

COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Ave., NW, Suite 750, Washington DC 20005
(202) 289-6655; (202) 289-6698 (FAX)

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TO: COGR Membership

FROM: COGR Staff

SUBJECT: Spring 2012 Update

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Congressional Action on the Digital Accountability and Transparency Act (DATA)

HR 2146, the Digital Accountability and Transparency Act (DATA) is scheduled for a vote in the House of Representatives today, April 25, 2012. As we have reported previously, the House of Representatives’ Committee on Oversight and Government Reform approved and sent to the full House the Digital Accountability and Transparency Act of 2011 on June 22, 2011. Authored by Rep. Darrell E. Issa (R-CA), the DATA goal is accountability and transparency in federal spending by enhancing the reporting requirements of Federal agencies and recipients of federal funds.

There are two levels of reporting required by the DATA Act: for recipients and for Federal agencies. Recipients would be required to report, not less than quarterly, basic location information, individual Federal awards by agency, the total amount of funds received and the amount of funds expended or obligated for an individual award per quarter, subawardees (or prime awardee depending on status of recipient) and any additional information requested. Agencies would be required to report obligations and expenditures as reported in a number of

Federal databases including the Federal assistance and procurement data systems. The agency information would identify recipients to enable a comparison between the two reports.

The DATA calls for data standardization across agencies and federal funding mechanisms, i.e., financial assistance and contracts, and requires full disclosure of the information reported on a publicly accessible searchable web site.

COGR issued a joint statement last summer with the Association of American Universities (AAU) and the Association of Public Land-grant Universities (APLU) opposing the Act when under consideration by the House Committee. With the timely assistance of the Federal Demonstration Partnership's (FDP) preliminary data on the costs of Recovery Act reporting we were able to highlight the costs of reporting under requirements similar to those included in the DATA.

Since last summer we have been working closely with House committee and member staff to address our concerns with DATA. Our primary concern is that the bill does not eliminate existing individual agency financial reporting requirements, thus resulting in significant increases in cost and burden. Modifications to DATA have been made to try to address our concerns, but we are still unable to fully support DATA in its current form. COGR joined AAU and APLU in expressing our gratitude for the revisions made to DATA and stating our intention to continue to work with House and Senate staff to improve the bill prior to passage. The joint Association letter is available on the COGR web site under [Latest News](#).

Grants Reform Update and Submission of Responses (APRIL 30 DEADLINE)

The February 23 and 24, 2012 Meeting Report (dated March 19, 2012) included a complete update on the status of Grants Reform, including notes from OMB Controller Danny Werfel's presentation at the COGR Meeting, COGR's initial perspectives on the Federal Register Advance Notice of Proposed Guidance (ANPG), and preliminary direction to the membership on how best to respond to the ANPG.

The Federal Register ANPG entitled: *Reform of Federal Policies Relating to Grants and Cooperative Agreements; Cost Principles and Administrative Requirements (including Single Audit Act)* was released on February 28, 2012. The Notice can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2012-02-28/pdf/2012-4521.pdf>

Since we released the Meeting Report, we also have shared regular updates via the COGR ListServe. The most notable ListServe notifications have covered:

- *Template for COGR Member Responses to "Questions for Comment"*. The *Template* includes notes to help you develop institutional responses to the 20 Questions for Comment (see section III. of the ANPG). This document is available at www.cogr.edu (see Latest News, April 18, 2012).
- **Deadline Extension**. COGR, along with our association partners at AAU and APLU, requested an extension to the public comment period. **OMB granted an extension to April 30, 2012**. The Federal Register Notice that grants the extension can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2012-03-26/pdf/2012-7056.pdf>

- DRAFT version of the COGR Response to the ANPG. The DRAFT includes a significant portion of the text from the *Template for COGR Member Responses to “Questions for Comment”* – however, the COGR Response is focused on Section II. Reform Ideas for Comment rather than answering the questions in Section III. Questions for Comment. This document also is available at www.cogr.edu (see Latest News, April 18, 2012).

Responses are due by 5:00 PM, Eastern Time on Monday, April 30, 2012. According to the Federal Register Notice, responses can be submitted by mail or electronically. The instructions to send by mail are described in the Notice. The instructions to submit electronically are: “*Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions under the “more Search Options” tab.”

COGR has found that the easiest way to submit your response letter electronically is to go to the regulations.gov website and enter “OMB-2012-0002-0001” into the initial Search window. You then will be taken to a screen that allows you to click on “Submit a Comment” (note, this is the first document on the screen, the subsequent documents are comments that already have been posted and are available for viewing). The “Submit a Comment” screen then allows you to complete your submission and to upload your response letter.

We encourage your institution to respond. As we have shared several times:

- Grants Reform is important to the research community and many of the ideas presented to the A-21 Task Force over the past 9 months should be prioritized by OMB.
- Any policy change related to Flat/Discounted F&A Rates is NOT SUPPORTED by COGR – we already are subject to discounted F&A rates due to arbitrary agency limitations, the 26% administrative cap, and discounts made during the negotiation of F&A rates.
- Specific policy changes that are most important to your institution should be highlighted in your responses to the Questions for Comment – DO NOT feel as though you need to answer every question. Use your resources wisely as you complete your response.
- Question for Comment # A4 asks for input on items not addressed in the ANPG. Don’t hesitate to resurrect topics that originally were submitted to the Task Force (but omitted in the ANPG), as well as new topics.
- If timing is an issue, you are welcome to focus your response letter simply on an endorsement of the COGR Response.

We will continue to provide updates on developments related to Grants Reform and if you have questions, contact David Kennedy at dkennedy@cogr.edu.

Grants Reform through the Spring, Summer, Fall ... and Beyond

We expect OMB will receive hundreds of letters from the higher education community, alone. This includes the research universities that are members of COGR, as well as smaller colleges and universities that have may have as little as several million (or less) of annual federal grant activity. In addition, States and Local governments, Indian Tribes, Nonprofit organizations (including the large independent research institutes, some of which are COGR members), and Hospitals (some also who are COGR members) will respond. Finally, individual responses, possibly from your faculty members, will add to the diversity of responses that OMB will receive.

The ANPG specifies the next steps, as follows:

*Based on the feedback that is received, as well as on the ongoing discussions among Federal agencies (including their Inspectors General) as well as with other stakeholders, OMB in the coming months will develop a set of proposed amendments that, later this year, will be published for public comment in the **Federal Register**. The public comments on that proposed set of revisions will in turn be considered as OMB develops a final notice that will adopt a set of reforms.*

The next steps described above suggest a long-process. The ANPG also states that “... OMB is considering implementing these reforms through the development and issuance of an integrated set of guidelines that would be contained in one consolidated circular ...” While we believe there is not wide support for a consolidated circular, if OMB is inclined to move forward with this idea, this could add even more time to the process.

There is one other logistical dynamic of which to be aware – the “COFAR”, not the A-21 Task Force, now is guiding the Grants Reform process. The ANPG references the October 27, 2011 OMB Memorandum M-12-01, *Creation of the Council on Financial Assistance Reform*, which established the COFAR. The COFAR is comprised of OMB’s Office of Federal Financial Management (Co-Chair) and the Chief Financial Officers from the eight largest grant-making agencies, which are the Departments of Health and Human Services (a Co-Chair), Agriculture, Education, Energy, Homeland Security, Housing and Urban Development, Labor, and Transportation; and one additional rotating member to represent the perspectives of other agencies, which for the first two-year term is the National Science Foundation.

The COFAR is made up of senior Federal officials, some who are from Departments where the external funding is not primarily for research. While we are not sure where the idea for flat/discounted F&A rates came from, we do know that any senior level discussion amongst Federal officials on the topic of indirect costs can result in a diverse range of perspectives. With our Association partners at AAU, APLU, and AIRI, we have spent a significant amount of time expressing disappointment and concern to OMB over the flat/discounted rate idea. The good news is that we believe OMB has heard our strong objection – however, our community must let OMB know, via our formal responses to the ANPG, that flat/discounted rates are unacceptable to research institutions.

If ideas concerning flat/discounted rates and the consolidation of the circulars are eliminated from further consideration, we should be in a strong position to dedicate resources to those parts of grants reform that are most important to the research community.

And this could mean that active COGR engagement will continue through the spring, summer, fall ... and beyond. Of course, the November Presidential election could impact developments into the winter, especially if there is a change in the White House. It is a possibility that OMB would like to promote grants reform “successes” prior to the November election, which if true, could expedite some action.

We are paying close attention to all developments. We are actively engaged with OMB and have begun to interact with the COFAR. We remain supportive of Grants Reform, excluding the flat/discounted rates and circular consolidation ideas, and we will continue to advocate for those

policy changes that would be most beneficial to the research community. Finally, as we look forward to the June COGR Meeting, we will reach out to those Federal officials that could share additional insight and update the membership with firsthand knowledge of what we might expect as Grants Reform progresses.

Arbitrary Agency Policies, F&A Caps and Grants Reform

We are disappointed that “Arbitrary Agency Policies” were not addressed in the Advance Notice of Proposed Guidance. This is one of the first and core concerns we raised with OMB in 2010 prior to the commissioning of the A-21 Task Force and the Grants Reform initiatives.

COGR members regularly share with the COGR staff examples of arbitrary agency policies and F&A caps. This topic was the subject of the November 2010 COGR Policy paper “*Federal Funding Agency Limitations on Cost Reimbursement: A Request for Consistency in the Application of Federal Guidelines*” (see www.coge.edu, Education Materials | Financial Management). The paper identifies financial reimbursement policies imposed by Federal funding agencies that are inconsistent with official federal guidelines and result in the significant under-recovery of federal funds by research institutions. The Appendix to the paper includes a sampling of Federal agencies and/or programs where arbitrary agency policy results in additional financial burden for research institutions.

COGR followed the November 2010 paper with a September 2011 letter to OMB (see www.cogr.edu, Latest News, September 8, 2011) – in that letter, we shared new examples where agencies either capped F&A reimbursement, provided “vague” requests for cost sharing, or promoted/encouraged a voluntary cost sharing commitment.

And in the past several months, you have shared with COGR similar examples from: 1) Department of State, Bureau of Educational and Cultural Affairs, 2) USAID, Higher Education Solutions Network, 3) U.S. Fish and Wildlife, White-Nose Syndrome Research, 4) U.S. Geological Survey, National Institutes for Water Resources, 5) Center for Medicare & Medicaid Services, Health Care Innovation Challenge, and 6) Department of Energy, Office of High Energy Physics.

In the COGR Response to the Advance Notice of Proposed Guidance, we reiterate our concern by asking OMB to:

Develop a mechanism to address the ongoing problem where agencies implement Arbitrary Cost Reimbursement Policies. These policies restrict reimbursement of selected payments and are manifested through F&A caps, “vague” requests designed to compel voluntary cost sharing, or other “creative” limitations (e.g., categorizing a cost item as a “subaward” rather than a vendor-purchase). If these agency practices go unchecked by OMB, the repercussion will be increasing institutional subsidies directed to specific research programs, at the expense of more strategic institutional investment in the research enterprise and other educational initiatives.

We hope to leverage the Grants Reform process to work with OMB to develop solutions to this problem – the examples that you share with COGR will continue to be helpful. Until then, and as we have indicated in the past, we will pursue these situations through a variety of means,

including contacting the applicable agency policy office and/or continuing to catalogue these examples with OMB.

NIH and Genomic Arrays (GAs) – YOUR INPUT IS NEEDED, BUT LAST CHANCE

Many of you may recall this issue from May 2010 and the stir it created. The NIH policy restricted F&A reimbursement on the bulk purchase of “high-throughput” Genomic Arrays, and the policy basis stated: *In the case of GA and other highly specialized tools, full inclusion in the application base for F & A development and recovery creates serious inequities and results in the application of F & A that is disproportionate to the actual administrative burden associated with these items.* The May 2010 NIH Policy can be found at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-097.html>

In a May 27, 2010 letter to NIH, COGR objected to the policy on a number of fronts, and most pointedly using the following argument: *Per OMB Circular A-21, F&A rate determination is premised on the “averaging concept” where it is recognized that the actual cost burden across both grants and cost items will vary. The averaging concept is the prescribed Circular A-21 solution – otherwise, an unmanageable number of F&A rates would have to be established. The Genomic Array policy opens the door to unilateral reduction of F&A in any situation where there is a real or perceived disproportionate administrative burden. Under this logic, other grants or cost items should be assessed higher F&A rates when administrative burden is disproportionately higher – most likely, this logic would not be acceptable to NIH.*

While we have not made progress on an NIH reversal of this policy, we have remained engaged. In a subsequent letter to NIH on July 11, 2011, COGR presented to NIH an analysis on the “Costing and the Science” of Genomic Arrays. We argued that certain types of genomic research that utilize GAs are facilities intensive and very expensive – F&A restrictions could result in the unintended consequence where some institutions choose not to participate in certain types of NIH-sponsored genomic research due to the prohibitive cost.

The door appears to be open to work with NIH to designate certain types of research that utilize GAs to be exempt from the policy. COGR needs several examples where the NIH policy has been enforced, but where it is questionable if the use of GAs meets the definition of “high-throughput.” More specifically, if the research in question is facilities intensive and very expensive and the financial implications to your institution are problematic, COGR would like to document these situations. **If you have an example that meets the criteria, please contact David Kennedy at dkennedy@cogr.edu as soon as possible and we can discuss further.**

Audit Update - General

The February 23-24 Meeting Report, and prior COGR Updates, included detailed updates on activities from the Federal Offices of Inspectors General (OIG). COGR regularly checks the HHS (NIH) and NSF OIG websites (see below), and the only recent activity relates to a new ARRA audit report (no findings, no cost disallowances) posted on the HHS OIG website.

<http://oig.hhs.gov/reports-and-publications/oas/nih.asp>
<http://www.nsf.gov/oig/auditpubs.jsp>

Most recently, we have focused on ARRA audit activity and the HHS OIG Administrative & Clerical Audits. However, other than the new ARRA audit report cited above, there are no

current updates that have been shared with us, publicly or privately. In the February Meeting Report, we also included the two excerpts below – the first is of particular interest to COGR, and if you have examples, please contact us.

Audit Resolution and “Unusual” Audit Interpretations. COGR members regularly share with the COGR staff examples of “unusual” auditor interpretations and findings – examples of these situations span many of the agency OIGs. While it is inappropriate for COGR to intervene with OIG personnel, the audit resolution process falls outside the OIG. Consequently, COGR can be helpful in tapping into each agency’s audit resolution process. Recently, COGR members have shared examples of “unusual” auditor interpretations emanating from the USDA (two unrelated situations – subrecipient monitoring and spending rates), NIST (subrecipient monitoring), and the EPA (use of rental cars). There are no guarantees that the audit resolution personnel at an agency can reverse an “unusual” audit interpretation – however, it is an avenue that is available to your institution and it is an avenue that should be pursued.

2012 A-133 Compliance Supplement. We expect that the 2012 A-133 Compliance Supplement will be available, shortly. We will keep the membership posted.

COGR always is interested in audit experiences at your institution so that we can update the general landscape for the membership. We have the most access to HHS OIG and NSF OIG initiatives, but also are interested in activity related to the OIGs at other agencies. Please contact COGR if your institution has been contacted by any agency to conduct an audit or review. We will keep all correspondences confidential.

Other Costing Developments and Discussions

Below are topics that are either new developments or items we have reported on in the past and/or continue to follow. If there are cost-related or financial topics that you would like to discuss with COGR, please contact David Kennedy at dkennedy@cogr.edu.

NIH and Selected “Fully-Funded” NIDDK Awards. Several COGR members have received letters addressed to the institution’s “Business Official” from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) referencing the October 2011 NIH Grants Policy Statement (GPS), Chapter 8.1.1.1, *Carryover of Unobligated Balances from One Budget Period to Any Subsequent Budget Period*:

All Federal agencies are required by PL 101-510 to close fixed year appropriation accounts and cancel any remaining balances by September 30 of the fifth fiscal year after the year of availability. In order for the NIH to meet its obligation to close these accounts and cancel any remaining balances by September 30, grantees must report disbursements on the quarterly cash transaction report (using the FFR) no later than June 30 of the fifth fiscal year after the year of availability. At the end of five years, the funds are cancelled and returned to the Treasury. This provision limits the availability of funds for carryover.

After contacting officials from the NIH Office of Policy for External Research Administration (OPERA), we learned that this situation is exceptional and unique to NIH multi-year awards where the funding for all years is “fully funded” in the first year of the

award (note, most NIH multi-year awards are funded “incrementally” where each year is funded by the current year NIH appropriation).

However, the “fully-funded” situations do occur and must be addressed uniquely where the project period end date does not allow the grantee or agency sufficient time to submit final reports prior to the cancellation of the disbursements (September 30 as referenced above). OPERA has consulted with their grants colleagues at NIDDK to request that they reach out to the Business Officials and PIs at institutions that are affected to provide guidance on how to address the submission of the final FFR. If your institution has been affected by this situation, we recommend that you contact your grant or program manager at NIDDK and ask them to clarify how this situation should be addressed. COGR also will track this issue and will provide follow-up, as needed.

NIH Salary Limitation and a Contract Clause. COGR has reported on the new NIH Executive Level II Salary Limitation since December. Several COGR members have shared a situation unique to contracts. An HHS Acquisition Policy Memorandum dated March 28, 2012 (see link below and scroll down to Acquisition Policy Memoranda, Appendix A) is problematic: <http://dhhs.gov/asfr/ogapa/acquisition/acquisitionpolicies.html>

The Contract Clause in question specifies: *(a) Pursuant to the current and applicable prior HHS appropriations acts, the Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date an expense is incurred.*

The “*date an expense is incurred*” is inconsistent with the January 2012 NIH Notice of Salary Limitation on Grants, Cooperative Agreements, and Contracts (NOT-OD-12-035) and the subsequent FAQs (see links below).

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-035.html>

http://grants.nih.gov/grants/policy/fy2012_salary_cap_faqs.htm

Application of the Executive Level II salary limitation on contracts, retroactive to December 23, 2012 (i.e., the effective date for the Consolidated Appropriations Act, 2012, Public Law 112-74), would be problematic. COGR is pursuing this issue with staff from the NIH Office of Acquisition Management and Policy (OAMP) and will provide an update as we learn more.

Division of Cost Allocation (DCA) Organizational Update. The DCA, responsible for negotiating F&A rates for most COGR institutions, continues to settle on new leadership at both the National and Regional levels. We reported in the February 23-24 Meeting Report that Arif “Mak” Karim is serving as the Acting National Director. Since the February Meeting Report, further developments suggest that there may be more changes announced over the next month. We will follow this development and keep the membership posted.

NRC “Study on Research Universities” – Report due in mid-June. The National Academies, National Research Council (NRC) committee report on Research Universities has cleared NRC internal review and we have been notified that the report should be released in mid-June. We will keep the membership posted on a more exact date for official release of the report.

Accelerating Spending on ARRA Programs: FAQs from NSF. We have reported on the status of “accelerating spending” guidance in the past several months. Most recently, we commented on the NSF FAQs, dated March 1, 2012, “*ARRA Acceleration Frequently Asked Questions (FAQ) for NSF Principal Investigators with awards funded under the American Recovery and Reinvestment Act of 2009 (ARRA).*” Those FAQs can be accessed at: http://www.nsf.gov/pubs/policydocs/arra/faqs_pi.jsp

Two of important take-aways from the NSF FAQs are: 1) Waivers that would allow an extension to the term of the award beyond September 30, 2013 will be difficult to obtain – in fact, waiver requests should have been made by March 2, 2012 (and March 9, 2012 for cooperative agreements), and 2) NSF CAREER awards are being recognized as the best candidates for extension beyond September 30, 2013. Currently, NSF is working with OMB to develop a strategy for a programmatic waiver request to cover all CAREER PIs; however, there is no guarantee that OMB will approve a waiver request. We will keep the membership updated on all developments.

Free Agency Debate Continues

We’ve noted in previous COGR Updates and Meeting Reports the ongoing debate and discussion over the concept of faculty “free agency,” under which faculty are given control over licensing of their inventions (see February 2012 Meeting Report for the most recent discussion). On February 13 AUTM established an online “No Free Agency Resource Center” to help its members understand the problems associated with the “free agency” concept. Resources include an AUTM position statement expressing strong opposition to the concept and proposing instead that funding be provided for partnerships between small institutions and nearby larger institutions with more sophisticated tech transfer offices. This proposal tracks well with alternative language that COGR working with other higher ed. associations proposed for Section 7 of the Startup Act (S. 1965) introduced by Senators Moran and Warner last December (see COGR Holiday 2011 Update). The AUTM materials include some additional background on the free agency concept (including the alternative Startup Act language that we proposed) and encourage AUTM members to work with their campus federal relations and research officers to develop advocacy strategies and express opposition to Section 7 of the Startup Act and to the free agency concept generally (see www.autm.net –President’s Blog).

On April 11 Senator Birch Bayh and Joe Allen (President, Allen and Associates and former legislative assistant to Sen. Bayh) published an article in The Atlantic “School Power: The Case for Keeping Innovation in the Hands of Universities.” The article discusses the success of the Bayh-Dole Act and asserts that the U.S. system of allowing universities to manage their technologies is the most successful (and widely imitated) in the world. It states that the advocates of the free agency concept ignore the realities of academic technology transfer and threaten the success of university commercialization. (For a copy of the article see <http://www.theatlantic.com/business/archive/2012/04/school-power-the-case-for-keeping-innovation-in-the-hands-of-universities/255751/>).

As discussed previously, the Kauffman Foundation has been the leading proponent of the free agency concept. It claims responsibility for the modified form of free agency in the current version (Sec. 7(b)(2)(C)) of the Startup Act (see http://www.kauffman.org/uploadedFiles/startup_act_factsheet.pdf). It also is a prominent feature of Kauffman’s Startup Act for the States (www.kauffman.org/Newsroom.aspx?page=2). We

understand that Kauffman recently invited a large number of economics bloggers to a forum in Kansas City to discuss policy issues related to entrepreneurship and innovation. One consequence may be further advocacy of free agency by such bloggers. COGR, AAU and APLU representatives recently met with a senior Kauffman representative to discuss our concerns about Kauffman's continuing advocacy of the free agency concept. One outcome was agreement to work together on improvements to the Startup Act, with the alternative language that we developed as the starting point.

CRS Issues Periodic Review of Bayh-Dole Act

On March 16 the Congressional Research Service (CRS) issued the latest of its periodic reviews of the Bayh-Dole Act. As with most CRS reports, the review is measured and well-balanced, with discussion of the accomplishments but also concerns that have been expressed about Bayh-Dole. It finds that Bayh-Dole has met its goals, and cites many statistics in support of the positive effects. It identifies and discusses several major ongoing issues and concerns: recoupment, government rights, distortion of university research and conflict of interest. While the report does not come to conclusions on these issues, it does cite the payback to the taxpayers and public benefits that have resulted from Bayh-Dole, and the importance of patent ownership and exclusivity to further development and commercialization of federally-funded R&D. The report may be found on the CRS website at <http://opencrs.com/document/RL32076/>.

Draft Legislation on Bayh-Dole Domestic Manufacturing Waivers Under Consideration

At the request of AUTM, COGR and AAU representatives recently met with staff of Rep. Lipinski (D-IL) to discuss possible legislation ("Bayh-Dole Accountability Act") regarding the domestic manufacturing waiver requirements in the Bayh-Dole Act. Rep. Lipinski's staff is concerned about the lack of standardization in requirements for federal agencies in granting waivers and the lack of overall oversight. There also is no central reporting mechanism.

In our discussion we indicated that we sympathized with the concern about the lack of guidance and transparency in the U.S. manufacturing waiver process. From time to time COGR member institutions have expressed concerns to us about inconsistencies in the waiver process with federal agencies. However we expressed concerns to the staff about opening up Bayh-Dole for any purpose in today's climate. We also noted concerns about provisions in the draft legislation for public postings of waiver requests with the opportunity for challenges, which could lead to abuses; and a requirement for annual reports to OSTP by federal agencies on invention disclosures, patents and licenses as well as waivers, including products manufactured and jobs created and detailed information about the technologies and products involved in the waivers. We noted that the latter requirement undoubtedly would be passed on to universities and the information would prove onerous if not impossible to collect. Also OSTP is not the appropriate agency for reporting requirements with regard to Bayh-Dole.

We encouraged the staff to consider working with Commerce to possibly develop more guidance in the Commerce Bayh-Dole regulations (37CFR401) with regard to waivers. Staff expressed interest in following up with Commerce/NIST, which currently has oversight responsibilities for Bayh-Dole. Subsequently we also discussed this possibility with an appropriate NIST official. We would have an opportunity to comment on any proposed regulatory changes in this area. It appears unlikely that the draft legislation will be formally introduced, but we will continue to follow the matter.

“America Innovates Act” to be Introduced in Senate

Senator Lautenberg (D-NJ) is introducing the “America Innovates Act” in the Senate this week. The bill creates an American Innovation Bank to help universities and other research institutions establish and grow “proof of concept” (POC) funds. It also provides scientists and researchers with industry training, by expanding graduate programs so that students can perform research in local companies and providing federally-supported graduate students with industry-related training, including on the importance of patenting and commercializing discoveries.

The Bank will consist of a Presidentially-appointed Board and Director. It will make grants to universities and other research institutions for research and facilities for POC activities aimed at attracting private investments. Priority will be given to institutions with significant federal research funding that have established relationships with local industry and a supportive institutional environment. Annual reports will be required on the companies, products, etc. that have resulted from the funding and the degree to which federal investments have been leveraged. Grants to individuals also are authorized, with applications required to be submitted jointly with an institution’s tech transfer office to demonstrate their support. Loans to private companies and individuals also are authorized.

The training component will expand NSF’s Integrative Graduate Education and Research Traineeship (IGERT) program. It also requires institutions with NSF Graduate Fellows, NIH National Research Service awards, and similar federal training programs to expand training to provide training in intellectual property protection and commercialization. NSF is authorized to award grants to develop training materials for such purposes. It also authorizes NSF to award grants to institutions to develop professional science masters programs.

COGR has joined with the other higher ed. associations in encouraging the federal government to provide funding for POC and other activities relating to commercialization (e.g. see COGR April 2010 [Update](#)). The POC activities authorized by the America Innovates Act are very much along these lines. We have not yet thoroughly analyzed the bill or discussed it with the other associations. While it is likely that we will be supportive of the concept, there may be concerns about who the new Innovation Bank will report to and what agenda it might develop. The training component might also raise concerns about the implications for existing training programs. As with any such initiative, there also is the issue of where the funding will come from. We understand that Senator Lautenberg currently is seeking co-sponsors.

Commerce “Deep Dive” Follow-up on NACIE Commitments

We reported last year (Spring 2011 [Update](#)) that a group of 137 university presidents and chancellors had signed a letter to the Secretary of Commerce pledging specific, expanded efforts to advance regional and national economic growth, under the auspices of the Secretary’s National Advisory Council on Innovation and Entrepreneurship (NACIE). AAU, APLU and AASCU also signed the letter. The letter promised to expand activities in several general areas: student innovation and entrepreneurship; faculty innovation and entrepreneurship; actively supporting the university technology transfer function; facilitating university-industry collaboration; and engaging with local and regional economic development efforts.

The Commerce Office of Innovation and Entrepreneurship has followed up with the seven universities represented on NACIE as well as others and is conducting a “deep dive” investigation of the full range of their efforts to promote innovation, entrepreneurship, and the commercialization of research results. Specifically, they have asked for documentation of each institution’s initiatives including the historical strategy and process which led to this point within the context of the institution’s overall mission; the lessons learned from their experience and how they contributed to the decision to sign the letter; and how they envision their efforts evolving into the future. Apparently Commerce also is planning site visits to at least several of these institutions.

Commerce also received similar pledges from over 100 community college presidents, as well as the directors of all 16 DOE national laboratories to promote entrepreneurship and expand contributions to innovation. We do not know to what extent they may be planning a “deep dive” investigation of these institutions as well, or of other signatories to the NACIE letter (most of whom are COGR members). A copy of the commitment letter is on the AAU website ([www.aau.edu/-Policy Issues/Intellectual Property/Technology Transfer](http://www.aau.edu/-Policy%20Issues/Intellectual%20Property/Technology%20Transfer)).

AIA: Implementing Rules, Technical Amendments and Prior User Rights

1. **Implementing Rules.** We discussed a number of the proposed rules issued by the Patent and Trademark Office (PTO) to implement the America Invents Act (AIA) in the February Meeting Report. While we initially planned to comment on the proposed rules to implement Post-Grant Review Proceedings (PTO-P-2011—0084) and *Inter Partes* Review Proceedings (PTO-P-2011-0083), ultimately the joint higher ed. association patent reform working group determined that comments from the higher ed. community were unnecessary. The proposed rules themselves are relatively straightforward and extensively cite the AIA. While some concerns have been expressed about the possible costs and tight deadlines set forth in the proposed rules, these may be beneficial to universities as patent owners in discouraging challenges. While there also is a concern about the estoppel provision for the Post-Grant Review as discussed in our February Report, this is set forth in the AIA and would require a statutory change (see below). None of the other proposed rules issued to date appear to require comment by the higher education community.
2. **Technical Amendments.** The February Meeting Report noted a number of concerns that have been raised about the grace period for publications included in the AIA. PTO has suggested that the “enablement” provisions of Section 112 of the patent law (35USC112) be incorporated into the Section 102 grace period, to clarify the scope of disclosure in a publication qualifying for grace period protection. However, other concerns have been raised that the grace period language might not fully protect inventors from others who derive an invention from the disclosure (and force inventors and/or their institutions to engage in the new “derivation” proceedings under the AIA; this issue was discussed in panel sessions at the AUTM Annual Meeting in March). The higher ed. working group currently is evaluating other possible clarifications that would address this concern. On estoppel, there is a view among some Congressional staff that including an estoppel in the AIA for issues that could have been raised in a post-grant review proceeding was a drafting error (the “could have been raised” estoppel was intended only for *inter partes* review). However, others disagree. Also the broader estoppel appears beneficial to patent holders including universities. Both the grace period and estoppel provisions may

be the subject of technical amendments to the AIA. The higher ed. association working group is continuing to evaluate these issues.

3. Prior User Rights. The COGR Winter 2012 Update discussed the February 1 House hearing on expanding the prior user rights defense to patent infringement for prior commercial use of the claimed invention, and the recent related PTO report. Proponents of expansion continue to push for three changes in the AIA provisions: reducing the required one-year period of prior commercial use to four months before filing of a patent application (or qualifying disclosure), broadening the defense to also include substantial preparation for commercial use, and clarifying that the defense applies to all commercial products and processes. A proposed amendment that would incorporate these changes includes a requirement for reasonable diligence in commercializing the subject matter so that it is available to the public. The existing AIA carveout for university-owned inventions would not be affected. Despite these protections, we remain concerned that expansion of prior user rights favors trade secrets over patent disclosures and may discourage innovation, even if university interests as patent holders are protected. Also, it does not appear that these changes could be accomplished by “technical” amendments to the AIA. The higher ed. working group is continuing to discuss these issues.

Supreme Court *Prometheus* Decision Raises Concerns About Biotech Patents

On March 20 the Supreme Court decided the case of *Mayo v. Prometheus* (No. 10-1150). Prometheus had sued Mayo for infringement of certain patented diagnostic tests. The Court unanimously held that Prometheus’ patent claims for determining the proper dosage of thiopurine drugs used for treatment of autoimmune gastrointestinal diseases based on the correlations of metabolite levels in patients’ blood were routine conventional applications of laws of nature and hence unpatentable. The Court found no inventive activity or transformation sufficient for patentability. According to the Court, the patent claims added nothing to the laws of nature involved beyond applying conventional knowledge.

On March 21 PTO issued a memo to patent examiners stating that the Court had made clear that to transform an unpatentable law of nature into a patentable application of such a law, one cannot simply apply conventional steps. The memo stated “...to be patent eligible, a claim...should include other elements or combination of elements such that, in practice, the claimed product or process amounts to significantly **more than** a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto.” (For a copy of the memo see www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf).

This case was viewed by some in the biotech community as critical for new “personalized medicine” diagnostic treatment methods (see e.g. www.patents4life.com/2012/03/page/2/). There has been much adverse commentary on the decision, as confusing 35USC103 “novelty” requirements for patentability with eligible subject matter under Section 101. Existing Supreme Court precedents cited in the opinion appear inconsistent and the Supreme Court’s discussion of these cases in *Prometheus* is not necessarily helpful in clarifying the situation. Many view the case as casting doubt on the validity of a wide range of biotech patents. Subsequently on March 26, the Court remanded the *Myriad* case (see COGR Summer and Fall 2011 Updates) back to the Federal Circuit for reconsideration in light of the decision in *Prometheus*. Opinion among commentators is split on the likely effect on *Myriad*. (However, it is important to note that the Federal Circuit already has ruled against the diagnostic claims in that case; the remaining claims

at issue involve the validity of the BRCA gene patents. As such they involve things, rather than processes; the core issue is whether the genes have been sufficiently transformed from those found naturally in the body to be patentable).

COGR did not join in an *amicus* brief on either side in *Prometheus*. AUTM participated in an *amicus* brief for Prometheus while AAMC filed a brief in support of Mayo, thus indicating no clear consensus in the community (a key consideration for COGR in considering *amicus* brief participation). In addition, we always have found cases involving correlation claims of this sort to be troublesome, with good arguments on both sides. In reality, the Court's decision in *Prometheus* appears less "muddy" than claimed by some commentators. As suggested in the PTO guidance, the Court appears to be saying that with patent claims involving natural phenomena, a high degree of inventiveness needs to be demonstrated. The claims in *Prometheus* fell short of this standard. Time will tell whether the decision will have the profound effect on biotech patents or discourage research and innovation on drug testing methods, as some fear.

Additional note: most observers felt during oral argument that Prometheus fared better and the treatment of Mayo by the Justices did not bode well. Yet the Court unanimously held for Mayo. As has been demonstrated many times, trying to predict Supreme Court decisions on the basis of oral arguments is a risky and uncertain undertaking.

Other CIP Developments

Export Controls. On April 13 Commerce Bureau of Industry and Security (BIS) issued a final rule (77*FedReg*22191) establishing the new Export Control Classification Number (ECCN) Series OY521. The OY521 series will be used for items that warrant control but are not yet identified in an existing ECCN. Establishment of the series was proposed as part of the July 15, 2011 proposed framework for migration of U.S. Munitions List (USML) articles to the Commerce Control List (CCL) as part of the Administration's Export Control Reform Initiative (see COGR Summer 2011 [Update](#)).

COGR commented jointly with AAU on the proposed migration framework on September 13, 2011 (copy available on COGR website—Latest News). We generally supported the proposed framework but expressed concern that it did not indicate that existing ITAR license exemptions would continue to apply to transferred articles, including particularly the bona fide employee exemption for institutions of higher education (ITAR 125.4(b)(10)) and the university exemption for articles fabricated for research satellites (ITAR 123.16(b)(10) although research satellites may not be transferred in any event without statutory authorization). Interestingly, the BIS notice states "BIS is conducting a comprehensive evaluation of the ITAR exceptions to determine if the EAR should be revised to add any exceptions available in the ITAR for defense articles. This review is ongoing, and any changes would be published in separate rulemaking notices" (pp.22194-95). In response to a public comment that including emerging technologies in the OY521 series has the potential to capture technologies that are the product of university fundamental research, the notice states such items are not subject to the EAR (p.22195). The notice indicates that public comments on the other July 15 proposals remain under BIS review. The new series was effective on April 13.

New DHS Academic Outreach Program. COGR and AAU representatives met with Department of Homeland Security (DHS) representatives on March 28 to discuss a

planned new DHS academic outreach program. The program will focus on export controls and is based on the DHS Project Shield America industry outreach program. The purpose of the meeting held at DHS request was to obtain our advice and suggestions. The program would be conducted by the DHS Homeland Security Investigations (HSI) unit under the auspices of the new Export Enforcement Coordination Center, which the DHS representatives indicated has just become operational. Establishment of the Center is one of the four “singularities” included in the Reform Initiative, which was discussed in a panel session at the COGR February 2011 meeting.

In response to concerns we expressed about possible duplication of the FBI’s academic outreach program, the DHS representatives assured us that such outreach efforts now will be coordinated under the Center. We discussed some of the other issues and concerns that institutions had experienced with the FBI program, and the compliance challenges that universities typically face. We suggested that DHS might contact the Association of University Export Control Officers (AUECO) for further information and suggestions. The DHS representatives indicated they found the discussion and advice helpful.

NSF Preparing New Review Criteria

On March 27, 2012 the National Science Foundation (NSF) sent an Important Notice to the research community announcing its planned implementation of the National Science Board’s (NSB) recommendations for clarification and enhancement of the merit review criteria used by NSF. The notice (Important Notice No. 132) outlines the three principles articulated by the NSB that guide NSF’s approach to its two criteria – intellectual merit and broader impacts – and describes the steps NSF has taken and will be taking to implement the revised NSB-approved criteria.

Following the publication of the NSB’s report, *National Science Foundation’s Merit Review Criteria: Review and Revisions* in December 2011, NSF convened an internal working group to develop a plan for implementation. Following review by NSF senior management, NSF will publish a *Federal Register* notice describing specific changes it proposes to implement the revisions to the merit review. These revisions will be combined with additional changes to the *Proposal and Award Policies and Procedures Guide* (PAPPG) and made available for public comment likely in May 2012. NSF anticipates issuing a revised PAPPG in October with an effective date in January 2013.

NIH Financial Conflicts of Interest Regulation Implementation

We reported earlier that COGR received a response in late March, 2012 from the National Institutes of Health (NIH) addressing our request to re-open the Public Health Service regulations on the Financial Conflicts of Interest. NIH did not recommend that the final rule be reopened arguing that the community had multiple opportunities to offer comment as the regulations went through the advanced and proposed rulemaking processes. The response to COGR’s specific concerns regarding the management of reimbursed and sponsored travel outlines how institutions can exercise greater flexibility under the current regulations in the timing and review of disclosed travel. Those flexibilities for institutional review (not investigator disclosure) appeared in the Frequently Asked Questions (FAQs) NIH posted to its website at: <http://grants.nih.gov/grants/policy/coi/>.

NIH's letter reminded us that certain provisions of the new regulation – the *de minimus* threshold and the public accessibility requirements – will be reviewed three years from implementation and that the travel provisions may be included in the evaluation as well. COGR will present to the membership at the June COGR meeting options for designing a systematic collection of data to provide clear and convincing arguments on the burden and related costs and benefits to NIH during its evaluation of the new regulation. The planned Thursday morning session will focus, in part, on identifying data that can be preserved by institutions during implementation of the regulations, e.g., number of travel disclosures, number of disclosures that are determined to be FCOI, etc., that can be collected intermittently, e.g., annual by COGR and/or other associations, to demonstrate the burden and costs associated with the new regulations.

Checklist - On April 12, 2012, NIH posted a **Checklist for Policy Development Related to the 2011 Revised Financial Conflict of Interest (FCOI) Regulation, Promoting Objectivity in Research (42 CFR Part 50 Subpart F)** on its Financial Conflicts of Interest website site at: <http://grants.nih.gov/grants/policy/coi/>. NIH's goal is "to provide an overview of the requirements of the 2011 revised FCOI regulation to serve as a checklist resource when developing, revising or reviewing an Institution's FCOI policy to determine compliance with all regulatory requirements." Institutions may find it useful to review the checklist as they develop policies.

AAMC Institutional Considerations and Approaches - The Association of American Medical Colleges (AAMC) has published *Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research: Preliminary Institutional Considerations and Approaches to Selected Provisions* (March 2012), drawn from a series of four regional meetings of institutional representatives convened by AAMC in late 2011. The report is available at: <https://www.aamc.org/initiatives/coi/>.

Government-wide Dual Use Research of Concern Policy

As we reported in an email to the membership, the Department of Health and Human Services' (HHS) Office of Biotechnology Activities (OBA) posted the new ***US Government Policy for Oversight of Life Sciences Dual Use Research of Concern*** (DURC) on March 29, 2012. The government-wide policy is available at: http://oba.od.nih.gov/biosecurity/bio_usg_activities.html. The undated document describes the principles informing the policy, establishes the scope and outlines the responsibilities of Federal departments and agencies. The policy addresses research using 15 select agents and toxins and 7 experimental models or aims. It recognizes that the current Select Agent and Toxin Regulations as administered by the Centers for Disease Control and Prevention and US Department of Agriculture provide biosafety and biosecurity oversight. This policy is focused on mitigating or "minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research."

We have invited Amy Patterson, Director of the NIH Office of Science Policy and Office of Biotechnology Activities (OBA), to join the COGR membership at the June meeting to discuss the new government-wide policy. OBA is the NIH office that provides staff support to the National Science Advisory Board on Biosecurity (NSABB) and, an area COGR members are more familiar with, the NIH program address research involving Recombinant DNA governing the activities of the Institutional Biosafety Committees (IBCs). Dr. Patterson will be joined by

COGR member institutional representatives to discuss the new government-wide policy and how institutions can approach the identification and management of (DURC).

The definition of DURC used in the policy relies on the definition developed by the National Science Advisory Board on Biosecurity (NSABB) definition as “life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad consequences to public health and safety, agricultural crops and other plants, animals the environment, materiel or national security.” The government-wide policy directs Federal agencies to conduct a review of their research portfolios to determine if any of the research falls within the scope (using the identified agents or toxins with the specific research aims) and meets the definition of DURC (research that, if directly misapplied, poses a significant threat). For those projects identified, the agency is required to assess the risks and, based on the assessment, “in collaboration with the institution or researcher, develop a risk mitigation plan.” New proposals and on-going projects may need to be modified to incorporate a plan.

Initially, Federal departments are asks to report on a series of metrics concerning the number of projects falling under the scope of policy (within 60 days) and summaries of the risk assessments and mitigation strategies in place (or proposed) to mitigate those risks (within 90 days). There is little detail in how the reviews will be conducted or how the mitigation plans will be developed with the institutions and/or investigators. However, the policy directs agencies to the NSABB website (at: http://oba.od.nih.gov/biosecurity/biosecurity_documents.html) for DURC educational tools for the extramural research institutions and to assist agencies in conducting risk assessments. As a consequence, understanding the work of the NSABB may assist institutions in addressing DURC on their campuses.

Brief Background:

The research community is aware of the most recent debate concerning the publication of two articles addressing the transmission of the avian flu (H5N1 influenza virus). Two separate groups of scientists working on the genetic basis of the transmissibility of H5N1 developed laboratory-modified H5N1 viruses capable of respiratory transmission between ferrets suggesting that with relatively few genetic changes, the H5N1 viruses could become more easily transmissible from person to person.

After articles describing the research findings were prepared for publication in *Science* and *Nature* but before publication, the papers were reviewed by the National Science Advisory Board for Biosecurity (NSABB) in the Fall of 2011 because of security concerns associated with the potential misuse of the research results. Similar questions were raised over the 2005 publication of articles in *Science* and *Nature* describing the reconstruction of the influenza virus strain responsible for the 1918-1919 pandemic. At that time, the NSABB unanimously supported publication in order to make the findings available to other scientists to permit further research on the development of diagnostic tests, treatments, and preventative measures. In this recent case concerning H5N1, the NSABB recommended that the research “not be fully communicated” to reduce the possibility that anyone seeking to misuse the knowledge could replicate the experiments with harmful intent. Specifically, the NSABB recommended that details of the research methods used and the specific mutations be deleted from the papers.

In response, the virology community called for a 60- day moratorium on similar research and the World Health Organization (WHO) convened a meeting in February 2012 to discuss the controversy and make recommendations on how the scientific community in cooperation with governments and agencies could address the challenges of DURC. The WHO recommended that the papers be published in full but that publication be delayed to provide time to increase public awareness and understanding of this research, and to provide for the review of biosafety and biosecurity aspects raised by the new laboratory-modified H5N1 influenza virus. The summary and recommendations from the WHO meeting are available at: http://www.who.int/mediacentre/news/releases/2012/h5n1_research_20120217/en/index.html.

The NSABB reconvened in late March, 2012, and examined two revised manuscripts and recommended publication of the revisions. In announcing its decisions, the NSABB noted that, with the authors' revisions, the risk/benefit calculation had changed. The NSABB believed that the data descriptions in the revised manuscripts would not immediately enable misuse, thus threatening public health, and evidence suggested that understanding specific mutations would aid in surveillance. The NSABB reiterated its strong support for the unrestricted publication of research information unless "that information could be directly misused to pose a significant and immediate risk to public health and safety." The NSABB statement is available at: <http://oba.od.nih.gov/biosecurity/biosecurity.html>.

The NSABB has been considering the oversight of DURC since it the Board was established in 2005 and has issued a number of reports. The report in which the NSABB outlines a broad collaborative oversight mechanism including investigator and institutional responsibilities is entitled *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information* and was published in 2007.