

Statement for the Record

**Chancellor Rebecca M. Blank
University of Wisconsin—Madison**

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Governmental Affairs**

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Chairman Johnson, Ranking Member McCaskill, and members of the Committee, thank you for inviting me to discuss regulatory requirements and their effect on scientific research at our nation’s major research universities including the University of Wisconsin in Madison, where I serve as Chancellor.

I was a practicing economist prior to becoming a university chancellor and I believe deeply that we must do everything we can to help research universities thrive. By providing both the skilled workforce and the innovative new scientific and technological ideas that will assure a strong and growing American economy, America’s universities hold the key to our nation’s prosperity.

The American people invest billions of dollars a year in scientific research at universities like UW, and we take very seriously our responsibility to be good stewards of that investment. That means not only complying with federal regulations, but also flagging unnecessary, ineffective, and duplicative administrative requirements that diminish our productivity.

Research universities are some of the most regulated entities in our economy. At UW, we have to meet regulations from at least 35 Federal agencies and Federal regulatory requirements have increased steadily over the past two decades. These regulations are

often a response to valid concerns, and many of them may be important to assure that we do our work as effectively and transparently as possible. But some of them have become overly burdensome.

I want to share a few of my observations with you this morning, and talk about how we can ensure safety and accountability while reducing costly administrative requirements that are burying our scientists in paperwork.

Recent legislation is a big step forward – but more can be done

The 21st Century Cures Act and the American Innovation and Competitiveness Act are big steps in the right direction. I want to thank the members of this committee for supporting these bills.

But there is still more that can be done, as the GAO notes in its report.

Like nearly every public university in this nation, UW-Madison is facing severe financial pressures. If we're going to continue to educate 43,000 students a year, run a more-than-billion-dollar research enterprise, and produce innovations that drive the economy, we cannot continue to waste precious resources on duplicative, unnecessary paperwork.

Let me add that this is a burden not only on major research institutions, but also on smaller colleges that do research.

Many of them, including the four-year colleges within the UW System, are having great success building small research enterprises that are driving the regional economy, but they don't have the financial ability to spend millions of dollars a year and hire dozens of people to work on compliance.

Excessive regulation can put these smaller schools out of the research business.

My message today is very clear:

We have spent many years adding layer upon layer of federal regulations, and we're at a point where this is seriously impeding the productivity of our scientists

There are as many as 23 different pre-and post-award administrative responsibilities associated with federal research grants. Each of these steps requires time from either the researcher or from support staff.

Ten years ago we had 50 full-time staff handling regulatory compliance on human and animal research projects. Today we have nearly 80, and we're hiring more. I cannot think of another function on campus that has added 30 full-time positions in the last decade. In fact, the staff in many of our offices has been reduced as we've dealt with budget cuts and worked to become more efficient.

Let me tell you a story.

There are 340,000 sports-related concussions each year in U.S. high schools. This is a major public health problem. One of our investigators wanted to send a survey to student athletes and athletic trainers in about 50 high schools around Wisconsin to improve our understanding of how often concussions are reported, factors influencing how they are managed, and how they affect quality of life in high school athletes.

This survey study triggered a raft of regulations under the Common Rule, additional Common Rule subparts related to participation of children, HIPAA Privacy Rule, HIPAA Security Rule, and FERPA.

Ultimately, the investigator had to enter into formal agreements with every one of the athletic trainers and jump through additional hoops for each local school district.

This imposed major delays and additional costs, and certainly didn't improve anyone's safety. If anything, the regulations made it harder for us to understand and address a major public health issue.

Much of this administrative burden falls directly on teachers and researchers, taking valuable time away from the classroom and the lab

The latest Federal Demonstration Partnership survey reveals that, nationwide, scientists with federal funding spend up to 42 percent of their time – or about four hours in a nine-hour day – on regulatory and administrative activities. Over the course of one year at UW-Madison, that's about two million hours our 2,200 faculty are spending on paperwork.

Imagine the discovery and innovation and teaching that could happen in two million hours!

In research involving human subjects, the preparation of compliance materials has become a science unto itself – in fact, it's spawned an entirely new job: Regulatory Specialist. These are people employed by individual research teams for the sole purpose of handling massive quantities of paperwork.

Scientists who cannot afford a Regulatory Specialist either cancel their research project or take on very high administrative burdens themselves.

We recently surveyed our scientists who do research involving human subjects. Nearly half (48.5 percent) told us that in recent years they had given up, or almost given up, pursuing at least one research study because of the red tape.

We can't afford to sideline potentially life-saving research.

And we *know* the system can work better, because we've seen it work better. Just consider the battle against the Zika virus:

Zika is a mosquito-borne illness that causes devastating birth defects. It has created an international public health emergency, and scientists at UW-Madison are leading the fight to control Zika. Several of them are posting their data publicly online in real time to quickly give others working to control the disease the best possible information.

Because of the threat to public health, their initial proposal was given high priority and approved by the UW Institutional Animal Care and Use Committee (IACUC) and biosafety committees about a month after the researchers submitted their materials for approval.

This was at a time when South America was seeing 20,000 new Zika infections every week, so even a one-month delay came at a significant cost, but this expedited process demonstrates what is possible with good communication and a common-sense approach.

What Can Be Done?

Let me turn to some specific recommendations for change.

First, key provisions of recently adopted legislation should be prioritized for implementation

The 21st Century Cures Act and the American Innovation and Competitiveness Act (AICA) take important steps towards reducing some of these administrative burdens, and there are two provisions in particular that should be top priorities.

- (1) OMB should immediately stand up the new Research Policy Board** required by the 21st Century Cures Act. This board will give us a new way to work with federal agencies to coordinate and improve regulation, spot gaps in the system, and assess and minimize the regulatory burden.

- (2) Current grant application and reporting requirements should be streamlined and simplified** as soon as possible, as required by the AICA. The

GAO report notes that Federal agencies have made efforts along these lines, but have not fully addressed variation in the requirements, which limits the effectiveness of the changes.

Right now nearly every agency has different formats for submitting a research proposal, reporting on research progress, and demonstrating compliance with regulations. And agencies have different requirements for how results should be saved and made publicly available.

But there have been important steps, as the GAO points out, toward standardizing some post-award requirements, such as financial reporting.

Possible additional changes include:

- Streamlining pre-award requirements
- Standardizing grant formats across agencies
- Eliminating duplicative reporting, and
- Implementing a unified federal system for report submission

Implementing and enforcing these changes – already part of the AICA – can have a transformative effect, which is why the Association of American Universities (AAU, the top 62 public and private research institutions in the U.S. and Canada), along with the Association of Public and Land Grant Universities (APLU) and the Council on Governmental Relations (COGR) are all asking that this be prioritized.

Second, the Final Rule should come with training and guidance to ensure proper interpretation and application

The recently adopted Final Rule, scheduled to take effect January 2018, modernizes the Common Rule (last updated in 1991) governing human subjects in research. It covers research supported by 16 Federal departments and agencies, and the National Science Foundation.

One important goal of the Final Rule is to reduce the regulatory burden on research that poses little or no risk to participants – for example, studies that involve simple observation.

Right now, Institutional Review Board committees, which review and approve research involving human subjects, apply the same federal regulations designed for high-risk studies, to these low-risk studies.

The Final Rule adds important exemptions and expedited review categories, but without better training for grant compliance officers and guidance to Institutional Review Boards to address differences in how these regulations are interpreted and applied, problems will persist.

Let me give you an example of the problems caused by dueling interpretations of the rules:

One of our pediatricians wants to create a registry to track health information from children across the state who have a very serious condition that can cause heart attacks at an early age.

Registries like these are critically important to good patient care because they give health-care professionals vital information on, for example, which treatments work and which don't. Among other things, that's the kind of information that helps keep health-care costs down.

We are now six months into this process, and full approvals still have not been granted because there are multiple sites providing information to the registry, and each interprets the regulations a little differently.

No one is arguing that this project should not comply with all applicable regulations. But this lengthy and expensive process is doing nothing to make these children safer. In fact, as with the concussion survey, the delays can have a negative impact.

We will be very happy to see the Final Rule go into effect, and hope to see an expansion of the kinds of low-risk research that can qualify for a reduced level of regulation.

Third, excessive audits should be reduced

Our research administrators work in a world of constant audits by Inspectors General. These are in addition to the on-going annual “A-133” audits that attest to our having systems and procedures in place to provide proper stewardship of federal funds.

These broad audits by Inspectors General from multiple Federal agencies are conducted frequently, and they’re usually duplicative and unnecessary. In recent audits of research universities around the country, OIG questioned about \$720 million in expenditures. Following review, only \$580,000 of that was sustained. In other words, less than 0.1 percent.

These excessive audits are precisely what the Single Audit was designed to eliminate. They create an enormous and costly administrative burden. One recent audit took 4,500 hours of staff time. And their public release, often with allegations that are not ultimately sustained, threatens our institutional credibility.

Time and money would be better spent on audits where there is due cause to believe that there’s a genuine risk of fraud, waste, and abuse.

We strongly support the call from both AAU and COGR to reduce this overreach by the Inspectors General.

I have been talking about regulations that relate to research, but let me also mention some of the other regulations that we deal with, which govern student affairs.

Regulations designed to protect students are enforced in ways that are confusing and contradictory, and may not serve the law’s intent

Let me give you three examples.

1. The Clery Act

The Clery Act, which we fully support, was designed to improve campus safety by sharing information with parents and students about crimes committed both on campus and non-campus property.

But we now have multiple agencies collecting multiple data and categorizing it in multiple ways. And the result – as the GAO report points out – is a system that at times is hindering, rather than helping, our understanding of campus crime.

Here's an example: the Department of Education has interpreted “non-campus property” to mean anyplace any student spends more than one night as part of a university event.

If a group of students goes on a research trip with a professor, or participates in an athletic event, we have to reach out to local law enforcement and gather crime statistics on the hotel where they're staying.

You can imagine that we spend hundreds of hours tracking information on properties all over the world. That's time that could be spent on actual crime prevention. But the worst part is, the information we gather is misleading because all non-campus properties are lumped together. So, many of the crimes we have to report occurred nowhere near our institution and have no bearing on campus safety.

We recommend that the Department of Education's interpretation of “non-campus” property be re-evaluated so that we're providing useful crime statistics to families and students, and reducing what has become a major administrative burden.

We also support the GAO's recommendation for an interagency forum to discuss the range of data collection efforts and determine if they are all necessary.

2. Title IX enforcement

We strongly support Title IX. It's been an extraordinarily valuable tool to address long-standing issues of discrimination.

Here's the problem. Because federal research grants are linked to Title IX compliance, every agency that provides funding must separately ensure that we're complying.

In the current academic year, we've been asked to respond to inquiries about our Title IX compliance by the Department of Education, the Nuclear Regulatory Commission, the U.S. Department of Agriculture, and NASA. Each group asks for different types of reports. Given the varied nature of the research activities taking place at UW-Madison, there is a long line of other Federal agencies that could, at any time, require us to demonstrate our Title IX compliance.

We recommend consolidating Title IX enforcement within a single agency, which will not only ease this substantial administrative burden, but also help to ensure more uniform interpretation and enforcement of the law.

3. Return to Title IV (R2T4) regulations

One of the most administratively burdensome regulations related to students is the Return to Title IV calculation, commonly known as R2T4. This governs how we handle federal student aid when the student withdraws from school.

This is consistently one of the top three most-cited weaknesses in the annual OMB A-133 audits and for good reason - it's complex, confusing and duplicative.

The Federal Student Aid Handbook dedicates a full 213 pages of instructions and guidance to this single regulation. Unfortunately, those 213 pages don't clarify a whole lot.

By comparison, guidance on the Federal Pell Grant and calculation of the Afghanistan Service Grant cover just 38 pages.

We recommend that the Department of Education simply use the information already reported to calculate how much the student owes, and notify students and institutions. This would ease a substantial administrative burden, reduce audit issues, and better ensure accurate calculations.

Not all regulation is wasteful and unnecessary

Let me be clear that I am not arguing that we should do away with all regulations governing students or research.

A number of them are important for the safety and well-being of the more than 20 million students at colleges and universities across this nation.

Similarly, we don't seek to return to the days when research was conducted with no rules. That's dangerous. We need only think of the Tuskegee Syphilis Study to be reminded of the need for effective regulation.

Federal research grants come with many strings for a number of good reasons:

- To guard against improper spending of taxpayer dollars.
- To help to ensure research integrity.
- To increase access to research data and results.
- And most important of all, to help protect humans and animals involved in research.

We must operate from a shared set of ethical principles that guide scientific research. But the way in which these principles are translated into regulations by various federal agencies has created a system of unnecessary delays and expenses.

Conclusion

Our system of higher education is the envy of the world. Nineteen of the world's top 25 universities – including UW-Madison – are in the U.S.

No nation on earth has been as successful as the United States at building remarkable institutions that offer an outstanding education and conduct the kind of basic research that fuels innovation and helps to solve immediate problems in the real world.

That's why the rest of the world sends their best and brightest students to be educated in the United States.

But international preeminence doesn't come with a longterm guarantee. If you doubt that, just try to remember the last time you flew Eastern Airlines, drove an American Motors car, or turned on a Zenith TV.

American research universities are a major reason why this country has been able to lead the world economy. Excess regulation of these institutions can only erode their success.

I thank you for your commitment to bringing this unwieldy system under control, and I urge you to continue to look for ways to cut unnecessary strings and maintain necessary safeguards. In that way, you will position great research institutions like the University of Wisconsin to thrive, allowing us to continue to conduct research that leads to big discoveries and keeps this nation on the cutting edge of innovation.

Thank you.