



# COSSA

Consortium of Social Science Associations

Volume 25, Issue 11

June 12, 2006

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## SPENDING BILLS MOVE FORWARD IN HOUSE; SENATE ABOUT TO BEGIN

Spurred on by appropriations committee chairman Rep. Jerry Lewis' goal that the House pass all its FY 2007 appropriations bills by July 4; seven of the twelve have emerged from that body. With the conference agreement on the FY 2006 supplemental spending reached on June 8, which included a provision deeming the spending cap for the Senate's appropriations bills, that body will soon begin its consideration of the FY 2007 funding legislation. Despite this, nobody expects enactment of all the bills by the time Congress adjourns in October for the 2006 elections.

The House has completed action on the bills funding Agriculture and Rural Development, Homeland Security, Energy and Water, Interior and Environment, Legislative Branch, and Military Quality of Life and Veterans' Affairs and Foreign Operations. The two largest bills - Defense and Labor, Health and Human Services, and Education - were marked up by their respective subcommittees on June 7 and are expected to go before the full appropriations panel the week of June 12. The State, Science, Commerce, Justice bill, which includes funding for the National Science Foundation (NSF), Census Bureau, National Institute of Justice (NIJ), and the Bureau of Justice Statistics (BJS), is scheduled for subcommittee markup on June 14.

The Senate will soon allocate its \$873 billion for discretionary spending, same total as the House, among its subcommittees and the mark up process will begin. There is still some dispute over the fate of the extra \$7 billion Senators Arlen Specter (R-PA) and Tom Harkin (D-IA) put in the budget resolution (see UPDATE, March 20, 2006) to help increase funding for NIH and education. Since a final budget resolution was never enacted, some informal arrangements will be necessary to preserve the additional funding.

## LABOR, HHS EDUCATION NUMBERS FROM HOUSE SPENDING SUBCOMMITTEE

On June 7, the House Labor, Health and Human Services Appropriations Subcommittee approved its version of the FY 2007 spending bill, via party-line vote, providing \$141.9 billion, an increase of \$712 million or 0.5 percent above the FY 2006 funding level, and \$4.136 billion more than the President's request.

The bill flat funds the **National Institutes of Health (NIH)** at a level equal to the President's request of \$28, 258 billion and a decrease of \$306,000 from the FY 2006 funding level.

In the statement released following the party-line vote of 9 -7, the Subcommittee notes that the "bill fully supports the peer review approach to the distribution of medical research grants by essentially following the NIH's recommended funding distribution among the various institutes."

The measure provides \$6.1 billion in funding for the **Centers for Disease Control and Prevention (CDC)**, \$27.5 million below the FY 2006 funding level and \$239.6 more than the President's request. The bill level funds the **Agency for Healthcare Research and Quality (AHRQ)** at \$319 million, consistent with the President's request. This year, however, the bill provides the money via direct appropriations rather than through Public Health Service evaluation funds.

The bill is scheduled to go before the full Appropriations Committee on June 13.

### HOUSE PANEL PROVIDES NO FUNDING FOR NATIONAL SECURITY LANGUAGE INITIATIVE

In early January, President Bush ballyhooed, as part of a major national security effort, a major new initiative to provide funding to increase the United States' capacity in less commonly taught languages. Americans' learning Chinese, Korean, Urdu, and other languages became an imperative to help the nation face looming foreign threats. The Department of Education's (ED) budget included \$24 million in new funds for its role in the initiative. However, the House Subcommittee decided not to fund the new program. In addition, it level funded the already existing International Education and Foreign Language Title VI programs, rejecting the Administration's request to increase them by \$1 million from last year.

The Subcommittee continued the Javits Fellowship program at last year's level of \$9.7 million. As it has done in the past, the panel zeroed-out the Thurgood Marshall Legal Education Opportunity program. In recent years, the Senate, against the House and the Administration's wishes, has restored the modest funding for this program. The Fund for the Improvement of Postsecondary Education (FIPSE) saw its budget yo-yo up again from the \$22 million FY 2006 and FY 2007 requested level to a recommended \$91.2 million. Although the Committee report has not yet been released, this significant increase for this program suggests last year's elimination of earmarking for this agency may be a one-year moratorium.

The Institute of Education Sciences' research, development, and dissemination account remained stable at \$162.6 million, while the National Center for Education Statistics (NCES) received its requested \$3 million increase to \$93 million. The Subcommittee also agreed with the Administration and increased the assessment account by \$4 million to \$92.1 million, but

rejected the full requested increase for the Statewide Data Systems, agreeing to a \$10.5 million boost to \$35 million, rather than the \$54.6 million asked for by the White House.

The panel recommended \$565.3 million for the Bureau of Labor Statistics, a \$28.2 million boost from FY 2006 and \$2 million more than the request. This additional increase will go to the Employment and Unemployment Statistics account.

## NIH: AN AGENCY AT A 'CROSSROADS'

According to Elias Zerhouni, Director of the National Institutes of Health (NIH), the NIH "benefits from the advice of over 30,000 advisors every year. It is the agency that consults the most," he declared, opening the 92<sup>nd</sup> Advisory Council to the Director (ACD) on June 2. In his legislative update to the Council Zerhouni noted that there is "still talk on the Hill of reauthorization" of the NIH, explaining that the Chair of the House Energy and Commerce Committee, Rep. Joe Barton (R-TX), continues to believe that the agency needs to be reauthorized.

As he has done while visiting the various advisory councils of the NIH's 27 institutes and center (ICs), Zerhouni explained to the ACD that the NIH is at a "Crossroads." The agency is facing changes in its budget and other factors that require the ACD to evaluate and advise the NIH on its analysis of the situation and on next steps for the agency.

Zerhouni emphasized that it is very important that they understand the factors the agency is experiencing and what internally the NIH staff calls the "Perfect Storm." To begin with, Zerhouni reported that the NIH's budget is being affected by matters such as the federal and trade deficits along with defense and homeland security needs which have primarily driven the policy of the government.

He stressed that there are also the unpredicted factors of Katrina and the possible bird pandemic flu. In addition, there are other concerns that the agency has to manage, which Zerhouni described as "the post-doubling effect" and are less defined: 1) Budget fatigue and a focus on the physical sciences, a focus that conflicts with the post-doubling era; 2) High expectations from the doubling of the agency's budget; and 3) Underneath all of those factors is the question of where is the NIH going. What has the doubling done for the country? It is a question that is being constantly asked by policy makers.

On top of all of those concerns, Zerhouni contended, the agency has to deal with the biomedical research inflation which is 3 - 5 percent and is higher than general inflation as a result of having a "very strong component of personnel in the agency's costs," he explained. It is calculated by the Department of Commerce (DOC).

It is one of the most difficult environments the agency has ever operated in, he indicated, reflecting on his conversations with Ruth Kirschstein, who has worked at NIH for several decades and served as the Acting Director for the agency for nearly two years directly prior to his appointment.

According to Zerhouni, this environment is well captured in a quote from former NIH Associate Director Research and Training William F. Raub who said in a 1982 strategy paper that *"Competition for funds from the NIH and other sponsors, intensifying year by year, now stands at an unprecedented level, and shows no sign of abating. Never before have so many established investigators faced so much uncertainty about their longevity as active scientists."*

*Never before have so many novices faced so many disincentives to entering or continuing a research career.”*

He recounted that he feels that distress whenever he goes around the country speaking with scientists. He says that he is amazed at the “tremendous anxiety, frustration and anger” he witnesses when he communicates with investigators in the field. It is something that “NIHers have lived before and we know what happens when these things happen” he shared.

## The Main Drivers

The NIH director says that he is astounded with the number of analyses and the reasons bandied about regarding the state of the NIH budget. He shared his analysis of the state of the agency with the Committee. It is one that is based on data accumulated since 2002 and 2003 when he was appointed director of the NIH, he explained. According to Zerhouni, one of the first things he did as director was to ask each of the ICs to produce a five-year forecast and analyze the trends each IC was dealing with. Based on this data, three factors explain 98 percent of the issues, related Zerhouni. They are what he called the “main drivers.”

The number one “overwhelming driver” he explained is the “large capacity building throughout U.S. research institutions and the increase in the number of new faculty.” To illustrate what he calls an informal competition among institutions, he noted the number of cranes on the campuses of medical schools and how that number reflects the school’s status. When you have a 15 -16 percent stimulus, “it changes the free-market of decision-making.” he explained.

The second driver impacting the state of NIH is that the agency has been receiving appropriations below the inflation rate since 2003 and the completion of the doubling of its budget. For instance, the NIH received a 3 percent increase in FY 2004, a 2 percent increase in FY 2005, and was flat funded in FY 2006. The biomedical inflation in 2004, on the other hand, was approximately 5 percent. The increases in the agency’s budget, Zerhouni explained, “are not enough to sustain the purchasing power of the NIH’s budget.”

The doubling of the budget, according to the NIH director, has done what it was supposed to do and that is to “increase the capacity for research.” “What the Nation wanted was expanded research capacity, not just to double the budget of everything [the NIH] did before, but to create new fields.” While we should be happy that the institutions responded to that call, it “is also the source of the tension we feel.” It’s a demand and supply issue, Zerhouni contended.

According to the NIH data, during the entire doubling period the agency received more than 8,300 competing grant applications. In the two years following the end of the doubling, the demand for grants almost doubled. “We had more incremental demand for grants than we did in the total years of the doubling,” Zerhouni maintained. That demand is the result of an increased number of applicants from new scientists, he further explained.

There was “a great period when the budget was increasing 16 percent a year but there was no corresponding increase in demand for the first four years of the doubling,” Zerhouni observed. Then “all of a sudden there was a marked increase in demand - a temporal shift - particularly in the two years post-doubling.” In FY 2007, Zerhouni stated that the agency *expects 49,000 grant applications* “which will exactly double the number of applications” the NIH received in 1998. In addition, the cost of each grant has risen from \$250,000 to \$350,000, a 40 percent increase.

The third driver is what Zerhouni termed the “budget cycling phenomenon,” where the funding from expired grants is recycled in the budget pool to provide the funding for new grants. The

“bottom line,” Zerhouni explained, is that the demand for grants “took off” just as the NIH budget was “landing.” The post doubling “boom” in applications has contributed to the imbalance the agency is experiencing.

## Common Myths and Misperceptions Operating Against NIH

Zerhouni told the ACD that there are common misperceptions and myths about the NIH of which they need to be aware. The most common misperception, he insisted, is that the NIH is overemphasizing applied research. Looking at the data collected since 1998, Zerhouni explained that basic research seemingly dipped in 2003 because 20 percent of NIH’s budget was being directed toward biodefense in response to 9/11. In addition, in 2003, the agency had a number of one-time expenditures where the dollars were then re-circulated in 2004 and 2005. He highlighted the fact that despite the lackluster increase in NIH’s annual appropriation in FY 2004, the agency did not feel the full impact as a result of these managerial decisions.

A second common misperception, Zerhouni noted, is that the agency is shifting towards solicited research with too many requests-for-applications (RFAs). This is the result of people not looking at the relationship, the percentage, between the budget and the number of initiatives, he stressed. As a result of the budget increases, the absolute number of RFAs and program announcements (PAs) go up, so you get the perception that there are more initiatives, he pointed out.

A third misperception is that the NIH Roadmap is shifting major funds away from the grant pool, Zerhouni indicated. He says that he is “frankly, puzzled by this.” He insisted that the Roadmap is not taking away funding from other projects and grants. Developed in 2003, the NIH Roadmap for Medical Research was “created to help facilitate synergy across NIH.” The most important factor that people miss about the Roadmap is that it is a series of initiatives set up to last anywhere between five and ten years. It is balanced, “40 percent translational, 40 percent basic, and 20 percent high impact research,” he emphasized. He also revealed that more than 345 individual Roadmap awards were made in FY 2005 to 133 institutions.

A fourth misperception, Zerhouni noted, is about the payline and that it is the cut off line for funding grants. He explained that the payline is the percentile score for which 99 percent of the grants will be funded. But if you have twice as many applicants, he explained, it is clear that high quality applications are going to be found in the lower percentile scores. But there is, however, always a higher success rate than the payline because no institute has a zero percent funding for things that are beyond the payline score. In addition, the success rate per applicant understates funding rates per applicant, he further explained, noting that many researchers apply for more than one grant.

## Adaptive Strategies Required

Where does the NIH go from here is the question, Zerhouni asked. The agency, he stressed, must develop adaptive strategies. He shared with the ACD the key principles that are driving the NIH’s response right now, Zerhouni noted.

First, the NIH must protect its core values and mission - “discovery and new knowledge.” Second, the NIH must protect its future: new investigators. Every IC is taking steps to protect the new investigator, he informed the ACD, referencing the newly created *Pathways to Independence* program the agency plans to institute in FY 2007. The third principle is to identify the main drivers of the situations and manage them. For the NIH it is the supply and demand of grants, he stressed.

The situation such as the one NIH is in always causes a vacuum of information, Zerhouni explained. Accordingly, the fourth principle emphasizes the need for NIH to communicate proactively. He pointed out that it is important to focus the message on the value for investment and the “need for sustainability.” He noted his testimony before the Senate in which he attempted to get the message across that “medical research is a marathon.” There is a need to manage the expectations of quick return in science along with the need to educate policy makers about the maturation of science. This requires the community as well as the NIH, he stressed. Finally, the fifth principle calls for the NIH to have a vision for the future and share that vision. The most important message is the need to maintain a balanced portfolio, Zerhouni concluded.

### Is Peer Review Becoming Too Conservative?

Responding to Zerhouni’s question to the ACD regarding “what else” would the Committee have NIH consider, ACD member David Botstein, Princeton University, noted that a “prominent cause for anxiety is a pretty general concern about the quality of the peer review.” He acknowledged that there was not a concern 10 years ago, but it “has clearly built up.” Acknowledging the “serious attempt” to revise it, Botstein indicated that he “is not sure the community is convinced that peer review is working the way that it is supposed to now.” He also noted that he is hearing that “study sections are looking for mistakes rather than good ideas.”

Referencing Botstein’s comment, newly appointed ACD member Alan Leshner (CEO, AAAS and former director of the National Institute on Drug Abuse) added that as success rates have gone down, “are we at risk getting more conservative with regard to peer review so that the most innovative high-risk research is having an even harder time than ever before.” Pioneer awards, Leshner emphasized are not going to do it. “How do we deal with the inherent conservatism of a tight budget,” he asked.

## SENATE SUBCOMMITTEE CALLS FOR ‘TRANSPARENCY’ FOR THE 2010 CENSUS

On June 6, the Senate Subcommittee on Federal Financial Management, Government Information and International Security Committee on Homeland Security and Governmental Affairs held a hearing to examine the rising costs of the 2010 census.

In the hearing entitled “Census 2010, Off-line and Off-budget: The High Cost of Low-tech Counting,” Subcommittee Chairman Senator Tom Coburn (R-OK) asserted that behind the U.S Census data collection is a “steadily increasing price tag which until recently has managed to stay below the radar of Congress.” “Costs are spiraling upward at a startling rate,” said Coburn. “This is all part of the disturbing trend in recent decades which witnessed dramatic cost increases from one census to the next.”

At the present time the 2010 census is projected to cost roughly 12 billion dollars; an 80 percent increase over the 2000 census. U.S. Census Bureau Director, Louis Kincannon, provided