Testimony for the Record: Gigi Kwik Gronvall, PhD

Submitted to the Committee on Science, Space, and Technology of the U.S. House of Representatives, Investigations and Oversight Subcommittee for the Hearing "Balancing Biotechnology Innovation and Biosecurity: Securing U.S. Leadership in a Global Race"
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Chairman McCormick, Ranking Member Sykes, and Members of the Subcommittee:

Thank you for inviting me to participate in today's hearing and thank you for your attention to a topic of critical national security importance.

My name is Gigi Kwik Gronvall. I am a Professor at the Johns Hopkins Bloomberg School of Public Health, where I co-direct the Health Security PhD track within the Department of Environmental Health and Engineering. I would like to state for the record that the opinions expressed herein are my own and do not necessarily reflect the views or positions of Johns Hopkins University or the Johns Hopkins Health System.

My central message is that biotechnology security requires both protection and achievement. Safeguards such as gene-synthesis screening, AI biosecurity evaluations, and intellectual-property protections are important, but they cannot substitute for the scientific talent, research capacity, manufacturing infrastructure, and international relationships needed to detect threats and develop countermeasures. A country that protects its science while allowing its scientific capabilities to decline will not be secure.

My background is in immunology, with training and experience including Johns Hopkins and the US Army Medical Research Institute of Infectious Diseases (USAMRIID). I have served on advisory committees related to biosecurity for the Department of Defense, Department of State, and the NIH, and I was the science advisor to the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism (2009-2010). I am currently the co-chair of the Safety and Security Advisory Committee for BioMADE, the DoD–sponsored public-private manufacturing innovation institute that brings together industry, universities, and government to strengthen US biomanufacturing capacity, workforce development, and national security. I helped write and testified in support of AB1963, California's gene synthesis screening legislation.(1) I have advised AI developers, including Anthropic, on biosecurity safeguards, participated in testing safeguards, and received compensation for that work. Neither Anthropic nor any other company contributed to or reviewed this testimony.

Why the US is falling behind in biotechnology and the life sciences

I am pleased this committee is addressing the April 2025 final report of the NSCEB, which concluded that biotechnology will be a defining strategic technology of the twenty-first century and warned that the US risks falling behind global competitors.(2) The picture the NSCEB report paints is one of US complacency about a technology that was born in the US, and in which the US was the unquestioned leader for many years. While many nations see biotechnology as a source of economic growth and prosperity, no country has invested more than the People's Republic of China, which has invested more than $100 billion in talent recruitment programs, government subsidies, research and development, as well as plans to translate research into products.(3–8) China's growth has led to sobering statistics for the US: Chinese researchers now publish more scientific papers than US researchers. China graduates more PhDs in science and technology fields. China aims for its bioeconomy to "be at the forefront globally" by 2035 to eclipse the US altogether.(9) China's biotechnology investments have yielded world-class scientists and breathtaking innovation. But as the NSCEB report makes clear, not all its successes have come from fair competition.

Since the NSCEB report was released, US policy decisions have further weakened our biotechnology research enterprise, exacerbating an already significant national security vulnerability. Billions of research dollars have been suddenly cut, which were intended to further scientific and medical advances, as well as train students and postdoctoral fellows. Clinical trials have been stopped. Offers were rescinded. Careers have been derailed. Even when decisions have been overturned after political pressure, the uncertainty lingered, delaying or stopping job offers and student training acceptances. And, research dollars are still not reaching researchers.(10–13)

While there have been news stories about the high-powered researchers who have been recruited to Canada, the EU, and other places including China, there are many more talented students from around the world choosing *not* to come to the US to study, and potential students in the US who now view the biological sciences as a too-precarious career option.(14,15) It should be noted that the US once was the best place for scientists around the world to work, and it was an absolute requirement to have US lab experience to succeed. But that is no longer the case. There are now many research institutions from which a student can embark on a productive career. As a result, these damaging blows to the US science ecosystem have only led talented scientists and would-be scientists from around the world to make reasonable choices to go elsewhere, and not contribute to US scientific advances.

Over the past several years, US policymakers have mostly reacted to China's rise by introducing ways to protect US research from being stolen. It is indeed important to protect IP and American innovation, and to make sure that CFIUS has relevant expertise to protect US interests in biotech and agricultural technologies (and avoid missteps like allowing BGI to acquire Complete Genomics in 2013, for example). **But protection alone cannot preserve American leadership. US science must continue producing something worth protecting.**

The US has faced a similar conflict between competitiveness and security before. In 1982, the CIA assessed that "virtually every Soviet military research project" – of which there were thousands, going back decades—benefited from US technical documents and hardware that were acquired through both legal and illegal means.(16) Predictably, there were calls to better protect research, classify information that Russians could use to develop missile guidance systems, cryptography or code-breaking, aerospace engineering, and nuclear weapons development. In an emergency committee formed by the National Academies known as the Corson Report after its chair, it was argued that rigorous, innovative science does not thrive in a classified environment, and that even with the risks, the US would be better off keeping science as open as possible, to practice "security by accomplishment." This became the basis for NSDD-189, which President Reagan signed in 1985, and which has been reaffirmed several times since.

The national security and economic stakes point to openness as being even more critical for the biological sciences. The study of biology occurs everywhere on the planet. Infectious diseases famously do not recognize national borders. Other nations, not just China, are moving ahead quickly, and will form the biotechnology ecosystem without scientific collaborators from the US. **If the US does not practice security by accomplishment, it will not protect the US. It will just mean that the US will not achieve what other nations will. It will mean that the US will be even more vulnerable.**

Scientific discovery alone is not sufficient for biotechnology leadership. The United States must also be able to translate discoveries into products and manufacture them at scale. Domestic biomanufacturing capacity, a skilled workforce, common standards, supply chains that are not entirely dependent upon China, and access to pilot-scale infrastructure are national security assets. Without them, American discoveries will be commercialized and manufactured elsewhere, leaving the US dependent on foreign suppliers for medicines, agricultural inputs, industrial chemicals, and other materials needed during a crisis. Organizations such as BioMADE help bridge the gap between laboratory discovery and commercial-scale production, incorporating safety and security into the development process. But there is much additional work to do to expand domestic biotechnologies,

build the workforce needed, and develop a clearer regulatory framework for emerging biotechnology products.

Anthropic recently described five case studies of trained scientists who circumvented, or used intermediaries to circumvent, the company's geographic access restrictions.(17) There are many reasons scientists might use AI models, most of which are not nefarious, and it is not clear those scientists were intending to develop biological weapons. Still, the cases are instructive. Much of the current biosecurity debate focuses on whether AI could give a biological novice access to sophisticated capabilities. These cases instead involved trained scientists using AI to assist their work.

They illustrate a broader reality: advanced biological expertise exists around the world, and potentially harmful activity may evade an American provider's safeguards or never involve a monitored AI platform. Prevention measures remain important. AI developers should evaluate their models for biosecurity risks and have mechanisms to report credible threats. Gene synthesis providers should screen their orders and have know-your-customer practices. But prevention alone cannot provide biological security. It is critical that the US maintain the scientific expertise needed to identify emerging threats, evaluate their significance, and develop effective countermeasures.

In addition to research funding, activities necessary for US science to advance have been cut or made much more difficult. These actions should be reversed. For example, scientific conferences are not only an important part of communicating science ahead of publications, they are also often integral to scientific innovation: Jennifer Doudna and Emmanuelle Charpentier met at an American Society for Microbiology conference in Puerto Rico in 2011, and their subsequent collaboration produced the foundational CRISPR-Cas9 work for which they received the 2020 Nobel Prize in Chemistry.(18) It has been increasingly difficult for scientific conferences to be held in the US, because of the challenges for international scientists to get visas to attend. But now, with incidents of scientists being denied entry or detained by US immigration officials, scientists are deciding not to attend conferences in the US.(19,20) US scientists increasingly do not have the funding to travel, either, to hear the latest scientific advances, or form the collaborations that will deliver future innovations and Nobel Prizes, or to take the next steps in what now is perceived to be an unwise career choice.

Visa challenges and denials were a major reason why the premier synthetic biology competition, the International Genetically Engineered Machine (iGEM) competition, moved from Boston to Paris in 2022.(21) The competition originally grew out of a class at MIT, and the first competition had just 5 teams. Now there are over 400 teams from at least 50 countries. The competition has led to over 250 startup companies, and there are more

than 86,000 iGEM alumni all over the world. Competitions like this – another is the Biodesign Competition, which is still based in New York City—are an important part of experiential learning in biotechnology, and they are a source of future innovation. The US should consider these competitions strategically.

US interests are also being harmed by detrimental research policies that are extremely vague, and which will make the most innocuous research legally risky. One example is the "United States Government Policy for Stopping High-Risk Life Sciences Research," which was released in July, 2026 in response to the May 2025 Executive Order "Improving the Safety and Security of Biological Research."(22,23) This policy prohibits "dangerous gain of function research" or DGOF. However, the definitions are exceptionally broad and would prohibit, or create disabling legal uncertainty around, activities that are required for medical countermeasure development, public health surveillance, animal model development, and ordinary research posing minimal biosafety risk. The policy nods to the fact that medical countermeasure development overlaps with what is prohibited, but doesn't offer any path for acquiring an exception.

The policy also creates a category called "International Research of Concern" (IROC). Its language appears to prohibit federal support for *any* life sciences research conducted in a designated country of concern. It also subjects research in other countries to a vaguely defined assessment of whether local oversight meets US standards. These provisions could impair basic international activities including influenza surveillance, sample sharing, and outbreak investigation.

Even when policies included exceptions for beneficial research, many scientists actively avoided work that could be construed as "GOF"—a term that has become an unstable policy label.(24) In a news report about how these vague policy terms harm true preparedness, one virologist described being able to secure NIH funding for experiments that sounded "less GOF-like" but were also less informative about potential pandemic threats and how to defeat them. As he put it, "The next flu pandemic is brewing in nature, but we have very little means of stopping it, very little means of identifying what the most dangerous viruses are."(25)

I personally witnessed the chilling impact of previous iterations of these policies. At the 2025 Vaccine Congress in Kyoto, Japan, virologists from around the world gathered to discuss the latest scientific research about H5N1 influenza. Hualan Chen, a preeminent Chinese researcher, shed light on one mystery—how dairy cows were spreading H5N1 in the US. She conducted a large study demonstrating how infected cows transmitted the virus by drinking each other's milk, spreading the virus from mouth to teat.(26,27) Instead of getting this important information from researchers in China, US researchers who have

the necessary expertise and facilities should have been able to investigate promptly how H5N1 spreads among cattle and which interventions could interrupt transmission. Answering questions like these is essential to controlling the outbreak and reducing opportunities for the virus to evolve toward efficient human-to-human transmission. Yet at the conference, one US scientist after another described experiments that could resolve important questions about H5N1 preparedness and response, only to explain that the work could not proceed in the existing regulatory and funding environment.

That was *before* many research activities were outright prohibited. H5N1 preparedness has been further weakened through the May, 2025 cancellation of a major mRNA vaccine contract.(28)

The detrimental actions and policies I described are isolating US researchers and American research, internationally. Many nations see research on pathogens causing human disease as a priority in the aftermath of SARS-CoV-2. Rather than leading the world to maintain and develop safe, secure practices and biosafety norms, which US researchers are exceptionally well-poised to do, US scientists are being hamstrung, unable to lead and influence safety or security practices at the international level. Other nations' scientists will certainly take the lead in understanding important characteristics of emerging pathogens that could lead to better surveillance and better vaccines, and the international norms for research and safety will be set by them—not by US scientists. This will have serious negative implications for the US bioeconomy and international biosafety norms.

Ideally, any additional oversight for virology or any other kind of research should target activities that require the most safety oversight, and should not impose unnecessary burdens that either slow needed advances or encourage work-arounds. There should be clear regulatory lines so scientists know which research activities do/do not require additional oversight or reporting. Such a review should specifically engage many scientists and subdomain experts, as well as safety, security, and regulatory experts. The intent should be to ensure that the rules are clearly understood, effective, and durable. It should be noted that virology research, particularly in high containment, already has a significant amount of oversight.

Similarly, federal agencies should apply consistent definitions and retain specialized expertise necessary for their different missions. NIH, NSF, DOE, USDA, EPA, and DoD fund very different kinds of biological research, and implementing vague or inconsistent rules creates gaps and unnecessary restrictions. Congress should require coordinated implementation guidance, review and appeal mechanisms, and there should be regular evaluation of whether any restrictions are actually reducing risks or displacing valuable research.

Advances in the life sciences and the development of new biotechnologies are essential to American economic competitiveness, public health, and national security. Congress should prioritize NSCEB recommendations to sustain biotechnology R&D, expand domestic biomanufacturing infrastructure and workforce development, strengthen biological data resources, and harmonize federal regulation of biotechnology.

Recommendations:

I respectfully urge the Committee to consider the following actions:

1. **Advance the NSCEB's biotechnology competitiveness recommendations.** Congress should require agencies to report on progress toward expanding domestic biomanufacturing capacity, pilot-scale infrastructure, workforce development, biological data resources, and regulatory coordination, including barriers that prevent American discoveries from being commercialized and manufactured domestically.

2. **Require accounting and disclosure of undisbursed, appropriated research funds.** Billions of dollars in federal research funding that Congress has appropriated — including funds restored to NIH in early 2026 after being targeted for cuts — have not reached researchers and institutions in a timely manner. This delay compounds the damage to the US biotechnology ecosystem. I urge the Committee to:
    - Direct the responsible agencies to report to Congress, on a recurring basis, the amount of appropriated research funding that remains unobligated or unapportioned more than 60 days after enactment, and the specific reasons for any delay;
    - Request that GAO continue and expand its review of the timeliness of apportionment and obligation of appropriated biomedical and life sciences research funding, building on its August 2025 finding, and report periodically to Congress on compliance with the Impoundment Control Act; and
    - Make clear, through appropriate oversight action, that delayed or withheld disbursement of appropriated research funds carries the same real-world costs to American competitiveness and biosecurity as a formal funding cut, in lost researchers, canceled trials, and rescinded offers, regardless of the mechanism by which the funds are withheld.

3. **I urge the Committee to call for the immediate suspension of the "United States Government Policy for Stopping High-Risk Life Sciences Research" and to temporarily use the 2024 United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential while a better policy is developed.** The 2024 policy was scheduled to take effect immediately before the May 2025 executive order directed that it be replaced. I do not offer it as an ideal solution. It and its P3CO-era predecessor shared a significant flaw: they required researchers and review panels to predict whether an experiment could reasonably be anticipated to produce consequential societal or public health harms. Such downstream consequences cannot be predicted reliably from a proposed genetic change or an isolated laboratory phenotype. Replication rate, host range, transmissibility, pathogenicity, and immune escape are distinct and complex characteristics, and a change in one does not necessarily predict a change in the others. Nevertheless, the 2024 policy provided a more workable interim framework and would not create the disabling ambiguity that now threatens valuable public health surveillance, animal model research, and medical countermeasure development.
    - **Require that a successor policy be developed with structured input from the regulated scientific community and independent outside experts.** The responsible agencies should conduct a formal, public process that includes a defined public comment period and structured technical consultation with practicing researchers, institutional biosafety officials, and non-governmental biosecurity experts, before issuing any successor to the current policy. This process should be transparent in its membership and methodology, and should not be limited to internal agency deliberation or a closed advisory process. The current policy's core defect is not simply that its definitions are vague, but that the policy was developed without meaningful input from the community expected to comply with it; a successor policy developed the same way will likely reproduce the same problems.
    - **Establish a defined exception pathway and appeal mechanism.** Require that any successor policy include an explicit, expedited process for medical countermeasure development, public health surveillance, and animal model development to proceed with appropriate oversight rather than default prohibition, and that any "International Research of Concern" designations be subject to a published review standard and a formal right of appeal.
    - **Commission an independent evaluation of the policy's effects.** Request that GAO or the National Academies conduct a biennial assessment of

whether these restrictions are measurably reducing biosecurity risk or are instead displacing valuable research, driving it to less-transparent settings, or discouraging expertise the United States needs to detect and respond to emerging threats.

4. **Hold a follow-up hearing within 12 months** on implementation of the NSCEB's recommendations, with relevant agency leadership reporting on which recommendations have been adopted, which remain outstanding, and why.

Thank you for the opportunity to testify, and I would be pleased to answer any questions you may have.

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