Good afternoon, Chairman Pallone, Ranking Member McMorris, sub-committee ranking Member Guthrie and members of the Subcommittee. I am Mike Shannon, and I am speaking as an expert witness on oversight and internal controls reinforcing research security associated with Federally funded research and development. I am the President of Government Solutions for IPTalons, Inc, a managed service risk and research security company. I am formally a member of the Senior Executive Service and Director of the Office of Management Assessment (OMA) for the National Institutes of Health.

Thank you for the opportunity to appear before you to discuss three pieces of legislation related disclosure requirements, participation in Foreign Talent Programs, and protecting America's biomedical research enterprise. I am not representing the NIH or the Federal Government but rather appear before you as a citizen with unique knowledge of government oversight and expertise in the subject matter at hand. Any comments I may make related to operations of the NIH are limited to my experience up to the time I left my position in January 2021. I left Federal service to engage more directly in protection of the U.S. research enterprise from risk associated with non-compliant actions and maligned foreign activity intended to take advantage of those actions. I joined my business partner, Allen Phelps, in building IPTalons to provide specialized research security services, training, and tools in support of this aim. As recognized thought leaders in this area we are regularly asked to assist in identifying solutions balancing the burden on awardees with the need for stewardship and accountable due diligence.

International collaboration is essential for innovation, discovery, and the benefit of science to all humankind. Transparency and reciprocity are the glue holding mutually beneficial research relationships together. As with any endeavor trust and due diligence protects effort and promotes best outcomes.

I have provided an extended review of the legislation in my written response but would like to speak to specific points here.

- We have all heard FBI Director Wray correctly say, "we cannot arrest our way out of this." The rest of the statements could be, "because the issues of conflicts of interest, commitment, and foreign influence are primarily compliance issues." Early overemphasis on criminality rather than compliance resulted in many missed opportunities to remediate risk and

contributed to an inaccurate perception of the actual scope and scale of the problem by pointing to the few high-profile events as indicia of a smaller problem.

- We have heard some tout resignations and terminations as a sign of activity and success; however, loss of researchers is not a "win" for anyone. Focus on terminations and resignations often fail to address compliance, can lead to lost opportunity to understand the full impact of the risk, and foments distrust among researchers and research administrations. We advise a restorative approach. Focus should be on restoring and maintaining compliance whenever possible and appropriate among Federally funded research programs and persons.

- Unreported affiliations and support have been a persistent issue for over two decades because of a lack of consistent oversight and internal controls. Individual and nation state actors have exploited the open and collaborative environment. The issue is one of individuals making decisions wittingly or unwittingly, influenced or independently, leading to non-compliance. Research security programs must be a part of the pre-award process and periodic reporting cycle to identify potential risk of unreported affiliations and support. Applicant organizations and awarding agencies must better validate certifications of complete and accurate submissions at application and throughout the life of the award.

- There is concern about discriminatory activity targeting specific persons and ethnicities. Avoiding prejudice is essential and focus on conduct is the only valid indictor of misconduct. Unfortunately, these allegations have also been used to deflect attention from exploitation activity. It is important to understand, this issue is about conduct not culture. Allen and I have conducted thousands of investigations on these issues and although one nation state is by far most prolific, offenders are of all stripes.

Legislation, policy, and guidelines should focus on requiring and enabling awardees to find and fix issues. Where a violation of law is found, proper referral is made; however, in most cases restoration to a compliant posture is possible. Prevention of recurrence is achieved through effective internal controls, adding research security considerations in award applications, and clearly allowing the use of grant funds for necessary oversight requirements. As much as possible, focus on elimination of risk rather than people because it is more appropriate to the threat and essential to U.S. research innovation to retain those persons and their contributions

mindfully and accountably. Congress should demand stewardship and due diligence on behalf of the U.S. taxpayer as a requirement for awarding agencies and as a condition for award recipients of Federal research and development funding.

Specific Comments by Legislative Proposal

HR 5442 – ''Fix Nondisclosure of Influence in Health Research Act''

To direct the Secretary of Health and Human Services to submit to Congress a report on actions taken by the Secretary to ensure compliance with disclosure requirements relating to foreign influence.

to address cases of noncompliance with disclosure requirements or research misconduct related to foreign influence, including—

(A) "the number of potential noncompliance cases investigated by the National Institutes of Health or reported to the National Institutes of Health by a research institution, including relating to undisclosed research support, undisclosed conflicts of interest or other conflicts of commitment, and peer review violations."

There are many non-compliance instances which do not include questions of undisclosed support, conflicts of interest or commitment.

The desire to track the number of undisclosed conflicts is understandable in the current climate to monitor the scope of the issue; however, this may be redundant to other reporting mechanisms, too general when seeking all "non-compliance," and at risk of being too specific if limited only to conflicts of interest, commitment and once the risk is better mitigated.

> Recommend requiring all funding agencies use existing reporting mechanism through their respective Inspectors General to provide metrics on non-compliance cases generally and specifically be tasked to include cases involving undisclosed support, conflicts of interest, and commitment.

Peer review is another matter which should examined more holistically. Unreported affiliations come up in peer review less frequently but not necessarily because they are infrequent occurrences. There are several vulnerabilities which could result in risk of conflict in the peer review process.

It is important to realize other than reputationally, peer reviewers do not represent their employee institution and are not Federal employees. Though unpaid, question exist whether they are more like contractors or special government employee or in special volunteer status. Peer Reviewers do not receive compensation and may not be compelled or motivated to disclose anything other than potential conflicts with the grant applications they are scheduled to review. Any disclosed

conflict is independently adjudicated by the Scientific Research Officer (SRO) managing the panel. Limited records of these decisions are maintained because NIH appears to have concluded that the peer review meetings and notes do not constitute "Federal Records" and are therefore not kept as such. From a records and compliance perspective, they probably should be. 44 U.S. C 3301 provides …

"Records include all books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of the data in them."

The language that likely applies to peer review notes and records includes, "made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business." Without specifying that peer review is "the transaction of public business," and having those records retained under an appropriate records schedule, there is no way to validate, audit, or otherwise know who disclosed what or the accuracy of an adjudicated question of conflict by the SRO.

Recommendation: Employ peer reviewer conflict vetting as part of the peer review panel construction process. Designate peer review SRO notes and other peer review information as "government records" requiring a records schedule. Require NIH to report on corrective action progress to address risks to the peer review process identified in the internal review conducted by OMA.

(B) "the number of cases referred to the Office of Inspector General of the Department of Health and Human Services, the Office of National Security of the Department of Health and Human Services, the Federal Bureau of Investigation, or other law enforcement agencies."

The language does not specify only referrals of "non-disclosure cases." NIH refers many other cases to the HHS OIG not related to non-disclosure. On non-disclosure referrals, NIH will not be able to accurately validate non-disclosure cases "referred" to the Office of the Inspector General (OIG), Office of National Security (ONS), or FBI. NIH has longstanding protocols for "properly referring" matters and communicating with OIG, FBI, and ONS. It should be noted NIH does not refer criminal matters to FBI directly, as NIH only makes criminal referrals to the HHS OIG as the office of jurisdiction for NIH on criminal matters. NIH does respond to appropriate law enforcement requests for information and supports other activity as appropriate. NIH does not refer "cases" to HHS ONS. HHS ONS and NIH have a symbiotic relationship on matters of National Security with ONS providing policy oversight and appropriate delegated responsibilities. NIH should be able to report on cases referred where proper protocols have been followed; however, on the matters of foreign influence and conflicts of interest investigations the process has been routinely not followed. Direct email, phone conversations, and personal relationships have overtaken the formal process, as a result, the definition of "proper referral"

has lost meaning. Therefore, any report associated with past or present "referrals," is likely not fully accurate and would be difficult to validate. FBI and OIG routinely receive emails with information which those sending the message may consider a referral while the FBI and OIG would not characterize as a referral. Following the established "proper referral" process is essential to enable fully accountable and verifiable referral data.

Recommend: Congress decide if it wants "all referrals" or just those associated with "non-disclosures" as the Act is intended to "fix non-disclosure of influence." That "referral" means a referral through designated processes to ensure accountability, avoid information spillage, and duplicate work.

(C) "a description or enforcement actions" taken for non-compliance related to undue influence…"

This report will be difficult to produce for NIH. The Administrative Procedures Act (APA) (5 U.S.C. Subchapter II) regulates the making and enforcement of rules by agencies. NIH is limited in what "enforcement actions" it is allowed to take. The compliance question on "undue foreign influence" rests primarily with undisclosed affiliation, support, time on task and location of research. These would likely be considered "material" to the award and award decision. NIH has some remedies available, however, much of identified non-compliance is for administrative violations and are more a function of the employer of the offending researcher. NIH should be cautious when advising any awardee on what to do with an offending researcher, except as it relates to the conditions of the grant under the agreement. Any change, addition, or new regulation beyond what is already in the Grant Policy Statement and the individual grant award agreement may require additional steps under the APA.

Suspension and debarment are among the actions available in cases of dishonesty, unethical, or otherwise irresponsible activity which threatens the integrity of government programs, Though an effective way to address administrative misconduct its purpose is not widely understood and therefore the process has not been as less effective as a mitigation measure in addressing conflicts or foreign influence. This process is appropriately deliberate; however, the current structure is not well equipped to adjudicate large numbers of referrals and proper imposition is slow in coming.

Recommend: Ask NIH to report of the "enforcement actions" and to provide the authoritative reference allowing them to take such actions for each." NIH should not be advising or otherwise credited in any way for influencing personnel matters of the awarded entity.

Assess suspension and debarment fairness and effectiveness as an administrative remedy and risk mitigation given the lack of speedy process and level of finding required to employ against dishonest, unethical, or otherwise irresponsible conduct putting the integrity of government programs at risk.

(D) "any other relevant information"

This statement is too vague and will result in the likely response of "nothing further." Notwithstanding strong personalities taking the lead, there is not one coordinated voice within HHS or NIH speaking on behalf HHS or NIH on this issue and therefore "relevance" of information is widely interpretive. A report of this type would likely suffer from issue avoidance and not fully coordinated responses at risk of excluding relevant information. Leaving the definition and decision on what is "relevant" and responsive requires a high level of accountable coordinated organizational communications to ensure complete and accurate responses.

Recommend: Reporting should include referrals associated with foreign influence non-compliance and alleged criminal activity. Specify "non-compliance associated with "undue foreign influence." Congress should know what the agency is spending on addressing this issue in total and that a cohesive plan is being employed to avoid waste and abuse. A report on non-compliance associated with foreign influence should be specifically tailored to include information with common definitions, coordinated data, and outcome statements including referenced authorities for actions taken.

Recommend: Congress should include Federal agencies who have intramural research programs in the oversight and reporting requirements. Federal agency intramural programs have the same risk as extramural fund recipients. They should have the same level of framework, oversight, and reporting requirements. For example, NIH has about 4200 researchers in their intramural programs. This makes them about the size of a larger R1 University, but the dollar amount of resources is greater than the top three R1's combined.

HR 5478- ''Protecting the Integrity of our Biomedical Research Act of 2021''

This appears a prudent requirement. The term "foreign talent" though may be too specific. In response to the oversight attention being paid to "talent programs" they are being re-titled. This back door approach to infiltrating U.S. research has been effective for many years. Changing the name could allow interpretative application and prevent reliable disclosure. Foreign state actors who have used foreign talent programs to facilitate conflicts have changed their tactics, including changing the names of these programs. They have also exploited the under reporting of gifts required in Section 117 of the Higher Education Act. Threat actors are now coming through the front door with offers of sponsorship for specific research, grants or awards, contracts, and gifts. Foreign funding is an important part of the research enterprise; however, the funding must be from transparent and reciprocal partners, comply with law and policy, and be properly reported and auditable. Many avoid the individual giving limits using third party associations. This is an area that needs to be addressed. The America Competes Act and U.S. Innovation and Competition Act (H.R. 4521) may attempt to address these concerns, however, there must also be an administrative agency and political will to enforce accountability.

HR 6305 - ''Protect America's Bio-medical Research Enterprise Act of 2021''

Much of what is desired in this proposal is captured in the America Competes Act and U.S. Innovation and Competition Act. The emphasis should be on ensuring a structure of Research and Innovation Security. The research enterprise has always had a strong emphasis on Research Integrity; however, research integrity is different than research security. Research security is focused on protection of information, intellectual property, and compliance with internal policies and external requirements. This bill does not address the role of compliance in protecting research and development information.

> Recommend: Development of a National standard on research security to include defined framework, scope of responsibilities, authorities, and best practices. A combined, agency, award recipient, and commercial

Peer Review is an additional are of consideration, specifically identification and adjudication of potential conflicts between peer review panel members and the award submissions they are assigned to review.

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