

**PREWITT LEAVES CENSUS; DECISION ON
ADJUSTMENT LOOMS** CR

Change at the Helm

Kenneth Prewitt recently ended his service as Director of the Census Bureau expressing his hope that important Census decisions will continue to be influenced by science rather than politics. Prewitt is returning to New York to accept the post of graduate dean of the New School University, where he will establish a demographics program and write a book about Census 2000. The Census is currently administered by Deputy Director William Barron, a federal official with many years of service in the nation's statistical agencies. Rep. Carolyn Maloney (D-NY), the ranking Democrat on the House Government Reform Subcommittee on the Census, concurred with Prewitt. Thus, she responded strongly to the rumor that President Bush is considering Republican National Committee redistricting expert Tom Hofeller to be the next head of the Bureau. Maloney declared that naming Hofeller to the post would be "political and wrong."

The Politics of Counting

The attention to the choice of the new Census Director concerns the decision of which numbers the Bureau will release. The national-level data, which determines each state's representation in Congress (apportionment), were made public at the end of December. However, the block-level data are scheduled to be available in March; these will include the raw "head count" figures. The controversy surrounds whether the Bureau will also release statistically-adjusted figures; this is currently unclear.

Statistical adjustment, or sampling, is used to correct for the two types of coverage error that usually results from the traditional Census methodology: failure to count individuals and mistakenly including individuals or counting them (see *Census*, page 4)

**IOM HEARS CONCERNS REGARDING
HUMAN SUBJECTS' PROTECTION** AS

Federal and non-federal organizations continue to examine the issue of human research participants protection. On January 22, the Institute of Medicine's (IOM) *Committee on Assessing the System for Protecting Human Research Subjects* held a public forum to gather information for its assessment of the system for protecting human research participants (see *Update*, January 15, 2001). The Committee heard the various perspectives (institutional, participant, and investigator) of those conducting research involving humans.

Representatives from the Department of Health and Human Services (Office of Human Research Protections, Centers for Disease Control and Prevention, and the Food and Drug Administration), the National Science Foundation, and the Veterans' Administration also provided testimony. Opening the meeting, Chair Daniel Federman (Dean for Alumni Relations and Clinical Teachings, Harvard) emphasized that the committee will "deliberate thoroughly" before writing its draft report and that no conclusions or recommendations by the Committee would be made at the meeting.

Several individuals offered perspectives regarding the difficult and challenging problem of how to accommodate the social and behavioral sciences in a system based on a model created to deal with biomedical and clinical research.

Felice Levine, Executive Committee member of COSSA and Executive Director of the American Sociological Association, addressed the Committee on behalf of COSSA and from the perspective of researchers. Levine informed the Committee that most of the professional associations within COSSA

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have developed ethical guidelines for researchers to follow in conducting their research, particularly where human participants are part of the research design. She emphasized COSSA's concern regarding the "growing fault lines in the system that protects human participants and the gap that has developed between law and policy 'on the books' and 'in action.'" For example, said Levine, researchers utilizing secondary data are being asked to seek approval by Institutional Review Boards (IRBs) to use these data though the information is anonymous and the subjects are already protected under earlier protocols.

Commenting on proposed standards for accreditation of institutions' human research protection plans, she noted that they provide further evidence of the inherent problem with the current system. If these standards are intended to be universal and to fit all research involving human participants, she said, they need to be framed in a way that meaningfully includes all research fields.

Levine informed the Committee that the social and behavioral science community framed its concerns as ten recommendations. COSSA's written testimony will provide specific illustrations of where the social and behavioral science community thinks that accreditation standards are problematic for achieving the proposed goals and where they are specifically problematic for the social and behavioral science community.

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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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1. Seize the moment for effective leadership on behalf of all science. The IOM has the opportunity to provide guidance on an accreditation system and a human research participant protection system that effectively reaches all areas of research and effectively serves all Federal funding agencies engaged in the support of such research — not just the biomedical sciences.

2. Slow the process down sufficiently to ensure quality. There is virtue in moving ahead, but there is also virtue to slowing the process down enough to ensure that the standards are meaningful for all science. If the standards for accreditation are to be more effective than the current process for obtaining assurances of compliance under the Common Rule, then the two important IOM studies (concerning the overall structure and function of human participant activities, including IRBs, and criteria for evaluating the performance of human subject protection activities) yet to be undertaken should logically proceed before crafting and finalizing accreditation standards (a message echoed by several participants).

3. Ensure That the Many Pieces of the Common Rule Fit. The proposed accreditation standards integrated many pieces of the Common Rule but use these regulations in a different context, often coupled with other ideas. The disjuncture between the Common Rule and accreditation standards needs careful analysis.

4. Attend to the Details. The proposed standards are not couched in the language of any one science or arena of research per se, but when coupled with the commentary, are biomedical and heavily clinical. Accordingly, they pay only lip service to other substantive arenas of work; this is especially problematic for the social and behavioral sciences. If the commentary will be presented, its role needs to be clear and the examples across areas of research specified.

5. Ensure That the Standards Emphasize Accrediting the Structure and the Procedures That Are Followed. While good ethics makes for good research, judgments of best ethical practices are distinct from judgments about the quality of the research. The proposed accreditation standards overreach what constitutes quality science and what constitutes ethical practices in science. The standards shift from the criteria for the accreditation

of Institutional Review Boards to the assessment of the research and the researcher.

6. Assure Clarity, Simplicity, and Transparency; These Attributes Are Fundamental to Accreditation Standards of Excellence. Many of the standards require judgments that are impossible to make. The standards should not tell an institution how it should achieve its goals, but should set forth what the standards or goals are.

7. Guarantee That the Standards Provide Education About How IRBs and the Human Research Protection System Should Operate. The proposed standards, especially the commentary, provide little in the way of education, particularly with regard to the social and behavioral sciences.

8. Safeguard the Human Research Protection System by Ensuring That It Does Not Overreach Its Role and Stays on Task. The human research protection system needs to ensure that research proceeds and knowledge are advanced in accordance with the highest standards of ethical practice with respect to human participant protection. The system needs to ensure that work that comports to ethical standards is facilitated and not impeded by the process.

9. Assure That the Accreditation Standards Clarify What the Scope of the Human Protection System Is and Is Not. Human research participants refer to actual participation in a study underway or being proposed. The analysis, for example, of public-use data where information is maintained in anonymous form and without personal identifiers is research about people but not *on* people.

10. Focus on the Ethical Considerations Regarding Human Research Participants in Various Types of Research. The answer to the concerns in the social and behavioral sciences is not necessarily to "specialize" the review process but to ensure a system that is more sophisticated about ethical practices across fields of science. Social and behavioral research is increasingly interdisciplinary within these fields and across other arenas, especially biomedical, environmental, and engineering fields. Separation of the review by field could create redundancy and limit researchers mutually benefiting from the ethical expertise of each other.

Levine emphasized that COSSA believes this guidance can help structure the next round of revisions for a final set of "testable" accreditation standards. COSSA, the social and behavioral science societies, as well as many, many top quality researchers behind us are eager to help in any way that we can, Levine concluded.

Comments from Federal Agencies

Individuals from several of the agencies that are part of the "Common Rule" offered insights. The Department of Health and Human Services (HHS) considers accreditation the cornerstone of overall improvement of the human participant system, stated Irene Stith-Coleman, Public Health Advisor to the Assistant Secretary of Health and the Surgeon General. Her comments were made on behalf of the agency and Office of Human Research Protections (OHRP) Director Greg Koski. The Department envisions a system of objective, uniform, nationally-recognized standards that provide the basis of accreditation, she stressed. The two-year IOM study, requested by OHRP, is designed to realize this system.

According to the Centers for Disease Control and Prevention (CDC) Deputy Associate Director for Science John R. Livengood, there are three areas of concern for the CDC: 1) diversity of IRBs; 2) ownership of the standards; and 3) plans for implementation. While the CDC agrees with the overall process, the agency asks the Committee to be sensitive to the entire range of IRBs. The CDC, said Livengood, believes that it is "important to strengthen the IRBs." Further, CDC encourages the Committee to realize there are other IRBs, "other than those associated with medicine." To narrow the focus on the biomedical models may create unintended consequences, stressed Livengood, noting that the CDC works with many partners. With regard to the ownership of the standards, Livengood emphasized that the copyrighted standards "strike the wrong tone." He noted that for implementation purposes, any final standards must be adaptable to different situations.

Philip Rubin, Director of the Behavioral and Cognitive Sciences Division at the National Science Foundation, expressed concern with the proposed standards and their impact on the social and behavioral sciences. Rubin warned the Committee that the draft standards have the potential to cause harm if a different kind of expertise is needed on

IRBs, other than biomedical and clinical. He highlighted the fact that interdisciplinary research is a priority throughout the sciences and the federal research agencies. Rubin further stressed that the federal government also collects data (e.g., Panel Study of Income Dynamics, housing, education, and medical care) and that the proposed standards could be detrimental to the federal government's ability to collect that data. Finally, Rubin reminded the Committee that it has an opportunity to be responsive to the needs of the social and behavioral sciences, emphasizing that the current standards are not.

Stephen Erickson, Director of the Office of Research Administration at Boston University, informed the Committee that his University was rapidly becoming more research intensive, overwhelmingly behavioral in nature. Erickson made several observations regarding the proposed standards.

- The standards appear to have been drafted with large academic biomedical and clinical programs in mind.
- The standards are so detailed as to impede flexibility.
- To participate in a voluntary accreditation process places additional administrative costs and burdens on institutions.
- Benefits to participating need to be made clearer. Benefits should outweigh the costs of participating.
- There is a need to incorporate a statement describing the accreditation process.
- Two core questions need addressing in the review/redraft of the standards: 1) Will the standards assist different sizes of institutions to better fulfill their mission?; and 2) Do the standards facilitate the work of IRBs, institutions, and researchers?

Written comments (to be considered in deliberations) on the proposed standards (which have not been endorsed by the committee) must be received by the IOM by February 2, 2001. The standards can be found on the IOM website at: www.iom.edu/IOM/IOMHome.nsf/Pages/human+research+protections. COSSA's written comments will be posted on our website (www.cossa.org) by February 2, 2001.

(CENSUS, from page 1)

twice. The degree of error is determined through the Accuracy and Coverage Evaluation (ACE), which is conducted independently of other Census activities and is open to scientific peer review. Most statisticians regard the adjusted figures as more accurate.

In September of last year, President Clinton's Secretary of Commerce, Norman Mineta, acting on the recommendations of professionals in the Bureau, delegated the decision on whether to release adjusted figures to the Director of the Census. The decision "requires the scientific expertise of the Bureau of the Census . . . This regulation is designed to ensure that politics are not a part of this important decision," Mineta explained.

The issue is politically charged because those not counted by the Census are not a random subset of the population; they tend to be poor and members of minority groups. The uncounted are accordingly denied political representation (at the federal, state, and local level) and the distribution of federal funding that the Census determines. Both parties agree that the use of adjustment would favor Democrats, who say it is their constituents who have been missed in the past.

The Supreme Court took up the sampling issue in January, 1999. Although they did not rule that sampling is unconstitutional, they did rule (5-4) that it is illegal under current federal census law for the purpose of reapportionment. The Court did not prohibit the use of such data for other purposes, such as redistricting (within states) and distributing federal funds.

Numbers and the New Administration

Concerned parties are now looking to the next administration for signs of how they will deal with the issue. Bush has chosen his campaign chairman and longtime friend, Donald Evans, for the post of Secretary of Commerce, which oversees the Census. When pressed on the matter by Sen. John Kerry (D-MA) in his confirmation hearing, Evans said he was unsure whether the decision would be his, and declined to state his position.

Bush's spokesman, when asked about Bush's intentions, has, of late, consistently responded that he supports an "actual head count," which appears to

be a softer way of conveying opposition to sampling. According to *Roll Call*, Bush aides said one of his first acts as president "would be to block the Bureau's release of census findings that are reached through sampling." While Democrats would like to see the decision made by scientists at the Bureau (after ACE reveals the accuracy of the 2000 Census by late February), Bush seems to be hinting he has already decided against sampling – hence the concern over the potential appointment of Hofeller, which they would see as politically-motivated.

The (Political) Climate Warms

Opposition to the Bush Administration's expected rejection of sampling is growing among Democrats and civil rights groups. Rep. Maloney and others have linked any decision that takes the authority to decide the sampling issue from the Census Director, or installs a politically-motivated appointee in that position (thereby preventing the use of adjustment), with charges of disenfranchisement of Florida voters.

Adding further ammunition to their cause, the Census Monitoring Board members who were appointed by President Clinton recently released a number of studies that reveal the expected consequences of failing to correct an undercount. One recent study, for example, shows that more than 20 percent of infants were missed in the 1990 Census, and warns that similar results are possible in Census 2000. Without statistical adjustment, the report cautions, health and education programs that serve the nation's children could be underfunded. The Census Monitoring Board is a bipartisan board that monitors the Census Bureau's conduct of the 2000 Census (see their website at www.cmbp.gov).

With political representation and federal funds at stake, the battle is likely to escalate soon. Although the deadline for release of the final census figures is April 1, the data could be released as early as March; action on the decision to adjust could come sooner.

See www.census2000.org for information and resources.

CONGRESS AND THE ADMINISTRATION TALK EDUCATION; DETAILS PENDING

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President Bush got off to an early start by introducing his education proposal on January 23.

As expected, the plan includes vouchers to help parents move their children out of failing schools. While this aspect drew the most attention, Bush downplayed its significance, preferring to focus on testing and standards. As of now, the proposal is not published in legislative form; it is too early to tell what it may hold for education research. Some indication of what may eventually pass Congress, however, is offered by Rep. Michael Castle (R-DE).

Castle is President of the moderate Republican Main Street Partnership, which released an Education Action Agenda several days earlier. The document highlights specific major education initiatives that Castle and the other partnership members believe can be enacted under the Bush Administration. The Agenda calls first for the reauthorization, reform, and improvement of the Elementary and Secondary Education Act (ESEA), which Congress failed to reauthorize last session.

Addressing research, the partnership makes four recommendations:

1. Enact legislation to ensure that all federal research, evaluation, statistics and dissemination activities conform to the highest standards of quality, are free from ideological agendas, and provide parents, educators and policymakers with reliable information on education practices that improve academic achievement.
2. Replace the national priorities board, which consists of Department heads and representatives of professional education organizations, to ensure that the priorities of our nation's federal research arm are determined by the needs of real teachers and school administrators.
3. Move the National Center for Education Statistics (NCES) out from under the Department of Education and give the National Assessment Governing Board the full authority over the National Assessment of Educational Progress (NAEP), the federal program that regularly tests national samples of students to measure achievement at different age and grade levels.
4. Ensure that education resources are used to support quality at all levels. . . Quality and applicability to state standards – not economics – should be the deciding factor in purchasing services, textbooks, tests, etc.

... This is one area federal researchers should examine closely.

Democrats Weigh-In

On the same day that Bush unveiled his education plan, members of the House and Senate New Democrat Coalition reintroduced their education package, describing it as a real opportunity to "break the education stalemate in Congress, and make substantial progress toward addressing our nation's educational challenges."

The "Three R's" plan (Reinvestment, Reinvention, and Responsibility), introduced by Senators Joseph Lieberman (D-CT) and Evan Bayh (D-IN) in the last Congress, shares many of the ideals touted by the Bush plan. Noticeably different, however, in the Democrats' plan is the lack of any proposal to move NCES or NAEP outside the Department of Education. At this point, however, specifics are few and far between.

SURGEON GENERAL RELEASES REPORT ON YOUTH VIOLENCE

In the aftermath of the shootings that occurred at Columbine High School in Colorado in April, 1999 (see *Update*, May 17, 1999), both the Administration and Congress requested a report summarizing what research can tell us about the causes and prevention of youth violence. The findings, presented by U.S. Surgeon General David Satcher in a January 17 press conference, reveal that "as a Nation, we possess knowledge and have translated that knowledge into programs that are unequivocally effective in preventing much serious youth violence."

This primary conclusion contrasts with the prevalent notion among many experts just a few years ago that nothing could be done to halt the tide of youth violence that erupted in the early 1980s. Researchers have found specific interventions to be highly effective in preventing youth violence. Such programs, Satcher explained, can be implemented efficiently, and ineffective, harmful, or understudied programs can be eliminated. The report, accordingly, looks to research-based approaches to "systematically confront the problem of youth violence."

Skills-oriented strategies are revealed to be among the most effective methods for reducing youth violence and associated risk factors. Life Skills Training, for example, which is designed to prevent or reduce gateway drug use, involves teachers training students in self-management skills, social skills, and information and skills related to drug use. Other proven program types include behavior management (which focuses on enhancing positive student behavior, attendance, and academic achievement through rewards and monitoring), capacity-building (which focuses on building a school's capacity to plan, implement, and sustain positive changes), teaching strategies (which targets academic failure, a risk factor for youth violence), and community-based programs (such as Boys and Girls Clubs and other after-school programs).

Certain programs are found to be consistently ineffective. These include peer-led programs (such as peer counseling, peer mediation, and peer leaders), Drug Abuse Resistance Education (DARE), which is the most widely implemented youth drug prevention program in the country, and gun buyback programs.

The report takes a public health approach to youth violence research. "With its emphasis on prevention of disease or injury, the public health approach to violence offers an appealing alternative to an exclusive focus on rehabilitation. Primary prevention identifies behavioral, environmental, and biological risk factors associated with violence and takes steps to educate individuals and communities and protect them from these risks."

This approach, the report states, relies on a multidisciplinary knowledge base. The report "draws conclusions from research in psychology, sociology, neuroscience, public health, epidemiology, communications, and education." Most effective programs, Satcher reported, similarly involve a comprehensive approach, and include family, teachers, peer groups, community groups, and others.

Looking to the future, Satcher stressed that it is critical that the research – experimental and behavioral – continue. To this end, the report recommended several courses of action, which include:

- Continue to build the science base

- Facilitate the entry of youths into effective intervention programs rather than incarcerating them
- Disseminate model programs with incentives that will ensure fidelity to original program design when taken to scale
- Improve public awareness of effective interventions
- Improve Federal, state, and local strategies for reporting crime information and violent deaths

On the day of the press conference, Senators Arlen Specter (R-PA) and Tom Harkin (D-IA), Chairman and Ranking Member, respectively, of the Senate's Labor-HHS-Education Appropriations Subcommittee, called for an increased focus on effective youth violence prevention programs. Harkin and Specter have worked together on the issue of youth violence in the past. "Based on the numbers in [the Surgeon General's] report – we still have work to do," Harkin announced. "Youth violence in our communities is still a problem."

The report on youth violence is available online at www.surgeongeneral.gov/library/youthviolence.

NAS TACKLES SUICIDE PREVENTION *AS*

The report on youth violence did not address the issue of youth suicide. However, the Office of the Surgeon General, in collaboration with other Federal health agencies, developed a National Strategy for the Prevention of Suicide in 1999 as part of a "call to action" to bring attention to suicide as a largely preventable public health problem.

Such attention is one major impetus for the National Academy of Sciences' (NAS) initiation of the project, *Pathophysiology and Prevention of Adolescent and Adult Suicide*. The project's committee held its first meeting on January 18 in Washington, at which the sponsors outlined their priorities.

The project is designed to:

1. Assess the science base of suicide etiology, including cognitive, affective, behavioral, sociological, epidemiological, genetic, epigenetic, and neurobiological components,

- including examination of the vulnerability of specific populations and age groups
2. Evaluate the current status of primary and secondary prevention including risk and protective factors
3. Evaluate and design strategies for studies on suicide, including consideration of the ethics of incorporating suicidal patients into drug trials, re-evaluation of the current classifications of suicides, and the design of scales to evaluate suicide risk and outcomes
4. Provide conclusions concerning gaps in knowledge, research opportunities, and strategies for prevention of suicide

The public health perspective advocated by the Surgeon General stems from the idea that suicide is a mental health issue. Many of the speakers' comments concerned the need for more and better research on suicide and mental health-related factors. These included:

- The integration of structural, social, and environmental factors, and attention to the interaction between individual and social scales
- A multidisciplinary approach to the issue
- The utilization of methods that have been successful in addressing other related problems
- The need for better suicide statistics
- The effects of alcohol use and other cofactors (other substances, cultural factors, etc.) on suicide risk
- Additional research on racial, ethnic, gender, and age in this area
- The importance of protective factors that can determine why certain populations are less at risk for suicide

A final report on the 18-month project will be issued in early Spring, 2002.

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