111th Congress Seeks Closure

With possibly less than a week to go, the 111th Congress seeks to complete its work and go home. The tax measure negotiated by President Obama and the Republicans is front and center on the agenda at the moment.

Following its disposition, the dying Congress will turn its attention to settling FY 2011 spending for the government's agencies and programs. The current Continuing Resolution (CR) expires on December 18. The still-Democratically controlled House has enacted a new CR that will fund agencies and programs at their FY 2010 levels for all of FY 2011, with some anomalies, e.g. the Census Bureau whose funding would be reduced from the large levels needed to conduct the 2010 count. The Senate Appropriations Committee, chaired by Sen. Daniel Inouye (D-HI), is trying to put together an Omnibus Appropriations package that would include funding normally found in the twelve separate spending bills. These would include negotiated levels for agencies for FY 2011 reflecting the earlier work of the twelve subcommittees that produce the individual spending bills. Whether Inouye can pull this off depends on cooperation from Senate Republican appropriators and the House.
Republicans eager to take over the House and impose their policy priorities are not enamored of an Omnibus bill or a full-year CR. They would like a FY 2011 CR that would expire sometime early next year, so that they could, as announced, roll back spending to FY 2008 levels. This proposal would cost the National Science Foundation (NSF) close to 20 percent of its budget and the National Institutes of Health (NIH) around nine percent and a small agency like the Bureau of Justice Statistics over forty percent.

In preparation for the takeover, the incoming House majority has announced some of its leaders. Rep. Ralph Hall (R-TX) will chair the House Science and Technology (S&T) Committee. With the America COMPETES legislation, which included the reauthorization of the NSF, unenacted by the current Congress, new Chairman Hall has announced he will forego large comprehensive science and science education legislation and concentrate on individual agencies. In addition, the S&T Committee will "scrutinize closely" the operations of NSF and other agencies under its jurisdiction.

Rep. Harold Rogers (R-KY) will chair the House Appropriations Committee in the new Congress. Rogers had been the Ranking Republican on the Homeland Security Subcommittee. The Republicans have not announced the "Cardinals," the chairs of the spending Subcommittees, yet.

Rep. Darrell Issa (R-CA) will chair the House Oversight and Government Reform Committee, which will spend its time investigating the Obama Administration's alleged shortcomings and the sins of the agencies. In the past, Issa has attempted to defund grants at the NIH he deemed unworthy of federal support, some in the area of sexual behavior and health. NIH should also face scrutiny from Rep. Joseph Pitts (R-PA), who has been named the Chairman of the Energy and Commerce's Subcommittee on Health. Pitts has also expressed his displeasure with some of the grants NIH has awarded in the past.

Aside from COMPETES, the 111th Congress will adjourn also failing to produce a long overdue reauthorization of the Elementary and Secondary Education Act. But then again, they did pass Health Care Reform, Financial Services Reform, and a Stimulus package that probably saved the country from a depression.

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**PCAST Report on Energy Includes Calls for More Social Science Research at DOE**

On November 29, the President's Council of Advisors on Science and Technology (PCAST) released a report to the President, *On Accelerating the Pace of Change in Energy Technologies Through an Integrated Federal Energy Policy*.

Among the report's recommendations was that the Department of Energy (DOE) along with the National Science Foundation "should initiate a multidisciplinary social science research program to examine the U.S. energy technology innovation ecosystem, including its actors, functions, processes, and outcomes. This research should be fully integrated into DOE's energy research and applied programs."

The report suggests "this research program should fund experts from the physical sciences, engineering, economics, sociology, public policy, political science, international relations, business, and other disciplines." Examples of questions that might be rigorously studied are:

- How and why are advanced energy technologies accepted or rejected by consumers?
- What are the barriers to adoption?
- Will the public accept a specific technology and why?
- What market conditions are needed for a technology to compete?
What is the role of public policy to efficiently and effectively push and pull advanced technologies into the marketplace?

How are technologies transferred and diffused internationally?

In addition, PCAST indicates that other types of multidisciplinary research are needed. These include strategic energy analyses and full life cycle assessments of new energy technologies. PCAST concludes that “the potential benefits of such a research program are significant,” with estimates as high $1.2 trillion in energy savings through 2020 from wide scale implementation of energy efficiency technologies in the U.S.

Furthermore, the report argues that “with or without new technologies, more behavioral research is also needed concerning the patterns, incentives, and decisions that determine individuals’ energy usage.” They recommend well-designed social science experiments to yield important insights about how people react to various policies and technologies.

PCAST notes that “in many cases, large-scale datasets exist or can be easily collected concerning such questions, but are not easy to study because of proprietary or regulatory obstructions. DOE should work with OMB, energy providers, and researchers to facilitate the compilation of energy usage data under both routine and experimental conditions.” They also note that other disciplines, such as history and international case studies, can also deliver important lessons.

These recommendations reflect the attempt by Rep. Brian Baird (D-WA) to enact legislation to create a DOE Office of Social Science research. The legislation was derided by Republicans on the Science and Technology Committee as “mind control” and although it emerged from that panel, it was never voted on by the House.

The report was produced by a PCAST Energy Technology Innovation System Working Group co-chaired by Ernest Moniz, Director of MIT’s Energy Initiative and a Professor of Physics and Engineering Systems, and Maxine Savitz, Vice President of the National Academy of Engineering. At the session releasing the report, Moniz indicated that the nation’s current energy policy occurs “at a high level of abstraction.” Therefore, the panel also recommended that the Executive Office of the President undertake a quadrennial review of energy policy, similar to the every-four-year review the Department of Defense conducts on national security policy. It also calls for increasing the annual energy research, development and demonstration budget to $16 billion. Some of those funds would come from small increases in the electricity and gasoline tax rates.

'Disruptive Innovation on an Institutional Scale:' SMRB Recommends Creation of a Center for Advancing Translational Science at NIH

On December 7, the National Institutes of Health (NIH) Scientific Management Review Board (SMRB) recommended to NIH director Francis Collins, by a vote of 12-1, the establishment of a center on translational medicine and therapeutics. (National Institute of General Medicine director Jeremy Berg was the dissenting vote.) On December 9, the NIH Advisory Committee to the NIH Director (ACD) agreed with SMRB’s recommendation to create the “National Center for Advancing Translational Sciences (NCAT).” Remark ing that the NIH is “at a critical juncture,” Collins contended that: “Structural change is needed to capitalize on new opportunities,” citing the need to “work with the private sector in a new paradigm.”

As NIH director, Collins has identified five NIH Opportunities, including translating basic science discoveries into new and better treatments and putting science to work for the benefit of health care reform. Accordingly, on May 19, 2010, he charged the SRMB to: “1) identify the attributes, activities and functional capabilities of an effective translational medicine program for advancing
therapeutics development, and 2) broadly assess the NIH landscape for extant programs, networks, and centers for inclusion in this network and recommend their optimal organization.” In response, the SMRB created the Translational Medicine and Therapeutics (TMAT) Working Group.

Collins pointed out that the accelerated pace of the SMRB’s deliberation occurred because he wanted to incorporate any recommendations into the NIH FY 2012 budget request, a process currently underway. Reviewing the charge, he emphasized that the Board was not asked to look at the consequences of the creation of such a center to the other NIH institutes and centers (ICs). He acknowledged, however, that “initiating change is unsettling;” adding that he “values the program and people in the ICs.” Nevertheless, he noted that the “proposed change is exciting, empowering, and challenging.”

The NIH Reform Act of 2006 (Public Law 109-482) created the SMRB to advise the NIH director and other appropriate agency officials regarding their organizational authorities to establish or abolish institutes and reorganizing "the offices within the Office of the Director, NIH, including adding, removing, or transferring the functions of such offices or establishing or terminating such offices." The statute also reaffirmed the director’s authority to “reorganize divisions, centers, or other administrative units within an NIH national research institute or national center, including adding, removing, or transferring the functions of such units, or establishing or terminating such units.”

In addressing the charge, TMAT also considered how the NIH “could leverage and organize a wide range of existing NIH resources and effectively implement the Cures Acceleration Network (CAN)," established as part of the American Recovery and Reinvestment Act (ARRA). TMAT considerations also extended to the following programs: NIH Therapeutics for Rare and Neglected Diseases (TRND); NIH Rapid Access to Interventional Development Program; and CAN. The Working Group also examined the NIH’s core facility program, Molecular Libraries Screening Center Network, and the NIH Clinical Center and the Clinical and Translational Sciences Awards (CTSAs), currently housed in the National Center for Research Resources.

Reporting the Working Group’s recommendation, Chair, Arthur Rubenstein (University of Pennsylvania Medical School), explained that the Working Group abided by the framework established within the report, Deliberating Organizational Change Effectiveness (DOCE), by the DOCE Working Group. DOCE developed a three step process for considering change: assess the need for change; evaluate options for change; and implement and evaluate the change.

According to the TMAT Working Group, the themes that emerged from its deliberations included: an evolving landscape of therapeutic discovery, emerging scientific opportunities, a synergy in leveraging resources effectively, authorization of CAN, the development and enhancement of appropriate collaborations, training and support of TMAT career paths, and communication of a clear mission. Based on these findings the TMAT Working Group and the full SMRB “unanimously agreed that the current NIH structure should be reorganized to capitalize upon emerging scientific opportunities, adapt to and help shape the evolving landscape of therapeutics development, create a home for the recently authorized CAN, and leverage existing NIH resources to speed the delivery of new, more effective medical products to patients.”

Per the SMRB’s recommendation, NCAT would include the NIH’s Molecular Libraries Program (MLP), TRND, the NIH Rapid Access to Interventional Development (RAID) program, the NIH-FDA Regulatory Science Initiative (which supports research on applicability of novel technologies and approaches to the development and regulatory review processes for drugs, biologics, and devices), and the CTSAs. The Working Group recommended and Board agreed that the NIH Clinical Center would remain outside of NCAT.

What Happens to NCRR?

The Working Group acknowledged that given many of “NCRR’s resources are germane to the resource function of the proposed Center; some consideration should be given to the incorporation of these relevant components. The programs, in combination with the CTSAs, could be housed
within the new Center. NCRR's non-translational programs, the Science Education Partnership Awards and the Research Centers in Minority Institution Programs, could be transferred to other NIH institutes and centers more suited to the aims of the program, according to the Working Group. Collins acknowledged that the CTSAs have many other roles besides translational research, "including behavior and health disparities that are a "critical part of their agenda." He wanted to "reassure the CTSAs that there is not going to be a jerking about of their scientific agenda..."

Presenting to SMRB, NCRR director Barbara Alving pointed out from the "viewpoint of NCRR," the SMRB's recommendation will require the Center "turn into something else." Conversely, she urged the expansion of NCRR and emphasized the need for assessing the financial impact of such a consideration.

Collins "underscored the value of NCRR's people and programs," and stressed that from the standpoint of the budget "no one can expect NIH's budget to grow in the [very near] future." He immediately tasked NIH Principal Director Lawrence Tabak and the Eunice Kennedy Shriver National Institute of Child Health and Human Development director Alan Guttmacher with forming a NIH group to "look at the programs in NCRR" to discern what would be "the most scientific way to choose the programs" that would be transferred to NCAT. He observed that the task was "analogous to the National Institute on Drug Abuse and National Institute for Alcohol Abuse and Alcoholism merger and an "appropriate task" for the group (see Update, November 22, 2010). The group was to begin immediately and had a meeting scheduled with the NCRR staff on December 8.

Tabak/Guttmacher are expected to report back to the SMRB at its February/March 2011 meeting with a proposal with ways to manage programs, seek input, allowing for a more refined report. "The goal is not to dismantle programs already in place," said Collins. He thanked the Board and noted that recommendation was done "in a way that achieves the goals from a lot of perspectives." Before he can formally act to create the Center, Collins pointed out that he still needs to consult with Secretary of Health and Human Services Kathleen Sebelius and is also required to notify Congress. Concluding the discussion, Collins noted that the recommendation could be considered a "disruptive innovation on an institutional scale."


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**Advisory Panel to NIH Director Meets; Agrees to Examine Biomedical Workforce**

The National Institute of Health (NIH) Advisory Committee to Director (ACD) met for its second and final meeting of the year on December 9th. In his report to the ACD, NIH director Francis Collins described the budget process for the agency as "distressingly uncertain," and noted that he expects "difficult budget circumstances" for the agency over the next few years. He also pointed out that incoming Majority Leader Eric Cantor (R-VA) has indicated that he would like to convene oversight hearings and referenced Cantor's "YouCut" website (http://republicanwhip.house.gov/YouCut/).

Noting the major changes in the Congress when it comes to those members familiar with the NIH, Collins expressed his desire to "have an opportunity to tell the NIH story." He acknowledged that "the NIH faces a challenging environment" and observed that many of the members of Congress on the committees with oversight jurisdiction over the NIH "have no track record on research and health issues."

ACD member Clyde Yancy questioned how in the coming limited spending environment noted by Collins, how NIH could accomplish the establishment of NCAT. Collins acknowledged that while the comments from GOP leaders are troubling . . . he is not asking for new funding but is asking to
Obama Requests Review of Federal Human Subjects' Protection Policies

Collins also highlighted President Obama recent issuance of a presidential memorandum to Amy Gutmann, President of the University of Pennsylvania and Chair of the Presidential Commission for the Study of Bioethical Issues, regarding the recent discovery that "the U.S. Public Health Service conducted research on sexually transmitted diseases in Guatemala from 1946 to 1948 involving the intentional infection of vulnerable human populations." Collins noted that the study was funded by an NIH grant and was not published. He stressed that the Commission's study "should be incredibly valuable."

In the memo, President Obama stressed that "The research was clearly unethical." Accordingly, he requested that Gutmann, as the Chair of the Commission, "convene a panel to conduct, beginning in January 2011, a thorough review of human subjects' protection to determine if Federal regulations and international standards adequately guard the health and well-being of participants in scientific studies supported by the Federal Government." The President further requested that "the Commission oversee a thorough fact-finding investigation into the specifics of the U.S. Public Health Service Sexually Transmitted Diseases Inoculation Study."

Obama expressed his belief that while he believes "the research community has made tremendous progress in the area of human subjects protection, what took place in Guatemala is a sobering reminder of past abuses. It is especially important for the Commission to use its vast expertise spanning the fields of science, policy, ethics, and religious values to carry out this mission. We owe it to the people of Guatemala and future generations of volunteers who participate in medical research."

ACD to Examine Developing Diverse, Sustainable 'Biomedical' Workforce

According to Collins, the NIH is facing many issues related to the biomedical workforce particularly in the face of the budget situation. He pointed out that many people are trained on research grants. A cause for concern is the increasing age, now 42, that individuals received their first investigator-initiated award. Many people are finding themselves in "very long post-docs," he noted, and declared it an "unsustainable situation."

To remedy the situation Collins suggested there is a need to consider alternative pathways, an issue that has not been a priority for the NIH. Another issue of concern, according to the NIH director, is the financing of the medical research enterprise." "We are spending too much on faculty," he insisted. He also called attention to the transition occurring in the international pipeline where individuals flock to the U.S. but do not stay given the appealing situations in such places as China and India. Collins further pointed to the crisis in education and the "undervaluing of the teaching role." He acknowledged that the NIH does not have a model for the workforce. He cited the need for an analysis of all of the pathways available for trained scientists, including industry, teaching, science policy, jobs in the media, among others. He shared that the NIH has been discussing the issue informally and that the ACD is the perfect body for further discussion of this issue.

Office of Extramural Research director Sally Rockey walked the ACD through the high points of the data that indicate that only 27 percent of NIH principal investigators are women and that the rate for African American principal investigators is 1.3 percent and has remained essentially unchanged for the past 25 years. Collins asked Shirley Tilghman, President of Princeton University, to lead a new ACD Panel that would "develop a model for sustainable and diverse U.S. biomedical research workforce."

The approved charge to the panel reads:

1. Develop a model for a sustainable and diverse biomedical research workforce that can inform decisions about training of the optimal number of people for the appropriate types of positions that will advance science and
promote health. Developing the model will include an analysis of the current composition and size of the workforce to understand the consequences of current funding policies on the research framework. The model should include an assessment of present and future needs in the academic research arena, but also current and future needs in industry, science policy, education, communication, and other pathways. The model will also require assessment of current and future availability of trainees from the domestic and international communities.

2. Based on this analysis and input from the extramural community, using appropriate expertise from NIH and external sources, and recognizing that there are limits to NIH's ability to control many aspects of the training pipeline, the committee will make recommendations for actions that NIH should take to support a future sustainable biomedical infrastructure.

Collins emphasized that the "NIH is not taking responsibility" for all of the pathways where training is needed. He further stressed that "diversity is a critical part" of the charge and "despite substantial efforts," the outcome is "discouraging."

Tilghman thanked Collins for identifying "this as an important issue." ACD members James Jackson, head of the Institute for Social Research at the University of Michigan and a former COSSA Board Member, and Clyde Yancey, Baylor University Medical Center, immediately volunteered to serve on the newly created panel. When considering the makeup of the rest of the panel, Collins indicated that it will need to include people highly knowledgeable about economics.

Goals for Healthy People 2020 'Unveiled:' Social Determinants of Health Emphasized

On December 2, 2010, the U.S. Department of Health and Human Services (HHS) unveiled the new "science-based" ten-year national goals and objections for health promotion and disease prevention for Healthy People 2020 (HP 2020). The Department also revealed a new challenge for technology application developers called "myHealthyPeople." Healthy People 2020 is a multiyear process that reflects input from a diverse group of individuals and organizations.

Unveiling the goals, HHS Secretary Kathleen Sebelius observed that the "launch of Healthy People 2020 comes at a critical time. Our challenge and opportunity is to avoid preventable diseases from occurring in the first place."

Assistant Secretary for Health Howard Koh, echoed the Secretary and stressed that "too many people are not reaching their full potential for health because of preventable conditions. Healthy People is the nation's roadmap and compass for better health, providing our society a vision for improving both the quantity and quality of life for all."

In Healthy People 2020, there is a renewed emphasis on identifying, measuring, tracking, and reducing health disparities by taking a determinants of health approach. This would include examining several broad categories: 1) Policymaking, 2) Social factors, 3) Health services, 4) Individual behavior, and 5) Biology and genetics. "It is the interrelationships among these factors that determine individual and population health. Because of this, interventions that target multiple determinants of health are most likely to be effective." HP 2020 emphasizes that: "Determinants of health reach beyond the boundaries of traditional health care and public health sectors; sectors such as education, housing, transportation, agriculture, and environment can be important allies in improving population health."

The report emphasizes that social determinants of health reflect social factors and the physical
conditions in the environment in which people are born, live, learn, play, work and age. Examples of social determinants cited in HP 2020 include: availability of resources to meet daily needs, such as educational and job opportunities, living wages, or healthful foods; social norms and attitudes, such as discrimination; exposure to crime, violence, and social disorder, such as the presence of trash; social support and social interactions; exposure to mass media and emerging technologies, such as the Internet or cell phones; socioeconomic conditions, such as concentrated poverty; quality schools; transportation options; public safety; and residential segregation.

Examples of physical determinants cited in HP 2020 include: natural environment, such as plants, weather, or climate change; built environment, such as buildings or transportation; worksites, schools, and recreational settings; housing, homes, and neighborhoods; exposure to toxic substances and other physical hazards; physical barriers, especially for people with disabilities; and aesthetic elements, such as good lighting, trees, or benches.

New Topic Areas in Healthy People 2020

Adolescent Health - The leading causes of illness and death among adolescents and young adults are largely preventable. Health outcomes for adolescents and young adults are grounded in their social environments and are frequently mediated by their behaviors. Behaviors of young people are influenced at the individual, peer, family, school, community, and societal levels. Two important issues influence how adolescent health will be approached in the coming decade. First, the adolescent population is becoming more ethnically diverse, with rapid increases in the numbers of Hispanic and Asian American youth. The growing ethnic diversity will require cultural responsiveness to health care needs and sharpened attention to disparate health and academic outcomes, which are correlated with poverty, especially among adolescents from minority racial and ethnic groups.

The second emerging issue is the increased focus on the use of positive youth development interventions for preventing adolescent health risk behaviors. Youth development interventions can be briefly defined as the intentional process of providing all youth with the support, relationships, experiences, resources, and opportunities needed to become successful and competent adults. There is growing empirical evidence that well-designed youth development interventions can lead to positive outcomes. Ongoing, rigorous evaluation will determine what works, why it works, and how successful interventions can be applied.

Blood Disorders and Blood Safety - Bleeding and clotting disorders result from genetic, biological, and environmental risk factors. Von Willebrand disease (vWD) is the most common blood disorder affects more women, while hemophilia is a disease that affects only men. The risks of deep venous thrombosis (DVT) and pulmonary embolism (PE) increase with age. Early recognition of signs and symptoms and prompt treatment can prevent most complications.

Dementias, Including Alzheimer's Disease - Dementia is the loss of cognitive functioning-thinking, remembering, and reasoning-to such an extent that it interferes with a person's daily life. Dementia is not a disease itself, but rather a set of symptoms. Alzheimer's disease is the most common cause of dementia, accounting for the majority of all diagnosed cases. Several factors determine the risk of developing dementia, including age and family history. Other factors affect the management of dementia by families, communities, and the health care system.

Over the past decade, there has been significant scientific progress in understanding and managing dementia, with most of the research focused on Alzheimer's disease. During the next decade, it will be important that progress be made in: improving the early diagnosis of Alzheimer's disease and other dementias; developing interventions to delay or prevent Alzheimer's disease and other dementias; finding better ways to manage dementia when other chronic conditions are present; and understanding the influence of lifestyle factors on a person's risk of cognitive decline and dementia.
Early and Middle Childhood - There is increasing recognition in policy, research, and clinical practice communities that early and middle childhood provide the physical, cognitive, and social-emotional foundation for lifelong health, learning, and well-being. Evidence shows that experiences in the 1st years of life are extremely important for a child's healthy development and lifelong learning. How a child develops during this time affects future cognitive, social, emotional, and physical development, which influences school readiness and later success in life. Research on a number of adult health and medical conditions points to predisease pathways that have their beginnings in early and middle childhood. Emerging issues in early and middle childhood include implementing and evaluating multidisciplinary public health interventions that address social determinants of health by: fostering knowledgeable and nurturing families, parents, and caregivers; and creating supportive and safe environments in schools, communities, and homes; and increasing access to high-quality health care.

Genomics - Traditionally, public health applications of genomics have focused on rare diseases, such as those identified through newborn screening programs. Much of the future promise of genomics rests on its application to common diseases. The new Genomics topic area and objectives for 2020 reflect the increasing scientific evidence supporting the health benefits of using genetic tests and family health history to guide clinical and public health interventions. Although the field of genomics is rapidly producing discoveries, there are a limited number of evidence-based recommendations for genetic tests and family health history tools. The existing recommendations, after translating them into practice, have the potential for improving health. In addition, more evaluation of the potential benefits and harms from the use of genomics is needed to guide the development of new recommendations.

Global Health - Global health concerns are not limited to infectious diseases. Non-communicable diseases, especially “lifestyle” conditions, are among the leading causes of disability worldwide. These conditions include: diabetes and obesity; mental illness; substance abuse/use disorders, including tobacco use; and injuries. As social and economic conditions in developing countries change and their health systems and surveillance improve, more focus will be needed to address non-communicable diseases, mental health, substance abuse disorders, and, especially, injuries (both intentional and unintentional).

Healthcare-Associated Infections - HAIs are infections that patients get while receiving treatment for medical or surgical conditions. They are among the leading causes of preventable deaths in the United States and are associated with a substantial increase in health care costs each year. Risk factors for HAIs can be grouped into three general categories: Medical procedures and antibiotic use; Organizational factors, and Patient characteristics. The behaviors of health care providers and their interactions with the health care system also influence the rate of HAIs.

Health-Related Quality of Life and Well-Being - Health-related quality of life (HRQoL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death, and focuses on the impact health status has on quality of life. A related concept of HRQoL is well-being, which assesses the positive aspects of a person's life, such as positive emotions and life satisfaction. Healthy People 2020, over the decade, plans to evaluate the following measures for monitoring HRQoL and well-being in the United States:

1) Patient Reported Outcomes Measurement Information System (PROMIS) Global Health Measure - assesses global physical, mental and social HRQoL through questions on self-rated health, physical HRQoL, mental HRQoL, fatigue, pain, emotional distress, social activities, and roles;
2) Well-Being Measures - assess the positive evaluations of people's daily lives - when they feel very healthy and satisfied or content with life, the quality of their relationships, their positive emotions, resilience, and realization of their potential; and
3) Participation Measures - reflect individuals' assessments of the impact of their health on their social participation within their current environment. Participation includes
education, employment, civic, social and leisure activities. The principle behind participation measures is that a person with a functional limitation - for example, vision loss, mobility difficulty, or intellectual disability - can live a long and productive life and enjoy a good quality of life.

**Lesbian, Gay, Bisexual, and Transgender Health** - LGBT individuals encompass all races and ethnicities, religions, and social classes. Sexual orientation and gender identity questions are not asked on most national or State surveys, making it difficult to estimate the number of LGBT individuals and their health needs. Research suggests that LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights. Discrimination against LGBT persons has been associated with high rates of psychiatric disorders, substance abuse, and suicide. Experiences of violence and victimization are frequent for LGBT individuals, and have long-lasting effects on the individual and the community. Personal, family, and social acceptance of sexual orientation and gender identity affects the mental health and personal safety of LGBT individuals.

A number of issues will need to continue to be evaluated and addressed over the coming decade, including: Prevention of violence and homicide toward the LGB community, and especially the transgender population; Nationally representative data on LGBT Americans; Resiliency in LGBT communities; LGBT parenting issues throughout the life course; Elder health and well-being; Exploration of sexual/gender identity among youth; Need for a LGBT wellness model; and Recognition of transgender health needs as medically necessary.

**Older Adults** - Older adults are among the fastest growing age groups, and the first “baby boomers” (adults born between 1946 and 1964) will turn 65 in 2011. More than 37 million people in this group (60 percent) will manage more than 1 chronic condition by 2030. Emerging issues for improving the health of older adults include efforts to: Coordinate care; Help older adults manage their own care; Establish quality measures; Identify minimum levels of training for people who care for older adults; and Research and analyze appropriate training to equip providers with the tools they need to meet the needs of older adults. There is growing recognition that data sources are limited for certain subpopulations of older adults, including the aging lesbian, gay, bisexual, and transgender populations.

**Preparedness** - Preparedness involves Government agencies, nongovernmental organizations, the private sector, communities, and individuals working together to improve the Nation’s ability to prevent, prepare for, respond to, and recover from a major health incident. The Healthy People 2020 objectives for preparedness are based on a set of national priorities articulated in the National Health Security Strategy of the United States of America (NHSS). The overarching goals of NHSS are to build community resilience and to strengthen and sustain health and emergency response systems.

To reach these goals, NHSS identifies the following objectives for urgent, focused attention: foster informed, empowered individuals and communities; develop and maintain the workforce needed for national health security; ensure situational awareness; foster integrated, scalable health care delivery systems; ensure timely and effective communications; promote an effective countermeasure enterprise; ensure prevention or mitigation of environmental and other emerging threats to health; Incorporate post-incident health recovery into planning and response; work with cross-border and global partners to enhance national, continental, and global health security; and ensure that all systems that support national health security are based on the best available science, evaluation, and quality improvement.

**Sleep Health** - Sleep, like nutrition and physical activity, is a critical determinant of health and well-being. Sleep is a basic requirement for infant, child, and adolescent health and development. Sleep loss and untreated sleep disorders influence basic patterns of behavior that negatively affect family health and interpersonal relationships. Fatigue and sleepiness can reduce productivity and increase the chance for mishaps such as medical errors and motor vehicle or industrial accidents. Progress in the following areas will yield more information on sleep health over the coming
Further evolution of biomedical sleep research; Quantification of health risks associated with untreated SDB across the lifespan; and Findings from the first U.S.-based phase III Sleep-disordered breathing (SDB), treatment trials in children and adults.

For more information on Healthy People 2020 see http://www.healthypeople.gov/2020/default.aspx.

Research Universities' Panel Hears About Challenges for Future

On November 22-24, the National Academies' Committee on Research Universities, chaired by Chad Holliday, held its second meeting. The Committee hopes to produce a report by next summer.

The panel received a congressional perspective from Senator Lamar Alexander (R-TN), one of the signers of the letter that requested the Academies to examine the future of the U.S. higher education enterprise. Alexander referenced *Rising Above the Gathering Storm*, the National Academies' report that raised concern about the future of American innovation and science education. He also noted the current condition of the country - war, deficits, debt - and how that impacts support for higher education, particularly the federal and state government capacity for providing funding. He suggested that the panel come up with recommendations that would not cost the federal government any additional expenditures.

He also called on America's research universities to prioritize, not an easy thing to do, in a very decentralized system. The Senator admitted that this might be easier in China where the government simply dictates changes it desires. Yet, he also suggested, that despite its improvements, China still lags behind America's higher education system, which Alexander called "still the best in the world."

Among his suggestions, Alexander endorsed the oft-heard plan to provide Green Cards to foreign graduate students upon their graduation, more cooperation between universities and the federal labs, creation of centers of excellence, increased utilization of university facilities, and perhaps a federal takeover of Medicaid to free up state budgets to increase their support for universities. He also acknowledged that many state universities now receive significantly reduced support from state governments and have therefore turned to private fundraising, in essence becoming almost-private universities with "some" public support.

Committee members told Alexander that the federal government provides too many administrative burdens on universities while not providing the full funding for the research conducted by faculty. Hunter Rawlings, President of Cornell, wondered about the tenor of some of the discussion, and asked whether a university's purpose was to only serve as an economic engine? He thought not and promoted the importance of the humanities.

Cora Marrett, Acting Deputy Director of the National Science Foundation (NSF), also addressed the group. She stressed the importance of the partnership of universities and the nation's need for scientific research first promulgated by Vannevar Bush in *Science: The Endless Frontier*. Just as important, she argued, was the freedom of inquiry that defines the nation's research universities.

NSF, she noted, cultivates talent, integrates research and education, provides significant support for certain fields, and allows for the intersection of disciplines to "serve the well-being of the country." She also indicated that new tools have allowed NSF to support projects that allow investigators to handle large data sets.

There are pressures on the research system aside from the instability of funding, she contended. Increasing number of proposals to NSF has raised the problem of finding enough reviewers and decreased the success rate. Yet, NSF remains the "innovative engine for the nation," she concluded.
Sally Rockey, Deputy Director for Extramural Research at the National Institutes of Health (NIH), informed the committee about the pressures on the Institutes because of up and down funding. Federal support for NIH funding doubled between 1998 and 2003. Regular appropriations have been pretty flat since then. Under the Recovery Act, NIH received a large infusion of funds, almost $8.5 billion for research, but that funding was temporary. All of this also creates havoc with training and facilities support, according to Rockey.

Both Marrett and Rockey expressed concern about the possible roll back of the NSF and NIH budgets, as proposed by some in the new Republican House majority, to FY 2008 levels.

Jonathan Cole, former Provost of Columbia, warned the Committee of the challenges facing America's universities. These include: the intrusion of ideology, restrictive visa policies, prior restraint on publication, politicization of science, a rising anti-intellectualism, compromises to the peer review system, and global competition. He urged the Committee to "tell the story better" of the universities' contributions to American success.

### PISA Results Highlight International Education Comparisons

On December 7, the Organization for Economic Cooperation and Development (OECD) released the 2009 Program for International Student Assessment (PISA) results. At the same time, the National Center for Education Statistics (NCES) also released its report, *Highlights from PISA 2009: Performance of U.S. 15 Year Old Students in Reading, Mathematics, and Science Literacy in an International Context*.

PISA is a system of international assessments that focuses on 15-year-olds' capabilities in reading literacy, mathematics literacy, and science literacy. PISA also includes measures of general or cross-curricular competencies such as problem solving. PISA emphasizes functional skills that students have acquired as they near the end of compulsory schooling. Begun in 2000, PISA is administered every 3 years. Each administration includes assessments of all three subjects, but examines one of the subjects in depth. The most recent administration was in 2009 and focused on reading literacy.

The average reading literacy score for the U.S was 500 compared to the OECD average of 493. This difference was not measurably significant. Despite education reform efforts in the last decade, the average U.S. reading score remains statistically unchanged from 2000. Eighteen percent of U.S students failed to achieve a proficiency level of two, considered the level where students can complete low level reading tasks. The PISA results also showed that female students in the U.S. scored higher on average, 513, than male students who scored an average of 488.

Math literacy scores for U.S. students did improve. However, they are still below the OECD average. The average U.S. score in 2009 was 487, and although it is an improvement over the 2006 score, it remains lower than the OECD average score of 496. Twenty-three percent of students scored below level two in math literacy proficiency. Unlike in reading literacy, male students scored higher on average, 497, than female students at 477.

The average science literacy score for U.S. students was 502, and while it is not measurably different than the OECD average score of 501, this is higher than the 2006 result. In science literacy eighteen percent of students scored below level two. Male students also scored higher in science literacy with an average of 509 as opposed to female students who scored an average of 495.

Although the U.S. has made some gains or remained steady in its PISA scores, there remains a considerable lag behind other industrialized countries. For complete 2009 PISA results as well as searchable database go to [http://nces.ed.gov/surveys/pisa](http://nces.ed.gov/surveys/pisa).
USDA and NSF Seeks Proposals to Study Disaster Resilience in Rural Communities

In a joint announcement, the U.S Department of Agriculture's (USDA) National Institute of Food and Agriculture (NIFA) and the National Science Foundation (NSF) call for proposals to advance basic research in engineering and the social, behavioral, and economic sciences on enhancing disaster resilience in rural communities. NSF will run the competition and peer review. Full proposals are due on March 4, 2011.

According to NSF, communities and their residents in the United States experience droughts, earthquakes, floods, hurricanes, tornadoes, tsunamis, and volcanic eruptions as well as accidents at facilities that handle dangerous materials such as explosive chemicals. These phenomena will continue, but their consequences need not be disastrous if communities and people reduce their vulnerabilities and increase their resilience. There is much research on vulnerability and resilience in urban communities, but much less about how rural communities and their residents are responding to natural and man-made hazards.

There are priorities for the competition. According to the solicitation, applicants must address at least one of the following topics, or a combination, in terms of the vulnerabilities and resilience of rural communities to natural hazards or risks from accidents at facilities such as chemical plants (This competition will not support terrorism research):

1. Hazard mitigation practices of rural communities;
2. Hazard preparedness and emergency response in rural communities; or
3. Disaster recovery in rural communities.

Although NSF/NIFA will consider applications on any of the topics identified above, the following are a few examples of potential emphases for research in rural communities:

- Measuring vulnerability and resilience, their causes and consequences;
- The role of markets, especially agricultural and labor, in understanding vulnerability and resilience;
- Vulnerability and resilience at the individual, group, and community scales;
- The role of culture, complexity, and social networks in vulnerability and resilience;
- Intergovernmental relations in hazard and disaster mitigation, preparedness, response, and recovery;
- Role of forces and organizations from outside rural communities in the vulnerability and resilience of rural communities;
- Risk perceptions and behavioral reactions to communications from official and other sources; and
- Land-use and housing decisions.

The agencies also encourage comparative research across cultural and national boundaries and multi-institutional and multidisciplinary proposals.

NSF and USDA-NIFA anticipate making approximately a total of four to six awards for research projects. These awards will be for one to three years in duration. Based on the results of the review panel, NSF and USDA-NIFA will select proposals for funding based on each agency's particular interest and fund them separately.
Pending availability of funds, USDA-NIFA and NSF expect to have at least $2 million available to support total award sizes (including indirect costs) not to exceed $400,000 in size. This maximum is for the total of the project, not a yearly maximum. Projects that exceed this maximum amount in total budget will be returned without review.

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Translating Basic Behavioral and Social Science Discoveries into Interventions: Funding Opportunity

Significant advances in basic behavioral and social science research have contributed to a more sophisticated understanding of the fundamental biological, cognitive, emotional, and social underpinnings of human behavior. Recent discoveries in fields such as cognitive and affective neuroscience, communication science and social marketing, decision-making and choice, the formation of habits, the psychophysiology of stress and behavior, behavioral economics, and the nature and impact of social networks, coupled with the development of more sophisticated tools for understanding the psychosocial determinants and physiologic bases of human behavior (e.g., brain imaging, systems dynamics theories, mobile technologies, geospatial methods), are yielding new and important insights about human cognition, affect, motivation and behavior. These findings suggest promising new directions for developing behavior change interventions to improve the public health.

At the same time, behaviors such as smoking, sedentary lifestyles, unhealthy dietary intake, alcohol or substance abuse or dependence and poor adherence to medical and behavioral treatments are major contributors to cardiovascular disease, cancer, type 2 diabetes and other chronic conditions.

The National Institutes of Health (NIH)-sponsored studies such as the Trials of Hypertension Prevention, Weight Loss Maintenance and the Diabetes Prevention Program have shown that behavioral interventions can improve behavior and prevent disease. However, even the most successful behavior change interventions are limited in their ability to induce significant, long-term behavioral changes in the majority of adults. Often change occurs only for the highly motivated and is limited to a single health behavior rather than multiple behaviors. Moreover, even individuals committed to behavior change find it hard to maintain healthy behavioral patterns over time.

The Nurse Home Visitation Program which has shown lasting and long-term effects is an example of an exception to this pattern. The ability for long-term maintenance of behavior change has been found in preventive interventions. In addition, some prevention research suggests that the greatest gains can be made with those at most risk. But even these successes are not as common as they should be and points to the need for innovative, high quality behavioral research is needed in both the prevention and intervention areas.

Accordingly, the NIH Office of Behavioral and Social Sciences Research (OBSSR), with participation from the NIH Cancer Institute (NCI), Center for Complementary and Alternative Medicine (NCCAM), Heart, Lung, and Blood Institute (NHLBI), Institute on Alcohol Abuse and Alcoholism (NIAAA), Institute of Child Health and Human Development (NICHD), Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Institute on Drug Abuse (NIDA), and the Office
The sponsors of the FOA emphasize that as with development of more effective drugs, surgical techniques and medical devices, the development of more powerful health-related behavioral interventions is dependent on improving our understanding of human behavior, and then translating that knowledge into new and more effective interventions with enduring effects. This FOA seeks to promote an innovative intervention development process, for the behavioral and social sciences, that is analogous to Type I translation in the biomedical sciences, with the ultimate goal of achieving greater effectiveness for health-related behavior change strategies.

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The FOA provides a description of how basic behavioral and social science translation research is analogous to pharmacotherapy development research: In pharmacotherapy development research, translation I research (treatment development) includes the conduct of small human trials or series (Phase I & II clinical trials) in which data on the safety of the drug and the dosages needed to affect biomarkers of the disease being studied are collected. In Phase I safety studies, the purpose is to gather information on which dosages are well tolerated by patients with minimal toxicity; in Phase II studies, the goal is to test for and characterize effects of the treatment, for example, to determine the amounts of treatment needed to produce biologic responses, such as reduction in the size of a tumor or lesion. If the treatment is found to be safe and effective in altering disease-related biomarkers in these early phase studies, large-scale randomized clinical trials or RCTs (Phase III studies) are then conducted to test the effects of the treatments developed on morbidity and mortality outcomes. Often, prior to instituting a full-scale RCT, a pilot or feasibility study is conducted in the population and setting of interest in order to assess feasibility and acceptance of the approach used, refine intervention and measurement procedures, gain experience in and information concerning screening, recruitment and retention of the target population (e.g., estimates of yield, pre-testing of screening/recruitment procedures), and determine estimates of variability and levels of response in the target population.

The same translation process can be applied to the development of behavioral treatments or interventions. For example, Translation I (intervention development) research in the behavioral and social sciences is a phased approach aimed at determining the Phase I safety profile of a treatment, the "dosages" required (i.e., intensity, frequency, duration of intervention) to effect change in the intermediate outcomes of interest, and in Phase II to identify whether and how a treatment works in specific patient groups under well-specified conditions, and the feasibility and acceptance of the intervention in the target population. This work would culminate in Phase III trials that would test the intervention in a large-enough sample of patients to determine its effects on health outcomes. Basic behavioral and social science research in humans is concerned with elucidating the fundamental principles and processes that govern how we perceive the environment, process information, make decisions, experience, express and regulate emotion, form
and change attitudes, beliefs and values, and become and remain motivated to change behavior.

As defined by the NIH, basic behavioral and social science research can involve research at the individual, small group, institution, organization, and community or population level. At the individual level, this research may involve the study of behavioral factors such as cognition, memory, language, perception, personality, emotion, motivation, and others. At higher levels of aggregation, it includes the study of social variables such as the structure and dynamics of small groups (e.g., couples, families, work groups, etc.); institutions and organizations (e.g., schools, religious organizations, etc.); communities (defined by geography or common interest); and larger environmental, demographic, political, economic, and cultural systems.

Conceptual examples of the types of topics and approaches relevant to the proposed FOA include:

- Translate basic research on learning, cognition, information processing, persuasive communications or message framing to develop more potent interventions for teaching children and adults about healthy behaviors and for encouraging adherence to self-monitoring, goal-setting, and other behavioral strategies that are important components of many health promotion and prevention programs.
- Use research findings from neuroimaging studies to map the neural mechanisms underlying the targeted behaviors to develop novel approaches to change behaviors.
- Make use of systems science and modeling techniques (e.g., network analyses, systems dynamics approaches) to construct systems-level interventions to encourage healthy lifestyle behaviors.
- Translate laboratory or observational studies into new avenues for intervention or prevention by developing interventions that target executive functioning and behavioral control; interoceptive awareness and signaling for behavior; emotional and behavioral self-regulation; and behavior in response to environmental, social or emotional cues.
- Use communication, gaming and computer science findings, to develop and test innovative interventions using technology that provides for the assessment of behavior(s) in real-time and locations in space, allowing for more interactive and/or individual tailoring of interventions.
- Use new paradigms of science (e.g., chaos theory, non-linear models) that address the unpredictability of behavior to construct interventions that foster motivation for behavior change and strategies that maximize chances for non-linear, non-rational change, such as occurs in certain natural phenomena (e.g., “tipping points” in disease and social epidemics).
- Develop new approaches derived from engineering models aimed at transforming environmental systems over time to promote desirable behavior to structure systems such as neighborhoods, worksites, schools and homes to promote healthy, as opposed to unhealthy, behaviors.
- Diet, alcohol and substance consumption, developmental exposures, the environment and behavioral factors can affect epigenetic regulation of the genetic blueprint and/or epigenetic changes in the regulation of gene activity and expression, independent of gene sequence. Utilize basic research on epigenetic processes, to develop interventions that change behavior and affect gene activity.
- Use research concerning genetic predispositions to behavior to develop novel intervention approaches or to enhance existing approaches to increasing behavior change.
- Use findings from behavioral economics and neuroeconomics to develop more potent forms, frequency and duration of reinforcements for encouraging and discouraging behavior, including the testing of economic incentives, tax structures, labeling and other policies to encourage industry, local governments, and community organizations to alter environments and market products that promote healthy behavioral choices.
- Use findings on impulsivity, emotional dysregulation, delay discounting, and risk-taking behavior to better design interventions that prevent cravings, promote delayed gratification, and improve individuals' abilities to cope with stimuli eliciting unhealthy
It should be noted that these examples should not be regarded as a call to pursue any specific line of investigation.

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**Funding Opportunity: Methodology and Measurement for Multiple Chronic Health Conditions**

Led by the National Institutes of Health (NIH) Office of Behavioral and Social Sciences Research (OBSSR), the Cancer Institute (NCI), Heart, Lung and Blood Institute (NHLBI), Institute on Alcohol Abuse and Alcoholism (NIAAA), and Institute on Drug Abuse (NIDA) have issued a notice designed to encourage applications to the Methodology and Measurement in the Behavioral and Social Sciences program announcement ([PAR-08-212](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-020.html)). The notice is in recognition of the need for more effective research methods and measures for conceptualizing, triaging and assessing the health behavior (e.g., adherence, mental health problems, diet and exercise, substance use and abuse disorders) or patients with multiple chronic health conditions.

According to the announcement, methodology and measurement encompass research design, data collection techniques, measurement, and data analysis techniques. The goal of this program announcement is to encourage research that will improve the quality and scientific power of data collected in the behavioral and social sciences, using humans or animals, relevant to the missions of the NIH ICs. Research that addresses methodology and measurement issues in diverse populations, issues in studying sensitive behaviors, issues of ethics in research, issues related to confidential data and the protection of research subjects, and issues in developing interdisciplinary, multimethod, and multilevel approaches to behavioral and social science research is particularly encouraged, as are approaches that integrate behavioral and social science research with biomedical, physical, or computational science research or engineering. Because the focus of this program announcement is developing methodology, rather than addressing a single, health-related research question, applicants are encouraged to propose approaches that would be broadly applicable to basic or applied behavioral and social sciences research related to health.

The announcement encourages applications addressing four general areas of methodology and measurement research in the social and behavioral sciences: 1) **research design**, 2) **data collection techniques**, 3) **measurement**, and 4) **data analysis**. The sponsors of the program announcement are particularly interested in:

- Development and refinement of measures, instruments, or surveys that fill a gap in assessing multiple chronic health behaviors in behavioral and social science research.
- Measurement issues in using technology, such as computer assisted data collection, web-based technology, mobile phones and personal digital assistants (PDAs).
- Development of instruments that assess not only degree of multiple behavior change, but also rate and variable direction of change in multiple health behaviors.
- Development of behavioral and social science measures that can be used for efficient data collection for assessment, triage, and/or outcomes research in clinical practice-based, research networks.


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**Research into the Impact of Economic Fluctuation on Alcohol Consumption, Drinking Patterns, and Prevention and Treatment**
of Problem Drinking and Related Problems

The current economic crisis has hit millions of Americans in the forms of forced unemployment, foreclosure, bankruptcy, and loss of a lifetime’s savings, while also affecting multiple sectors of American society. Research suggests that economic downturns can significantly impact rates of problem drinking. Evidence, however, about the nature of the relationship between economic woes and various health effects, including societal drinking level is conflicting.

Accordingly, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is seeking grant applications that investigate the impact of national or local economic fluctuations on alcohol consumption, alcohol drinking patterns and the prevention and treatment of problem drinking. The funding opportunity announcement (FOA), Research into the Impact of Economic Fluctuation on Alcohol Consumption, Drinking Patterns, and Prevention and Treatment of Problem Drinking and Related Problems, (PA-11-61), encourages research that will significantly add to existing knowledge about the relationship between economic fluctuations and drinking rates and patterns and drinking-related problems. The FOA also seeks to support the examination of the likely effectiveness of established and developing approaches to the prevention and treatment of problem drinking, alcohol use disorders, and drinking-related problems.

Successful proposals might explore whether particular alcoholism treatment approaches—such as pharmacologically-based, cognitive-behavioral therapy-based, or motivational enhancement approaches—may be relatively more effective than others during times of economic stagnation or recession, or compare the relative efficacy during such periods of in-patient and out-patient treatment approaches, or standard treatment practices in comparison to spirituality-based approaches, referral to Alcoholics Anonymous, etc. Similar questions may be asked about the success likelihood of various problem drinking prevention approaches during periods of economic downturn. Proposals might:

- Investigate the relative strengths—as prevention tools—of, for example, brief interventions, community coalitions to fight underage drinking, and employee assistance programs during such times
- Evaluate the added benefits of stepped-up screening for drinking problems performed by primary care specialists during such times
- Explore the relative effectiveness during such times of, for example, structural/environmental compared to psychosocial prevention approaches, or group-based individually-based approaches, or in-person versus on-line approaches

The FOA emphasizes that modeling for purposes of making projections about the size and direction of needed prevention measures—as well as the likely demand for treatment, relapse rates, etc.—in the wake of such economic change likely will be a useful addition to the literature.

RTI International Newest COSSA Member

RTI International, one of the world’s leading research institutes, dedicated to improving the human condition by turning knowledge into practice, has joined the Consortium. RTI provides research and technical expertise to governments and businesses in more than 40 countries in the areas of health, education and training, surveys and statistics, advanced technology, international development, economic and social policy, energy and the environment. COSSA looks forward to the support RTI International brings to the social science enterprise.
Editor's Note:
This is the last COSSA Washington Update for 2010. We will return on January 10, 2011. In the meantime, for late news concerning the conclusion of the 111th Congress see www.cossa.org.

Happy Holidays, Merry Christmas, and All the Best for the New Year!

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