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SPECIAL EDITION: POSSIBLE LEGISLATIVE ISSUES AFFECTING THE FASEB SOCIETY MEMBER COMMUNITY IN 2006

This edition of the Washington Update, produced by staff from FASEB's Office of Public Affairs, provides an overview of the legislative activities and proposals we expect to confront in 2006. We will be monitoring the following issues, and initiating strategies to influence the legislation in ways most helpful to FASEB society member scientists:

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FY2007 APPROPRIATIONS/BUDGET OUTLOOK

When President Bush reveals his FY2007 budget request in one week (February 6, 2006), we expect that overall (non-defense, non-homeland security) discretionary spending will be held flat or possibly even reduced below FY2006 levels. This does not bode well for the six scientific agencies (NIH, NSF, DOE, Dept. of Agriculture, Dept. of Veterans' Affairs, and NASA) FASEB monitors and tracks. We anticipate that the President will propose to flat fund NIH in FY2007, but may provide NSF and DOE with small increases because of the recent interest and attention being paid to the National Academies of Science Report, "[Rising Above the Gathering Storm](#)," which advocates a new commitment to competitiveness and innovation (please see the separate write-up on "Innovation Policy").

The Administration is increasingly under pressure to reduce the budget deficit. The White House has acknowledged that the budget deficit will climb back above \$400 billion this year, erasing the brief improvement last year and complicating President Bush's vow to cut the deficit in half by 2009. Therefore, in tonight's State of the Union address, we expect that the President will argue for greater restraint in non-

defense, non-homeland security discretionary spending, even though it accounts for only one-fifth of the total budget.

While Social Security, Medicare, and Medicaid account for 43 percent of all federal spending, Congress finds it extremely difficult to reduce the benefit programs' costs. This political difficulty is illustrated by the fact that the House and Senate still haven't finalized a deficit-reduction bill left over from last year. A vote in the House is scheduled for Wednesday (February 1, 2006) on the \$40 billion plan to cut various entitlement programs over the next five years.

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NIH REAUTHORIZATION

House Energy and Commerce Committee Chairman (Representative Joe Barton [R-TX]), continues to insist that NIH Reauthorization remains one of his top priorities, and therefore, we fully expect him to revisit the issue in 2006.

In 2005, Chairman Barton provided the greater NIH research community with discussion draft legislation to reauthorize NIH. Chairman Barton's proposal was quite controversial within the community for two main reasons:

- 1) The legislation divided Institutes and Centers (ICs) into two categories. ICs were classified as "mission-specific" (14 ICs included) or "science-enabling" (10 ICs included). Mr. Barton proposed that appropriators provide a total dollar amount allocation for the "mission specific" and "science-enabling" categories, but discouraged them from appropriating a specific dollar amount to the individual ICs.
- 2) Chairman Barton's draft legislation does not describe how an individual ICs budget would be determined because, in essence, it would eliminate authorizations of appropriations for individual ICs. The research community also expressed strong concern with the committee's plan to set specific funding levels for NIH instead of using the language, "such sums as necessary." The "such sums as necessary" language prevented Members of Congress from raising a point of order to prohibit NIH's budget from doubling during the 1998-2003 period.

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ENHANCED PUBLIC ACCESS

Congressional interest in open access to scientific publications is expected to continue. Two bills would make the NIH enhanced public access policy mandatory.

A bill introduced by Senators Joe Lieberman (D-CT) and Thad Cochran (R-MS) to establish an "American Center for Cures" within NIH includes a provision on public access to publications. In addition, Senator John Cornyn (R-TX) is expected to introduce legislation requiring a 6-month public release of manuscripts from NIH. Representatives from not-for-profit society publishers met with staff in Senator Cornyn's office to discuss his plans. The Senator's staff assured us that they would consider publishers' perspectives before moving forward.

In addition, an NIH report to Congress is expected in late spring in response to report language in the L/HHS appropriations bill requesting a progress report on the policy's implementation.

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THE 2007 FARM BILL

The Senate and House Agriculture committees will likely spend much of 2006 working on the Farm Bill, officially titled the renewal of the Farm Security and Rural Investment Act, which is expected to be completed in 2007. Although much of the contents of the Farm Bill will be of little interest to biomedical researchers, it is a piece of legislation that FASEB will be watching very carefully. Because the U.S. Department of Agriculture (USDA) oversees the Animal Welfare Act (AWA), bills related to USDA activities are prime targets for language or amendments that could have consequences for the use of animals in research and education. Previous attempts by animal rights activists to expand the AWA to cover rats, mice, and birds (whose use in research is already primarily regulated by the Public Health Service) were defeated through an amendment to the 2002 Farm Bill. While this was a positive outcome for the research community, a less desirable provision could potentially be added to the upcoming renewal. For example, the amendment offered by Senator Daniel Akaka (D-HI), which would have prohibited federal funding to universities dealing with a particular regulated class of animal dealers (Class B), was removed from the FY2006 agriculture appropriations bill but could easily be modified and added to the Farm Bill. The broad language of such an amendment would have severe negative repercussions for land grant institutions, in particular, and biomedical research in general. (For more information on the Akaka amendment, please see [Washington Update, Sept. 23, 2005](#).)

Another issue that could be raised through construction of the Farm Bill is establishment of a National Institute for Food and Agriculture (NIFA). This proposal arose from a Task Force at the USDA, which was exploring a way to expand and enhance the competitive basic research program in agricultural sciences. FASEB was [supportive](#) of the idea of NIFA as an independent science agency under the USDA, where the current competitive research program, the National Research Initiative, has received limited support. However, in 2004, NIFA took an interesting turn when Senator Kit Bond (R-MO) introduced a bill that would place NIFA under the auspices of the National Science Foundation (NSF). Because the bill language was taken nearly directly from the Task Force's report, it would impose an administrative structure that may not easily fit into the current structure of NSF. Moreover, given the current fiscal climate, it is unclear where the money for such a new 'agricultural directorate' would come from, presenting the potential for constraint of NSF's existing programs. Senator Bond reintroduced the bill during the 109th Congress (S.767), and the 2007 Farm Bill is a potential vehicle for this legislation to move forward, either by being integrated into the Farm Bill or added as an amendment.

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BARDA AND OTHER HOMELAND SECURITY

The “Biodefense and Pandemic Vaccine and Drug Development Act of 2005,” introduced by Senator Richard Burr (R-NC), could potentially move towards a vote in the upcoming year. The purpose of the legislation (S.1873) according to Burr, is to “provide a comprehensive approach to combat deliberate, accidental or natural outbreaks of infectious diseases.” Essentially, the bill would establish a new agency within the Department of Health and Human Services (DHHS) that would serve to coordinate biodefense research conducted throughout the federal government, as well as provide direct funding of advanced research and development of countermeasure (i.e., vaccines, drugs, devices) against infectious diseases.

The Biodefense Advanced Research and Development Agency (BARDA) is modeled after the Defense Advanced Research Projects Agency (DARPA) in that part of its purpose is to coordinate advanced R&D and to support innovative research that might not be funded by existing programs. However, based on language in the bill, BARDA’s emphasis seems less on funding high risk research and more on providing industry incentives (in the form of tax breaks, patent extensions, market exclusivity, grants to increase capacity, etc.) to try to encourage private development of vaccines and drugs. It is not clear how the research functions of BARDA would interact with or duplicate the biodefense research currently carried out by the National Institute for Allergies and Infectious Diseases (NIAID). FASEB met with Dr. Robert Kadlec, staff director of the subcommittee on bioterrorism and public health preparedness, to discuss our concerns about the establishment of a new agency in times of tight fiscal constraint, particularly when its programs may be redundant with those at NIH. Other groups have criticized provisions of the bill that would exempt the agency’s programs from the Freedom of Information Act (FOIA).

All indications are that Senator Burr is at least interested in the scientific community’s point of view regarding the bill, although he is clearly also determined to move it forward. This may result in the introduction of a modified bill or amendments to the current bill to try to clarify issues or address some of the concerns raised. However, some of the momentum to move this bill forward may have diminished in light of passage of other bills related to pandemic influenza and avian flu. There is currently no House version nor are there any Democratic co-sponsors for the Burr bill.

There are a few more homeland security related issues to watch in the upcoming year. The Departments of Commerce and Defense are expected to issue regulations related to deemed exports and the licensing of foreign nationals to use equipment for basic research. FASEB joined others in the research community in commenting on initial proposals related to these regulations, which could severely limit foreign scientists from conducting research on university campuses, and early indications are that the revised regulations will be favorable to our position. The Centers for Disease Control and Prevention (CDC) is currently reviewing the forms used to collect information for registration to use Select Agents, in terms of burden on researchers; they are accepting input from the research community. The resulting comments may shed light on how well the Select Agent registration system is working, and whether the stringent regulations are impeding research in any way. Finally, a number of the bills related to innovation (see below--*Innovation Policy Featured Prominently*) have provisions to facilitate foreign scientists receiving visas to study or work in the United States. Although visa processing has improved

substantially since 2001, the perception that the U.S. is no longer a welcoming country for foreign scientists persists. It is hoped the new provisions, which range from creating a new visa class to just encouraging the State Department to continue making improvements in processing, will help repair the image damage caused by post-September 11th visa delays and denials.

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ATTACKS ON THE PEER REVIEW SYSTEM

During House debate on the FY2006 L/HHS appropriations bill, Congressman Randy Neugebauer (R-TX) offered an amendment to prohibit the National Institute of Mental Health (NIMH) from funding two grants that previously had been peer-reviewed and approved for funding. One of the targeted grants, at the University of Iowa, uses an animal model to understand how the brain processes information. The other grant, at the State University of New York at Buffalo, investigates the factors that contribute to successful marriage and how personal feelings of self-esteem influence the capacity to sustain satisfying close relationships.

Dr. Elias Zerhouni, NIH Director, released the following statement in response to the effort to defund the NIMH grants: “Defunding meritorious grants on the floor of Congress is unjustified scientific censorship. It undermines the historical strength of American science which is based on our world renowned, apolitical, and transparent peer review process.”

The House accepted Representative Neugebauer’s amendment by voice vote. Fortunately, the amendment was dropped during conference negotiations with the Senate.

However, FASEB’s Office of Public Affairs fully anticipates that Rep. Neugebauer and others in Congress will again attempt in 2006 to defund NIH grants it does not deem worthy of receiving funding. Our office will continually look for opportunities to educate Members of Congress and its staff on the peer-review process and ask them to oppose any amendment that seeks to rescind funding from peer-reviewed research.

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THE “ANIMAL ENTERPRISE TERRORISM ACT”

In January 2006, FASEB sent [letters](#) to the cosponsors of the “Animal Enterprise Terrorism Act,” Senator James Inhofe (R-OK) and Representative Thomas Petri (R-WI), thanking them for their efforts on the issue of animal rights extremism. The bill has been referred to the House and Senate Judiciary committees and the language is likely to be subject to negotiation over the coming months. Democratic members of the Senate Environment and Public Works committee, chaired by Inhofe and originator of the bill, had expressed concerns at hearings about the need to balance protection of animal research facilities with civil liberties. Some of their concerns may be addressed through modification of the language of the existing bill by the Judiciary committees or via amendment. The Senate and House versions of

the bill are identical, with one exception: the Senate bill allows capital punishment as a criminal penalty, while the House bill does not.

This bill may move forward within the upcoming year, but it is doubtful it will move out of committee before Congress leaves for spring recess. The Senate Judiciary committee, chaired by Arlen Specter (R-PA), has been busy with the confirmation hearings of Supreme Court nominee Samuel Alito, and will likely remain occupied examining issues related to the renewal of the PATRIOT Act, the death penalty, and the National Security Agency's wiretapping program. Moreover, the recent announcement that 11 suspects have been indicted for a series of animal rights extremism and ecoterrorist incidents in the western United States may delay the bill from progressing. If the Department of Justice is successful at prosecuting the alleged extremists under existing law, it may diminish enthusiasm for the Inhofe legislation, one justification for which is that current law is inadequate to prosecute members of underground groups like the Animal Liberation Front.

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STEM CELL RESEARCH

The second session of the 109th Congress is scheduled to start the week of January 31, 2006. During the upcoming year, biomedical research supporters hope the Senate will follow their House counterparts and vote on legislation providing federal funding for embryonic stem cell research—a tough task in this election shortened legislative season.

In May 2005, 50 Republicans joined 188 Democrats to pass H.R. 810, *The Stem Cell Research Enhancement Act of 2005*. This legislation would expand the number of stem cell lines available for federal funding. However, since this historic vote, the legislation has been stalled in the Senate awaiting a final vote.

Originally, supporters of the Senate version of H.R. 810 (S. 471)—including its sponsors Senators Arlen Specter (R-PA) and Tom Harkin (D-IA)—predicted an overwhelmingly supportive vote on their bill. In fact, many in the Senate believed that the bill would receive enough votes to override a veto threat by President Bush. Since that time, five additional stem cell bills have been introduced in the Senate.

Many supporters of the Specter and Harkin proposal contend that these alternative bills were introduced as an attempt to peel away support for S. 471, thus preventing its passage. Others, such as Senator Orrin Hatch, believe that having a debate on each of these bills is good for the issue. Senate Majority Leader Bill Frist (R-TN) is working to find a compromise where he can bring these bills up for a vote, but to date has failed to reach such an agreement.

In late June, during consideration of the Senate FY 2006 Labor Health and Human Services and Education Appropriations bill (L/HHS), Senator Specter threatened to attach S. 471 to this legislation—which funds the NIH. Because this legislation must be passed in order to fund the agencies and programs under its jurisdiction, it would force the President to veto a bill that funds three agencies of the federal government (Departments of Labor, HHS and Education) or sign the bill and thus expand the number of stem cell lines available for federal research.

A major development occurred on July 29, 2005 when Senate Majority Leader Frist voiced support for legislation that would expand funding for stem cell research, thus reversing his previous stance. On the floor of the U.S. Senate, Frist said, “While human embryonic stem cell research is still at a very early stage, the limitations put in place in 2001 will, over time, slow our ability to bring potential new treatments for certain diseases.” In order to avert a showdown with the Labor HHS funding bill, Senator Frist made a deal with Senator Specter: take the stem cell legislation off the appropriation’s bill and he will schedule a vote on S. 471. Specter agreed to this request.

On December 20, 2005, stem cell research gained momentum again when the Senate passed S. 1317, the Stem Cell Therapeutic and Research Act of 2005. This legislation sponsored by Senators Christopher Dodd (D-CT) and Orin Hatch (R-UT), would, among other things, establish a national registry of 150,000 umbilical blood cord units. During consideration of this bill, Senator Tom Harkin (D-IA) tried to block passage of S. 1317 so he could attach the Harkin/Specter bill. Frist denied this request for fear of jeopardizing the bill’s passage.

There have been rumors that a vote on S. 471 could be scheduled as early as February 2006. However, with an election year looming and only 60 or so days to accomplish a host of issues, including reauthorizing the PATRIOT Act, improving health care, addressing education policy issues, and reforming rules on lobbying, it looks highly unlikely that stem cells will reach the Senate floor this year.

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INNOVATION POLICY

Tonight, when President George W. Bush makes his State of the Union address, he will likely call on Congress to support initiatives aimed at enabling America to remain globally competitive in science and technology. This is a theme that has been gaining momentum on Capitol Hill.

Last year, the National Academies of Science (NAS) responded to a request from Senators Lamar Alexander (R-TN) and Jeff Bingaman (D-NM) on what actions federal policymakers could take “to enhance the science and technology enterprise so that the United States can successfully compete, prosper, and be secure in the global community of the 21st Century.” The NAS responded with a report titled: [Rising Above the Gathering Storm: Energizing and Employing America for a Brighter Economic Future](#). This document laid out twenty actions the United States government could take in order to make the U.S. more globally competitive. Among the group’s recommendations were:

- Call for strengthening the U.S. commitment to long-term basic research by increasing the federal investment in such research by 10% a year over the next seven years
- Increasing the number of trained math and science teachers by creating incentive awards
- Proposing that at least 8% of federal research agencies’ budgets be dedicated to discretionary, “high-risk, high-payoff research.” To deal with the nation’s long-term energy problems, a special agency should be established in the U.S.

Department of Energy to support “creative, out-of-the-box transformational generic energy research that industry by itself cannot or will not support.”

On December 6, 2005, a group of nationally recognized leaders in business, science, and academia met in Washington, D.C., to discuss the need for increased investment in U.S. research and development (R&D), and the need for improved educating of our nation’s students in math, science, and engineering, in order to keep up with the ever-growing challenge of international competition. This group provided a public call to action on increasing innovation, followed by high level meetings with Congress and Administration officials on this subject. A [report](#) from the summit and a [list](#) of participants are available online.

The increased focus on this issue has paid off in the form of legislative attention from both sides of the Capitol and political spectrum. House Democrats responded to this call by releasing their [innovation agenda](#). The Democratic innovation agenda asks Congress to create a workforce educated in science and mathematics, an investment in a sustained federal research and development initiative that promotes public-private partnerships; guaranteed affordable access to broadband technology for all Americans; achievement of energy independence in 10 years by developing emerging technologies for clean and sustainable alternatives that will strengthen national security and protect the environment; and, providing small businesses with the tools to encourage entrepreneurial innovation and job creation. In a speech on Jan. 26, Democrat Minority Leader Nancy Pelosi (D-CA) noted the importance of innovation: “Nothing less is at stake than America’s economic leadership,” she said. “As our competitors copy our blueprint for preeminence—with investments in education, long-term research and development, and cutting-edge technologies—we are departing from it.”

Congressman Bart Gordon (D-TN) has introduced three pieces of legislation designed to implement many of the gathering storm report’s recommendations. Most significant to the current funding climate is H.R. 4596, the Sowing the Seeds through Science and Engineering Research Act. This legislation authorizes 10% increases per year in funding for basic research in the physical sciences, mathematical sciences, and engineering at the principal federal agencies supporting such research. These increases, if sustained, would lead to a doubling of basic research funding in these critical areas over 7 years.

The bill also takes action to develop the research talent needed for the future by providing for up to 200 new awards per year worth \$100,000 per year for 5 years, to outstanding early-career researchers. It seeks to enlarge the pool of graduate students in science, math, and engineering by creating a graduate fellowship program, with 5,000 new fellowships per year for individuals pursuing studies in areas of national need.

There is talk on Capitol Hill that House Republicans are planning on releasing legislation similar to Gordon’s bills in early 2006.

The Senate is moving at a quicker pace. On December 15, Senators John Ensign (R-NV) and Joseph Lieberman (D-CT) introduced S. 2109, the National Innovation Act of 2005. This bi-partisan legislation would implement the recommendations of [the Council on Competitiveness report](#) and includes three major components: research

investment, increasing science and technology talent, and creating an innovation infrastructure.

Two weeks ago, yet another set of “innovation” legislation was introduced by Senators Lamar Alexander (R-TN), Jeff Bingaman (D-NM), Pete Domenici (R-NM) and Barbara Mikulski (D-MD). This collection of bills is known as [Protecting America’s Competitive Edge \(PACE\) Act](#). Similar to the Ensign/Lieberman legislation, PACE is a package of 3 separate bills aimed at strengthening our investment in energy research through increases for the Department of Energy’s Office of Science and the National Science Foundation, investing in math and science education, and providing tax incentives to encourage research and development.

During a briefing on PACE, Senate staff noted that Sen. Domenici, Chair of the Senate Energy and Natural Resources Committee, plans to hold a hearing on the energy portion of PACE within the next few weeks and hopefully move it onto the Senate floor shortly thereafter.

The scope and fate of these pieces of legislation could get a major boost tonight if President Bush speaks of the need to push this issue forward. During a press conference on Thursday, January 26, Bush said “We live in a competitive world, and so policies must be put in place to recognize the competition of the global economy and prepare our people to be able to continue to compete so America can continue to lead.” White House Chief of Staff Andrew Card recently told a Chamber of Commerce audience that the gathering storm report is getting a “very close look.”

While a supportive gesture in President Bush’s State of the Union address will add fuel to the fire for passing innovation legislation, the real gauge of success will come on February 7, 2006—the release of the President’s fiscal year 2007 budget. Without adequate financial support for these programs, Congress will have a hard time coming up with necessary monies to enact these policies.

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