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CONGRESSIONAL SCHEDULE

The House and Senate are in recess. Both chambers are scheduled to reconvene on Tuesday, November 13, following the elections.

OTHER CONGRESSIONAL ISSUES

SENATOR WARNER INTRODUCES REVAMPED DATA ACT

Senator Mark Warner (D-VA) has introduced a new version of the Digital Accountability and Transparency (DATA) Act that is simpler than both his previous bill (S. 1222) and the House-passed version of the bill (H.R. 2146). The Senate may consider the new bill during its post-election session.

The goal of these bills is to improve and make more transparent financial reporting on federal research contracts and grants. The new measure (S. 3600), which is cosponsored by Senator Rob Portman (R-OH), focuses on improvements in data standards and collection. For example, it directs the Department of the Treasury to establish financial data standards in consultation with the White House Office of Management and Budget (OMB) and other government agencies.

Unlike the House-passed bill, the new Senate bill places no additional reporting requirements on universities and other federal award recipients. Rather, it requires OMB to review the current financial reporting that federal agencies require of award recipients and to reduce duplicative financial reporting and compliance costs for recipients. The Senate measure also specifies that OMB request comments from institutions of higher education in that process.

EXECUTIVE BRANCH
The Centers for Disease Control and Prevention (CDC) and the Department of Agriculture (USDA) have issued a **final revised rule** on the use of biological select agents and toxins in research. While the final rule reflects some of the recommendations made by AAU and the Association of Public and Land-grant Universities (APLU) in the comments they submitted on the proposed rule last December, the new rule generally increases compliance and monitoring requirements.

The CDC and USDA have scheduled a webcast workshop on the changes in the rules for Friday, November 16. Details on the workshop and registration information are available [here](#).

Among the highlights:

**Tiering of select agent list.** The new rule designates 11 agents as Tier 1 agents, requiring additional security measures. But the rule does not provide the risk-based tiering of other agents that AAU and APLU had recommended. Essentially, the agencies have created higher regulatory walls around very dangerous agents and retained the already-high regulatory walls around the remaining agents and toxins. The new requirements for labs and personnel that handle Tier 1 agents include a personnel reliability program, consisting of both pre-access screening and ongoing monitoring, as well as increased physical security.

**Select agent list:** Based primarily on recommendations from the scientific and security communities, three agents—the SARS virus and two hemorrhagic fever viruses—have been added to the list of select agents and 13 have been removed or excluded from the regulations.

**Security plans/information security:** The new rule recognizes that the requirements proposed originally for information security were both vague and potentially burdensome—as mentioned by AAU and APLU and other commentators. The rule modifies that language and notes, “We anticipate that these requirements are already being met and will merely require entities to document the systems and processes currently in place.” The rule adds that additional guidance on information security will be available at [www.selectagents.gov](http://www.selectagents.gov).

**Inventory:** AAU and APLU included in their comments a longstanding position of the scientific community that the inventory requirement under the select agent rule is meaningless and burdensome when applied to living organisms. These entities can multiply and their risk is not necessarily correlated with volume or mass. The final rule, however, expands the inventory requirement, requiring complete inventory audits for all agents whenever there is a physical movement of that collection, upon the departure or arrival of a principal investigator, or in the event of the theft or loss of an agent. The final rule notes, “While we are aware of the burden resulting from the requirement to maintain an accurate and current inventory of each select agent and toxin held in long-term storage, we believe this is an essential element to establish security of select agents or toxins.” The rule acknowledges that “it still may be possible for an insider to steal a sample of an agent either from working stock or inventory without being detected.”

**Harmonization between CDC and USDA:** The rule states that the Federal Experts Security Advisory Panel’s recommendation for coordination of select agent inspections between CDC and
USDA’s Animal and Plant Health Inspection Service is outside the scope of this rulemaking process.

ASSOCIATIONS COMMENT ON PROPOSED IMPLEMENTATION OF FIRST-INVENTOR-TO-FILE PROVISIONS

The six higher education associations that have worked together on patent reform, including AAU, submitted comments to the U.S. Patent and Trademark Office on October 5 regarding the agency’s proposed implementation of the First-Inventor-to-File (FITF) provisions of the America Invents Act. The comments address proposed Examination Guidelines for the FITF provisions, as well as companion FITF Rules.

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