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THE PRECARIOUSNESS OF PEER REVIEW: HOUSE BARELY DEFEATS ATTEMPT TO STOP NIH GRANTS

“Who are these peers?” the late Senator Russell Long (D-LA) once asked during a post-midnight Senate debate on earmarking Federal funding many years ago. On July 11, the process used to award grants at the National Institutes of Health and the National Science Foundation once again came under attack during the House of Representatives’ debate on the Labor, Health and Human Services Appropriations bill. Combine the questioning of peer review with grants given to study topics viewed by some as illegitimate for Federal funding, such as research on sexual health, and you have the formula for a 212-210 vote on the House floor, barely defeating an amendment to stop funding for five research grants awarded by the National Institutes of Health.

The amendment, sponsored by Rep. Pat Toomey (R-PA), would have eliminated money for research he deemed “much less worthy of taxpayer funding than the kind of research the NIH is generally doing to cure...devastating diseases.” He and co-sponsor Rep. Chris Chocola (R-IN) cited five grants, each of which, as Subcommittee Chairman Ralph Regula (R-OH) explained, had passed through the NIH’s “elaborate two-tiered peer review process that is mandated by the Public Health Service Act.”

Regula, strongly opposing the amendment, further explained the process: “Outside review panels of distinguished scientists from universities nationwide gather to review each application, which can easily run on to several hundred pages... Then these

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ACTION TRANSPIRES ON KEY APPROPRIATIONS BILLS: LABOR-HHS-ED AND CJS

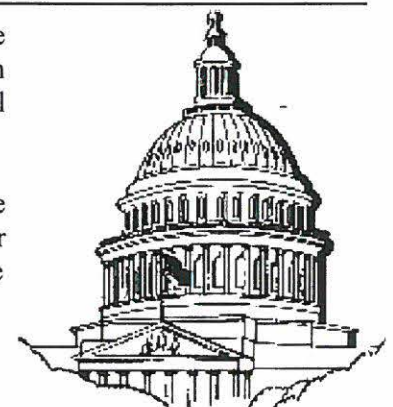
On July 10, the House, by a narrow vote of 215-208, approved its version of the massive Labor-HHS-Education bill. By a two-vote margin, the Congress defeated an amendment by Rep. Patrick Toomey (R-PA) which would have de-funded five National Institutes of Health (NIH) research projects. (See related story above).

The early consideration of this massive spending bill represents a striking departure from Congress’ pattern in recent years to consider the bill after completing all of the other funding bills. The bill is nearly always contentious because, as noted in the committee

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recommendations are reviewed by advisory councils comprised of scientists and members of the public whose nominations are cleared through the Department (of Health and Human Services)." The Chairman of the full House Appropriations Committee, Rep. C.W. "Bill" Young (R-FL), also spoke in strong opposition to the amendment, calling it "mischievous."

The studies Toomey objected to included: an analysis of a longitudinal data set of aging males to examine trends in their sexual behavior and how it impacts the quality of their lives; a study of drug use and HIV-related behaviors among Asian female commercial sex workers in San Francisco to ascertain intervention strategies to promote protective behaviors; surveys of American Indian and Alaskan Native lesbian, gay, bisexual, transgendered, and two-spirited populations at risk for multiple health and mental health problems; systematic research on emotional states and sexual risk-taking; and an examination of spatial and temporal linkages between human population and the environment in the Woolong Nature Reserve of China.

The Way to Ruin Science Research

Rep. David Obey (D-WI), ranking Democrat on the Appropriations panel, also condemned Toomey's amendment, arguing "that the day we politicize NIH research, the day we decide which grants are going to be approved on the basis of a 10-minute horseback debate in the House of Representatives with 434 of 435 Members in this place who do not even know what the grant is, that is the day we will ruin science research in this country. We have no business making political judgments about those kinds of issues." Obey also reminded his colleagues that grants that sound silly today can often lead to important discoveries, citing a study on Polish pigs that led to the development of a new blood pressure medicine.

Democratic House Leader Rep. Nancy Pelosi (D-CA), echoed Obey in a statement issued following the debate: "The [Toomey] Amendment offered today was an attempt to undermine the peer-review process. Decisions about medical research should be made by scientists, not by politicians promoting an ideological agenda."

Also defending peer review and the grants under scrutiny were Reps. Brian Baird (D-WA) and Mike Rogers (R-MI). They specifically defended the research in China, suggesting, as Baird noted: "The research has to do with population dynamics, the pressure on an ecosystem that supports the pandas, and the development

of a population, including how those people can provide fuel and food for their children." Rogers noted that the research could also lead to understanding the transmission of diseases, such as SARS, from animals to humans.

Rep. Randy "Duke" Cunningham (R-CA), also spoke against the amendment, saying "I personally believe that things and discoveries should be left up to NIH...once you get into politicians...directing what NIH does, it is not what you are trying to eliminate, it is the whole broad perspective of what we could do in the long run... In the past, many of the diseases were politicized... and I want to stay away from that." In the end, however, Cunningham voted with Toomey.

Despite all this and the efforts of many groups in the science community, including COSSA, to persuade the House of the importance of peer review and the research under question, the amendment only failed by two votes. In addition, the House report accompanying the Labor, HHS, Education Appropriations bill states emphatically: "The Committee reiterates its longstanding view that NIH should distribute funding on the basis of scientific opportunity. The Committee urges the Director and the Administration to continue to resist pressures to earmark, set aside and otherwise politicize these resources... The Committee does not presume to judge which criteria should take precedence or carry the greatest weight in individual funding decisions, but urges NIH to consider the full array of relevant criteria as it constructs its research portfolio." Apparently, there were 210 Members of the House who thought otherwise. Russell Long may be dead, but his words continue to echo through Congress.

APPROPRIATIONS, (Continued from Page 1)

report, it "provides a safety net of social protections for the needy while stimulating advances in human achievement and the life sciences."

Earlier, on June 25, the Senate Labor, Health and Human Service and Education (Labor-HHS-Education) Appropriations Subcommittee approved its version of the Fiscal Year (FY) 2004 bill, with the full Appropriations Committee approving it one day later. The bill may come to the Senate floor as early as July 15.

Senators Arlen Specter (R-PA) and Tom Harkin (D-IA), the Chair and Ranking Member of the Subcommittee, fulfilled their pledge to increase the **National Institutes of Health's** (NIH) budget by \$1

billion or 3.7 percent to \$27.98 billion. This is \$318 million more in funding than provided by the House. (See *Update*, June 23, 2003).

The report language accompanying the Senate bill is replete with language recognizing the value of social and behavioral science research at NIH and applauds the Institutes supporting this research. It further urges the various Institutes and Centers to maintain and increase their support. Below is a sampling:

- The Office of Behavioral and Social Sciences Research (OBSSR) and the 10 Institutes and Centers contributing to the OBSSR-sponsored trans-NIH initiative on the challenges of maintaining positive behavior change, particularly regarding the strategies people use to maintain diet or exercise regimens are commended for their efforts by the Committee.
- The National Cancer Institute is encouraged to dedicate more funding to research and education programs focused on diet and nutrition.
- The National Institute of Diabetes and Digestive and Kidney Diseases is strongly encouraged to build upon its investment in behavioral research, particularly in areas that would add to the science base maintenance of positive behavior change.
- Regarding the National Institute for Child Health and Human Development, the Committee expressed its concern about the rising rates of childhood obesity and supports continued initiatives to promote healthy behaviors in children and adolescents and prevent health-risk behaviors.
- The National Institute on Aging is encouraged to add to fundamental and applied knowledge of how memory works and may be enhanced, and how age or behavior may affect memory.
- It is noted by the Committee that the National Institute on Nursing Research's decision to include research on children at the end of life is a groundbreaking research initiative in an area that has not received the attention that it deserves. The Institute is also lauded for new approaches in its research on self management of chronic illnesses that tailors interventions to diverse and vulnerable populations.
- The National Institute on Alcohol Abuse and Alcoholism is urged to expand its research to

understand the mechanisms of action of successful behavioral therapies as well as behavioral therapies for patients with co-occurring substance abuse and psychiatric disorders.

- The National Institute on Drug Abuse is encouraged to continue its support of behavioral research that will lead to further understanding of the underlying cognitive, emotional, and behavioral factors that lead to drug abuse relapses.
- The National Institute of Mental Health is encouraged to continue its efforts to understand depression, to develop new treatments, to decrease the impact of depression on comorbid illnesses, and to reduce suicide. The Institute is lauded for its leadership in its public education campaign entitled *Real Men. Real Depression*.

CDC

For the **Centers for Disease Control and Prevention (CDC)**, the Committee recommends \$4.43 billion, an increase of \$147.85 million above the FY 2003 funding level. Included in the total is \$801.84 million for chronic disease prevention and health promotion, of which \$50 million is for obesity prevention. The agency is commended for its "substantial, comprehensive efforts" to stem the obesity epidemic.

The bill also contains \$944.7 million for programs to increase physical activity, improve nutrition, and reduce obesity and overweight. This represents an increase of \$34.2 million above the FY 2003 funding level.

The Committee recognizes that "the benefits of basic research alone cannot be fully recognized unless results of this important work are effectively translated into public health interventions to address costly and prevalent conditions such as chronic diseases."

For the **National Center for Health Statistics**, the Committee recommends \$127.6 million, \$1.5 million more than the FY 2003 funding level and \$3 million above the President request.

AHRQ

The Committee freezes the funding at last year's level of \$303.69 million for the Agency for Healthcare Quality and Research (AHRQ). The entire funding for the Agency would be provided through transfers via the Public Health Service Act.

AHRQ is directed to devote \$84 million to research on health costs, quality, and outcomes to determining ways to reduce medical errors. This is a \$29 million increase over the FY 2003 funding level.

Noting that it is “seriously concerned” about the prevalence of undiagnosed and untreated mental illness among older Americans, the Committee urged AHRQ to support evidence-based research projects focused on the diagnosis and treatment of mental illness in the older populations and to disseminate this information to physicians and other health care professionals.

BLS

The Senate committee provided the **Bureau of Labor Statistics** \$515.2 million, almost \$23 million above the FY 2003 level. The total includes \$75.1 million from the unemployment trust fund. The increase above the budget request of \$512.3 million will provide full-year funding for Occupational Employment Statistics. The House provided the requested budget amount.

Education

The committee’s recommendation reduced the funding for **International Education and Foreign Language Studies** \$7 million below last year’s level. The total of \$100.8 million includes \$86.2 million for domestic program activities, \$12.9 million for overseas programs under Fulbright-Hays, and \$1.6 million for the Institute for International Public Policy. The Committee report provides no explanation for the reduction. The House provided last year’s funding level.

In **Graduate Education**, the Senate panel followed the House and recommended last year’s level of \$9.9 million for the Javits Fellowship Program. Unlike the House, the Committee did not provide funding for the Thurgood Marshall Legal Educational Opportunity program.

With regard to the new **Institute of Education Sciences**, the Senate panel recommended \$144.1 million for education research, development, and national dissemination activities, a \$5 million increase over last year but considerably below the House figure of \$185 million. Like the House, the Committee rejected the Administration’s attempt to eliminate the Regional Laboratories, keeping their funding at \$67.1 million.

The Committee provided \$89.4 million for the National Center for Educational Statistics. This is the same level as in FY 2003, and almost \$6 million below both the House and the requested figure.

CJS Bill

On July 9, the House Appropriations Subcommittee on Commerce, Justice, State, and the Judiciary (CJS) marked up its FY 2004 spending bill. The measure includes a number of programs of interest to social scientists, including the Census Bureau and the Bureau of Economic Analysis (BEA) in the Commerce Department, the Office of Justice Programs, and the State Department’s Bureau of Educational and Cultural Affairs. As of press time, only figures for the Commerce programs were available.

The panel provided \$441.1 million for the **Census Bureau’s** Periodic Censuses and Programs account, a \$30.5 million increase over the FY 2003 level. The Subcommittee also allocated \$221 million for the Bureau’s Salaries and Expenses account, a \$39.2 million boost from last year. Both of these totals mirror the President’s request. The **BEA**, however, did not fare as well. The Subcommittee provided only \$75 million for the Economic and Statistics Administration (ESA), a \$4.3 million cut from FY 2003. BEA makes up about 92 percent of the ESA budget.

The full Appropriations Committee plans to take up the CJS bill during the week of July 14.

SCHOLARS WEIGH RULES CHANGE ON SENATE HOLDS

On June 17, a group of congressional scholars testified at a Senate Rules Committee hearing on the practice of placing secret holds on bills or nominations. The desire to place a hold is communicated by a Senator to his or her party floor leader (either Majority Leader Bill Frist, R-TN, or Minority Leader Tom Daschle, D-SD) and generally indicates that the Senator has a problem with the legislation or nomination and will try to block or even filibuster the measure if it comes up for consideration. Holds are usually kept secret unless the Senator is willing to divulge his or her action.

Committee Chairman Trent Lott (R-MS) noted in his opening statement that “Holds are an esoteric process that most Americans don’t understand or comprehend the significance of.” He also explained

that holds often have nothing to do with the bill or nomination being blocked. Sen. Robert Byrd (D-WV), who like Lott is a former party leader, defended holds, asserting that they usually aren't placed for frivolous reasons.

Sens. Ron Wyden (D-OR) and Charles Grassley (R-IA) appeared together to discuss a rules change (S. Res. 151) they have proposed that would require Senators to place notice in the Congressional Record within two days of placing a hold. Wyden and Grassley have attempted such a change in the past but have been stymied on multiple occasions. In 1999, Lott, then Majority Leader, and Daschle sent a letter to their colleagues that required any Senator placing a hold to send a letter of notification to the bill's sponsor and the committee of jurisdiction within two days. This was quickly overcome, however, by a tactic called "rolling holds." Rolling holds involve a group of senators placing successive holds of short duration on a contentious bill or nomination. None of the holds exceed the 48-hour threshold; therefore no senator is forced to send the letters of notification.

Grassley defended his proposal by noting that it's important for a bill's sponsor to be able to ask the objecting Senator why the hold has been placed. "How can concerns be addressed if they aren't public?" he asked. Wyden added, "The public's business ought to be conducted in public." Byrd backed the intent of the resolution but stressed that it may not be the best idea to codify the practice of holds in the Senate rules.

The Law of Unintended Consequences

Sarah Binder, Senior Fellow at the Brookings Institution, cautioned that the Grassley/Wyden proposal could produce unintended consequences such as formal recognition of holds, which may force leaders to honor them, and the use of holds by Senators to further a public political agenda. Sen. Christopher Dodd (D-CT), the Committee's Ranking Democrat, picked up on this argument by contending that the resolution could limit the powers of the leaders to seek consensus too much. He also stressed that care must be taken not to disrupt the balance of comity that the Senate operates on.

Steven S. Smith, the Kate M. Gregg Professor of Social Sciences and Director of the Weidenbaum Center on the Economy, Government and Public Policy at Washington University in St. Louis, laid out six objections to S.Res. 151:

- No effective means of enforcement is proposed or implied by the resolution.
- Holds would be given official status in the Senate's rules for the first time.
- The proposal does not provide for notice of the removal of a hold.
- The proposal does not address "rolling" holds in an effective way.
- The proposal may encourage senators to wait until the last moment to place holds in order to avoid premature disclosure of their identity.
- The proposal does not guarantee disclosure for senators placing holds through intermediaries (other senators).

Based on these points, Smith concluded that the problems inherent in the practice of secret holds can be best addressed by the party leaders. It will take action on the part of these individuals, and acceptance of such action by the party caucuses, to end dirty tricks and ensure public disclosure. He conceded, however, that "My hunch is that secrecy remains because it is convenient for both leaders and their party colleagues. . . . Minority leaders, in particular, . . . found it convenient to attribute an objection to action on a measure or nomination to an anonymous colleague."

Lott and a number of his colleagues seem committed to the notion of reform, but what structure it will take is unclear. Lott suggested in early July, however, that it might be optimal to change the Senate's standing orders rather than the body's rules. This would require 60 instead of 67 votes for passage.

AHRQ EXAMINES PATIENT SAFETY

Although society has seen vast progress in modern medicine as a result of advancements in medical technology, more people die each year from medical errors than from breast cancer, AIDS, or motor vehicle accidents. According to the Agency for Healthcare Research and Quality (AHRQ), "Each year, as many as 98,000 people die in hospitals as a result of preventable medical mistakes." Due to this alarming figure, Congress has charged AHRQ with researching possible solutions to enhance patient safety. Accordingly, the Agency has committed its research efforts to reducing medical errors through efficacy.

Carolyn Clancy, Director of AHRQ, has stated that “only 50% of Americans receive recommended preventive care.” To confront these troubling statistics, AHRQ sponsored a June 4 briefing entitled, “Patient Safety: AHRQ’s Research at Work,” in conjunction with the Friends of AHRQ and AcademyHealth, to inform policymakers and healthcare analysts that the issue of patient safety is a much bigger problem than most Americans think.

Improving Patient Safety through Research

David Helms, President and CEO of AcademyHealth, defined medical errors as anything from an incorrect procedure or drug to a meal that violated a patient’s dietary restrictions. Lucian Leape, Adjunct Professor of Health Policy at the Harvard School of Public Health, stressed that there are two types of research needed to combat medical errors. Translational research and evaluative research, he noted, are the two methodological approaches to improve patient safety measures. “Translation research involves the safe practices such as how do we make it happen and ensure things are used properly. Evaluative research involves proper use of medicine and then examining the outcome,” Leape explained. AHRQ contends that by funding this research, the American public will be investing in people and saving lives.

Clancy asserted that medical errors could be greatly reduced if “effectiveness research focuses on actual daily practice and not ideal situations.” She discussed the epidemic model of AHRQ’s Patient Safety Initiative, which includes:

1. Identifying errors, raising awareness, building capacity
2. Implementing proven practices, developing innovative practices, developing a culture
3. Sustaining improvements

Echoing the same concerns about patient safety in an appearance before the Senate Governmental Affairs Permanent Subcommittee on Investigations on June 11th, Clancy emphasized that medical errors and patient safety issues represent a national problem of epidemic proportions. However, she stressed that AHRQ cannot implement the Patient Safety Initiative without the collaboration of key domestic organizations that work on identifying and reducing health errors. With these partnerships, AHRQ hopes to disseminate research and evaluation findings within and outside the Agency.

At the Senate hearing, James Bagian, Director of the National Center for Patient Safety, noted, “In order to reduce medical errors, programs must first identify the underlying causative factors so that they can be understood, and then implement effective preventative strategies. Unfortunately, most healthcare systems and regulators have not modified their tactics to focus on prevention.” In recent years, patient safety has become a bigger problem than most people anticipated largely because organizational leaders at hospitals and medical institutions do not take the necessary steps to improve the conditions of the people who utilize those facilities. Practitioners need to remember that “patient safety is the foundation upon which quality patient care is built,” Bagian added.

Medical Malpractice Litigation

In related news, the Senate failed on July 9 to pass a bill (S. 11) that was aimed at capping damages and curbing lawsuits in medical malpractice cases. President Bush and the Republican leadership backed the bill, but Senate Majority Leader Bill Frist (R-TN) was unable to round up enough votes to overcome a Democratic filibuster of the measure. In the end, the 49-48 vote fell well short of the 60 votes needed. Republicans claimed the legislation, which passed the House in March, would protect doctors from skyrocketing insurance costs. Democrats countered that the bill would do too much to harm patients’ rights.

REPORT EXAMINES COSTS OF UNINSURANCE IN AMERICA

Continuing to add fuel to the debate on health insurance policy, the Institute of Medicine (IOM) has released a report on the social and economic costs of having 41 million people in the United States without health insurance. *Hidden Costs, Value Lost: Uninsurance in America* estimates that the United States loses between \$65 and \$130 billion in value because of the poorer health and earlier death of the uninsured.

Speaking at a press conference on June 17, University of Michigan President Mary Sue Coleman, who chairs the IOM Committee on the Consequences of Uninsurance, asserted: “The lack of health insurance across the United States can be thought of as imposing a risk to the health and longevity of the American population.” Uninsured Americans are more likely to have poorer health and die prematurely than those who are insured. The committee estimated that, on average, a person experiences a health loss worth between \$1,600 and \$3,300 for every year spent without health insurance.

Coleman noted that the panel examined U.S. national health policy within a cost-benefit framework. "Our findings are based on the same approach that Federal agencies use to determine whether the benefits of reducing a particular risk or harm justify the costs to society," she said.

To capture the hidden costs of uninsurance's effects, the committee developed the concept of "health capital." IOM President Harvey Feinberg called this concept "new analytical ground." According to the report, health capital represents, in monetary terms, "the value of an individual's health over future years of life, and includes the subjective value of being alive and healthy, earning potential, and children's physical and mental development."

The Committee also concluded that a lack of health insurance, or even fear of losing coverage, places financial and other stresses on individuals and families. These psychological and social costs of uninsurance "undermine family stability and social cohesiveness [and] need to enter into our calculations even if they do not enter into the calculations of the economic returns to health insurance," according to Coleman.

Finally, the Committee looked at the ethical costs of leaving 15 percent of the nation uninsured. Since those who have insurance usually have access to better and more effective care, the report concluded that "as health care interventions become ever more effective in improving health and extending life, the disparity in access to effective health care will become more inequitable and socially divisive." Coleman indicated that "deeply ingrained American cultural and political values of equality of opportunity, mutual concern, and equal respect among member of our national community are betrayed when we afford some members – but not everyone – the ability to achieve a longer, more productive, and healthier life through public support of health insurance."

This latest report is the fifth in a series of IOM reports on the consequences of uninsurance. The Subcommittee on the Societal Costs of Uninsured Populations, chaired by James Mongan, President and CEO of Partners HealthCare Inc., helped prepare the new report. All five reports are available at www.nap.edu. A final report will identify promising strategies for addressing the problem of uninsurance.

COSSA TRANSCRIPTS NOW AVAILABLE

Transcripts from the Consortium's first Congressional Seminar of 2003 are now available. *Obesity, What Can be Done Now?: Examining Environment and Lifestyle* features Sally Davis of the University of New Mexico Health Sciences Center, Barry Popkin of the University of North Carolina School of Public Health, and Tom Wadden of the University of Pennsylvania School of Medicine. For more on the Seminar, see *Update*, April 28, 2003.

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