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COSSA Washington Update

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ECONOMIC RECOVERY LEGISLATION ENACTED; SCIENCE FARES VERY WELL

On February 17, President Obama signed the American Recovery and Reinvestment Act (aka the Stimulus Package). After weeks of negotiations among the White House, the Congress, and three key Republican Senators, the legislation emerged with the hope that it will help the American economy recuperate from its current illness. Within its many provisions are significant amounts of funding for science activities.

The National Science Foundation (NSF) will receive \$3 billion. This is the number from the House version and Speaker Nancy Pelosi (D-CA) advocated strongly on behalf of NSF to her Senate colleagues, who wanted NSF to get only \$1.4 billion. Of the \$3 billion, \$2.5 billion will go the Research and Related Activities Account, which funds the research directorates, including the one for Social, Behavioral, and Economic Sciences. Within the \$2.5 billion, \$300 million will add funds to the Major Research Instrumentation program and \$200 million will support academic facilities modernization.

The Education and Human Resources Directorate will receive \$100 million. Congress designated this funding as follows: \$60 million for the Robert Noyce Scholarship program to encourage undergraduates to go into K-12 science and math teaching; \$25 million for the Math Science Partnership program; and \$15 million to support a Professional Master's Degree program. The law also provides NSF with \$400 million for its Major Research Equipment and Facilities program to fund the construction of large science infrastructure projects. The Inspector General's office will also receive an additional \$2 million.

NSF is required to provide an Operating Plan detailing how they will spend the \$3 billion within 60 days of the enactment of the law. Congressional staff has suggested that NSF will probably use its regular submission and evaluation process to distribute the research funds.

With Sen. Arlen Specter (R-PA) as one of the three Senators key to the enactment of the package, it is no surprise that the National Institutes of Health (NIH) became one of the big winners in the legislation. Specter ensured the inclusion of \$10 billion for NIH. Of that amount, \$8.5 billion will support research and \$1.5 billion will fund construction projects. At a meeting for the science community, NIH Acting Director Raynard Kington spelled out how NIH will use this windfall (see following story).

The \$1 billion for the Census Bureau survived through the negotiations and made it into the final bill. The funds, according to the conference report, are "to hire additional personnel, provide required training, increase targeted media purchases, and improve management of other operational and programmatic risks." In addition, of the amounts provided, "up to \$250 million shall be for partnership and outreach efforts to minority communities and hard-to-reach populations."

Also surviving through the final version of the legislation was the \$1.1 billion for comparative effectiveness research. Within the total, \$300 million shall be administered by the Agency for Healthcare Research and Quality (AHRQ), \$400 million shall be transferred to the National Institutes of Health (NIH), and \$400 million shall be allocated at the discretion of the Secretary of Health and Human Services. (For more on this provision and its accompanying language see later story on CER).

The Conference also managed to salvage \$1 billion for a new Prevention and Wellness Fund. The House version included \$3 billion; the original Senate version had raised that to \$5.8 billion. The Nelson-Collins amendment, which became the version passed by the Senate, had zeroed out the funding.

Also making into the final version of the legislation was the \$250 million the House allocated to the Institute of Education Sciences for Statewide Data Systems to track student achievement.

Among the provisions dropped in conference were the \$100 million in the original Senate version (reduced to \$50 million in the Nelson-Collins Amendment) for the Agriculture Food and Research Initiative (AFRI) in the Cooperative State Research, Education and Extension Service. The House had provided no funds.

With this legislation out of the way, the Congress can turn its attention to completing the FY 2009 appropriations process. The Continuing Resolution that is currently funding all of the agencies except Defense, Homeland Security, and Veterans' Affairs expires on March 6.

KINGTON BRIEFS SCIENTIFIC COMMUNITY ON NIH'S PLANS FOR STIMULUS

On February 17, Acting National Institutes of Health (NIH) Director Raynard S. Kington met with a gathering of more than 200 representatives of the scientific community to discuss NIH's approach to the \$10.4 billion in stimulus funding provided in the American Recovery and Reinvestment Act (ARRA). He began by summarizing the legislative breakdown of the funding.

The bill allocates \$8.2 billion to the Office of the Director for research priorities. Of that sum, \$7.2 billion will be transferred to the NIH Institutes and Centers (ICs) and the Common Fund, based on their proportion in the most recent appropriations bill. There is also \$800 million set aside from that allocated to the Common Fund for the Office of Director for scientific and public health priority research identified by the ICs, "without a pre-formula" and designed to support a range of activities. According to the Joint Explanatory Statement of the conferees, the intent is for the funds to be used "for purposes that can be completed within two years" with priority placed on "short-term grants that focus on specific scientific challenges, new research on public and international health priorities."

The National Center for Research Resources (NCRR) receives \$1 billion for renovation, improvement and construction of extramural research facilities. Another \$300 million will go to NCRR for shared instrumentation and other research equipment. NIH will use \$500 million for renovation and construction of building and facilities on its campus. The Agency for Healthcare Research and Quality (AHRQ) will transfer \$400 million to NIH to fund competitive effectiveness research (see related story).

According to Kington, "the agency is at a good position and well poised to make good decisions" and credited former NIH director Elias Zerhouni's leadership. He stressed that the funds must be obligated by September 2010, and that none of the funds have been added to the NIH's base. He emphasized that "this is not business as usual" and that the community should not look at the funding as an opportunity to recoup prior cuts. He repeatedly emphasized that the ARRA funding has a strict two-year horizon. NIH will make all of the spending decisions associated with the distribution

of these dollars with the recognition that the funds must be obligated within this two-year time frame. He noted that some kinds of research, such as clinical trials, do not lend themselves well to this time restraint.

Using the buckets as a metaphor, Kington explained that most of the funding will be allocated to three "big buckets" that will be subject to peer review. The distributions will be based on the ICs strategic plans and the overall mission of the agency.

1. **Funding R01s or Investigator-Initiated Research** - The FY 2008 funding cycle did not allow the funding of approximately 14,000 applications for four-year awards that were approved via the peer review process. ICs will examine the grants to identify those proposals that are candidates for two-year funding, with the reasonable expectation that two year funding would be productive and allow for important scientific findings. "There are no promises for future funding."
2. **Supplements to Existing Grants** -- This includes competitive, administrative, and theme-oriented supplements to existing NIH-supported grants. The supplements would allow for expansion of the research of the original grant. Training and equipment were cited as possible themes. The agency would follow its usual procedures.
3. **Challenge Grants** - Two-year awards in areas ICs identify as priority areas for their respective institutes, representing important research and public health areas, or are viewed as cross-cutting. These new grants that will be funded via new requests for applications (RFAs), with shortened applications, via expedited peer review, and will be supported at a level up to \$500,000 each year, for two years. NIH expects that the total amount of funding for this mechanism would be \$100 - \$200 million, conditioned on the quality of the responses. The details of the program, however, are still being developed.

Kington stressed that the NIH will rely on the peer review process to determine scientific merit and will be guided by scientific and public health needs in identified areas for funding. Sensitivity to geographical areas would be a consideration given that the purpose of ARRA is to provide an economic impact to the country, but the process would not be formulaic.

He also emphasized that ARRA requires recipients and NIH to provide an unprecedented level of reporting, including the number of jobs created and preserved. To that end, on February 18, OMB transmitted initial implementation guidance for ARRA to the heads of departments and agencies. It is the first installment of government-wide guidance for carrying out programs and activities under the recovery act. The Guidance outlines the "necessary enhancements to standard processes for awarding and overseeing funds to meet accelerated timeframes and other unique challenges posed by the Recovery Act's transparency and accountability framework."

Responding to a question regarding comparative effectiveness research, Kington stated that the NIH currently does a fair amount of this research and would work closely with the Agency for Healthcare Research and Quality Research and the Office of the Secretary in determining how to spend the funds.

Regarding new investigators, Kington noted that concern for these and other young faculty would be integrated into everything the agency does. He suggested that supplements were possible and that the agency was looking at the array of opportunities before it.

Kington was asked whether the recent changes to the peer review process might be suspended or expedited due to the expected crush on the system. He answered that the improvements to the system have made the NIH better situated to deal with the expected volume, noting that the timing could not be better for implementing the changes, and that some of the changes may actually be accelerated, such as the on-line review process.

Another questioner wanted to know whether the two-year spending window was firm and whether no-cost extensions would be available. Kington underscored that if a researcher or institution could not spend the funds within the two-year time frame allotted, they should not apply. The NIH is committed to the goal of using these funds to stimulate the economy. To do otherwise, he concluded, would be an embarrassment to the community.

SENATE COMMITTEE HEARS FROM OSTP AND NOAA NOMINEES

On February 13, the Senate Commerce, Science, and Transportation Committee, chaired by Sen. Jay Rockefeller (D-WV) held confirmation hearings for John Holdren, nominated by President Obama as the new director of the White House Office of Science and Technology Policy (OSTP), and Jane Lubchenco, designated by the Administration as the new Administrator for the National Oceanographic and Atmospheric Administration (NOAA).

Holdren is the Teresa and John Heinz Professor of Environmental Policy and Director of the Program on Science, Technology, and Public Policy at the Kennedy School, as well as Professor of Environmental Science and Public Policy in the Department of Earth and Planetary Sciences at Harvard University. He is also the Director of the Woods Hole Research Center and a past President of the American Association for the Advancement of Science (AAAS). Lubchenco is the Wayne and Gladys Valley Professor of Marine Biology Distinguished Professor of Zoology, Oregon State University. She is also a past President of the AAAS and the Ecological Society of America.

Before the hearing began Rockefeller announced the Committee's new Subcommittee leaders. Sen. Bill Nelson (D-FL), who has flown in space, will chair the Science and Space panel, while Sen. John Kerry (D-MA) will lead a panel on Communications and Technology. Rockefeller also committed the Committee to "tough oversight."

Holdren told the Committee that Science and Technology (S&T) Policy consists of two major strands: "policy for science and technology," i.e., policies related to strengthening the research and development enterprise; and "science and technology for policy," i.e., how to use insights from science and engineering to help shape sensible policies. OSTP's role, according to Holdren, is to cover "this wide and critically important terrain in the White House and in interaction with other Executive Branch agencies and the Congress."

In discussing the "major challenges facing our country at the intersection between S&T and the economy, the environment, and national security," Holdren began by joining countless other defenders of investment in S&T by citing economic studies concluding that a large proportion of the economic growth in the U.S. in the past half century "are directly attributable to scientific and technological advances." To continue this growth, Holdren asserted, the U.S. must maintain "strong and balanced federal research programs that support promising areas of R&D [research and development] that are too far from obvious application, too uncertain in outcome, too costly, or too related to public as opposed to private goods to attract private funding." Even in these times of economic crisis, Holdren warned, "we must resist the temptation to reduce our investments in these foundations of our prosperity."

OSTP has an important function, Holdren maintained, to promote the translation of R&D results into new products and services that benefit Americans. Nowhere will that be more important in the near future, Holdren declared, than at the "demanding intersection of energy, national security, and climate change." In his testimony, Holdren also touched on information technology, space, international research partnerships, nuclear nonproliferation, and science education.

Lubchenco told the Committee that the role of science is to inform, not dictate policy. At the same time, she suggested that she hoped that social decisions would rely on scientific information. She viewed NOAA as the premier government agency for applied research. In discussing NOAA's role in climate change research, she advocated for a National Climate Science Council similar to the National Space Council that President Obama has announced he will revive.

Hutchison and the Social Sciences Again

In questioning Holdren, Sen. Kay Baily Hutchison (R-TX), the Ranking Republican on the Committee, expressed her strong support for more research in the basic sciences. As she has done on previous occasions, the Senator suggested that this did not include the social sciences (see Update, May 15, 2006). In fact, she again expressed her concern that these sciences had become too large a part of the National Science Foundation (NSF). Holdren agreed with her on the importance of basic research, but did not respond to her concern about the social sciences. He did note the enactment of the America COMPETES Act as indicating congressional support for basic research. The COMPETES Act includes the social sciences as one of the priority areas for NSF support (see Update, August 6, 2007).

Rockefeller asked the witnesses how one protects the use of science especially on controversial political questions. He was concerned about the arguments over climate change that created opportunities for the previous administration to move slowly. Holdren noted that in policy discussions, "scientific facts are something, but not everything." Even in science, he related, there will always be a diversity of opinions, but that decision makers should go with the center of gravity or the consensus of experts. Furthermore, he also suggested, that all "science is contingent" in the expectation of future knowledge. However, Holdren strongly asserted that global warming is real and accelerating, it is caused by human activity, and it is time to do something about it.

Although praise for both nominees was high from both political sides, there was one exception. Sen. David Vitter (R-LA) sharply questioned Holdren about statements he made beginning in the 1970s that the Senator found alarming and “disqualifying.” These included remarks about the possibilities of mass deaths from starvation because of climate change and some predictions about the future that have not come to pass.

Rockefeller hoped the nominations could pass the Senate under unanimous consent in the very near future.

HOUSE PASSES NEW NANOTECHNOLOGY INITIATIVE BILL; MUCH EMPHASIS ON HEALTH, SAFETY AND SOCIAL IMPLICATIONS

On February 11, the House of Representatives passed the National Nanotechnology Initiative Amendments Act of 2009, which revises the 21st Century Nanotechnology Research and Development Act enacted in 2003. A similar bill passed the House last year, but Senate inaction meant starting all over in 2009.

The legislation has many provisions regarding the Ethical, Legal, and Social Implications of this new technology, explained so well by Julia Moore of the Woodrow Wilson Center’s Project on Emerging Technologies at COSSA’s Annual Meeting in 2007 (see Update, December 10, 2007). In the revised version, the focus shifts from ethical and legal issues to education, environmental, and safety concerns.

The legislation requires the National Nanotechnology Coordination Office to develop a database that provides information to the public concerning projects funded under the Environmental, Health and Safety, Education and Societal Dimensions, component.

The bill makes the National Nanotechnology Advisory Panel a distinct entity. It instructs the Panel to form a sub-panel to assess whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the program.

The Director of the Office of Science and Technology Policy, according to the legislation, must designate an associate director of that Office as the Coordinator for the Societal Dimensions of Nanotechnology. The Coordinator would assume responsibility for overseeing the coordination, planning, and budget prioritization of activities required by the program to ensure that the ethical, legal, environmental, and other appropriate societal concerns, are considered during the development of nanotechnology.

The bill requires that a panel develop a research plan for the Environmental, Health, and Safety program component area. It specifies that the above-noted Coordinator’s responsibilities also include: (1) ensuring that the plan for the environmental, health and safety research activities is developed, updated, and implemented and that such plan is responsive to the recommendations of the sub-panel of the Advisory Panel; (2) encouraging and monitoring the efforts of participating agencies to allocate resources and management necessary to ensure that such societal concerns related to nanotechnology, including human health concerns, are addressed; and (3) encouraging the agencies to identify, assess, and implement mechanisms for the establishment of public-private partnerships for support of environmental, health, and safety research.

In the education area, the bill directs the Director of the National Science Foundation (NSF), as part of the mathematics and science education partnership program, to provide one or more grants to establish Nanotechnology Education Partnerships and requires each such partnership to include one or more businesses engaged in the production of nanoscale materials, products, or devices. These partnerships should be designed to recruit and to help prepare secondary school students to pursue postsecondary level courses in nanotechnology.

The Education and Societal Dimensions program component area should, according to the bill, support efforts to introduce nanoscale science, engineering, and technology into undergraduate science and engineering education through a variety of interdisciplinary approaches. These include: the development of courses or modules to existing courses; faculty professional development; and the acquisition of equipment and instrumentation suitable for undergraduate education and research in nanotechnology. In addition, activities involving informal, precollege, or undergraduate nanotechnology education must include education regarding the environmental, health and safety, and other societal aspects of nanotechnology.

Finally the bill directs the National Science and Technology Council to establish under the Nanoscale Science, Engineering, and Technology Subcommittee, an Education Working Group to coordinate, prioritize, and plan the educational activities supported under the Program.

YOUTH VIOLENCE PROBLEM AND SOLUTIONS EXAMINED BY HOUSE JUDICIARY PANEL

In the FBI's 2009 National Gang Assessment, one million street gang members were counted in 2008, representing a 25 percent increase in new gang members since 2005. The assessment shows that gang membership is on the rise in cities, suburbia, and rural areas.

On February 11, the Committee on the Judiciary's Subcommittee on Crime, Terrorism and Homeland Security, chaired by Bobby Scott (D-VA), held a hearing on "Youth Violence: Trends, Myths and Solutions." The witnesses included: Barry Krisberg, President, National Council on Crime and Delinquency; Dorothy Johnson-Speight, Founder, Mothers in Charge, Philadelphia, PA; Steve Trubow, Head of Olympic Behavior Labs, Port Angeles, WA; Irving Bradley, Jr., Chief, Trenton, New Jersey Police Department; Robert Woodson; Founder and President, Center for Neighborhood Enterprise, Washington, DC; and Beverly Coleman-Miller, Senior Medical Consultant, Health Education Network, Washington, DC.

Krisberg reported on an Annie E. Casey Foundation-funded study to assess the intersection of media coverage of youth crime, public perceptions, public policy, and trends in youth crime in three US cities: Dallas, Texas, Washington, DC, and San Mateo, California. The study found that public perception of violent crime is largely a function of media coverage of crime, especially youth crime. This media coverage does not reflect a sufficiently thorough or, in many cases, accurate understanding of youth or youth crime. Far too much coverage focuses on infrequent but heinous cases, without any context. Professionals in the juvenile justice system recognize that discussions of crime trends need to have a comprehensive, evidence-based perspective that should be founded on accurate and timely data. Communities often need to respond to shorter-term crime trends, and changes in police tactics can be an effective part of that response. Public fear can be kept in check when the system is responsive. However, the study concluded, the law enforcement response needs to be planned and carried out responsibly, strategically, and not in a panic mode.

Bradley testified on behalf of FIGHT CRIME: INVEST IN KIDS—a nationwide, bipartisan group of chiefs, prosecutors, sheriffs, and victims of violence dedicated to examining the research on what brings kids into contact with the criminal justice system, and the most effective ways to direct them toward lives of safety, responsibility, and positive achievement. As a police chief, Bradley has embraced community problem solving as the key to reducing youth crime. Woodson's group has pioneered a youth crime reduction program called the "Violence Free Zone" (VFZ) initiative. Young adults are recruited from the same communities experiencing the problems, and they serve as moral mentors and character coaches to other young people. According to Woodson, the program's success has been validated by researchers at Baylor University.

Coleman-Miller is associated with UNITY, a national initiative funded by the Centers for Disease Control and Prevention to support cities in preventing violence before it occurs through what has been called the public health approach. Cities working with UNITY have identified a set of key strategies that would support violence prevention efforts in cities. The "upfront" strategies are: positive early care and education; positive social and emotional development; parenting skills; mentoring; quality after school programming; youth leadership; social connections in neighborhoods; quality education; and economic development. "In the thick" strategies are mental health services, family support services, street outreach, and mentoring. Aftermath strategies are successful reentry and mental health services.

Mothers-in-Charge, Johnson-Speight testified, provides mentoring services to youths in places like the Philadelphia Industrial Correction Center and believes there is a culture of violence among our youth. Trubow's group focuses on the dropout problem among minority youth seeing a direct connection between that situation and juvenile crime.

Youth PROMISE Act Reintroduced to Help Reduce Crime

In addition to holding the hearing, Scott and Rep. Mike Castle (R-DE) re-introduced the Youth Prison Reduction through Opportunity Mentoring, Intervention, Support and Education, or Youth PROMISE Act on February 13. Companion legislation was also introduced in the Senate by Sens. Robert Casey (D-PA) and Olympia Snowe (R-ME).

"All the credible research and evidence shows that a continuum of evidenced-based prevention and intervention programs for at risk youth will greatly reduce crime and save much more than they cost. This is what the Youth PROMISE Act will do," said Scott. Research evidence on youth crime was part of the discussion at a recent policy briefing sponsored by George Mason University's Center for Evidence Based Crime Policy (see Update, February 9, 2008).

The Youth PROMISE Act would implement policy recommendations from policy makers, researchers, practitioners, analysts, and law enforcement officials, using evidence and research-based strategies to reduce youth violence and crime. Local councils called the Promise Coordinating Council (“PCC”), which would include representatives from law enforcement, court services, schools, social service organizations, health and mental health providers and community-based organizations, would be formed to help develop a comprehensive plan for implementing these evidence based prevention and intervention strategies.

The bill would also provide law enforcement support through the “Youth Oriented Policing Services” (YOPS), and a victim/witness assistance program. The Youth PROMISE Act also includes new provisions to provide additional grants to high intensity gang localities to fund police and community programs to provide crime prevention, research, and intervention services.

Chairman Scott remarked during the hearing that “law enforcement alone will not reduce crime.” There is now evidence that Congress and communities across the country are interested in more comprehensive approaches to youth violence than “lock them up and throw away the key.”

Testimony from the hearing can be found at: http://judiciary.house.gov/hearings/hear_090211.html

COMPARATIVE EFFECTIVENESS RESEARCH: THE VIEW FROM NHLBI; FUNDING INCLUDED IN THE STIMULUS BILL

At the 233rd advisory council of the National Heart, Lung, and Blood Institute, the Council was heard about the status of Comparative Effectiveness Research (CER) from the Institute’s and the National Institutes of Health’s (NIH) perspective. NHLBI’s Director of the Division of Prevention and Population Sciences, Michael S. Lauer discussed the Institute’s support for CER. Noting that health care is front and center for the Obama Administration, Lauer began by quoting the President, “Homes have been lost, jobs shed, business shuttered. Our health care is too costly, our schools fail too many. . . The question we ask today is not whether our government is too big or too small, but whether it works, whether it helps families find decent jobs at a decent wage, care they can afford, a retirement that is dignified.”

Accordingly, CER is a “hot” issue, he noted. He pointed to the 2007 Congressional Budget Office (CBO) paper prepared by then- CBO director and current Office of Management and Budget director Peter R. Orszag at the request of the Chairmen of the Senate Budget and Finance Committees. The paper examines options for expanding support for research on comparative effectiveness and reviews the current state of the research in both the public and private sectors. Additionally, the CBO paper discusses the different types of research that could be pursued and their likely benefits costs. Mechanisms for organizing and funding additional research efforts are also discussed. The paper further considers the “potential effects that such research could have on health care spending and the difficult steps that public and private insurers would probably have to take to achieve substantial savings on the basis of that research - in particular, changing the financial incentives for doctors and patients to reflect that information.”

Noting that our health care is excessively costly as a result of our doing more procedures along with paying more for them, Lauer explained that policy makers are beginning to ask what are we getting for our dollars. There are multiple metrics that one can use to assess population health, but in general the U.S. does not fare well. He pointed out that Japan has higher life expectancy despite the fact that they spend less than the U.S. on health care. At the same time, Medicare and Medicaid spending is rising and in the near future spending on these two programs will squeeze out spending on all other programs if action is not taken. Lauer also explained that according to the data, health care costs varied by geographic regions with unexplainable differences in adjacent regions.

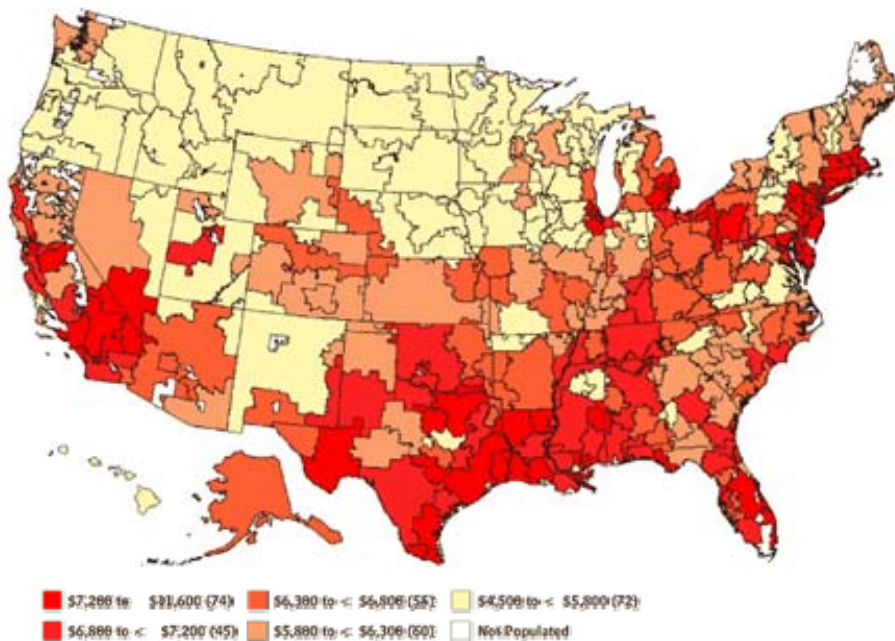
The data also suggest that “higher costs do not lead to better outcomes.” Lauer explained that the aging of the population is only a tiny part of health care costs. He noted that according to the 2007 CBO report, “Only a limited amount of evidence is available about which treatments work best for which patients and whether the added benefits of more-effective but more-expensive services are sufficient to warrant their added costs - yet the current trends to adopt more-expensive treatments even in the absence of rigorous assessments of their impact. . . .”

CER, Lauer explained, is defined as a “rigorous evaluation of the impact of different options that are available for treating a given medical condition, for a particular set of patients.” It may “compare similar treatments, such as competing drugs - or analyze different approaches, such as surgery vs. drug or it may focus only on the relative medical risks and benefits or may weigh both costs and benefits,” he explained to the Council. “It is not a new concept,” he clarified and cited several examples of CER supported by the NIH, including Coronary Artery Surgery Study (CASS),

Cardiac Arrhythmia Suppression Trial (CAST), Diabetes Prevention Program (DPP), Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack (ALLHAT), and National Lung Screening Trial (NLST).

Medicare Spending per Capita in the United States, by Hospital Referral Region, 2003

Source: *The Dartmouth Atlas of Health Care.*



CER, while not new, is not so simple, Lauer declared, noting that the biomedical community is often more interested in efficacy than effectiveness. Common themes of CER include the ability to make a valid comparison, “real world” effectiveness, and “real outcomes, including length of life, quality of life, major clinical events, and costs. The major policy assumptions driving the interest in CER include the belief that technology is a major driver of costs, geographic variations reflect no evidence of benefit, the need for better evidence to slow cost increases while at the same time maintaining or improving quality and outcomes, and the belief that cost savings may be substantial.

CER efforts at the federal level include: the Agency for Healthcare Research and Quality (AHRQ), which is a major focus of the CBO report and funds evidence centers and CER reviews, and currently spends \$50 million of its \$300 million budget with a staff of 300; the Center for Medicare and Medicaid Services (CMS) which has an indirect role in research through its payment of certain procedures that are part of a trial; the NIH which spends more than any other entity (approximately \$700 million); and the Institute of Medicine which convenes an Evidence-Based Medicine Roundtable of which NHLBI Director Betsy Nabel is a member.

Lauer stressed that CER is a priority for NHLBI. It is goal 3 in the Institute’s Strategic Plan-- “To generate an improved understanding of the processes involved in translating research into practice... evaluate its risks, benefits, and costs of diagnostic tests and treatments in representative populations and settings”

<http://apps.nhlbi.nih.gov/strategicplan/Default.aspx>.

The wider CER debate, according to Lauer, has focused on governance (a federal structure?) and priorities (how should they be assessed?), levels of evidence (randomized controlled trials, practical clinical trials or observational studies which are perhaps cheaper, faster, and generalizable), translation into practice, inclusion of cost effectiveness, diagnostic tests, imaging, genomics, and the degree of cost savings. Concluding his presentation, Lauer reiterated that CER is front and center with a political environment that is ripe to move the field forward and that the NIH has been highly successful in initiating, supporting and conducting CER and should promote its interest in furthering CER.

Congress Provides Funding for CER in the Stimulus Bill

The recently passed American Recovery and Reinvestment Act includes \$1.1 billion in funding for CER. Of that sum, \$300 million is provided to AHRQ, \$400 million is assigned to the NIH via transfer from AHRQ to NIH, and \$400 million is

provided to the Office of the Secretary of the Department of Health and Human Services (HHS). The conference agreement notes that the Congress uses the term, "comparative effectiveness research," as proposed by the House and deleted without prejudice the term "clinical," which was included by the Senate. The report language accompanying the conference report emphasizes that "it is not the intent of the Congress for the comparative effectiveness research funding included in the conference agreement to be used to mandate coverage, reimbursement, or other policies for any public or private payer." The funding provided via ARRA is for the conduct or support of research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition. The conferees stated that a "one-size-fits-all" approach to patient treatment is not the most medically appropriate solution to treating various conditions and included language to ensure that subpopulations are considered when research is conducted or supported with the funds provided in the conference agreement.

The Congress, via ARRA, also instructs the HHS Secretary to support an Institute of Medicine (IOM) study and provides up to \$1.5 million in support. The IOM report is to be submitted to the Congress and the Secretary by June 30, 2009. The report is to include recommendations on the national priorities for comparative effectiveness research to be conducted or supported with the funds provided in the stimulus and "must consider input from stakeholders." The Congress also directs the Secretary to consider any recommendations of the Federal Coordinating Council for Comparative Effectiveness Research also established by the stimulus legislation, as well as any recommendations included in the IOM report.

Any grants and contracts awarded ARRA funding will be required to offer an opportunity for public comment on the research. In addition, research conducted with funds appropriated under ARRA will be required to comport with HHS policies relating to the inclusion of women and minorities in research. The Secretary will be required to submit an annual report on the research conducted or supported by ARRA funds to the House and Senate Committees on Appropriations, Senate, the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate.

In addition, the Secretary jointly with the Directors AHRQ and NIH are required to provide the House and Senate Appropriations Committees a FY 2009 operating plan for the funds appropriated under this heading prior to making any "Federal obligations of such funds" in FY 2009, but not later than July 30, 2009. Likewise, a FY 2010 operating plan is required prior to making any Federal obligations of funds in FY 2010, but not later than November 1, 2009. The plans are required to include such details as the type of research being conducted or supported, including the priority conditions addressed; and specify the allocation of resources within the Department of Health and Human Services. Lastly, the Secretary, jointly with the Directors of AHRQ and NIH, will be required to provide the Appropriations Committees a report on the actual obligations, expenditures, and unobligated balances for each activity funded under this heading not later than November 1, 2009, and every 6 months thereafter as long as funding provided under this heading is available for obligation or expenditure.

STATE DEPARTMENT HISTORY OFFICE DISPUTE THREATENS FOREIGN RELATIONS DOCUMENT SERIES

In her last days as Secretary of State, Condoleezza Rice received a report from a hastily convened review panel that examined the management of the Historian's Office (HO) at the Department. The review was precipitated by the resignation of former American Historical Association President Roger Louis who was chairing the Department's Historical Advisory Committee (HAC). Warren F. Kimball, Professor Emeritus of History at Rutgers University chaired the panel. He was joined by Ron Spector, Professor of History and International Affairs at the Elliot School at George Washington University, and Ruth Whiteside, Director of the Foreign Service Institute.

The report concluded that "the current working atmosphere in the HO and between the HO and the HAC poses real threats to the high scholarly quality of the Foreign Relations of the United States (FRUS) series and the benefits it brings." The FRUS, according to the State Department, presents the official documentary historical record of major U.S. foreign policy decisions and significant diplomatic activity. The series began in 1861 and now comprises more than 350 individual volumes. The volumes published over the last two decades increasingly contain declassified records from all the foreign affairs agencies. It is a major source for scholars of diplomatic history and international relations.

The panel also suggested that "there are major management challenges in the HO that warrant serious consideration of a reorganization of the office." It noted further, "whosoever is the Historian should have clear and unequivocal work requirements that set forth improving morale and trust within the office as a primary and immediate goal." In addition,

there is a need to “develop clear paths for the HAC” to bring serious professional concerns to the attention of the appropriate authorities.

One result of the review is the suspension of the current search for a new editor of the FRUS series until after the management decisions have been made, presumably by new Secretary of State Hillary Clinton.

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