

**FOREIGN THREATS TO TAXPAYER-FUNDED
RESEARCH: OVERSIGHT OPPORTUNITIES
AND POLICY SOLUTIONS**

HEARING

BEFORE THE

**COMMITTEE ON FINANCE
UNITED STATES SENATE**

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FOREIGN THREATS TO TAXPAYER-FUNDED RESEARCH: OVERSIGHT OPPORTUNITIES AND POLICY SOLUTIONS

WEDNESDAY, JUNE 5, 2019

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:45 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Cornyn, Thune, Toomey, Cassidy, Daines, Wyden, Cantwell, Carper, Cardin, Brown, Bennet, Casey, Whitehouse, Hassan, and Cortez Masto.

Also present: Republican staff: Daniel Boatright, Investigative Counsel; Joshua Flynn-Brown, Deputy Chief Investigative Counsel; and Delisa Ragsdale, Chief Investigative Counsel. Democratic staff: David Berick, Chief Investigator; Sal Christ, Fellow; and Joshua Sheinkman, Staff Director.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. I welcome everybody to today's hearing on foreign threats to taxpayer-funded research. Normally I do not start until Senator Wyden gets here, but he said we could go ahead and he will be here shortly. Also, another reason for starting on time is because we have some votes that are going to interfere with exactly how much of this committee's work I do not know, so we want to keep it moving.

Taxpayer-funded research has been integral in keeping America's medical, defense, information technology, and many other products at the forefront of our world's market. Simply said, the United States is the best of the best when it comes to conducting cutting-edge medical research. Our scientists push the envelope to make crucial discoveries and better products, whether it is vaccines or medical treatments generally, and they all fall into the category of great development of the intellectual property.

These projects can produce important breakthroughs for patients and industry, for the United States, and the entire world. We did not develop this reputation overnight. We earned it through the persistent hard work and dedication of researchers across the country.

I would like to call that a good old-fashioned American work ethic. I thank them for their service to our country. I want them

to know that this committee's oversight is not designed to interfere with the pursuit of knowledge and the free exchange of information by researchers. Rather, this committee's oversight is intended to strengthen the integrity of taxpayer-funded research, and especially to preserve our valuable work product. Truly free collaboration and exchange of information is only possible when data and sources are credible and the research process can be trusted.

That trust is destroyed when foreign governments or other entities interfere in our research for their gain and to our detriment. Accordingly, Congress, the executive branch, and research institutions must work together to properly balance the robust development and exchange of ideas in the research field with reasonable and proportionate common-sense efforts to protect the integrity of the research.

That is why I have engaged in oversight efforts in this field. Beginning in October of last year, I wrote to the National Institutes of Health, the Department of Health and Human Services, and the Health and Human Services Inspector General about threats to taxpayer-funded research. Since then, I have also written to the National Science Foundation and the Department of Defense.

Today we will focus on foreign threats to research funded by the National Institutes of Health, its granting process, and downstream grantees. Those threats include spying, theft of intellectual property, the disclosure of confidential information, and other related efforts that undermine the integrity of research. The National Institutes of Health spend \$39 billion of taxpayer money each year on medical research.

So the American people have worked hard for that money, and the people deserve to know how the government is working to protect that research and the resulting intellectual property from foreign threats.

We know that China is by far the most prolific offender. However, they are not the only country acting against our interests. In October 2018, while chairman of the Judiciary Committee, I held a hearing on China's non-traditional espionage against the United States. During that hearing, I broached the issue of China's focus on our research institutions and taxpayer-funded research. Today we can get into more detail regarding the threats. It is without dispute that China has focused its energy on leveraging our hard work for their benefit, and of course to our detriment.

One example hits home for me. In 2011, Chinese nationals tried to steal genetically modified corn seeds from an Iowa field. They tried to ship that seed back to China. Those seeds were the product of years of research and development. The Chinese Government says that they are, quote, "picking flowers in foreign lands to make honey in China," end of quote. And of course we believe them.

Whether we are talking about Confucius Institutes' spreading propaganda on college campuses, China's "Talent Programs" that are being called "brain gain" programs, or China planting spies in our industries, the Government of China is a serious problem. In 2013, Chinese nationals were charged with conspiring to steal research funded by a multi-million-dollar NIH grant for the benefit of the Chinese Government and a direct competitor of the American university where the research was conducted.

In an August 20, 2018, letter to NIH grantee institutions, NIH called attention to a series of threats posed by foreign entities to the integrity of U.S. biomedical research. In that letter, NIH warned that foreign actors have “mounted systematic programs to influence NIH researchers and peer reviewers,” may have worked to divert intellectual property produced by NIH-supported research to other countries, and may have contributed resources to NIH-funded researchers in ways that could impact the integrity of that research.

In January of this year, the HHS Inspector General notified me that NIH recently made 12 referrals in this area to the Inspector General. Those referrals primarily involved principal investigators—essentially the prime researchers—on NIH grants conducting medical research at U.S. universities. Those researchers allegedly failed to meet NIH requirements to disclose foreign affiliations on their grant applications, which turns out to be a very serious problem. Researchers who are secretly supported by a foreign government while working in our research projects can be more susceptible to the influence and control of the foreign parent.

We must know who is financially supporting researchers to better understand whether they might be more dedicated to securing the interests of an adversary than to rigorous scientific and medical advancement. Our witnesses can speak to those specific threats and the government’s capability to detect and deter them.

Today we have witnesses from the National Institutes of Health, the Health and Human Services Office of National Security, the Health and Human Services Inspector General, and the Department of Homeland Security.

Now you can see an empty chair at the table. The FBI was invited by the committee, given that they are a critical aspect of counterintelligence in this field. The committee invited the FBI April 30th. That is 26 business days before the hearing date.

On May 6th, the FBI said that it would be unable to participate in the hearing, but failed to explain why. My staff followed up via email and phone. On May 7th, the FBI reiterated that they were not able to appear, but again failed to explain why. On May 16th, the FBI responded via email and said the “Counterintelligence Division respectfully declines the hearing invite,” yet again failing to explain why.

On May 23rd, I wrote a letter to the FBI again inviting their attendance. On May 29th, the FBI responded in writing and stated that it “does not have a witness available to attend the hearing and the briefing.”

After just about 1 month of communications between the FBI and my staff, the FBI failed at every turn to explain why the entire Counterintelligence Division did not have a single employee available to attend today’s hearings. That is inexcusable and, quite frankly, it is a shame because of their responsibilities. What a wasted opportunity for the FBI to explain to this committee and the American people what they are doing to help these agencies detect and deter threats to our research. The American people deserve more than a stiff arm from the FBI. However, I appreciate the cooperation of expert witnesses who are here today, and I look forward to a robust conversation.

Generally speaking, there are four main issues related to taxpayer-funded research.

First, the failure to disclose. Some researchers hired to work on U.S. research projects have not disclosed that they have received financial contributions from foreign countries.

Number two, espionage. Some researchers are spies, and their only purpose is to infiltrate taxpayer-funded research projects to steal intellectual property and bring it to their home country.

Third is vetting. The Federal Government does not vet all researchers hired by U.S. institutions to work on taxpayer-funded research, and neither do the institutions.

Lastly, the issue of integrity. Some peer reviewers have shared confidential information from grant applications with foreign governments which would allow them to potentially skip research steps. Some have also attempted to influence funding decisions, undermining the integrity of this taxpayer-funded research.

These threats to our research are ongoing, aggressive, and real. The question is: does the government have the capability to detect threats, combat threats, and determine how to protect our research and any financial intellectual property created from that research?

Today is an opportunity for our witnesses to engage in a frank discussion about what that threat is and what we in Congress and the executive branch can do all together to solve the problem.

So the two branches must be on the same page. So if you believe that there are legislative and policy solutions that will assist you with your already difficult jobs, now is the time to bring them forward. And I hope you can do that at this hearing.

I look forward to a robust discussion today on these matters. After this morning's hearing, the committee will then move this afternoon to a classified briefing on the same subject matter. I strongly encourage the witnesses to take advantage of the highly classified environment to provide as much information to the committee as possible.

When Ranking Member Wyden gets here, I will call on him, and now I will introduce the witnesses.

[The prepared statement of Chairman Grassley appears in the appendix.]

The CHAIRMAN. I just called on you. Are you ready?

**OPENING STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON**

Senator WYDEN. I am. Mr. Chairman, you are ever gracious, and I thank you and always appreciate the chance to work together.

Just a couple of points I would like to make as we begin this morning's inquiry. Our country is more entrepreneurial, our economy is stronger, and our lives are better because the scientific community in America is able to attract so many of the world's brightest minds. That is a strength to be protected, a part of our national security that we must always bolster.

Foreign-born scientists put Americans on the moon. They worked for the Manhattan Project. Nearly a third of all American Nobel Laureates were born outside the United States. If you look back at 2016, that year six U.S.-based scientists won Nobel Prizes. There were many born in other countries.

It goes without saying that individuals and governments outside the United States are always going to be out there looking at chipping away at our lead. That is particularly true when it comes to scientific breakthroughs that lead to valuable IP and entrepreneurship. Academic institutions and other research organizations based in this country must understand this, and must respond to those concerns just like Federal agencies and private companies do.

But let us be careful not to over-reach with barriers that turn away bright students, or cut off lines of communication with scientists from other countries that can end up doing more harm than good. And targeting Americans who happen to be descendants of recent immigrants in my view would just be a major mistake.

Dr. Verita Currie, a distinguished professor at Iowa State University, put it this way, and I will quote: “Without foreign-born researchers, the entire system of higher education in the United States would collapse in a minute.”

This morning we are going to hear from Dr. Joe Gray of our very own Oregon Health and Science University. I had a chance to visit with Dr. Gray yesterday, and nobody knows better than he how vitally important foreign-born researchers and international collaboration are to America and to American institutions. Our country would not be able to achieve some of the scientific breakthroughs without them, period.

Second, all breakthroughs in medicine or technology are to be cheered as long as they result in better lives for the American people. And if our country suspects that American IP or technology is being stolen, is being ripped off from us, we have the power to do something about it.

Finally, while the committee examines the issues today, it is also important to take a step back to look at the broader context of our commitment to scientific research. When you take inflation into account, Federal investments in science and research have unfortunately been declining, and declining steadily for decades.

State investments in higher education have also dropped, which in a lot of instances can end up really almost starving research universities of the funds they need. The quickest way to turn the lights out in healthy research laboratories across America, in my view, would be to actually enact into law the Trump administration’s proposed cuts to the National Institutes of Health.

A few months ago the President also signed an executive order threatening to cut off research funding for universities, in my view over an unwarranted panic dealing with speech on campus. Fortunately, the order was toothless.

So when you take the broader view of threats to research in America, it is clear that we have substantial dangers from within, and too often they stem from the administration taking anti-science positions.

With regard to foreign threats, what is true with private businesses and government agencies is true for research institutions. They can and must take responsible steps to protect themselves. I intend to work with all of my colleagues on both sides of the aisle to ensure that they have the tools to do so. But I also do not want to close the door or place undue burdens on foreign-born students

and scientists who can make life-changing discoveries because they work together with Americans.

Mr. Chairman, I look forward to working with you and appreciate the chance to be here.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. I am now going to introduce our witnesses. I will introduce all four now. First, Captain Michael Schmoyer, Assistant Deputy Secretary for National Security at HHS. Captain Schmoyer serves as the Secretary's Senior Intelligence Official and Federal Senior Intelligence Coordinator for HHS. The Office of National Security functions as a Federal Intelligence Coordinating Office for the Department. As the FICO, the Office of National Security provides departmental oversight to areas of intelligence, counterintelligence, personnel security, and the safeguarding of classified information.

Dr. Lawrence Tabak is Principal Deputy Director of the National Institutes of Health. Dr. Tabak was appointed Principal Deputy Director at NIH in 2010. Previously he served as Acting Principal Deputy Director at NIH between 2008 and 2009.

Mr. Les Hollie is Chief of Investigative Operations at the Department of HHS, Office of Inspector General. He is the senior-level executive responsible for coordinating OIG's national initiative pertaining to research integrity. Under his leadership, the OI has recovered more than \$5 billion through investigations.

Mr. Louis Rodi is Deputy Assistant Director of Homeland Security Investigations at the Department of Homeland Security. In this capacity, Mr. Rodi is responsible for strategic planning, national policy implementation, and the development and execution of operational initiatives. He oversees the Department's national security programs, including the national security unit that partners with FBI's Joint Terrorism Task Force, the Human Rights Violators and War Crimes Unit, and the Counter Terrorism and Criminal Exploitation Unit. He also oversees the student and exchange visitors program.

So we are going to start with Captain Schmoyer.

STATEMENT OF CAPTAIN MICHAEL SCHMOYER, Ph.D., ASSISTANT DEPUTY SECRETARY FOR NATIONAL SECURITY; AND DIRECTOR, OFFICE OF NATIONAL SECURITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. SCHMOYER. Good morning, Mr. Chairman, Ranking Member Wyden, and distinguished members of the committee.

It is an honor to appear before you today to discuss the U.S. Department of Health and Human Service's efforts to address foreign threats. My testimony today will focus on the threats foreign governments and foreign agents present to U.S. Government-funded medical research; the efforts undertaken by HHS to detect the threats and protect the integrity of medical research—an area that is critical for our Nation's ability to provide health care and for bio-defense; and the role of HHS's Office of National Security, or ONS, and its capabilities.

My name is Captain Michael Schmoyer, and I am the Assistant Deputy Secretary for National Security, and the Director of HHS's

ONS. I report directly to the HHS Deputy Secretary and also serve as the Secretary's Senior Intelligence Official on intelligence and counterintelligence issues.

ONS's responsibilities include integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to HHS, and national security in general; and providing policy guidance on and managing the implementation of the Department's national security intelligence and counterintelligence programs.

In coordination with the Director of National Intelligence, ONS is the Department's Federal intelligence coordination office, and I serve as the Department's Federal Senior Intelligence Coordinator.

I am also the designated senior official within the Department who is responsible for countering threats from foreign intelligence agencies. ONS has a critical mission that focuses on protecting HHS's ability to conduct research that will lead to the development of treatments, diagnostics, and vaccines to address public health needs, including the ever-evolving threat of newly emerging and re-emerging infectious disease caused by pathogens that could be biological threats to the homeland.

While appreciating the value of scientific advancement, HHS has an equal interest in maintaining the integrity of the Department's scientific enterprise. Similarly, HHS embraces the contributions that foreign partnerships have made to expanding scientific knowledge that protects, promotes, and advances public health and medical research pursuits worldwide.

Through work with our national security partners over the past 2 years, ONS became aware of threats to the grants process and intellectual property that is a cornerstone of the Department's core values and biomedical research integrity. ONS quickly worked with NIH, the OIG, the FBI, and the National Counterintelligence and Security Center to identify steps to mitigate these threats to U.S. biomedical research. We mitigate threats in three fundamental ways.

First, identifying foreign intelligence threats and sharing of threat information with our agencies, including NIH, the FBI, and the broader intelligence community. Second, safeguarding HHS's sensitive information, relationships, property, and activities. And third, preventing and detecting insider threats.

ONS takes full advantage of the resources and authorities that we currently have to build interdisciplinary partnerships, both internally and externally, to conduct assessments of HHS's sensitive information, property, and activities. We have found these assessments are the cornerstone for all of our corresponding security and counter-threat activities.

ONS also works closely with the Department of Justice and the broader intelligence community to identify researchers who may have engaged in problematic practices with foreign entities that may have unduly influenced and capitalized on U.S.-conducted research. ONS has access to a variety of databases that enable us to vet employees, as well as visitors to HHS facilities, including NIH. These database results are linked to our national security partners to ensure the results we have are both reliable and valid.

Additionally, we have recently initiated new efforts within ONS that will be dedicated to working with universities to empower their programs to address threats to research integrity. We have been excited to work with NIH, FBI, OIG, and NCSC to see this new effort grow.

ONS will continue to ensure our national security-related efforts support successful relationships with foreign scientists in all countries, supporting the research enterprise while simultaneously protecting national security equities.

In closing, thank you for the opportunity to review the national security role and work of ONS and our efforts to address foreign threats to research.

[The prepared statement of Dr. Schmoyer appears in the appendix.]

The CHAIRMAN. Dr. Tabak?

STATEMENT OF LAWRENCE A. TABAK, D.D.S., Ph.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. TABAK. Thank you, Chairman Grassley, Ranking Member Wyden, and committee members.

I am honored to be here today to represent the National Institutes of Health as its Principal Deputy Director. As this is not a committee before which we frequently appear, I think it would be helpful to say a bit about the work we do to provide some context for the hearing.

NIH is the world's leading public funder of the global biomedical research enterprise, supporting more than 300,000 researchers and staff across the Nation. Groundbreaking research funded by NIH conducted at institutions in each of your home States has transformed the health of America. Every generation has benefited from the scientific advances and increased life expectancy that NIH helps usher in.

To support the very best science, NIH pioneered the gold standard for peer review of research grant applications. In fiscal year 2018, we asked more than 26,000 peer reviewers to assess the scientific merit of more than 80,000 applications that were being considered for funding.

Unfortunately it has become apparent that a small proportion of scientists have received foreign research support that they did not properly disclose on their grant applications, have obligations to institutions other than those identified in their grant applications, and have attempted to subvert the peer review process to improve their own funding chances.

In all instances, these behaviors may lead to inappropriate funding decisions and ultimately the diversion of proprietary information from American institutions. As of May 2019, we have contacted 61 awarding institutions about specific concerns we have related to this issue, and this process is ongoing.

Partnering with research institution leadership is a key, as our awards are made to institutions, not to individuals. Our efforts have led to specific personnel being removed from grants or even being terminated from their institutions. And increasingly, institutions are adopting better monitoring and reporting systems.

NIH staff has been explicitly trained to identify suspicious activity of peer reviewers and of key personnel listed in grant applications, and to report this to NIH research integrity officers. We regularly partner with colleagues at the Department of Health and Human Services and other Federal agencies, such as the FBI, to exchange information on emerging threats. We also engage our stakeholder community in a variety of forums, including the Advisory Committee of the NIH Director, which next week will meet to continue the public discussion about best practices to prevent and detect untoward foreign influences in our system.

That stated, we remain conscious of how these actions could affect the morale of honest and dedicated foreign-born researchers who are hard at work assisting and often leading the advancement of scientific knowledge. Since 2000, 39 percent of U.S. Nobel Prizes in physics, chemistry, and medicine have been awarded to foreign-born scientists. U.S. scientists routinely collaborate productively with investigators in foreign countries. Furthermore, because disease emerges from many parts of the world, we must rely on productive research collaborations with foreign entities to share information on seasonal and pre-pandemic influenza or emergent or re-emerging infectious diseases such as SARS, MERS, Zika, and Ebola.

The individuals violating laws and policies represent a small proportion of scientists in and with U.S. institutions. We cannot afford to reject brilliant minds working honestly and collaboratively to provide hope and healing to millions around the world.

In closing, we at NIH are devoted to ensuring that American taxpayers get the full benefit of their investment in NIH: the very best science conducted in the most ethical way that leads to improvements in health for them and their families.

Thank you, and I look forward to your questions.

[The prepared statement of Dr. Tabak appears in the appendix.]

The CHAIRMAN. Mr. Hollie?

STATEMENT OF LESLIE W. HOLLIE, CHIEF OF INVESTIGATIVE OPERATIONS, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Mr. HOLLIE. Good morning, Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee. I am Les Hollie, Chief of Investigative Operations with the Department of Health and Human Services Office of Inspector General.

I appreciate the opportunity to appear before you to discuss how OIG is working in conjunction with our HHS and law enforcement partners to protect taxpayer-funded medical research. Today I will cover how OIG enhances the Federal Government's ability to detect, deter, and take enforcement action to ensure integrity of taxpayer-funded medical research against foreign threats.

The National Institutes of Health have recently referred to OIG for investigation 16 allegations of noncompliance with its terms and conditions for receiving a medical research grant. The allegations primarily deal with the failure of principal investigators to disclose foreign government affiliations. These referrals are still active. To avoid compromising ongoing investigations, I cannot pro-

vide further details at this time. However, I can cover how we generally handle grant fraud allegations.

Although the foreign threat to research is a high-profile, complex issue, the cases under our purview all involve aspects of grant fraud, a subject which OIG has extensive experience investigating.

HHS is the largest grant-making organization and third largest contracting agency in the Federal Government. Given this nexus, OIG has made oversight and enforcement of grant and grant-related program integrity a priority. We take a two-pronged approach to preventing and acting against grant fraud.

First, OIG works collaboratively to mitigate grant fraud through efforts to minimize vulnerabilities, including audits, evaluations, and proactive training.

Second, we investigate allegations of criminal misconduct and make appropriate referrals for criminal, civil, and administrative action. OIG receives allegations of grant fraud or uncovers potential grant fraud in a variety of ways, including OIG hotline complaints, referrals from HHS operating divisions, law enforcement partners, whistleblower disclosures, and proactive data analysis.

Upon receiving an allegation pertaining to grant fraud involving NIH or another HHS operating division, OIG evaluates the allegation and determines whether we will open an investigation, refer the matter to another agency with appropriate authorities, or, when appropriate, refer the matter back to the HHS operating division involved for administrative review and potential action.

When OIG identifies a violation of civil or criminal law during an investigation, OIG presents the facts to the Department of Justice for consideration. To protect the integrity of medical research, OIG coordinates with the HHS Office of National Security and works together on matters with the FBI and the Department of Homeland Security when appropriate.

OIG also works collaboratively with stakeholders to increase their ability to prevent and detect grant fraud through proactive training. OIG increases HHS employee, contractor, and grantee awareness of how to identify and report allegations pertaining to grant fraud, including foreign threats, through training and presentations.

For instance, OIG has provided numerous grant fraud training sessions at the NIH regional seminars and town hall meetings. To educate grant recipient organizations, OIG has partnered with several academic entities to address best practices to ensure research integrity officers and compliance officers are informed on the roles, responsibilities, and authorities of OIG.

OIG also conducts oversight of NIH through audits and evaluations. Utilizing the \$5 million in fiscal year 2019 appropriations we received for oversight of grant programs and operations of NIH, we have ongoing work looking into NIH's cybersecurity, pre-award processes, and peer review procedures and controls.

In conclusion, OIG is committed to working collaboratively to address foreign threats to taxpayer-funded medical research through preventive efforts to mitigate risk and minimize vulnerabilities in HHS programs and conduct enforcement actions whenever necessary.

Thank you for your ongoing leadership in this area and for affording me the opportunity to discuss this important topic with you.

[The prepared statement of Mr. Hollie appears in the appendix.]
The CHAIRMAN. Thank you as well. Now, Mr. Rodi?

STATEMENT OF LOUIS A. RODI III, DEPUTY ASSISTANT DIRECTOR, NATIONAL SECURITY INVESTIGATIONS DIVISION, IMMIGRATION AND CUSTOMS ENFORCEMENT, DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Mr. RODI. Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to discuss the role U.S. Immigration and Customs Enforcement's Homeland Security Investigations (HSI) plays in addressing foreign threats to taxpayer-funded research.

The threat posed by nation-states illegally or subversively seeking to exploit legitimate educational research opportunities in the United States is evolving. HSI is well-positioned to mitigate this threat through the programs I will highlight today, all of which provide a multi-layered level of security aimed at protecting the homeland from illicit transnational activities of its adversaries.

Each year, thousands of foreign nationals seek visas to travel to the United States to pursue educational degrees or conduct research, and thousands more are already present in the United States engaged in such activity. While openness in international collaboration in academia and research is important, it can also create an environment that U.S. adversaries exploit as a means to gain access to sensitive technology and information.

The largest number of ongoing HSI Counter-Proliferation Investigations, or CPI, on controlled exports, including intangible exports, involve China, Iran, and Russia. From these investigations, and based on trend analysis, HSI knows that these countries are actively working to illicitly or subversively acquire and transfer export-controlled military and dual-use technology and commodities.

Exploitation of academia and U.S. research institutions is just one of the schemes these countries are employing to obtain access to sensitive research in export-controlled information and technology and facilitate its transfer abroad. Foreign nationals from China, Iran, and Russia represent a sizeable portion of the overall non-immigrant student population currently in the United States. As of May 2019, there are over 350,000 F-1 Chinese students, over 11,000 F-1 Iranians, and over 6,100 F-1 Russians in the United States, many of whom are enrolled in STEM-related programs.

HSI has established a multi-dimensional approach to combat these efforts. HSI's first line of effort is preventative and executed by the HSI-led Visa Security Program, or VSP, through which HSI and interagency partners screen, vet, and investigate potential applicants, including those applying for student or exchange visitor visas, prior to admission into the United States. If sufficient derogatory information is uncovered relating to the intentions of these applicants, HSI, working in conjunction with the Department of State, can recommend refusals of visas on a number of grounds, in-

cluding suspected involvement in the elicit procurement of controlled technology.

HSI also has multiple programs to identify and protect against foreign entities already present in the United States. The Student Exchange Visitor Program, SEVP, fulfills a compliance-centric role and is responsible for monitoring certified educational institutions and the nonimmigrant students they enroll.

SEVP also regularly conducts compliance site visits to schools to ensure that the programs are functioning as reported in SEVIS, the Student and Exchange Visitor Information System. HSI actively identifies and initiates enforcement action on nonimmigrant visa overstay violators who pose a concern for national security, border security, or public safety, and works closely with SEVP and CPI to mitigate risks.

HSI's Counterterrorism and Criminal Exploitation Unit, CTCEU, conducts outreach as well as in-depth analysis on potential school fraud violations, focusing attention on a number of indicators to include schools receiving Federal funding for sensitive research. HSI has also initiated the Domestic Mantis Program, which identifies students who have changed their field of study from a nonsensitive to a sensitive area and evaluates those individuals against risk-based targeting criteria. If students or exchange visitors appear to be involved in efforts to acquire and transfer sensitive information or technology obtained during the course of their research or academic pursuits, HSI's CPI program coordinates an investigative and enforcement response to those activities.

HSI is designated as a primary law enforcement agency for investigating violations of the U.S. export laws. Many of these laws are being circumvented by state actors who are making a concerted effort to take advantage of academic openness in the name of fundamental research to acquire U.S. technology, processes, and other intellectual property. To mitigate this threat, HSI's CPI program has recently taken proactive steps to increase outreach to export control officers and other officials within the academic community, particularly at universities or research institutions with large foreign student populations enrolled in STEM-related programs.

These outreach efforts, conducted in conjunction with SEVP and CTCEU, are designed to raise awareness of the potential proliferation risks posed by students and researchers to help institutions recognize potential instances of elicit procurement, intellectual property theft, or other possible violations of U.S. laws, and to provide a conduit to report any suspicious activities detected by universities or research institutes.

Together these programs form the backbone of HSI's efforts to identify and mitigate the threats posed by foreign entities seeking to exploit legitimate academic and research opportunities within the United States. Enhancements and expansion of these programs, combined with enhanced administrative and criminal enforcement authorities, will only improve HSI's ability to identify and thwart the efforts of foreign actors who pose national security or public safety concerns to the United States.

HSI looks forward to continuing to work with the committee regarding its HSI programs.

[The prepared statement of Mr. Rodi appears in the appendix.]

The CHAIRMAN. Thank you all very much.

My first three questions are to all of you, and I hope I can get a one- or two-word answer from each. So the first one is kind of a “yes” or “no.”

Is the foreign threat to the integrity of taxpayer-funded research real, aggressive, and ongoing? Captain?

Dr. SCHMOYER. Sir, thank you for your question. HHS Office of National Security and the Department in general is concerned about any threats, whether they are foreign or domestic. We spend a very large amount of our resources addressing any of those threats that would be coming in. And so we work very closely with our counterparts across the table, as well as the intelligence community. We use their guidance and their intelligence that they provide us, and address our efforts in that particular fashion.

The CHAIRMAN. You cannot separate foreign, whether foreign is a threat? Because you mixed it up with everything else. I am kind of getting at an answer. I want to know what you think about foreign. Is it a threat to taxpayer-funded research, real, aggressive, and ongoing?

Dr. SCHMOYER. We do appreciate the intelligence that we receive from the intelligence community, as well as our law enforcement partners, which does provide us these particular types of data that allow us to tailor our efforts to those threats that are focused on specific behaviors in the Department. In a more sensitive environment, sir, I am more than happy to go into specifics.

The CHAIRMAN. Thank you. We will do that. Dr. Tabak?

Dr. TABAK. So again, sir, I would concur with my colleague and, in a more sensitive environment, we can go into more detail.

The CHAIRMAN. Okay; let us go to question number two. Based on your experience, which country is the greatest threat to the integrity of taxpayer-funded research?

Dr. SCHMOYER. Thank you for your question, sir. Again, in a more sensitive environment—thank you, sir.

The CHAIRMAN. Thank you. Let us go to a whole different subject, then. According to the NIH, it operates the intramural program and the extramural program for research activities. Within the intramural program—this is for Dr. Tabak—NIH employees, contractors, affiliates who are U.S. citizens undergo background investigations. Further, prior to that background check, a special agency check is conducted requiring fingerprints to be cross-checked with the FBI criminal database, including the terrorist watch list.

According to NIH, in the extramural program, a grantee institution such as a university is responsible for any vetting, not your agency.

So the first question to you: NIH has said U.S. citizens in the intramural program are subject to background checks. Do foreign nationals working in the NIH intramural program undergo the same screening as U.S. citizens?

Dr. TABAK. Yes, sir, they do.

The CHAIRMAN. Okay. Also to you, with respect to the extramural program, more than 8 dollars out of 10 appropriated to the NIH go to this program. Does NIH conduct background checks, including a

review for counterintelligence purposes, on principal investigators prior to awarding a grantee institution taxpayer money?

Dr. TABAK. No, sir, we do not, as they are employees of their home institutions.

The CHAIRMAN. Okay. According to HHS OIG, NIH has recently referred for investigation 16 allegations of noncompliance related to medical research. The IG stated the allegations primarily deal with the failure of principal researchers to disclose foreign government affiliations.

So again to you, how is NIH discovering these cases for referral? And is NIH doing its own review? Or are the research institutions fighting potential problems for your agency?

Dr. TABAK. We flag these in various ways. Our own staff uses algorithms to detect potential untoward behavior. We also receive referrals from our colleagues at HHS and the FBI. And increasingly universities, as they become more and more aware of the issue, are alerting us to potential issues as well.

The CHAIRMAN. Then finally for you, but you will have to do it in writing, because I do not think you are prepared to do this now. Would you provide us in writing to the committee a specific breakdown of how each referral originated, whether by NIH or a research institution?

Dr. TABAK. We would provide that for the record, but it would have to go in concert with the IG. We have already made those referrals, and they are ongoing investigations.

The CHAIRMAN. Okay; thank you.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman. I was just looking at my friend, Senator Cornyn. The two of us are on the Intelligence Committee, and so we have watched you all try to respond to Chairman Grassley's questions, his always good questions.

Let me, if I could, kind of see if—because we are not going to be able to ask some important questions in a classified session in a way that the American people are going to actually learn something about the important questions being raised here. So I am going to see if I can tease out some answers to these issues that also are sensitive to what Senator Cornyn and I know are classified matters of what are called sources and methods.

At page 3 of your testimony, Dr. Tabak—and you are at NIH, a crown jewel for health-care research—you say: “A few foreign governments have initiated systematic programs to in effect capitalize on research and unduly influence U.S.-based researchers.”

What is “a few”? Are we talking about three? Are we talking about seven? How many are we talking about? That is not something that compromises sources and methods or American security.

Dr. TABAK. Again, sir, I think that is best discussed in a more sensitive environment.

Senator WYDEN. Senator Cornyn and I deal with classified materials. I mean, giving a range of the number of countries is not something that would damage American security. So three? Seven? Five? How many?

Dr. TABAK. Sir, again I think that is just something that we should discuss in a more sensitive—

Senator WYDEN. I do not share your view. Then you say that these foreign governments unduly influence U.S.-based researchers. How do they do that?

Dr. TABAK. So this is done in a variety of ways, sir. They provide financial remuneration to individuals. In some instances these individuals have signed contracts which require them to spend a certain percent of their time in a foreign government, in a foreign country. They might set up a laboratory in that situation.

In other instances, they expect that the individual will share with that government grant applications, which obviously is a theft of intellectual capital. And in some instances, because they are interested in recruiting additional individuals to this process, they will set up cabals, if you will, in peer review to have sort of a quid pro quo.

Senator WYDEN. Okay. In the area of genomic research, you all did not agree with the HHS Inspector General's recommendations to develop a new kind of security framework. I gather that you felt that existing procedures are adequate to address the concerns that were raised by the Inspector General. Is that true? Do you by and large think that existing procedures are adequate to address those issues that you just described to me are problems?

Dr. TABAK. Sir, it is important to note that the OIG report was on genomic data sharing specifically.

Senator WYDEN. Let's talk about that. Do you think the existing procedures are adequate there?

Dr. TABAK. We continue to work on these to enhance them. The main reason for our nonconcurrence on that report, sir, was the specific indication that by sharing genomic data, human genomic data, we were putting the Nation at risk. And frankly, sir, that was based on speculation that was unsubstantiated. And I will quote from the report directly, sir, on page 3 of that report, and I quote: "We have not performed audit work to verify the FBI's conclusions."

Senator WYDEN. Okay. Let me ask you one other question, if I might, because again—and I do not want to be deliberately obstreperous, but the American people want answers in open session to these kinds of issues in a way that does not compromise, as Senator Cornyn and I know, sources and methods and classified information.

Tell us, if you would, how prevalent a problem you think this is. In other words, you made that statement at page 3, a few foreign governments have these systematic programs. You outlined some things which certainly strike me as wrong.

But I think, before I wrap up my first round—how serious a problem is this? Tell us that in English so people have a sense of what we are dealing with here.

Dr. TABAK. So the numbers are relatively small, but the problem is important. Thus far, as I indicated in my testimony, we have been working with 61 institutions, and that number changes. That number will undoubtedly increase as we learn more.

Senator WYDEN. Okay. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Now, Senator Cornyn?

Senator CORNYN. Mr. Chairman, thank you for holding this hearing today. Among all the issues that we deal with here in Wash-

ington, DC, and particularly in Congress, this ranks right up there as one of the most urgent and important issues to our economy and our national security. China's aggressive plan to dominate the United States economically, militarily, and technologically includes the willingness to use whatever means are necessary, legal or not, overt or covert, to achieve its goals.

As the FBI has previously told us—and I agree with you, Mr. Chairman, it is a shame that they are not here today, the FBI, because of course they are the primary counterintelligence investigation arm of the Federal Government. No longer are challenges so much as they were in the cold war, spy versus spy. Now we have spy versus nontraditional collectors. And this is what Director Wray of the FBI said in February. He said the use of nontraditional collectors, especially in the academic setting, whether it is professors, scientists, students—we see it in almost every field of office that the FBI has around the country. It is not just in major cities. It is in small ones as well, and it is across basically every discipline. And I think the level of naivete on the part of the academic sector about this creates its own issues.

As a leader of a major research institution in my State told me recently, he said, “We are under attack.” And I think after today those of us in attendance will come to concur with that statement.

Our universities and other research institutions are under threat by both human actors and by the cyber-threat. American institutes of higher education and the agencies that provide billions of dollars in taxpayer dollars to conduct research every year must work together to confront this very real danger.

According to my statistics here, the U.S. Government alone spends about \$120 billion in research and development grants, the private sector, another \$500 billion. And if China or any adversary can simply steal it, obviously that is a huge threat not only to us from a security standpoint but from an economic standpoint. Because China is not—they are not unclear about what their goals are. Their goals are to dominate the United States militarily and economically.

Well, next week I am going to introduce a piece of legislation that I would hope my colleagues would join me in working on called the “Secure Our Research Act.” This will establish an inter-agency working group to develop an agency-wide compliance framework to enhance cybersecurity protocols and protect federally funded research from foreign interference, espionage, and exfiltration.

I simply will not be able to vote in good conscience for any taxpayer dollars to be used for research at public institutions unless these institutions up their game significantly and can give us some confidence that those taxpayer dollars are not only being well spent in research and development, but that that research information is not being stolen right under our nose.

It is high time we address this threat and find solutions to fix the vulnerabilities that exist today. U.S. colleges and universities, I agree with the ranking member, have long been a Mecca for foreign nationals because of the high quality of the education we provide, and the academic and cultural freedoms that exist in our country.

But that same sort of open society and these institutions represent a vulnerability that we can protect against. I think we can continue to be that Mecca for foreign students to study at our colleges and universities and, at the same time, protect the taxpayer and the important scientific research that is generated from these institutions. Because we are in a global competition, whether we like it or not, and it is, to use the words of the FBI Director, naive of any of us to think that it does not exist and that it is not an urgent matter that deserves our attention.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cassidy?

Senator CASSIDY. Mr. Rodi, long before I was in politics, I remember reading about Russian, Soviet scientists coming here, going to our different resources, and they had been trained to memorize, to notice detail. So industrial espionage is not new. I have read about French sitting behind our scientists on airplanes and looking over their shoulder to see the notes that they are reading. So whether that is true or not, it makes a great story, doesn't it?

So this is not new. I am assuming that we have established protocols: these folks are at high risk; these are not. The grad student who is doing finance presumably has less access to patentable research than the one who is doing advanced carbon technology for weaponry sort of thing. Is that a fair statement?

Mr. RODI. Yes, sir.

Senator CASSIDY. So, as Senator Cornyn expresses his concerns, I can imagine the university administrators being a little nervous. How do we isolate the subset of folks we need to be aware of, if we have this many hardworking, very talented, bright students, but most of them in fields where really you could steal it, but who cares, as opposed to the few who are a concern? Do we have a mechanism that allows that university administrator to begin to make a judgment as to whom they should have under closer watch, and those whom you can kind of not spend your scarce resources on?

Mr. RODI. Yes, sir. That is the whole purpose of our outreach program. Our Project Shield America, it is our Counter-Proliferation Investigation's outreach program. We have a certain subset Project Shield America for Academia to meet with academia and address these issues, to inform them of some of the threats and the concerns that are out there, what to look for. What are the proliferation concerns of the United States? What should they be looking for? What should they not be sharing with foreign students, and the like? So, yes, we have a very robust outreach program to address these issues.

Senator CASSIDY. Dr. Tabak, I am a physician. I am a liver doctor, and I remember there was a pathologist I worked with, a very talented young man, and this was years ago, 30 years ago, and he just took a job back in Hong Kong, or Taiwan, or maybe the mainland, probably Hong Kong or Taiwan at the time, and he was just a talented doc. He had done research, all clinically oriented, and he just got a great job offer.

Now in one sense I can see that could be seen as a threat, because he was very involved in research, but in reality it was just

a great job offer. How do we differentiate that from systematic espionage?

Dr. TABAK. Senator, that is a success story. Unless the individual is not playing by the rules and tries to divert work that was supported by the U.S. Government to a foreign—

Senator CASSIDY. Now let me ask, because some of that work is now in his neurons. And so wherever he goes, he is influenced by the fact that he has learned—at the time, PCR was cutting-edge technology. So he is familiar with the implications of PCR. We cannot erase his neurons. So again, how do we differentiate that which is just organic and that which is espionage?

Dr. TABAK. So again, what you described in the former case is how science advances, building upon building. In the latter case, people diverting things inappropriately for untoward purposes, that can be espionage.

Senator CASSIDY. Now, I accept that. So is the bright line here, okay, I am going to put in a thumb drive and download a lot of material and try to sneak it across, or send it over on my gmail account as opposed to my official account, is that the bright line versus, I just know this because I have been working very hard in the lab in 18-hour days and now, wherever I go, I am going to bring that body of knowledge?

Dr. TABAK. How that knowledge is transferred can make a difference, sir, yes.

Senator CASSIDY. So it can make a difference—no offense, but a little bit of a wiggle word. I am actually looking for some guidance for those university administrators.

So I learned it. It is in my brain. It may be in my notes, because I kept notes as I did experiments. That is okay. Downloading on my thumb drive and/or otherwise trying to electronically communicate or bring huge stacks is not okay.

Dr. TABAK. As you know, sir, that information that is gathered while you are employed by the university supported by U.S. Government grants is the property of the university, not the individual. So they would have to have that conversation as to what is being taken and not taken.

Senator CASSIDY. I get that. I can still imagine the—I mean, because classically the post-doc who is so bright might be a Chinese national, but he might be employing Chinese nationals because you have a lot of bright kids over here who work so hard. So I am trying to give some guidance to our institutions as to when they should say, “Okay, we need to vigilant.” Captain, did you have something to say to that? May I go over a little bit, Mr. Chairman? I am over my time. Can I have a minute more?

The CHAIRMAN. Yes.

Senator CASSIDY. Okay, Captain.

Dr. SCHMOYER. Yes, sir. I had mentioned in my remarks that we are excited to be working with the National Institutes of Health and a variety of our law enforcement partners on some efforts to address the work that we are doing with institutes of higher education.

A specific element of that work, sir, is looking at these particular factors that are out there, being able to look at what type of methodology that individuals are using, looking at lessons learned that

we use with NIH as well as the other parts of our department to determine, when you are addressing these types of issues, these are the things to look for. Being able to train those institutes to be able to look at those particular factors is critical for their success in being able to prevent them.

Senator CASSIDY. So we have guidelines that we can give the university that they follow—or at least they are doing due diligence?

Dr. SCHMOYER. Yes, sir. We have these guidelines that we use within the Department. We have these guidelines that we have done in conjunction with the NCSC as well as FBI. Our goal over the next couple of months is to be able to continue those activities to expand that educational process to our funded partners.

Senator CASSIDY. Thank you all.

The CHAIRMAN. Let's see. Senator Whitehouse, if you are ready. You are not ready. [Laughter.]

I have one question of Mr. Rodi. The focus of our hearing today is on the theft of our research and intellectual property by China and others. What other countries or governments are you concerned about that are exploiting loopholes in our immigration system to further that theft? And could you give some specific examples of the exploitation?

Mr. RODI. Yes, sir. Well the top three, as I have stated, are China, Iran, and Russia, but there are other countries of concern as well. We look at the empirical data of the investigations that are being conducted by our counter-proliferation investigations unit. Other countries of concern include India and Pakistan. There are other countries as well.

And I have some specific examples that I will give later today in the classified setting, but just off the top of my head, a really good example that I like to highlight is someone who is coming here from Iran to study civil engineering. And as we delve deeper into what the person is here actually studying, we learn that they are here to study about concrete, and the effects of concrete, and the uses of concrete. Well, we all know that Iran is building tunnels to hide their nuclear program, their nuclear missile launching pads, their entire nuclear program. So when we are looking into an Iranian student who is here to learn applied techniques of concrete, that is of concern to me and to my agency, the fact that they are using that technology to build these bunkers. And there are other examples as well.

The Iranian students who come here to study welding. And then as we dig deeper into their theses and their dissertations, what type of welding are they actually looking at? And you look at, well, they are looking at learning how to weld titanium, titanium for air frames. Well, we gave the Iranians their air force back in the 1970s, and those planes are falling apart now because they cannot get spare parts. But they are coming here to learn how to fix those planes by learning welding techniques to salvage the planes that they do have.

The CHAIRMAN. Senator Whitehouse?

Senator WHITEHOUSE. Thank you very much, Mr. Chairman.

Probably this is a question more for Homeland Security, but I will take an answer from anyone, and that is: have you seen any efforts to try to obscure the true identity of a foreign country or in-

terest in this effort to expropriate American scientific research or talent to a foreign country, along the lines of shell corporations, or any devices for masking real identities? Or is it just, students come here, study things, go home?

Mr. RODI. I do not have any specific examples to address that specific question. We are focused mainly on students, what they are here to study, and what we can do to address that threat.

Senator WHITEHOUSE. So it is basically, students come here, study, go home? That is the plot that you are looking for?

Mr. RODI. Yes, sir.

Senator WHITEHOUSE. Okay. If anybody else has anything to add, you are welcome to. If not, I would just like to make it a question for the record, if you could check with your staffs and see if, in your experience in dealing with this concern, whether or not you have seen any efforts to try to mask or conceal identities in any way, or whether it really is just as simple as student comes, student studies, student goes home. Okay?

Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Okay. Thank you. Senator Carper?

Senator CARPER. Thanks, Mr. Chairman. Welcome one and all. As you know, there is a lot going on on Capitol Hill today. We are glad you could visit with us and spend at least a short time with us.

Early in my life I was a naval flight officer, 5 years active duty, three tours in the Vietnam War, and top secret clearances, and I understand the need to protect that which is sensitive. And it sounds like we have been asking some questions and you are unable to discuss the answers to some of those questions in a setting like this. We understand that. I understand we may have the opportunity to meet some of you in a classified setting in the SCIF later today, and hopefully we can more fully question you on some of these issues.

In the meantime, I want to steer away from things we should not be talking about in an open setting and see what we can talk about in this open setting that would be informative to our committee and informative to the people we represent across this Nation.

I will start with Mr. Hollie. Hi, Mr. Hollie. Where are you from?

Mr. HOLLIE. Originally from Texas.

Senator CARPER. Okay. I used to be stationed at Corpus Christi Naval Air Station. It is nice to see you.

Mr. Hollie, you note in the cases that your office has looked into, they all involve grant fraud. And I just want to know, are there certain things that you would recommend that the NIH and other grant-making agencies look for to spot instances where a foreign actor might be trying to take advantage of a Federal research grant program? And are there best practices in grant management that you would direct agencies to turn to to get some assistance and guidance? A two-part question, please.

Mr. HOLLIE. Thank you for your question, sir.

Senator CARPER. You are welcome. Mr. Chairman, do you know what I love? I love hearings where all the witnesses say "thank you for your question." [Laughter.]

And do you know what I say when they say that? "You're welcome."

Mr. HOLLIE. Speaking not on topic today, but with regards to grant fraud as a general topic, we see the foreign influence as a subset of our general grant fraud portfolio, those best practices. And we are currently engaged with NIH and have been over a number of years, as I expressed in oral testimony. With regards to when we can speak about closed case investigations coming back to the operating divisions and speaking on the vulnerabilities that were discussed, or examined, or observed in the investigation process, we think that is a very important process of closing the loop and educating not only the awarding agency but the sub-grantees as well, about things that we have seen in an investigation after it has been concluded that we could speak on. The educational process, having a proactive training program in place when we are conducting outreach at the various seminars around the country for not only NIH but other operating divisions within the HHS portfolio, is very, very important.

Another area is being there actually to have the grantees and the grant management officials ask, "What can we do best? What are we doing, or what should we be doing?" I think it is very important to be accessible to those individuals, and that has been something that has been very robust within the IG community, because, in law enforcement generally speaking, not only within HHS and OIG as law enforcement arms, there is a level of anxiety with regards to individuals reaching out to law enforcement and speaking openly and freely. And we believe in the principles of, you know—we do think of those areas, and reducing those anxieties, so those engagements give us the opportunity to be accessible.

We have one-on-one sessions with individuals—

Senator CARPER. I am going to ask you to hold it right there. That is good. That is great. Let me just ask the others. I am not going to ask you to say "yes" or "no," but do any of you agree with anything that he has just said? Raise your hand if you do.

[Hands are raised.]

Senator CARPER. All right, let the record show that everybody except Mr. Rodie agreed. Is there anybody who agrees with everything that he has just said? Raise your hand.

[Hand raised.]

Senator CARPER. Let the record show that one witness has raised two hands. [Laughter.]

Okay, fair enough. Here is my second question. My second question is for the retired Navy Captain, Dr. Tabak, and Mr. Hollie.

What role does poor information security and failure to protect sensitive information produced through Federal research play here? Is there more that NIH and grant recipients need to do to protect their work? Is there more that the Congress can do to empower you to protect the work that is being done? So, Captain?

Dr. SCHMOYER. Thank you, sir. A couple of things. Number one, we are very grateful for the resources that we have for our small office to be able to address a very large need within the Department, as well as the overall Federal Government.

When we look at this particular challenge, we are making fantastic strides as far as being able to balance both security as well as science. And the work that we have been doing in conjunction

with NIH as well as the other elements of the Department could not be done unless that balance was there.

I think as we continue to go forward, we would continue to also be interested to speak with you, as well as your staff, to be able to provide technical assistance as you are looking at potential legislation or other areas and how they might affect any organization like the Department of Health and Human Services and our mission to be able to preserve national security efforts.

Senator CARPER. I know, Mr. Chairman, I am over time. Can we ask these other two witnesses to just briefly respond to my question, please?

The CHAIRMAN. Yes.

Senator CARPER. Thanks. All right, Dr. Tabak, same question.

Dr. TABAK. So we work very closely with our colleagues at HHS. The oversight that Mr. Hollie spoke to makes us better, points out things that we can enhance and improve.

In turn, we reach out to our grantee organizations to make sure that what they are doing at the local level is as robust as possible. So it is a partnership, sir.

Senator CARPER. Good. Thank you. Very briefly, Mr. Hollie, same question, please.

Mr. HOLLIE. Yes, sir. We are currently engaged in work in Audit and Evaluation Division to look at internal controls at the NIH. I would like to get back with the committee when that work is mature and completed to speak on it with a level of specificity.

Senator CARPER. Good. Thank you, Mr. Chairman. Senator Portman, who is not able to be here with us today, he and I are the senior Republican and senior Democrat on the Senate Permanent Committee on Investigations, and he and I both sent a letter to Secretary Azar on May 17th for information on foreign efforts to exploit NIH-funded research. We have asked to have a response by, I think July 7th. It looks like it is going to be delayed. When we get to July 7th, what I want to ask is—this is for the DHS people, Health and Human Services people—I am going to ask, if we do not have an answer to the letter by July 7th, I want, for him and for me, I want you to give us a date by which we will have a response to our question. Thank you, Mr. Chairman, for your generosity.

The CHAIRMAN. I was told Senator Daines is coming, and if he comes in, we will go to him. In the meantime, Mr. Hollie, where do the 16 referrals from NIH currently stand? Were any investigations opened or matters referred to other agencies such as the FBI? And you should be able to answer to at least what agencies they were referred to.

Mr. HOLLIE. Mr. Chairman, I refer you back to my oral testimony. We have the 16 referrals. They are currently in our portfolio. I cannot make any comments beyond that.

The CHAIRMAN. Okay.

Senator WYDEN. Mr. Chairman, before we go to Senator Daines, could I just ask unanimous consent to put a statement from the Association of American Universities into the record?

The CHAIRMAN. Yes, without objection.

[The statement appears in the appendix on page 74.]

The CHAIRMAN. Okay. Senator Daines?

Senator DAINES. Thank you, Mr. Chairman, Ranking Member Wyden. Chairman Grassley, I want to thank you for holding this hearing. I want to thank the witnesses for coming before this committee to help us address threats to taxpayer-funded research.

As someone who personally spent over 5 years living and working in China—we were expats in Guangzhou; I was working for Proctor & Gamble. In fact, I had two children born in Hong Kong during that time. I have led multiple codels to visit China and its neighbors over the past 4 years. I have seen the rapid rise of the Chinese economy and seen the progress they have made.

When I first went to China in 1991, it was a \$500-billion economy. Today, depending on whose numbers you believe, it is somewhere probably north of \$13 trillion in GDP. Unfortunately, a lot of the progress that has been made has been made through illegal acquisition of intellectual property from United States companies. We need to ensure this valuable information is not just protected for DoD, but for other critical areas including biotech and health services.

Over the past 5 years, the State of Montana has received nearly \$300 million worth of grants from the Department of Health and Human Services. It is critical that we ensure that the valuable work being performed by Montanans is directly benefiting the United States and not China.

Dr. Tabak, as the title of this hearing suggests, there are real concerns that China is seeking to steal research funded by American taxpayers. And with the improvement that China has proposed to its intellectual property system for new medicines, a part of “Made in China 2025,” the country could be in a strong position to commercialize that research.

What do we need to do to ensure that American researchers, American inventors, remain competitive and that intellectual property is protected?

Dr. TABAK. It starts with making people aware of the problem. Our grantee institutions are increasingly partnering with us to ensure that their faculty, the researchers that receive our grants, are appropriately indicating all levels of support, regardless of where it is from—all commitments to institutions if they are outside of the one that they work at—and are serious about maintaining the integrity of the peer review process.

And if institutions ensure those three things, that will go a long way in protecting the NIH equities that you are speaking to.

Senator DAINES. So, Dr. Tabak, a follow-up question. China appears to have taken some important steps to open up its pharmaceutical markets by reforming its industry to better align with international drug standards and reducing some tariffs on imported drugs. However, when you look at the “Made in China 2025,” it is pretty clear that China’s goal is not to build an open market, but to build its own domestic industry. What actions are being taken to ensure that China is not reverse-engineering these technologies and, frankly, stealing intellectual property?

Dr. TABAK. Well again, sir, it is the diligence that we all have to have to ensure that that which is supported by U.S. taxpayer money not be bled off into foreign countries. That which is in the open market, obviously, can be reverse-engineered. You are quite

right. But the nefarious, inappropriate behavior, those are things that we have to detect and stop at the earliest possible intervention.

Senator DAINES. Yes. I have a question for you, Captain, here next, but I am a chemical engineer myself. I may be the only one in Congress, actually. Most are smarter than to run for Congress than anyone here. China is graduating eight times more STEM grads right now than we are here in the United States. They are building an innovation ecosystem that is very, very powerful. And I think the rate of the acceleration in their innovation ecosystem is something that we are underestimating, in my opinion, here in the United States. I think of it as a competitive threat short-term and long-term here in the U.S.

I want to shift to Captain Schmoeyer. The Chinese Government is active in gaining access to health-care and genomic data on U.S. persons, which not only allows them to drive new discoveries by analyzing large data sets but also creates risk of blackmail and potential exploitation.

What steps is your department taking to ensure the protection of Americans' health records from the Chinese Government?

Dr. SCHMOYER. Sir, we looked at that mission in a couple of different ways. Number one, we are a very active partner in the CFIUS process. And so HHS over the last year has had several dozen CFIUS cases that we have been involved in that have been looking at foreign acquisitions in general to be able to determine whether or not there is a potential risk to national security. It is a huge area of involvement that our office has in our portfolio.

Secondly, looking at the overall importance, as I think the panel had mentioned earlier on, of education. Being able to let people know that there needs to be that balance again between science, research and development, and security. Being able to work with the NIH faculty members, as well as the rest of the parts of the Department, to be able to educate their subject matter experts on the need to be aware of how those challenges created by the work they may be doing, while it seems innocuous, maybe very benign, can actually potentially threaten national security.

So that education is really the second part.

And then the third part, sir, is our interagency collaboration with the intelligence community, as well as Federal law enforcement, to be able to determine whether or not there are potential risks in those areas to our department and the overall biomedical research field.

Senator WYDEN. Senator Daines, I feel badly. We are just in the middle of a vote, and I want to get Senator Cantwell in—

Senator DAINES. Yes, thank you.

Senator WYDEN. Senator Cantwell?

Senator CANTWELL. Mr. Chairman, thank you very much for this important hearing. What I would like to focus on—obviously we have a lot of research institutions in the State of Washington—is how the Federal agencies are working with those local counterparts on threat assessment. I am not sure that we are painting a broad enough picture if we are not sharing actual threat assessment information with them.

So is the White House Office of Science and Technology, or some other body, coordinating this policy area? And what can we do to make sure there is a comprehensive approach to that, particularly when it is Federal research and development? So, anybody on the panel. Yes, go ahead.

Dr. SCHMOYER. Ma'am, we do work very closely with the National Security Council on those particular matters, looking at the overall impact as far as the broader Nation. In addition, we work very closely with our Federal law enforcement partners. Their regional offices are engaging, for example, with institutes of higher education and corporate partners that are in those areas.

A third important partner for us is the work that we do with Homeland Security. And so we are very delighted that we actually have a liaison that sits over in Mr. Rodi's area, so we can make sure that the information that they are getting is getting sent to the Department as well.

Senator CANTWELL. Yes?

Dr. TABAK. If I may add, the NIH Director in August 2018 sent out a "Dear Colleague" letter to every one of our grantee institutions to alert them to this issue. And we have been working very closely with the professional organizations, APLU and AAMC and so forth, to ensure that their membership is increasingly aware. And again, in partnership with my colleagues here, we are doing more and more outreach to university communities to make sure that they understand these issues.

Senator CANTWELL. Since we are involved in this on a broad scale with cybersecurity issues, one of the things that we constantly face is ever-changing landscape and tactics that people are using. So I am more interested in what is the—instead of the "Dear Colleague" letter, what is the ongoing infrastructure for threat assessment? That is what I would like to know. And if we have one, that is good to know. If we do not have one, what can we do to create one?

Dr. SCHMOYER. Ma'am, a couple of quick things. Number one would be mentioning—I had earlier—the developing program in conjunction with NIH as well as our OIG partners, looking at working with institutes of higher education, especially those that are specifically funded by NIH, is a huge part of that.

Secondly, in the afternoon briefing I will be able to provide you specific details on what we are doing and how we are doing it.

Senator CANTWELL. Okay; so you are the ongoing coordinating entity?

Dr. SCHMOYER. So we work with a variety of different partners. The primary one at the larger level is the National Security Council. At other levels, the National Counterintelligence and Security Center in conjunction with the FBI is a coordinating part. And then when it comes to NIH-funded partners, we are the coordinating element in that body.

Senator CANTWELL. So, Senator Wyden and our colleagues here, for the utility sector there are organizations that play this role in coordinating with everybody, so I would hope that we would figure out some formal way to make sure that these institutions are working on this collaboratively with us. But I think we have to give them some ongoing information. In the utility sector, NERC plays

that role. And so they continue to monitor and feed that information. Because a lot of our utilities are hacked on a daily basis by state actors. So we just have to up our game here, and so I appreciate working with all of you on how we do that to communicate to the local entities about what is happening.

Thank you, Mr. Chairman.

Senator WYDEN. Thank you, Senator Cantwell and colleagues. I very much share Senator Cantwell's view. I am kind of calling some audibles here because we have some votes.

Senator Cornyn is going to ask some things briefly, and then I am going to see if I can start the next process with the chairman coming back. Senator Cornyn?

Senator CORNYN. Dr. Tabak, is there a gold standard by which an institution, a research institution, can be certified by either a professional association or by the Federal Government to have met certain minimum standards to protect the integrity of their data and their research?

Dr. TABAK. Part of the terms and conditions for all of our awards—there are standards that every institution needs to meet and attest to. And if they fail to meet those standards, then they are put under a more careful watch.

Senator CORNYN. Because it strikes me that once the cat is out of the bag, it is pretty hard to get it back in. I am familiar with—and this is my last point. The Defense Security Service issues recognitions—for example they had a ceremony for Texas A&M that got a Defense Security Service Award for Excellence in Counter-intelligence, which is the highest honor given by the DoD to defense contractors who demonstrate extraordinary results in enhancing national security.

What I am looking for is, is there some standard Congress could set or we could recognize so everybody would know sort of how they need to up their game in order to keep this information safe? That is my last question.

Dr. SCHMOYER. Yes, we would work with you on that, sir.

Senator CORNYN. That is a great answer.

Senator WYDEN. Senator Cornyn quits while he is ahead.

What we are going to do now is, we will excuse all of you gentlemen. Thank you, and I believe we are going to see you a bit later. So we will excuse you at this time.

I would like to have Dr. Joe W. Gray come forward. He is an Oregonian. We are delighted to have him from the Oregon Health Sciences Center. And I want to just describe what will happen now. There are only a couple of minutes left in the vote.

Dr. Gray is a distinguished professor and chair of the Department of Biomedical Engineering, director of the Center for Spatial Systems Biomedicine, associate director for biophysical oncology at the Knight Cancer Institute at OHSU, and he is also a principal investigator on some important projects at the NCI Center for Cancer Systems Biology. He works at the NIH Library of Integrated Network-Based Cellular Signature Center, the NCI Human Tumor Atlas Network Research Center, and is co-director of the Serial Measurement of Molecular and Architectural Responses to Therapy.

That is a mouthful, but in plain English, Dr. Gray is a very distinguished scientist, and he is from my home State. We are delighted to have him.

I am going to be juggling not just the vote, but also I have a meeting coming up. Chairman Grassley will be coming back. And I would just like for the record, Dr. Gray—apropos of what we talked about—I am going to give you some questions in writing. I hope you will also talk with Chairman Grassley about the points behind these questions, because I think you made an important case with respect to the essential value of foreign researchers to the enterprises you are involved with.

I think you have made a critical point with respect to the role of foreign researchers in developing U.S. patents and intellectual property, and have also had important comments about the very damaging consequences of the Trump NIH budget cuts.

So I am going to ask you to respond to those questions in writing for all issues that you and I have talked about. I hope you will discuss them with the chairman when he comes back, and we will make your remarks part of the record in their entirety.

I am going to run and vote, and Chairman Grassley will be coming right back after the vote. So, thank you for your patience. I am sorry that it is bedlam, even by traditional Senate bedlam standards, and we will stand in a brief break at this time until the chairman comes back. We will have those questions for the record, and I hope you will highlight those important points with the chairman as well. We will be taking a quick break. The chairman will be back in just a couple of minutes.

[The questions appear in the appendix.]

The CHAIRMAN. Before you give your testimony, I want to apologize. For people like you who travel as far as you did to do this, and then to get in an environment where we have four votes, and I am probably going to be the only one to hear you and the only one to ask questions, it is very rude of us. But I do not know what we can do about it, because we do not run the Senate floor, we just run this committee.

You have been introduced by Senator Wyden, so would you proceed with your testimony, please, and then I will have some questions. And I imagine I am the only one who is going to ask you any questions, but you may get questions in writing from some of us.

STATEMENT OF JOE W. GRAY, Ph.D., GORDON MOORE CHAIR OF BIOMEDICAL ENGINEERING; AND ASSOCIATE DIRECTOR FOR BIOPHYSICAL ONCOLOGY, KNIGHT CANCER INSTITUTE, OREGON HEALTH AND SCIENCE UNIVERSITY, PORTLAND, OR

Dr. GRAY. Senator Grassley, I appreciate the invitation from you and Senator Wyden and the other members for the opportunity to present my views as an academic scientist on the foreign threats to taxpayer-funded research.

My formal training is in engineering and physics, but I have spent the last 40 years of my research career doing biomedical research, basically working to improve the detection and treatment of cancers and other diseases. I began my career at the Lawrence Livermore National Laboratory, where I held a top secret clear-

ance. I then moved to positions at the University of California San Francisco, Lawrence Berkeley National Laboratory, and now Oregon Health and Sciences University. And I participated in several large international research programs, including the Human Genome and the Cancer Genome Atlas projects.

During the course of my career, I have co-authored almost 500 papers, and I am co-inventor on 80 U.S. patents. It is important to note that foreign nationals made key contributions to many of these, including inventions that were successfully commercialized by U.S. companies.

As a consequence of my employment at the Lawrence Livermore National Lab, I am well aware of the need to protect information that is of strategic importance to the United States. I am also aware of the constraints that strict control of information imposes on scientific exchange, innovation, and biomedical translation.

During my time at Livermore, the entry and movement of foreign nationals within the laboratory was strictly controlled, as were my trips to foreign meetings and my exchanges with individuals there. I certainly consider my time at Livermore to have been scientifically productive. Indeed, several inventions that have been successfully commercialized by U.S. companies were initiated at Livermore, so innovation can and does occur in controlled environments. However, the full development and exploitation of these inventions required national and international interactions that would have been difficult in the constrained Livermore environment. Moreover, the cost in money, time, and efficiency of research in that controlled environment was extraordinarily high. My move from Livermore to the University of California-San Francisco was motivated in part by my desire to escape those constraints.

Innovation drives scientific and economic growth, and I am a strong proponent of the idea put forth by Steven Johnson in his book "Where Good Ideas Come From" that innovation results from planned and unplanned interactions between individuals, and that the level of innovation increases with the number and diversity of those interactions. Foreign nationals bring different educational backgrounds, new skill sets, new ways of thinking, and access to new resources and technologies. Their participation in U.S. research programs increases intellectual diversity and, in so doing, increases innovation. We run the risk of stifling innovation whenever we impose constraints. Sometimes that is necessary, but I think it needs to be kept to an absolute minimum.

Scientists in the U.S. today face many challenges: uncertain funding, burdensome requirements for reporting, increasing workplace regulations, and keeping up with the daunting flow of new ideas and data that are being generated worldwide. We are successfully dealing with these challenges, but just barely. If additional requirements are put into place that regulate interactions with foreign nationals, the natural tendency of many scientists will be to avoid the interactions. This may significantly diminish innovation within the United States.

Mining the unprecedented amount of rich data that are now being generated worldwide is especially challenging. It is impossible to anticipate at this point how these data might be most effec-

tively used for societal and economic benefit. We rely heavily on the international community for help in that.

It is equally impossible to anticipate how they might be misused. The controls on data sharing that are now in place do protect against many forms of misuse, and I believe that further efforts to control access to these data will not have a measurable impact on their misuse but might have a significant negative impact on their effective use.

Instead of imposing constraint on interactions, which would be very expensive to implement, I think that we should make it easier to protect our intellectual property, accelerate its transfer to the U.S. private sector, and aggressively protect the intellectual property that we do generate using existing legal and political means.

The best and brightest scientists in the world come to the U.S. to study and work because of our free and open system. I believe that adding constraints will not effectively deter nefarious activities but will diminish innovation, slow the development of solutions to important societal problems, and slow U.S. economic growth.

I think it is very important not to let the transgressions of the few, which are real, inhibit the successes of the many. Thank you.

[The prepared statement of Dr. Gray appears in the appendix.]

The CHAIRMAN. Thank you, and I will have three questions. And then I assume that, with four votes, nobody else is going to come back to ask questions.

We wrote a letter on August 20, 2018, to NIH grantee institutions. NIH called attention to a series of threats posed by foreign entities to the integrity of our biomedical research. In that letter, NIH warned that foreign actors have, quote, “mounted systematic programs to influence NIH researchers and peer reviewers,” end of quote, but may have also worked to divert intellectual property produced by NIH-supported research to other countries and may have contributed resources to NIH-funded researchers in ways that could impact the integrity.

So with that background, Dr. Gray, given the strong evidence presented by the first panel that foreign governments and foreign actors have succeeded in efforts to improperly influence researchers and taxpayer-funded research, would you agree that we need more robust vetting procedures and processes?

Dr. GRAY. I certainly acknowledge that there have been misuses of data and intellectual property. And I do agree that there needs to be vigorous enforcement of laws that punish individuals and countries that participate in that.

The issue of whether or not we should impose additional vetting is a difficult one, because the process of doing this vetting in essence stigmatizes the whole community that is being vetted. And so in doing that, it decreases their enthusiasm for actually coming to the United States to work with us to advance our scientific ideas.

In essence, what I am worried about is that it will diminish our own ability in the United States to innovate. And that is a problem. The United States comprises 5 percent of the population of the world, and we draw the best minds from all of the world. And what we do not want to do is to diminish our brain gain by making it unattractive for those individuals to come to the United States and

work with us to solve our societal problems and to help us form the companies that are really, quite frankly, driving the U.S. economy today.

The CHAIRMAN. My second question may be a little easier for you to answer, and I know the sincerity of your answer. I guess you know where I am coming from. I believe that there needs to be more vetting.

The second question is: have you personally experienced any of those foreign-government efforts?

Dr. GRAY. So I have not personally experienced any efforts on the part of a foreign government, to my knowledge, to illegally acquire any information that I have been in the process of generating. That said, we go out of our way to make genomic and other comparable data available to the world.

And the reason for that is that we are in the very early stages of even beginning to understand how to interpret those data. And it takes the minds of many, many people to come up with the best ways of wringing the knowledge that one can get out of that data, and there are a lot of international efforts in which we participate, actually, that deliberately make the data available and ask the scientific community to help us solve vexing problems.

And one of the things that becomes clear from those efforts is that the wisdom of the crowd is smarter than the wisdom of any individual. And so having more minds think about these complex data sets is actually advantageous to us in trying to solve the problems that we generated the data to solve in the first place.

The CHAIRMAN. The last question. If you found that one of your researchers on a taxpayer-funded project failed to disclose foreign financial contributions, what would you do?

Dr. GRAY. I think that one of the things that is not clear today, to me at least, is the extent to which information needs to be disclosed. The rules on that are changing, and have changed over the last while, and so I think at this point in time the answer would be, I would counsel them on how to do a better job of disclosing the information.

If I thought that the information was being disclosed for some nefarious activity, I think that that would be grounds for termination. But for the most part, people are often not clear about the exact rules about what needs to be disclosed, about the extent to which it needs to be disclosed. And so, until that gets clarified, then I think that we are going to be unable to probably comply with what you would like to see disclosed.

The CHAIRMAN. Okay. I thank you for your testimony and for coming a long distance, and thank you for your research and what you are doing.

The hearing is adjourned.

Dr. GRAY. Thank you for the opportunity.

The CHAIRMAN. You bet.

[Whereupon, at 11:35, a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

Good morning. I'd like to welcome everyone to the Finance Committee's hearing on foreign threats to taxpayer-funded research. Taxpayer-funded research has been integral in keeping American medical, defense, information technology, and many other products at the forefront of the world's market.

Simply said, the United States is the best of the best when it comes to conducting cutting edge medical research. Our scientists push the envelope to make crucial discoveries and better products, whether it be vaccines, or other medical treatments and intellectual property. These projects can produce important breakthroughs for patients and industry—for the United States and the world.

We didn't develop this reputation overnight. We earned it, through the persistent *hard work* and *dedication* of researchers across the country. I'd like to call that a good old-fashioned American work ethic.

I thank them for their service to our country and want them to know that this committee's oversight isn't designed to interfere with the pursuit of knowledge and the free exchange of information in the research field. Rather, this committee's oversight is intended to strengthen the integrity of taxpayer-funded research and to *preserve* our valuable work product.

Truly free collaboration and exchange of information is only possible when data and sources are credible and the research process can be trusted. That trust is destroyed when foreign governments and other entities interfere in our research for their gain and to our detriment. Accordingly, Congress, the executive branch, *and* research institutions, must work together to *properly balance* the robust development and exchange of ideas in the research field with reasonable and proportionate common-sense efforts to protect the integrity of the research.

That's why I've engaged in oversight efforts in this field. Beginning in October of last year, I wrote to the National Institutes of Health, the Department of Health and Human Services, and the Health and Human Services Inspector General about threats to taxpayer-funded research. Since then, I've also written to the National Science Foundation and the Department of Defense.

Today, we will focus on foreign threats to research funded by the National Institutes of Health, its granting process, and downstream grantees. Those threats include spying, theft of intellectual property, disclosure of confidential information, and other related efforts that undermine the integrity of research.

The NIH spends \$39 billion of taxpayer money each year on medical research. *The American people worked hard for that money.* And the people deserve to know how the government is working to protect that research and the resulting intellectual property from foreign threats.

We know that China is by far the most prolific offender; however they aren't the only country acting against our interests. In October 2018, while chairman of the Judiciary Committee, I held a hearing on China's non-traditional espionage against the United States. During that hearing, I broached the issue of China's focus on our research institutions and taxpayer-funded research. Today, we can get into more detail regarding those threats.

It's without dispute that China has focused its energy on leveraging our hard work for their benefit—and to our detriment. One example hits home for me. In 2011, Chinese nationals tried to steal genetically modified corn seeds from Iowa. They tried to ship them back to China. Those seeds were the product of years of research and development. The Chinese Government says they're "picking flowers in foreign lands to make honey in China." I believe them.

Whether we're talking about Confucius Institutes spreading propaganda on college campuses, China's "Talent Programs" that have been called "brain gain" programs, or China planting spies in our industry, the government of China is a serious problem. In 2013, Chinese nationals were charged with conspiring to steal research funded by a multi-million dollar NIH grant for the benefit of a Chinese governmental entity and a direct competitor of the American university where the research was conducted.

In an August 20, 2018, letter to NIH grantee institutions, NIH called attention to a series of threats posed by foreign entities to the integrity of U.S. biomedical research. In that letter, NIH warned that foreign actors have "mounted systematic programs to influence NIH researchers and peer reviewers," may have worked to divert intellectual property produced by NIH-supported research to other countries, and may have contributed resources to NIH-funded researchers in ways which could impact the integrity of the research.

In January of this year, the HHS Inspector General notified me that NIH recently made 12 referrals in this area to the Inspector General. Those referrals primarily involved principal investigators—essentially the primary researchers—on NIH grants conducting medical research at U.S. universities. Those researchers allegedly failed to meet NIH requirements to disclose foreign affiliations on their grant applications. That's a serious problem.

Researchers who are secretly supported by a foreign government while working on U.S. research projects can be more susceptible to the influence and control of the foreign parent. We must know who is financially supporting researchers to better understand whether they might be more dedicated to securing the interests of an adversary than to rigorous scientific and medical advancement.

Our witnesses can speak to those specific threats and the government's capabilities to detect and deter them. Today, we have witnesses from the National Institutes of Health, the Health and Human Services Office of National Security, the Health and Human Services Inspector General, and the Department of Homeland Security.

The FBI was invited by the committee, given that they are a critical aspect to counterintelligence efforts in this field. The committee invited them on April 30th. That's 26 business days before the hearing date. On May 6th, the FBI said it would be "unable to participate" in the hearing but failed to explain why. My staff followed up via email and phone. On May 7th, the FBI reiterated that they would not be able to appear but again failed to explain why. On May 16th, the FBI responded via email and said the "Counterintelligence Division respectfully declines the hearing invite," *yet again* failing to explain why. On May 23rd, I wrote a letter to the FBI again inviting their attendance. On May 29th, the FBI responded in writing and stated that it "does not have a witness available to attend the hearing and briefing."

After just about 1 month of communications between the FBI and my staff, the FBI *failed* at every turn to explain why the entire Counterintelligence Division did not have a single employee available to attend today's hearing. That's inexcusable, and it's a shame. What a wasted opportunity for them to explain to this committee and the American people what they're doing to help these agencies detect and deter threats to our research.

The American people deserve more than a stiff-arm from the FBI. However, I appreciate the cooperation of the expert witnesses who are here today and I look forward to a robust conversation.

Generally speaking, there are four main issues relating to taxpayer-funded research that we will touch on:

1. Failure to Disclose: Some researchers hired to work on U.S. research projects haven't disclosed that they've received financial contributions from foreign countries.

2. Espionage: Some researchers are spies, and their only purpose is to infiltrate taxpayer-funded research projects to steal intellectual property and bring it to their home country.
3. Vetting: The Federal Government doesn't vet all researchers hired by U.S. institutions to work on taxpayer-funded research, and neither do the institutions.
4. Integrity: Some peer reviewers have shared confidential information from grant applications with foreign governments, which would allow them to potentially skip research steps. Some have also attempted to influence funding decisions, undermining the integrity of taxpayer-funded research.

These threats to our research are ongoing, aggressive, and real. The question is, does the government have the capabilities to detect these threats, combat them, and deter them to protect our research and any intellectual property created from it?

Today is an opportunity for the witnesses to engage in a frank discussion about what that threat is and what we in Congress and the executive branch can do together to solve the problem. Congress and the executive branch *must* be on the same page. So, if you believe there are legislative and policy solutions that will assist you with your already difficult jobs, now is the time to bring them forward.

I look forward to a robust discussion today on these matters. After this morning's hearing, the committee will move this afternoon to a classified briefing on the same subject matter. I strongly encourage the witnesses to take advantage of the highly classified environment to provide as much information to the committee as possible.

PREPARED STATEMENT OF JOE W. GRAY, PH.D., GORDON MOORE CHAIR OF BIOMEDICAL ENGINEERING; AND ASSOCIATE DIRECTOR FOR BIOPHYSICAL ONCOLOGY, KNIGHT CANCER INSTITUTE, OREGON HEALTH AND SCIENCE UNIVERSITY

Senator Grassley and members of the committee, thank you for the opportunity to present my views on aspects of foreign threats to taxpayer-funded research. I am the Gordon Moore chair of biomedical engineering and associate director for biophysical oncology in the Knight Cancer Institute at Oregon Health and Science University. My formal training is in engineering and physics, but I have spent my research career of more than 40 years in biomedical research, developing and deploying advanced measurement technologies to elucidate the mechanisms that are important in the development and treatment of cancer and other diseases.

I have participated in aspects of several large-scale international research programs such as the Human Genome Sequencing Project, the NIH Cancer Genome Atlas project, NCI Cancer Systems Biology projects, and the NCI Cancer Moonshot program. All of these projects have benefited from the work of foreign nationals and from robust international data exchange. During the course of my career, I have published nearly 500 papers, and I am a co-inventor on 80 U.S. patents. Importantly, foreign nationals made key contributions to many of these. In fact, scientists from Finland, Canada, Japan, and Russia were co-inventors on some of the most important including several that were successfully commercialized by U.S. companies.

I began my career at the Lawrence Livermore National Laboratory where I held a top-secret security clearance. I then moved to faculty and research positions at the University of California San Francisco, the Lawrence Berkeley National Laboratory and now Oregon Health and Science University.

As a consequence of my employment at the Lawrence Livermore National Laboratory, I am well aware of the need to protect information that is of strategic importance to the United States. I am also aware of the constraints that the strict control of information imposes on scientific exchange, innovation and translation to improved patient outcomes. During my time at Livermore, the entry and movement of foreign nationals within the laboratory was strictly controlled as were my trips to meetings in foreign countries. The administrative and financial cost of these monitoring efforts was substantial.

I certainly consider my time at Livermore to have been scientifically productive. Indeed, several of my most significant inventions that have been successfully commercialized by U.S. companies were initiated at Livermore. So, innovation can and does occur in controlled environments.

However, the full development and exploitation of these inventions required national and international interactions that would have been difficult in the con-

strained Livermore environment. It was also clear that the cost in money, time and efficiency of doing research in this controlled environment was extraordinarily high. In fact, my move from Livermore to the University of California San Francisco was motivated in part by my desire to achieve relief from these controls.

I am a strong proponent of the idea put forth by Steven Johnson in his book, "Where Good Ideas Come From," that innovation results from the integration of ideas and facts that arise through planned and unplanned interactions with other individuals. I also support his contention that the level of innovation increases with the number and diversity of those interactions. We run the risk of stifling innovation whenever we constrain interactions. Sometimes that is necessary but it should be kept to an absolute minimum.

It has been my experience that the way people approach problems is colored strongly by their past experiences and by the nature of their education. It is also my experience that individuals educated in other countries bring different ways of thinking and different facts. Further, these individuals undergo extensive vetting to ensure a high level of education and potential. Thus, I believe that innovative solutions to the complex problems we are trying to solve throughout the biomedical community today will occur most rapidly through the free and open exchange of information and ideas, including with a broad range of foreign nationals.

I believe that scientific innovation is one of the cornerstones of economic growth in the United States. I also believe that regulatory constraints that interfere with the free exchange of information and ideas will substantially decrease our level of innovation and therefore our economic and scientific competitiveness.

Scientists in the United States today face many challenges. These include uncertain funding, burdensome requirements for reporting, increasing workplace regulations and keeping up with the daunting flow of new ideas and data that are being generated worldwide. We are still successfully dealing with these challenges but just barely. Should additional requirements be put in place that regulate interactions with foreign nationals, the natural tendency of many scientists will be to avoid the interactions. I believe that this will significantly diminish innovation within the United States.

It is also important to know that many remarkable measurement tools now being developed around the world are providing an unprecedented amount of rich information about normal and diseased tissues, information that can be mined to yield new insights into disease prevention, detection and treatment. It is impossible to anticipate at this point how these data might be most effectively interpreted. It is equally impossible to anticipate how these data might be misused. The controls on data sharing that are now in place do protect against most forms of data misuse and I believe that efforts to further control access to these data will not have a measurable impact on data misuse but will have a significant negative impact on innovation.

In sum, I believe that the economic strength of the United States depends on innovation and on the speedy implementation and commercialization of innovative ideas. I believe that the controls that are already in place provide a workable balance between protecting data and intellectual property and allowing the free exchange of data and information needed for effective innovation. I believe that additional efforts to control interactions with foreign nationals will decrease innovation and, in so doing, will diminish the economic power of the United States and will have little impact on foreign misappropriation and misuse of information and ideas. Most innovative ideas and data will in any case eventually become available through the published literature and in published patents and so will be available for misuse. Instead of imposing constraints on innovation, which would be very expensive to implement, I advocate for adding supports to make it easier to protect the intellectual property that is generated with taxpayer dollars. I also recommend supporting the rapid and efficient transfer of information from academia to the private sector as well as between researchers worldwide so that maximum benefit can occur from the massive new technological advances and the big data being generated.

There are many barriers now in place to the kinds of technology transfer that will enable us to rapidly exploit academic innovations. I believe that our efforts would be best spent in reducing these barriers. This includes providing support for intellectual property development and substantially increasing support for early-phase business developments. In the end, economic success will come from rapid innovation and development, and aggressive protection of intellectual property using exist-

ing legal and political tools. The misappropriation of data and ideas is serious but should be dealt with through already existing legal and political means and not by placing constraints on the free information and idea exchange on which the U.S. competitive advantage depends.

I believe the best and most intelligent scientists in the world come to the United States to study and work because of our free and open system. Additional constraints will not effectively deter nefarious activities but will diminish innovation and U.S. economic growth. It is very important to not let the transgressions of a few inhibit the successes of the many.

QUESTIONS SUBMITTED FOR THE RECORD TO JOE W. GRAY, PH.D.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Essential Value of Foreign Researchers: Dr. Alicia Carriquiry, president's chair in statistics and distinguished professor at Iowa State University, has stated that "without foreign-born researchers, the entire system of higher education in the United States would collapse in a minute." Do you agree with Dr. Carriquiry's assessment of the importance of foreign-born researchers for U.S. medical science and our system of higher education?

Answer. I do agree with Dr. Carriquiry's assessment. The importance of foreign-born researchers to the United States scientific and health-care enterprise cannot be overstated. Since World War II, the United States has been the most popular destination for science and engineering students who choose to study abroad. Many of these individuals stay in the United States and make their lives here, contributing in profound ways both to society and to the U.S. economy. This openness to immigration has helped make the U.S. a world leader in science and technology. However, short-sighted domestic policy threatens both our research and development system and our economy. Foreign-born entrepreneurs helped start one-fourth of all new U.S. engineering and technology businesses between 1995 and 2005, including Google and eBay. As I stated in my testimony, the best and most intelligent scientists in the world come to the U.S. today to study and work because of our free and open system. Importantly, we keep the best and most impactful here after they complete their training. They serve as a key part of the U.S. "innovation engine" that drives our economy. In my view, additional constraints will not effectively deter nefarious activities but will diminish innovation and U.S. economic growth.

Question. Role of Foreign Researchers in Developing U.S. Patents/Intellectual Property: The most recent data from the U.S. Patent and Trademark Office shows that more than 50 percent of patents granted are held by foreigners—either as the primary inventor or co-inventor. Your own work is described in more than 80 patents. To what extent would that work and those patents have been possible without the aid of foreign researchers and what discoveries might have remained unearthed in the absence of those researchers?

Answer. Foreign researchers were co-inventors and key innovators on approximately half of my issued U.S. patents. The foreign researchers were key to our being first and to the issuance of U.S. patents that were subsequently licensed to U.S. companies. Had we not been first, it is likely that the discoveries would have been made by researchers in other countries and led to their commercial development there. The key contribution of foreign researchers is also apparent in many of the high-impact scientific research programs I have had the opportunity to contribute to in my career. These include the Human Genome Sequencing Project, the National Institutes of Health's Cancer Genome Atlas project, the National Cancer Institute's Cancer Systems Biology projects, and the Cancer Moonshot program. The innovations taking place in these important programs are advancing our ability to understand and mitigate the impact of many aspects of human disease. This is important to the well-being of U.S. citizens and citizens of the world. The solutions are, of course, enabled by commercial developments and these will be made by companies that learn about them first and that have the skilled leaders and workers to execute on development. This now happens in the U.S. because the discoveries are made here and because we have the skilled workers for development. Foreign scientists and technologists in U.S. laboratories and companies are essential to these activities.

Question. Other Threats to U.S. Research: Foreign students are becoming a more and more important source of tuition for U.S. colleges and universities due to State

and Federal funding cuts. A recent study by the Association of International Educators noted that over a million foreign students attended U.S. colleges and universities in the 2017–2018 academic year and contributed an estimated \$39 billion to the U.S. economy. On the other hand, President Trump's fiscal year 2020 budget request would cut NIH funding by nearly \$5 billion compared to fiscal year 2019 funding levels. Given that the bulk of OHSU's research awards come from NIH, what kind of an effect would decreased NIH funding have on the scientific output of your laboratory, your university and U.S. universities overall?

Answer. Approximately half of the research in my research program comes from the NIH. This research is directed primarily at developing more durable and tolerable treatments for metastatic cancers. The work is quite promising and takes advantage of the remarkable amount of new data being generated around the world. However, converting data into knowledge and biomedical insight requires a lot of “thinking time.” I, like most scientists in the U.S. today, spend far too much time writing grant proposals, preparing progress reports for successful grants, worrying about job security and complying with an increasing number of regulatory requirements instead of thinking about science so we can make progress. Young U.S.-born scientists see this and are shying away from science as a consequence. Decreasing the NIH budget will continue this trend so that discoveries that we could be making will be discovered first in other countries by foreign researchers who are better supported.

This is being played out at OHSU and in universities across the country. OHSU, Oregon's only academic medical center, relies heavily on NIH funding to carry out life-saving research. In 2018, OHSU scientists received more than \$245 million in NIH funding, across 486 awards. While Congress has increased NIH funding in recent years, total funding as a share of GDP is still 12 percent below that of 2003. Far from cutting NIH funding, it is critical that we increase support for basic and translational research, which in turn drives economic growth in communities across the country. NIH funding supported nearly 380,000 jobs and \$65 billion in economic activity in 2016 alone.

While it is tempting to focus on the direct value to foreign students and U.S. research, I believe that it is more important to focus on the larger value that these students make to the U.S. economy. Many of the best and brightest of these students stay in the U.S. and contribute to academic medicine and to the development of biotechnology and pharmaceutical industries—the combined market value of which is approaching \$1 trillion.

Question. Administrative Burden: You mentioned the administrative burden additional regulatory constraints could have on innovation in your lab. We know that, according to the National Science Foundation, top researchers in the United States spend 50 percent of their time writing grants. Yet, in 2016, only 17 percent of NIH grant applications were approved. Can you give examples of current administrative burdens you face and please explain the amount of time you and researchers in your lab spend on paperwork (grants, etc.), as well as the additional costs you anticipate should the Federal Government impose additional constraints—like vetting requirements—on your research?

Answer. My research is heavily oriented toward “translation.” That is, elucidation of aspects of biology and technology that we need to improve cancer care. This is fundamentally a team science effort and requires organization of and participation in local, national, and international meetings that are needed to move projects forward. The interactions that occur during these meetings are both planned and spontaneous with all participants contributing new ideas as they occur. Many good ideas occur spontaneously during the course of discussions and so are impossible to anticipate. The ideas are innovative only in the context of the discussion and so are impossible to vet. It seems the only way to ensure that individuals do not receive information deemed sensitive would be to exclude them from meetings where sensitive topics would be discussed. This would then require a detailed assessment of topics that might be sensitive. I expect compiling such a list would be enormously time consuming and would require a detailed assessment of future U.S. economic strategy. This is certainly not something that universities have the resources to undertake. If such a list were compiled by a collection of Federal agencies, it would have to be updated continuously and the information communicated to all universities and other research institutions so that risk assessment could be made. This would be an enormous and ongoing risk education process. Any time spent learning about risk would be time not spent thinking.

In direct answer to the question, I estimate conservatively that I already spend 75 percent of my time on aspects of science administration. That time includes preparing grant proposals; preparing progress reports for grants that are successful; clinical trials reporting; complying with FDA guidelines; seeking support from industry and philanthropy to supplement, extend, or commercialize our research findings; participating or coordinating phone calls and face-to-face meetings; and organizing data and managing data sharing rules so it can be analyzed by ourselves and by the international community. Adding continual risk assessment to the set of tasks I now do would bring my scientific program to a halt. The only practical way around that would be to exclude foreign researchers from the laboratory which I believe would eliminate access to some of the best minds in the world, reduce access to important data and destroy our ability to compete with the best and brightest in the world.

QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. The competition for global scientific talent is growing. Does the United States risk falling behind other countries if our visa rules and processes diminish our ability to recruit the best and brightest global talent?

Answer. The United States absolutely risks falling behind other nations. In order to maintain its competitive edge, the U.S. must do more to attract international talent, not less. Policy measures that discourage foreign researchers from fully contributing to our scientific endeavors will reduce American competitiveness. The economic strength of the United States depends on innovation and on the speedy implementation and commercialization of innovative ideas. The controls that are already in place provide a workable balance between protecting data and intellectual property and allowing the free exchange of data and information. Additional efforts to control interactions with foreign nationals will decrease innovation and, in so doing, will diminish the economic power of the U.S., while having little impact on foreign misappropriation and misuse of information and ideas. The best way to make the U.S. more competitive economically is to increase the innovation engine through increased NIH funding, to make funds available to support protection of intellectual property and to encourage early phase startup companies in the U.S. so that discoveries are translated rapidly and successfully. The small loss to nefarious activities will be far outweighed by the resulting economic gain.

I will close with an analogy: people speed when they drive. We don't solve that problem by putting governors on cars. We enact laws to punish those who speed.

PREPARED STATEMENT OF LESLIE W. HOLLIE, CHIEF OF INVESTIGATIVE OPERATIONS,
OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee. I am Leslie W. Hollie, Chief of Investigative Operations with the Department of Health and Human Services (HHS) Office of Inspector General (OIG). I appreciate the opportunity to appear before you to discuss how HHS-OIG is diligently working, in conjunction with our HHS and law enforcement partners, protect taxpayer-funded medical research.

OIG is charged with overseeing all HHS programs and operations. We combat fraud, waste, and abuse in those programs; promote their efficiency, economy, and effectiveness; and protect the beneficiaries they serve. To accomplish this, OIG employs tools such as data analysis, audits, evaluations, and investigations. We are a multidisciplinary organization comprised of investigators, auditors, evaluators, analysts, clinicians, and attorneys. We depend on our strong public and private partnerships to ensure coordinated enforcement success.

The Office of Investigations is the law enforcement component of OIG that investigates fraud and abuse against HHS programs. Our special agents have full law enforcement authority and effect a broad range of actions, including the execution of search warrants and arrests. We use traditional as well as state-of-the-art investigative techniques and innovative data analysis to fulfill our mission.

INTRODUCTION

Today, I will cover how OIG enhances the Federal Government's ability to detect, deter, and take enforcement action to ensure the integrity of taxpayer-funded medical research against foreign threats.

The National Institutes of Health (NIH) has recently referred to OIG for investigation 16¹ allegations of noncompliance with its terms and conditions for receiving a medical research grant. The allegations primarily deal with the failure of principal investigators to disclose foreign government affiliations. Because these referrals are all still active, to avoid compromising ongoing investigations, I cannot provide further details at this time. However, I can cover how we generally handle grant fraud allegations related to taxpayer-funded medical research.

Although foreign theft of taxpayer-funded medical research is a high-profile, complex issue, the cases under our purview all involve aspects of grant fraud—something which OIG has extensive experience investigating. HHS is the largest grant-making organization and third-largest contracting agency in the Federal Government. It is also the second-largest payer under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. Given this nexus, OIG has made oversight and enforcement of grant fraud and related grant program integrity a priority.

PROACTIVE GRANT FRAUD EDUCATION, WITH ENFORCEMENT WHEN NEEDED

We take a two-pronged approach to preventing and acting against grant fraud. First, OIG works collaboratively to educate key stakeholders—including HHS operating divisions and Grant Recipient Organizations—on ways to detect and prevent grant fraud through proactive training. Second, we take action, when needed, against grant fraud by investigating allegations of criminal misconduct and making appropriate referrals for criminal, civil, or administrative action.

OIG receives allegations of grant fraud or uncovers potential fraud in a variety of ways, including OIG hotline complaints, referrals from HHS operating divisions and law enforcement partners, whistleblower disclosures, and proactive data analysis. In addition to our standard hotline, we also provide a “grant and contract portal” especially for HHS employees to refer grant and contract matters to OIG.

Upon receiving an allegation pertaining to grant fraud involving NIH or other HHS operating division, OIG evaluates the allegation and determines whether we will open an investigation; refer the matter to another agency with appropriate authorities; or, when appropriate, refer the matter back to the HHS operating division involved for administrative review and potential action.

When evaluating referrals involving allegations of foreign threats to taxpayer-funded medical research, OIG is sensitive to the fact that academic and professional reputations could easily be damaged by erroneous allegations. All complaints are treated with confidentiality and discretion and we only proceed with investigations when sufficient factual information supports such investigative activity. When OIG identifies a violation of civil or criminal law during an investigation, OIG presents the facts to the Department of Justice (DOJ) for prosecutorial consideration.

To protect the integrity of medical research, OIG coordinates with the HHS Office of National Security (ONS). In some instances, OIG works on matters with the Federal Bureau of Investigation's (FBI's) Joint Terrorism Task Forces and National Cyber Investigative Joint Task Force, the Department of Homeland Security, and components at FBI Headquarters and local field offices. When appropriate, we work together with NIH and ONS to develop follow-up approaches and mitigation strategies for such cases.

To illustrate the types of grant fraud investigations OIG conducts, I will offer two summaries of recently resolved research integrity investigative cases.

A doctor who worked in a laboratory at Iowa State University, which received research grants for an experimental HIV/AIDS vaccine, falsified scientific data to make it appear an experimental HIV/AIDS vaccine neutralized, or controlled, the HIV/AIDS virus in rabbits, and contaminated rabbit blood samples with human antibodies to make it appear the rabbits produced neutralizing antibodies against the HIV/AIDS virus. The data from

¹ This number includes four additional referrals from NIH since our January 31, 2019 letter of response to Chairman Grassley's January 17, 2019 letter on the topic in which we reported having a dozen such complaints on hand.

these actions were used in a grant application and progress reports to NIH. The doctor was sentenced to 57 months in Federal prison, 3 years of supervised release, and \$7.2 million restitution.

Another doctor founded two companies, GenPhar and Vaxima, to perform research and produce a vaccine for diseases such as Ebola, Marburg Virus, and Dengue Virus. GenPhar and Vaxima obtained Federal grant money (including NIH SBIR funds) for biodefense research and vaccine development, but actually used the funds for other purposes, including construction of a commercial office building and to pay lobbyists and others who were seeking to secure more Federal funding on the doctor's behalf. The doctor was sentenced to 70 months in Federal prison and ordered to pay over \$3 million in restitution.

As mentioned earlier, OIG's approach to preventing and enforcing grant fraud includes working collaboratively with stakeholders to increase their ability to detect and prevent grant fraud through proactive training. OIG works with representatives of the intelligence community and HHS's Office of Research Integrity (ORI) to promote awareness of research misconduct and helps with efforts to improve protections. For instance, before I received the invitation to testify here today, I was scheduled to deliver a joint presentation along with an ORI colleague entitled "When Research Misconduct Involves Potential Criminal Behavior: New Collaboration Strengthens Protection of U.S. Biomedical Research Funding." In addition to such joint training efforts, ORI notifies OIG when conduct that might be criminal activity arises in the course of a research misconduct investigation. OIG's work is independent of ORI's, and ORI must refer all credible allegations of criminal conduct they uncover to OIG. In short, OIG's enhanced collaboration with ORI adds a layer of scrutiny to ensure that both ORI and OIG can take appropriate actions to protect U.S. biomedical research investments.

OIG increases HHS employee, contractor, and grantee awareness of how to identify and report allegations pertaining to grant fraud as well as foreign threats to taxpayer-funded medical research through training and presentations. For instance, OIG has provided numerous grant fraud training sessions at NIH Regional Seminars and NIH SBIR and STTR Town Hall meetings.

To educate grant recipient organizations, OIG has partnered with several academic entities to address best practices to ensure Research Integrity Officers and Compliance Officers are informed on the roles, responsibilities, and authorities of OIG. We tailor our efforts for each grant recipient organization to address what best practices are most helpful to serve its unique needs.

RISK MITIGATION THROUGH MINIMIZING VULNERABILITIES

OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. In fiscal year 2019, OIG received \$5 million in appropriations for oversight of grant programs and operations of NIH, including NIH efforts to ensure the integrity of its grant application evaluation and selection processes.² We have evaluations underway to assess NIH's vetting and oversight of its peer reviewers, including its efforts to prevent or identify inappropriate disclosure of information by peer reviewers, and an evaluation of how NIH monitors the financial conflicts of interest (including foreign financial interests) reported by grantee institutions. In addition, we are examining NIH's adherence to its policies for evaluating and selecting grant applications.

OIG is also initiating audits that will assess NIH's Institutes and Centers to review their (1) pre-award process for assessing risk of potential recipients of Federal funds; (2) policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all relevant affiliations, sources of support, and financial interests, including intellectual property interests; (3) internal controls for identifying and addressing potentially duplicative grant funding and overlap; (4) testing of select cybersecurity controls within the NIH Electronic Health Records system; and (5) controls to ensure that NIH has an accurate inventory of hardware, software, and Internet Protocol resources.

²The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245). As required by this law, OIG submitted a comprehensive NIH oversight plan to the Committee on Appropriations of the House of Representatives and the Senate; the Senate Committee on Health, Education, Labor, and Pensions; and the House Committee on Energy and Commerce.

CONCLUSION

OIG is committed to working collaboratively to address foreign threats to taxpayer-funded medical research through preventive efforts to mitigate risk and minimize vulnerabilities in HHS programs and conducting enforcement actions whenever necessary. In cooperation with our HHS and law enforcement partners, OIG will continue to leverage our grant fraud investigative work and capabilities to maximize our efforts in this area as authorities, resources, and funding allow.

Thank you for your ongoing leadership in this area and for affording me the opportunity to discuss this important topic with you.

QUESTIONS SUBMITTED FOR THE RECORD TO LESLIE W. HOLLIE

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. According to the Health and Human Services Inspector General, NIH has recently referred for investigation a 16 allegations of noncompliance related to medical research. The Inspector General stated the allegations primarily deal with the failure of principal researchers to disclose foreign government affiliations.

Where do those referrals from NIH currently stand? Were any investigations opened or matters referred to other agencies, such as the FBI? If so, how many and to what agency?

Answer. The referrals that OIG received from the National Institutes of Health (NIH) have all become open and active investigations. Therefore, we cannot provide further details at this time.

Question. According to NIH, it operates both the intramural program and the extramural program for research activities. Within the intramural program, NIH's employees, contractors, and affiliates who are U.S. citizens undergo background investigations. Further, prior to that background check, a Special Agency Check is conducted requiring fingerprints to be cross-checked with FBI criminal databases including terrorist watch lists. According to NIH, a grantee institution in the extramural program, such as a university or other research institution, is responsible for any vetting, not NIH.

More than \$8 out of \$10 appropriated to NIH goes to the extramural program. At the committee hearing, I asked Dr. Tabak whether NIH conducts background checks, including a review for counter-intel purposes, on Principal Investigators prior to awarding a grantee institution taxpayer money. He answered, "No sir, we do not, as they are employees of their home institution."

If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, how would those checks help strengthen grant integrity?

Answer. OIG has found that background checks can be an important tool for program integrity in certain contexts, such as for high-risk providers in Medicare. We have not assessed the costs and benefits of requiring background checks for NIH principal investigators. Given the number of principal investigators funded by NIH, conducting background checks for all of them would likely present logistical and resource challenges. In general, OIG supports using risk-based approaches to maximizing the impact of program integrity investments.

Question. If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, would those checks improve the government's security posture? If so, how? If not, why not?

Answer. OIG defers to the Department of Health and Human Services' (HHS's) Office of National Security because the question being asked falls under their purview.

Question. What additional changes would improve the integrity of the grant system and taxpayer funded research? For example, should any changes be made to government grant forms?

Answer. OIG conducts oversight of NIH through audits and evaluations, some of which relate to protecting the integrity of NIH-funded research. In fiscal year 2019, OIG received \$5 million in appropriations for oversight of grant programs and operations of NIH, including NIH efforts to ensure the integrity of its grant application

evaluation and selection processes. We have evaluations underway to assess NIH's vetting and oversight of its peer reviewers, including its efforts to prevent or identify inappropriate disclosure of information by peer reviewers, and an evaluation of how NIH monitors the financial conflicts of interest (including foreign financial interests) reported by grantee institutions. In addition, we are examining NIH's adherence to its policies for evaluating and selecting grant applications.

OIG is also initiating audits that will assess NIH's Institutes and Centers to review their (1) pre-award process for assessing risk of potential recipients of Federal funds; (2) policies, procedures, and controls in place for ensuring that both foreign and domestic grantees disclose all relevant affiliations, sources of support, and financial interests, including intellectual property interests; (3) internal controls for identifying and addressing potentially duplicative grant funding and overlap; (4) testing of select cybersecurity controls within the NIH Electronic Health Records system; and (5) controls to ensure that NIH has an accurate inventory of hardware, software, and Internet protocol resources.

OIG would be happy to brief you on this body of work as these reports are completed.

In February 2019, OIG released a report, *Opportunities Exist for the National Institutes of Health to Strengthen Controls in Place to Permit and Monitor Access to Its Sensitive Data*. Several of our recommendations address improvements that NIH could make to bolster the integrity of taxpayer-funded research.

Regarding government grant forms, we would encourage NIH to require principal investigators and project directors to sign forms with attestations and to require information about "other income" from these individuals at an appropriate point in the process. OIG would be happy to consult with NIH or provide further technical assistance to Congress on this issue.

Question. What foreign governments pose the greatest threats to intellectual property created by taxpayer-funded research at American universities? How are they working to exploit our academic institutions to steal critical IP? Can you share any specific examples of that exploitation?

Answer. HHS-OIG defers to the Federal Bureau of Investigations' (FBI's) Counterintelligence Division, because the question being asked is one that falls within the scope of their jurisdiction.

Question. Have foreign nationals, acting surreptitiously on behalf of foreign governments, penetrated critical U.S. industries, including but not limited to health-care and pharmaceutical research, infrastructure, financial services, defense, robotics and advanced chip processing? If yes, please explain what changes, including legislative changes, are needed to stop or slow these incursions.

Answer. HHS-OIG defers to HHS's Office of National Security and to FBI's Counterintelligence Division, because the question being asked falls under their purview.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. How Prevalent Is the Problem: In a January 31, 2019 letter to Chairman Grassley, HHS Inspector General Daniel Levinson responded to several questions the chairman raised about foreign threats to taxpayer funded medical research. Among the IG's responses: in the past 5 years, OIG conducted one investigation of failure to disclose foreign government funding and did not conduct any investigations involving researchers who were allegedly foreign government agents; in the past 5 years, OIG conducted one investigation of alleged theft of intellectual property created by taxpayer-funded research; and in the past 5 years, OIG made two referrals for possible prosecution for failure to disclose receipt of foreign government funding.

In your testimony, you say that OIG is now investigating 16 allegations of non-compliance by grantees. Has there been a dramatic increase in the number of violations of these types of activities since the IG wrote his response to Chairman Grassley on January 31st? If not, does the OIG have reason to believe that these types of activities are much more widespread than the handful of these incidents that were reported to Chairman Grassley in the IG's letter? If so, what are the reasons for this increase?

Answer. In our January 31st letter to Chairman Grassley, we explained that we had recently received 12 referrals from NIH that primarily involve principal inves-

tigators on NIH grants conducting medical research at U.S. universities who allegedly have failed to disclose foreign affiliations on their grant applications. Since that time, we have received another 4 such referrals from NIH, bringing the total to 16 allegations, which OIG is now investigating. Over the past 6 months, we have seen a very small increase in OIG hotline complaints received primarily involving allegations of principal investigators on NIH grants conducting medical research at U.S. universities who allegedly have failed to disclose foreign affiliations on their grant applications. We attribute this very small increase to both NIH's ramped-up efforts to address such allegations over the past year as well as greater awareness of the issue among other stakeholders due to both increasing and widespread media reports and the Senate Finance Committee's oversight efforts.

Question. Policy on Mixed Government and Non-Government Witnesses on Panels: Your agency told the Finance Committee that its witness would not participate on a panel at this hearing that included both government and non-government witnesses, claiming there is a longstanding OMB policy prohibiting this. However, there are numerous examples where your agency has allowed witnesses to testify on "mixed panels." Over the past 10 years, Federal Government witnesses, including those from your agency, have testified before the Finance Committee on panels with non-government witnesses more than 40 times. This has also been the case with other Senate committees. In April 2019, an NIH witness testified on a panel with non-government witnesses before the Senate Aging Committee. An NIH witness also testified on a panel with non-government witnesses before this same committee in July 2017. In March 2018, the Secretary of DHS herself testified on a panel with non-government witnesses before the Senate Select Committee on Intelligence. Why were these witnesses permitted to testify before other Senate Committees on mixed panels, but your witness was not permitted to do so at the Finance Committee's June 5th hearing? If waivers were granted for witnesses to testify on mixed panels at other committee hearings, why were those waivers granted for the other hearings but not the June 5th hearing? Please provide copies of (1) the OMB policy that allegedly prevents government witnesses from testifying on panels with non-government witnesses; (2) any waivers granted for the recent Aging and Intelligence hearings where government witnesses from NIH and DHS respectively testified with non-government witnesses; and (3) any request submitted to OMB for your witness to testify at the June 5th hearing and the OMB response along with an explanation why a waiver was not granted for the June 5th Finance Committee hearing?

Answer. This discussion was between HHS's Office of the Assistant Secretary for Legislation and the committee. Therefore, HHS–OIG defers to the Department.

Question. Source of Foreign Threats: During the hearing, Senator Wyden asked Dr. Tabak and the first panel of government witnesses to identify the general number, or a range, of countries that currently constituted the source of the foreign threat. Dr. Tabak responded that he could not do so in an unclassified setting and would do so in the classified briefing. Would you please provide a separate, classified response that identifies the specific countries that you believe currently present a threat to U.S. research and describe the nature of that threat?

Answer. HHS–OIG defers to HHS's Office of National Security and FBI's Counterintelligence Division, because the question being asked falls under their purview.

QUESTION SUBMITTED BY HON. JOHN THUNE

Question. Mr. Hollie, as you know, the HHS Office of Inspector General recently released a report stating that NIH did not concur with the inspector general's recommendation to develop a security framework, conduct a risk assessment, and implement additional controls for sensitive data in the context of NIH Genomic Data. In your view, why did NIH not concur with this recommendation? In your view, does NIH have valid reasons for rejecting your office's recommendation?

Answer. NIH's written response to our report indicated that they believed additional internal controls were not necessary based on our findings. We explained to NIH that, consistent with Federal regulations, NIH should document its acceptance of the risks we presented. Further, the NIH Advisory Committee to the Director, issued a report, *ACD Working Group for Foreign Influences on Research Integrity* (December 2018). This report identifies similar risk and includes recommendations that are consistent with our recommended actions. We are hopeful that NIH will adopt its internal Working Group recommendations, which will likely address the findings in our report. We are still waiting for the OIG Clearance Document re-

sponse from NIH. That document will provide any action that NIH has taken to address the recommendations in the report and provide the basis for OIG to determine whether a recommendation is close or is unimplemented.

QUESTION SUBMITTED BY HON. TODD YOUNG

FIVE EYES INTELLIGENCE ALLIANCE

Question. The Five Eyes is widely regarded as the world's most significant intelligence alliance. The origins of it can be traced back to the context of the Second World War and by its necessity of sharing vital information mainly between Britain and the United States so both countries could enhance the allied war effort. "Five Eyes" was formally founded in the aftermath of the Second World War, through the multilateral agreement, known as the UKUSA Agreement, on 5 March 1946.

Initially, compromising only the UK and the United States, it expanded to also include Canada in 1948 and Australia and New Zealand in 1956. Thereby, the "Five Eyes" term was created from the lengthy "Australia/Canada/New Zealand/United Kingdom/United States Eyes Only" classification level that included the "eyes" that could have access to high-profile papers and information. For more than 70 years this alliance of like-minded allies has served our intelligence community well.

Just like sharing access to sensitive intelligence information, should we think similarly about opening up certain programs or research areas to certain students or professors depending on their home country?

Is there a model here for academia that is worth following?

Should we be limiting what countries we conduct sensitive research and development with?

Answer. HHS-OIG defers to HHS's Office of National Security, NIH, and FBI's Counterintelligence Division, because the questions being asked all fall within the scope of their respective jurisdictions and are beyond the purview of HHS-OIG.

PREPARED STATEMENT OF LOUIS A. RODI III, DEPUTY ASSISTANT DIRECTOR, NATIONAL SECURITY INVESTIGATIONS DIVISION, IMMIGRATION AND CUSTOMS ENFORCEMENT, DEPARTMENT OF HOMELAND SECURITY

INTRODUCTION

Chairman Grassley, Ranking Member Wyden, and distinguished members of the committee, thank you for the opportunity to discuss the role U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) plays in addressing foreign threats to taxpayer-funded research. The threat posed by nation-states illegally and/or subversively seeking to exploit legitimate educational and research opportunities in the United States is evolving. ICE HSI plays a pivotal role in identifying the avenues, methods, and strategies that foreign nationals use to attack our research institutions. State actors routinely engage in or facilitate the procurement of U.S. technology and theft of intellectual property, sometimes in violation of Federal laws and regulations. Combatting these activities is at the forefront of HSI's priorities, with multiple divisions and mission sets within the agency collaborating to identify and uncover foreign actors and networks exploiting U.S. academic and research institutions and to strategically disrupt their operations.

HSI is the principal investigative arm of the U.S. Department of Homeland Security, responsible for investigating a wide range of domestic and international activities arising from the illegal movement of people and goods into, within, and out of the United States. As part of its mission, HSI oversees a diverse portfolio of investigative and administrative programs that safeguard the United States against national security and public safety threats, and against the violation of customs and immigration laws of the United States. As part of today's testimony, I would like to highlight some of the initiatives HSI has implemented and is seeking to further enhance.

CURRENT STATE OF PLAY/NATURE OF THE THREAT

The United States is home to thousands of universities and colleges, many of which are among the most advanced institutions in the world for higher education and scientific, technological, and medical research. As a result, each year thousands

of foreign nationals seek to obtain nonimmigrant visas to enable them to travel to the United States to pursue educational degrees or research at these institutions. Thousands more are already present in the United States attending U.S. colleges and universities or conducting advanced research in a multitude of fields.

As of May 2019, there are just over 1.13 million nonimmigrant students present in the United States. This includes 1,129,816 active F-1 students and 9,755 active M-1 students. There are 558,784 F-1 students who are studying or engaged in research in science, technology, engineering, and mathematics (STEM)-related fields.

While openness and international collaboration in academia and research are important aspects of facilitating significant enhancements in science and technology, they also can create an environment that U.S. adversaries exploit as a means to gain access to sensitive technology and information, some of which is controlled for export, and transferred to foreign entities. The largest number of ongoing HSI Counter Proliferation Investigations (CPI) cases on controlled exports, including intangible exports (*i.e.*, the transmission of technical data from the United States, or transfer to foreign nationals within the United States) involves China, Iran, and Russia. From these investigations and based on trend analysis, HSI knows that these countries are actively implementing a multitude of schemes to illicitly or subversively acquire and transfer export-controlled military and dual use technology and commodities, and are employing myriad schemes to circumvent U.S. export control laws.

Exploitation of academia and U.S. research institutions is just one of the schemes these countries are employing to obtain access to sensitive research and export-controlled information and technology, and to facilitate its transfer abroad. These countries are attempting to obtain this information, in many instances in an illegal or subversive manner, in order to advance their own military capabilities or economic goals, many times in contravention to the national security of the United States.

Foreign nationals from China, Iran, and Russia represent a sizeable portion of the overall nonimmigrant student population currently in the United States. As of May 2019, there are 357,863 F-1 Chinese students in the United States with 181,980 such students enrolled in STEM-related academic programs at U.S. institutions. There are also 11,323 F-1 Iranian students and 6,196 F-1 Russian students, with the respective STEM student breakdown of 9,057 for Iran and 2,008 for Russia.

HSI EFFORTS TO IDENTIFY AND MITIGATE THE THREAT

HSI has established a multi-dimensional approach to safeguarding the homeland against transnational threats of this nature. HSI's first line of effort is preventative, and aims to identify and disrupt the ability of known or suspected national security or public safety threats from obtaining nonimmigrant visas to lawfully travel to, and obtain entry into, the United States. A core component of this effort is the HSI-led Visa Security Program (VSP). Through the VSP, HSI analysts and special agents work in conjunction with U.S. interagency and foreign government partners to maximize the opportunity to screen, vet, and investigate potential threats prior to the U.S. Department of State (DOS) making a visa determination and well before the applicant presents for admission to the United States. This includes those applying for student or exchange visitor visas. If sufficient derogatory information is uncovered relating to the intentions of visa applicants, HSI—working in conjunction with DOS—can recommend refusing visas on a number of grounds, including for suspected involvement in the illicit procurement or attempted procurement of controlled technology.

In addition to these preventative measures, HSI also implements multiple programs to identify and protect against foreign entities already in the United States who may seek to exploit legitimate academic and research opportunities for the ultimate benefit of adversarial state actors. The Student and Exchange Visitor Program (SEVP) fulfills a compliance-centric role, and is responsible for monitoring certified educational institutions and the nonimmigrant students they enroll. The Counterterrorism and Criminal Exploitation Unit (CTCEU) coordinates investigative and enforcement actions in cases in which nonimmigrant visa holders, including students and exchange visitors, overstay their visas or violate the terms of their visas and are suspected of posing a concern to U.S. national security or public safety. If students or exchange visitors appear to be involved in efforts to acquire and transfer sensitive information or technology obtained during the course of their research or academic pursuits, HSI's CPI plays a role in coordinating an investigative and enforcement response to those activities.

Together, these programs form the backbone of HSI's efforts to identify and mitigate the threats posed by foreign entities seeking to exploit legitimate academic and research opportunities within the United States. Each of these programs is described in more detail below.

HSI Visa Security Program:

The HSI VSP leverages resources in the United States and abroad to screen and vet non-immigrant visa applicants, identify and prevent the travel of those who constitute potential national security or public safety concerns, and launch investigations into transnational criminal- and terrorist-affiliated networks operating around the globe. The VSP was formed in response to the September 11, 2001 attacks, authorized by section 428 of the Homeland Security Act of 2002 and implemented by a 2003 Memorandum of Understanding between the Secretaries of State and Homeland Security.

Currently, HSI VSP operations are conducted at 36 visa-issuing posts in 27 countries. In FY 2018, VSP screened 2,196,708 visa applications, made 1,251 nominations or enhancements to the terrorist watchlist, and recommended the refusal of 9,007 visa applications. Additionally, deployed special agents conducted 5,101 interviews and initiated 348 investigations in support of VSP operations. One key facet of VSP operations is the overseas assignment of HSI Special Agents to diplomatic posts worldwide. Embedded within American Embassies and Consulates, these agents work alongside DOS Consular Affairs personnel, other partner agencies at post, and appropriate host country officials to identify and investigate terrorists, criminals, or other individuals who pose a threat to the United States.

A second critical component to VSP is the Pre-Adjudicated Threat Recognition Intelligence Operations Team (PATRIOT), administered by HSI International Operations (IO) in collaboration with U.S. Customs and Border Protection (CBP), which conducts centralized screening and vetting in the National Capital Region (NCR) in support of VSP operations. PATRIOT enables the automated screening of visa application information against DHS holdings, as well as holdings of other U.S. agencies, at the earliest point in the visa process, well in advance of the visa applicant's interview and visa adjudication. Derogatory information discovered during automated screening process is manually vetted by PATRIOT personnel utilizing law enforcement techniques, open source information, and classified systems. PATRIOT analysts then provide HSI Special Agents assigned to VSP posts with relevant information to use during interviews of visa applicants or other investigative activities conducted abroad prior to visa adjudication. Following the analysis of all known derogatory information, HSI Special Agents at VSP posts provide a unified DHS recommendation to DOS on visa eligibility.

In addition to the PATRIOT process, VSP personnel also participate in other U.S. government screening and vetting efforts focused on protecting the homeland from diverse national security and public safety threats. Generally, these processes entail collaboration between HSI, DOS, and other partner agencies involved in screening and vetting. This includes conducting intensive reviews of visa applications from visa-issuing posts worldwide that are considered high risk for the applicant's potential involvement in the unlawful procurement, transfer, or export of sensitive military or dual-use U.S. information and technology. At times, these applications may involve individuals seeking to exploit the U.S. educational system by enrolling in graduate level studies or engaging in research, teaching, or exchange programs as a way to acquire and transfer sensitive, export-controlled technology or information on behalf of adversaries or organizations that pose a national security risk to the United States. In some instances, a more intensive screening and vetting of a visa application is prompted by risk factors indicative of a visa applicant's potential involvement in activities related to the unlawful procurement, transfer, or export of sensitive U.S.-origin military or dual-use goods or technology on behalf of foreign adversaries or criminal organizations. After such reviews, VSP personnel then provide consular officers advice and background information to properly adjudicate immigrant and nonimmigrant visa applications of security or foreign policy interest.

Whether through the PATRIOT process or other screening and vetting efforts in which the VSP is engaged, the VSP ultimately provides recommendations for visa issuance or refusal to DOS based on information uncovered during the review, vetting, and investigative process. In all cases where the VSP team recommends the refusal of a visa, the VSP coordinates in advance with CBP's National Targeting Center-Passenger (NTC-P) regarding the applicant's admissibility or inadmissibility, per the Immigration and Nationality Act (INA). This ensures that DHS presents a single, uniform position on visa eligibility and admissibility to DOS.

The combination of the international and domestic dimensions of VSP equips HSI with a unique capability to investigate suspicious travelers, enhance existing information, and identify previously unknown threats, rather than simply denying visas and potential travel of these applicants. These efforts allow VSP to operate as a counterterrorism tool that mitigates threats posed by transnational terrorist and criminal networks. Utilizing information obtained through the visa application process, the VSP enhances the national security and border security of the United States by identifying national security or public safety concerns at the earliest part of the visa lifecycle and preventing their travel to and admission into the United States.

HSI Student and Exchange Visitor Program:

Foreign nationals who receive nonimmigrant visas to pursue educational, vocational, or research programs in the United States will interact with the Student and Exchange Visitor Program (SEVP). As of May 2019, there are 1,139,571 nonimmigrant students attending 6,410 SEVP-certified schools.

SEVP uses the Student and Exchange Visitor Information System (SEVIS) to monitor F and M students and the schools that enroll them while in the United States. SEVIS also contains the information for the Exchange Visitor program (J-visas), which is administered by DOS. SEVIS contains information such as a student's name, physical and mailing addresses, date of birth, phone number, email address, academic major, and employment information (if applicable). SEVIS information is updated by Designated School Officials (DSOs), but the system will auto-terminate a student's record if the student fails to enroll or report to school, meaning the student must depart the United States or he or she may be put into removal proceedings.

SEVP is also responsible for the school certification process. The certification process is rigorous and continual. To obtain initial certification, schools must submit required evidence and applications, undergo site visits, and recommend DSOs. These school officials must be U.S. citizens or lawful permanent residents and must affirm their knowledge and intent to comply with all Federal regulations. The schools are furthermore subject to biennial recertification, unannounced site visits and out-of-cycle reviews at any time. Schools that do not comply with the regulations may be withdrawn and, subsequently, ineligible to enroll nonimmigrant students until successfully re-petitioning for approval and meeting all certification standards.

Beyond the certification process, SEVP uses SEVIS data to engage in risk management and has enhanced its risk management framework by developing a compliance dashboard to identify schools with risk indicators. SEVP employs this risk analysis tool to identify schools that may have violated SEVP regulations when conducting recertification reviews, adjudicating school updates, and determining whether to initiate out-of-cycle reviews. SEVP regularly conducts compliance site visits to schools to ensure that approved programs are functioning as reported in SEVIS. In addition, SEVP continuously vets leads reported by the public concerning both schools and students, acting decisively to protect public safety and the integrity of the immigration system.

While many of SEVP's processes and programs have proven to be effective, HSI strives to improve and enhance these programs. For example, SEVP has mitigated previously identified national security gaps and system vulnerabilities within SEVIS and is using an adaptive maintenance approach to continuously add enhancements to the system. These enhancements have improved data integrity and the stability of the system. SEVP is currently working towards transforming SEVIS into a person-centric database. In March 2018, SEVP launched the SEVP Portal for students participating in Optional Practical Training (OPT) related to STEM degrees. The Portal allows nonimmigrant students to directly upload their required SEVIS information, including their employer's name and address, as well as other key information for monitoring purposes. The portal interfaces with SEVIS and shares information but does not give students direct access to SEVIS. The Portal has been a success with more than 166,402 registered portal users (*i.e.*, 74.7 percent of the students eligible for Portal Accounts). The portal will be expanded to all F and M students, resulting in SEVIS data that is more accurate, captures changes in a student's information quicker and ensures students are accountable for the data inputted.

Additionally, SEVP started conducting criminal background checks on proposed DSOs in May 2017, due to the fact that these individuals have access to a secure government database and a role in reporting information in that database. HSI is actively working to expand this process and incorporate such vetting as part of its

regular review of approved schools and DSOs, both to safeguard against potential vulnerabilities and to ensure the integrity of the information in SEVIS. SEVP's current programs, ongoing enhancements, and proposed expansion will further secure our Nation from those wishing to exploit the Nation's education system. For more information about the privacy risks that HSI takes on while operating SEVP and the subsequent mitigations, please view the SEVIS privacy impact assessment (PIA) and subsequent updates available at mitigations, please view the SEVIS privacy impact assessment (PIA) and subsequent updates available at mitigations, please view the SEVIS privacy impact assessment (PIA) and subsequent updates available at

HSI Counterterrorism and Criminal Exploitation Unit:

HSI's CTCEU actively identifies and initiates enforcement action on non-immigrant visa overstay violators, and works closely with SEVP and CPI to ensure leads and other information related to potential status violators are referred to HSI field offices for appropriate action. Within the agency, CTCEU focuses on overstay violators who pose a national security, border security, or public safety concern. This includes individuals who entered the United States as nonimmigrant students or exchange visitors. CTCEU leverages special agents, analysts, information systems, and interagency partnerships to determine viable national security related overstay leads to pursue.

In an average year, CTCEU analyzes over one million potential status violator records, incorporating data from various government systems, such as SEVIS and CBP's Arrival and Departure Information System (ADIS). CTCEU conducts both batch and manual vetting against government databases, public indices, and open source information. The vetting helps determine whether an individual who overstayed has departed the United States, adjusted to a lawful status, has a pending immigration benefit application, or would be appropriate for an enforcement action.

CTCEU proactively develops cases for investigation, monitors the latest threat reports, and addresses emergent issues. This practice is designed to detect and identify individuals and schools exhibiting specific risk factors; it is formulated based on intelligence reporting, travel patterns, and in-depth criminal research and analysis. It has contributed to the counterterrorism mission by initiating and supporting high-priority national security initiatives, based on specific intelligence. CTCEU considers several fraud indicators when reviewing schools, such as a high volume of students engaged in OPT or Curriculum Practical Training (CPT), low completion rates, over-enrolled schools with student populations exceeding indicated I-17 amount, schools receiving Federal funding for sensitive research, or schools exhibiting various other fraud indicators. CTCEU also reviews SEVP Analysis Operation Center (SAOC) Tip Logs and HSI Tip Line information to further enhance or corroborate information received on schools or school officials.

LeadTrac is the database owned by CTCEU and is used to vet and manage leads pertaining to visitors in the United States who are suspected of overstaying their period of admission or otherwise violating the terms of their admission, as well as organizations suspected of immigration violations. LeadTrac's structure supports a subject-centered data model, ensuring multiple leads about a single subject are linked within the system. For more information about the privacy risks that HSI CTCEU takes on while operating LeadTrac and the subsequent mitigations, please view the LeadTrac PIA available at www.dhs.gov/privacy.

In FY 2018, CTCEU reviewed 1,429,395 leads regarding potential overstays. Numerous leads were closed through an automated screening process, most commonly due to subsequent departure from the United States. A total of 8,968 leads were sent to HSI field offices for investigation. Of these, 2,212 were pending further investigation, 2,795 were closed for being in compliance (pending immigration benefit application, granted asylum, approved adjustment of status application, or departed the United States) and the remaining leads were returned to CTCEU for continuous vetting and further investigation. In FY 2018 alone, HSI made 1,808 arrests pursuant to visa violator leads. In FY 2019 through March 31, 2019, CTCEU has reviewed 765,543 leads regarding potential overstays and sent 4,940 leads to HSI field offices for further investigation. HSI has made 1,025 arrests pursuant to visa violator leads in FY 2019.

CTCEU refers leads that do not meet HSI criteria for further investigation to ICE Enforcement and Removal Operations (ERO) National Criminal Analysis and Targeting Center (NCATC) which works in close coordination with CTCEU for further vetting. If necessary, the lead is forwarded to the respective ERO field office for enforcement action.

Key Initiatives on Overstay Enforcement

Outreach is an important component of CTCEU's operations. HSI special agents have been conducting outreach visits to SEVP-certified institutions as part of HSI's Project Campus Sentinel (PCS) program. This outreach program, which was established in 2011, aims to build a mutual partnership between local HSI special agents and SEVP-certified institutions by collaboratively preventing the criminal exploitation of SEVP through direct and open communication. It furthermore creates an avenue for improved direct communication between DSOs and local HSI special agents. In recent years, this outreach program has been expanded to include SEVP field representatives and campus public safety entities. This partnership provides all stakeholders the opportunity to openly exchange information, improve cooperation, and bolster the safety and security of students, faculty, and institutions. Since inception, HSI special agents have conducted over 4,000 PCS outreaches.

Other key initiatives in HSI's overstay enforcement efforts include the Domestic Mantis and Visa Lifecycle programs. The Domestic Mantis and Visa Lifecycle programs help identify nonimmigrant students who have access to sensitive technology, better capture the overarching visa lifecycle, provide another layer of security for the Nation, and serve as innovative investigative tools to support the enforcement of U.S. immigration laws.

CTCEU developed the Domestic Mantis Program in response to a Government Accountability Office (GAO) assessment that identified a potential vulnerability with nonimmigrant students who enter the United States to study in a non-sensitive field of study and subsequently transfer to a sensitive field of study. These individuals could pose a substantial risk related to the diversion of sensitive technology, materials, or information.

The Domestic Mantis Program aims to enhance national security by preventing the export of goods, technology, or sensitive information through activities such as graduate-level studies, teaching, research, training, or employment. The program works by identifying students that have changed their field of study to a sensitive area and evaluates those individuals against risk-based targeting criteria. To accomplish this, CTCEU manually extracts and reviews SEVIS data pertaining to students from countries that have an elevated risk of proliferation activity. The potential leads are analyzed using a comprehensive vetting process, including a review against intelligence community holdings for additional derogatory information, open source information, and academic journals. These Domestic Mantis checks are performed twice a year to identify new students who enroll at varying times within the school year.

Visa Lifecycle Program

The Visa Lifecycle Program tracks nonimmigrant visitors from the time they file visa applications to the time they depart from the United States, become overstays, or otherwise fail to comply with their terms of admission (*i.e.*, become "out-of-status"). This program allows HSI to continuously vet and identify derogatory information on nonimmigrant visitors for the validity of the visa. In instances where violators are identified, appropriate enforcement actions are initiated.

The Visa Lifecycle Program focuses on nonimmigrants seeking business/tourist (*i.e.*, B1/B2) or student/exchange (*i.e.*, F, J, and M) visas from five DOS visa issuing posts. These posts were selected to complement existing HSI screening efforts in response to recent global acts of terrorism perpetrated in those countries. Working in coordination with HSI's VSP, CTCEU receives information on these visa applicants pulled from PATRIOT and the DOS Consular Consolidated Database (CCD). CTCEU ingests this data into its lead management system and continuously vets these nonimmigrant visa holders using an automated open source vetting platform in conjunction with intelligence community holdings.

HSI Counter Proliferation Investigations Program:

Cases involving the attempted acquisition and transfer of sensitive, export-controlled commodities, technology, or information fall within the purview of the HSI CPI program. HSI is designated as the primary law enforcement agency for investigating violations of U.S. export laws related to military items, controlled dual-use goods, and sanctioned/embargoed countries. HSI, through its CPI program, has statutory authority to investigate violations of U.S. export control laws, and is uniquely equipped—as the only agency enforce with border search authority, undercover authority, forfeiture authority, and an extensive international footprint—to combat the trafficking of weapons and technology, to include chemical, biological, ra-

biological, nuclear materials, and other items required to produce weapons of mass destruction (WMD).

HSI's CPI mission is directly aligned with U.S. national security and defense strategies, as they pertain to protecting the American war fighter and the homeland from having sensitive U.S.-origin military and WMD technology fall into the hands of U.S. adversaries; securing the U.S. border from firearms being smuggled to transnational criminal organizations; disrupting the supply chains of illicit procurement networks by preventing terrorist groups and hostile nations from acquiring U.S. military hardware, firearms, sensitive technical data, dual-use technology, and materials used to develop weapons of mass destruction; protecting U.S. industry from sensitive intangible technology transfers; and keeping U.S. industry's intellectual property, as well as ground breaking research and development, from being exploited by U.S. adversaries.

HSI, and its predecessor agency, the U.S. Customs Service, has been exercising its export enforcement authority for over 100 years. Although other Federal law enforcement, regulatory, intelligence, and military agencies are involved in the overall U.S. export control efforts, HSI is empowered with full statutory authority to investigate violations of all U.S. export control laws, such as the Arms Export Control Act (AECA) and International Traffic in Arms Regulations (ITAR); the Export Controls Act of 2018 (ECRA) and the Export Administration Regulations (EAR); the International Emergency Economic Powers Act (IEEPA); and Trading with the Enemy Act (TWEA). From 2012 to 2018, HSI CPI investigations have resulted in over 17,000 cases initiated, 4,006 arrests, and 8,288 seizures.

U.S. export control laws are comprehensive and include restrictions on tangible exports (*i.e.*, the actual shipment of items from the U.S.), intangible exports (*i.e.*, the transmission of technical data from the United States, or transfer to foreign nationals within the United States), re-exports and transshipments (*i.e.*, exports from one foreign country to another), and controls on services and other business activities (*i.e.*, training, brokering, and financing services). Because of the complexity of U.S. export control laws and the multiple licensing agencies involved, HSI CPI special agents conduct outreach visits and provide presentations to private industry and academic institutions. This program, known as Project Shield America (PSA), is designed to increase public awareness of export control laws and regulations, and to equip private industry and the academic community with the knowledge needed to aid in recognition, detection, and resolution of attempted illegal acquisitions of sensitive, export-controlled goods and technology. Since 2001, HSI special agents have conducted more than 32,000 PSA outreach presentations, resulting in successful HSI criminal investigations worldwide.

Currently, the United States is facing an unprecedented threat from foreign governments, such as Iran, China, and Russia, who have launched far-reaching campaigns to illicitly acquire sensitive, and in some cases export-controlled, commodities, technology, research, and/or information needed to further their strategic military and economic goals. One area targeted by these state actors is academia. These adversarial nations take advantage of academic openness in the name of "fundamental research" to target U.S. institutions of higher learning to capture U.S. technology, processes, and other intellectual property. This process is generally labeled non-traditional collection. In the context of academia, this entails foreign adversaries facilitating or supporting academic research and expertise development in sensitive fields by student and exchange visitor nonimmigrant visa holders. Through this process, these students and researchers acquire, export, or transfer information or technology to foreign entities in a subversive manner and without licenses, if the information or technology is export controlled. These activities pose a threat to U.S. national security and compromise the integrity of the U.S. academic and research system.

To mitigate this threat, HSI has recently taken proactive steps to increase outreach to export control officers and other officials within the academic community, particularly at universities or research institutions with large foreign student populations enrolled in STEM-related programs. These outreach efforts are conducted in conjunction with SEVP and CTCEU representatives. The goal of this increased focus on academia outreach is to raise awareness of the potential proliferation risk posed by students and researchers seeking to acquire and transfer sensitive research, technology, and/or intellectual property (some of which may be export controlled) on behalf of foreign governments or sanctioned entities. This initiative also aims to enhance the capacity of academic institutions to recognize potential instances of potential illicit procurement, intellectual property theft, or other possible violations of

U.S. laws, and to provide a conduit to report any suspicious activities detected by universities or research institutes.

While raising awareness within the U.S. academic sector and the private sector is an important step, HSI is also making a concerted effort to prevent the acquisition and transfer of technology by foreign nationals through non-traditional collection means. To that end, HSI has initiated efforts to combine and coordinate resources and information available to CPI, CTCEU, SEVP, and VSP in a joint effort to identify, investigate, and prevent destination-controlled technology and export-controlled technology transfers out of the United States that violate U.S. laws and/or weaken the U.S. technological advantage in key fields. This effort will focus on the role foreign students, primarily from sensitive countries, studying at U.S. universities and colleges play in these activities, and will aim to utilize the full breadth of HSI's administrative and criminal authorities to combat the threat posed by these foreign actors.

HSI is committed to free and open academic environment, but this must be balanced against national security measures; if not, these institutions will be taken advantage of and critical U.S. technology and research can be acquired easily by adversaries.

CONCLUSION

In closing, mindful of the United States' historical role in the development of critical technology in coordination with foreign partners and U.S. academic institutions, HSI remains committed to maintaining a free and open academic environment within the United States; however, this must be balanced with an appropriate focus on national security and public safety. The threat posed by adversarial nation-states illegally and subversively seeking to exploit legitimate educational and research opportunities in the United States, many of which are funded with U.S. taxpayer dollars, is real, and the United States must continue to pursue all appropriate means to combat it.

HSI will continue to work with academia, law enforcement partners, and other agency partners, to use its extensive administrative and criminal authorities to identify and disrupt the activities of individuals or organizations who seek to harm the United States in this arena and the multitude of others in which HSI is engaged. HSI is well positioned to mitigate this threat through the many programs highlighted today, all of which provide a multi-layered level of security aimed at protecting the homeland from illicit transnational activities of its adversaries. From the preventative angle of the VSP, to the compliance focus of SEVP, and through the investigative and enforcement programs executed by the CTCEU and CPI programs, HSI is and will continue to be engaged in countering this critical problem. Enhancements and expansion of these programs, combined with enhanced administrative and criminal enforcement authorities, will only improve HSI's ability to identify and thwart the efforts of foreign actors who pose national security or public safety concerns to the United States. HSI looks forward to continuing to work with the committee regarding these HSI programs.

Thank you again for inviting me today to explain HSI's critical role in protecting the national security and public safety of the United States. I would be pleased to answer your questions.

QUESTIONS SUBMITTED FOR THE RECORD TO LOUIS A. RODI III

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

OTHER COUNTRIES

Question. Since 2008, the Chinese military has sponsored more than 2,500 Chinese military scientists and engineers to travel to universities in the U.S. and elsewhere as students or visiting scholars. According to the Australian Strategic Policy Institute, these arrangements have empowered China to make significant advances in developing military technology by leveraging U.S. and other countries' experience, facilities, and resources in high-tech industries. In fact, the United States has been the number one destination for PLA scientists since 2006. Chinese state media proudly refer to this strategy as "picking flowers in foreign lands to make honey in China."

What other countries and governments are you concerned about exploiting loopholes in our immigration system to further that theft? Can you share any specific examples of that exploitation? Please indicate which of the responses will be classified.

Answer. The three primary countries of concern are China, Iran, and Russia. Based on U.S. Immigration and Customs Enforcement (ICE) Homeland Security Investigations (HSI) reporting, students from India and South Korea have also exhibited risk factors for exploiting loopholes in the U.S. immigration system to further sensitive technology and intellectual property theft. Other countries experiencing instability and/or threats at home may also be of significant concern for immigration fraud.

The following examples relate to China's policy and direction for Chinese students to function "as intelligence collectors" for the benefit of the Chinese government:

- The Federal Bureau of Investigation arrested a Chinese student attending the Illinois Institute of Technology for providing information to China's Ministry of State Security officials in Nanjing City regarding U.S. scientists and engineers. The Department of Defense and Department of Homeland Security (DHS) helped identify the student through collaboration on the Military Accessions Vital to National Interest program.
- A Chinese student who was studying musicology through a summer exchange program was detained for having wandered onto a U.S. Naval Station in Key West, FL and taking photos of antenna fields and various military installations.

Other examples of ICE HSI investigations related to this threat would be Law Enforcement Sensitive or classified, and more appropriately briefed in a closed setting.

COURSE CHANGES

Question. Are foreign students entering the U.S. to study something that isn't suspicious, like English literature, then changing their course of study to an area that is highly sensitive, such as biomedical or semiconductor research for nefarious purposes? Do these course changes pose a national security risk, and are these changes often at the direction of foreign governments? If yes, what actions are needed to close these loopholes?

Additionally, if action is needed to close these loopholes, will HSI work with Congress to draft potential legislative fixes? Can we close loopholes and protect national security without limiting our ability to attract the best and brightest talent from around the world?

Answer. There have been instances in which nonimmigrant students who were approved to study non-sensitive fields pursuant to F-1 nonimmigrant status entered the United States and subsequently transferred into programs of study in sensitive fields. Some foreign nationals have also obtained tourist visas and, once in the United States, changed their nonimmigrant status to attend U.S. colleges and universities without going through the traditional visa-vetting process applied to prospective nonimmigrant students seeking to study sensitive fields. In 2016, ICE HSI established the Domestic Mantis Program (DM) to monitor any national security and public safety risks posed by foreign students who transferred into programs to study in sensitive fields. ICE HSI had initiated Project Steady Stare (PS2), aimed at building on the DM Program and equipping ICE HSI with the capability to conduct a targeted intelligence and investigative analysis on those foreign students who pose the highest risk for nontraditional collection, unapproved technology transfer, and/or potential criminal or administrative violations of law. Since the inception of this project, ICE HSI has partnered with DHS in a Department-wide effort and rebranded this initiative as the Stellar Sunrise Project (SSP).

As the principal investigative arm of DHS, ICE HSI plays a pivotal role in safeguarding national security and is committed to working with Congress to develop potential legislative fixes that enable the United States to maintain a free and open academic environment, balanced with an appropriate focus on national security and public safety. In response to prior questions for the record and requests for congressional technical assistance on this subject, ICE HSI provided its assessment of potential legislative action that may be considered to help close loopholes that are being exploited in this space.

In general, these recommendations entail a combination of:

- Ensuring DHS has full discretionary authority to review and recommend that the Department of State revoke the nonimmigrant visas of students deemed to be high risk for sensitive technology transfer and strengthening the legal authority and ability for DHS and the U.S. Department of State to execute revocations;
- Increased administrative removal authorities for students posing a proliferation risk;
- When deemed appropriate by DHS, the mandatory re-evaluation of the non-immigrant visa status of foreign students studying in the United States in sensitive fields;
- The ability to implement nonimmigrant visa debarment for violators; and
- Connected administrative sanctions for non-compliance by academic and research institutions.

DHS needs express and specific additional law enforcement authorities to address these incursions. ICE HSI needs reinstatement of HSI's export subpoena authority for Export Control Reform Act investigations, which was lost when the Export Administration Act was repealed and replaced. This authority could directly contribute to ICE HSI's ability to investigate Export Administration Regulations controlled research violations.

CRITICAL INDUSTRIES

Question. Have foreign nationals, acting surreptitiously on behalf of foreign governments, penetrated critical U.S. industries, including but not limited to health care and pharmaceutical research, infrastructure, financial services, defense, robotics, and advanced chip processing? If yes, please explain what changes are needed to stop or slow these incursions.

Answer. Foreign nationals are functioning in all the listed areas and have access to uncontrolled research, as well as to potentially controlled research. Controlled research is typically defined by those items or information regulated under the International Traffic in Arms Regulations (ITAR) or the Export Administration Regulations (EAR). However, with the advent and expediency of new or emerging technologies, there could be items that are not explicitly controlled under ITAR or EAR. The manner in which foreign governments might be directing their citizens falls into classified channels.

DHS needs express and specific additional law enforcement authorities to address these incursions. First, ICE HSI needs a reinstatement of HSI's export subpoena authority for Export Control Reform Act investigations, which was lost when the Export Administration Act was repealed and replaced. This authority could directly contribute to ICE HSI's ability to investigate ITAR and/or EAR controlled research violations. Second, ICE HSI needs discretionary, administrative removal authority vested to the Secretary of Homeland Security and delegated to ICE HSI. These new authorities would give ICE HSI the ability to administratively remove non-immigrant visa holders who may be involved in the unlawful or surreptitious collection and/or transfer of sensitive technology or research to foreign governments or their proxies. The visa categories most likely to pose a substantial risk related to the diversion of sensitive technology, materials, or information are academic students (F-1) and exchange visitors (J-1) but are not limited to these two visa categories.

DETECT AND MONITOR THREATS

Question. Are we, as a government, doing enough to detect and monitor efforts by foreign nationals to improperly influence or appropriate sensitive research funded by U.S. Government grants? If not, what changes are needed to more effectively identify and remove these threats?

Answer. As the principal investigative arm of DHS, ICE HSI plays a pivotal role in safeguarding U.S. national security. With unique and wide-ranging criminal and administrative authorities, combined with access to all nonimmigrant foreign student visa information, ICE HSI is well-positioned to detect, monitor, and disrupt efforts by foreign nationals to exploit U.S. academic and research institutions.

Leveraging the existing operations of the ICE HSI Counter-Proliferation Investigations Program, the Counter-Terrorism and Criminal Exploitation Unit, the Student and Exchange Visitors Program, and the Visa Security Program, ICE HSI initiated Project Steady Stare (PS2), a proactive and holistic agency effort to target and

prevent the potential illicit procurement and theft of technology and intellectual property by foreign students, researchers, and professors involved in science, technology, engineering, and mathematics programs at U.S. colleges and universities across the Nation. Since the commencement of this project, ICE HSI has partnered with DHS and created an interagency task force that would give analysts access to additional data sets to analyze and help further identify and detect more threats, and would streamline and facilitate coordination among interagency partners to take action against these threats. This initiative is called the Stellar Sunrise Project (SSP).

SSP equips ICE HSI with the capability to conduct comprehensive law enforcement intelligence and investigative analysis on those foreign students who raise national security concerns to determine potential risk for nontraditional collection, unapproved technology transfer, and/or potential criminal or administrative violations of law.

SSP builds on ICE HSI's DM, which was established as part of the 2016 overstay enhancements. DM reviews F-1 visa holders who have switched from a non-sensitive field of study to a sensitive field of study and are publishing at their U.S. institution on sensitive topics. DM consequently does not review the following populations that may also be at a heightened risk of facilitating illicit technology transfer:

- F-1 nonimmigrants who were admitted to the United States to study sensitive fields of study;
- J-1 nonimmigrants (research associates and professors), including visiting researchers studying in the United States for short periods of time; and
- Spouses or other dependents of F and J nonimmigrants who change visa classification to study or research sensitive majors themselves.

Despite ICE HSI programs and initiatives designed to identify these threats, additional steps could be taken to enhance ICE HSI's ongoing efforts. This includes:

- Additional resources specifically dedicated to this issue, which would enable ICE HSI to comprehensively vet more foreign students who pose a nontraditional collection or technology transfer risk.

However, even with additional resources and interagency coordination, ICE HSI and its partners may still be limited in the action they are able to take to mitigate foreign student threats, particularly since in many cases the conduct of foreign students may not be illegal. Through prior questions for the record and technical assistance provided to Congress on other proposed bills, ICE HSI provided its assessment of potential legislative action that could be considered to help close loopholes that are being exploited in this space. In general, these recommendations entail a combination of:

- When a potential risk is identified, DHS will conduct an evaluation of options impacting the nonimmigrant status of foreign students studying in sensitive fields of study in the United States to include visa cancellation and expedited removal from the U.S.;
- Increased administrative removal authorities related to students posing a proliferation risk;
- A reinstatement of ICE HSI's export subpoena authority for Export Control Reform Act Investigations; and
- Connected administrative sanctions for non-compliance by academic and research institutions.

QUESTIONS SUBMITTED BY HON. RON WYDEN

PANELS

Question. Your agency told the Finance Committee that its witness would not participate on a panel at this hearing that included both government and non-government witnesses, claiming there is a longstanding OMB policy prohibiting this. However, there are numerous examples where your agency has allowed witnesses to testify on "mixed panels." Over the past 10 years, Federal Government witnesses, including those from your agency, have testified before the Finance Committee on panels with non-government witnesses more than 40 times. This has also been the case with other Senate committees. In April 2019, an NIH witness testified on a

panel with non-government witnesses before the Senate Aging Committee. An NIH witness also testified on a panel with non-government witnesses before this same committee in July 2017. In March 2018, the Secretary of DHS herself testified on a panel with non-government witnesses before the Senate Select Committee on Intelligence. Why were these witnesses permitted to testify before other Senate committees on mixed panels but your witness was not permitted to do so at the Finance Committee's June 5th hearing? If waivers were granted for witnesses to testify on mixed panels at other committee hearings, why were those waivers granted for the other hearings but not the June 5th hearing? Please provide copies of (1) the OMB policy that allegedly prevents government witnesses from testifying on panels with non-government witnesses; (2) any waivers granted for the recent Aging and Intelligence hearings where government witnesses from NIH and DHS respectively testified with non-government witnesses; and (3) any request submitted to OMB for your witness to testify at the June 5th hearing and the OMB response along with an explanation why a waiver was not granted for the June 5th Finance Committee hearing.

Answer. DHS welcomes the opportunity to testify before Congress to discuss our programs, challenges, and need, and to address any questions the legislative branch may have. Upon receiving an invitation to testify, DHS works with the requestor, in most cases the chairman or ranking member of the committee, to determine the most appropriate witness available to provide the testimony and expertise desired, in the most appropriate environment. Except under extraordinary circumstances, DHS observes the historical practice of not appearing with non-federal witnesses on a single panel. In almost all cases, the appropriate environment to receive DHS testimony is on a government-only panel. While DHS cannot speak for other Departments, agencies, or officials who have chosen to appear on mixed panels before Congress in the past, presently, DHS officials do not testify alongside non-governmental witnesses.

In making its determination, the Department considers whether such appearance would: (1) draw the DHS witness into conflicts that may compromise the legal, commercial, or security interests of the United States; (2) introduce subject matter beyond the scope of the hearing or expertise of the witness; and/or (3) undermine the DHS witness's ability to communicate clearly with the committee.

SOURCE OF FOREIGN THREATS

Question. During the hearing, I asked Dr. Tabak and the first panel of government witnesses to identify the general number, or a range, of countries that currently constituted the source of the foreign threat. Dr. Tabak responded that he could not do so in an unclassified setting and would do so in the classified briefing. Would you please provide a separate, classified response that identifies the specific countries that you believe currently present a threat to U.S. research and describe the nature of that threat?

Answer. For ICE HSI, the largest number of active criminal counter-proliferation investigations on controlled exports, including intangible exports (*i.e.*, the transmission of technical data from the United States or transfer to foreign nationals within the United States), involves China, Iran, and Russia. These three countries are actively implementing a myriad of schemes to illicitly or subversively acquire and transfer export-controlled military and dual-use technology and commodities and are employing numerous ways to circumvent U.S. export control laws.

ICE HSI National Security Investigations Division provided a classified briefing on the referenced topic on June 5, 2019.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

FIVE EYES EXPANSION

Question. The Five Eyes is widely regarded as the world's most significant intelligence alliance. The origins of it can be traced back to the context of the Second World War and by its necessity of sharing vital information mainly between Britain and the United States so both countries could enhance the allied war effort. "Five Eyes" was formally founded in the aftermath of the Second World War, through the multilateral agreement known as the UKUSA Agreement, on March 5, 1946.

Initially, compromising only the UK and the United States, it expanded to also include Canada in 1948 and Australia and New Zealand in 1956. Thereby, the "Five Eyes" term was created from the lengthy "Australia/Canada/New Zealand/United

Kingdom/United States Eyes Only” classification level that included the “eyes” that could have access to high-profile papers and information.

For more than 70 years this alliance of like-minded allies has served our intelligence community well.

Just like sharing access to sensitive intelligence information, should we think similarly about opening up certain programs or research areas to certain students or professors depending on their home country?

Is there a model here for academia that is worth following?

Should we be limiting what countries we conduct sensitive research and development with?

Answer. As many research areas fall under fundamental research, the data is already open to Five Eyes (FVEY) partners and others. Restrictions placed on sensitive fields of study are limited and generally do not impact foreign nationals from FVEY partners. We need to strike a delicate, albeit necessary, balance between the open academic environment that is necessary for fundamental research, while also mitigating threats from foreign actors that pose a risk to U.S. national security. This may include placing limitations on which countries we partner with to conduct sensitive research and development.

PREPARED STATEMENT OF CAPTAIN MICHAEL SCHMOYER, PH.D., ASSISTANT DEPUTY SECRETARY FOR NATIONAL SECURITY; AND DIRECTOR, OFFICE OF NATIONAL SECURITY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning, Mr. Chairman, Ranking Member Wyden, and distinguished members of the committee. It is an honor to appear before you today to discuss the U.S. Department of Health and Human Services’ (HHS) efforts to address foreign threats. My testimony today will focus on the threats foreign governments and foreign agents present to U.S. Government-funded medical research, the efforts undertaken by HHS to detect the threats and protect the integrity of medical research—an area that is critical for our Nation’s ability to provide healthcare and for bio-defense; and the role of HHS’s Office of National Security (ONS), formerly known as the Office of Security and Strategic Information (OSSSI), and its capabilities.

My name is Captain Michael Schmoyer, the Assistant Deputy Secretary for National Security and Director of HHS’s ONS. ONS is headed by the Assistant Deputy Secretary for National Security, who reports directly to the Department’s Deputy Secretary and also serves as the Secretary’s Senior Intelligence Official on intelligence and counterintelligence issues. ONS’s vision is for HHS personnel to successfully accomplish missions worldwide in a security-informed manner and with the actionable intelligence needed for operational and policy decisions. ONS’s responsibilities include: integrating intelligence and security information into HHS policy and operational decisions; assessing, anticipating, and warning of potential security threats to HHS and national security in general; and providing policy guidance on and managing the implementation of the Department’s national security, intelligence, and counterintelligence programs.

ONS’s programs include handling national security clearances for employees, classified national security information management, secure area (*i.e.*, Sensitive Compartmented Information Facilities) management, communications security, safeguarding and sharing of classified information, cyber-threat intelligence, insider threat, and counterintelligence. In coordination with the Director of National Intelligence, ONS has been designated since 2012 as the Department’s Federal Intelligence Coordination Office, and I serve as the Department’s Federal Senior Intelligence Coordinator. ONS has responsibilities to establish implementing guidance, provide oversight, and manage the Department’s policy for the sharing, safeguarding, and coordinated exchange of information relating to national or homeland security with other Federal departments and agencies, including law enforcement organizations and the intelligence community, in compliance with the HHS policies and applicable laws, regulations, and Executive Orders.

THE THREATS FOREIGN GOVERNMENTS AND FOREIGN AGENTS PRESENT TO TAXPAYER-FUNDED RESEARCH

ONS has an important mission that focuses on supporting HHS’s ability to conduct research that will lead to the development of treatments, diagnostics, and vaccines to address public health needs, including medical countermeasures to address

the ever-evolving threat of newly emerging and re-emerging infectious disease caused by pathogens, including those that are select agents and other biological threats to the homeland. While appreciating the value of scientific advancement, HHS has an equal interest in maintaining the integrity of the Department's scientific enterprise. Similarly, HHS embraces the contributions that foreign partnerships have made to expanding scientific knowledge that protects, promotes, and advances public health and medical pursuits worldwide.

Through work with our national security partners over the past 2 years, ONS became aware of threats to the grant process and intellectual property that is a cornerstone of the Department's, including the National Institutes of Health (NIH), core values and biomedical research integrity. After becoming aware of foreign entities' systematic approaches to influence NIH researchers and peer reviewers, ONS quickly worked with NIH, the Office of the Inspector General (OIG), the Federal Bureau of Investigation (FBI), and the National Counterintelligence and Security Center (NCSC) to identify steps to mitigate these threats to U.S. biomedical research.

ONS is a supporter of NIH's initiative to stand up a working group of the Advisory Committee to the NIH Director that addresses ways to mitigate risks to intellectual property as well as measures to protect the peer review process. In fact, ONS provided a briefing to the Director's working group on the risks that U.S. Government-funded partners face as well as strategies that we are using, together, to mitigate those risks.

THE ROLE OF HHS'S OFFICE OF NATIONAL SECURITY AND ITS CAPABILITIES TO DETECT THREATS AND PROTECT THE INTEGRITY OF MEDICAL RESEARCH

As mentioned previously, a large part of the ONS mission is to counter foreign intelligence entity threats. ONS does this in three fundamental ways:

- identification of foreign intelligence threats and sharing of threat information with our agencies (including NIH), the FBI, and the broader intelligence community;
- safeguarding HHS's sensitive information, relationships, property, and activities; and
- prevention and detection of insider threats.

I am the designated senior official within the Department who is responsible for countering threats from foreign intelligence entities. Utilizing the resources and authorities that we currently have, ONS builds interdisciplinary partnerships throughout HHS, including NIH, in a variety of areas that include, but are not limited to, physical security, chief information officers, human resources, and acquisition/procurement. We have worked with partners, both internally and externally, to conduct assessments of HHS's sensitive information, property, and activities; we have found that these periodic risk assessments are the cornerstone for all of our corresponding security and counter-threat activities.

We have also developed measures and strategies that are commensurate with the risk assessment-identified threats to HHS and have specifically focused on elements such as information security measures, personnel security practices, foreign contact and visitor vetting, supply chain risk management, Committee for Foreign Investment in the U.S. proposed acquisitions, and prevention of unauthorized disclosures. Specific examples of these measures and strategies include: (1) implementing long-standing policies relating to distribution of badges, vetting visitors, coordination with the intelligence community, and addressing insider threats; (2) regularly evaluating the application of adjudication suitability standards relating to onboarding new personnel (civil service, contractors, detailees and fellows); (3) utilizing existing mechanisms to share threat and vulnerability information across the enterprise; (4) continually promoting workforce awareness of the threat from foreign intelligence entities and providing awareness and reporting instructions to HHS personnel; and (5) implementing specific measures to detect intrusions.

THE EFFORTS UNDERTAKEN BY HHS AND NIH TO VET RESEARCHERS

ONS works closely with the Department of Justice, including the FBI; with other HHS components, including the OIG and NIH; and with the broader intelligence community to identify NIH-employed researchers who may have engaged in problematic practices with foreign entities that may have unduly influenced and capitalized on U.S.-conducted research. ONS has access to a variety of databases that enable us to vet employees, as well as visitors, to HHS facilities (including NIH).

These database results are linked with National Security partners to ensure the results we have are both reliable and valid.

Our conversations relating to vetting for derogatory information occur with the FBI and others (both in and outside of the intelligence community) on a daily basis. In addition, we share our results with other departments which often have similar missions to HHS. Currently, HHS vets new civilian employees, U.S. Public Health Service Commissioned Corps officers, contractors, research fellows, interns, and foreign national visitors to HHS properties. We have had both onboarding-related policies as well as a foreign visitor policy in place since at least 2011; these policies are updated as needed. HHS does *not* vet funded research partners who are not employees, or contractors, of HHS (for example, NIH-funded university principal investigators).

Additionally, we have initiated a new focus within ONS that will be dedicated to working with universities to empower their programs to, among other things, conduct vetting similar to what we do for employees/contractors within HHS. We have been excited to work with NIH, FBI, OIG, and NCSC to see this new national security-related effort comes to fruition. With this focus we are better able to address potential threats of foreign influences on research integrity at the grantee level.

THE ROLE THE FBI PLAYS IN ASSISTING HHS AND ITS SUB-AGENCIES IN
DETECTING AND COMBATING FOREIGN THREATS

Over the past 2 years, all of the efforts undertaken by ONS to prevent, detect, and mitigate threats to the integrity of medical research have been done in conjunction with national security partners across the government. We have worked especially closely with the FBI, including instituting a formalized full-time detailing of a Supervisory Special Agent to our office.

Since the spring of 2017, ONS became acutely aware of specific challenges relating to the threat of foreign influences on HHS, and specifically NIH, research integrity. We became involved in two whole-of-government working groups, led by the FBI, to address the challenges since some foreign governments have initiated systematic programs to unduly influence and capitalize on U.S.-conducted research, including that funded by NIH. We became aware that some HHS-funded scientists had not been disclosing foreign grant support, affiliation with laboratories outside of the U.S., or even faculty appointments with foreign nations. Additionally, we learned about threats to the NIH grant peer review process where confidentiality was compromised and information shared that attempted to alter the NIH funding decision process.

While the relationship with FBI and ONS had existed since the early 2000s, our work in early 2017 with the FBI surrounding the threats posed to the NIH campus and its extramural grant process galvanized our relationship even further. HHS quickly became even more active with the Baltimore FBI field office and the Washington field office's counterintelligence programs. Together, in close coordination with our OIG, NIH, and NCSC colleagues, we quickly worked on a strategy to address the threat of foreign nontraditional counterintelligence collection. Our main focus was to ensure that our national security-related efforts continued to support successful relationships with foreign scientists in all countries supporting the research enterprise while simultaneously protecting the Nation's, and HHS's research integrity.

In closing, thank you for the opportunity to review the national security role and work of the HHS ONS and our efforts to address foreign threats in research.

QUESTIONS SUBMITTED FOR THE RECORD TO CAPTAIN MICHAEL SCHMOYER, PH.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, how would those checks help strengthen grant integrity?

Answer. Standard background checks for new Federal employees involve a criminal records check, as well as inquiring about the prospective employee with their former employers. The average NIH employee is not reviewed for counterintelligence purposes as many do not hold national security clearances.

Reviewing *all* principal investigators (PIs) (both NIH PIs and extramural investigators) for counterintelligence purposes could strengthen grant integrity, but must be pursued as a whole-of-government solution as opposed to a fragmentary approach. This is largely due to the sheer number of applications involved in the effort. For example, just handling PIs on NIH grants alone would require the ability to process over 20,000 applications *quarterly*. An additional consideration is that the above only covers NIH; it does not include other Federal departments and agencies who conduct research.

ONS recently stood up an NIH-focused branch with a team specifically focused on working directly with NIH-funded extramural entities to train institutes of higher education staff on how to identify counterintelligence threats. As noted above, if deemed appropriate, such approaches could be considered from a whole-of-government perspective, rather than remaining solely focused on NIH-funded entities.

Question. If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, would those checks improve the government's security posture? If so, how? If not, why not?

Answer. For the same reasons cited above, while usage of counterintelligence screenings in the grants process would improve the government's security posture, performing such checks would increase the administrative burden behind every grant, slowing down important research.

Question. How many people within the Office of National Security work on vetting foreign visitors and other individuals within your office's purview? Is your staffing sufficient?

Answer. The HHS/Division of Operations (DO), within ONS, has one individual designated full time for vetting of foreign visitors to the Department and several agencies (including NIH). DO has one NIH detailee who assists with the function, and DO flexes the other staff if a particularly sensitive or urgent matter occurs (four additional personnel)—but can only do this for short periods of time before suffering mission degradation in other areas (such as Committee on Foreign Investment in the United States, Supply Chain Risk Management, Technical Surveillance Countermeasures, Foreign Travel, and counterintelligence reviews of other employee types and incidents).

Two additional FTEs will be coming onboard to assist, full-time, with vetting foreign visitors. At DO's current staffing level, DO can conduct counterintelligence checks on just over 20,000 visitors annually without mission degradation; thus, DO's current staffing is sufficient for steady-state operations. Staffing is not sufficient to vet other areas, such as principal investigators of research programs.

Lastly, by the end of the fiscal year, the new NIH-focused team mentioned above will have two to three new individuals to assist with vetting NIH-specific visitors, employees, and contractors.

Question. How are you leveraging your resources to improve vetting for individuals running critical projects?

Answer. Please see the memo depicting classified responses to unclassified QFRs.

Question. What foreign governments pose the greatest threats to intellectual property created by taxpayer-funded research at American universities? How are they working to exploit our academic institutions to steal critical IP? Can you share any specific examples of that exploitation?

Answer. Please see the memo depicting classified responses to unclassified QFRs.

Question. Have foreign nationals, acting surreptitiously on behalf of foreign governments, penetrated critical U.S. industries, including but not limited to healthcare and pharmaceutical research, infrastructure, financial services, defense, robotics, and advanced chip processing? If yes, please explain what changes, including legislative changes, are needed to stop or slow these incursions.

Answer. Yes. This requires a whole-of-government approach to strengthen the ability of individual agencies to examine counterintelligence concerns throughout the entirety of the supply chains for products and services procured. Additionally, government-funded intellectual property must be better protected when developed in tandem with private industry; while public-private cooperation is critical to maintaining the current pace of scientific advancement, the ability of the government to

safeguard particularly critical information, while balancing the need for collaboration, must remain a priority.

Question. Should NIH consider the risks presented by foreign principal investigators when permitting access to United States genomic data? If so, why? If not, why not?

Answer. ONS supports both the NIH and HHS/OIG to address security issues so that all NIH-funded assets, including data, are appropriately protected.

ONS is aware that NIH is clarifying policies that require disclosure of all other support (including support from foreign entities), foreign components, and significant financial conflict of interest. NIH is in the process of implementing other risk mitigation recommendations from the ACD, as described by the NIH ACD Working Group, and is also collaborating closely with ONS and the security and intelligence communities to broadly assess and dedicate resources to address risks related to NIH equities.

Specific to genomic data, ONS is aware that the NIH Genomic Data Sharing Policy (GDS) sets forth expectations and responsibilities to ensure the timely, broad and responsible sharing of genomic data. NIH oversight and control procedures have been implemented to verify that investigators and entities using such data do so in a manner consistent with the NIH mission.

Question. Should NIH assess the risks to national security and intellectual property when permitting data access to foreign principal investigators? If so, why? If not, why not?

Answer. HHS/ONS will continue to work with NIH to address scientific data misuse. NIH could strengthen its controls by continuing to support ONS's effort as it relates to counterintelligence and insider threat activities, conducting a risk assessment, and implementing additional appropriate security controls designed to safeguard sensitive data. We also recommend that NIH continue its development and implementation of mechanisms to ensure data security policies keep current with emerging threats. Lastly, we concur with HHS/OIG that NIH make security awareness training and security plans a requirement for its funded PIs.

ONS is aware that NIH is working with Federal security and intelligence agencies to address security issues appropriately for protection of all NIH-funded assets, including data.

It is imperative that risk assessments are conducted and commensurate with emerging threat issues. This is exemplified by the fact that China has instituted policies that regulate access to biological data and materials. The new Chinese regulations implement new requirements for the use of human genetic resources that come from Chinese participants. The rules, which went into effect on July 1, 2019, require international scientists using biomaterials from China to have a Chinese collaborator. Article 21 states that foreign organizations that use the materials must abide by Chinese law and work in cooperation with Chinese institutes. Article 24 states that all data and patents derived from such a collaboration must be shared with the Chinese institution [www.the-scientist.com/news-opinion/china-clamps-down-on-foreign-use-of-chinese-genetic-material-and-data-66016]. This development could exacerbate the lack of data access reciprocity and negatively impact future research partnerships and collaborations.

Question. Can genomic information be used to track or surveil individuals?

Answer. ONS would be delighted to, in conjunction with NIH, respond to this question in a more secure environment.

Question. What is the most effective unclassified tool you have to detect the threat to taxpayer-funded research and deter that threat? What additional tools do you need?

Answer. NIH conducts outreach on a variety of policy issues of importance to the biomedical research enterprise. Initiatives and programs are continually refined to educate, improve situational awareness, and develop a mechanism to report suspicious activities at research entities that could represent an emerging national security threat. Continued efforts are needed to improve and expand efforts to educate and provide training on security issues, elaborate on the "real world" threat, and provide resources for mitigating identified risks. We can provide a more thorough response within the accompanying classified memo responding to unclassified QFRs.

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. What are HHS and NIH, respectively, doing to prevent racial bias and a talent drain in their efforts to address foreign threats to U.S.-funded research?

Answer. HHS/ONS applies the same screening standards for all non-U.S. person visitors, regardless of origin. Further examination is based on identified risk factors which are best discussed in a secure setting.

Question. Policy on Mixed Government and Non-Government Witnesses on Panels: Waivers and waivers granted.

Answer. ONS is not positioned to answer this question.

Question. Source of foreign threats.

Answer. This was covered in HHS/ONS prior response on appropriately classified systems.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

Question. Just like sharing access to sensitive intelligence information, should we think similarly about opening up certain programs or research areas to certain students or professors depending on their home country?

Answer. Identification of national security threats can be done in a number of ways; shortcuts such as national origin, however, tend to introduce serious errors that undermine the process and may lead to a chilling effect on research cooperation. Focus should be on the individual, rather than the country, in order to ascertain legitimacy of access, verification of professional bona fides, competencies, and references.

Question. Is there a model here for academia that is worth following?

Answer. Recent proposed legislation and other policy shifts in the works may provide a good foundation for academia to follow; however, all systems have vulnerabilities and flaws. The 2012 revision of the U.S. Select Agents and Toxins Regulations required the implementation of a personnel security program for vetting and continuously monitoring personnel holding or seeking access to thirteen pathogens and toxins classified as significant public safety and security risks to the United States (referred to as "Tier 1 agents"). In response, several institutions that support research with these pathogens have independently established behavioral threat assessment teams; these teams help institutional officials evaluate the suitability and reliability of incoming and existing laboratory personnel that work with Tier 1 agents. These teams draw on the institutional offices of human resources, general counsel, security and law enforcement, environmental health and safety, and occupational health.

Personnel threats come in two forms: insider threats and external threats. The overall effectiveness and acceptance of personnel security programs hinges on sensitizing employees to the possibility that people in their workplace might harm others for personal reasons or be recruited or manipulated by outside groups.

Representatives from the research community agreed that addressing personnel security in practice relies on employers:

- A. Identifying individuals who pose a threat prior to hiring;
- B. Identifying existing employees whose risk potential changes over time;
- C. Identifying a threat when it arises; and
- D. Managing threats safely and effectively after they are detected.

While these strategies can provide a baseline for risk mitigation as institutions begin to develop their personnel security programs, each institution should carefully consider all possible strategies and incorporate those approaches that best fit their facilities, threats, and community. The key is to develop programs that focus on minimizing and effectively mitigating the threat without limiting creativity and unconventional thinking, or creating a risk averse environment that might be detrimental to scientific advancement.

Question. Should we be limiting what countries we conduct sensitive research and development with?

Answer. HHS/ONS does not recommend such limitations, as they are based on a security threat identification shortcut that has, historically, led to significant errors

that undermine processes and minimize international cooperation based on temporary trends and political changes. Rather than limiting the countries, which is already reviewed by the visa application process, a risk assessment should be conducted to determine vulnerabilities and security concerns as a means to ascertain “need to-know.” This would facilitate proper vetting of individuals and further the research effort.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. How do we make sure that the United States maintains a competitive edge in an age of increased cooperation with hostile actors/countries?

Answer. Ensuring a competitive edge while maintaining open and continuous contact with potentially hostile actors and countries requires the individuals involved in that contact to be acutely aware of the potential risks involved with the contact, and how to respond to those risks once actualized.

An example could involve researchers focusing on influenza variants. Certain variants of influenza arise in natural reservoirs that are outside the United States—such as certain phenotypes of Swine and Avian flu. Simply closing off research to countries in direct competition to the United States would also shut off the ability to access those other phenotypes—leaving the United States particularly vulnerable should those phenotypes become involved in a pandemic. Thus, shutting off other countries itself becomes a national security concern. Instead, researchers in this (and similar) spaces should be continuously educated on the risks to intellectual property inherent in the places they conduct their research, as well as with whom they conduct their research. This education must include more than simply advising the researchers of the risk; it must also include how to handle that risk—specifically, reporting and safeguarding. This will vary based on the details of each project. However, a whole-of-government approach will simplify reporting of such concerns when actualized, and may help identify such risks at an earlier stage when mitigation is simpler and more likely to protect the intellectual property. Further, connecting the requirement for this education with the receipt of grant funding from any source will help ensure saturation of the information throughout the research community.

Question. What tools does Congress have to help our domestic pharmaceutical industry and protect them from foreign influence?

Answer. The Committee on Foreign Investment in the United States, provides certifications to Congress regarding cases that do not pose a national security concern. HHS/ONS is also happy to work with Congress to ensure we have the tools to address this issue.

Question. What additional efforts are needed in new and cutting-edge fields like genomics?

Answer. NIH is exploring different options for dealing with this important issue, and we are engaged in conversations with relevant partners. Working with ONS to have continued outreach, both internally and externally to NIH, and education on this topic is also essential. We are looking at many different approaches, and it should be said that restricting access to genomic data risks delaying the advancement of important research that could lead to treatment or cures for many diseases, and could hinder the U.S., and global, bioeconomy, so the risks and benefits of restricting access to genomic data must be weighed carefully. Consideration of negative impacts should go beyond just genomics, as restricting access to other scientifically valuable resources (*e.g.*, biospecimens, other data types) also has the potential to delay important research and life-saving cures, and significantly affect our competitiveness on a global scale.

QUESTION SUBMITTED BY HON. SHELDON WHITEHOUSE

Question. How are Federal agencies working together to assist universities in safeguarding their data? What more can agencies do to coordinate better with each other?

Answer. HHS/ONS works closely with NIH to discuss the risks they and their academic partners face. Additionally, HHS/ONS works closely with both FBI and the ODNI/National Counterintelligence and Security Center to assist universities in

safeguarding their data. Additionally, ONS's new NIH-focused branch has an external team that will work directly with universities.

PREPARED STATEMENT OF LAWRENCE A. TABAK, D.D.S., PH.D.,
PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH

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.

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

¹<https://nfbp.com/wp-content/uploads/2017/10/DAY-OF-RELEASE.Nobel-Prize.October-20171.pdf>.

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

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.

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 as 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 website).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 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 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 *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.

QUESTIONS SUBMITTED FOR THE RECORD TO LAWRENCE A. TABAK, D.D.S., PH.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

Question. According to NIH, it operates both the intramural program and the extramural program for research activities. Within the intramural program, NIH's employees, contractors and affiliates who are U.S. citizens undergo background investigations. Further, prior to that background check, a Special Agency Check is conducted requiring fingerprints to be cross-checked with FBI criminal databases, including terrorist watch lists. According to NIH, a grantee institution in the extra-

⁵ <https://acd.od.nih.gov/working-groups/foreign-influences.html>.

⁶ <https://science.sciencemag.org/content/363/6433/1290>.

⁷ <https://science.sciencemag.org/content/363/6433/1292.full>.

mural program, such as a university or other research institution, is responsible for any vetting, not NIH.

More than \$8 out of \$10 appropriated to NIH goes to the extramural program. At the committee hearing, I asked Dr. Tabak whether NIH conducts background checks, including a review for counter-intel purposes, on principal investigators prior to awarding a grantee institution taxpayer money. He answered, "No sir, we do not, as they are employees of their home institution."

Can NIH condition the receipt of taxpayer money on the principal investigator passing the same background check that NIH employees must pass? If so, why has NIH not made that a condition?

Answer. Through ongoing discussions with the extramural community, the Department's Office of National Security, and our Federal partners, in particular those in security and law enforcement, NIH is actively exploring options and additional actions to address research integrity concerns. If extramural investigators have long term (more than six month) access to Federal facilities or information systems, they are required to undergo background investigation for a determination of eligibility for a PIV credential. The standards for this determination is whether the issuance of a credential would pose an unacceptable risk to people, property or information systems. At this time, we do not know whether implementing such a background check requirement for extramural investigators that do not have long-term access to Federal facilities or systems would be feasible or helpful. We must consider adverse effects on university administrative burden, especially if such an effort were to be taken at scale (involving hundreds of thousands of scientists every year).

Question. If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, how would those checks help strengthen grant integrity?

Answer. It is unclear whether this would strengthen grant integrity. There is a risk that institutions might see these background checks as a rationale for loosening their oversight.

Question. If principal investigators were subject to the same background check as NIH employees, and were also subject to a review for counterintelligence purposes, would those checks improve the government's security posture? If so, how? If not, why not?

Answer. This question is outside the purview of the NIH.

Question. What additional changes would improve the integrity of the grant system and taxpayer-funded research? For example, should any changes be made to government grant forms?

Answer. NIH understands and supports interest in modifying government grant forms and/or application information, *e.g.*, to include an assurance/certification from the authorized organization representative (AOR) that the investigator(s) designated in the grant application do(es) not have a criminal background or findings of sexual harassment, and that the investigator(s) fully disclosed all affiliations and other research support. This additional assurance/certification would be governed by the existing, express acknowledgement by the AOR that any intentional or negligent misrepresentation of the information contained in the certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. § 3801 et seq.); (4) civil recovery of award funds; (5) suspension and/or debarment from all Federal procurement and non-procurement transactions (FAR Subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties.

Question. According to the Health and Human Services Inspector General, NIH has recently referred for investigation 16 allegations of noncompliance related to medical research. The Inspector General stated the allegations primarily deal with the failure of principal researchers to disclose foreign government affiliations.

At the committee hearing, I asked Dr. Tabak how NIH discovered cases for referral to the Inspector General. In response, he stated, "We flagged these in various ways, our own staff use algorithms to detect potential untoward behavior. We also receive referrals from our colleagues at HHS and the FBI and, increasingly, universities as they become more and more aware of this issue, are alerting us to potential issues as well." I also asked Dr. Tabak whether he would provide this committee

a specific breakdown of how each referral originated, whether by NIH or a research institution. Dr. Tabak stated, “We would provide that for the record, but it would have to go in concert with the IG. We’ve already made those referrals and they are ongoing investigations.”

In the past 5 years, how many referrals have HHS and the FBI sent to NIH? Please list each institution, all researchers subject to the referral, and the reason for the referral.

Answer. NIH is not positioned to provide this information due to dynamic, ongoing investigations.

Question. For those referrals that NIH sent to the Health and Human Services Inspector General, how many originated with NIH and how many originated with a research institution or another agency? In your response, please provide the name of each research institution and agency. In addition, did any of the grantees receive new NIH grants or have NIH grants renewed after NIH decided to refer the cases? If so, what was the total value of those grants?

Answer. From the current list of referrals to the OIG, two thirds originated at NIH and one-third came to NIH from the FBI. We have put all new grant funding and renewals associated with these investigators on administrative hold as questions are being addressed.

Question. What foreign governments pose the greatest threats to intellectual property created by taxpayer-funded research at American universities? How are they working to exploit our academic institutions to steal critical IP? Can you share any specific examples of that exploitation?

Answer. This question falls outside of NIH’s purview.

Question. Have foreign nationals, acting surreptitiously on behalf of foreign governments, penetrated critical U.S. industries, including but not limited to health-care and pharmaceutical research, infrastructure, financial services, defense, robotics, and advanced chip processing? If yes, please explain what changes, including legislative changes, are needed to stop or slow these incursions.

Answer. This question is outside the purview of the NIH.

Question. A recent Inspector General report raised concerns with the fact that NIH gave access to U.S. genomic data to for-profit companies from China “even though the FBI has identified those companies as having ties to the Chinese Government.” The report also found that “NIH did not consider the risk presented by foreign principal investigators when permitting access to United States genomic data and has not assessed the risks to national security when permitting data access to foreign principal investigators.”

Is NIH still providing companies with ties to the Chinese Government access to U.S. genomic data? If so, why?

Answer. NIH does not verify affiliations of principal investigators beyond that of their home institution. NIH oversight and control procedures, such as data access request review by Data Access Committees and ongoing tracking of data use, allow NIH to verify that stewardship of the data by investigators and responsible entities is consistent with the terms and conditions for use of the data.

Recognizing the importance of transparency in how these data are being used, NIH does publicly provide information related to data submitted to dbGaP, such as a list of all approved users for each dataset, their institutional affiliations, and their proposed research use of those data.

Question. Has NIH changed its policy to now consider the potential national security risks in giving foreign Principal Investigators access to U.S. genomic data? If not, why not?

Answer. NIH continues to take national security risks into consideration regarding all of its assets and is working with our partners in the Federal security and intelligence agencies to address these issues appropriately. NIH notes that these risks are not limited to (or even typically focused on) human genomic data.

NIH’s commitment to tackling these important challenges are reflected in a variety of recent actions, including the convening of a NIH Advisory Committee to the Director (ACD) Working Group for Foreign Influences on Research Integrity. From this engagement, the ACD recommended that NIH should increase communication and awareness with institutions and organizations, mitigate and prevent risks, and

work with partners across the government to monitor, report, and enhance security to protect America's research integrity.

As it pertains to risk mitigation, NIH is clarifying policies that require disclosure of all other support (including support from foreign entities), foreign components, and significant financial conflict of interest. NIH is in the process of implementing other risk mitigation recommendations from the ACD, as described by the NIH ACD Working Group, and is also collaborating closely with the HHS Office of National Security and the security and intelligence communities to broadly assess and dedicate resources to address risks related to NIH equities.

Question. What particular areas of genomic data did NIH provide to WuXi Nextcode Genomics, Shenzhen BGI Technology Company, and other genomics entities associated with the Chinese Government? Have the FBI and the intelligence community received relevant information about the type of genomic information these entities accessed? How many Americans' genomic information was provided to these foreign entities?

Answer. The table below provides the study name, number of participants, and type(s) of data that were accessed by Shenzhen BGI Technology Company, BGI Americas, BGI Research, and WuXi Nextcode Genomics. Given that the majority of the security conversations on this topic have taken place in classified settings, we cannot speak to the spectrum of briefings received by the FBI and the intelligence community.

| Study Name and Number of Participants | Disease Area | Data Types Included |
|---|--|---|
| The Cancer Genome Atlas (TCGA) (11,429 Participants) | Cancer | Whole Genome Genotyping Whole Genome Sequencing Whole Exome Sequencing RNA Sequencing |
| Foundation Medicine Adult Cancer Clinical Dataset (FM-AD) (18,004 Participants) | Cancer | Targeted Genomic Sequencing |
| Genotype-Tissue Expression (GTEx) (752 Participants) | Normal tissue, no disease | Whole Genome Genotyping Exome Genotyping Whole Exome Sequencing RNA Sequencing Gene Expression Whole Genome Sequencing |
| Whole-Genome Sequencing of Acute Myeloid Leukemia (170 Participants) | Acute Myeloid Leukemia | Whole Genome Genotyping |
| Transcriptome Sequencing of Pediatric AML FAB-M7 (15 Participants) | Acute Myeloid Leukemia | Whole Genome Genotyping Whole Genome Sequencing |
| Sequencing of Medulloblastoma (93 Participants) | Medulloblastoma (type of brain cancer) | Whole Genome Genotyping |
| Estrogen Receptor Positive Breast Cancer: Aromatase Inhibitor Response Study (115 Participants) | Breast Cancer | Whole Genome Genotyping |

Question. What is the most effective unclassified tool you have to detect the threat to taxpayer-funded research and deter that threat? What additional tools do you need?

Answer. NIH is employing a multi-pronged approach to develop proactive programs to minimize the likelihood of problems in the future. To date, informing the research community and the extramural staff at NIH to raise awareness, and partnering with other agencies have been effective strategies.

Informing the research community: Raising awareness of the threat at awardee institutions has been a powerful tool. We continue to urge universities to look closely at their organizations to mitigate unscrupulous practices by individuals that aim to capitalize on the collaborative nature of the U.S. biomedical enterprise. Regular communications to the extramural community over the last several years have focused on protecting the integrity of U.S. biomedical research and the imperative to inform NIH of any foreign support. These communications have included a number of notices and statements to the community, including the unprecedented step of the NIH Director issuing a letter to officials at ~10,000 recipient institutions. This letter informed the research community that the agency is aware that some foreign entities have mounted systematic programs to influence NIH-supported researchers and peer reviewers, as well as to take advantage of the long tradition of trust, fairness, and excellence of NIH supported research activities.¹ Furthermore, NIH convened a working group of the Advisory Committee to the NIH Director (ACD) on Foreign Influences on Research Integrity. This panel comprised leaders in higher education, members of the extramural community, and experts in security, and was charged with assisting the ACD, which made recommendations to the agency which are currently being implemented.

NIH regularly communicates with grantees to provide training and compliance support for issues involving conflict of interest requirements at NIH-led conferences such as the NIH Regional Seminars. This information is also communicated by NIH through professional organizations such as the Federal Demonstration Partnership, Society for Research Administrators, American Association of Universities, Council on Governmental Relations, Association of Public and Land-grant Universities, and the National Council of University Research Administrators. There have been a number of special meetings involving these groups and others to address the recent concerns on foreign influence. In addition, NIH recently developed an online training module² on Financial Conflict of Interest as a resource for both NIH staff and the extramural community. NIH's outreach and engagement have facilitated extensive faculty outreach at research organizations as well as led to developing and sharing best practices.

NIH has also been reaching out to recipient institutions directly. NIH has contacted over 60 institutions regarding specific scientists who may have failed to disclose substantial foreign research support or financial conflicts of interest or who may have engaged in substantial breaches of peer review integrity. This outreach has led to referrals to OIG, communications with FBI, disciplinary actions by the relevant institutions (including terminations or resignations), revisions of grant terms, and new efforts on the part of institutions to enhance oversight and security of their research operations.

We have strong indication that these communication strategies are working. A report on Actions Taken by Universities to Address Growing Concerns about Security Threats and Undue Foreign Influence on Campus,³ issued by the American Association of Universities (AAU) and the Association of Public and Land-grant Universities and updated in April 2019, shares practices that universities are employing to "ensure the security of research, protect against intellectual property theft and academic espionage, and prevent actions or activities by foreign governments and/or other entities that seek to exert undue foreign influence or which infringe on core academic values."

Partnering with other agencies: NIH is actively partnering with other Federal departments and agencies to address concerns related to undue foreign influence on the biomedical research enterprise. These Federal partners include the Central In-

¹ <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-protecting-integrity-us-biomedical-research>.

² <https://nexus.od.nih.gov/all/2018/12/03/new-financial-conflict-of-interest-training-module-available/>.

³ <https://www.aplu.org/members/councils/governmental-affairs/Effective-Sci-Sec-Practices-What-Campuses-are-Doing.pdf>.

telligence Agency, Federal Bureau of Investigation, HHS Office of Inspector General, HHS Office of National Security (ONS), Department of Defense, Department of State, Department of Energy, and the National Science Foundation. Staff within the intelligence community, FBI, DOE, and NSF, for example, have noted that NIH is well ahead of other Federal agencies in addressing and communicating concerns of possible undue foreign influence on research funding.

The most effective unclassified tool we've used to date has been close work and partnership with institutions and with law enforcement on specific cases. These partnerships have led to extensive discovery about the nature of the threats, to actions by the relevant institutions against certain investigators, to referrals to the OIG, and to institutional implementation of additional internal systems control measures.

We look forward to ongoing work with institutions, with OIG, and with other agency offices/contacts (including FBI, DNI, DOE, NSF, DOD, HHS/ONS, and State).

QUESTIONS SUBMITTED BY HON. RON WYDEN

Question. Potential Damage to U.S. Research from Attacks on Foreign Researchers: *The Houston Chronicle* recently reported that over the past 18 months, three MD Anderson senior researchers or administrators of Chinese descent have retired, resigned, or been placed on administrative leave. Some believe a toxic climate and perception of racial profiling hastened their departures. Two of the researchers subsequently took positions at Chinese institutions. In March, a group of Chinese American scientists voiced concern in a strongly worded letter in the journal *Science* that recent rhetoric and proposals by the NIH and FBI could lead to unjust targeting of Chinese scientists. In May, the magazine ran an editorial entitled "Two Threats to U.S. Science." The two threats it identified were inadequate research funding and disparagement of foreign scientists working in the U.S. and the immigration roadblocks to their staying in the U.S. What are HHS and NIH, respectively, doing to prevent racial bias and a talent drain in their efforts to address foreign threats to U.S.-funded research?

Answer. NIH has a responsibility, in coordination with other Federal agencies and with institutions, to strive to assure an environment of compliance and ethical conduct of research. Stealth employment and research support in foreign countries and egregious violations of peer review norms pose a serious threat to the integrity and credibility of the entire research enterprise.

NIH is focusing its efforts on enhancing research integrity across all our processes and systems. The extraordinary contributions of foreign nationals to American science are indisputable. As just one example, 24 percent of U.S. Nobel prizes have been awarded to foreign-born scientists. The biomedical research workforce continues to be greatly enriched and strengthened by scientists who come to our shores from many parts of the world. The overwhelming majority of researchers participating in NIH grants, whether U.S.- or foreign-born, are honest contributors to the advancement of knowledge that benefits us all. Driving away talented scientists from other countries would have a profoundly negative effect on American productivity. See NIH Director Statement in *Science*⁴ responding to concerns of Chinese scientists.

The Hoover Report⁵ highlights a systematic effort to keep American employers in the dark about Thousand Talents awards. Our observations are consistent with the Hoover Report statement.

The challenge is to find ways to build and continue important and successful relationships with foreign scientists around the world while simultaneously protecting the Nation's biomedical innovations and proprietary information. The Advisory Committee to the Director, with the assistance of a working group,⁶ has made recommendations to NIH on best approaches to deal with this issue, and NIH is taking action on these recommendations. Also, NIH is working with other Federal agencies, scientific professional societies, and grantee institutions to address this challenge. NIH is making clear statements about the importance of international collaboration

⁴ <https://science.sciencemag.org/content/363/6433/1292>.

⁵ <https://www.hoover.org/research/chinas-influence-american-interests-promoting-constructive-vigilance>.

⁶ <https://acd.od.nih.gov/working-groups/foreign-influences.html>.

with each statement⁷ or presentation⁸ on the topic of threats to the U.S. biomedical research enterprise.

Question. Policy on Mixed Government and Non-Government Witnesses on Panels: Your agency told the Finance Committee that its witness would not participate on a panel at this hearing that included both government and non-government witnesses, claiming there is a longstanding OMB policy prohibiting this. However, there are numerous examples where your agency has allowed witnesses to testify on “mixed panels.” Over the past 10 years, Federal Government witnesses, including those from your agency, have testified before the Finance Committee on panels with non-government witnesses more than 40 times. This has also been the case with other Senate committees. In April 2019, an NIH witness testified on a panel with non-government witnesses before the Senate Aging Committee. An NIH witness also testified on a panel with non-government witnesses before this same committee in July 2017. In March 2018, the Secretary of DHS herself testified on a panel with non-government witnesses before the Senate Select Committee on Intelligence. Why were these witnesses permitted to testify before other Senate Committees on mixed panels, but your witness was not permitted to do so at the Finance Committee’s June 5th hearing? If waivers were granted for witnesses to testify on mixed panels at other committee hearings, why were those waivers granted for the other hearings but not the June 5th hearing? Please provide copies of (1) the OMB policy that allegedly prevents government witnesses from testifying on panels with non-government witnesses; (2) any waivers granted for the recent Aging and Intelligence hearings where government witnesses from NIH and DHS respectively testified with non-government witnesses; and (3) any request submitted to OMB for your witness to testify at the June 5th hearing and the OMB response along with an explanation why a waiver was not granted for the June 5th Finance Committee hearing?

Answer. The Department of Health and Human Services received guidance stating this administration would continue the longstanding practice of prior administrations by allowing executive branch officials to testify at a congressional hearing only on a first panel that is separate from non-executive branch witnesses. Accommodations may be made on a case-by-case basis, as appropriate. HHS and NIH are appreciative that we could agree to an arrangement that provided for our testimony at the hearing alongside other executive branch witnesses.

Question. Source of Foreign Threats: During the hearing, Senator Wyden asked Dr. Tabak and the first panel of government witnesses to identify the general number, or a range, of countries that currently constituted the source of the foreign threat. Dr. Tabak responded that he could not do so in an unclassified setting and would do so in the classified briefing. Would you please provide a separate, classified response that identifies the specific countries that you believe currently present a threat to U.S. research and describe the nature of that threat?

Answer. We defer to the Department of State, as this question falls within their jurisdiction.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. One of the purposes of this hearing is to explore how foreign countries may be exploiting our open research institutions. What countries would you say are the top three or four countries that engage in this activity? Do you see these countries primarily targeting the larger research universities, or do you see them targeting small universities in the Midwest, for example?

Answer. We defer to the Department of State, as this question falls within their jurisdiction.

Question. The HHS Office of Inspector General recently released a report stating that NIH did not concur with the Inspector General’s recommendation to develop a security framework, conduct a risk assessment, and implement additional controls for sensitive data in the context of NIH Genomic Data. Why did NIH not concur with this recommendation?

Answer. NIH is sensitive to the concerns raised in the OIG report. As stated in NIH’s agency comments, NIH did not concur with OIG’s finding and corresponding recommendation in regard to its specificity to foreign investigator access to genomic

⁷ <https://science.sciencemag.org/content/363/6433/1292>.

⁸ <https://acd.od.nih.gov/documents/presentations/06142019Foreign.pdf>.

data in particular. NIH did not concur with the OIG's recommendations for several reasons, listed below.

- The principal documentation cited by OIG in their report is based on a single congressional testimony that speculates a “theoretical risk” of negative implications for the U.S. by the open sharing of genomic information. This argument seems specious, since it is not limited to human genomic data maintained in controlled access.
- The current NIH process includes institutional sign-off and agreement to follow certain norms and standards practices which is the standard NIH process to establish controls for many mechanisms such as the submission of funding applications, contracts, and other types of agreements. Thus, institutions maintain the responsibility to follow these norms and standards. NIH does not independently administer policies to different types of investigators as this would be inefficient, burdensome, and difficult to monitor and enforce, ultimately leading to inconsistent policy implementation.
- A robust security framework is already in place in the form of dbGaP. When requesting access to human genomic data in dbGaP, all institutions, whether foreign or domestic, must sign off and agree to the same participant protection principles and data security practices described in the NIH Genomic Data Sharing Policy, thus assuring their responsible stewardship and appropriate use of human genomic data. Also, a NIH Data Access Committee will only approve a request if the proposed research use is consistent with the appropriate uses of the data, as delineated by the institution that submitted the data. Such policies and guidelines have been established to control the access or transfer of human genomic data, irrespective of whether the investigator is foreign or domestic.

In addition, the NIH Security Best Practices document outlines expectations and best practices for key provisions such as security guidelines, controls for servers, controls for copies of data and their destruction, and guidance for cloud computing. The document also references the Center for Internet Security, NIST, and the U.S.G. Configuration Baseline for benchmarks and best practices for security configurations, standards, and baselines, which are widely accepted by Federal agencies. Thus, based on process and guidelines that have been established for data submission, access, management, and security, NIH has mechanisms and controls in place that have successfully addressed the risks associated with the sharing of human genomic data through controlled-access repositories.

QUESTIONS SUBMITTED BY HON. TODD YOUNG

FIVE EYES INTELLIGENCE ALLIANCE

Question. The Five Eyes is widely regarded as the world's most significant intelligence alliance. The origins of it can be traced back to the context of the Second World War and by its necessity of sharing vital information mainly between Britain and the United States so both countries could enhance the allied war effort. “Five Eyes” was formally founded in the aftermath of the Second World War, through the multilateral agreement, known as the UKUSA Agreement, on March 5, 1946.

Initially, comprising only the UK and the United States, it expanded to also include Canada in 1948 and Australia and New Zealand in 1956. Thereby, the “Five Eyes” term was created from the lengthy “Australia/Canada/New Zealand/United Kingdom/United States Eyes Only” classification level that included the “eyes” that could have access to high-profile papers and information.

For more than 70 years this alliance of like-minded allies has served our intelligence community well.

Just like sharing access to sensitive intelligence information, should we think similarly about opening up certain programs or research areas to certain students or professors depending on their home country?

Is there a model here for academia that is worth following?

Should we be limiting what countries we conduct sensitive research and development with?

Answer. We defer to the Federal Bureau of Investigation, the HHS Office of National Security, or the Office of the Inspector General for the U.S. Department of State, as this question falls within their jurisdiction.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. U.S. versus Global Research: The United States' leadership role is being threatened as other countries are pouring more and more money into research, with some estimates claiming that China will outspend the United States in total research and development by the end of this decade. Combine this with the fact that China has continuously tried and succeeded in infiltrating our publicly funded research initiatives, it is not hard to see the U.S. ceding more ground to our adversaries when it comes to innovation and technology.

How do we make sure that the U.S. maintains a competitive edge in an age of increased cooperation with hostile actors/countries?

Answer. Provision of support for biomedical research is crucial to ensuring the U.S. position. However, it is more than money that drives the biomedical research system; it is also the integrity of the system and the flexibility of independent investigators balancing scientific opportunities with public health needs.

Question. What tools does Congress have to help our domestic pharmaceutical industry and protect them from foreign influence?

Answer. This question is outside the purview of the NIH.

Question. What additional efforts are needed in new and cutting-edge fields like genomics?

Answer. NIH's current system for protecting against the risks and emerging threats identified by NIH for the sharing of human genomic data has been successful thus far. This system involves rigorous NIH controls, such as access request review by Data Access Committees, that verify investigators and entities using genomic data are doing so (1) in a manner consistent with the NIH mission, (2) to advance science and health, and (3) to enable NIH to maximize its return on investment. Data Access Committees also provide ongoing tracking of who has access to data and how it is used over the course of the project. Recognizing the importance of transparency in how these data are being used, NIH provides information and statistics accessible by the public on the data submitted to the NIH database of Genotypes and Phenotypes (dbGaP), as well as a list of all approved users for each dataset, their institutional affiliations, and their proposed research use of those data.

As technologies progress, there may be a need to further refine NIH's system of providing access to human genomic data. The Novel and Exceptional Technology and Research Advisory Committee, or NExTRAC, may be able to assist NIH with such efforts. The NExTRAC is a Federal advisory committee that provides transparent advice to the NIH Director about the scientific, safety, ethical, and social issues associated with emerging biotechnologies. The NExTRAC will be an important tool to help NIH make sure that its policies, guidance, and oversight systems keep pace with the rapidly accelerating landscape of biomedical research.

Question. Budget: We've seen a reoccurring theme from this administration of abdicating our global leadership on a broad range of issues.

What is the current President's budget request for our research and development agencies/institutions, including NIH, NASA, the Department of Energy's Science Office, the EPA, and the National Science Foundation?

Answer. The President's FY 2020 budget request included a proposed budget for NIH of \$34.4 billion. While NIH cannot speak on behalf of NASA, DOE, EPA, and NSF, the "Research and Development" chapter of the Analytical Perspectives volume of the President's budget includes a table showing Federal R&D funding by agency. Note that figures in that table for NIH do not include NIH research training and research funded by program evaluation financing resources.

Question. While protecting intellectual property and our scientific research and technology is critical, how does cutting the funding of these programs allow the United States to remain competitive?

Answer. The President's FY 2020 budget request includes funding for NIH to support the highest priority biomedical research. This funding is also key to ensuring a strong biomedical research workforce that can effectively advance discovery.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

A few key points to make this morning on taxpayer-funded research in America. First, our country is more entrepreneurial, our economy is stronger, and our lives as Americans are better because our scientific community attracts so many of the world's brightest minds. That is a strength to be protected—a part of our national character that must not be diminished.

Foreign-born scientists put Americans on the moon. They worked on the Manhattan Project. Nearly a third of all American Nobel laureates were born outside the U.S. Look back at 2016, when six U.S.-based scientists won Nobel Prizes. All were born in other countries.

It goes without saying that individuals and governments outside the U.S. are going to want to chip away at our lead. That's particularly true when it comes to scientific breakthroughs that lead to valuable IP and entrepreneurship. Academic institutions and other research organizations based in this country need to understand and respond to those concerns—just like Federal agencies and private companies do.

But overreaching with barriers that turn away bright students or cut off lines of communication with scientists from other countries would do a lot more harm than good. And targeting Americans who happen to be descendants of recent immigrants is as bone-headed as it gets.

Dr. Alicia Carriquiry, distinguished professor at Iowa State University, put it this way: "Without foreign-born researchers, the entire system of higher education in the United States would collapse in a minute."

Later this morning, the Finance Committee will hear from Dr. Joe Gray of the Oregon Health and Science University. Nobody knows better than Dr. Gray how vitally important foreign-born researchers and international collaboration are to this country and our institutions. The U.S. would not be capable of scientific breakthrough without them—period.

Second, any breakthrough in medicine or technology ought to be cheered as long as it leads to better lives for Americans. And if the U.S. suspects that American IP or technology has been stolen, this Nation has the power to do something about it.

Finally, while the committee examines this issue today, it's also important to take a step back to look at the broader context of our commitment to scientific research.

When you take inflation into account, Federal investments in science and research have steadily declined for decades. State investments in higher ed have also dropped, starving research universities of funding.

The quickest way to turn the lights out in health research laboratories across America would be to enact the Trump administration's proposed budget cuts to NIH.

And just a few months ago, the president also signed an executive order threatening to cut off research funding for universities over a baseless panic dealing with speech on campus. Fortunately, the order was toothless.

So when you take the broader view of threats to research in America, it's clear the biggest danger comes from within, especially with an administration that often takes anti-science positions.

With respect to foreign threats, what's true with private businesses and government agencies is true for research institutions. They need to take responsible steps to protect themselves and their work. That doesn't mean closing the door to or placing undue burdens on the foreign-born students and scientists who make life-changing discoveries together with Americans.

I want to thank our witnesses for joining the committee today, and I look forward to questions.

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America's leading research universities take national security threats posed by international actors seriously and are actively working to mitigate those threats. Universities share a vested interest with the federal government in protecting intellectual property, proprietary information, trade secrets, and classified or otherwise controlled government information resulting from federally funded research.

Striking the right balance between controlling sensitive technological information and maintaining the free flow of fundamental scientific knowledge and international talent is vital to protecting America's national security, maintaining the nation's role as the world's leader in science and innovation, and continuing the economic growth enabled by scientific and technological advances.

In light of recent concerns about foreign security threats, AAU and other higher-education associations are working together with law enforcement, the intelligence community, federal science agencies, and Congress to secure research on our university campuses. For example, last September AAU, along with the American Council on Education, the Association of Public and Land-grant Universities, and the FBI, held a summit on security that brought together high-level university administrators, key FBI leadership, and representatives from agencies that fund federal scientific initiatives. This April, Senator Mark Warner (D-VA) and Marco Rubio (R-FL) convened representatives from the Office of the Director of National Intelligence, the FBI, and the Department of Homeland Security in two classified briefings that engaged over 75 university presidents and chancellors. APLU plans to hold a similar briefing at its upcoming Counsel of Presidents meeting.

AAU and other higher education associations have also actively engaged our members in discussions about how better to secure academic research. Last fall, AAU and APLU conducted a survey of universities on effective practices for securing research and guarding against undue foreign interference. In April, our two associations sent a report on these effective practices to our institutions to help improve how they secure the important research they perform on behalf of the federal government.

Even as we continually improve our security protocols, we must guard against measures that would stifle the very openness and collaboration that are necessary to advance science and technology. This is key to maintaining America's scientific and technological preeminence—itself critical to our national security, economic competitiveness, and quality of life.

Likewise, we must guard against measures that would unnecessarily stem the flow of foreign research talent to our shores. America has remained on the cutting edge of science because U.S. institutions attract and retain the best and brightest foreign researchers. U.S. visa and immigration policies must continue to encourage talented students and scholars from around the world to come to this country and actively contribute to advancing American science and the U.S. economy.

Finally, the United States must invest more in critical areas of scientific research and scientific talent development to ensure that we do not fall behind China and other competitors who are currently making such investments. We must commit to developing stronger domestic STEM talent; making strong investments in the research programs supported by the National Science Foundation, the NIH, NASA, the Departments of Defense and Energy, and other major federal research agencies; and increasing funding for emerging areas of science such as quantum information, artificial intelligence, robotics, advanced manufacturing, and biotechnology.

In 2006 AAU released a report calling for the creation of a new National Defense Education and Innovation Initiative that highlighted the need for major investments in domestic research and talent development. The report envisioned modern-day investments similar in magnitude to federal investments in science during the years following the launch of Sputnik in 1957. It's thanks to this forward-looking leap in investment that we have the Defense Advanced Research Projects Agency, NASA, and the National Defense Education Act. AAU urges Congress to consider the report's recommendations to bolster our nation's security, strength, and competitiveness on an ever-changing global stage.

COMMUNICATIONS

AMERICAN ASSOCIATION OF IMMUNOLOGISTS (AAI)

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STATEMENT OF JOANNE L. FLYNN, PH.D., PRESIDENT

The American Association of Immunologists (AAI), the nation's largest professional association of research scientists and physicians who study the immune system, appreciates having this opportunity to submit testimony for the record regarding the Senate Finance Committee's June 5, 2019, hearing on "Foreign Threats to Taxpayer-Funded Research: Oversight Opportunities and Policy Solutions." AAI members are research scientists and physicians who live and work in the United States and in countries throughout the world. What they share is an academic expertise in, and professional commitment to, understanding the immune system and to advancing ways to prevent, treat, and cure disease.

AAI recognizes and greatly appreciates the strong support—and robust funding—that Congress and American taxpayers have provided for biomedical research. Most AAI members receive funding from the National Institutes of Health (NIH) to support their research, and are gratified that their work is strongly supported on a bipartisan basis. Our members know that, with this funding, comes the responsibility to work hard to both advance our research and protect the integrity of science and the scientific enterprise. AAI has been made aware in recent months by the NIH, this Committee, and press reports, among other sources, of concerns about threats posed by foreign countries and foreign nationals to U.S. national security and U.S. intellectual property. AAI looks forward to working with Congress and the NIH to address threats to the research and innovations to which our members devote their professional lives.

It is essential, however, before moving forward, for Congress to understand fully the collaborative nature of science and the urgent need for international collaborations if the U.S. is to advance science, foster innovation, and remain the world's leader in biomedical research. I can best illustrate this, I believe, by describing my own experience. As a professor in the Department of Microbiology and Molecular Genetics at the University of Pittsburgh School of Medicine, I have spent most of my career studying tuberculosis (TB), an infection caused by a bacterium. With 10 million cases and 1.3 million deaths in 2017, TB causes even more deaths than HIV. According to the Centers for Disease Control and Prevention (CDC), 25 percent of the world's population is currently infected with TB; if left untreated, about 5–10 percent of those infected will develop the disease. Preventing TB globally not only protects the U.S. from this disease, but also improves the health of people in some of the poorest nations in the world.

As a result of—and to further—my research, I have developed extensive ties in the international research community. I have deep experience collaborating with scientific partners in other countries through research projects sponsored by both the NIH and the Bill and Melinda Gates Foundation. In my view, it is essential for U.S. researchers studying TB to work with scientists in countries where the incidence of TB is high. Therefore, while TB research is performed in many countries, I have worked closely with scientists in Asia and Africa, where several poor countries have the largest number of cases. My lab has partnered with outstanding scientists in South Africa, where the incidence of TB is very high; by coordinating our efforts, we are working to identify new methods for treatment and prevention of this disease. My colleagues and I are also working with scientists in the United Kingdom and Denmark, where new drugs, diagnostics, and vaccines against TB are being de-

veloped, providing these collaborators with an important avenue for testing potential interventions. I have also traveled to many different countries around the world, speaking about my research at seminars and international meetings, and discussing with individual scientists our shared interests. These interactions are critical to maintaining collaborative relationships and promoting outstanding science in all countries.

In conjunction with my research, I have trained more than a dozen young researchers from many different countries (including Bosnia and Herzegovina, Canada, China, Iceland, India, Malaysia, Moldova, New Zealand, Nigeria, and the former Soviet Union). I believe strongly that these young scientists are critical not only to the advancement of TB research, but also to the scientific enterprise of the U.S. While some of these scientists return to their home countries to perform research there (and may collaborate with U.S. scientists), others stay in the U.S. to run their own labs or work in the broader research enterprise.

Although AAI does not have sufficient expertise to recommend ways to promote national security or prevent the theft of intellectual property, we believe that better educating NIH funded scientists and the institutions where they work about required disclosures (including of foreign grant support or faculty appointments, and affiliations with foreign labs); prohibited commercial and institutional relationships; and appropriate handling of proprietary or other confidential information; will go a long way towards addressing the Committee's concerns. Providing clear, specific guidance will help prevent inadvertent missteps by well-intentioned scientists and institutions, and may help limit increased scrutiny to those individuals and areas of the scientific or technological enterprise that pose a genuine threat.

AAI strongly believes that the vast majority of NIH-funded scientists are conducting research in a fair and transparent manner, and are abiding by rules governing the safeguarding of data and confidential manuscript or grant information. It is essential, therefore, that any steps that Congress takes to address these few bad actors do no harm to the ability of U.S. and foreign scientists to exchange ideas, work collaboratively, or travel freely. The U.S. must continue to be an open, welcoming place that will attract the most talented scientists and students from all over the world. If we lose those qualities, or if we impose burdensome rules that deter U.S. or foreign scientists or institutions from pursuing international collaborations, then our adversaries—who strive to surpass us and from whom Congress rightly seeks to protect us—will have won.

FEDERATION OF AMERICAN SCIENTISTS
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The Federation of American Scientists has engaged with the U.S. research community on the issue of foreign interference in federally funded research and development. For U.S. leadership in science and technology, competitiveness, economic opportunity, and national security, it is important that we do not diminish the U.S.' status as the most desirable country for the best minds from around the world to come to and do research, nor harm collaborations with expert research groups abroad. We have collated stories from the U.S. research community that are related to these concerns.

The personal experiences of U.S. researchers

I was born and raised in Iran and came to the U.S. for graduate school in 2006. I received a Ph.D. from Princeton University and after a 5-year long postdoctoral training at Rockefeller University in New York City, I joined University of California, San Francisco in 2016. At UCSF, I am a member of the Helen Diller Family Comprehensive Cancer Center and the Bakar Computational Health Sciences Institute, and I lead a lab devoted to cancer research. I have received numerous awards for my work in cancer research, most recently the AAAS Martin and Rose Wachtel Cancer Research Award and the AACR Nextgen Stars in Transformative Cancer Research Award. Throughout my training, I have learned from, worked with, and mentored many international students and scholars. Both my Ph.D. advisor and postdoc mentors were immigrants. For many years I trained alongside brilliant scientists from Iran, Greece, Chile, Korea, China, and Germany. Even now, more than half of my lab hail from countries other than the U.S. The contribution of international community to scientific progress is not limited to immigrants and visiting scholars who relocate to the U.S. to both take advantage of and contribute to our scientific enterprises. As the scientific gap between the U.S. and other countries

closes, there are areas of research that are in fact led by research groups outside of the U.S.

Modern science is multidisciplinary and sprawling. Therefore, we rely on collaborative teams, often spanning multiple countries, to take on fundamental scientific questions. My lab collaborates with a number of computational groups outside of the U.S. and some of these works have already been published. Grand scientific and biomedical challenges that face the humanity today are borderless, and we need every help we can get to tackle them. This is not to say that we should not safeguard our national interests and strive to maintain our edge in modern technologies, but the reality is that scientific progress, for the most part, has no immediate impact on technology. Rather, it is a form of investment for our future and those of our children for generations to come. Strict rules and policies that seek to limit and regulate academic interactions and collaborations will surely impede scientific progress and the policy makers should think hard about such ramifications. Moreover, uneven implementation of restrictive policies will result in the exclusion of scientists and academics from specific backgrounds or countries. This is simply not acceptable. We have no control over our countries of birth and there is no evidence that the use of nationality for risk stratification is an effective solution. Scientists everywhere are over-worked and underpaid, but they choose to devote their lives for the betterment of humanity. Safeguarding the world-wide collaborative environment where scientists can share ideas and work as teams towards the common good is crucial for our long term survival.

- Dr. Hani Goodarzi, Assistant Professor, Department of Biochemistry and Biophysics, UC San Francisco

Since joining our faculty just a few years ago, Hani Goodarzi has become a driving creative force within UCSF, helping to both pushing the boundaries of discovery and its translation into new insights into cancer. If we want to develop a new generation of scientific insight and cures for deadly diseases, we need a new generation of groundbreaking scientists, regardless of where they might have been born. True breakthroughs in science are rare, and we need to assemble the best team of bright, young scientists we can, scientists just like Dr. Goodarzi.

- Dr. Jeremy Reiter, Professor and Chair, Department of Biochemistry and Biophysics, UC San Francisco

I grew up in China and received my training there. After receiving my Ph.D. degree and completing several years of postdoctoral training in various laboratories around the world, I came to the U.S. in 1999. I worked for six years at Harvard Medical School (HMS) in Boston as a research associate and an Instructor with Professor Thomas Walz, who himself came to HMS from Switzerland. Together, we established a cryo-electron microscopy (cryo-EM) facility to study the structures of proteins with important biological functions. I was recruited to the University of California San Francisco (UCSF) in 2006 as a tenure track faculty member in the Department of Biochemistry and Biophysics. My laboratory at UCSF focuses on methodological developments of single particle cryo-EM and structural studies of many challenging biological macromolecules that play important biological and pharmacological roles in health and diseases. Together with my colleagues at UCSF, our work facilitated some major technological breakthroughs in structural biology. I became an Investigator of Howard Hughes Medical Institute (HHMI) in 2015, and was elected to the American Academy of Arts and Sciences in 2019.

Throughout my scientific career, I have worked in different countries and worked with scientists from many more countries. Here at UCSF, some of our best trainees are international students and scholars. Just to name a few examples: Dr. Xueming Li developed an algorithm to correct the image blurring caused by a high-energy electron beam, a critical technological progress that enables us to determine protein atomic structure by single particle cryo-EM. Ors. Maofu Liao and Erhu Cao determined the first atomic structure of a membrane protein by using single particle cryo-EM, work that triggered the so-called “resolution revolution” in structural biology that is being driven by this new type of cryo-EM. The above three were postdoctoral fellows at UCSF who came from China originally. They are now faculty members at Tsinghua University (Xueming Li), Harvard Medical School (Maofu Liao) and University of Utah (Erhu Cao), respectively. During their time at UCSF, each made important contributions to scientific discoveries and technological developments in our research field, increasing our university’s attractiveness for more such talent from around the world. And as is normal for such postdocs, they are continuing their scientific careers at other institutions.

The U.S. has been a world model for scientific openness and international collaboration. For that reason, this nation has attracted large numbers of the most talented and gifted young trainees from around the world. Here, they not only receive training, but also to contribute in major ways to scientific discoveries and technological developments. Many tens of thousands, like me, have chosen to remain in the U.S. The few examples that I mention here demonstrate the importance of continuing such openness and international collaborations for the future vitality of U.S. science.

- Dr. Yifan Cheng, Professor, UC San Francisco Department of Biochemistry and Biophysics; Investigator, Howard Hughes Medical Institute

Yifan Cheng is a major reason why I moved my lab to UCSF and why UCSF is a world-leading center for structural biology. Yifan is a world-leading expert in atomic-resolution electron microscopy. Among his many accomplishments, Dr. Cheng led the effort to apply electron microscopy to determine the structure of the TRP-family of ion channels, with the structure of TRPV1 (Nature, 2013) being the first near-atomic resolution structure of a transmembrane ion channel determined by single particle cryoEM. Yifan also led the effort that led to the structure of TRPV1 and other TRP-family channels in lipid nanodiscs, a hugely important step forward in studying these nanoscopic machines in their near-native state embedded in a lipid bilayer. Both of these landmark accomplishments were facilitated by Yifan's work, together with UCSF professor David Agard, on the use of direct electron detectors to improve the information content of cryo-electron micrographs. Yifan Cheng's work changed the way we study membrane protein structure and function, and the methods his lab developed are now used throughout the world.

- Dr. Adam Frost, Associate Professor, UC San Francisco Biochemistry and Biophysics

Some examples from our (University of Iowa) faculty born outside the U.S., all with histories of NIH funding:

- Azeez Butali, born in Nigeria: Has collected DNA samples across Africa with a focus on genes associated with cleft lip and palate. Long-term intent for the African and U.S. samples: develop genetic interventions for facial anomalies. He also has developed an App for expectant mothers in Nigeria regarding prenatal care.
- Liu Hong, Born in China: Has an R01 regarding ability to grow bone using micro RNA technology. Implications are for places where bone is deficient with wide potential: clefts, periodontal disease, trauma, post cancer surgery, etc.
- Satheesh Elangovan, born in India: Using non-viral gene delivery technology to develop scaffolds for bone growth.
- Isabelle Denry, born in France: International expert on ceramics to improve characteristics of ceramic dental restorative materials. (Receiving the IADR Distinguished Scientist Award for Materials this year).
- Karen Weber-Gasparoni, born in Brazil, Head of Pediatric Dentistry: Behavioral interventions for children at high risk for early childhood caries.
- Lina Moreno, born in Colombia: Genetics of facial morphology and dysmorphology with long-term intent of interventions for facial morphologies with functional deficiencies.
- Jun Cao, born in China: Research on inflammation with collaborations in our Diabetes Center. Implications with the strong connection between diabetes and periodontal disease.
- From University of Iowa College of Dentistry Dean, David Johnsen

I am an immigrant to this country who teaches, does research, and owns a small biotechnology company. Over the past 20 years, my research efforts as a faculty member and chief scientific officer (CSO) have brought in \$20 million in grant money to the state of Iowa. I was the principal investigator or company CSO responsible for bringing in \$12 million. For the remainder, I contributed as a co-principal investigator. Most of this money has moved into the Iowa economy through wages and taxes. I hope to contribute a lot more to the economy as developments in my company move into the market.

- Dr. Marit Nilsen-Hamilton, Professor, Iowa State University

I emigrated to the U.S. 11 years ago as a postdoctoral fellow and have since made significant contributions to its research enterprise and educational system. I am currently an associate professor and director of a laboratory at an R1 university. I have published over 40 peer-reviewed articles and trained more than 35 individuals from undergraduate students to postdoctoral fellows who have gone on to research and industry careers. I have received several awards for my science outreach, service,

promotion of diversity, and scientific achievements. I have collaborated with colleagues around the world in our common efforts to reduce mortality resulting from air pollution exposures. I have also represented the U.S. as a young science leader in international gatherings.

- Dr. Patricia Silveyra, Associate Professor and Biobehavioral Laboratory Director, The University of North Carolina at Chapel Hill

I am a Hispanic immigrant, moved to the United States in 1982. In 1989 I received a Ph.D. in Statistics and Animal Breeding, and joined the faculty in Statistics at Iowa State University in 1990. Since then, I have mentored the doctoral work of 24 students (at least half of them, American), taught class for thousands of other students, attracted approximately \$30 million in sponsored research funding to Iowa, was elected member of the National Academy of Medicine, and was honored with fellowships from most major statistical organizations in the U.S. and abroad. Without foreign-born researchers, the entire system of higher education in the United States would collapse in a minute.

- Dr. Alicia Carriquiry, President's Chair in Statistics and Distinguished Professor, Iowa State University; Member, National Academy of Medicine

I came to the U.S. in 1982 from New Zealand after obtaining my Ph.D. in Biochemistry from Massey University. I came for additional training in the sciences, and in 1988 I was hired to the faculty of Iowa State University. I rose through the ranks and am currently the Frances M. Craig Professor of Biochemistry at Iowa State University. I became a U.S. citizen and my research program has been continuously funded since 1988 by the National Science Foundation, the U.S. Department of Energy, the U.S. Department of Agriculture, or the National Institutes of Health. Currently I am serving at the National Science Foundation, as a Division Director in the Biological Sciences Directorate. In the past 30 years I have trained and mentored over 50 Ph.D. and MSc graduates, who have matriculated from Iowa State University. And through this body of work, my group has published over 130 peer-reviewed research manuscripts. During this period, I have had the pleasure of collaborating with colleagues from Japan, Korea, France, the United Kingdom, India, New Zealand, and Australia.

- Dr. Basil Nikolau, Frances M. Craig Professor of Biochemistry, Iowa State University

I was born in Central America and came to the USA for college. I received a BA from Harvard and a Ph.D. from UC Berkeley. I've been at Rice University for the last 10 years and have supervised 6 doctoral students, all of whom are U.S. citizens, as well as 8 post-doctoral scholars, 6 of whom are U.S. citizens. Several of these students and post-docs have continued in academia, and are training the next generation of STEM students. Others have moved into important industrial positions (data science, medical fields). While my research has been largely theoretical, it has found application in the construction of cloud storage systems. I am incredibly grateful for the opportunities I have been afforded in the USA, and expect to continue to contribute to the development of its STEM workforce.

- Dr. Anthony Varilly-Alvarado, Professor of Mathematics, Rice University

I moved to Iowa in 2001 from Norway, but I had taught at the University of Maine and received my Doctor of Natural Sciences degree from the ETH Zurich in Switzerland. I had moved to Zurich from Italy, my home country, to study geology. I spent the last 35 years of my life working with people from all over the world, and my research has been made stronger and richer by my multicultural background and what I learned from the many people I have worked with. I have educated thousands of Iowa and U.S. students at Iowa State University, and taught them about our planet, how it works, and how humankind interacts with it and depends on it. I strive to show them how their choices and decisions impact the rest of the world, and share with them the astonishing beauty and power of the planet we live on.

My professional experience and successful career in science and education research are an example of the benefits of living and working in a multicultural and diverse society, and am grateful for the opportunities to work with colleagues in Europe and elsewhere that I had while a faculty member at Iowa State University.

- Dr. Cinzia Cervato, Morrill Professor, Iowa State University

Nanshu Lu (originally from China; graduated from Harvard; now professor of biomedical engineering at University of Texas-Austin), http://www.nafsa.org/Policy_and_Advocacy/What_We_Stand_For/Welcoming_International_Students/Meet_International_Students/Nanshu_Lu/.

Anirban Sen Gupta (originally from India; graduated from University of Akron; now professor in biomedical engineering at Case Western Reserve University), http://www.nafsa.org/Policy_and_Advocacy/What_We_Stand_For/Welcoming_International_Students/Meet_International_Students/Anirban_Sen_Gupta/.

Yu Takahashi (originally from Japan; graduate of Embry-Riddle Aeronautical University and University of Colorado Boulder; now a navigation engineer at NASA's Jet Propulsion Laboratory working on the Dawn, Juno, and OSIRIS-REx missions), http://www.nafsa.org/Policy_and_Advocacy/What_We_Stand_For/Welcoming_International_Students/Meet_International_Students/Yu_Takahashi/.

I have collaborations with several groups around the world. Over the years this has included labs located in Japan, Spain and Korea, as well as 3 in Germany, 3 in England, and 10 in China. This has provided complimentary expertise to the biochemical studies that are the expertise of my own group, and allowed us to not only remain competitive, but also develop new areas of research, with important implications for not only agriculture, but health (medicinal natural products) as well.

– Dr. Reuben Peters, Professor, Iowa State University

Non-U.S. citizens and international collaborations are essential to innovation and progress within the U.S. scientific community. I am a Ph.D. candidate in biomedical engineering at the University of Virginia. I work with numerous non-U.S. citizens who contribute greatly to the work that I do. A postdoctoral researcher in our lab is a citizen of Iran and is working here on a visa. He completed his Ph.D. at Tulane University and is now working as a postdoctoral researcher at UVA. He is pursuing novel research to identify more effective treatments for diabetes. Additionally, our lab collaborates with a company based in Sweden that allows us to develop and test a novel drug to accelerate diabetic wound healing. Our research and the future of medical therapies would suffer tremendously without the benefit of international talent and collaboration.

– Ms. Michaela Rikard, Ph.D. Candidate in Biomedical Engineering, University of Virginia

About 15 years ago, the National Science Foundation offered a program called the Materials World Network, which was a program to initiate and develop international collaborations. Some of my research efforts in magnetic materials were supported through this program, in an effective collaboration with a group in Germany at the RWTH-Aachen, one of the premier universities in Germany. The scientific effort led to the discovery of new magnets along with chemical interpretations of how their structures and properties are related. A part of the project supported graduate student exchange between our groups. During these exchanges, students learned new techniques not available at their respective home institution as well as how academic life in the other location compared with their own. As a result, some important fundamental science about magnetic solids emerged from this collaborative research and many of the student participants are now filling faculty positions across the U.S. The experiences for both groups were outstanding and led to further interactions between us after the program ended. I feel that these experiences for our students were a vital part of their subsequent professional success because science has always been an international effort, relying on discussion and collaboration among people with very different perspectives and goals.

– Dr. Gordon Miller, University Professor of Chemistry, Iowa State University

I study machine learning algorithms and how they help us understand social media data. As part of this work, I traveled to North Korea in 2015 and 2016 to teach North Korean citizens how to work with social media data. I taught classes at the Pyongyang University of Science and Technology (PUST), and had North Korean students collaborating with U.S. citizens to make the first North Korean contributions to open source software. This was a great thing for those students personally, but also for the relationship between our two countries. This gave the North Korean students a chance to better understand American culture first hand, and gave Americans like me a first-hand understanding of the real North Korea. Unfortunately, recent federal policy with North Korea has prevented me from visiting North Korea to teach at PUST. This means that these North Korean students are no longer getting to learn firsthand about American culture, and American citizens no longer get to learn about North Korea. Rather than limiting our academic exchange programs, I believe we should be extending them.

– Dr. Mike Izbicki, Assistant Professor, Claremont McKenna College

About 20 years ago, an interdisciplinary research group at Iowa State University developed a new way to analyze and design large electric power systems. The new

design incorporates nonlinear elements into the formerly linear world of power systems design using a mathematical theory known as “normal forms.” This approach was approved by the IEEE about 10 years ago, and is now being used by many U.S. utilities. It makes stressed systems more stable and reliable and thus supports important safety considerations for our national infrastructure. At this moment, researchers are incorporating statistical elements into this design model to account for alternative sources of generation, such as sun or wind, which are not always available.

Key investigators on these projects were engineers born in India, Egypt, and Chile, with substantial support from German mathematicians. IEEE stands for the U.S. Institute of Electrical and Electronics Engineers. It is the world’s largest technical professional organization dedicated to advancing technology for the benefit of humanity, with U.S. headquarters and a global presence of seven international offices.

– Dr. Wolfgang Kliemann, Professor of Mathematics, Iowa State University

I have worked with many foreign-born researchers. In every case they were highly skilled, imaginative and essential to the success of my projects. Talent is agnostic to geopolitical boundaries and I believe the U.S. should welcome with open arms top researchers and engineers from any country.

– Dr. Matthew Gruner, Postdoctoral Fellow, UC San Francisco

I am an American scientist with a basic research background, who volunteers with grassroots science policy groups, and is now a AAAS S&T Policy Fellow. In all these pursuits I have witnessed how scientific research hinges upon the principles of open science—the public and transparent sharing of knowledge in collaboration with any scientist regardless of nationality. My Ph.D. research was in lab with a majority of international researchers, coming from France, India, China, and Japan. Their presence contributed novel ways of thinking, different cultures and experiences in life, and new ways to approach challenging scientific obstacles. The participation of the international research community within the American research ecosystem is vital for the continued preeminence of our country’s research enterprise. I recognize the concern over the welfare and security of our country, and the risks involved in the unwanted dissemination of technology. But this is a balancing act, not a decisive unilateral action. American research thrives with the open exchange of ideas and unhindered communication.

– Dr. Avital Percher, National Science Policy Network (opinions are his own)

This information is to give background information about the professoriate in the mathematical sciences. All numbers following, are for the period July 1, 2015 through June 30, 2016, and are as reported in <http://www.ams.org/2016Survey-NewDoctorates-Report.pdf>. In the mathematical sciences, 1,921 Ph.D.s were awarded by 279 doctoral-granting departments in the U.S. The mathematical sciences includes mathematics and applied mathematics, as well as statistics and biostatistics.

The proportion of Ph.D.s awarded to U.S. citizens is at a 6-year high, 49% (937). While this is a 7% increase from last year, it is the same percentage as in fall 2010–11. Non-U.S. citizen counts decreased 4% to 984 from 1,021 last year. While this is the first year-to-year drop in six-years the non-U.S. citizen count has increased 16% over that in 2010–11.

– Karen Saxe, Associate Executive Director, American Mathematical Society

Suggestions for questions for the record

- (1) How many cases of foreign-born researchers accused of various violations or even fired by their institutions are specifically due to the theft or inappropriate sharing of intellectual property?
- (2) Are there currently clear and uniform policies in place across U.S. research institutions that would permit constructive responses to the accusations by the National Institutes of Health and Department of Justice?
- (3) Have the National Institutes of Health and the Department of Justice sufficiently supported U.S. research institutions to give transparent education to their researchers on clearly what to do and not do before accusing any researcher?
- (4) Does the National Institutes of Health believe its policies and guidelines for international collaboration and sharing scientific knowledge are clear and accessible enough for all researchers to interpret? What needs to be done by the National Institutes of Health, federal law enforcement, and research institutions to improve their education of researchers?

- (5) A bill, the Securing American Science and Technology Act of 2019—H.R.3038—has been introduced in the House, which would (1) require the Director of the Office of Science and Technology Policy to establish an interagency working group for improved coordination, reporting, and policy among the federal science and security agencies on the issue and (2) establish a new National Academy of Science, Engineering and Medicine (NASEM) “Science, Technology, and Security Roundtable” so that the research community can provide input as the government works toward the proper balance of security and the open exchange of scientific information and knowledge. How rapidly would such working groups and roundtables have to mobilize in order to have a productive impact on the challenges you face?
- (6) Foreign-born researchers in the U.S., including American citizens, are being accused of transgressions such as violating peer-review confidentiality, incompletely disclosing ties to foreign research programs or other foreign entities, and failing to disclose foreign sources of research funding. Some research institutions, such as MD Anderson and Emory, have moved to terminate researchers’ positions. Others, such as Baylor, have worked with their researchers to amend disclosures and foregone disciplinary action. How are research institutions, NIH, and DOJ making these decisions?
- (7) *The Houston Chronicle* recently reported that over the past 18 months, 10 MD Anderson senior researchers or administrators of Chinese descent have retired, resigned, or been placed on administrative leave. Some believe a toxic climate and perception of racial profiling hastened their departures. Two of the researchers subsequently took positions at Chinese institutions. In March, a group of Chinese-American scientists voiced concern in a strongly worded letter in *Science* that recent rhetoric and proposals by the NIH and FBI could lead to unjust targeting of Chinese scientists. What are HHS, NIH, and DHS doing to prevent racial bias and a talent drain?
- (8) Recent data show that the number of new international students choosing to study in the United States is in decline, dropping 6.6% in the fall of 2017. The significant presence especially of international graduate students and researchers makes it possible for many colleges and universities to support STEM departments and courses that also benefit the education of U.S. students in these fields; if we were to restrict international students and researchers from our campuses, what impact do you believe this would have on our nation’s capacity to lead in science and innovation?
- (9) Many nations, like Canada and China, have whole-of-government strategic plans in place to invest in creating an academic, scientific, and immigration environment that attracts and welcomes talent from around the world. Do we have a strategic plan that achieves this, and if so, who is leading it within the government?

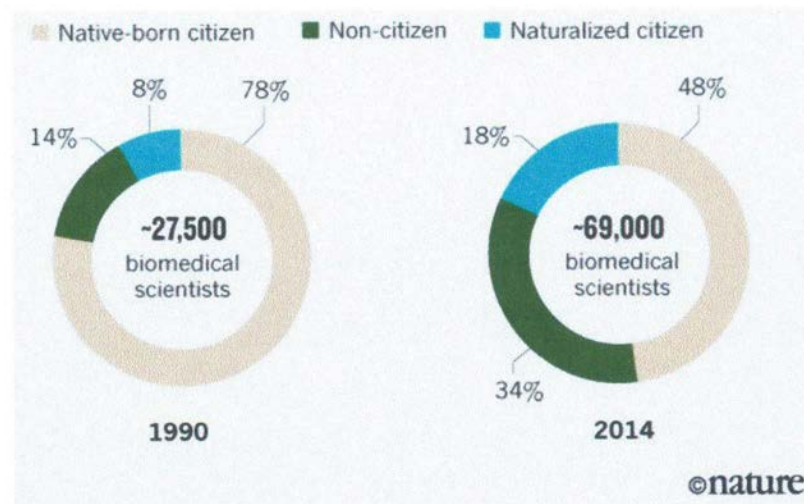
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The Importance of Foreign Researchers to U.S. Research

The resources and intellectual freedom that are hallmarks of the United States research enterprise attract talented scientists from across the globe. For example, it is estimated that $\frac{2}{3}$ of current biomedical postdocs in the United States are foreign-born.¹ Using U.S. Census data, we found that by 2014, 52% of the Ph.D.-holding U.S. biomedical workforce was composed of foreign-born workers, having increased dramatically from only 22% in 1990.²

¹ *Postdoctoral Researchers—Facts, Trends, and Gaps*, NIH Office of Extramural Research, <https://nexus.od.nih.gov/all/2012/06/29/postdoctoral-researchers-facts-trends-and-gaps/>.

² “The New Face of U.S. Science,” *Nature*, <https://www.nature.com/news/the-new-face-of-us-science-1.21229> (working paper: <http://sjscience.org/article?id=570>).



Research in the U.S. is highly dependent on the labor of foreign-born researchers. Studies have shown that foreign-born researchers are highly productive and increase the scientific output of the U.S., producing more publications than their domestic counterparts.³ The importance of foreign-born researchers to the U.S. economy was also recently demonstrated in an open letter signed by 150 biotech leaders citing concerns about immigration policy in 2017.⁴

It is therefore in the national interest to ensure that there is not a loss of foreign talent by overly burdening the research enterprise with arduous vetting processes, by appropriately reacting to, and preventing, the efforts a minority involved in foreign interference. However, we recognize that there are opportunities to strengthen oversight.

Current Rhetoric and Plans for Increased Vetting May Do More Harm to the U.S. Than Good

As discussed in the NIH's Foreign Influences Working Group report⁵ and a recent study,⁶ countries reap most benefit from investment by funding the best science, regardless of where it takes place, or who performs it, and ensuring that their domestically based scientists are involved. Recruiting and retaining foreign talent is one facet of ensuring that the NIH is maximizing its chance to produce the best science in the U.S.

A greater hostility to the foreign-born researchers, in concert with other countries increasing investment in their own research infrastructure and in attracting their citizens back home, foreign-born but U.S.-trained scientists could be inclined to return to their home countries to conduct research, or even feel disinclined to train in science in the U.S., in the absence of efforts to train and sustain their work.

As a group studying and advocating for those early in their research careers, we are particularly concerned about the effects of increased vetting of foreign-born researchers. Recent changes in immigration policy already have the potential to dissuade foreign-born researchers, such as those with spouses, from carrying out study or research in the U.S.

³"Exceptional contributions to U.S. science by the foreign-born and foreign-educated," *Population Research and Policy Review*, <https://link.springer.com/article/10.1023/A:1010682017950>.

⁴"U.S. immigration order strikes against biotech," <http://blogs.nature.com/tradesecrets/2017/02/07/us-immigration-order-strikes-against-biotech>.

⁵NIH Advisory Committee to the Director (ACD) ACD Working Group for Foreign Influences on Research Integrity, https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf.

⁶"Open countries have strong science," *Nature*, <https://www.nature.com/news/open-countries-have-strong-science-1.22754>.

The Committee may wish to consider that the current reaction to threats from foreign influences, the swift reaction of the intelligence community, and the failure of agencies to issue clear guidance to institutions, thus causing confusion and panic among the research community, may be playing exactly into the strategy of foreign actors keen to absorb the fruits of U.S. taxpayer-funded research.

Below we wish to particularly highlight that, while the biomedical research enterprise is particularly dependent on foreign labor, a lack of attention to populations such as the postdoctoral research community is failing to capitalize on the potential brain gain from foreign-born researchers, and may even provide an opportunity for exploitation from foreign influences.

Opacity in the Biomedical NIH-Funded Training Enterprise

Despite the fact that $\frac{2}{3}$ of the NIH's extramural and intramural workforces are foreign-born, it is unclear what the return is on the NIH's investment in training foreign-born researchers, as (in the NIH's own words) "we do not collect much information about foreign-trained Ph.D.s who come to the U.S. to do a postdoc, and we have no idea how long they stay or how many leave after their training."⁷ **It is clearly not appropriate for a federal agency to be unable to provide such basic data about taxpayer-funded researchers, not least when possible foreign influences are under consideration.**

With little attention to the training of foreign-born scientists, and subsequent efforts to benefit from the "brain gain" of retaining the best foreign-born talent, the NIH are missing an opportunity to ensure long-term investment in the best science. It is also possible that by paying little to no attention to the workforce they support, particularly postdoctoral researchers, NIH is providing an opportunity for foreign interference through generating opacity in the biomedical workforce.

As a result of the unavailability of NIH training support, the majority of foreign-born researchers are funded from research project grants, which currently provide no assessment of training nor evaluation of scientific ability. It is therefore not only very difficult to identify talented, foreign-born investigators to be retained in the U.S.; it also difficult to discern whether labs are being staffed by cheaper foreign labor to the detriment of domestically trained talent.

By placing foreign researchers at a disadvantage relative to their domestic counterparts, the U.S., which currently leads in training the world's scientists, may face more fierce competition in coming years for the world's best talent. In addition, by placing their own researchers at a disadvantage in competing against a cheaper labor force for positions in the U.S., we may be dissuading homegrown talent from entering the NIH workforce.

NIH has claimed that it is unable to support foreign researchers on training and fellowship mechanisms—which could allow oversight into research activities of foreign-born researchers while ensuring the potential brain gain is developed to the benefit of the research enterprise—due to legal barriers. Requests to NIH, including to their legal counsel, have not resulted in a clarification of what these "legal barriers" are, or whether they exist. The existence of legal barriers is contradicted by the existence of mechanisms to support foreign-born talent, such as the NCI- and NIDDK-specific Predoctoral to Postdoctoral Fellow Transition Award (F99/KOO) and the NIH Pathway to Independence Award (K99/ROO). These mechanisms facilitate transitions to independence into the postdoctoral experience, and into an independent faculty position, respectively. Foreign postdocs compete with U.S. citizens and permanent residents in application for these awards.

⁷*Postdoctoral Researchers—Facts, Trends, and Gaps*, NIH Office of Extramural Research, <https://nexus.od.nih.gov/all/2012/06/29/postdoctoral-researchers-facts-trends-and-gaps/>.

Summary

Ultimately, we urge the Senate Finance Committee to consider that there should be more support for the foreign-born research population, not less. It is clearly in the interests of foreign states to cause the United States to drive out foreign-born talent, which they can then absorb. The Committee may consider that the current reaction to threats from foreign influences and the swift reaction of the intelligence community may be playing exactly into the strategy of foreign actors keen to absorb the fruits of U.S. taxpayer-funded research.

We thank the U.S. Senate Finance Committee for their work and interest in the role of foreign researchers in the U.S.

