

CONGRESS RECESSES; ECONOMIC SLOWDOWN, TAX CUT TO IMPACT SPENDING BILLS *HS*

Congress has recessed until after Labor Day, President Bush is in Texas, and Washington is experiencing the hot and humid "dog days" of August. Although the town is somewhat lethargic, the unfinished business of this year's legislative session awaits, most significantly the FY 2002 spending bills.

When Congress left town on August 3, the House had passed nine of the 13 appropriations bills. The Senate had cleared five. The VA, HUD, Independent Agencies bill, which includes FY 2002 spending recommendations for the National Science Foundation, is one of five that have passed both Houses and which are now entering the conference committee part of the process (see story in opposite column). The others are Interior (which includes funding for the National Endowment for the Humanities), Legislative Branch, Energy and Water, and Transportation.

The two largest bills, Defense and Labor, Health and Human Services, and Education, are at the beginning stages of the process and have not yet been marked up at the subcommittee level. For Defense the President seeks increases, but not as much as some in Congress would like. For Labor, the President and others are committed to very large increases for the National Institutes of Health. In addition, both the President and the Democrats want boosts in education spending, with the Democrats wanting more.

Complicating the spending decisions will be a partisan fight over the significance of surpluses that are lower than previously projected for FY 2002, a result of the slowing economy. Sen. Kent Conrad (D-ND), Chairman of the Budget Committee, has already expressed his concern that the non-Social Security surplus for next year has disappeared. The Democrats hope to force the administration to scale (see *Spending*, page 7)

Editor's note: Due to the Congressional recess, *Update* will take a break for a month. The next issue will be September 10. Enjoy the summer . . .

NSF APPROPRIATIONS BILLS PASS SENATE AND HOUSE *HS*

On August 3, the Senate passed the FY 2002 VA, HUD, Independent Agencies appropriations bill by a vote of 94-5. The House did the same by a vote of 336-89 on July 30. The bills now go to a House-Senate conference committee for reconciliation.

The Senate bill contains \$4.673 billion for the National Science Foundation (NSF), a \$256.1 million or 5.8 percent increase over last year's appropriated level (for details on the Senate allocations for NSF see *Update*, July 30, 2001). Upon presenting the bill to her Senate colleagues for consideration, Sen. Barbara Mikulski (D-MD), Chair of the VA, HUD, IA Subcommittee, noted that "we had hoped to provide more" for NSF, but "we did the best we could do given our allocation." Mikulski declared that she and Sen. Bond (R-MO), Ranking Republican on the Subcommittee, "believe it is in the national interest to double the NSF budget over the next five years." However, she also made clear that "our overriding goal was to make sure that the core programs in veterans and housing were taken care of first, and we did that." Sen. Bond also provided a ringing endorsement of NSF and vowed
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Inside *UPDATE* . . .

- Carter Unveils Election Reform Report
- Human Subjects Advisory Group Makes Recommendations
- Marjorie Speers Named Executive Director of AAHRPP
- Researchers Address Rural Prosperity at COSSA Seminar

to continue to work in the conference this year and in the future to increase NSF's budget.

The House provided NSF with \$4.84 million for FY 2002, a \$414 million or 9.3 percent increase. (For details of the House allocation see *Update*, July 16, 2001.) During the debate on the House floor Rep. Mark Foley (R-FL) sponsored an amendment that would have decreased NSF's research funding by \$92 million in order to increase spending for Veterans' programs. With strong opposition from House VA, HUD, IA Subcommittee Chairman Rep. James Walsh (R-NY), Foley's amendment was defeated 107-311.

CARTER UNVEILS ELECTION REFORM REPORT

On July 31, former President Jimmy Carter came to Washington to reveal and discuss the conclusions of the National Commission on Federal Election Reform's report (see *Update*, March 12, 2001). The Commission is a bipartisan group, chaired by former Carter and Clinton White House Counsel Lloyd Cutler and former House Minority Leader Robert Michel (R-IL), and organized by the University of Virginia's Miller Center of Public Affairs and the Century Foundation. Carter and former President Gerald Ford serve as the group's Honorary Co-Chairs.

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The Consortium of Social Science Associations (COSSA), an advocacy organization for federal support for the social and behavioral sciences, was founded in 1981 and stands alone in Washington in representing the full range of social and behavioral sciences.

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Carter, joined by Michel and several of the Commissioners, first visited the White House to deliver a copy of the report to President Bush. In a Rose Garden ceremony, Bush asserted his support for the general outlines, if not all of the specifics, of the report. Then the Commission leaders held a press conference to unveil their recommendations, which include:

- Every state should adopt a system of statewide voter registration.
- Every state should permit provisional voting by any voter who claims to be qualified to vote in that state.
- Congress should enact legislation to hold presidential and congressional elections on a national holiday.
- Each state should allow for restoration of voting rights to otherwise eligible citizens who have been convicted of a felony once they have served their sentence, including any term of probation or parole.
- Each state should set a benchmark for voting system performance, uniform in each local jurisdiction that conducts elections.
- The Federal government should develop a comprehensive set of voting equipment system standards for the benefit of state and local election administration.
- Each state should adopt uniform statewide standards for defining what will constitute a vote on each category of voting equipment certified for use in that state.
- News organizations should not project any presidential election results in any state so long as polls remain open elsewhere in the 48 contiguous states.
- The Federal responsibilities envisioned in this report should be assigned to a new agency, an Election Administration Commission (EAC).

The facet of the report that caused the most controversy, both among the Commissioners and in Congress, was the recommendation that the Federal government provide funds to the states on a matching basis that would add \$300-400 million to the annual spending on election administration. The Federal outlay would total about \$1 billion over a three-year period.

In discussing this recommendation, Carter called on Commissioner Christopher Edley, Jr., a Harvard law professor and former Carter and Clinton White House aide, to explain a disagreement that arose during the group's deliberations. Edley stated that while there was unanimous support for the Federal grants to the states, the Commission members disagreed on the circumstances under which the states would receive funding. A majority of the Commissioners felt that Congress should use a conditional grant mechanism, in which the various states would receive the money once they have met a number of prescribed requirements. But a fervent minority, including Edley, believes that Congress should mandate the states to meet certain election reform standards, regardless of the Federal funding.

Picking up on this last viewpoint, Senator Chris Dodd (D-CT) and Congressmen John Conyers (D-MI) held a press conference on the East Front of the Capitol to assert the need for Federal mandates to the states. Dodd marked up a bill, S. 565, on August 2 that would impose the mandates. He has stated that his bill has the support of the entire Senate Democratic Conference and that Senate Majority Leader Tom Daschle (D-SD) will make election reform a priority this fall, but Congressional Republicans have asserted that mandates will not pass the House of Representatives.

[Editor's Note: The edited transcript from COSSA's March 16 Congressional Briefing on election reform is available. Contact coffa@coffa.org for a free copy.]

HUMAN SUBJECTS ADVISORY GROUP MAKES RECOMMENDATIONS

The interest and activity surrounding the protection of human research participants intensified with the recent suspension of all federally supported medical research involving human participants at Johns Hopkins University by the Office of Human Research Protection (OHRP) in July.

At the July 30-31 meeting of the National Human Research Protections Advisory Committee (NHRPAC), the advisory body to the Office of Human Research Protections, the Social and Behavioral Science Working Group updated the committee on its efforts. Felice Levine (Executive

Officer of the American Sociological Association and member of the COSSA Executive Committee) and Jeffrey Cohen (Director of OHRP's Division of Education) co-chair the workgroup.

The group was created in an effort by NHRPAC to reach out further to the social and behavioral science community. At its inaugural meeting in December, 2000, the committee agreed to issue a formal request for guidance on how to approach issues particular to nonbiomedical research (see *Update*, January 15, 2001).

Levine informed NHRPAC that while its efforts are clearly a work in progress, the group has made significant advancement on the objectives it outlined to NHRPAC in April. The group, she explained, focused much of its attention on three areas of the human subjects protection system as it relates to the social and behavioral sciences: public use data files, risk and harm, and third parties. The group now invites the input of NHRPAC and the wider community as it continues "to further revise and refine the ultimate guidance that the group provides to NHRPAC."

The group has also begun to examine other areas of human participant protection. Those include informed consent, privacy and confidentiality, and exemptions and expedited review. The group anticipates submitting draft recommendations on these topics at NHRPAC's October meeting.

Public Use Data Files

A great deal of social science research involves secondary analysis of survey data files intended for public use. "There is a fair amount of confusion in both the social science and human subjects regulatory communities," Levine observed, "about the analyses of data from public use files and what requires IRB review." The group's recommendations are intended to provide guidance to IRBs and also to OHRP and the research community about public use data files and the protection of human participants, she emphasized.

1. OHRP should clarify that a "public use data file" is not data from human participants and thus not under the purview of IRBs. Investigators should be free to use public use data files without prior review, permission, or notification.

2. OHRP should clarify that there is no need to classify research using existing data as exempt because in reality it is not research involving human participants, either because the existing information is otherwise publicly available or because private information is not readily identifiable under the definition of human participants.
3. The responsibility for demonstrating that data in a public data file does not permit identification of participants should be vested in the supplier of the data rather than in the user.
4. OHRP should develop a mechanism by which certain organizations can certify data files as de-identified if the production of public use data files was not previously reviewed.
5. OHRP should advise IRBs that investigators in the social and behavioral sciences are encouraged to make public use data files accessible to secondary users in order to maximize the benefit of human participants providing information and to minimize the burden on new pools of human participants.
6. OHRP should advise IRBs on human participants review procedures for research analyzing existing data that are not public use files. If an investigator plans to use extant data under conditions already specified by an IRB or other established procedures, then there should be no additional review by an IRB.
7. Investigators seeking to merge public data files or enhance a public data file with identifiable data should obtain IRB review and approval.
8. A web-based training module on confidentiality issues involved in the preparation and analysis of public data files should be developed.

Risk and Harm

The group addressed the social and behavioral science community's concerns that the definition of minimal risk as set forth in the Common Rule may not be sufficiently understood in practice by IRBs and researchers.

1. OHRP should issue guidance to IRBs, the research community, and others associated with the human participant protection system regarding the definition of minimal risk.
2. OHRP should clarify that much of the research in the social and behavioral sciences involve minimal risk; that is, that the potential harm and its likelihood

of occurrence are no more than would be encountered in daily life or during the performance of routine medical tests or psychological examinations.

3. OHRP should emphasize the "daily life" standard for minimal risk. Guidance should also make clear that the "daily life" standard refers to low-level harms which are transient in nature and easily ameliorated either by passage of time, adequate debriefing, or both.
4. OHRP should clarify that, in much social and behavioral science research, the most serious harm that could occur to participants would result from breach of confidentiality. Thus, OHRP should emphasize to IRBs the importance of research protocols addressing how information from human participants will be protected.

Third Parties

In January, 2000, the Office of Protection from Research Risks issued a ruling in a compliance case that, although not intended as policy, created confusion among IRBs, investigators, and funding agencies. The case involved the definition of human subjects and whether information collected about third parties should require their informed consent. The group's recommendations address the situation of third parties in research (e.g., individuals who do not actually participate in research but become associated with research through information about them provided by human participants).

While NHRPAC has also formed a specialized Working Group on Third Parties, the NHRPAC Social and Behavioral Science Working Group is providing independent input on the issue. Levine serves as a consultant to the Third Party Working Group and has informed that group of the activity and interest of the Social and Behavioral Science Group on these issues.

The Social and Behavioral Science Working Group considers third parties not to be human subjects, but believes efforts should be directed towards ensuring the highest standards for the protection of all data on both human subjects and third parties.

Accordingly, the group's recommendations concerning third parties in research focus on the importance of protecting the privacy of these parties

and the confidentiality of the information obtained at all stages of the research, through publication and the creation of any public use data files. The group believes that emphasis should be placed on privacy and data protection rather than on broadening the definition of "human subject" to include third parties or developing a framework to allow for consent (or waiver of consent) by these individuals.

1. Absent a change in the Federal Regulations, OHRP should issue guidance to IRBs that other persons referenced by human subjects in the course of research should not be considered human participants in that research.
2. OHRP should clarify that identifiable private information in the context of the Federal Regulations should be understood as not only private information provided by human participants about themselves but also private information provided by human participants that is both relevant to them and about any other identifiable individuals.
3. OHRP should clarify that the capacity to consent to participate in research should belong to the actual individuals who are deciding whether to participate, not with those about whom human participants might provide identifiable private information. The requirement to obtain informed consent should not apply to third parties. Such consent could be in conflict with the consent provided by human participants by revealing, even implicitly, the identities of those participants or by jeopardizing them through revealing that they had provided certain information.

Next Steps

Levine informed NHRPAC that in August the Working Group will convene at the annual meetings of social and behavioral science organizations. They have also made contact with the new National Academy of Science panel launched by the Commission on National Statistics (see *Update*, July 22, 2001).

Based on the feedback from those meetings, the Working Group will submit final recommendations to NHRPAC for consideration at its next meeting in October. To review and/or submit comments on the group's recommendations, go to www.asanet.org.

MARJORIE SPEERS NAMED EXECUTIVE DIRECTOR OF AAHRPP

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The Association for the Accreditation of Human Research Protection Programs (AAHRPP) has announced the appointment of Marjorie Speers as its new executive director. Speers currently serves as Acting Executive Director at the National Bioethics Advisory Commission (NBAC), on detail from the Centers for Disease Control and Prevention (CDC). She will begin her new position at AAHRPP in Rockville, Md., on October 1.

Speers joined NBAC in 1999 as project director for a comprehensive report on human subjects protection in the United States. (For information about the report see *Update*, June 4, 2001). From 1995-2000, she was deputy associate director for science at the CDC in Atlanta, where she oversaw all domestic and international research. In addition, she served as CDC's Behavioral and Social Science Coordinator. From 1991-1995 she served as director of the Division of Chronic Disease Control and Community Intervention at CDC. COSSA worked closely with her on adding social and behavioral concerns to the CDC's agenda and she has briefed the COSSA Executive Committee on NBAC's activities. She has taught at the University of Connecticut and the University of Texas Medical Branch. Her doctorates are in psychology and epidemiology from Yale, her B.A. is from Dickinson College.

AAHRPP, a new national accrediting entity formally announced in May, is developing a voluntary, peer-driven, educationally focused accreditation program for human research protection, using a site visit model that employs a rigorous set of performance standards and outcome measures. AAHRPP's founding member organizations are the Association of American Medical Colleges, Association of American Universities, Consortium of Social Science Associations, Federation of American Societies for Experimental Biology, National Association of State Universities and Land-Grant Colleges, National Health Council, and Public Responsibility in Medicine and Research. Representatives from each organization served on the search committee for the executive director.

RESEARCHERS ADDRESS RURAL PROSPERITY AT COSSA SEMINAR Cl

As Congress debated the next Farm bill, a distinguished panel of researchers briefed Congressional and agency staff, researchers, and practitioners on the findings of recent research on building rural and community prosperity on July 20 in Washington.

Before introducing the speakers, Janet Bokemeier, Associate Director of the Michigan Agricultural Experiment Station and Professor of Sociology at Michigan State University, prefaced the speakers' remarks by commenting on the character of rural communities, and the significant differences between them.

Rural areas, she said, differ in their relationship to agriculture, their economic vitality, their access to health care, social services, and education, and their ability to respond to opportunities. Given such variation, Bokemeier submitted, how can different communities develop social capacity?

Building Social Capacity

Communities with high social capacity, explained Cornelia Flora, Professor of Agriculture at Iowa State University and Director of the North Central Regional Center for Rural Development, are able to involve diverse perspectives to look at alternatives, have strong internal and external networks, and can mobilize financial, human, technical, and information resources to get things done.

Flora found that such places were more able than others to create new private sector jobs and income. Flora's work also demonstrated that high social capacity is essential to the success of, for example, a community's ability to protect the quality of their drinking water.

What communities with high social capacity have in common, Flora found, are intervention and investment. Specific methods of building this capacity include providing community spaces where residents can interact and learn to trust each other, and cooperative extension, which brings together diverse groups and interests to discuss opportunities for investment and cooperation.

Flora cited one such program that involved planning a local transportation system. The program was resisted by the experts, who said the roads would be fine so long as there is a good engineer. But what the expertise did not consider, Flora explained, is "what kind of road makes sense for this place, where are the appropriate places to put it, and how can we do this in ways that don't put us in court?"

Prosperity and Rural Families

Turning to the people who live in rural areas, Diane McLaughlin, Professor of World Sociology and Demographics at Pennsylvania State University and Associate at the Population Research Institute, focused on rural families and their prospects for prosperity.

Rural families' vision of prosperity, according to McLaughlin, includes better jobs with higher earnings and benefits, and the ability to continue to live in a small town or the open country. Various factors, however, limit the opportunities for some families to improve their prosperity.

These include poverty and low income, limited access to community resources like good jobs, schools, and services, limited access to external resources, and limited opportunity to participate in decisions that affect them. Scientists' ability to measure some of these factors, McLaughlin noted, depends on the Census and the American Community Survey (see *Update*, July 30, 2001).

One family dynamic revealed by research is the increase in female-headed families in rural areas which, she said, contributes to the high poverty rates, "a clear example of the interaction between demographic change and family prosperity."

McLaughlin discussed two other main factors besides poverty that are challenges to the prosperity of rural families. The first is youth risk behavior and youth outmigration. Although rural youth face many of the same risks as their urban counterparts (e.g., drugs and teen pregnancy), counseling and social services are less available in rural areas. Lack of quality jobs, she suggested, may contribute to the debilitating outmigration of youth. McLaughlin called for more research on the role of families, schools, and communities in youth risk behaviors,

strategies to help youth avoid risk, and demographic change and youth retention strategies.

The final main challenge McLaughlin identified is the concentration of elders in some parts of rural America. "Aging in place" elders are more likely to be faced with poverty and minimal health, social, and transportation services.

Economic Development Options

Building on the observations of the other speakers, Michael Woods, Professor of Agricultural Economics at Oklahoma State University, tackled the issue of how to promote economic development, given the challenges faced by rural communities.

Woods identified three pillars that enable a community to develop. First, it needs a diverse, resilient economy that does not depend on one sector. Second, it needs an infrastructure of services and facilities, which includes access to the digital infrastructure. Finally, Woods said, a community needs informed, trained leaders.

Woods discussed some of the research-based tools that extension offices employ to help communities develop their capacity, drawing on their particular strengths. For example, demographic analysis can help a community better understand where their income comes from, what they can expect from demographic trends, and what their strengths and weaknesses are. Economic impact analysis can predict the effects of enhancing tourism or opening a small manufacturing plant.

Woods described the experience of Sulfur, Oklahoma, which won support to expand its national recreation area. They achieved this with the help of an economic impact analysis of tourism and their positive relationship with the federal employees. Such development, he said, demonstrates the importance of both research-based initiatives and external linkages.

Public Policy Implications

Tying the speakers' comments together was Charles (Chuck) Fluharty of the Rural Policy Research Institute. Fluharty said that the strengths of rural communities that the speakers discussed must be integrated – particularly diversity, community and family capacity, and entrepreneurship.

The public policy challenge in exploiting diversity, he said, is integrating local actions with the state and federal levels. Key here, he continued, is community-based public policy and the importance of place. The public policy challenge in enhancing entrepreneurship is finding a structure that enhances and links both public and private entrepreneurship, and moves agriculture policy away from dependency to empowerment.

Also in the realm of public policy, Fluharty emphasized the importance of policy flows from the Federal government. Unfortunately, he said, there is little understanding at the federal level of important differences between the urban and the rural. But, he qualified, we have the research capacity to bring this understanding to the committees and jurisdictions in Washington.

Fluharty's comments culminated in three public policy recommendations. First, though he is excited about the current Farm bill's community capacity component, its funding level is too low, he said, and should be more substantial. He also called for a large commitment to broadband technology.

Finally, he said, the basic research commitment to rural data, information, and decision support is lacking. "It is absolutely critical," he said, that the American Community Survey moves forward "if we are going to get good data for informed decisionmaking in rural America."

(SPENDING, from page 1)

back its Defense increases to keep from using Social Security or Medicare funds to pay for it. The Democrats also hope to point to the recently enacted tax cut as another impediment to funding programs, particularly in education. The House Republicans led by Budget Committee chairman Rep. Jim Nussle (R-IA) have different ideas. Nussle and his budget hawk allies urge the President to use his veto pen to keep the appropriations bills from breaking the budget resolution limit on overall spending. They have also raised the idea of sequestration or across-the-board cuts to keep the spending bills within the overall limit.

In this idle August time in Washington, the budget endgame scenarios are on the drawing boards, and very few of them predict anything less than the usual mess.

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