

**LAME DUCK, POST-ELECTION
WRANGLING CONTINUE**

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On December 8, Congress passed and the President signed the 18th Continuing Resolution to keep the government operating for three more days in the now over two-month-old Fiscal Year 2001. On December 11, the same ritual will result in the 19th Continuing Resolution. All hope it will be the last.

With the Republicans anticipating a George W. Bush presidency, they have emboldened themselves to challenge some of the waning Clinton administration's prerogatives on the four remaining appropriations bills that need enactment before the 106th Congress becomes history. Most prominent is the GOP's attempt to reduce the Labor, Health and Human Services, Education spending bill by \$6 billion from the level nearly agreed to by both parties before the election. The various schemes for achieving this cut could impact the National Institutes of Health's (NIH) presumed 15 percent increase and reduce appropriations for Clinton's education initiatives.

The Commerce, Justice, State and the Judiciary spending bill remains under discussion while the administration and Congress try to agree on provisions affecting immigration. Once again, emboldened Republicans are forcing the lame-duck administration to reconsider its earlier positions. Once these two bills are worked out, the Legislative Branch and Treasury, Postal Service bills will be signed by the President and, perhaps, Congress will adjourn. A tax bill and changes in Medicare and Medicaid are also in the works as the lame-duck session enters its second week.

At the same time the 106th Congress tries to finish up, preparations for the 107th Congress are underway. Senate leaders Trent Lott (R-MS) and Tom Daschle (D-SD) continue to meet and try to figure out how a Senate divided 50-50 will work

(Cont'd on page 6)

COSSA HOLDS ANNUAL MEETING

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In the midst of post-election turmoil, unprecedented legal challenges, and prolonged political uncertainty, COSSA held its annual meeting on December 3 in Washington, DC. More than 70 representatives of COSSA's members, affiliates, and contributors attended the event.

The speakers discussed engaging and timely topics, including the 2000 elections, the 107th Congress, the issue of human research protection, the National Science Foundation (NSF) and the social sciences, and the 2000 Census.

NSF: Looking Ahead

NSF Director Rita Colwell presented the day's luncheon speech. Referring to the pervasive influence of science and technology, Colwell remarked that although elections bring many changes, "there are some forces that have a life of their own." NSF just received a 14% budget increase, the largest in its history. If the trend continues, NSF will double its budget in about six years (see *Update*, October 23, 2000).

Colwell, however, made the case that "larger investments are needed to repair the erosion that's occurred in the nation's fundamental research enterprise." Although NSF funds about 10,000 new proposals each year, there are some "real gems" in the 20,000 or so proposals that the agency cannot fund. The nation pays a significant price for such lost opportunities, she remarked. "We need to reduce the cost to the nation of *not* pursuing promising ideas and proposals, and the cost of *not*

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supporting and training the nation's most talented researchers, students, and educators."

Turning to social science specifically, Colwell discussed the new initiative NSF will be funding in the social, behavioral, and economic sciences (the SBE initiative). "There can be no question that the social sciences are an integral part of NSF's vision of research at the frontiers of discovery."

Therefore, each of NSF's special initiatives, she continued, addresses the need for interdisciplinary research that includes social, behavioral, and economic components. These initiatives include the Information Technology Research Initiative, the Biocomplexity in the Environment Initiative, the 21st Century Workforce Initiative, and the Nanoscale Science and Engineering Initiative.

To clarify the themes of the SBE initiative, Colwell described its five "focal points." These are 1) looking more closely at the process of innovation; 2) increasing the benefits of technology through research on learning and cognition; 3) understanding responses and adaptations to technological changes; 4) illuminating the social, economic, and environmental effects of new technologies; and 5) developing improved methodologies throughout the social sciences.

Colwell concluded by urging everyone to continually explain to those outside the scientific community "why fundamental research not only deserves their support, but why it should be at the top of the national agenda."

The 2000 Census

Kenneth Prewitt, Director of the Bureau of the Census, offered his observations on and hopes for the 2000 Census. The most important question concerning the Census, declared Prewitt, is the credibility of the data: "Are they believable?"

Politics, Prewitt said, has surrounded the 2000 Census. The issue of whether to use statistically-adjusted figures in an effort to avoid excluding and double-counting people has been a politically-charged issue, with some in Congress proclaiming that such a methodology would open the door to future political tampering (see *Update*, June 26, 2000).

While discrediting the assertion that it is possible to design a methodology to produce a known, desirable outcome, Prewitt said that the accusation is nevertheless pernicious and that it undermines the integrity of the Census. The accusation "is disastrous for national statistics," he argued.

The 1990 Census, Prewitt explained, was associated with the words "failure" and "partisan." In 2000, the Census Bureau has worked hard to point out the achievements of the current Census, emphasizing its operational successes, which include reversing the trend of declining response rates (which helped to bring the 2000 Census five to six percent under budget) and being on schedule to release apportionment figures. We have to come out of this Census with those charges (of failure and partisanship) laid to rest, Prewitt proclaimed.

When the data come out over the next few years and social scientists analyze them and present them to the public, the really important story will be what the data tell us about ourselves as a society, Prewitt concluded.

Human Research Subjects Protection

Improving the system for protecting the subjects of human research is a prominent issue once again, and COSSA invited two speakers to address the subject.

Greg Koski, Director of the newly formed Office of Human Research Protection (within the Department of Health and Human Services [HHS]), briefly described the present system for protecting human subjects, and then described what a new, better system would look like (see *Update*, October 9, 2000). Prior to Koski's speech, Jonathan Knight of the American Association of University Professors (AAUP) provided a summary of the current state of human subjects protection.

Most major research arms of the government, Knight explained, currently subscribe to the Common Rule (the Federal Policy for the Protection of Human Subjects). Although only publicly-funded research is required to undergo human subjects review, Knight believes the law will increasingly extend to non-publicly-funded research as well.

Recent studies have questioned the performance of IRBs, Knight remarked. For example, a study performed by the General Accounting Office concluded that the functions of IRBs have been impaired because they relied on researchers' self-assurances that they were following the rules. As a result of such studies, Knight said, there is strong pressure on institutions to require their IRBs to be more exacting and more rigorous in their reviews.

More and more social science researchers are "expressing surprise and concern that their research is now becoming subject to IRB review," Knight observed. In an informal survey of social science researchers, the AAUP found that respondents' experiences with IRBs, both as researchers and as members of IRBs, were mostly positive. However, there were some criticisms. These concerned excessive delays, failures of IRBs to follow rules, IRB members' low level of familiarity with social science, and the structure of the IRB serving to restrain research. The underlying theme, according to Knight, was a significant concern that IRBs are applying a clinical/biomedical research model to social science research — a model that does not fit.

The AAUP has incorporated the experiences and concerns voiced by the social scientists into a draft report which can be found at www.aaup.org/IRBdoc.htm. Comments are welcome and should be received by January 15, 2001.

Describing the present system for protecting human subjects, Greg Koski remarked that it is based in regulation, which leads to confrontation and a focus on compliance. The system also places sole responsibility for protecting human subjects with the IRB, he added.

A new system must be simpler, more uniform, more efficient, and more effective, Koski asserted. The confrontation associated with regulation should be replaced by collaboration between all parties with an interest in protecting human subjects, he explained. Koski further recommended that the IRB be removed from its position between the investigator and the subject in order to "put the interests of the research participant squarely in the middle and have everyone share responsibility for the conduct of the research."

Specifically, Koski pointed to the trend towards private-sector, voluntary certification of individuals

as an example of one component of an effective system for protecting human subjects. Such recognition, he continued, rewards people for their efforts while providing the latitude necessary to allow them to meet their responsibilities. Koski also described the current effort to pull together other agencies outside of HHS that support social science research into a management group, while at the same time recognizing the individual differences in research.

Koski concluded that amidst public demand for increasing research, "the stars are aligned now," and the opportunity to develop a better system for protecting human subjects is ripe. "If we're going to do the research, we need to do it right."

The 2000 Elections

CBS News' Kathleen Frankovic tried to make some sense of what happened on Election Day and in the following days and weeks. Interpreting CBS survey data, she began with an analysis of the political landscape of the election season.

Looking first at the voters, Frankovic characterized the electorate as ambivalent. Voters generally believed that both major candidates were capable, both were competent, and both had good knowledge of the issues; most characterized both Gore and Bush as "establishment candidates"; most also believed that both say what the people want to hear. While 45 percent of voters gave credit for the strong economy to Clinton/Gore, a similar portion (47 percent) gave credit to Congress.

The polls revealed that, overall, voters had equal levels of ambivalence, concern, and reservations about each candidate. "It is no surprise, then," Frankovic reasoned, "that we had such an incredibly close election."

Voters did, however, see some differences between Bush and Gore. The polls found that those who believed issues to be more important favored Gore, while those who gave more importance to personal qualities favored Bush. Frankovic also found an interesting contradiction — while 52 percent of voters wanted smaller government, most were in favor of expanding social programs, as both candidates proposed.

When the voters' attitudes were cast as votes on Election Day, the results, of course, were historic. Al Gore narrowly beat George W. Bush in the popular vote and, when *Update* went to press, the electoral vote was still in dispute. The result has been a post-election period of tension, drama, and uncertainty.

107th Congress: Prospects and Problems

The next Congress will be more evenly divided between Democrats and Republicans than at any time since the Eisenhower administration. COSSA invited a staff member from each party to comment on the next Congress and how it may affect the social sciences. David Goldston, from the Office of Representative Sherwood Boehlert (R-NY), and Mark Harkins, from the Office of Representative David Price (D-NC), both offered their insights.

Summarizing the changes underfoot in the Federal government, Goldston remarked, "The House is plagued by changes in chairmanship, the Senate is plagued by changes in membership, and the Executive branch is plagued by changes in sportsmanship." Having firsthand knowledge of legislative matters, however, Goldston soon focused on Congress. What can we say, substantively, about the 107th Congress?, asked Goldston. "Nothing . . . but I'll elaborate," he quipped.

Goldston, whose boss will probably head the House Science Committee, was commenting on the gridlock that tends to characterize a closely divided Congress. "Everyone has enough votes to block [legislation]; no one has enough votes to pass." In that atmosphere, he said, contentious legislation is difficult to pass.

Fortunately, support for scientific research is generally not one of the more controversial issues, and wild swings are unlikely on such issues. Research budgets, Goldston predicted, should continue to flourish as long as the economy stays healthy. The National Institutes of Health (NIH), Goldston asserted, "will continue to prosper as long as the sun comes up." Furthermore, on the issue of social science research, Congress usually takes its lead from the administration, he explained, and within the administration, the President is less consequential than his appointees.

Harkins offered a similar reading of the next Congress. He predicted that the status quo will be maintained: as neither party has a big majority, he explained, everything can be filibustered.

Harkins also addressed the issue of accountability for social science research funding. He noted that research, including social science research, is more likely to attract federal funding if costs are to be shared, private organizations are to be used for leverage, and the results from such research are highlighted.

Because the chairs of committees that affect the social sciences can impact the attention paid to funding, Harkins speculated on who may chair the relevant committees in the next Congress. However, with the uncertainty that characterizes national politics today, even those on the inside cannot predict the organization of the 107th Congress or its consequences with much certainty.

NBAC REPORT TO CALL FOR OVERHAULING RESEARCH PROTECTIONS OVERSIGHT

There is no necessary conflict between the goal of promoting research and the goal of protecting human research participants, argues the National Bioethics Advisory Commission (NBAC). The Commission met on December 7 to discuss its forthcoming draft report regarding the oversight of human-participant research. The draft, which is expected to be released prior to the end of the year for a 60-day comment period, will be the fifth report issued by the Commission since its inception in 1995 (see *Update*, November 6, 2000). This report, like the previous four reports, will contain recommendations regarding human subjects protections.

Almost all of the forthcoming recommendations are expected to directly or indirectly affect investigators, Institutional Review Boards (IRBs), and institutions. The report is expected to suggest three broad changes: 1) a general shift of requirements away from procedure and towards education; 2) a more strategic use of IRB review; and 3) a more strategic use of monitoring. Some of the recommendations will likely increase the responsibilities of the aforementioned groups.

In its previous reports, NBAC, chaired by Harold Shapiro, President of Princeton University, focused on specific types of research. This report, however, will address the basic purpose, structure, and implementation of research oversight. The Commission is expected to recommend broad, strategic changes to the oversight system. The report will be designed to provide only guidance, direction, and justification for change; it is not intended to be a rewrite of federal regulations.

In its discussion of the draft report, which will soon be available on the NBAC website (www.bioethics.gov), the Commission outlined the major challenges facing the current oversight system, including: inconsistent interpretation and implementation of regulations at the federal level; incomplete protection of vulnerable groups; difficulty in amending the Common Rule, which is not readily adaptable to emerging ethical issues or scientific developments; limited scope (existing regulations provide incomplete coverage of non-Federally-sponsored research); weaknesses in the mechanisms enforcing the regulations; emphasis on procedural requirements over ethical principles; failure to adequately address ethical issues for different types of research; burdens imposed on IRBs by excessive paperwork; the challenge of multi-site research for IRBs; and the lack of adequate training or preparation by individuals and institutions that conduct and review research.

In its year-long discussion of the research oversight issue, NBAC has repeatedly emphasized that, faced with all of these challenges, the oversight system for protecting human participants in research is losing credibility among investigators, IRBs, institutions, and the public. The Commission continues to emphasize that the problems are serious and are made more so by the continuing and rapid growth of the research enterprise. The Commission believes that the system's credibility can be restored if everyone involved in the human research enterprise identified the following as their guiding principle: that the entire oversight system should protect human participants while promoting research that is consistent with ethical principles.

NBAC Calls for a National Office of Research Ethics

The Commission is expected to call for the creation of a single set of regulations promulgated

and interpreted by a single office. Accordingly, NBAC believes that federal oversight of all federally-sponsored, as well as privately-sponsored, research would make the current system (led by multiple departments) more unwieldy, if not impossible, to sustain. A single office (with individual departments and agencies playing important administration, monitoring, and enforcement roles), would provide leadership and direction, NBAC says.

NBAC contends that such an office, with the working title of National Office of Research Ethics (NORE), could be located in a single lead department or could be established as a separate office located outside the current departmental structure. NORE would have government-wide authority. Establishing an independent federal office would allow for visibility, impact, avoidance of actual or perceived conflicts, and accountability, NBAC asserts.

In addition to recommending the creation of such an office (which would require an act of Congress), NBAC is expected to recommend that the office have six functions: 1) policy development, which includes rulemaking and interpretation; 2) education; 3) ethical review of research; 4) monitoring; 5) enforcement; and 6) accountability. In its discussions regarding the creation of such an office, NBAC emphasizes that it is important that these six functions be integrated, but performed by separate units within the office. The unit with responsibility for setting and interpreting policy would serve as the lead unit. Additionally, the Commission is expected to recommend that NORE be given the authority to interact with other federal departments and organizations outside government as well as a coordinating role.

The Commission's draft report is also expected to discuss selected ethical issues related to regulation and guidance. Chapter 3 of the draft will include an analysis of risks and potential benefits associated with research. Also included in the chapter are discussions of the process of informed consent, the issues arising from concerns over privacy and confidentiality, and protecting vulnerable individuals.

Chapter 4 of the draft report will review the oversight system at the local level and will likely focus on six major issues related to infrastructure at

the local level. These are: 1) appropriate education in research ethics of all parties participating in human research; 2) monitoring the process of ongoing research; 3) review of cooperative or multi-site research studies; 4) compensation for research-related injury; 5) conflicts of interests; and 6) mechanisms to ensure that the institutions, IRBs, and investigators are in compliance with regulations, guidance, and procedure for protecting research participants.

As in its previous reports, NBAC insists that research not be circumvented by lack of resources. The final chapter of the report will make recommendations surrounding the provision of resources needed to implement the recommended changes.

PORTER HONORED BY HEALTH AND EDUCATION COMMUNITY

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Representative John Edward Porter (R-IL), chair of the House Labor, Health and Human Services and Education Appropriations Subcommittee (Labor-HHS) urged the research community to push Congress and the White House towards resolution of the Labor-HHS appropriations bill. Porter made the appeal at a December 1 reception held in his honor. Porter, an ardent and consistent supporter of biomedical and behavioral research and an instrumental force in the drive to double the budget of the National Institutes of Health (NIH) over a five-year period, strongly encouraged the packed room of advocates, legislative staff, and federal agency staff to "impact this process as we have never before."

After two decades in Congress, Porter is leaving Capitol Hill (see *Update*, October 25, 1999). Porter informed the crowd that he "does not intend to retire," but to remain very much involved. His goal, he announced, is to continue work on issues important to America — health, research, and education. He emphasized that he is seeking to move to a place where he can continue to work with the research community. There are so many important issues that remain on the table, Porter observed. This is not the time to let the guard down or slack off, he remarked.

The conference report on the Labor-HHS bill, explained Porter, was completed in July. He

expressed his "great worry" that the bill will "continue to drift." It would be a "disaster for our country"; we cannot allow that to happen, Porter declared. Porter noted his meeting with the chair of the Senate Appropriations Committee, Ted Stevens (R-AK), who said he shares his commitment to see that Congress passes the Labor-HHS bill.

Concluding his remarks, Porter emphasized that while there are good people coming to the 107th Congress, they do not necessarily know the things they need to know about health policy; they need to be educated, said Porter. He urged the science community to reach out to them.

LAME DUCK (Cont'd from page 1)

(once again assuming a Bush presidency). The Democrats want power-sharing. At the moment, they are calling for co-chairmanships, equal representation, equal staffs on committees, and certain privileges regarding floor scheduling and activity. The Republicans, assuming a Cheney Vice Presidency, proclaim that, as tiebreaker, he gives them majority status and thus power sharing should be limited at best.

In the House, barring any changes in recounts or party-switching, the lineup will be 221 Republicans and one Republican-leaning Independent, and 212 Democrats and one Democratic-leaning Independent. In addition to keeping their majority for the fourth straight Congress, the Republicans maintained their rule, instituted in 1995, to limit Committee and Subcommittee Chairs to three terms. Thus, the "musical chairs" reorganization of leadership positions will create new power centers and shift old relationships. In addition, the resulting contests for committee chairmanships on the GOP side could leave a bitter taste in the losers' mouths that may have policy implications.

This unique situation is spurring calls for bipartisanship. A number of members of both the House and Senate, mostly those who call themselves "moderates," are meeting to form groups that proclaim the need for bipartisan solutions to problems. They hope to forge working relationships that will transcend any partisan bitterness left from the presidential contest and the close divisions in the party makeup of the two Houses. Their chances of

success may depend on their ability to isolate the ideologues in both parties, including House Majority Whip Tom DeLay (R-TX), who has spent the last few weeks declaring the dominance of the GOP in America and his desire to enact a Continuing Resolution to last the rest of the fiscal year, which would keep many agencies, including NIH, at last year's funding levels.

JANET NORWOOD ELECTED COSSA'S NEXT PRESIDENT

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Former U.S. Bureau of Labor Statistics Commissioner Janet Norwood was elected the next President of the Consortium of Social Science Associations (COSSA) at the Board of Directors meeting on December 3. Norwood will serve a two-year term beginning on January 1, 2001. She replaces Carnegie Mellon criminologist Al Blumstein, who will remain on the Board of Directors.

Norwood is currently Chair of the National Research Council's Committee on National Statistics Panel to Evaluate the 2000 Census. She is also a member of the National Academy of Public Administration's Panel to Evaluate the Environmental Protection Agency. From 1992 to 1999, she was a Senior Fellow at the Urban Institute where she worked on statistical policy and labor market issues. She served as the U.S. Commissioner of Labor Statistics from 1979 to 1991, having been appointed by Presidents Carter and Reagan. She also was named by Presidents Bush and Clinton as Chair of the Advisory Council on Unemployment Compensation. She has testified often before Congressional Committees, has written articles and monographs on statistical issues, and is the author of *Organizing to Count: Change in the Federal Statistical System* (1995).

Norwood is a past President and Fellow of the American Statistical Association, past Vice President of the International Statistical Institute, and a Fellow of the National Association of Business Economists and the National Academy of Public Administration. She has a B.A. from Douglass College at Rutgers University and a Ph.D. in Economics from the Fletcher School of Law and Diplomacy at Tufts University. She has been

awarded honorary degrees by Harvard, Carnegie Mellon, and Florida International Universities.

Also named to two-year At-Large terms on the COSSA Board were: **Ann Masten**, Distinguished Teaching Professor of Child Psychiatry and Director of the Institute for Child Development at the University of Minnesota; **Claudia Mitchell-Kernan**, Vice Chancellor for Graduate Studies and Dean of the Graduate Division at the University of California at Los Angeles; **Wallace Oates**, Professor of Economics at the University of Maryland; **Orlando Taylor**, Dean of the Graduate School and Professor of Communications at Howard University; and **Gregory Ward**, Professor and Chair of the Department of Linguistics at Northwestern University. **Carl Monk**, Executive Director of the Association of American Law Schools, will replace **Felice Levine**, Executive Officer of the American Sociological Association, as the new Chair of the COSSA Executive Committee.

UPCOMING EVENTS . . .

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On January 29 - 30, the National Institutes of Health (the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Mental Health, and the Office of Behavioral and Social Sciences Research) are sponsoring a conference, *Depression and Mental Disorders in Patients with Diabetes, Renal Disease, and Obesity/Eating Disorders*, to highlight the fact that major depression and mental disorders are more common in patients with chronic diseases than in the general population. The conference will address gaps in current knowledge and develop recommendations for future research. For more information, contact Maria Smith of TASCOS, Inc. at 301/315-9000 or msmith@tascon.com.

Editor's Note: This is the last issue of *Update* for the year 2000. We will be back mid-January.

Happy Holidays!

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