



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Testimony Before the United States Senate Committee on Finance

***“Foreign Threats to Taxpayer-Funded Medical Research:
Oversight Opportunities and Policy Solutions”***

Testimony of:
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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.

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

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 followup 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 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.

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

² The 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.

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.