Testimony
Before the Committee on Commerce, Science, and Transportation
Subcommittee on Science, Oceans, Fisheries, and Weather
Of the U.S. Senate
On Securing U.S. Leadership in the Bioeconomy
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Chairman Gardner, Ranking Member Baldwin, Senate Subcommittee members and staff, thank you for the opportunity to share with you today my thoughts on steering the trajectory of the bioeconomy to reflect U.S. values and public interests.

My Ph.D. is in biological engineering from M.I.T., but I have spent the last decade focused on governance issues coupled to the science and engineering of living systems. I am now a Senior Research Scholar at the Center for International Security and Cooperation (CISAC), part of the Freeman Spogli Institute for International Studies (FSI), at Stanford University. My group studies how we contend with the responsible development of biotechnology, including issues of safety and security. I also lead a number of domestic and international programs in responsible biotechnology leadership and strategy.

You will have heard from the other witnesses about the enormous potential of the bioeconomy. We must nourish this potential to ensure a future that supports rather than undermines U.S. security and values. The stakes are high and time is short to make the strategic decisions needed to steer towards a bioeconomy that makes the U.S. more secure and avoid the futures that make the U.S. more vulnerable.

What is the bioeconomy future we want to secure? It is a future where we develop the foundational science of the living world. It is a future where diverse products made with biotechnology help us to feed, fuel, and heal this nation, and the world, in ways that are safer, more sustainable and more secure. It is a future with communities of diverse innovators developing possibilities and products with biotechnology and with a citizenry that participates in, benefits from, and is empowered to make wise choices about technologies that interact with their bodies, their data and our shared environments. It is a future where biological threats - from emerging diseases to biological weapons - might be rendered obsolete because we can prevent, rapidly detect, diffuse, and deter them.

There are many ways to be vulnerable; what are the futures we must avoid? We must avoid a future where other nations attract away talent. Biological innovations will only become more important to the economy and security of nations. Without talented people driving innovations we become vulnerable to many threats, including remaining unprepared for the next emerging infectious disease. We are also vulnerable when we become too dependent on other nations for the things we need to sustain our societies when things get bad and borders may close, just as we are seeing during the current COVID-19 outbreak.

We must also avoid a future that undermines American values when development of biotechnologies can be used to suppress freedoms in the U.S. and abroad. The same data and technologies used to enable precision medicine can be used to track and target populations and minority

groups.[1] Other nations are already penetrating the security of our bioeconomy industries including firms that hold valuable health and genomic data. Other nations will use our data to develop innovations while we are made more vulnerable.[2] At the same time we must avoid a future in which we close down a rich science and innovation ecosystem that relies upon an open exchange of ideas that we all benefit from, where we can no longer access talented people all over the world and bring them and their ideas here to be developed.

We must also avoid a future where careless development of biotechnology causes threats to our health and to our environment. Biotechnology is profoundly valuable, but it can carry profound risks of accidents, reckless behavior, and deliberate misuse.[3,4] We must avoid a future where we fail to manage this dual use nature of biotechnology. Foremost, we must avoid a future where misinterpretation of our activities leads other nations to reconsider biotechnology's use as a weapon. This is a future none of us want.

What does the U.S. need to secure a desirable future and to ensure bioeconomy leadership? It needs at least three things.

First, the U.S needs *Tools & Infrastructur*e: The U.S. must position itself as a world leader in measuring and making with biology. It is essential to develop scalable and secure infrastructure to connect government, academia and industry to the information and materials needed to seed and support innovation and translation.

Second, the U.S. needs *Strategy & Coordination*. The U.S. needs people and programs squarely focused on figuring out *how* to develop biotechnologies in ways that can deliver benefits without compromising our security and our values. The U.S. will only get to do this if it builds the tools and infrastructure and bakes in these choices and values from the start. This is largely not current practice and it calls for policy innovation along with shifts in how technological innovation is incentivized and supported. For this work to be successful, it will be essential to closely coordinate across communities focused on science, security and the economy.

Third, the U.S needs *Community & Citizenship.* The U.S. must enable everyone to engage with this technology and its many uses to foster the best ideas and to make sure they are genuinely in the public interest. Everyone in the country should be trained to be literate in biotechnology and the U.S. should be building the diverse training programs needed to grow the interdisciplinary bioeconomy workforce of the future.

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[1] For example: Wee, Sui-lee. (2019, Feb. 21). China Uses DNA to Track Its People, With the Help of American Expertise. *The New York Times*. www.nytimes.com/2019/02/21/business/china-xinjiang-uighur-dna-thermo-fisher.html

[2] National Academies of Science, Engineering and Medicine. (2020). Safeguarding the Bioeconomy. (Report No. 25525). Retrieved from https://doi.org/10.17226/25525.

[3] Palmer, M. J. (2020). Learning to Deal with Dual Use. *Science.* DOI: 10.1126 Retrieved from https://science.sciencemag.org/content/early/2020/02/26/science.abb1466.

[4] Palmer, M. J., Fukuyama, F., & Relman, D. A. (2015). A more systematic approach to biological risk. *Science*, *350*(6267), 1471-1473.

Where is the U.S. now in securing leadership in the bioeconomy ? The U.S. is in a position of global leadership, having made foundational early investments in biotechnology research and development. However, continued leadership is by no means assured. Many other countries are prioritizing investments in biotechnology to support their own growing bioeconomies.

There have been promising recent steps to securing U.S. leadership in the future. Last October the U.S. Office of Science and Technology Policy (OSTP) convened the *White House Summit on America's Bioeconomy* that gathered leaders from across government, industry, academia and civil society to discuss the strategic importance of biotechnology.[5] In December, the U.S. House of Representatives passed H.R. 4373, *The Engineering Biology Research and Development Act of 2019*, which outlines some interagency coordination functions with important attention to economic, social, security and ethical aspects of the bioeconomy.[6] An additional bill under consideration by members of this chamber, S. 3191, *The Industries of the Future Act of 2020,* outlines similar coordination functions and calls for specific increases in federal investment in several technology areas, including biotechnology research, which could also help pave the road to the biotechnology future we want.[7] The 2018 U.S. *National Biodefense Strategy* also made important steps in acknowledging the need to adapt policies toward mitigating the complex risks associated with biological incidents.[8]

There have also been a number of recent studies from the U.S. National Academies of Science, Engineering and Medicine (NASEM) that outline challenges and opportunities in biotechnology and the bioeconomy. Notably, in January the NASEM released the *Safeguarding the Bioeconomy* report that emphasized a need to couple the promotion and protection of an emerging bioeconomy industry, and included a series of useful recommendations.[9] There has also been formation of interagency working groups on topics including synthetic biology, and we are seeing some new agency-specific strategic efforts, like the recent announcement of the Bioindustrial Manufacturing Innovation Institutes from the Department of Defense.[10]

These are important and necessary steps but I do not believe they will be sufficient to secure U.S. leadership in the future. These efforts will need to be supplemented with increased ambition, resources, and leadership to form a successful strategy for future biotechnology leadership in a rapidly changing world.

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[5] Summary of the 2019 White House Summit on America's Bioeconomy. 7 Oct. 2019, www.whitehouse.gov/wp-content/uploads/2019/10/Summary-of-White-House-Summit-on-Americas-Bioeconomy-October-2019.pdf.

[6] Engineering Biology Research and Development Act of 2019, H.R. 4373, 116th Cong. (2019)

[7] Industries of the Future Act of 2020, S. 3191, 116th Cong. (2020)

[8] *National Biodefense Strategy* (2018). Retrieved from https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf

[9] National Academies of Science, Engineering and Medicine. (2020). Safeguarding the Bioeconomy. (Report No. 25525). Retrieved from https://doi.org/10.17226/25525.

[10] Bioindustrial Manufacturing Innovation Institute (MII). (2020, January 24). Retrieved from https://beta.sam.gov/opp/bc5905578334429a8a29c0150eb94b45/view.

What specifically could be done to secure future U.S. leadership in the bioeconomy?
There are several strategic actions that I believe would enhance current efforts to position the U.S. to be a continued world leader.

One strategic action is to *support a national lab-scale effort focused on biometrology.* Such an effort would focus on ensuring U.S. leadership in the foundational science and tools of measuring and making living systems. This effort is critical so that the U.S. is in a position to define and promulgate the standards and specifications for the transactions underlying the U.S. and global bioeconomy. These technology-agnostic capabilities, tools, and standards underpin more applied agency- and industry sector-specific efforts. Such an effort will require professional researchers drawing upon the knowledge and capabilities across DOE, DOD, HHS, DOC (NIST) and NSF.

A second strategic action necessary for guiding such efforts is to *co-situate a center for strategic policy scholarship in direct conversation with foundational science and technology development*. There are many unaddressed foundational questions in *how* to design and deploy infrastructure and policies for a growing bioeconomy in a way that effectively balances innovation and security. We should support ongoing basic and applied scholarship on these issues including professional researchers from a number of disciplines. It is critical that this work not be divorced from technology development, as one of the most powerful ways to understand and guide future governance options is by having governance considerations directly inform technical design criteria.

A third strategic action would be to *form a concerted bioeconomy coordination and leadership function in government* whereby agencies focused on science, security and economy work closely together. This could be something akin to the National Nanotechnology Initiative, where there is a staff whose first priority is to develop and deploy U.S. biotechnology strategy.[11] This work is important to inform and guide efforts across many different agencies including developing robust interfaces with academia, industry and civil society.

A fourth strategic action is to *develop new lines of basic and applied biotechnology research funding across agencies that integrates consideration of social, economic and security issues*. We should support a variety of funding mechanisms to ensure a broad ecosystem of researchers. Major multi-year and multi-disciplinary centers are an important part of this ecosystem as they are nexuses for training, interdisciplinary research, and commercialization in high-risk high-reward areas. It is important that such centers have transition plans and that their goals are coordinated across mission agencies so we don't lose the people and companies that they have fostered when these centers sunset. Critically, such centers should support basic and applied interdisciplinary work on social, political, ethical, legal, economic, environmental, safety, security and other issues coupled to getting better at the engineering of living systems. These should be treated as central research topics, not as afterthoughts that can be outsourced or done for free.

I helped lead such an effort within a National Science Foundation (NSF)-supported multi-university Engineering Research Center (ERC) in Synthetic Biology, called Synberc, which defined and

[11] "What Is the NNI?" National Nanotechnology Initiative, www.nano.gov/about-nni/what.

developed much of the field of synthetic biology as we know it today.[12] By the end of 10 years of NSF funding, Synberc involved approximately 40 university labs and 40 industry partners, many of which were formed during the lifetime of the center, such as Ginkgo Bioworks. I served for 5 years as deputy director of the "Policy and Practices" thrust of Synberc, which involved supporting basic and applied research, education, and knowledge brokering, and represented approximately 25% of the center's federal funding at its 10 year sunset. These efforts generated new technology and policy approaches that helped anticipate and mitigate concerns about new biotechnology approaches and products, and they trained a next generation of practitioners to engage with social and policy issues proactively. Some of these efforts continue to be supported through the Engineering Biology Research Consortium (EBRC)[13], but without research funding coupled to these types of coordination networks, we risk losing what we gained from these early strategic efforts.

A fifth strategic action is to *support world-class training programs from K-12 through to graduate studies including specialized programs*. The bioeconomy of the future will require many different skill sets and a citizenry equipped to participate and make wise choices about the products they develop and use. We should continue to develop and expand world-leading interdisciplinary training programs at the undergraduate and graduate level but also supplement these with renewed efforts at the K-12 level and in specialized training programs, such as 1- and 2-year associate degree programs, to meet specific growing industry needs.

It is notable that the world leading training program in synthetic biology, the international Genetically Engineered Machine Competition, known as iGEM, was started in the US 15 years ago at M.I.T. thanks in part to NSF funding directed through Synberc. Today the yearly competition has trained over 40,000 students from over 60 countries working in more than 2700 teams to prototype biotechnology innovations. These students are learning not only *how* to engineer biology but also to ask *why* their innovations are desirable, and *for whom*. For the last decade I have been a volunteer director of what we call the "Human Practices" element of the competition,, which provides incentives for teams to address social and policy issues coupled to their innovations.[14] I have also helped lead safety and security programs at iGEM, and the competition has become a world-leading testbed for adaptive governance of dual use technologies.[15]

While the U.S. has been a leader in developing the innovators of the future through iGEM and other related efforts, such as the BioBuilder program focused on middle- and high-school students[16], it now risks losing this long term strategic advantage. In 2021, the iGEM competition will be moving to

[12] Bernstein, Rachel. (2016) Synberc Building the Future with Biology: Ten Years at the Genesis of Synbio. Edited by Leonard Katz et al., Engineering Biology Research Consortium, ebrc.org/wp-content/uploads/2019/07/Synberc-10-years-book.pdf.
[13] "About." Engineering Biology Research Consortium, 2020, ebrc.org/about/.
[14] "Human Practices Hub." *iGEM*, 2019, 2019.igem.org/Human_Practices.
[15] Millett P, Binz T, Evans SW, Kuiken T, Oye K, Palmer MJ, Yambao K, Yu S, van der Vlugt C.Developing a Comprehensive, Adaptive and International Biosafety and Biosecurity Program for Advanced Biotechnology: The iGEM Experience, Applied Biosafety, In press, 2019. DOI: 10.1177/1535676019838075
[16] "The BioBuilder Educational Foundation." *BioBuilder*, 2020, biobuilder.org/foundation/about/.

Europe and the quickest growing constituency in the competition are high school teams from China.[17,18] The teams that perform the best in the competition are often those that receive support from their home countries to seed their efforts, and the U.S. teams have suffered without this support. The U.S. government should be supporting multiple iGEM teams and other bioeconomy clubs across every congressional district in the country and we should make sure we continue to invite the world to work with us and learn about our values.

Thank you for holding this hearing. Biology is a technology that will only grow in importance to our societies in the future, and you have the power to set a course for a future U.S. bioeconomy that makes us all more secure. I hope you seize the opportunity.

[17] Headquarters, iGEM. "We Have a Big Announcement: #IGEM Is Moving, the #GiantJamboree Will Be in #Paris in 2021! Pic.twitter.com/UQJw8WRaK8." *Twitter*, Twitter, 4 Nov. 2019, twitter.com/igem/status/1191424787307999234?lang=en.
[18] iGEM 2018 Annual Report. (2019, March 13). Retrieved from https://igem.org/wiki/images/d/d1/IGEM_2018_report.pdf.