THINGS HAVE CHANGED II

The defection from the Republican party of Vermont Senator James Jeffords has shaken up the Washington political scene. The switch in majority power from the Republicans to the Democrats will occur on June 6, the day after the Senate returns from its Memorial Day recess. New Majority Leader Tom Daschle (D-SD) will become the key Democrat in the Capital, if not the country. Soon-to-be Minority Leader Trent Lott (R-MS), stung by the Jeffords defection and the target of potential challenges to his leadership, vows to fight on for the President’s agenda.

The changeover of committee and subcommittee leadership will make a significant difference on issues like judicial appointments, energy legislation, health and education proposals, and many other items. The switch in leadership of the Judiciary Committee from Senator Orrin Hatch (R-UT) to Senator Pat Leahy (D-VT) provides, perhaps, the most stark contrast and the most difficulties for the Bush administration. Senator Edward Kennedy’s (D-MA) return to the leadership of the Health, Education, Labor and Pensions panel, replacing Jeffords who will now lead the Environment and Public Works Committee, pushes a number of Democratic legislative priorities to the fore, such as a patient’s bill of rights and an increase in the minimum wage. Senator Joseph Biden’s (D-DE) ascension to the head of the Foreign Relations panel, replacing Senator Jesse Helms (R-NC), will also change the focus of that committee. Senator Carl Levin (D-MI), new chairman of the Armed Services panel, has also made it quite clear that he is very skeptical of National Missile Defense, a key part of President Bush’s agenda. Another stark ideological contrast occurs at the Banking, Housing and Urban Affairs Committee, with Senator Paul Sarbanes (D-MD) replacing Senator Phil Gramm (R-TX).

Changes may be more subtle on the Appropriations Committee, which has acted in a (see Changes, page 7)

WRITTEN CONSENT MEASURE THREATENS RESEARCH, AGAIN

Among the slew of amendments proposed for H.R. 1, the President’s education bill that reauthorizes the Elementary and Secondary Education Act (ESEA), is an amendment sponsored Rep. Todd Tiahrt (R-KS) that passed the House by voice vote on May 23. Dubbed “Parental Freedom of Information,” the measure could end school-based survey research as we know it.

The language requires prior written consent from a parent before a minor can participate in federally-funded research in school. In practice, written consent is difficult to obtain, not because of parental disapproval of the research but due to a lack of involvement or time on their part. Research demonstrates that such restraints severely compromise both the sample size and validity of the study.

The problem is not with written consent per se, but that the amendment imposes written consent as “the single and only method of obtaining informed parental consent,” according to Felice Levine, Executive Officer of the American Sociological Association. “It is a ‘one size fits all’ solution that disregards what might be the best ethical practices in

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different circumstances and also ignores human subjects procedures already in place for assessing the adequacy of consent processes in school-based research."

The amendment also denies funds under any applicable program to any educational agency that effectively prevents parents from inspecting a broad array of surveys, analyses, evaluations, and curriculum. Researchers object that allowing parents to view research instruments before they are administered can compromise the data they collect. The amendment covers a broad range of research topics, including political affiliations, mental and psychological problems, illegal, anti-social, or high-risk behavior, income, and others.

Current law, as defined by the Grassley Amendment to the Goals 2000: Educate America Act of 1994, is similar in nature but has been interpreted to apply only to research sponsored by the Department of Education. The Tiahrt amendment, however, would apply to all federal agencies.

This expanded reach would involve research sponsored by Health and Human Services (including the National Institutes of Health), which accounts for a large portion of school-based research and includes studies important to the health and well-being of children. The Monitoring the Future Project, for example, examines changes in public opinion on alcohol and drug use, as well as a variety of other issues like government and politics, gender roles, and environmental protection.

The issue also arose several years ago when a coalition of organizations concerned about research (which included COSSA) effectively averted a similar bill from becoming law (see Update, November 13, 1995 and April 29 and June 24, 1996). The recent re-emergence of this issue caught many by surprise as it was not preceded by hearings.

The ESEA bill, to which the Tiahrt amendment was attached, passed the House by 384-45 on May 23. No companion amendment has appeared yet in the Senate, which has not completed work on ESEA, but is expected to soon. Organizations concerned that this measure will become law have once again joined forces, this time as the Coalition to Save School-Based Research, of which COSSA is a part.

SENIOR LEGISLATIVE ASSOCIATES

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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www.cossa.org
explained in detail this last area of study, stating that “women provide the majority of informal caregiving work — and often pay a steep price for their efforts. Caregivers suffer reduced wages and job security, which inevitably lead to diminished retirement security. Informal caregivers also experience emotional and physical stress that can take a toll on their own health.”

Discussing his agency’s strategy for keeping on top of research in the field, Thompson also stated in his testimony that the AoA is using some of the appropriated funds to maintain “...a moderated listserv, on which expert researchers prepare monographs on specific issues related to caregiving and enter into a dialogue with the aging network on how best to implement that issue in our country.” The first listserv session was held from January 30-February 5 of this year, with Rhonda Montgomery of the University of Kansas serving as the research resource. For more on this session see www.aoa.gov/aoacarenet/summary1.html.

IOM HOSTS SYMPOSIUM ON THE BEHAVIORAL AND SOCIAL SCIENCES

On May 23, the Institute of Medicine (IOM) hosted a day-long symposium entitled, “Through a Kaleidoscope: Viewing the Contributions of the Behavioral and Social Sciences to Health.” The event, sponsored by Barbara and Jerome Grossman, featured presentations by several noted experts in the health field.

Lisa Berkman of the Harvard School of Public Health opened her duties as the event’s chair by giving an introductory address. She told the audience that socioeconomic status, societal conditions, and individual behaviors have come to the fore in the last 20 years as factors that greatly impact health. Berkman also noted that population health (health generalities about distinct groups), disease causation, and social environment issues have recently become popular topics of study. Finally, she posited that the social and behavioral sciences are poised to assume a central role in understanding and influencing the determinants of health. But this advancement, she contends, will require bold new thinking in research design and grant-making.

Following Berkman’s opening, other prominent researchers made presentations about the impact of the social and behavioral sciences on the health field. Included among the morning speakers were two former COSSA Congressional Seminar participants: Robert Sampson of the University of Chicago, who focused on the role that neighborhood social structure plays on individual residents’ health, and Margaret Chesney of the University of California, San Francisco, who addressed the importance of population-wide intervention strategies. Raynard Kington, Director of the Office of Behavioral and Social Science Research at the National Institutes of Health, concluded the morning session with a discussion of the changing U.S. population and the charge this places on social and behavioral scientists to reach diverse groups of people by designing targeted interventions.

The afternoon session was highlighted by S. Leonard Syme’s presentation. Syme, a professor emeritus at the University of California, Berkeley, talked about the need for research-based public policy actions. He stated that smoking levels have decreased as a result of cigarette tax increases and limits on public advertising. He also asserted that there is a vital need for NIH and other sponsors of research to support interdisciplinary studies. These collaborations, bringing together biological, psychological, behavioral, and social experts, will best seize on modern advancements as scientists jointly strive to improve health.

IOM RELEASES HEALTH AND BEHAVIOR STUDY

“Health and disease are determined by dynamic interactions among biological, psychological, behavioral, and social factors. These interactions occur over time and throughout development. Cooperation and interaction of multiple disciplines are necessary for understanding and influencing health and behavior.” So states the primary finding of a recently released Institute of Medicine (IOM) report – Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences.

Accordingly, the report’s primary recommendation is that “funding agencies should direct resources toward interdisciplinary efforts for research and intervention studies to integrate biological, psychological, behavioral, and social
variables.” Echoing other recent documents, the new report calls attention to the need to encourage and expand collaborations across disciplines.

The report was produced by the IOM Board on Neuroscience and Behavioral Health’s Committee on Health and Behavior: Research, Practice, and Policy. Terry Pellmar is the Board’s Director. This updates the landmark 1982 IOM report — *Health and Behavior: Frontiers of Research in the Biobehavioral Sciences*. The IOM committee acknowledges that the 1982 report “stimulated research and training in the biobehavioral sciences,” and that, although the report is “now 18 years old, much of it is still current.”

In growing recognition of the importance of behavior to health since 1982, the National Institutes of Health’s Office of Behavioral and Social Science Research and the National Institute of Mental Health, the Centers for Disease Control, and The Robert Wood Johnson Foundation provided funding to the IOM to not only update scientific findings about the links between biological, psychosocial, and behavioral factors, and health addressed in the 1982 report but also to:

- identify factors involved in health and disease for which research on these factors and effective behavioral and psychosocial interventions is incomplete
- identify and review effective applications of behavioral and psychosocial interventions in a variety of settings
- examine implementation of behaviors
- review evidence of cost-effectiveness
- make recommendations concerning further research, applications, and financing

The following is a summary of the findings and recommendations included in the report:

Finding 2: Psychosocial factors influence health directly through biological mechanisms and indirectly through an array of behaviors. Social and psychological factors include socioeconomic status, social inequalities, social networks and support, work conditions, depression, anger, and hostility.

Rec. 2: *Research efforts to elucidate the mechanisms by which social and psychological factors influence health should be encouraged. Intervention studies are needed to evaluate the effectiveness of modifying these factors to improve health and prevent disease.*

Finding 3: Behavior can be changed: behavioral interventions can successfully teach new behaviors and attenuate risky behaviors.

Rec. 3: *Funding for health-related behavioral and psychosocial interventions should support realistically long duration efforts.*

Finding 4: Individual behavior, family interactions, community and workplace relationships and resources, and public policy all contribute to health and influence behavior change.

Rec. 4: *Concurrent interventions at multiple levels (individual, family, community, and society) should be encouraged to promote healthy behaviors. Assessments of coordinated efforts across levels are needed.*

Finding 5: Initiating and maintaining a behavior change is difficult.

Rec. 5: *Resources should be allocated to the promotion of health-enhancing behavior and primary prevention of disease. This should be a priority for public health and health care systems.*

Finding 6: Many behavioral intervention trials document the capacity of interventions to modify risk factors, but relatively few measured mortality and morbidity.

Rec. 6: *Intervention research must include appropriate measures (including biological measures) to determine whether the strategy has the desired health effects.*

Finding 7: Changing unhealthy behavior is not simply a matter of “willpower.” Individual behavior has biological underpinnings and consequences and is influenced by the social and psychological context in which it occurs. While biological interventions and exhortations to individuals to change their behavior are easier to administer, changes in social factors, policies, and norms are necessary for improvement and maintenance of population health.

Rec. 7: *Program planners and policy makers need to consider modifying social and societal conditions to enable healthy behaviors and social relationships. Longitudinal research designs, natural experiments,*
quasi-experimental methods, community-based participatory research, and development of new research methods are necessary to advance knowledge in these areas.

NBAC CALLS FOR A SINGLE FEDERAL POLICY TO PROTECT HUMAN RESEARCH PARTICIPANTS

In its key conclusion that the federal oversight system should protect the rights and welfare of human research participants, regardless of whether the research is publicly or privately sponsored, the National Bioethics Advisory Commission (NBAC) recommended that there be a unified, comprehensive federal policy embodied in a single set of regulations and guidance. The Commission further highlighted the fact that there is not a single federal entity with the authority to develop federal policy for all research involving human participants.

Accordingly, the Commission’s recently released recommendations call for legislation creating a single, independent federal office, the National Office for Human Research Oversight (NORHO), to lead and coordinate the research oversight system. “This office should be responsible for policy development, regulatory reform, research review and monitoring, research ethics education, and enforcement.”

In a year-long discussion of research oversight issues, the Commission examined the effectiveness of the oversight system, paying particular attention to the “Common Rule,” a set of regulations followed by 17 agencies of the federal government.

NBAC released its recommendations during its 48th meeting on May 15, 2001. The recommendations, available on the Commission’s website (www.bioethics.gov), will be incorporated into the Commission’s upcoming report, Ethical and Policy Issues in Research Involving Human Participants. The report, requested by the White House in October, 1999, is expected to be available later this summer.

In addition to changes at the national level, NBAC’s recommendations also address:

- protecting privacy and confidentiality
- developing a research agenda for research ethics
- the need for education
- certification and accreditation
- ensuring compliance
- managing conflicts of interest
- institutional review board membership
- monitoring ongoing research
- central or lead institutional review boards
- study of research-related injury compensation issues, and
- the need for resources

NBAC, established in October, 1995, was created to advise the National Science and Technology Council and other appropriate government entities regarding bioethical issues arising from research on human biology and behavior. This is the Commission’s fifth report.

GROUP LAUNCHES HUMAN SUBJECTS PROTECTION ACCREDITING AGENCY

At a Capitol Hill press conference on May 23, seven research and university organizations, including COSSA, launched the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Joining the Consortium in this effort are the Association of American Medical Colleges, the Association of American Universities, the Federation of American Societies of Experimental Biology, the National Association of State Universities and Land Grant Colleges, the National Health Council, and Public Responsibility in Medicine and Research (PRIM*R).

With the human research participants protection system under scrutiny from many different groups, one issue that has gained attention is the desire to accredit these systems and the Institutional Review Boards that are their backbones (see Update, February 26, 2001 and NBAC story in this issue).

AAHRPP hopes to provide increased credibility through voluntary assessments and accreditation. Working with human protection entities, it will provide guidelines for successful implementation of best practices for protecting participants in research. The new group is currently reviewing standards for the accreditation and is searching for an executive director.
COSSA joined the group to ensure that the social and behavioral sciences are represented in the discussions that continue to surround this important subject. As Executive Director Howard J. Silver noted at the AAHRPP Press Conference, “Too often the framework [for human participant protection] emphasizes biomedical-clinical research and fails to adequately consider its application to social and behavioral science research, for which a more appropriate framework would better serve both science and the participants.” The social and behavioral sciences will have at least three representatives on AAHRPP’s 21 person board expected to be appointed on June 13. The Board, which will also include five representatives of the public, will be independent of the seven founding groups in its accreditation decisions.

AAHRPP will pilot test its accreditation standards in the Fall and expects to begin its full accreditation operations early in 2002.

**SCIENCE BOARD CONCERNED WITH ALLOCATION OF FEDERAL RESOURCES**

The National Science Board (NSB), chaired by economist and former Tulane President Eamon Kelly, held a symposium on May 21 and 22 focusing on the “Allocation of Federal Resources for Science and Technology (S&T).” This is a perennial topic for the S&T community as it seeks a rational model for the way policy makers deal with its funding and oversight. In addition to the symposium, the NSB issued a draft report on “The Scientific Allocation of Scientific Resources.”

Former House Speaker Newt Gingrich delivered the keynote address. Now CEO of the Gingrich Group, a management consulting firm, and a Senior Fellow at the American Enterprise Institute, the former Speaker gave a rousing speech touting his vision for transforming (his favorite word) government and politics in the 21st Century. He declared, “It is clear that we are on the edge of an extraordinary revolution in scientific knowledge that will in the next 25 years probably increase our understanding of the natural world by more than all the breakthroughs of the 20th century combined.”

He remarked that these new breakthroughs in science, technology, entrepreneurship, and managerial capabilities will lead to enormous increases in productivity and in problem solving over the next two to three decades. He urged scientists to act like citizens and to boldly take up the “moral burden” of explaining why science matters. “Think big,” Gingrich thundered; “let’s aim at tripling the NSF budget.” He called for very large-scale science projects, including a manned mission to Mars, to “mobilize the human imagination.” Gingrich, like many others, also called for the transformation (there’s that word again) of basic math and science education by bringing scientists into the process and making classrooms more like movie theaters with George Lucas’ Industrial Light and Magic-like instruction materials.

The other participants in the symposium, including former NSF Director Erich Bloch, University of Maryland President Donald Langenberg, former NSB Chairman Lewis Branscomb, OMB Associate Director Kathleen Peroff, and House Science Committee staffer Scott Giles, focused their remarks on the uncoordinated policy making process that Congress and the Executive Branch use to scrutinize federal S&T budgets. Bloch noted that enhanced industrial support for university research, the increased role of the States in providing funds for S&T, and most importantly, the globalization of research and development have shifted the focus from the Federal government’s activities. Peroff discussed the tradeoffs of “setting priorities” with “balancing the portfolio,” suggesting these are often contradictory.

Giles declared that there was too much focus on “microbudget issues” and not enough on the macro issues of the totality of the science enterprise. He cited the Science Committee’s recent hearing during which heads of four agencies – NSF, NASA, Department of Energy Office of Science, and NOAA – all testified together. Unfortunately, other science agencies’ budgets, such as NIH, are not under the jurisdiction of the panel, making it difficult to have a discussion of the imbalance between large increases for NIH and small or no increases for the others in the FY 2002 budget. Branscomb also decried the “balkanization of Congress” when it came to examining science issues.

Langenberg suggested that the title of the report should be changed since achieving “scientific” allocation was impossible. He said that “emotion” was as important as rationality in S&T budgeting.
He also declared that trying to answer Congress’ favorite question – How much is enough? – is impossible.

The NSB report is available online at www.nsb.gov.

(CHANGES, from page 1)

mostly bipartisan manner in the Senate. New full committee chairman Senator Robert Byrd (D-WV) has always worked quite well with the Senator he replaces, Ted Stevens (R-AK), since both fiercely guard Congress’ prerogative to determine how and where the federal dollar will be distributed. The replacement of Senator Arlen Specter (R-PA) by Senator Tom Harkin (D-IA) will not affect the National Institutes of Health (NIH) very much since both are strongly committed to doubling the agency’s funding. Specter, now given an undefined leadership position in the Republican Senate hierarchy, may also have more impact on convincing his colleagues of the value of stem cell research.

For the National Science Foundation (NSF), Senator Barbara Mikulski (D-MD), new Chair of the VA, HUD, Independent Agencies Appropriations Subcommittee, has joined with her predecessor Senator Christopher Bond (R-MO) to lead the effort to double the Foundation’s budget over the next five years. During her earlier tenure as head of this panel, Mikulski once tried to push NSF to restructure itself to resemble NIH. Although she toned down that effort shortly thereafter, NSF has heeded some of her advice to focus on large, relevant research activities.

As for agricultural and criminal justice research, the dynamics are unclear. Senator Herb Kohl (D-WI) replaces Senator Thad Cochran (R-MS) as head of the Agricultural and Rural Development panel, while Senator Ernest Hollings (D-SC) returns as chair of the Commerce, Justice, State and Judiciary subcommittee.

With Senator Strom Thurmond’s (R-SC) age and health problems, Senator Robert Torricelli’s (D-NJ) legal problems, Senator John McCain’s (R-AZ) dallying with the new Democratic leadership, and Republican efforts to convert some of the more conservative Democratic senators, these new arrangements are tenuous at best, and the 2002 elections are a long way off. At the moment, the Bush Administration’s task to build on their tax cut success has become more challenging.

SOURCES OF RESEARCH SUPPORT

COSSA provides this information as a service and encourages readers to contact the sponsoring agency for further information. Additional application guidelines and restrictions may apply.

Research Integrity

The Department of Health and Human Services Office on Research Integrity (ORI), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Nursing Research (NINR) invite applications to support studies on research integrity (adherence to rules, regulations, guidelines, and commonly accepted professional codes or norms). The request for applications seeks to address the need for more and better information on the factors that encourage and/or discourage integrity in publicly funded research (societal, institutional, and individual aspects of the enterprise).

A letter of intent is due by October 15, 2001 and the application is due November 19, 2001. Additional information can be found at: http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-02-005.html.

International Peace

The United States Institute of Peace invites applicants for the 2002-2003 Senior Fellowship competition in the Jennings Randolph Program for International Peace. The Institute funds projects related to preventive diplomacy, ethnic and regional conflicts, peacekeeping and peace operations, peace settlements, post-conflict reconstruction and reconciliation, democratization and the rule of law, cross-cultural negotiations, U.S. foreign policy in the 21st century, and related topics. The competition is open to citizens of all nations; women and members of minorities are especially encouraged. Applications must be received by September 17, 2001. See www.usip.org/fellows.html.
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National Council on Family Relations
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North Central Sociological Association
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