DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

Testimony before the Senate Homeland Security and Governmental Affairs

Permanent Subcommittee on Investigations

Hearing on

^ μŒ]vPšZ hX^XZ• ŒZ všŒ‰Œ]• (Œ}u Z]v[•dovšZ

Michael S. Lauer, M.D. Deputy Director for Extramural Research National Institutes of Health

November 19, 2019

Good morning Chairman Portman, Ranking Minority Member Carper, and distinguished members of the Subcommittee. 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 taxpayerfunded 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.

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 NIH has taken, and continues to take, a proactive approach to <u>identifying</u>, <u>resolving</u>, and <u>preventing</u> 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 October 2019, we have contacted more than 70 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.

4

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 Research⁴, 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.

We are

5

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 letter⁶ 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 Science⁷, 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 also 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, 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.

7