DEPARTMENT OF HEALTH AND HUMAN SERVICES

Testimony before

The Senate Committee on Finance

Hearing titled

Foreign Threats to Taxpayer Funded Research: Oversight Opportunities and Policy Solutions

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Good morning Mr. Chairman, Ranking Member Wyden, and distinguished members of the Committee. Thank you for your long-standing support of the biomedical research enterprise and of the National Institutes of Health (NIH) specifically. It is an honor to appear before you today to discuss how NIH works to protect the integrity of the U.S. biomedical enterprise and neutralize foreign threats to the integrity of taxpayer-funded research.

The United States is the world leader in biomedical research. As the largest public funder of that research, NIH sets the standard for innovation and scientific discovery that aims to advance the health of all Americans. We exemplify and promote the highest levels of scientific integrity, public accountability, and social responsibility in the conduct of science. We promote open collaboration by leveraging formal and informal collaborations with scientists at research institutions around the world, which is imperative to solving the most pressing and perplexing health challenges that are facing the American public. This exchange of knowledge is an essential part of innovation, and it is critical to our global competitiveness. Foreign-born scientists contribute to improving health, fostering innovation, and advancing science.

Many recent scientific advances, such as sequencing the human genome, or the development of the gene-editing tool kit known as CRISPR-Cas were predicated upon international collaborations. Since 2000, 39 percent of U.S. Nobel prizes in physics, chemistry, and medicine have been awarded to foreign-born scientists[1]. Foreign-born scientists, trainees, and employees at American universities are hard at work assisting in the advancement of knowledge. U.S. scientists routinely collaborate productively with investigators in foreign countries, resulting in many scientific successes.

[1] https://nfap.com/wp-content/uploads/2017/10/DAY-OF-RELEASE.Nobel-Prize.October-20171.pdf

Partnerships with numerous foreign entities are also essential for predicting, and rapidly identifying and responding to threats from emerging infectious diseases and pathogens. For example, a joint working group made up of NIH and National Natural Science Foundation of China (NSFC) representatives developed a strategic research program that identifies, reviews, and jointly funds bilateral projects that address high priority infectious disease concerns, including antimicrobial resistant bacteria and evolving strains of influenza that could cause global epidemics[2]. Furthermore, because diseases can and do occur in many parts of the world, we must rely on productive research collaborations and partnership programs with foreign entities to share information on seasonal and pre-pandemic influenza viruses, and to access strains of emerging infectious diseases such as SARS and MERS, Zika, Ebola, and many others.

Unfortunately, we are aware that a few foreign governments have initiated systematic programs to capitalize on the collaborative nature of biomedical research and unduly influence U.S.-based researchers. It is essential for us to continue vigilance and take additional actions to protect the integrity of the U.S. biomedical research enterprise, while also protecting important relationships with foreign scientists worldwide.

NIH's three areas of concern are:

1) failure by some researchers at NIH-funded institutions to disclose substantial contributions of resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds;

2) diversion of proprietary information included in grant applications or produced by NIH-supported biomedical research to other entities, including other countries; and

3) failure by some peer reviewers to keep information in grant applications confidential; including, in some instances, disclosure to foreign entities or other attempts to influence funding decisions.

[2] https://www.niaid.nih.gov/research/us-china-collaborative-biomedical-research-program

NIH has taken, and continues to take, a proactive approach to identifying, resolving, and preventing issues of concern.

NIH identifies and monitors concerns through several channels. We regularly partner with colleagues at the Department of Health and Human Services (HHS), and other federal agencies, such the Federal Bureau of Investigation (FBI), to exchange information on emerging threats. A new dashboard is being developed to assist NIH in responding to data requests needed for its reviews in this context. In addition, NIH maintains an open channel of communication with our funded research institutions and their investigators, several of which have proactively contacted us with concerns.

We have also actively taken steps to increase awareness about peer review integrity with our employees who lead scientific programs and review meetings. For example, NIH staff were specifically trained to identify and report suspicious activity on the part of key scientists designated in grant applications and peer reviewers to the Research Integrity Officer in their NIH Institute or Center, or directly to our central research integrity official within the Office of the Director.

When concerns are identified, we work with leadership within the awardee institution to quickly address the issue as appropriate. As of May 2019, we have contacted more than 55 awardee institutions related to this issue, and this process is ongoing. Our efforts have directly or indirectly led to actions by awardee institutions (who have the authority to take certain actions as employers). Such actions include:

- Terminations or suspensions of scientists who have engaged in egregious violations of NIH grant terms and conditions and institutional policies.
- Interventions to address previously un-reported affiliations with foreign institutions.
- Relinquishment or refund of NIH funds.
- Prohibition of certain individuals from serving as investigators on NIH grants.
- Outreach to FBI for assistance.
- Discovery (through acquisition of certain foreign grants and contracts) of overlapping or duplicative work, or conflicts in stating committed effort to research projects. This discovery has led to NIH suspensions of active grants as appropriate.

- Efforts to raise awareness among institutional faculty about government and institutional policies dealing with foreign affiliations and relationships (see, for example, the Penn State web site).[3]

There have also been situations in which honest mistakes were made by research investigators who were unaware of the requirement to disclose other funding sources (both domestic and international) or affiliations with foreign entities. In these cases, we worked with the institutions, which took steps to help their employees understand disclosure policies; both why they are important, and how to comply with relevant rules.

We will continue to address issues of concern. To mitigate security breaches, we have improved the electronic systems that are used by researchers to submit applications to NIH, and that are also used by peer reviewers to access applications for evaluations. Our security updates include: two-factor authentication for electronic research system logins; using an all-electronic conflict-of-interest certification; and, development of a dashboard.

A major focus of our preventive efforts is proactive communication to engage the research community as partners. For example, on August 23, 2018, the NIH Director issued a statement on protecting the integrity of U.S. Biomedical Research[4], and sent a letter to officials at approximately 10,000 organizations applying for NIH funding. The letter reinforced that NIH and the U.S. biomedical research community at large have a vested interest in mitigating these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

[3] https://www.research.psu.edu/international_affiliations.
[4] https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research

We are developing resources to help awardee institutions understand our expectations regarding research investigators who - in addition to NIH funding - receive additional research funding from domestic or foreign sources.

As I mentioned, the U.S. biomedical research community at-large has a vested interest in mitigating these unacceptable breaches of trust and confidentiality. Community engagement is such an important part of our activities. Last year, we convened a working group of the Advisory Committee to the NIH Director (ACD) to develop recommendations related to foreign Influences on research integrity[5]. We charged them to identify robust methods to: 1) improve accurate reporting of all sources of research support, financial interests, and affiliations; 2) mitigate the risk to security of proprietary information while continuing NIH's long tradition of collaborations, including foreign scientists and institutions; and, 3) explore additional steps to protect the integrity of peer review. Many of their recommendations, which were considered and adopted by the ACD, and conveyed to NIH through the ACD, have already been acted upon by NIH, as described above. As recommended by the ACD, following input from the working group, we are working with key stakeholders to figure out how best to collate and disseminate best practices, with the Association of American Universities and the Association of Public and Land-Grant Universities taking a lead role in these efforts. An update on these activities will be presented and discussed publicly at the June 2019 meeting of the Advisory Committee to the NIH Director**.** We also recognize that we will not be successful in our domestic efforts to protect the integrity of the R&D enterprise if we do not work together internationally with allies and like-minded partners to take coordinated action. As such, we are working with the Department of State to engage key allies and partners to identify effective approaches to promote U.S. scientific and technological advances through

[5] https://acd.od.nih.gov/working-groups/foreign-influences.html

international S&T cooperation, while simultaneously identifying and minimizing improper influence on the integrity of the American R&D enterprise.

While we have taken bold and concrete steps to bolster research integrity and neutralize foreign threats against U.S. biomedical research, we remain conscious of how these actions could affect the morale of honest and dedicated foreign researchers. In March 2019, we responded to a joint letter[6] from three Chinese American biomedical professional societies, in which they expressed concerns that policies designed to protect biomedical proprietary information may be singling out Chinese students and scholars working in the United States. In our response, published in the journal Science[7], we acknowledge these concerns, and that the vast majority of Chinese scientists working in America are committed to the cause of expanding knowledge for the betterment of humankind, and to do so in a fair and honest way. Importantly, NIH reviews have identified concerns involving individuals who are not of Chinese ethnicity

The individuals violating laws and policies represent a small proportion of scientists working in and with U.S. institutions. We must ensure that our responses to this issue do not create a hostile environment for colleagues who are deeply dedicated to advancing human health through scientific inquiry. We cannot afford to reject brilliant minds working honestly and collaboratively to provide hope and healing to millions around the world.

In closing, as Principal Deputy Director of NIH, I can assure the Committee that the senior leadership at NIH will continue to diligently protect the integrity of U.S.-taxpayer funded research.

Thank you, Mr. Chairman.

[6] https://science.sciencemag.org/content/363/6433/1290
[7] https://science.sciencemag.org/content/363/6433/1292.full