Stanford | CISAC Center for International Security and Cooperation

FSI Freeman Spogli Institute for International Studies

November 13, 2015

From: Megan J. Palmer, Ph.D.
Senior Research Scholar; William J. Perry Fellows in International Security
Center for International Security and Cooperation (CISAC), Stanford University
Encina Hall, 616, Serra Street, Room C238, Stanford, CA, 94305
Office: 650.725.8929 Mobile: 617.894.4447 Email: mjpalmer@stanford.edu

To: National Science and Technology Council
Emerging Technologies and Interagency Policy Coordination Committee
Office of Science and Technology Policy
1650 Pennsylvania Avenue N.W., Washington, CA, 20504

Re: Docket No. FDA-2015-N-3403, Request for Information: Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology (ID: OSTP-2015-0011-0001)

Dear Office of Science and Technology Policy,

Thank you for the opportunity to provide information on *Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology*. The comments expressed here are my own. They primarily concern the general framing of this effort but contain suggestions and potential case studies to help address the specific questions posed. I appreciate the chance to share my thoughts with the Government, and welcome further involvement.

My response is informed by 12 years working in biotechnology research. This includes completing a Bioengineering PhD at the Massachusetts Institute of Technology (MIT), a postdoctoral fellowship at Stanford University, and, for the last five years, co-directing the policy-related research portfolio and activities of the Synthetic Biology Engineering Research Center (Synberc; synberc.org). Synberc was established by a National Science Foundation (NSF) grant in 2006 to lay the foundation for synthetic biology. It is composed of leading researchers from University of California (UC) Berkeley, UC San Francisco, Stanford, Harvard, and MIT, and affiliate investigators comprising from more than 30 labs across the United States, in partnership with more than 30 Industry Partners ranging from start-ups to multi-national corporations.

I also founded in 2011, and now serve as Executive Director of, the Synthetic Biology Leadership Excellence Accelerator Program (LEAP; synbioleap.org). LEAP is an international fellowship program in responsible biotechnology development that brings together next generation leaders and mentors from across academia, industry, policy and amateur communities. I also lead policy, safety and security programs within the international Genetically Engineered Machines (iGEM; igem.org) competition and have advised the synthetic biology programs at the Department of Energy Joint Genomics Institute (JGI, jgi.doe.gov), the Alfred P. Sloan Foundation and NASA. I am now a Senior Research Scholar at Stanford University, leading efforts focused on the governance of biotechnology and other emerging technologies.

Thank you for taking this important step in revisiting our regulatory framework to ensure the development of biotechnology in the public interest.

Biotechnology is becoming increasingly important to our national and international prosperity and security (see The US Bioeconomy Blueprint). As the scale, complexity and importance of biological technology increases it is essential that we improve the infrastructure and institutions that enable everyone to better understand biotechnology: its benefits and its risks, and its policies and its practices. Through conducting and managing programs on biotechnology policy-related topics, I have experienced first-hand the frustration of practitioners and regulators alike trying to navigate and evolve our current regulatory system. Rapid advances since the last review of the coordinated framework are revealing considerable uncertainties and ambiguities in our systems of governance.

I want to highlight three general points that I urge OSTP, FDA, USDA and EPA to consider as they review the current framework and assess potential improvements.

First, it is critical to promote transparency and access to both the process and the evidence base on which we assess the efficacy and safety of new biotechnology products. This is not a simple task, but publicly accessible, comprehensible and searchable information on regulatory frameworks, processes and precedents is essential to ensuring accountability and resolving emerging problems more efficiently over time. Transparency requires investment in platforms that leverage the way we communicate today (i.e. using easily searchable digital repositories across agencies), incentives instruments through which to collect data in the performance of our regulatory systems (e.g. requirements for structured reporting), and standards for information sharing and harmonization of protocols across agencies (e.g. comparing ontologies used between agencies). Moreover, it may require reassessing and limiting what is considered sensitive business information.

Second, it is critical to build more easily accessible and scalable communication interfaces between practitioners and regulators. This is especially important for small business and new investors who have little experience in and resources to explore the regulatory landscape. Moreover, encouraging a diversity of new applications with ambiguous precedents or jurisdictions (e.g. transgenic mosquitos, probiotics) will require increased interactions between practitioners and regulators at the early stages of research and development. Lowering the bar to getting advice could take the form of a digital hot-line (such as the DIYbio.org 'ask a biosafety officer' portal and iGEM's safety and security and policy committee emails). Capturing FAQs in a publicly accessible format, connected between agencies, may help to relieve some burden over time.

Third, the regulation of emerging biotechnologies should be treated as a sustaining challenge that requires ongoing research and engagement. To meet this challenge we need new programs and people willing and able to identify, articulate and work on immediate and long-term challenges. We must experiment with mechanisms that incentivize and empower the best minds developing these new technologies to also care about regulation. I urge OSTP to

consider building research programs that create partnerships between agencies, industry and academia. We have piloted such efforts within iGEM, Syberc and LEAP, in partnership with institutions such as the Woodrow Wilson Center, which embed research programs in policies and practices alongside science and technology. These efforts may be useful case studies in terms of their format, the organizations involved, and the products and processes developed within them, many which are now coming to market. Continued public support for such integrated policy and regulatory science research and practice programs will be critical.

Lastly, I recognize that such improvements are not cheap and are they are not easy. **The US government must ensure that the people and organizations facing these challenges are resourced to meet an increasing number, diversity and sophistication of products.** In particular, regulatory agencies must be properly resourced to manage their current portfolio, coordinate, and pursue joint research programs aimed at anticipating new challenges and adapting. This will require the capacity to acquire and develop new talent.

Thank you again for the opportunity to comment and for your continued commitment to ensuring biotechnology is developed in the public interest.

Best,
Megan J. Palmer, Ph.D.