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NIH REAUTHORIZATION ON HORIZON: TOUGH ISSUES AHEAD

As we move toward 2004, Congress is expected to shift its attention to reauthorizing the National Institutes of Health (NIH), explained Marc Smolonsky, NIH Associate Director for Legislative Policy and Analysis. Presenting to the NIH Council on Public Representatives (COPR), Smolonsky observed that the agency's basic authority has come from the appropriations committees over the last decade.

Since Congress last reauthorized the agency as a whole in 1993, NIH's budget has grown from \$10.3 billion, to \$27.2 billion in 2003. He noted that most of the increase came a result of the doubling of NIH's budget beginning in 1998 from \$13.6 billion to its current funding level of \$27.2 billion. For FY 2004, the House would fund the agency at \$27.6 billion and the Senate provided \$27.9 billion, relatively small increases. According to Smolonsky, these levels of increases are what the NIH can expect for the foreseeable future.

The Public Health Service Act is the authorizing legislation for the NIH, he related. The Act sets research priorities through organizational structure; authorizes unrestricted biomedical research, authorizes grant making authority, authorizes the peer review process, and allows for training, dissemination of information, human subjects research, and solicitation of input from the public, among many other things.

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GAO RELEASES REPORT ON NIJ'S OUTCOME EVALUATION GRANTS

In September 2003, the United States General Accounting Office (GAO) released a report to Representative Lamar Smith (R-TX), former Chairman of the House Judiciary Subcommittee on Crime, specifying why and how the National Institute of Justice (NIJ) should focus more attention to the design and implementation of the agency's studies that are not producing definitive results. Congress has taken an inordinate interest in the operations of the agencies of the Office of Justice Programs (OJP), of which NIJ is a part, in recent years. A previous GAO study had examined grant monitoring in the Bureau of Justice Assistance, the Office of Juvenile Justice and Delinquency Prevention, and the

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The reason that it has not been particularly urgent for Congress to reauthorize the agency is that programs can continue without being authorized if funds are appropriated. Smolonsky acknowledged, however, that at any time Congress may change existing programs. In addition, Congress may add prohibitions and requirements at will.

During the agency's last reauthorization in 1993, Congress mandated the establishment of the Office of Research Integrity in the Department of Health and Human Services and mandated the inclusion of women and minorities in clinical research. The 1993 reauthorization also created the Office of Behavioral and Social Sciences Research, the Office of Research on Women's Health, the Office of Minority Health, the National Center for Human Genome Research, the Office of Alternative Medicine, and expanded the authority of the Office of AIDS Research.

In 1996 the Senate passed a reauthorization bill but the House did not. The Senate bill elevated the National Center for Human Genome Research to an Institute, created the Office on Rare Diseases, established a pain consortium, increased the amount of funding authorized for Parkinson's Research, and more. All of these actions were subsequently taken either through administrative procedures or separate legislation.

To date, the House Energy and Commerce Committee has held hearings on various aspects of NIH, genomic research and taking the research from "bench to bedside." A rare joint hearing of the Energy and Commerce panel and the Senate Health, Education, Labor and Pensions Committee on the NIH structure was also held on October 2. (See *Update*, October 6, 2003). The hearings, related Smolonsky, are steps towards a reauthorization bill to be introduced in the spring of 2004.

Controversial Issues

There is more potential risk to reauthorization than benefit, Smolonsky explained to COPR members. This is due to a number of controversial issues expected to be focused on by Congress, including sexuality research, stem cell research, fetal tissue research, and politics and science.

Smolonsky informed COPR members that the Toomey amendment to the House Labor, Health and Human Services appropriations bill, which would have rescinded the funding to five specific grants pertaining to sexual behavior and function (see *Update*, July 14, 2003),

was significant in that Congress was attempting to "defund peer-reviewed research." This type of amendment is the "scariest and most dangerous" and was defeated by only two votes. It "needs to be taken seriously" as the "wake up call" that it is.

Grants that relate to sexuality research raise the question of priority setting, noted NIH Director Elias Zerhouni in his Director's report to COPR members. Members of Congress question the value of sexual dysfunction research and want to be assured that the research has merit, he explained.

Smolonsky emphasized to COPR members that Congress is constantly concerned about priority setting. Other potential reauthorization issues include:

- A DARPA-like authority for NIH [The Defense Advanced Research Projects Agency (DARPA) is the central research and development organization for the Department of Defense.];
- Bioterrorism;
- Priority setting (most important);
- Peer review;
- Director's authority (needs to be looked at and expanded in some way);
- NIH structure;
- Small states (Many Congressional districts have no NIH presence, but all 50 states do have at least some NIH presence.);
- Recruitment and training;
- Human subjects protection; and
- Centers of Excellence.

Justifying 200 Grants

Since the October 2 joint House/Senate hearing, the Energy and Commerce Committee has submitted a list of approximately 200 grants for NIH to justify. Many of these grants involve issues related to HIV/AIDS, sexual behavior, homosexual populations, minority populations, and adolescents. A number of institutes are listed, including Mental Health, Drug Abuse, Alcohol Abuse and Alcoholism, Child Health and Human Development, Allergy and Infectious Diseases, Nursing, and Cancer.

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Violence Against Women program. A report on NIJ's Science and Technology office is still to come.

According to the released report, from 1992 to 2002, NIJ managed 96 evaluation studies that sought to measure the outcomes of criminal justice programs. GAO concluded: "Our methodological review of 15 of the 96 studies, totaling about \$15 million and covering a broad range of criminal justice issues, showed that sufficiently sound information about program effects could not be obtained from 10 of the 15." Funded by NIJ through grants and cooperative agreements, seven of the 15 evaluations focused on programs designed to reduce domestic violence and child maltreatment, four focused on programs addressing behavior of law enforcement officers, two focused on programs tackling drug abuse, and two focused on programs dealing with juvenile justice issues. GAO's standard for assessment was whether the studies utilized the randomly assigned experimental method for evaluations.

After examining the evaluations, GAO found that 11 of the 15 studies began with sufficiently sound designs. Five of the 11 studies, totaling about \$7.5 million, were sufficiently well designed, implemented, and had follow up measures that led to meaningful conclusions. These included an Urban Institute study of NIJ's Breaking the Cycle program. The GAO classified these five studies as successful because they had control groups, appropriate comparison groups, or random assignment to treatment, which all lead to producing definitive results.

Six of the 11 studies, totaling \$3.3 million, began with sufficiently sound designs, but encountered implementations problems that limited the extent to which the study objectives could be achieved. These included an evaluation of Chicago's Citywide Community Policing program conducted by researchers at Northwestern University. "In some cases, implementation problems were beyond the evaluators' control, and resulted from the decisions made by agencies providing program services after the study was underway," the GAO emphasized.

Four of the remaining 15 studies had serious methodological problems from the start. "Methodological shortcomings in these studies, which totaled about \$4.5 million, included the absence of comparison groups or appropriate statistical controls, outcome measures with doubtful reliability and validity, and lack of baseline data," the GAO noted. These included an evaluation of the Rural Domestic Violence

and Child Victimization Enforcement grant program conducted by the Cosmos Corporation.

"Although our sample is not representative of all NIJ outcome evaluations conducted during the last 10 years, it includes those that have received a large proportion of the total funding for this type of research, and tends to be drawn from the most recent works," the report asserted. GAO recommends that NIJ: 1) Review its ongoing outcome evaluation grants and develop appropriate strategies and corrective measures to ensure that methodological design and implementation problems are overcome so the evaluations can produce more conclusive results; and 2) Continue efforts to respond to GAO's recommendation that NIJ assess its evaluation process with the purpose of developing approaches to ensure that future outcome evaluations are funded only when they are effectively designed and implemented. The assessment could consider the feasibility of such steps as:

- Obtaining more information about the availability or outcome data prior to developing a solicitation for research; and
- More carefully calibrating NIJ monitoring procedures to the cost of the grant, the risk inherent in the proposed methodology, and extent of knowledge in the area under investigation.

NIJ officials have informed the GAO that the agency has begun to take several steps to increase the likelihood that outcome evaluations will produce more definitive results. With the establishment of an Evaluation Division in NIJ's Office of Research and Evaluation and a new strategy of evaluability assessments, NIJ is confident that these innovative assessments will be quick, cost efficient, and improve its grant making process. Moreover, in Fiscal Year 2004, "NIJ plans to develop new grant 'special conditions' that will require grantees to document all changes in the scope and components of evaluation designs and also conduct periodic reviews of its evaluation research portfolio to assess the progress of ongoing grants."

Assistant Attorney General for OJP Deborah Daniels, however, also noted that GAO's preference for randomized control trials "are not always feasible, and sometimes even non-random comparison groups are unavailable." She continued: "In these cases, evaluators must choose from among other designs that have sufficient scientific rigor while also taking into account numerous factors, such as data availability, cost opportunities for randomization, risk to subjects, likely effect size of the intervention and the availability of appropriate comparison groups. We do not believe GAO

sufficiently took this fact into account in its report or recognizes that these other methods of evaluation are valid means of scientific endeavor.”

The report is available on the web at www.gao.gov/cgi-bin/getrpt?GAO-03-1091.

NCHS HOLDS BOARD OF SCIENTIFIC COUNSELORS MEETING

On October 10, the National Center for Health Statistics (NCHS) held its first meeting with the agency’s newly appointed Board of Scientific Counselors (BSC). The BSC, consisting of 15 members, will provide advice and make recommendations to the Director of NCHS regarding scientific and technical program goals, objectives, strategies, and priorities of the agency. Moreover, BSC shall provide advice on statistical and epidemiological research and activities that focus on issues such as determinants of health, the prevalence of chronic diseases, reducing health disparities, and other top priorities of NCHS.

The meeting convened with opening remarks from NCHS Director Edward Sondik emphasizing the various challenges that NCHS faces as well as enlightening BSC on how the agency has stayed resilient despite inadequate funding. (See *Update*, November 18, 2002). According to Sondik, “We are meeting our mission with limited funding and accommodations. The agency needs sufficient resources for research and development to support Health Statistics.” For FY 2004, the Senate included \$127.6 million plus a one percent set-aside for NCHS, a 1.2 percent increase over the President’s budget request. The House allocated \$126 million plus the one percent set aside, a one percent increase from FY 2004 budget request. The difference between the figures will be worked out in a conference committee.

Sondik informed BSC that without adequate funding, NCHS would have to change field procedures and reduce field staff for the National Health and Nutrition Examination Survey (NHANES) and also reduce the number of surveys in the field for the Health Care Surveys program. Although NCHS is aware of the many future challenges for the agency, Sondik explained that more problems might occur because new health needs have not been accounted for. According to Sondik, “there are a number of areas that need to be addressed, including trajectory of the

elderly, obesity in children, how the health care system works, and lifestyle challenges for people in middle age. We need more funding to address these new problems.”

Following Sondik, Kathryn Porter of the NCHS staff discussed how vital NHANES is to disseminating data to policymakers and government officials. Porter stressed that NHANES is significant to the health of the nation because this survey estimates the prevalence of selected health conditions and risk factors, explores emerging health issues, and monitors health trends over time. NHANES is critical to NCHS because the sample design of this longitudinal survey is comprised of various ethnicities and special populations, which will ultimately provide good epidemiological data. With the new Community Health and Nutrition Examination Survey in its future, NHANES hopes to “establish and maintain a repository of stored biologic specimens for future research” and also gain a better understanding of chronic diseases through studying the relationship of diet, health, and behavior.

Echoing that the National Health Care Survey (NHCS) does not have adequate funds to take its effort to the next stages, Tommy McLemore emphasized that NHCS’ “primary goal is to provide nationally representative data on the use of health care resources in the major sectors of the U.S. health care delivery system.” McLemore asserted that many health organizations utilize NCHS and its data, but often forgot how vital the agency is when funds are appropriated. NHCS data, he explained, is used to:

- Understand healthy care practice;
- Identify and track specific conditions and problems;
- Identify differences in the provisions of services;
- Establish national priorities;
- Provide national comparative points; and
- Measure Healthy People objectives.

With many significant resources needed and not now available, the future of NCHS is very uncertain. Although the agency has tracked national health objectives and provided the nation with essential health statistics, the fact remains that progress will remain stagnant if the agency does not receive adequate funding. NCHS hopes that larger appropriations will allow the agency to develop new initiatives while also maintaining necessary trend data.

COSSA SEMINAR ADDRESSES GLOBALIZATION

As policymakers continue to adapt to the new world scene caused by ongoing fears of terrorism and efforts to combat it, COSSA focused its final congressional briefing of 2003 on globalization. The September 25 seminar was entitled “Rebuilding the World Community: Global Institutions and Interactions in an Era of Terrorism.”

International Organizations

Beth Simmons, Professor of Government at Harvard University, focused her presentation on “Collective Problems, Collective Responses: International Organizations and U.S. Interests in an Era of Terrorism.” She noted at the outset that the last year has been a critical time for the UN because the Security Council has rarely had such a lead role in international events and because “the debate continues over whether the UN is central to world affairs or irrelevant.”

Simmons asserted that the post-September 11 world has created a set of collective problems and that “the U.S. must participate in collective responses.” While “our encounters with the Security Council have been rancorous . . . the United States is going to have to think about the extent and the ways in which it will engage international organizations” to try to solve collective problems.

To provide some historical context, Simmons explained that the United States faced similar choices immediately following World War II as it does today. Rather than taking a unilateral approach to leadership at that time, however, the U.S. adopted a strategy of working through multilateral institutions. The “U.S. supported the creation of the UN to address both the security as well as economic and social issues which were viewed as the roots of WW II.” She also noted that fair international trading and banking systems were established with U.S. support. And the creation of NATO fostered collective security in Europe and organized the U.S.’s closest allies.

Simmons argued that investment in these institutions has paid off handsomely over time for the U.S. NATO has prevented any major wars in Europe over the past 50+ years, the opening of markets around the world has benefited the U.S. economically, and working through the UN, the U.S. received international approval and support for its actions in the Korean War and the Gulf War.

Despite her praise for international institutions, Simmons took time to point out some problems inherent in them. First off, there’s the phenomenon of “soft balancing,” in which an organization will work to frustrate the efforts of a superpower to promote balance. This is similar to what the U.S. has experienced at the Security Council in several of its efforts related to the conflict in Iraq.

Another problem with international organizations is that they have goals separate from those of their member states. They may institutionally push for one course of action over another or take on responsibilities to boost their budget or bureaucracy. Finally, the problem of “democratic deficits” is created because decisions by international organizations are so far removed from the citizens of member states. Simmons mentioned that this has been a particular problem for the European Union, which is often charged with “making decisions over the heads of average Europeans.”

Looking at present events, Simmons noted that the Iraq conflict is demonstrating the cost of going at it alone and that the U.S. would have benefited greatly by working within the frame of UN. She mentioned specifically that the U.S. went outside of the typical application of international law when it asked the Security Council to authorize preemptive force against Iraq last year. This reduced our chance of winning the support that would have brought financial and manpower backing with it.

To conclude, Simmons asserted that the U.S. would benefit in many ways by working through international organizations in the years to come. They help by making solutions to difficult world problems – humanitarian intervention, peacekeeping situations – more palpable. They have a socializing effect – other nations are more likely to support and trust us if they see we are working through established organizations. Finally, they promote public support for national leaders – polls have consistently shown greater public support for military action the U.S. undertakes through NATO or the UN.

International Negotiations and Interactions

Linda Putnam, Professor of Communication at Texas A&M University, discussed “Framing and Transforming Issues in Global Negotiations and Interactions Among Leaders.” She followed up on Simmons’ remarks by noting that the UN is at “its gravest point in history” and that improving communication between global leaders in this day and age is absolutely imperative.

Putnam explained that there are three dominant models of international negotiation: soft negotiation, hard bargaining, and interdependence. Soft negotiation involves trusting your adversaries, making a strong commitment to reach agreement, assuming people will act amicably towards you, and yielding to avoid confrontation. She noted that we know from history that this model only works if everyone is taking the same line and soft negotiation can place you at a competitive disadvantage.

Hard bargaining involves opening negotiations from an extreme position, using coercion and pressure, and seeking, and even pressing, for concessions from the other party. This method is problematic because it makes it very difficult to form alliances and negotiations often progress very slowly. Putnam asserted that the U.S. has used this approach in the war against terrorism – but that agreements are likely to suffer over time as a result.

The interdependence model involves give and take and requires a posture between that of soft negotiation and hard bargaining. It also encourages the participants to take a new look at the situation – understand the needs of the other party while still maintaining firmness on your position. It is imperative to be sensitive to cultural and historical difference and try to resolve sticking points by asking questions and gathering information.

Putnam asserted that the interdependence model isn't used enough in the world community. We need to shift the focus to promote more collaboration. She concluded, "The ultimate goal and ultimate win-win of any conflict is when we change the way we approach the whole situation and we come together . . . where all parties are getting something and gaining from the process."

Economic Leadership

Lael Brainard, Senior Fellow in Economic Studies and Foreign Policy Studies at the Brookings Institution, addressed "U.S. International Economic Leadership Post-Cancun." She explained that there's been a major shift in international economic policy post-September 11 that many people haven't been aware of owing to attention focused on security issues.

Brainard noted that generally, "the exercise of international economic power by the U.S. is more often than not fairly incoherent." Over time, our leadership has been affected by both domestic politics and foreign policy concerns. Historically, the U.S. long had a multilateral approach to trade policy. This was revised slightly in the 1980s as we adopted a bilateral agreement

with Israel and in the 1990s as the bilateral pact we formed with Canada was ultimately regionalized into the North American Free Trade Agreement.

Brainard asserted, however, that the current Administration shifted drastically towards a bilateral approach, driven largely by philosophy. She explained that economists worry about a bilateral trade policy because it "diverts trade from the most efficient trading partners to the ones that have the best deal worked out among governments." A bilateral policy has also put the U.S. in a very complicated foreign policy position.

For example, we recently finished new pacts with Australia and Singapore, while negotiations with New Zealand and Chile stalled. This is due, in large part, to the fact that Australia and Singapore supported us on the Iraq war, while New Zealand and Chile defied us on votes. As a result of this policy, Brainard pointed out that the list of the top 10 countries we should open business with differ greatly between the U.S. Chamber of Commerce and the Administration. She noted "We have tremendous power on bilateral agreements . . . but that our interests as a global leader are very badly served" by adopting the position we have.

In turning to the issue of foreign aid, Brainard explained that our use of aid can greatly help our situation in global politics. For example, the European Union tends to outmaneuver the U.S. in international organizations because it is currently providing about 70 percent of the development assistance around the world. When the disagreement arose between the U.S. and France and Germany over the Iraq war, this could have played a role in the fact that we couldn't win UN backing for the conflict. As a result, we have paid 93 percent of the costs in the current war, versus only 15 percent of the costs in the Gulf War, which had UN support.

COSSA will prepare edited transcripts of the seminar, which included a lively question and answer period. These should be available in December. If you would like to request a copy, please e-mail cosssa@cosssa.org.

NIH CHOOSES POPULATION HEALTH AND HEALTH DISPARITIES CENTERS

On October 2, the National Institutes of Health (NIH) announced the creation and recent grant awards, which total \$60.5 million over the next five years, for eight Centers for Population Health and Health Disparities. The Centers, which derived from recommendations of recent reports from the National Academy of Sciences (NAS), are a trans-NIH initiative designed to support cutting edge research to understand and reduce differences in health outcomes, access, and care.

Funded by the National Institutes of Environmental Health Sciences (NIEHS), the National Institute of Aging (NIA), the National Institute of Cancer (NCI), and the Office of Behavioral and Social Science Research (OBSSR), the Centers "will follow a community-based research approach that involves community stakeholders in the planning and implementation of research focusing on obesity, cardiovascular disease, breast cancer, prostate cancer, cervical cancer, mental health, gene-environment interactions, psychosocial stress, and other factors."

"We, at NIH, realize there are complex challenges ahead to reduce health disparities in communities. However, our holistic approach will address public health problems through a community based research approach," stated NIH Deputy Director Raynard Kington. During his remarks, Dr. Kington explained that this research would address the health disparities that are at the core of NIH priorities and that "progress in reducing disparities will happen because we [the community of scientists] will make it happen." The eight grants will be awarded to:

1. **Ohio State University and the University of Michigan** – address barriers to cervical cancer screening in women;
2. **RAND Corporation** – assess the impact of Los Angeles park improvements on the physical activity and health of local residents;
3. **Tufts University and Northeastern University** – understand the factors that lead to poor health outcomes, and determine how these processes link to the health disparities observed in minority communities;
4. **University of Chicago and University of Ibadan in Nigeria** – test the hypothesis that social isolation and excess stress in African-American women of African ancestry increase the risk of early, lethal breast cancers;
5. **University of Illinois at Chicago** – examine the effects of social context on stage of breast cancer diagnosis;
6. **University of Pennsylvania** – evaluate how biological, clinical, and behavioral factors are predictive of various prostate cancer outcomes;
7. **University of Texas at Galveston** – explore the relationship between neighborhood context and measures of health among Hispanics;
8. **Wayne State University** – examine the effects of stressors, obesity, and genetic variation on the salt sensitivity in African Americans who are at risk for hypertension and cardiovascular diseases.

"These centers will perform innovative research, collaborating extensively to address the important and complicated issue of health disparities," noted NIH Director Elias Zerhouni, who was not in attendance because of a Senate NIH Oversight Hearing. The announcement concluded with various remarks from the institute directors giving insight as to how their institutes will share more information and form special task force to efficiently work together and reach the common goal of reducing health disparities.

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