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APPROPRIATIONS UPDATE

It is expected that the Senate will take up the L/HHS appropriations bill (which provides funding for agencies within the Department of Health and Human Services, including NIH) during the week of October 24th. Chairman Arlen Specter's (R-PA) threats to attach stem cell legislation to the L/HHS appropriations bill complicated efforts to bring the measure to the Senate floor. However, it appears that Senator Specter and Majority Leader Bill Frist (R-TN) are close to reaching an agreement on how to proceed. Senator Frist has indicated that he will allow a vote on the stem cell legislation on a "date certain" in 2006 if Specter agrees to drop his threat to attach the stem cell legislation to the L/HHS appropriations bill.

Chairman Specter's L/HHS bill provides NIH with nearly a \$1 billion increase for FY2006. However, Senate appropriators used budget gimmicks (such as moving the pay date on the Supplemental Security Income program into FY2007) to increase the bottom line for several programs, including NIH. House leaders have indicated that the gimmicks are a "nonstarter" for House appropriators. The House proposed to increase NIH's budget in FY2006 by \$195 million (roughly \$800 million less than the Senate committee-passed bill).

BUDGET RESOLUTION/RECONCILIATION

House Budget Committee Chairman Jim Nussle (R-IA) has given House congressional committees until October 28, 2005, to identify reductions in the rapid growth of mandatory programs, such as Medicaid and Medicare.

You may remember that the FY2006 Congressional Budget Resolution directed congressional committees to find \$37.4 billion in mandatory program savings to be combined into a reconciliation bill for enactment. A few weeks ago, Chairman Nussle and the House leadership stated that congressional committees would be asked to raise the net savings amount in mandatory programs to \$50 billion. Chairman Nussle also announced that he would introduce a proposal to amend the budget resolution by cutting FY2006 discretionary spending accounts by 2 percent (an across-the-board cut). Trimming all discretionary accounts, which total \$843 billion under the FY2006 budget resolution, by 2 percent, would save \$16 billion.

When FASEB's Office of Public Affairs learned of Chairman Nussle's plans for the across-the-board cut, it partnered with a diverse group of patient organizations and advocacy groups, including the American Diabetes Association, the American Heart Association, the American Cancer Society, the Alzheimer's Association, the Society for Neuroscience, and Research America, to send a [letter](#) to all Members of Congress urging them to oppose any proposal for an arbitrary across-the-board cut.

Faced with a lack of party unanimity, Chairman Nussle and House Republican leaders decided to postpone plans to implement a 2 percent across-the-board cut in the FY2006 budget resolution. However, House leaders are indicating that the budget resolution may include a commitment to implement the across-the-board cuts during later spending negotiations rather than specify the percentage now.

FASEB's Office of Public Affairs also scheduled a meeting with Congressman Nussle's staff to communicate the consequences of cutting funding for biomedical research. FASEB invited and sponsored a distinguished researcher from the University of Iowa (Dr. Kevin Kregel) to travel to Washington to help make its case (please see the write-up from this meeting under the "Congressional meetings" section).

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INSIDE (the Beltway) SCOOP – Jon Retzlaff, Legislative Director

The L/HHS appropriations bill is the last funding item on the Senate agenda. L/HHS appropriations committee staff has been patiently waiting for a signal from Senator Majority Leader Bill Frist (R-TN) on when the bill will go to the floor. However, Bettilou Taylor, L/HHS staff director, recently became quite concerned because House leaders have refused to work with the Senate until it passes its own version of the appropriations bill. The House is insisting that the Senate follow regular order and is vowing to avoid a year-end omnibus bill. Therefore, to maintain proper order and thus avoid being included in an omnibus bill (which the House is saying will not occur), the Senate must pass the L/HHS appropriations bill. If the

Senate does not act, a year-long continuing resolution is very likely for NIH at the FY2005 level (or even less, if an across-the-board cut is adopted).

Chairman Specter (R-PA) has two weeks of availability to manage the L/HHS bill on the Senate floor before he will be consumed with the confirmation hearings for Supreme Court nominee Harriet Miers, which are scheduled to begin on November 7, 2005.

Next week, FASEB plans to send an alert to its members asking them to encourage Senators to support Chairman Specter's bill. If the full Senate passes the L/HHS appropriations bill (and thus, goes on record as endorsing the NIH increase), it will provide Chairman Specter and Ranking Member Tom Harkin (D-IA) with some leverage during negotiations with the House (even as the House appropriators dismiss the Senate gimmicks as a non-starter during conference negotiations). While a \$1 billion increase is out of the question for the agency, we will have reason to hope that the final number for NIH will be more than the Administration or House proposed.

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CONGRESSIONAL MEETINGS

FASEB Meets with House Budget Chairman Jim Nussle's Staff Regarding His Proposal for Across-the-Board Cuts

On October 20, 2005, a large contingent of advocacy organizations and patient groups met with Joseph Wheeler, Legislative Director, Jim Nussle (R-IA), and James Cantwell, Health Policy Analyst, House Budget Committee [Chairman Jim Nussle (R-IA)], to express our concerns regarding Chairman Nussle's support for a 2 percent across-the-board cut in discretionary spending programs .

The following individuals attended the meeting: Jon Retzlaff, Director of Legislative Relations, FASEB; Kevin C. Kregel, PhD, Professor, Department of Exercise Science and Free Radical and Radiation Biology Program, Department of Radiation Oncology, The University of Iowa, [FASEB Member – APS Society]; Claudia Louis, Government Relations Manager, American Heart Association; Sue Nelson, Vice President of Federal Advocacy, American Heart Association; Jennifer Zeitzer, Associate Director, Federal Policy, Alzheimer's Association; Bill Leinweber, Executive Vice President, Research America; Kevin Cain, Manager, Federal Government Affairs, American Diabetes Association; and Andy Fish, Senior Director, Federal Government Relations, American Cancer Society.

Dr. Kregel discussed the economic effect of NIH dollars on the State of Iowa and voiced concern that young scientists are beginning to look at other career options because of the uncertainty surrounding the NIH budget. He talked about the scientific opportunities that exist today and discussed how the research enterprise at the University of Iowa would struggle to maintain its current efforts if NIH is flat-funded.

Mr. Cantwell stated that Chairman Nussle believes NIH provides a good return on taxpayer dollars. Mr. Cantwell remarked that Budget Committee members believe they have allocated an appropriate level of Federal dollars for discretionary spending programs in FY2006. He suggested that the Appropriations Committees need to do a better job of prioritizing programs. Mr. Cantwell also said that Chairman Nussle believes that any across-the-board cut must be shared by all agencies. Therefore, defense and homeland security should not be exempted from such a cut. Finally, Mr. Cantwell asked us to identify areas that would be ripe for reduction or elimination. We informed him that our groups do not have the level of expertise that would be needed to make those decisions.

FASEB Meets with Environment and Public Works Committee Staff regarding NYSE's Surrender to Animal Rights Extremism

On October 14, 2005, Jon Retzlaff and Carrie Wolinetz, staff from the FASEB's Office of Public Affairs, met with Malcolm Woolf, Minority Council to the Committee on Environment & Public Works [Ranking Member James Jeffords (I-VT)], to discuss the Senate Environment and Public Works Committee plans to investigate the New York Stock Exchange's (NYSE) recent decision to cancel the listing of Life Science Research (LSR), Inc. Life Science Research, Inc. is the parent company of Huntington Life Sciences, an animal testing company that has been the target of the animal rights (AR) extremist group, Stop Huntington Animal Cruelty (SHAC). The NYSE's last minute cancellation of the LSR listing appears to have been as a result of threats from SHAC, whose past tactics have included violent assault, arson, and intimidation campaigns.

FASEB provided Mr. Woolf with background information on AR extremism and offered to submit testimony. Mr. Woolf was appreciative of our willingness to help and thanked us for communicating our concerns. He informed us that the Democrats on the committee have been unclear as to the outcome Chairman Inhofe (R-OK) is interested in achieving. Although FASEB has been grateful that this series of hearings has brought attention to the serious issue of AR extremism, Mr. Woolf expressed concern that the hearings could have the unintended consequence of giving credibility to groups like SHAC. The Senate Committee on Environment and Public Works has scheduled the hearing for October 26, 2005.

CONGRESSIONAL HEARINGS

Senate Labor-HHS Committee Holds Hearing on Stem Cell Research and SCNT

Senator Arlen Specter (R-PA) held a hearing of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies (Labor-HHS) in support of stem cell research and somatic cell nuclear transfer (SCNT). According to Specter, this was the 16th such hearing since human embryonic stem cells (hESC) were first isolated in 1998. Witnesses included: former FASEB President, Dr. Steven

Teitelbaum, Washington University Medical School; Dr. Rudolph Jaenisch of the Whitehead Institute; Dr. Judith Gasson, Director of UCLA's Jonsson Comprehensive Cancer Center; Dr. John Wagner, Director of the Stem Cell Institute, University of Minnesota; and Mr. Anthony Herrera, a cancer survivor and author who has been successfully treated with stem cell therapy.

Each witness was given only a very short time to testify, and all spoke of the importance of studying both embryonic and adult stem cells, as well as the promise of SCNT. Senators Specter, Cochran (R-MS), and Harkin (D-IA) attended the hearing and were supportive of the current legislation (S. 471) which would expand the current federal funding policy of hESC research, a bill already passed by the House of Representatives. Senator Specter also advocated moving forward the Human Cloning Ban and Stem Cell Research Protection Act (S. 876), which would criminalize reproductive cloning while legalizing the use of SCNT to produce stem cells. The only dissenting opinion was expressed by Senator Mary Landrieu (D-LA), who stated that she did not believe the destruction of embryos for research was consistent with protection of human dignity.

Senators Specter and Cochran both indicated that they were willing to attach S. 471 to the Labor-HHS appropriations bill, which is expected to come to the floor next week, and that they expected a great deal of debate over the measure. Since the hearing, as discussed in today's Inside the Beltway Scoop, Majority Leader Frist and Senator Specter have come closer to reaching an agreement which would guarantee an early 2006 vote on the stem cell bill in exchange for not attaching it to Labor-HHS. FASEB submitted [testimony](#) in support of the hearing and both S.471 and S. 876.

House and Senate Hold Hearings on NAS Competitiveness Report

On Tuesday, October 18, the Senate Energy and Natural Resources (ENR) Committee held a hearing on "Innovation in Energy Technologies and Impacts on Global Competitiveness," focusing on the national capacity for producing innovation in energy technologies and the results of the forthcoming National Academy of Sciences (NAS) Report: *Rising Above The Gathering Storm: Energizing and Employing America for a Brighter Economic Future*. On Thursday, October 20th, the House Science Committee held a similar hearing. For a copy of the report, please click [here](#).

The NAS report was requested by Senators Lamar Alexander (R-TN) and Jeff Bingaman (D-NM). The Senators asked the committee to list the top 10 actions, in priority order, that federal policy makers could take to enhance the science and technology enterprise so that that United States could compete. Their recommendations vary from improving science and math in America's K-12 programs to investing more resources in US basic research.

During the Senate hearing, ENR Chairman Pete Domenici (R-NM) said it would be hard to undertake an NIH doubling campaign for the physical sciences. He said that with NIH there was a resolution to double the budget

of NIH, it passed and the rest is history. It is hard to do this with basic science because it is spread out over many agencies—DOE, NSF, DOD, etc.

Senator Alexander said he was pleased with this report and glad to hear that Senator Domenici indicated this issue should be the priority of the Senate. Alexander also noted that Senators Kit Bond (R-MO) and Barbara Mikulski (D-MD) supported the report. Alexander said that he not only wanted this to be a priority of the Senate, he wanted to see it in President Bush's State of the Union Address and a focus of his administration for the next three years. He recommended that Bush put some of these recommendations in his budget for next year.

According to Senator Alexander, requesting an increase in the federal investment in long term basic research by 10% over seven years (roughly a \$10 billion figure) is high but we need to find a way to fund it. As Governor of Tennessee, he had to make choices, and those things he felt were most important he put on top of the list to be funded. He used an example of restraining Medicaid growth as a way to find the money and said that new innovations that come out of this research might actually help save money in health care costs. Alexander also asked the panelists if they could form a subcommittee to help with technical advice as the Senate moves forward with trying to establish legislation out of these recommendations. They agreed they would.

During the House Science Committee hearing, Science Committee Chairman Sherwood Boehlert (R-NY) mentioned that while the United States is still ahead of its foreign competitors in science and innovation, other countries are catching up. Boehlert told the panelists that even in Congress this issue needs to be given importance, noting that very few Members campaign on a pro-science platform. Chairman Boehlert also implored the science community to make this an issue, noting that Congressional office average zero letters in support of these issues from constituents.

Representative Bart Gordon (D-TN) the Ranking Member on the Science Committee, asked why the NAS committee recommends a 10% increase in the federal investment in long term basic research. Dr. Norm Augustine, Chair of the NAS panel that produced the report, replied that they wanted to quickly increase the budgets of those fields (physical sciences) that have been flat funded over the past few years.

Gordon followed up by asking if there was an action plan to get this done. He mentioned that it has been very hard to come up with money in these tight fiscal times for current priorities and they are asking for a 10% increase. Augustine, speaking for himself, said that in a country like the United States, with a gross domestic product (GDP) as large as we have, there must be some place to find the money. Gordon suggested a small tax on business to get this money. Augustine said he could support such an effort.

Stem Cell Bill Update in Ohio

On Tuesday, October 18th, the Juvenile Diabetes Research Foundation (JDRF) informed FASEB's Office of Public Affairs about a very harmful piece of stem cell legislation making its way through the Ohio House of Representatives.

This legislation, H.B. 355, sponsored by Representative Mike Gilb (R-76th), would ban human reproductive cloning but would also ban therapeutic cloning—which provides another means for researchers to get stem cells to study. In addition, this legislation would also limit Ohio researchers' ability to participate in federally supported research on stem cell lines, which is needed for scientists to explore the full potential of this research. You can [view a copy](#) of this legislation online.

FASEB worked with its member societies and those FASEB e-action subscribers in Ohio to [urge their colleagues](#) in the state to contact their Representatives and tell them to vote no on this issue.

FASEB has learned that our efforts may have resulted in preventing this legislation from coming to the floor. As of this writing, the bill has not been taken up and sources indicate that it might not be considered this session. FASEB will keep you updated as events unfold.

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BILLS, BILLS, BILLS

"Biodefense and Pandemic Vaccine and Drug Development Act of 2005"

A bill titled the "Biodefense and Pandemic Vaccine and Drug Development Act of 2005" was introduced this week by Senator Richard Burr (R-NC), and was marked up rapidly by the Senate Health, Education, Labor and Pensions (HELP) committee. 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). Moreover, the Burr bill would establish an advisory board to advise the BARDA director, whose mission seems to overlap with the recently formed National Science Advisory Board on Biosecurity, whose first meeting took place in July of 2005. Finally, some of the development incentives and procurement functions of BARDA are clearly duplicative with those outlined by Project Bioshield. FASEB sent a [letter](#) to members of the Senate Health committee expressing our concern over potential redundancy in a time of tight fiscal constraints, as did FASEB member society, the American Association of Immunologists.

In addition to creating BARDA, S.1873 would establish a new awards program at the National Institutes of Health (NIH) to develop and study animal models for responses to “chemical, biological, radiological or nuclear agents or toxins or potential pandemic infectious disease.” This program would be under the control of NIH and guided by a newly formed Animal Model / Research Tool Scientific Advisory Committee. The Burr legislation would also establish a National Pathology Center at NIH whose mission would include: conducting and supporting research and training programs related to pathology; maintaining a pathology tissue repository; and providing pathology consulting services to federal agencies and health officials. This is apparently intended to replace the current Armed Forces Institute of Pathology, which will likely be eliminated when the Walter Reed Army Medical Center is closed, as recommended by the Base Closure and Realignment Commission (BRAC).

The HELP committee markup, which was held on October 18, less than 24 hours after the bill was introduced, was illustrative of how quickly this legislation was moving. Overall, the committee was thoroughly supportive of the legislation, in particular the establishment of a “DARPA-like” biodefense agency, but the Senators in the minority had concern over some of the patent protection and market exclusivity provisions. However, all seemed confident that the differences could be resolved within 48 hours, and the bill was passed nearly unanimously, with not much discussion, out of committee. Chairman Enzi (R-WY) suggested the bill could come to the Senate floor as early as next week. The members of the committee expressed a great urgency to pass the bill in light of growing concerns over a looming avian influenza pandemic.

The Biodefense *et al* Act is an authorization bill, and thus has no funding authority without support from appropriators, which could burden DHHS with a large, unfunded mandate. There is currently no indication that there is a House version or champion of this bill. It is difficult to measure what the impact of the Burr legislation would be, if enacted, because it is unclear where the money would come from and what programs would be affected. Furthermore, because the language of the bill is still under negotiation and potentially amendable, we do not know for sure what the final legislation will look like. But given the current budgetary climate, it seems likely that the establishment of BARDA and the other programs described in the bill will come at the expense of current research programs. FASEB will continue to follow this piece of legislation very closely.

OTHER FASEB ACTIVITIES

NIH Stakeholders Town Hall Meeting

Purpose

On October 20, 2005, Dr. Elias Zerhouni, NIH Director, invited NIH stakeholders to attend a meeting on NIH's campus. The purpose of this meeting was for Dr. Zerhouni to describe his vision for NIH, elaborate on the mechanisms for stimulating cross-cutting research, address topical issues, and respond to questions about NIH. In addition, Dr. Zerhouni stated that he hoped to establish a wider dialogue with shareholders.

NIH Scientific Roadmap:

Dr. Zerhouni remarked that since the NIH doubling was completed in 2003, the environment has changed substantially in terms of the support NIH is receiving on Capitol Hill. He remarked that he wants to take steps to maintain the momentum for our nation's patients. To do this, Dr. Zerhouni commented that NIH must follow scientific opportunities and be responsive to public health needs. He cited the importance of translating research from the bench to the bedside and conveyed his interest in focusing on emerging trends in science that will transform medicine. He spoke of the unprecedented and largely untapped scientific opportunities, including the human genome project, functional genomics, proteomics, integrative biology of disease, revolutionary research methodologies and information sciences.

Trans-NIH Research Activities:

Dr. Zerhouni highlighted the trans-NIH research activities, including the NIH Roadmap for medical research, the NIH strategic plan for obesity research and the NIH Neuroscience Blueprint, and expressed his desire to formalize the ad hoc priority setting process that has led to these initiatives.

Office of Portfolio Analysis & Strategic Initiatives:

Dr. Zerhouni outlined his goals for the new Office of Portfolio Analysis and Strategic Initiatives (OPASI) at NIH. The purpose of OPASI is to provide the ICs with the methods and information necessary to improve the management of their large and complex scientific portfolios. It also is charged with identifying (in concert with other multiple other inputs) important areas of scientific opportunities. Dr. Zerhouni remarked that OPASI will help NIH become more nimble, dynamic and responsive. He compared OPASI's role to that of a radar that continues to scan the environment.

NIH Reauthorization:

Dr. Zerhouni was asked if his vision for NIH is consistent with the most recent NIH Reauthorization (House Energy and Commerce Committee) discussion draft. He stated that the section of the bill that would establish the Division of Program Coordination, Planning and Strategic Initiatives within the Office of the Director as well as the creation of a common fund to

encourage interdisciplinary research, are consistent with his vision. He stated that the common fund would provide NIH with the opportunity to be nimble.

NIH Common Fund:

Dr. Zerhouni clarified that the common fund is not a transfer authority, but instead is a set-aside fund. Each year, NIH ICs would provide a percentage of their annual budgets to this fund to support research identified through the OPASI planning process. The common fund's budget would be 1.1 percent of the total NIH budget in FY2006. The goal is to grow the fund to 1.7 percent of the total NIH budget by FY2008. However, this will depend on the overall growth rate for the NIH budget.

Actually, Dr. Zerhouni would like to see the common fund increase to five percent of the total budget over time, but this would happen only if NIH's budget increases (over many years) by a greater amount than the biomedical research inflation index.

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CONGRESSIONAL SCHEDULE

The House and Senate are in session.

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