

WRITTEN STATEMENT

BY

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FOR

HEARING

***ACADEMIC RESEARCH REGULATORY RELIEF: A REVIEW OF NEW
RECOMMENDATIONS***

THE SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

REPRESENTATIVE BARBARA COMSTOCK, CHAIRWOMAN

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Chairwoman Comstock, Ranking Member Lipinski, and distinguished Members of the Committee. Thank you very much for holding this important hearing today, and for the opportunity to provide comments.

At the outset, let me say how much we at Mason, appreciate your efforts to address the concerns of research universities regarding the increasing complexity, burden, and cost of research regulations and how they are impacting the nation's ability to remain innovative. In particular, your bill Madam Chair, H.R. 1119, and your bill, Mr. Lipinski, H.R. 5583, make meaningful contributions to addressing concerns with the regulatory system and reducing unnecessary administrative burden for researchers and research institutions. I will comment further on both bills later in the testimony.

Research and Education at Mason

I am honored to be here today. I am Ángel Cabrera, President of George Mason University, the Commonwealth of Virginia's largest public university. Mason enrolls more than 35,000 students from 130 countries and all 50 states. We offer 208 degree programs, including 88 masters and 38 doctoral. Last year Mason conferred 8,877 degrees, with over a third of that number constituting graduate and professional degrees. Mason employs 6,500 faculty and staff to serve our growing student body.

Mason is distributed among three campuses spanning over 800 acres in Fairfax, Arlington, and Prince William counties. In addition, Mason operates a site in Loudoun County and has partnered with the Smithsonian Institute to offer a Global Conservation Studies Program at the Conservation and Research Center in Front Royal. Each of our four locations has a distinctive academic focus that plays a critical role in the economy of our region.

We are committed to providing the education and skills for our students to succeed in a globally competitive workforce. Mason's Pathway initiative with the Northern Virginia Community College has resulted in higher graduation rates, faster time-to-degree, and lower overall costs to underserved student communities. Mason has one of the best student diversity rankings, with no discernable learning gaps among student groups, while maintaining a low cohort default rate. We have created these fabulous educational opportunities while also recently achieving the Carnegie Highest Research Activity (R1) designation.

Mason's growing research portfolio includes such important areas as cybersecurity, biomedical science, bioinformatics, computational sciences, Health IT, economics, criminology, modeling and simulation, telecommunications, geospatial intelligence, neuroscience, forensics, data analytics and many more. These have led to advances producing clear benefits to society, such as a greatly improved Lyme disease test, new cancer treatments, enhanced understanding of the role of transnational crime in supporting terrorism, improved protection for our cyber-physical systems, advanced civil infrastructure monitoring techniques, and many others.

The Research Enterprise

Research and scholarship advances made by Mason researchers are moved downstream from lab-to-patent-to commercialization-to-market, generating opportunities for start-ups,

business creation, and economic development. While initially their impact may be regional, eventually they become the antecedents of next generation advances. This is how innovation occurs. Hundreds of research universities creating new knowledge that benefitted from and contribute to what is being done at other research universities, working in partnership with the private sector, each leveraging the other, all serving as precursors for the next “game-changing” breakthrough. The discovery of new knowledge feeds directly into the classroom and is critical to the academic mission. That in a nutshell, is America’s research enterprise.

Madam Chair, you and some of your staff toured our Institute for Biomedical Innovation and our Virginia Serious Games Institute. You were able to talk with those conducting the research and see first-hand how research advances education, leads to jobs and improves lives. But, you saw only a glimpse of the great work being done at Mason. We have many more outstanding faculty, labs and research facilities. I would be remiss, Mr. Lipinski, if I did not extend the opportunity for you and your staff to visit us and see how Mason advances science and knowledge with the benefit of federal and other sponsor funding, and contributes to success in the nation’s research enterprise.

Now, let me provide some observations on the two reports you mentioned in your letter inviting me to testify: first, the National Academy of Sciences report, “Optimizing the Nation’s Investment in Academic Research”; and the Government Accountability Office report, “Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements.”

The Challenge of Resources

We certainly agree with the premise behind many of the regulations in question: the need to protect the interests of taxpayers, preserve the integrity of the research enterprise, and hold institutions accountable for the management of Federal investment. As a public institution, Mason is accountable to its local community, the Commonwealth, and to the Federal government and other sponsors. One of the larger challenges we and other public research universities face is that State budgets are tied to prevailing economic conditions, which are by their nature cyclical. In constrained economic environments, State budgets do not keep up with demand, and the competition for resources becomes intense. Until public universities make a better case to taxpayers regarding the value they provide, State funding will be constrained. This is not all negative as it incentivizes campus innovation in our institutions, encouraging us to identify alternative revenue sources and find efficiencies in administration. But, what that means in practice is that Mason and other institutions like us, while trying to hold the line on tuition increases, cannot afford to hire additional administrative staff to comply with increased regulations. Increased administrative burden then falls on the researchers themselves, which reduces the amount of time they can spend in their labs doing research that advances our national innovation agenda. We have experienced firsthand the results described in the Federal Demonstration Partnership’s 2012 faculty workload survey that found that ,on average, 42% of faculty research time associated with federal projects was spent on meeting regulatory requirements rather than conducting active research.

The regulatory predicament stems from the simple fact that there is no overarching authority to weigh the relative merits of each new regulation against the cumulative cost. Without being attentive to the big picture, it is hard to understand the full impact of new agency-specific regulations with their own peculiarities and requirements. It reminds me of the concept of the “Tragedy of the Commons” where all have access to a resource, but no one is responsible for its preservation. To carry that analogy to the hearing today, multiple agencies issue their regulations, but no one is in charge of reviewing them in totality and ensuring they don’t overly burden the research enterprise. These agencies are staffed with hard-working, public servants dedicated to the public good. But, without a portrait of the entire regulatory enterprise, there will continue to be an inexorable march to more regulation.

Government Accountability Office Report

Let me turn to the Government Accountability effort. On a macro level, the GAO report captured the essence of the challenges Mason researchers face, with its finding that the various research agencies have different implementation requirements. Mason participated in the GAO study. We felt that GAO provided a thorough and fair process. GAO asked a series of questions, regarding budget preparation and management, documentation of personnel expenses, purchasing competition and documentation, subrecipient reporting, subaward reporting, biographical sketches, research monitoring and development, sharing research data and results, and scientific conflicts of interest. Mason’s experience was consistent with those of other universities in virtually all of the areas identified. This was not surprising because when we talk to colleagues at other research universities the challenges that we face are similar regardless of the type of institution.

Let me provide some some specifics on those areas that GAO highlighted as problematic and solvable. Many of our researchers receive awards from more than one agency. This means that they have to spend an inordinate amount of time identifying and responding to different requirements regarding proposal submissions, conflict-of-interest, purchasing, subrecipient monitoring, reporting, and close out. This problem is compounded by the fact that the success rate for awards in many agencies is getting lower, while the time and cost of applying is getting higher. This paradox is discouraging faculty, many of whom balance teaching, mentoring and research loads, from pursuing more research opportunities.

Despite efforts on the part of many agencies over the past several years to target funding towards early investigators, we still see that the average age of first time Principal Investigators is alarmingly high. We are pleased that agencies have identified this problem and are taking steps to target funding at new investigators, but this alone will not address the problem. Continued efforts to eliminate redundant and unnecessary administrative requirements for our researchers will help ensure that our best and brightest continue to pursue research careers and remain active researchers once they begin to have success.

We agree with the GAO that the Office of Management and Budget and research funding agencies have made continuing efforts to reduce administrative workload and the costs for complying with select requirements. But, as GAO found, results have been limited. We endorse

the GAO's call to OMB and the agencies to identify additional areas in which standardization and flexibility promise research efficiencies.

On a more granular level, let me highlight just a few issues of the Academies report that have the most relevance to our situation.

The National Academies Report – Common Rule

First is the Notice of Proposed Rulemaking – the NPRM - on the Common Rule. We share the Academies' concerns regarding redefining all research with de-identified biospecimens as human subjects covered under the proposed Common Rule. Mason researchers in our Center for Proteomic and Molecular Medicine routinely work with biospecimens for which they have secured informed consent. However, they also obtain de-identified specimens from biological repositories, and there is no way such biospecimens could be identified in order to obtain informed consent.

What does this mean? It means that our Center, under the NPRM, might not have the variety of biospecimens they need to continue to conduct groundbreaking research that, for example, has led to a new test for Lyme disease. It means that the tremendous progress made on using the proteome to personalize treatment protocols for breast, colorectal, lung and other cancers would be slowed significantly.

We agree with the Academies' recommendation that the NPRM be withdrawn, and that a new independent national commission be established to examine and update, "the ethical, legal, and institutional frameworks for protecting human subjects", and how they might be applied to de-identified biospecimens and a range of other complex issues. The university community has weighed in on this issue and it is clear that the right path is to reconsider this and other problematic elements of the NPRM.

Export Controls

Second is the issue of Export Controls. On the surface it should be viewed as a positive development for the Department of State to transfer certain export controls from the International Traffic in Arms Regulation (ITAR) to the Commerce Department's Export Administration Regulations. The Academies' report correctly points out that universities, including Mason, continue to be concerned about efforts by the State Department to modify the definition of fundamental research in ITAR. If the result is a restricted fundamental research exemption that does not include tools and instrumentation for example, we believe that technological innovation will be significantly constrained. At Mason, a diminished definition of fundamental research could severely restrict not only the involvement of our brightest non-US students and researchers, but also the broad sharing of fundamental information that fuels innovation around the world. Multiply that throughout the research university enterprise and you can see how innovation could be stifled. The report correctly highlights the 1985 National Security Decision Directive 198 (NSDD 189) that established the principle that the products of fundamental research remain unrestricted to the maximum extent possible. This has served the US well, with no diminution of national security. With the spirit of NSDD 189 in mind, we believe the State

Department should also narrowly define “Defense Services” to clearly permit faculty collaborations with non-US students and research colleagues when such work involves only fundamental research or public domain information.

Effort Reporting

The third area I’d like to comment upon is that of Effort Reporting. In 2011 Mason was the first of four pilot schools to participate in a Payroll Certification Pilot project under the auspices of the Federal Demonstration Partnership (FDP), a cooperative initiative among 10 Federal agencies and 155 research universities focused on reducing administrative burdens associated with research.

Effort reporting is often cited as one of the most burdensome administrative requirements for researchers. Effort incurred across multiple activities is difficult to measure and track and administration is inefficient and costly. The Payroll Certification pilot project had two main goals. First, improve oversight over personnel charges to federal awards by simplifying the salary certification process. Second, enable universities to focus resources toward the efficient and effective oversight of federal awards. In short, Payroll Certification aimed to improve productivity of research without compromising responsible stewardship of federal funds.

The result of implementing Payroll Certification at Mason has been very successful. We have seen a reduction in the number of reports generated by over 85%, but have been able to improve the oversight of personnel expenses by developing a methodology that is easy to understand, aligns with project periods for certification, and targets a smaller group of certifiers (PIs). We have found that with a straightforward methodology we were able to implement with very little upfront and ongoing investment. From an administrative standpoint, we were able to redirect resources to more value added areas and our researchers are now spending less time on effort reporting and more time on research.

At a recent webinar from the Office of Management and Budget (OMB), *Promising Practices in implementation: Personnel Services*, Payroll Certification was identified as a promising strategy to provide flexibility and accrue efficiencies in ways not typically seen in more traditional effort reporting approaches.

Chairwoman Comstock, Ranking Member Lipinski, we believe Payroll Certification pilot is an example where we were able to show that more does not necessarily mean better compliance and the same principle may be applied to other regulatory areas. The FDP should continue to explore ways that the Federal agencies and research universities can collaborate to find specific ways that achieve accountability with reduced administrative burdens.

Office of Inspector General Audits

The fourth issue I’d like to comment on is OIG Audits. The Academies’ report notes that there needs to be better alignment between Agency policy and the interpretation of that policy by that Agency’s Office of Inspector General (OIG). When there is misalignment, universities often

have no choice but to develop overly restrictive policies and procedures based on anticipated audit findings that are often more restrictive than originally intended by the Agency.

We agree with the Academies that the OIG semi-annual reports should provide examples of innovative, cost-saving initiatives undertaken by the agencies and universities. Furthermore, for reasons of transparency, it makes sense to ask that the OIG's report the total cost of their audits of research institutions. The Academies report elaborates on this and I won't take the time here to repeat it, but providing these data would help make the public aware of the scale of the activities undertaken and the value and expense involved.

Just-In-Time Submissions

Fifth, as mentioned earlier, proposal preparation is becoming increasingly cumbersome and time-consuming with varying demands from multiple agencies. Combined with lower percentages of award winners, researchers are finding it more difficult to make the time commitment necessary to submit high quality proposals. Mason supports the Academies recommendations regarding proposal preparation efficiencies, including uniform grant proposal documents and greater use of just-in-time strategies for submission of supplementary materials. In its analysis, the Council on Government Relations noted that, in some, cases, particularly involving NSF, legislation amending the COMPETES Act may be needed. But, according to COGR, other changes, such as just-in-time submission of detailed budgets and current and pending support can be implemented through changes in agency policy.

Since we all work within a resource constrained environment, it would be much more desirable to see our resources focused on the substantive aspects of a research proposal. Given the fact that the majority of proposals are not funded, the just-in-time mechanism proposed makes sense.

Subrecipient Reporting

Sixth, Mason endorses the Academies recommendation for amending the Uniform Guidance to clarify that subrecipient monitoring applies to universities only to the extent necessary for prudent project and performance monitoring, and does not require more extensive monitoring of subrecipients' institutional compliance with all federal rules and regulations.

We understand the need to monitor more closely subrecipients who may be high risk because of their size, location or other factors, but at Mason, the majority of subrecipients are organizations such as other universities who are already monitored through the Single Audit process; we would see a significant reduction in administrative burden if we could rely on the Single Audit process to meet subrecipient monitoring requirements for these organizations.

Conflict of Interest

Seventh, Mason supports harmonizing Conflict of Interest policies across Federal agencies. The fact that agencies have issued different COI requirements both prior to and in response to the Uniform Guidance has created significant burdens for us and our sister

institutions. Differing compliance requirements regarding the reporting and management of individual and organizational COIs have become exceedingly cumbersome. What happens in reality is that Mason, and many other institutions, format their systems to comply with the most stringent requirements in some areas, and they create specialized systems for others. This is quite inefficient.

H.R. 1119 and H.R. 5583

Finally, the Academies Report calls for Congress to create a Research Policy Board, and establish a new Associate Director, Academic Research Enterprise in the White House Office of Science Technology Policy. To some extent, Madam Chair, your bill H.R. 1119, which passed the House, and your Bill, Ranking Member Lipinski, H.R. 5583, implement what the National Academies are recommending. We are grateful to both of you.

Regarding H.R. 1119, it seems to me that calling on OSTP to develop a dedicated process for harmonizing and minimizing the impact of regulations, and refocusing the enterprise's efforts on performance-based goals is eminently reasonable. OSTP is the logical leader since they already play a coordinating role among relevant federal agencies. Chairwoman Comstock, as we said in our letter to you last Sept. 21, "we believe that your bill constitutes an important step in balancing regulatory relief with accountability. Your bill is consistent with previous reports by the National Research Council and other organizations." A copy of the letter is included with the testimony.

Your bill Congressman Lipinski also has tremendous promise. H.R. 5583 adopts many of the recommendations in the Academies report. But, again, harkening back to the cumulative nature of the problem, forming a Research Policy Board would provide research universities an opportunity to share valuable input before a Notice of Proposed Rulemaking is issued so those with the rulemaking authority can understand if there is a better way of achieving the rule's goal.

Madam Chair, Ranking Member Lipinski, I think your bills will allow for broader discussion of that monster that lurks behind every rule – the law of unintended consequences. By providing a pause button, or the ability to raise a Red Flag, a means for redress, and revisiting existing rules, you have done a tremendous service to the research enterprise and the nation's future innovation.

Thank you again for the opportunity to be here today and provide comments on this important issue.