

**CEASE-FIRE ON APPROPRIATIONS;
CONGRESS TO RETURN FOR LAME-DUCK
SESSION**

Congress and the President have declared a cease-fire in the appropriations war until after the election. Congress left town on November 2 after passing the 14th Continuing Resolution (CR) to keep the government operating. The President signed the legislation the next day.

The battle will resume on November 13. Whether either side will be chastened by the election results will depend on the outcome. The remaining business for the third lame-duck congressional session in the past six years includes six appropriations bills and a possible tax package.

Just prior to passage of the 12th CR on November 1, President Clinton vetoed the combined Legislative Branch and the Treasury and General Government Appropriations bill, which provides the funding for Congress and the White House. He declared, the “business of the American people remains unfinished,” and urged the “Congress to get its priorities in order.”

Agreement on the perennially contentious Labor-Health and Human Services-Education appropriations bill still remains elusive. It is expected to serve as the vehicle to complete the FY 2001 appropriations process. While the Congress and the White House have seemingly reached agreement over the President’s education priorities, the dispute over the workplace ergonomics rule keeps the bill in play.

The joint Commerce-Justice-State and District of Columbia spending measure has been cleared by Congress, but is under a veto threat from the White House because of its immigration provisions (see story on p. 3).

The President signed the VA-HUD-IA bill on October 27, which includes a nearly 14 percent increase for the National Science Foundation.

**CONGRESS CREATES NEW NIH CENTER
ON HEALTH DISPARITIES**

Despite its inability to come to an agreement on the remaining appropriations measures, the Congress cleared for the President S. 1880, the Minority Health and Health Disparities Research and Education Act (see *Update*, August 7, 2000). The legislation, which the President is expected to sign, won approval after Senate leaders modified language to address concerns raised by the Department of Justice.

“The Minority Health and Health Disparities Research and Education Act will expand research and education for the biomedical, behavioral, economic, institutional, and environmental factors contributing to health disparities in minority and medically underserved populations,” said Senator Bill Frist (R-TN), who introduced the amended version of the legislation in the Senate with Senators Edward Kennedy (D-MA) and Jim Jeffords (R-VT). Frist emphasized that “health disparities may be the result of many factors, including limited access to prevention and treatment services, poverty and socio-economic factors, exposure to environmental toxins, and even cultural factors.”

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Kennedy, the original sponsor of the Senate legislation, stressed that “the reality of poverty clearly affects the nation’s health” (see *Update*, May 15, 2000). S. 1880 provides “the needed resources for research, data collection, medical education, and public awareness in order to understand the root causes of diseases and poor health outcomes and to develop the strategies to meet the health needs of these vulnerable communities.” Each of these aspects, Kennedy declared, has an important role to play in the reduction and eventual elimination of the unacceptable disparities in health outcomes that now exist.

ORMH Elevated to Center Status

As passed, S.1880 amends the Public Health Service Act to expand federal research and education efforts to address health disparities. Additionally, the measure elevates the current National Institutes of Health (NIH) Office of Research on Minority Health, established in 1990, to the National Center on Minority Health and Health Disparities. The newly established Center would fund research not already supported by one of NIH’s other 25 Institutes and Centers. The measure also requires NIH to report to Congress the amount of money it spends on minority health

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research. S. 1880 also allows the federal government to repay up to \$35,000 of the educational loans of researchers, regardless of their race, for each year they conduct studies of the disparities that exist in health outcomes. For fiscal year 2001, the measure authorizes \$100 million in funding.

Anticipating the bill’s requirement of a trans-NIH plan for health disparities research, the agency recently posted such a plan on its website seeking public comment through December 1 (See *Update*, October 23, 2000). Each of the Institutes and Centers (ICs) (including the Office of Behavioral and Social Sciences Research) were also required by Principal Deputy Director Ruth Kirchstein to come up with individual health disparities strategic plans (see related story on page 5). Most of the ICs have posted these plans on their individual websites or they may be viewed at: www.nih.gov.

AHRQ

S. 1880 requires the Agency for Healthcare Policy and Research (AHRQ) to conduct research on the causes and barriers to reducing health disparities, taking into consideration such factors as “socioeconomic status, attitudes toward health, language spoken, the extent of formal education, the area or community in which the population resides, and other factors the Director determines appropriate.” AHRQ is also directed to conduct and support research and demonstration projects to identify, test, and evaluate strategies for reducing or eliminating health disparities.

National Academy of Sciences Study Required

The bill mandates the National Academy of Sciences to conduct a “comprehensive study of the Department of Health and Human Services’ (HHS) data collection systems and practices and any data collection or reporting systems required under any of the programs or activities of the Department relating to the collection of data on race or ethnicity, including other Federal data collection systems (such as the Social Security Administration) with which the Department interacts to collect relevant data on race

and ethnicity.” The report is due one year after the enactment of the legislation.

Cultural Competency Addressed

The Secretary of HHS, acting through the Health Resources and Services Administration (HRSA), is authorized to award grants, contracts, or cooperative agreements to public or nonprofit entities to carry out research and demonstration projects (including research and demonstration for continuing health profession education), training, and education for the reduction of disparities in health care outcomes and the provision of culturally-competent health care. HRSA is also required to convene a national conference on health professions education as a method for reducing disparities in health outcomes.

The bill also requires the HHS Secretary to conduct a national campaign to inform the public and health care professionals about health disparities in minority and underserved populations.

COSSA joined nearly 40 organizations in a letter organized by the National Medical Association and sent to the House and Senate leadership urging passage of the bill.

CONGRESS APPROVES FUNDING FOR CJS; BILL AWAITS POSSIBLE VETO

On October 25, Congress approved FY 2001 funding for the Departments of Commerce, Justice, and State, and related agencies. The bill, which includes funding for the Census Bureau and the National Institute of Justice, passed by small margins in both houses.

The President has indicated he will veto the bill as the Republicans’ immigration proposal does not meet his approval. The major point of contention concerns GOP disapproval of President Clinton’s amnesty proposal for illegal aliens. Despite the likely veto, it is unlikely that the final bill will contain major changes in funding levels given that the disagreement concerns authorizing language.

Census Bureau Shifts Gears

The bill that cleared Congress provided \$733.6 million for the Census Bureau. This huge reduction from \$4.759 billion last year reflects the transition of Census 2000 from data collection to analysis and data dissemination.

Within the Census Bureau, funding for the American Community Survey (ACS) increased to \$21.6 million from \$20 million in FY 2000. The yearly survey, which is designed to provide timely economic, social, and housing data, is expected to replace the long form of the decennial census by 2010. The Bureau plans to implement the ACS in every U.S. county beginning in 2003 (see *Update*, August 7, 2000). Funding for the Bureau of Economic Analysis increased from \$43.8 million to \$48 million.

National Institute of Justice Sees Increase

Although the House and Senate proposed about \$41.5 million and \$46 million, respectively, for the National Institute of Justice (NIJ), the conference agreement provides the Institute with \$70 million. This is a large increase over the \$43.4 million allocated last year. The difference includes \$24.5 million for three new earmarks (one of which is an \$8 million appropriation for smart gun technology research and development) and \$5.8 million for three continuation earmarks.

In addition to the \$70 million appropriation, the agreement provides \$42.7 million to other sources to be administered by NIJ. This includes \$20 million (as was provided in previous years) from the Local Law Enforcement Block Grant to assist local units to select, develop, and purchase new law enforcement technologies; \$17.5 million from technology funding in the Community Oriented Policing Services account for safety technologies for safe schools (\$2.5 million more than last year); and \$5.2 million for NIJ research and evaluation on the causes and impact of domestic violence under the Violence Against Women Grants program (the same amount that was allocated last year).

The agreement provides the Bureau of Justice Statistics \$28.8 million, \$1.5 million more than the

Senate amount, \$3.3 million more than the House amount, and \$3.3 million more than last year. This figure includes \$2 million to collect tribal criminal justice statistics and \$725,000 for Computer Crime and Cyber-Fraud statistics.

Juvenile Justice programs will receive \$298.6 million. This includes \$279.1 million for Juvenile Justice and Delinquency Prevention programs, \$11 million “to develop, demonstrate and test programs to increase the perception among children and youth that drug use is risky, harmful, or unattractive,” and \$8.5 million for various programs authorized under the Victims of Child Abuse Act.

Education Programs Receive Increase

The Education and Cultural Exchange Programs under the Department of State were allocated \$231.6 million, a substantial increase of \$26.6 million over FY 2000. Of this amount, the Fulbright Program will receive \$114 million. Other programs include Humphrey Fellowships, the Muskie Fellowship Program, the Citizen Exchange Program, the International Visitors Program, and more.

RESEARCHERS DISCUSS THE DECLINE IN CRIME, LOOK TO FUTURE

A forum entitled, *The Decline in Crime: Why and What Next?*, brought some of the top criminal justice researchers to the National Press Club on October 26 to discuss the recent decline in crime and to identify successful policies for continuing the downward trend.

Al Blumstein¹, one of the editors of *The Crime Drop in America* and President of COSSA, offered an overview of recent crime trends. The mid- to late 1980s saw rising crime rates. Much of the increasing crime involved the factors of drugs, guns, and youth. Blumstein explained that the juvenile arrest rate of non-whites shot up in the mid-1980s partly because they filled the void left by adult drug

¹Blumstein also spoke at a congressional briefing organized by COSSA in June of this year, entitled, *Controlling Violence in America*. Transcripts are available from COSSA.

dealers who were being locked up in increasing numbers. Guns accompanied the drug activity, he continued, and the availability of guns to resolve drug-related disputes led to homicides.

Crime rates began to decline in the early 1990s. Much of the decline in weapons arrests of young people, Blumstein said, can be attributed to the efforts of local police, the Bureau of Alcohol, Tobacco, and Firearms (ATF), and community groups. But the extent to which these and other efforts contributed to the decline is not easy to determine. Many of the other panelists addressed this question of causality since the continuation of the decline of crime rates may depend on knowing what caused crime to drop in the first place.

Besides the availability of firearms, the effect of incarceration on crime is another hot topic in crime research. The U.S. has the highest incarceration rate in the world after Russia, Blumstein said, and the 1980s and '90s saw large increases in the number of inmates in U.S. prisons. However, concluding that this increased incarceration caused the decline in crime is too simplistic, he explained. With each new inmate we are digging deeper into the pool of offenders, he said, and the benefits are decreasing.

Effects of Prisons and Policing

Looking at the impact of prisons, Richard Rosenfeld of the University of Missouri at St. Louis (and participant in COSSA's 1997 Congressional Seminar on juvenile crime) noted that while there is some benefit in expanding incarceration, prisons are expensive and their construction diverts resources from longer-term crime reduction strategies. William Spelman of the University of Texas at Austin determined that each new prison bed is one-third as effective as it was in the early 1970s. He concluded that there is no good reason to go further with prison expansion.

Among other initiatives in crime reduction, researchers have considered the effect of policing. Unfortunately, it is difficult to determine the effect of different policing policies on violent crime rates, according to John Eck of the University of Cincinnati. The effect of “community policing,” for

example, is difficult to assess because it is a vague concept and can refer to very different strategies.

Crime and the Strong Economy

Politicians may take credit for the booming economy, but can the economy take credit for the decline in crime rates? Although research suggests there is no relationship between the unemployment rate and the crime rate, Jeffrey Grogger of the University of California at Los Angeles noted a relationship between wages and economically-motivated crime. Wages for low-skilled 16 to 24 year-old males dropped between 1979 and 1993, and have risen since then as crime has dropped. Some at the forum expressed concern over what may happen when the economy recedes.

Other factors mentioned that may be related to crime levels include crime and anti-drug coalitions, immigration, the influx of gangs, the positive impact of faith-based community groups, and culture.

Crime Policy Into the Future

Blumstein expressed some concerns about the implications of present policies on future crime. He noted that if current incarceration trends continue, for example, more people will soon be coming out of prison than going in. Incarceration, he lamented, is seen as the dominant solution regardless of its effectiveness. Politicians and the press want simple solutions, he concluded, but the decline in crime came from the combination of many factors and initiatives. Blumstein expressed the hope that in the future, the wisdom and rationality of the forum's panelists will be a part of the public debate.

The event was sponsored by the Urban Institute's newly-formed Justice Policy Center and moderated by former NIJ Director Jeremy Travis. The Center "carries out nonpartisan research to inform the national dialogue on crime, justice, and community safety."

OBSSR'S HEALTH DISPARITIES STRATEGIC PLAN ON THE WEB

The National Institutes of Health's Office of Behavioral and Social Sciences Research (OBSSR) has posted its strategic plan for health disparities research on the agency's website (<http://obssr.od.nih.gov>).

The OBSSR's plan emphasizes that the projects it describes are the result of discussions with the extramural research community and the NIH Behavioral and Social Sciences Research Coordinating Committee and represents important areas of investigation or development which may not be highlighted in the rest of the Institutes and Centers' (ICs) strategic plans."

According to OBSSR, the project represents directions that the Office would like to pursue in the next five years as funding allows. These projects "fall into broad categories of background risk factors, intervention research, and training and communications and are not listed in priority order." It is noted that the OBSSR may also pursue projects not identified in the plan if opportunities for collaboration with the ICs arise.

The OBSSR's plan includes four areas of focus: 1) racial bias and health; 2) racial/ethnic and socioeconomic inequalities in health; 3) behavioral change interventions to diminish racial/ethnic health disparities; and 4) health disparities and health care systems.

Racial Bias and Health — The OBSSR plans to assess the state-of-the-science on racial bias and health and stimulate research on areas identified as gaps in knowledge. Initiatives designed to stimulate research on racial/ethnic and socioeconomic inequalities in health will follow the assessment. The plan emphasizes that the influence of racial bias is not limited to access to health care. "Discrimination can restrict the educational, employment, economic, residential, and partner choices of individuals, affecting health through pathways linked with what psychosocial scientists refer to as human capital." An insufficient focus on the impact of societal forces has hindered the ability to understand and effectively

address the influence of racial biases on health disparities.

Racial/Ethnic and Socioeconomic Inequalities in Health —The OBSSR plans to assess the state-of-the-science in measuring SES (socioeconomic status) and race/ethnicity and plans to examine current research on SES and race as they affect health. SES and race/ethnicity have been found to relate to a variety of health outcomes. “While it is well known that minority groups are disproportionately represented in low socioeconomic strata in the United States, less recognized is that at most levels of SES, morbidity and mortality rates are higher for blacks than for whites.” Study is needed on the roles of environment, family, workplace, and community contexts as they interact with SES, race/ethnicity, and health. The report notes that another largely unexplored topic is the way that psychosocial, biological, familial, community, and environmental risk factors can be utilized as potential targets for interventions designed to disrupt the negative effects of low SES or race/ethnicity on health.

Behavioral Change Interventions to Diminish Racial/Ethnic Health Disparities — OBSSR will examine current research on the availability, delivery, and effectiveness of barriers to intervention as a function of racial/ethnic group membership, as well as the mechanisms of intervention which best manage the health outcomes of particular ethnic or racial groups. OBSSR will develop initiatives to stimulate research on behavioral interventions for different ethnic/racial groups.

Health Disparities and Health Care Systems — Increased conceptual and empirical efforts are needed to identify and understand the processes leading to differential health care and to develop intervention strategies. The OBSSR plans to assess the state-of-the-science and develop an agenda for research on racial/ethnic group health differences and health care systems. The research initiatives arising from this assessment are likely to address gaps in both basic and intervention research on racial/ethnic group interactions with health care systems.

The OBSSR’s plan also addresses the need for training and developing scientists. The office will increase its activities to expand the pipeline of minority researchers in behavioral and social sciences, especially students interested in research on health disparities. OBSSR is establishing goals to increase the number of scientists who study health disparities from a multidisciplinary perspective.

The plan also aims to improve NIH Public Health Messages. OBSSR will assess the state-of-the-science in communicating health information to diverse racial and ethnic populations. Working in collaboration with the ICs, OBSSR will organize a task force to review relevant communication theory and research and identify knowledge gaps in developing health communications for specific populations. If significant gaps are identified, the OBSSR, in collaboration with the Institutes and Centers, will develop an initiative to stimulate research in needed areas.

NIH PUBLIC REPS DISCUSS HUMAN SUBJECTS PROTECTIONS

Human subjects research protections was the focus of the fourth meeting of the National Institutes of Health (NIH) Council of Public Representatives (COPR) held on the Bethesda campus October 31 through November 1, 2000. National Bioethics Advisory Commission (NBAC) representative Tom Murray, President of the Hastings Center, and the Department of Health and Human Services’ new Office of Human Research Protection (OHRP) Director Greg Koski presented recommendations and directions for protecting human subjects in research.

The Common Rule (the Federal Policy for the Protection of Human Subjects adhered to by 17 federal agencies and departments) is an albatross to change under an exceedingly difficult set of circumstances, said Murray. The Common Rule, he stressed, is “unsupple,” exemplified by the fact that it took many years for all of the agencies and departments involved to ratify it through a consensus process. To make even minor changes, he continued, is extremely cumbersome.

Murray told COPR members that while the Commission's recommendations regarding human subjects protections are still in draft form, they are the most ambitious recommendations NBAC has made to date. The Commission has released four other reports that discuss ethical challenges and make recommendations concerning specific issues. (see *Update*, October 9).

NBAC has tried to work around changing the common rule, explained Murray. The forthcoming NBAC report, "Ethical and Policy Issues in the Oversight of Human Participants Research," takes the Common Rule head on, he said. In part, he said, the report recommends establishing an independent office with jurisdiction over all research — public and private — that involves human subjects.

The major issues in the oversight project, Murray contends, are the adequacy of the current regulatory framework (including the Common Rule) and the adequacy of the local oversight system of IRBs.

According to Murray, the Commission is considering other specific issues, including analysis of risk and potential benefit, informed consent, privacy and confidentiality, vulnerability, education, monitoring, cooperative research review, accountability mechanisms, and resources.

Some of the key features of the oversight system NBAC is proposing include: a new framework for analysis of "vulnerability;" compensation for research injuries (an issue that has been unresolved for the last 25 years); education of IRB members and investigators in the ethics of human subjects research; increased representation of non-experts and unaffiliated members on IRBs; accreditation of institutions; and greater scrutiny of protocols with high or unknown risk.

Although much of human subjects research is innocuous, Murray explained, educational, social, and behavioral science research is subject to the same intensity of protocol and attention from IRBs.

HHS: The Appropriate Home for OHRP?

Koski differed with NBAC's recommendation for the creation of a new entity outside the Department of Health and Human Services, noting that "HHS is the appropriate home for such an office." He added that there is not a lot of enthusiasm for the creation of a new federal agency. Koski emphasized that OHRP's jurisdiction is broader than many realize and would apply to the private sector.

Echoing many of the comments he made in his presentation before NBAC, Koski explained that the system of funding research has changed significantly since the system was set up 30 years ago (see *Update*, September 25, 2000). Then, most of the research was done by the NIH. The system has not evolved to keep up with change, stressed Koski. The largest sponsor of research now, he continued, is the pharmaceutical industry. That is not bad, he added — just different.

The current system, Koski remarked, was built on respect, benevolence, and justice. Unfortunately, in an environment of limited resources, one gives only what is necessary to meet the minimum obligation. We do not want to provide only the minimum required protection to human subjects, Koski declared, but it is an artifact of the system.

Koski again emphasized the need for a conceptual change, where everyone is engaged and embraces the system. The current system is based on compliance and confrontation. IRBs have been placed in the role of the "worthy adversary." We provide a mechanism that allows the parties involved to say it is not my problem, he remarked. Furthermore, the system is based on impartiality, assuming that the members of the IRBs will forget that their background can color their discussions. We need to reconsider how we construct the process, said Koski.

What Is the OHRP Doing?

Koski told COPR members that the key to changing the system is to remove the IRBs from their position between the subjects and the investigators. He questioned the way that IRBs are

constituted and whether the system for forming IRBs was adequate. Human subjects protection needs to mimic that of the medical research system, he claimed, with apprenticeship and proper training. Koski applauded NIH for its initiation of specific training in bioethics as a step in the right direction.

OHRP, with the support of the NIH, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality, will engage the Institute of Medicine (IOM) to recommend uniform, performance-, and resource-based standards for private, voluntary accreditation of human research review boards, said Koski.

The IOM is expected to complete the report by April 1, 2001. After the accreditation standards have been created, the IOM will also be asked to conduct a study of the human research system to determine the extent to which the issues raised by the Department of Health and Human Services Office of the Inspector General and the recommendations of the forthcoming NBAC report are addressed. The IOM will also be asked to develop objective criteria for measuring the effectiveness of the system for protection of human subjects in research. These criteria will then be used on an ongoing basis for continuing assessment of the system.

Koski concluded his remarks by informing the COPR that his office is in the final stage of selecting the individuals to serve on the newly established National Human Research Protection Advisory Committee (NHRPAC) which will hold its inaugural meeting in December.

NBAC has held a number of public meetings to discuss the issue and receive input from the public. Transcripts of all of its meetings can be found on the NBAC website: www.bioethics.gov. Information regarding OHRP can be found at www.hhs.gov.