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CONGRESSIONAL SCHEDULE

Congress remains in recess. The Senate will return on Monday, September 13 and the House on Tuesday, September 14.

OTHER CONGRESSIONAL ISSUES

AAU URGES ENACTMENT OF NASA REAUTHORIZATION BILL

AAU wrote to House and Senate leaders on August 12 urging them to enact the NASA Reauthorization Act of 2010 before adjournment of the 111th Congress.

Prior to the August recess, the full Senate and the House Science and Technology Committee approved their respective versions of the bill (S. 3729, H.R. 5781). That progress came after months of debate in Congress and the space community over the future direction of NASA. Both bills authorize three years of funding for the space agency and its programs.

The AAU letter applauds both the Science and Technology Committee-passed bill and the Senate-passed bill for including important provisions worthy of inclusion in a final bill. These include sustained funding for NASA’s Space and Earth Science programs, sustained support for fundamental aeronautics research, and robust support for space technology development. The letter also addresses the pressing need for the restart of plutonium-238 production, a material essential for the powering of spacecraft batteries.

The letter was signed by AAU President Robert Berdahl and the co-chairs of the AAU NASA Presidential Working Group: Chancellor Philip DiStefano of the University of Colorado at Boulder and President Robert N. Shelton of The University of Arizona.
A chart that compares the House and Senate versions of the NASA Authorization Act of 2010 (S. 3729, H.R. 5781) is now available on the AAU website.

EXECUTIVE BRANCH

ASSOCIATIONS SUBMIT FINANCIAL CONFLICT OF INTEREST COMMENTS TO NIH

Four higher education associations, including AAU, submitted comments to the National Institutes of Health (NIH) on August 17 in response to the agency’s May 20th Notice of Proposed Rulemaking (NPRM) on financial conflicts of interest. The letter—sent by AAU, the Association of American Medical Colleges, the Association of Public and Land-grant Universities, and the American Council on Education—also includes comments on the amendment to the NPRM that NIH released on July 21.

The associations’ letter states, “[a]dvancing the interests of the public and providing them the information they need to make informed judgments in assessing the research record and the scientific basis of clinical decisions should be at the core of federal regulations on financial conflicts of interest.” It adds, however, “[t]here is a paucity of evidence that the disclosure and management of financial conflicts of interest affect objectivity and integrity. In the absence of such evidence, onerous regulations are not only unwarranted, but could create a glut of policies that increase activity without adding protections and at the same time erode the trust between the regulators and those being regulated.”

Included in the letter are several recommendations for improving the proposed regulations. Regarding the proposed public reporting system for disclosing significant financial interests, the letter notes that all of the information NIH proposes to be reported would be collected by the Department of Health and Human Services (HHS). For that reason, says the letter, NIH should consider maintaining the public reporting system in a single website rather than requiring each institution to maintain its own reporting website.

The associations also point out that the proposed regulations will carry added costs for universities, which institutions will not be able to recover because of the 26 percent cap on administrative costs imposed through OMB Circular A-21. The letter urges HHS to work with OMB “to lift the administrative cap so that the federal government can more readily fund the true cost of federally sponsored research and help restore vitality to the federal-academic research partnership.” The associations also recommend that HHS create an institutional grant program—similar to one created when HHS imposed new regulations on human subjects research—to assist in implementation of the new compliance requirements associated with the proposed regulations.

--COGR Submits Conflict of Interest Comment Letter to NIH  NEW

The Council on Governmental Relations (COGR) submitted a separate letter on the NIH proposed regulations on financial conflicts of interest on August 18, which includes additional,
detailed comments on such issues as enforcement authorities, public posting of conflict of interest information, and the date of enactment.

The COGR letter affirms that Public Health Service (PHS) enforcement authorities are clear and sufficient regarding the issue of problematic individuals or projects transferring between institutions. These authorities include withholding payments, disallowing costs, suspending or terminating an award, or withholding future awards.

The letter adds that the goal of promoting objectivity in research is not well served by requiring conflict of interest information be published on a publicly accessible website, as outlined in the proposed rule. Says the letter:

“The value to the public of posting financial conflicts of interest (FCOI) in the manner proposed by PHS is debatable because the general public may not have the context to measure the relevance of the information. The damage that can result from this requirement is predictable. The danger lies in the assumption by a less-informed public that any and all FCOI is bad and will, with certainty, bias the research outcome. Because such an assumption will result in a diminution of the reputation of the investigator, we fear investigators will either limit or abandon useful translational relationships with industry…”

The association urges the agency instead to consult with the affected communities to determine “the most effective approach to providing useful information to a general public on the management of financial interests as they relate to federally supported research.”

The letter adds that the effective date of the new requirements should be October 2013. That date coincides with the deadline for HHS to meet the requirements of the Affordable Care Act to post information concerning industry payments to physicians and teaching hospitals.

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