assessment activities, including reasons for differences and strategies for greater harmonization across the government. It should also identify any gaps in current risk assessment practices related to field release of synthetic organisms. These reviews should be completed within 18 months and the results made public.

Coordination and careful risk analysis are essential steps for responsible stewardship, but they are not sufficient. There are several additional approaches, which are known today and continue to evolve as our abilities in this field grow, to limit uncertain risks in synthetic biology. Technology can be harnessed to build in safeguards. A number of safety features can be incorporated into synthetic organisms to control their spread and life span. Surveillance or containment of synthetic organisms is a concrete way to embrace responsible stewardship.

Recommendation 6: Monitoring, Containment, and Control

At this early stage of development, the potential for harm through the inadvertent environmental release of organisms or other bioactive materials produced by synthetic biology requires safeguards and monitoring. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President should direct an ongoing review of the ability of synthetic organisms to multiply in the natural environment and identify, as needed, reliable containment and control mechanisms. For example, "suicide genes" or other types of self-destruction triggers could be considered in order to place a limit on their life spans. Alternatively, engineered organisms could be made to depend on nutritional components absent outside the laboratory, such as novel amino acids, and thereby controlled in the event of release.

The timing of deliberate release of synthesized organisms into the environment and the need to analyze risks prior to release raises special concern. We must proceed carefully, particularly when the probability or magnitude of risks are high or highly uncertain, because biological organisms may evolve or change after release. For any field release, there must be adequate consideration of risk.

Recommendation 7: Risk Assessment Prior to Field Release

Reasonable risk assessment should be carried out, under the National Environmental Policy Act or other applicable law, prior to field release of research organisms or commercial products involving synthetic biology technology. This assessment should include, as appropriate, plans for staging introduction or release from contained laboratory settings. Exceptions in limited cases could be considered, for example, in emergency circumstances or following a finding of substantial equivalence to approved products. The gap analysis described in Recommendation 5 should determine whether field release without any risk assessment is permissible and, if so, when.

Synthetic biology is an international enterprise. Oversight and regulatory mechanisms should adopt an analogous approach, so that the United States is involved in regular discussions with other national and transnational organizations so they may seek coordination and consistency when possible.

Recommendation 8: International Coordination and Dialogue

Recognizing that international coordination is essential for safety and security, the government should act to ensure ongoing dialogue about emerging technologies such as synthetic biology. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President, through the Department of State and other relevant agencies such as the Department of Health and Human Services and the Department of Homeland Security, should continue and expand efforts to collaborate with international governments, the World Health Organization, and other appropriate parties, including international bioethics organizations, to promote ongoing dialogue about emerging technologies such as synthetic biology as the field progresses.

Responsible conduct of synthetic biology research, like all areas of biological research, rests heavily on the behavior of individual scientists. Creating a culture of responsibility in the synthetic biology community could do more to promote responsible stewardship in synthetic biology than any other single strategy. There are actors in the world of synthetic biology, namely engineers, chemists, materials scientists, computer modelers, and others, who practice outside of conventional biological or medical research settings. These groups may not be familiar with the standards for ethics and responsible stewardship that are commonplace for those working in biomedical research. This poses a new challenge regarding the need to educate and inform synthetic biologists in all communities about their responsibilities and obligations, particularly with regard to biosafety and biosecurity.

Recommendation 9: Ethics Education

Because synthetic biology and related research cross traditional disciplinary boundaries, ethics education similar or superior to the training required today in the medical and clinical research communities should be developed and required for all researchers and student-investigators outside the medical setting, including in engineering and materials science. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President, in consultation with the National Academy of Sciences, the National Academy of Engineering, the scientific community, and the public, should convene a panel to consider appropriate and meaningful training requirements and models. This review should be completed within 18 months and the results made public.

Additionally flowing from the principle of responsible stewardship, the Commission observed that careful and deliberate attention should be paid to discussions of potential moral objections as the field advances. Such moral objections include concerns that synthetic biology may conflict with essential conceptions of human agency and life; that its overall impact may be harmful to biodiversity, ecosystems, or food and energy supplies; and that it may fail to respect the proper relationship between humans and nature. The Commission devoted particular time and attention to discussing these possible moral objections during its deliberations. It heard relatively few objections from reli-

gious or secular ethicists concerning the present status of the field. Although the field currently is capable of significant but limited technical achievements, potential developments might raise further moral objections—for example, applications relying on the synthesis of genomes for higher order or complex species. Current objections to synthetic biology on moral grounds are often based on concerns regarding activities that the field is currently incapable of carrying out. However, continued evaluation and efforts to reach and maintain consensus will be needed as this field develops.

Recommendation 10: Ongoing Evaluation of Objections

Discussions of moral objections to synthetic biology should be revisited periodically as research in the field advances in novel directions. Reassessment of concerns regarding the implications of synthetic biology for humans, other species, nature, and the environment should track the ongoing development of the field. An iterative, deliberative process, as described in Recommendation 14, allows for the careful consideration of moral objections to synthetic biology, particularly if fundamental changes occur in the capabilities of this science and its applications.

Promoting Intellectual Freedom and Responsibility

The principle of intellectual freedom and responsibility asserts that restrictions on research, whether by self-regulation by scientists or by government intervention, should limit the free pursuit of knowledge only when the perceived risk is too great to proceed without limit. A moratorium at this time on synthetic biology research would inappropriately limit intellectual freedom. Instead, the scientific community—in academia, government and the private sector—should continue to work together to evaluate and respond to known and potential risks of synthetic biology as this science evolves. This effort may require the government to expand current oversight or engagement activities with non-institutional researchers. National Institutes of Health or the Department of Energy, for example, could be charged to sponsor education programs and workshops that bring together these groups. They could fund training grants or related programs to promote a culture of responsibility among this community. To exercise the appropriate level of oversight, the government will need to monitor the growth and capacity of researchers outside of institutional settings.

Recommendation 11: Fostering Responsibility and Accountability

The government should support a continued culture of individual and corporate responsibility and self-regulation by the research community, including institutional monitoring, enhanced watchfulness, and application of the *National Institutes of Health Guidelines for Recombinant DNA Research*. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President should evaluate, and re-evaluate periodically, the effectiveness of current research oversight mechanisms and determine what, if any, additional steps should be taken to foster accountability at the institutional level without unduly limiting intellectual freedom. Academic and private institutions, the public, the National Institutes of Health, and other federal funders of synthetic biology research should be engaged in this process. An initial assessment should be completed within 18 months and the results made public.

The norms of safe and responsible conduct that have evolved over time for many researchers in institutional settings may not be understood or followed by those new to the field or outside of these settings. It is important to note that presently there appears to be no serious risk of completely novel organisms being constructed in non-institutional settings including in the DIY community. Scrutiny is required to ensure that DIY scientists have an adequate understanding of necessary constraints to protect public safety and security, but at present the Commission sees no need to impose unique limits on this group.

Recommendation 12: Periodic Assessment of Security and Safety Risks

Risks to security and safety can vary depending on the setting in which research occurs. Activities in institutional settings, may, though certainly do not always, pose lower risks than those in non-institutional settings. At this time, the risks posed by synthetic biology activities in both settings appear to be appropriately managed. As the field progresses, however, the government should continue to assess specific security and safety risks of synthetic biology research activities in both institutional and non-institutional settings including, but not limited to, the "do-it-yourself" community. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President, working with the Department of Homeland Security, the

Federal Bureau of Investigation and others, should undertake and periodically update this assessment. An initial review should be completed within 18 months and the results made public to the extent permitted by law.

Certain risks—generally involving national security—often warrant additional protections. Completely free exchange of data and materials might endanger public safety, but unilateral action to limit exchange could damage American research efforts in synthetic biology if U.S. scientists and students are excluded from full collaboration with the international community. Several recent advisory groups have recommended ongoing discussions among research universities, industry, and government on this topic. The Commission agrees that scientists should be actively engaged in these debates.

Recommendation 13: Oversight Controls

If the reviews called for in Recommendation 12 identify significant unmanaged security or safety concerns, the government should consider making compliance with certain oversight or reporting measures mandatory for all researchers, including those in both institutional and non-institutional settings, regardless of funding sources. It may also consider revising the Department of Commerce's export controls. Any such change should be undertaken only after consultation with the scientific, academic, and research communities and relevant science and regulatory agencies such as the National Institutes of Health, the Department of Homeland Security, and the Environmental Protection Agency. Export controls should not unduly restrain the free exchange of information and materials among members of the international scientific community.

Promoting Democratic Deliberation

Through democratic deliberation, questions about synthetic biology can be explored and evaluated on an ongoing basis in a manner that welcomes the respectful exchange of opposing views. This principle yields several opportunities for government and non-government actors alike to work together to ensure that synthetic biology advances in ways that respect divergent views and that avoid some of the misunderstanding and confusion, which at times,

have hampered other scientific endeavors. To enhance democratic deliberation and thereby ensure that the progress in synthetic biology is widely understood and policy choices are thoughtfully considered, the Commission makes the following recommendations.

Recommendation 14: Scientific, Religious, and Civic Engagement

Scientists, policy makers, and religious, secular, and civil society groups are encouraged to maintain an ongoing exchange regarding their views on synthetic biology and related emerging technologies, sharing their perspectives with the public and with policy makers. Scientists and policy makers in turn should respectfully take into account all perspectives relevant to synthetic biology.

Recommendation 15: Information Accuracy

When discussing synthetic biology, individuals and deliberative forums should strive to employ clear and accurate language. The use of sensationalist buzzwords and phrases such as "creating life" or "playing God" may initially increase attention to the underlying science and its implications for society, but ultimately such words impede ongoing understanding of both the scientific and ethical issues at the core of public debates on these topics. To further promote public education and discourse, a mechanism should be created, ideally overseen by a private organization, to fact-check the variety of claims relevant to advances in synthetic biology.

This publicly accessible fact-check mechanism is among the most concrete ways by which public perception and acceptance of emerging technologies could be improved. Education also plays a key role in building public support for otherwise unfamiliar technologies. In light of our Nation's dependence on socially responsible scientific innovation for economic progress and individual well-being, the urgency of expanding effective science and ethics education cannot be exaggerated. Dialogue among individuals and public, private, and community groups demonstrates that science and its oversight do not belong exclusively to experts, highly trained professionals, or government officials. Science is a shared resource, affecting and belonging to all citizens.

Recommendation 16: Public Education

Educational activities related to synthetic biology should be expanded and directed to diverse populations of students at all levels, civil society organizations, communities, and other groups. These activities are most effective when encouraged and supported by various sources, not only government, but also private foundations and grassroots scientific and civic organizations. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President, with input from the scientific community, the public, and relevant private organizations, should identify and widely disseminate strategies to promote overall scientific and ethical literacy, particularly as related to synthetic biology, among all age groups.

Promoting Justice and Fairness

The principle of justice and fairness, at this very early stage of synthetic biology, yields two general recommendations that can be applied to both this technology and other emerging technologies. It directs those in government to consider rules for distribution of risks and benefits in research, and it directs those both in and outside of government to consider processes for just distribution of benefits and risks.

Recommendation 17: Risks in Research

Risks in research should not be unfairly or unnecessarily borne by certain individuals, subgroups, or populations. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President should lead an interagency evaluation of current requirements and alternative models to identify mechanisms that ensure that the risks of research in synthetic biology, including for human subjects and other affected parties, are not unfairly or unnecessarily distributed. Relevant scientific, academic, and research communities, including those in the private sector, should be consulted. This review should be completed within 18 months and the results made public.

Recommendation 18: Risks and Benefits in Commercial Production and Distribution

Risks to communities and the environment should not be unfairly distributed. Manufacturers and others seeking to use synthetic biology for commercial activities should ensure that risks and potential benefits to communities and the environment are assessed and managed so that the most serious risks, including long-term impacts, are not unfairly or unnecessarily borne by certain individuals, subgroups, or populations. These efforts should also aim to ensure that the important advances that may result from this research reach those individuals and populations who could most benefit from them. As part of the coordinated approach urged in Recommendation 4, the Executive Office of the President should evaluate current statutory mandates or regulatory requirements for distribution of risks and benefits and consider developing guidance materials and voluntary recommendations to assist manufacturers as appropriate.

In summary, the ability to easily manufacture and manipulate DNA in the laboratory has enhanced scientists' productivity and opened new directions for scientific exploration. In the future, scientists may be able to create entirely new organisms and systems previously unknown in the world today. But breakthroughs such as this raise a host of complex and sometimes controversial issues. They can help humanity in many ways, but they invariably carry some risks and often raise public concerns and fears. With these unprecedented achievements comes an obligation to consider carefully both the promise and potential perils that they could realize.

The recommendations detailed in this report provide a publicly accountable basis for ensuring that the field of synthetic biology advances to improve human health and public welfare with processes in place to identify, assess, monitor, and mitigate risks on an ongoing basis as the field matures. Risk assessment should precede field release of the products of synthetic biology. Ongoing assessment and review is required in several areas to avoid unnecessary limits on science and social progress, and to ensure appropriate restrictions to protect individual safety and our shared environment. Ongoing dialogue about concerns regarding the implications of synthetic biology for

humans, other species, nature, and the environment should continue as synthetic biology develops from its infancy to a fully mature field of scientific inquiry and innovation.