

December 16, 2010

Dr. Amy Gutmann
Chair, Presidential Commission for the Study of Bioethical Issues
1425 New York Avenue, NW, Suite C-100
Washington, DC 20005

Cc: *Dr. Steven Chu, Secretary, Department of Energy*
Kathleen Sebelius, Secretary, Department of Health and Human Services
Dr. Francis Collins, Director, National Institutes of Health
Janet Napolitano, Secretary, Department of Homeland Security
Tom Vilsack, Secretary, Department of Agriculture
Lisa Jackson, Administrator, Environmental Protection Agency
Dr. Margaret Hamburg, Commissioner, Food & Drug Administration
Dr. Thomas R. Frieden, Director, Centers for Disease Control and Prevention
Robert Mueller, Director, Federal Bureau of Investigation
Dr. John Holdren, Director, White House Office of Science and Technology Policy
Nancy Sutley, Chair, Council on Environmental Quality

Dear Dr. Gutmann,

Thank you for this opportunity to comment on the Commission's recommendations on synthetic biology. We applaud the transparency and openness of the Commission's deliberations. Unfortunately this process has not resulted in recommendations that recognize the serious threats synthetic biology pose to the environment, workers' health, public health, and social justice.

The undersigned 58 organizations from 22 countries do not support the Commission's recommendations on synthetic biology. They are an inadequate response to the risks posed by synthetic biology because they: 1) **ignore the precautionary principle**, 2) **lack adequate concern for the environmental risks of synthetic biology**, 3) **rely on the use of "suicide genes" and other technologies that provide no guarantee of environmental safety**, and 4) **rely on "self regulation," which means no real regulation or oversight of synthetic biology.**

A precautionary regulatory framework is necessary to prevent the worst potential harms. This requires a ***moratorium on the release and commercial use of synthetic organisms until a thorough study of all the environmental and socio-economic impacts of this emerging technology has taken place.*** This moratorium should remain in place until extensive public participation and democratic deliberation have occurred on the use and oversight of this technology. This deliberative process must actively involve voices from other countries - particularly those in the global South - since synthetic biology will have global impacts and implications.

The Precautionary Principle Should Guide Synthetic Biology Regulations

The Commission's recommendations fail to implement the precautionary principle, and instead referenced the so-called "prudent vigilance" concept. The precautionary principle is recognized by

international treaties including the United Nations Convention on Biological Diversity, the Cartagena Biosafety Protocol, the new Nagoya/Kuala Lumpur SubProtocol on Liability and Redress for Damages Due to the Transboundary Movement of Transgenics, and the UN Framework Convention on Climate Change. Although "prudent vigilance" is used as a guiding principle by the Commission in its recommendations, it is a completely new concept, apparently invented by the Commission without legal or policy precedent. When dealing with novel synthetic organisms that pose serious risks to the environment and public health, we cannot rely on a new concept with no agreed upon definition, framework, or precedent.

The precautionary principle often is mischaracterized as anti-science, anti-technology, or anti-progress. This is far from the truth. The precautionary principle, as outlined by the Wingspread Consensus Statement on the Precautionary Principle, states: *"When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action."*ⁱ

Precaution does not derail progress; rather, it affords us the time we need to ensure we progress in socially, economically, and environmentally just ways. In the face of uncertainty and the potential for serious harm, synthetic biology will often require risk analysis. We do not yet know what the full environmental or socio-economic risks of synthetic biology are, nor has our regulatory system evolved to keep up with the science. That is why we need a precautionary approach.

Precedent exists within the executive branch to support the use of precaution. The President's Cancer Panel released a report in April 2010 on reducing environmental cancer risks, recommending that:

*"A precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action is taken to reduce or eliminate exposure. Though not applicable in every instance, this approach should be the cornerstone of a new national cancer prevention strategy that emphasizes primary prevention, redirects accordingly both research and policy agendas, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation..."*ⁱⁱ

This should be a guiding precept for the Presidential Commission for the Study of Bioethical Issues.

In October 2010 at the United Nations Convention on Biological Diversity (CBD), 193 nations unanimously agreed to apply the precautionary principle to the introduction and use of synthetic organisms. The CBD also recognized this technology to be a potential environmental threat in need of further review -- particularly as it is applied to biofuels production.ⁱⁱⁱ This was the first time the United Nations addressed the issue of synthetic biology; ignoring this important decision would be negligent.

Lack of Environmental Risk Assessment

The Commission's lack of attention to ecological harms posed by synthetic biology is irresponsible and dangerous. The only ecologist to speak to the Commission, Dr. Allison Snow, raised serious concerns about the environmental risks of synthetic biology -- but none of these concerns are reflected in the recommendations.

In her testimony, Dr. Snow presented four cautionary precepts to keep in mind about the ecological risks of synthetic biology and novel genetically engineered organisms (GEO):

- 1) *“We need to be very careful whenever novel, self-replicating organisms are let loose in the environment (intentionally or by accident). Many will do no harm out in the environment, but important exceptions could occur, especially if the GEO can multiply and become more abundant.*
- 2) *Novel GEOs that seem innocuous or weak might evolve to become more successful when they start reproducing. Even if they are highly domesticated, mutations or unexpected properties might allow them to multiply in some environments.*
- 3) *Once these organisms are released into the environment, novel GEOs cannot be taken back.*
- 4) *Predicting which new organisms might cause irreversible harm can be extremely challenging. . . we have little or no experience with cultivating microalgae and bacteria outdoors, let alone new life forms that are entirely synthetic.”^{iv}*

These points are mostly ignored in the guidelines.

The potential environmental impacts of the commercial use of organisms with synthetic DNA must also be examined. Many commercial applications of synthetic biology will undoubtedly lead to the environmental release of synthetic organisms - since it is impossible to prevent organisms from escaping from unsecured operations conducting activities described by some synthetic biology proponents as “akin to brewing beer.”^v More study also is needed on the risks of introducing synthetic organisms into the human body for biomedical and health-related applications, as well as on the risks posed by uses of synthetic organisms in agriculture. Since this technology is already being used to replicate pathogens, serious study of biosecurity risks is also necessary.

Even more troubling is the impact that synthetic biology could have on ecosystems and communities in the global South. A new “bioeconomy,” in which any type of biomass can be used as feedstock for tailored synthetic microbes, is being enabled by synthetic biology. Biomass to feed synthetic microbes will be grown mostly in the global South, disrupting fragile ecosystems and exacerbating environmental damage from industrial crop production. Further pressure will be placed on land and water, which already are in short supply for food production, to produce fuels and chemicals that will be consumed mainly by wealthier nations. The Commission ignores these socio-economic and environmental harms despite the fact that already countries such as Brazil have felt their effects.

Unfounded Reliance on “Suicide Genes”

Despite the fact that “suicide genes” were explicitly described as having uncertain efficacy in Dr. Snow’s testimony, the Commission relies solely on these and other types of self-destruction modalities as the main form of mitigating potential environmental harm. In fact, one of the main studies cited by the Commission in support of using methods to create “suicide genes” is still in an early development stage and has not been field tested.

Scientists who have studied “terminator technologies” in seeds have concluded that the process is never completely effective. They found that frequently occurring mutations allow organisms to overcome the intended sterilization thereby allowing those organisms to remain viable. Specifically, “suicide genes” and other genetic use restriction technologies (GURTs) represent an evolutionary disadvantage; selective pressures will lead organisms to overcome intended biological constraints.^{vi} Biological

containment of synthetic organisms – which reproduce quickly, escape confinement, and cannot be recalled – is impossible.

Importantly, the UN Convention on Biological Diversity has mandated an international moratorium on the use of “terminator technologies” such as “suicide genes,” and other GURTS that has been in place for the past decade. Reliance on an unproven technology that has been deemed unacceptable by 193 nations as the main method to “contain” synthetic organisms is irresponsible.

Reliance on a technology that will not guarantee biosafety or biosecurity and that has been prohibited by the international community is not a solution. Synthetic biology requires the strictest levels of physical, biological, and geographic containment as well as independent environmental risk assessment for each proposed activity or product.

Self-Regulation Amounts to No Regulation and Undercuts the Rights of Workers and the Public

Self-regulation cannot be a substitute for real and accountable regulatory oversight. Some synthetic biologists already have made several unsuccessful attempts at self-regulation. The second annual synthetic biology conference in May 2006, SynBio 2.0, was portrayed by proponents as “Asilomar 2.0,” in reference to the 1975 meeting that proposed voluntary guidelines on recombinant DNA. At the 2006 meeting, synthetic biologists attempted to write a set of self-regulations intended to protect the environment and promote the field. This conference failed to produce serious results. Synthetic biologists were too concerned about promoting research and development to agree on even weak attempts at self-regulation.

The lack of open dialogue with concerned parties also contributed to the failure of the industry’s attempt at self-governance. Civil society and the public, blocked from participating in these discussions of self-governance, issued an open letter to the conference participants. Signed by 38 organizations working in 60 countries, this letter called on synthetic biologists to abandon their proposals for self-governance and to engage in an inclusive process of global debate on the implications of their work.^{vii}

The current state of “self-governance” permits students to create synthetic organisms on campuses; and stretches of synthetic DNA may be purchased online, allowing laypeople to create organisms in their garages where, with no oversight, life forms not previously found in nature may be dumped down drains and flow, freely, into the environment.

The J. Craig Venter Institute and the Massachusetts Institute of Technology also attempted to draft self-regulations the following year in their report, *Synthetic Genomics: Options for Governance*. This report was limited in scope to biosecurity and biosafety in laboratory settings, focused solely on the U.S., and, importantly, completely avoided the topic of environmental safety. These experiences reinforce the need for real oversight to ensure that the real threats synthetic biology poses are never actualized.

The support of the Presidential Commission for the Study of Bioethical Issues for self-regulation undercuts the fledgling efforts of the Occupational Safety and Health Administration (OSHA) to put new safety requirements in place to protect workers using biologically engineered materials, nanomaterials, and novel organisms. The Commission’s support for self-regulation undercuts the ability of workers to speak out and protect themselves. Becky McClain, a former Pfizer scientist, recently won the first lawsuit regarding a worker’s right to discuss publicly the health and safety issues of the genetic engineering laboratory.^{viii} The Commission’s failure to support lab scientists’ basic right to know which synthetic organisms they may have been exposed to means those workers could become ill without

being able to inform their doctors of the potential causes of their illness. There is nothing “ethical” about this kind of self-regulation.

Conclusion

The Commission’s recommendations fall short of what is necessary to protect the environment, workers’ health, public health, and the public’s right to know.

We repeat our call for a moratorium on the release and commercial use of synthetic organisms until we have a better understanding of the implications and hazards of this field and until we have properly updated and effectively implemented public regulation of synthetic biology.

The time for precaution and the regulation of synthetic biology is now.

Sincerely,

African Biodiversity Network (Kenya)

African Centre for Biosafety (South Africa)

Alliance for Humane Biotechnology

Amberwaves

Asociación para la Promoción y el Desarrollo de la Comunidad CEIBA / Friends of the Earth Guatemala

Associação para do Desenvolvimento da Agroecologia (Brazil)

Biofuelswatch

Center for Environmental Health

Center for Food Safety

Center for Genetics and Society

Centro Ecológico (Brazil)

COECOCEIBA-Friends of the Earth Costa Rica (Costa Rica)

Columban Center for Advocacy and Outreach

Columban (Missionaries) Justice, Peace, and Integrity of Creation Office (Australia)

Development Fund (Norway)

Ecumenical Ecojustice Network

Edmonds Institute

Environmental Rights Action/Friends of the Earth Nigeria

ETC Group (Canada)

Food & Water Watch

Friends of the Earth Australia

Friends of the Earth England Wales and Northern Ireland

Friends of the Earth Canada

Friends of the Earth Cyprus

Friends of the Earth Spain

Friends of the Earth Uganda

Friends of the Earth U.S.

GE Free New Zealand

Gene Ethics, Australia

GeneWatch UK

GLOBAL 2000/Friends of the Earth Austria

Groundwork/ Friends of the Earth South Africa

Human Genetics Alert (UK)
Institute for Agriculture and Trade Policy
Institute for Social Ecology
Institute for Sustainable Development (Ethiopia)
International Center for Technology Assessment
Loka Institute
Lok Sanjh Foundation (Pakistan)
MADGE Australia Inc.
Maudesco/ Friends of the Earth Mauritius
Movimiento Madre Tierra (Honduras)
National Association of Professional Environmentalists (Friends of the Earth Uganda)
National Toxics Network (Australia)
Natural Capital Institute
Natural Justice (South Africa)
Oregon Physicians for Social Responsibility
Our Bodies, Ourselves
PENGON (Friends of the Earth Palestine)
Pureharvest (Australia)
RAFI-USA
Research Foundation for Science, Technology and Ecology and Vandana Shiva (India)
Safe Alternatives for our Forest Environment (SAFE)
Say No To GMOs!
Sempreviva Organização Feminista (Brazil)
South Australia Genetic Food Information Network (SAGFIN)
TestBiotech (Germany)
Washington Biotechnology Action Council

ⁱ "The Wingspread Consensus Statement on the Precautionary Principle." Science & Environmental Health Network, 26 Jan. 1998. <<http://www.sehn.org/wing.html>>.

ⁱⁱ *Reducing Environmental Cancer Risk: What We Can Do Now*. President's Cancer Panel, Apr. 2010. <http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf>

ⁱⁱⁱ "COP 10 Outcomes." *United Nations Convention on Biological Diversity*. 2 Nov. 2010. <<http://www.cbd.int/nagoya/outcomes/>>.

^{iv} Snow, Allison A. "Transcript: Benefits and Risks of Synthetic Biology." *The Presidential Commission for the Study of Bioethical Issues*. 8 July 2010. Web. <<http://www.bioethics.gov/transcripts/synthetic-biology/070810/benefits-and-risks-of-synthetic-biology.html>>.

^v Keasling, Jay. Amyris Biotechnologies. Testimony to the House Committee on Energy and Commerce hearing on Developments in Synthetic Genomics and Implications for Health and Security. May 27, 2010. <<http://energycommerce.house.gov/documents/20100527/Keasling.Testimony.05.27.2010.pdf>>

^{vi} Steinbrecher, Ricarda A. *V-GURTs (Terminator) as a Biological Containment Tool?* Rep. EcoNexus, June 2005. <http://www.econexus.info/sites/econexus/files/ENx_V-GURTs_brief_2005.pdf>.

^{vii} ETC Group. *Global Coalition Sounds the Alarm on Synthetic Biology, Demands Oversight and Societal Debate*. 19 May 2006. <http://www.etcgroup.org/upload/publication/8/01/nr_synthetic_bio_19th_may_2006.pdf>.

^{viii} Pollack, Andrew and Duff Wilson, "Pfizer Whistle Blower Awarded \$1.4 million," *New York Times*, 2 April 2010. <<http://www.nytimes.com/2010/04/03/business/03pfizer.html>>