Talking Points on Synthetic Biology

In response to Craig Venter's announcement that he created the first organism with a fully-synthetic genome the President Obama's Commission on Bioethical Issues will host its first meeting to review the emerging field of synthetic biology on July 8th & 9th 2010. While only a few critical voices of synthetic biology will be heard at the hearing, there is opportunity for the public to submit comments to the Commission. It is crucial that critics of synthetic biology - or "extreme genetic engineering" - make their voices heard. Below are talking points that can be used when writing comments. Please feel free to copy, paste, change, or edit anything from below to fit your own organization's needs.

Comments should be directed to the chair of the Commission, Ms. Amy Gutmann and e-mailed to the Acting Executive Director Diane M. Gianelli at Diane.Gianelli@bioethics.gov, who will collate and present all comments. **Public comments are due by August 1, 2010.**

Genetic Contamination

- As we've seen with genetic genetically engineered crops, genetic contamination is a serious threat to our environment and biodiversity. Unlike other forms of pollution, genetic pollution cannot be cleaned up and will transfer down through generations indefinitely.
- Synthetic DNA can be passed down to naturally occurring organisms – forever contaminating entire species with DNA sequences designed on a computer and with unknown environmental risks.
- As the Supreme Court recently agreed (see: Monsanto Co. v Geertson Seed Farms), genetic contamination is a sufficient cause of environmental and economic harm.
- Synthetic biology threatens the world's biodiversity through the contamination of genomes that have evolved over billions of years with synthetic DNA. Once it has contaminated a species, this synthetic DNA cannot be recalled and will pass on indefinitely through generations.

Unknown Risks

- We cannot successfully predict the risks associated with synthetic biology and the task will only become more difficult, if not impossible, as the technology evolves and becomes more complex.
- We can guess what risks genetically engineered crops can pose since they have genes that have existed in nature and were transferred to a new plant.

- We cannot predict what dangers to the environment and public health are created when we are working with synthetic DNA that has never existed in nature before, was designed on a computer, and has not undergone any evolutionary pressures.

Unable to Contain

- The last U.S. government assessment of biological containment was conducted in 2005 and barely addressed the containment of bacteria and other microbes. We do not have the technology or infrastructure to guarantee that these organisms will not escape into the environment.
- Algae with synthetic DNA are currently being grown in open ponds to produced biofuels. There is no way to prevent algae from open ponds from escaping into the local environment or waterways.
- Some applications of synthetic biology would involve the intentional release of synthetic organisms into the environment – such as using synthetic microbes to eat oil from oil spills. There is no way to prevent these organisms from spreading once released intentionally or unintentionally.

Socioeconomic Impacts

- We must look at the economic and social effects synthetic biology as well as the environmental threats.
- Amyris Biotechnologies has created synthetic organisms that produce a precursor to artemisinin, a potent anti-malarial drug. While the ability to produce affordable anti-malarial medicine in large quantities is important, we must analyze any "externalities." For example, tens of thousands of farmers in Africa and Asia are growing sweet wormwood that naturally produces artemisinin and have made serious investments into this crop's production. Amyris' synthetic organisms will likely cause these farmers to lose their livelihood and push them further into poverty. If we want to end malaria we must end poverty – not create more poverty to the benefit of a California based corporation. While it is not being argued that an affordable and reliable source of medicine should be abandoned, it is crucial that these other factors be taken into account when reviewing the benefits and risks of this emerging technology. If we are perpetuating a major cause of malaria – poverty – are we really solving the problem?
- Amyris Biotechnologies is also planning on using its synthetic yeast to break down sugarcane in Brazil to produce biofuels. Industrial sugarcane production in Brazil is already a serious problem that is leading to mass deforestation in the Cerrado, soil degradation, air pollution, and water contamination, among other problems. People are also being displaced who live in and depend on the Cerrado to survive.

- Only 4% ($15.9 million) of the $430 million the U.S. government has spent on synthetic biology research has gone to examine the ethical, legal, and social implications of synthetic biology. If this research moves forward, this amount should be increased significantly.

Biosecurity

- The poliovirus and the 1918 Spanish Influenza have already been recreated using only mail-order DNA from a DNA synthesis company. These viruses were proven to be deadly in lab rats.
- The only regulation in the U.S. around synthetic biology is the voluntary screening on DNA synthesis orders to identify potential bad actors that can create dangerous select agents. This program is voluntary and does not prevent people from using DNA synthesis machines on their own that can be purchased on the internet.
- There is a growing movement called Do-it-Yourself Biology (DIY-Bio) that opens up the field of biology to laypeople all across the country. While DIY-Bio does not always use synthetic biology processes, it often does. This means people are able to create organisms with synthetic DNA in their basements with minimal financing or know-how. There are no mechanisms in place to prevent someone from intentionally creating a deadly virus or pathogen – or more likely creating an organism in good faith that escapes from their "lab" and can pose an unknown but real risk to the environment and public health.

Ownership of Life & Intellectual Property

- Genetic engineering and intellectual property laws have allowed biotechnology corporations to privatize life at all levels. Over 90% of our country's soy and 84% of the corn is owned by Monsanto through its ownership if gene patents.
- Thousands of plants and animals are owned through patents, as is 20% of the human genome.
- Synthetic biology will open up the door to the private ownership of all life forms – those that exist naturally and can be engineered with synthetic DNA or organisms that have never existed but will be created with synthetic DNA.
- Craig Venter has already applied for patents on his synthetic organisms and on DNA that he has found out in nature in bacteria.
- While many synthetic biologists believe the field should be "open-source" where synthetic DNA and synthetic pathways are available to everyone and are left in the commons, this has not stopped the rush to patent any and all DNA segments that are found in nature or synthesized on a computer.

- All genes and DNA sequences, whether naturally occurring or synthetic, should be outside the realm of patentable material. If one owns the genes, they own the organism. If they own the organisms, they can own a species.
- Since 2005, the U.S. government has spent approximately $430 million of taxpayer money on synthetic biology research. Corporations and researchers should not be allowed to patent their findings or products that were funded with public money.

Agriculture

- Genetic engineered seeds have been used in agriculture for the past few decades to the benefit of a few agriculture corporations and at the expense of the environment (genetic contamination, significant increases in pesticide use) and public health (unknown health effects since GE foods are not labeled or tested, yet much research shows that there is serious reasons to be concerned). These threats are only exacerbated when we start using "extreme genetic engineering" with synthetic DNA in our crops for food and fuel.
- Researchers are already using synthetic biology in hopes to create corn that fixes its own nitrogen from the atmosphere.
- We cannot contain GE traits from contaminating conventional or organic crops and we should prevent the planting and sale of plants with synthetic DNA.

Needed Regulations/Precautionary Principle

- Since there is no way to know the risks of each synthetic organism, we must move forward with precaution.
- It is the role of the government to protect its people and environment – not promote untested and unproven technologies that will benefit a few corporations and place profit before people.
- The President should implement a moratorium on the release of synthetic organisms into the environment and also their use in commercial settings. This moratorium should remain in place until there is an adequate scientific basis on which to justify such activities, and until due consideration of the associated risks for the environment, biodiversity, and human health, and all associated socio-economic repercussions, are fully and transparently considered.
- As an immediate step, all federally funded synthetic biology research should be subject to a comprehensive environmental and societal impact review carried out with input from civil society, also considering indirect impacts on biodiversity of moving synthetic organisms into commercial use for fuel, chemicals and medicines. This should include the projects that received $305 million from the Department of Energy in 2009 alone.

- All government funded synthetic biology projects must be reviewed by the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health. Since each synthetic organism can pose its own unique risks and challenges all projects, regardless of the length of the nucleotide sequence, should be reviewed and approved by the RAC before moving forward.
- The Toxic Substances Control Act (TSCA) needs to be amended to define any chemical products derived from synthetic biology or any synthetic organism as new toxic substance. This would ensure that all products derived from synthetic biology are included in the TSCA inventory and those manufacturers, importers, and processors are responsible for testing the safety of new synthetic biology-based chemical substances.
- Commercial DNA synthesis companies should be required by Health and Human Services (HHS) to screen all orders to verify that all buyers are associated with recognized research institutions, and that the ordered DNA cannot be used to create select agents such as biological weapons or known viruses. All synthetic DNA orders should be stored in a database to ensure synthetic DNA can be traced back to the buyer and seller at any time.
- All those using DNA synthesis machines, for both commercial and non-commercial use, must be registered with HHS.
- Those who are using synthetic DNA, for both commercial and non-commercial use, must be licensed by HHS. This should be applied even to those conducting DIY (do-it-yourself) biology experiments. If licensing and registration can be required for one to become a tattoo artists or hairdresser, it is far from unreasonable to require those creating synthetic organisms (possibly in their basement) to require basic education, training, and licensing.
- The U.S. Government should support the proposed international moratorium on the release of synthetic organism into the environment at the next Conventional on Biological Diversity of the United Nations. This moratorium would be in place until **"**there is an adequate scientific basis on which to justify such activities and due consideration of the associated risks for the environment and biodiversity, and the associated socio-economic risks, are considered." This language was proposed in May 2010 at the CBD meeting in Nairobi and waits final censuses by all parties at the October 2010 meeting in Japan.