

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Shaky Start For FY11 Appropriations Cycle As Parties Feel Pressure To Cut Spending

By Paul Goldberg

The appropriations cycle for 2011 is off to a shaky start, Capitol Hill sources say.

Though the Senate Budget Committee passed a resolution on April 22, the measure has not been brought to the full Senate, presumably because the leadership cannot get sufficient votes to assure passage.

The House version of the budget resolution has not been through markup by the budget committee. The absence of budget resolutions means that the 12 appropriations subcommittees cannot move on to crafting spending bills.

“This is going to be an extraordinarily tough appropriations cycle,” said Mark Smith, principal with Liberty Partners Group, a government relations

(Continued to page 2)

In the Cancer Centers:

Karmanos Cancer Institute, CDC, Blue Cross To Begin Environmental Cancer Program

BARBARA ANN KARMANOS CANCER INSTITUTE, in cooperation with Blue Cross Blue Shield of Michigan and the Centers for Disease Control’s Agency for Toxic Substances and Disease Registry, plans to introduce an Environmental Cancer Program to Michigan physicians on July 1.

The program trains primary care physicians to accurately identify and diagnose cancers and other serious illnesses resulting from exposure to arsenic, radon, and asbestos, three of the state’s most frequently encountered carcinogens.

Michael Harbut, of Karmanos is director and author of the program, and an occupational and environmental medical expert. “We began introducing the medical evidence-based approach to doctors participating in BCBSM’s Physician Group Incentive Program at Providence Hospital in Southfield and within the St. John Health System earlier this year,” said Harbut. “We are pleased that we are now rolling this out statewide.”

By using existing data identifying workplace and environmental arsenic, asbestos and radon, physicians can determine who is at risk, what preventive care may be recommended and can more accurately diagnose and treat those at risk.

“The Michigan Environmental Cancer Program addresses four important design elements for clinical preventive environmental health services:

(Continued to page 4)

Washington Roundup:
**Medicare Cuts Payments
To Physicians By 21%**
... Page 2

**House Bill Would
Mandate Medicare
Coverage Of CT Scans
For Colorectal Screening**
... Page 3

NIH News:
**Science Agencies Seek
To Measure Effect
Of Research Funding**
... Page 7

Medicare Cuts Physician Payments By 21 Percent

(Continued from page 1)

firm, which includes former Sen. Connie Mack. "This is an election year marked by pressure to curtail spending by Republicans and fiscally conservative Democrats."

If there is no political will to approve spending resolutions, Congress can "deem" some overall spending levels, clearing the way to appropriations. This could occur at any point, even after the elections, potentially leaving it to a lame duck Congress to passing an omnibus spending bill.

The resolution that seems to be a non-starter in the Senate doesn't have the appearance of a tax and spend document. It cuts spending as a share of the economy by 11 percent, includes \$671 billion more deficit reduction than President Obama's budget and cuts taxes by \$780 billion.

Also, it freezes all non-security discretionary spending for three years, from 2011 through 2013. And it invests in education and energy, laying the foundation for long-term economic security.

* * *

The event doctors feared for almost a year occurred on June 1: Medicare cut payments to doctors by 21 percent.

Congress has granted doctors a series of short-term reprieves, but the strategy failed before Memorial Day,

as the House approved a bill that would delay the cut by 19 months, through 2012. However, the Senate failed to take up the legislation and left for week-long recess.

The bill, dubbed "extenders" bill (H.R. 4213) also extended jobless benefits. The Medicare portion of the bill passed the House by 245-171 vote. The issue is complicated, because ultimately it requires Congress to repeal the Sustainable Growth Rate formula for controlling medical costs.

SGR has mandated cuts, which have not gone in effect. In fact, since the first scheduled cut in 2004 through this year, Congress spared physicians, sometimes even producing small increases.

However, the cuts continued to accumulate, at least on paper, reaching the current level of 21 percent.

Sources said Centers for Medicare and Medicaid Services planned to hold claims for 10 business days, to give the Senate the opportunity to pass the extenders bill before cuts are made.

"This is complete mismanagement of a health care program that America's seniors and the disabled rely on," said James Rohack, president of the American Medical Association, said of Congressional inaction. "Already, about one in four Medicare patients looking for a new primary care physician have trouble finding one, and congressional inaction will make it much worse."

Senate's inaction will affect military families as well, as Tricare, the health care program for military families, pegs its rates to Medicare.

"It's sad and ironic as we enter the Memorial Day holiday that Congress' inaction on the 21 percent cut puts health care for America's military heroes and their families at risk," Rohack said. Congress needs to buckle down, stop growing the problem and fix it once and for all to save the Medicare and Tricare programs for America's seniors and military families."

Other medical groups similarly slammed Congress for its inaction.

"They have withheld their support even though they knew that the result will be to further undermine physicians' and patients' faith in Medicare and Tricare," said Fred Ralston, president of the American College of Physicians. "They withheld their support, even though they knew it would introduce chaos into physician practices. Physicians, once again, are left with trying to keep their doors open for their patients without knowing, from month to month, how much Medicare and Tricare will reimburse them for their services."

So far, Congress has shown no political will to deal with the problem.



® The Cancer Letter is a registered trademark.

Editor & Publisher: Kirsten Boyd Goldberg

Editor: Paul Goldberg

Editorial, Subscriptions and Customer Service:

202-362-1809 Fax: 202-379-1787

PO Box 9905, Washington DC 20016

General Information: www.cancerletter.com

Subscription \$375 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd.

- Last November, the House passed H.R. 3961, a bill that would have repealed SGR, replacing it with a payment system that would have been based on targets that medical groups describe as more realistic. However, the bill died in the Senate.

- Last Month, the House and Senate leadership attempted to offer a bill that would have provided updates to Medicare through 2014. The bill's goal was to move toward replacing SGR in 2012 through 2014. The measure was withdrawn after it became clear that it lacked sufficient support.

- Last week, H.R. 4213 was amended to include small increases through 2013, This provision, too, was eliminated when it became clear that it didn't have sufficient support.

The impact on the deficit from the latest version of the measure was scored by Congressional Budget Office at \$54.2 billion.

Physician fees paid to oncologists are subject to separate 6 percent cut, which is being phase in over the next four years (The Cancer Letter, July 10, Nov. 6, 2009).

* * *

A House bill seeks to require the Centers for Medicare and Medicaid Services to provide coverage of screening with computed tomography colonography.

The measure, introduced May 28 and called the Virtual Screening for Colorectal Cancer Act of 2010 (H.R. 5461), was introduced by Rep. Danny Davis (D-IL) and cosponsors Mark Kirk (R-IL), and Dan Boren (D-OK)

Medicare doesn't cover the exam, and the U.S. Preventive Services Task Force guidelines, written by generalists and methodologists, doesn't recommend the CT procedure. The task force, which relies on rigorous analysis of several screening strategies, recommends three modalities: colonoscopy, sigmoidoscopy, or fecal occult blood testing.

However, both colonoscopy and colonography are on the list of recommended screening modalities published by the American Cancer Society-led Multisociety Task Force. Those guidelines, written with buy-in from gastroenterologists and radiologists, discussed the pros and cons of screening methods that have an over-50 percent chance of detecting colon cancer (The Cancer Letter, Oct. 10, 2008).

Recently, President Barack Obama underwent a colonography, triggering a turf war between professional societies. Colonoscopists argued that the President had foregone their procedure, which they describe as

the "gold standard." Radiologists, on the other hand, pointed out that while the President was right to choose their procedure, ordinary Medicare recipients would not be able to make the same choice (The Cancer Letter, March 5).

Now, radiologists are hopeful that the House bill would short-circuit the scientific debate and lead to greater utilization of the CT procedure.

"The very facility where President Obama was screened saw a 70 percent increase in colon screenings after virtual colonoscopy was offered as an option," said Judy Yee, chair of the ACR Colon Cancer Committee. "Medicare coverage of CT colonography will allow far wider screening for this deadly disease, find more cancers early when they are most treatable and less costly to treat, and ultimately save thousands of lives each year."

* * *

In another Congressional challenge to USPSTF recommendations, Sen. David Vitter (R-LA) urged HHS Secretary Kathleen Sebelius to remove the controversial breast cancer screening recommendation from the department's web site.

The text of Vitter's letter follows:

"As you know, Section 2713 of the Patient Protection and Affordable Care Act included a provision effectively requiring the federal government to set aside the November 2009 United States Preventive Services Task Force recommendations related to breast cancer screening and mammography. This provision, which I offered as an amendment to the bill, received wide bipartisan support and was adopted by unanimous consent. In light of this support, I am writing to request that your office immediately require the Agency for Healthcare Research and Quality (AHRQ) to remove the November 2009 recommendations from their website and that they, and all other agencies under your purview, immediately cease all promotion of the impugned recommendations.

"The fact that these recommendations are still being presented to the general public as 'current' is only serving to further confuse women on this critical issue. The recommendations were ill-conceived from the start – developed via a process without transparency, without input from those with experience and expertise in the field, and without due regard for the thousands of lives that could be impacted by the recommendation. They represent a step backward in our fight against a horrible disease and the taxpayers' dollar must not be spent in further promotion of them."

In the Cancer Centers:

UNC-Chapel Hill Opens New Research Imaging Center

(Continued from page 1)

potential exposure to such specific environmental hazards as arsenic, asbestos and radon with known cancer health risks; low-cost screening that physicians can perform to identify exposures; a health plan that encourages physicians to provide preventive care for their patients; and the need to not only care for persons with cancer but look for ways to prevent it," said Michael Hatcher, chief of ATSDR's environmental medicine and educational services program.

Michigan residents are at particular risk for potentially contracting an illness or cancer related to environmental factors, because the state has the nation's largest arsenic-contaminated water table, located primarily in the southeastern part of the state. Also, an estimated 300,000 homes have attic insulation that contains asbestos. Radon gas that seeps into basements also poses a health threat, as well as cigarette smoke.

"Physicians need to be aware of the symptoms they should look for when it comes to diagnosing and treating environmental-related cancer and other illnesses," Harbut said. "The risk is real."

Physicians who sign up for the program take four, hour-long online Continuing Medical Education courses developed by the ATSDR. These courses teach physicians about identifying at-risk patients and using appropriate diagnostics and treatment. The program also provides referrals to appropriate specialty centers if needed.

Eligible physicians include members of a Blue Cross "PGIP physician organization" and are considered a primary care physician, a pulmonologist, a pediatrician or oncologist, as defined by BCBS. There is no fee to enroll. Blue Cross will provide physicians a \$500 honorarium on completion of the CME part of the program.

"This program has the potential to help identify the risk of environmental exposure, which can lead to cancer," said **David Share**, executive medical director of Blue Cross Blue Shield Michigan. "It also holds promise as an approach to decrease such risks. Blue Cross Blue Shield of Michigan actively supports health programs which prevent cancer as part of our commitment to optimizing the health of Michigan residents."

UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL opened the UNC-Olympus

Research Imaging Center, providing researchers with advanced microscopes and camera equipment, software, consultation and expertise, in an environment intended to encourage the highest levels of scientific inquiry. The center is designed to stimulate collaboration among top life science research faculty members and will be available to guest researchers as well.

The new imaging center has been endowed by Olympus America Inc., which is providing comprehensive imaging systems featuring state-of-the-art research microscopes, confocal instruments, digital imaging equipment, intravital imaging tools, incubation microscopes, software and substantial ongoing staffing and technical support.

The center, which comprises nearly 2000 square feet of dedicated space, is operating under co-directors **Ken Jacobson**, the Kenan Distinguished Professor of Cell and Developmental Biology, and **James Bear**, associate professor and Early Career Scientist of the Howard Hughes Medical Institute. Both are affiliated with the Department of Cell and Developmental Biology at the UNC School of Medicine and the Lineberger Comprehensive Cancer Center.

Researchers using the center work in cell biology, neuroscience, pharmacology and other specialties that contribute to the study of cancer, Alzheimer's Disease and other conditions.

MEMORIALSLOAN-KETTERING CANCER CENTER said **Sergio Giralt** was appointed chief of the Adult Bone Marrow Transplantation Service in the Division of Hematologic Oncology in the Department of Medicine.

Giralt's research has primarily focused in the area of stem cell transplantation. He is known for his work in the development of nonmyeloablative bone marrow transplantation, which led to an increase in bone marrow transplants for a broader group of patients. This work established that older patients, who had previously been excluded from the procedures, could benefit from transplantation. Giralt also specializes in myeloma and is currently the leader on several clinical trials combining both allo- and autotransplant in myeloma. He serves on the steering committee of the Bone Marrow Transplant Clinical Trial Network and the Board of Directors of the National Marrow Donor Program.

Prior to his appointment at MSKCC, Giralt served as the Blood and Marrow Center Medical Director and Deputy Chair of the Department of Stem Cell Transplantation at MD Anderson Cancer Center.

Also at MSKCC, **Murray Brennan** has been

named vice president for International Programs and director of the Elmer and Mamdouha El-Sayed Bobst International Center at Memorial Sloan-Kettering Cancer Center. Brennan formerly served as chair of Memorial Sloan-Kettering's Department of Surgery.

Brennan, who will continue to treat patients, is a widely respected educator and mentor, as well as a clinician and researcher. During his 20-year leadership of the Department of Surgery (1985–2006), he developed one of the preeminent surgical training programs in the world, educating more than 150 surgical oncology fellows who now practice in hospitals around the world. As a surgeon, Brennan has special expertise in the treatment of soft tissue sarcomas, endocrine tumors, and cancers of the pancreas and stomach. Over the course of his career he has designed and conducted numerous clinical trials, which have produced major findings in the management of patients with soft tissue sarcomas and pancreatic cancer.

Brennan is the incumbent of the Benno C. Schmidt Chair in Clinical Oncology at Memorial Sloan-Kettering and is a member of the Institute of Medicine of the National Academies. He succeeds **Thomas Fahey**, founding director of the International Center, who remains on the attending staff of the Department of Medicine and will serve as an advisor to the International Center.

YALE CANCER CENTER is providing a free podcast called "Cancer Bytes," hosted by **Ellen Matloff**, director of Cancer Genetic Counseling. The program includes interviews with people who have gone through the genetic counseling and testing process.

Matloff covers issues from men with breast cancer, sexuality and intimacy for survivors, and what it is like to carry a genetic mutation (BRCA, HNPCC, and CDH1 are a few covered thus far). To subscribe to the Cancer Bytes podcast, or listen to past interviews visit <http://yalecancercenter.org/surviving/bytes.html>.

HOLLINGS CANCER CENTER at Medical University of South Carolina has recruited **Zihai "Zack" Li**, through the state's Centers of Economic Excellence Program. Li will join MUSC as the CoEE Endowed Chair in Cancer Stem Cell Biology. MUSC and Clemson University are partners in the Center along with Health Sciences South Carolina. Li's work revealed the potential for human stem cells to be used in the creation of a vaccine to protect against colon cancer and potentially for other types of cancer as well.

Li will lead the Center of Economic Excellence

in Cancer Stem Cell Biology. Also, he will direct the cancer immunology program at the Hollings Cancer Center, and serve as co-director of the Cell Therapy Facility and professor of Medicine, Microbiology, and Immunology at MUSC.

In other news at Hollings, the center recently led a statewide effort by healthcare advocacy groups to obtain a voluntary agreement by insurers to reimburse clinical trials participants for standard-of-care procedures for phase II-IV trials.

UNIVERSITY OF NEW MEXICO will dedicate its new UNM Cancer Treatment and Clinical Research Facility in a series of programs June 11-12. UNM Cancer Center provides cancer diagnosis and treatment in its new \$90 million, five-story, 206,000-square-foot facility.

"Our new facility is a welcoming and gracious healing environment where we not only provide state-of-the-art cancer medicine, but also holistic, supportive care to our patients and their families," said **Cheryl Willman**, director and CEO of the UNM Cancer Center. "We are honored and privileged to present this new facility as a gift to the people of New Mexico, who have given us so much support to create our programs and facilities, and we are committed to providing the very best cancer care to them in return—right here in our home state."

Reflecting New Mexico's strong artistic heritage, the first event of "Healing through Arts and Medicine" is a special dedication ceremony and musical performance at UNM's Popejoy Hall on June 11. The Mistress of Ceremonies will be opera singer **Marilyn Horne**, a recent pancreatic cancer survivor. Maestro **Guillermo Figueroa** and the New Mexico Symphony Orchestra, and opera singers **Susan Graham** and **Matthew Worth**, who along with Horne have donated their performances to the UNM Cancer Center for the occasion, will perform "Healing Ceremony," a special musical composition of hope and healing composed by **Marc Neikrug**, artistic Director of the Santa Fe Chamber Music Festival.

"This is a great time for the UNM Cancer Center and the entire UNM Health Sciences Center," said **Paul Roth**, UNM executive vice president for Health Sciences. "The dedication events culminate years of hard work and support from the governor's office, the legislature and the UNM administration to build and staff this state-of-the-art facility that will serve all New Mexicans."

A dedication ceremony and ribbon cutting will be held at the new facility on June 12, and it will be open for public tours.

COLORADO GOV. BILL RITTER signed two bills into law that increase access to anti-cancer therapies.

House Bill 1202 requires insurance companies in Colorado to cover oral chemotherapy drugs for the same co-insurance or copay patients would pay for IV or injected drugs. House Bill 1355 requires insurance companies to cover the cost of anti-cancer drugs recognized by the US Department of Health and Human Services (HHS) as effective against cancer regardless of the specific type of cancer the drug was initially approved to treat—so called “off label” use.

“Frequently we are prevented from using the best treatment or combination of treatments because we don’t want the patient to be stuck with tens of thousands of dollars of medical costs due to lack of insurance coverage,” said **Wells Messersmith**, co-leader of the University of Colorado Cancer Center’s Developmental Therapeutics Program. “Both of these bills are reasonable solutions to patient access to appropriate care.”

About half of all cancer drugs are used “off label”—the drug wasn’t initially approved by FDA to treat a specific type of cancer that experts now agree it is effective against. Lists of acceptable drugs for specific cancers are maintained as “compendia.” HB 1355 requires insurance companies to cover drugs listed by HHS as effective and appropriate, rather than what’s on the label. HB 1202 solves another problem with access to care. Many anti-cancer treatments—and especially new targeted therapies—are developed as pills, rather than intravenous-delivered or injected drugs. Despite the fact that chemotherapy pills are as powerful as their infused or injected versions, let alone more convenient for patients to take, some insurance companies cover the drug only if it is given by IV.

Professional Societies:

Larson, McBride To Receive ASTRO Gold Medals For 2010

AMERICAN SOCIETY FOR RADIATION ONCOLOGY will present its Gold Medal to **David Larson** and **William McBride** during the society’s annual meeting Oct. 31-Nov. 4, in San Diego.

Larson is a former ASTRO president and a 25-year member of the Society. He is currently a professor in the departments of radiation oncology and neurological surgery at the University of California San Francisco and co-director of the Gamma Knife Radiosurgery Program at Washington Hospital Healthcare System in Fremont, Calif.

McBride is a former member of the ASTRO Board of Directors and a 20-year member of the Society. He is currently a professor and vice-chair of research for the UCLA Department of Radiation Oncology and was previously a lecturer at the University of Edinburgh in Edinburgh, Scotland. His research investigates the role of tissue damage responses to radiation in normal tissues and tumors and how to modify these so as to increase the benefit to be derived from cancer radiotherapy.

AMERICAN SOCIETY OF CLINICAL ONCOLOGY and The ASCO Cancer Foundation are honoring 13 community oncology groups for clinical trials and programs that improve the care of people living with cancer and five state affiliates for projects that will have great potential to positively impact their members, ASCO members, other societies and the oncology community.

The Community Oncology Research Grant, the Clinical Trials Participation Awards, and the State Affiliate Grants, awarded by ASCO and TACF, will be presented on June 5-6 at ASCO’s annual meeting in Chicago.

The CTPA recognizes community-based clinical research sites while the projects being supported by the CORG and SAG programs include: the formation of a statewide clinical trial network; a comprehensive state-focused list of cancer providers; an expansion of a community based clinical trials program; as well as a process for identifying quality improvement strategies to help oncology practices improve patient care.

Community Oncology Research Grant, designed to help practicing oncologists enhance their clinical trials programs, a one year grant of \$30,000: Kellogg Cancer Care Centers; Missouri Baptist Cancer Center Research Program; Saint Francis Cancer Treatment Center.

Clinical Trials Participation Award, provides travel grants to attend ASCO’s annual meeting: Gunderson Lutheran Center for Cancer and Blood Disorders; New Hanover Radiation

Oncology Center; Dean Hematology Oncology; Oncology Alliance; Southeastern Medical Oncology Center; Sanford Hematology and Oncology; Saint Francis Medical Center/Cancer Treatment Center; The Virginia Mason Cancer Institute; Sandra and Malcolm Berman Cancer Institute; The West Clinic.

State Affiliate Grant Program: Alabama Society of Clinical Oncology, Kansas Society of Clinical Oncology, Northern New England Clinical Oncology Society, Washington State Medical Oncology Society, West Virginia Oncology Society.

Funding Opportunities:

Administrative Supplements to Advance Special Translational Research Acceleration Projects on Immune Response Modifiers Currently Funded by NCI. (NOT-CA-10-025) <http://grants.nih.gov/grants/guide/notice-files/NOT-CA-10-025.html>.

NIH News:

Science Agencies To Measure Effect Of Research Funding

The next time a member of Congress asks what is the value to Americans from federal funding for research, NIH and the National Science Foundation hope to provide specific answers.

The science agencies, along with the White House Office of Science and Technology Policy, are leading a multi-agency project to monitor the impact of federal science investments on employment, knowledge generation, and health outcomes.

The project is called “Science and Technology for America’s Reinvestment: Measuring the Effect of Research on Innovation, Competitiveness and Science,” or STAR METRICS. NSF and NIH have committed \$1 million for the program’s first year.

“STAR METRICS will yield a rigorous, transparent review of how our science investments are performing,” said NIH Director Francis Collins. “In the short term, we’ll know the impact on jobs. In the long term, we’ll be able to measure patents, publications, citations, and business start-ups.”

Data for the program will come from research institutions that volunteer to participate and the federal agencies that fund them. Information will be gathered from the universities in a highly automated way, with minimal or no burden for the scientists and the university administration.

“It is essential to document with solid evidence the returns our Nation is obtaining from its investment in research and development,” said John Holdren, assistant to the President for science and technology and director of the White House Office of Science and Technology Policy. “STAR METRICS is an important element of doing just that.”

STAR METRICS is based on a pilot program that includes seven research institutions. Now the program is being extended to more universities, with 60 having expressed interest in taking part.

“This project will greatly help science agencies and the research community collaborate in describing

and assessing the impacts of federal investments in science and engineering research and education,” said Arden Bement Jr., director of the NSF.

There are two phases to the program. The first phase will use university administrative records to calculate the employment impact of federal science spending through the American Recovery and Reinvestment Act and agencies’ existing budgets. The second phase will measure the impact of science investment in four areas:

- Economic growth will be measured through indicators such as patents and business start-ups.
- Workforce outcomes will be measured by student mobility into the workforce and employment markers.
- Scientific knowledge will be measured through publications and citations.
- Social outcomes will be measured by long-term health and environmental impact of funding.

The program’s website: http://nrc59.nas.edu/star_info2.cfm.

Interagency Report Identifies Research Needs To Study Climate Change And Health

A report released by a federal working group highlights 11 key categories of diseases and other health consequences that are occurring or will occur due to climate change.

The report, “A Human Health Perspective on Climate Change,” provides a starting point for coordination of federal research to better understand climate’s impact on human health. The recommendations of the working group include research to identify who will be most vulnerable, and what efforts will be most beneficial.

“This white paper articulates, in a concrete way, that human beings are vulnerable in many ways to the health effects of climate change,” said Linda Birnbaum, director of the National Institute of Environmental Health Sciences and the National Toxicology Program, whose institute led the interagency effort. “It lays out both what we know and what we need to know about these effects in a way that will allow the health research community to bring its collective knowledge to bear on solving these problems.”

The white paper highlights the state-of-the-science on the human health consequences of climate change on: asthma, respiratory allergies, and airway diseases; mental health and stress-related disorders; cancer; neurological

diseases and disorders; cardiovascular disease and stroke; waterborne diseases; foodborne diseases and nutrition; weather-related morbidity and mortality; heat-related morbidity and mortality; vectorborne and zoonotic diseases; human developmental effects.

The report also examines a number of cross-cutting issues for federal research in this area, including susceptible, vulnerable, and displaced populations; public health and health care infrastructure; capacities and skills needed; and communication and education efforts.

The ad hoc Interagency Working Group on Climate Change and Health was formed following a 2009 Institute of Medicine Roundtable on Environmental Health Sciences, Research, and Medicine meeting on climate change. At the gathering, leaders from NIEHS, the U.S. Environmental Protection Agency, the National Oceanographic and Atmospheric Administration, and the Centers for Disease Control and Prevention recognized that the scientific discussion around climate change needed to be reframed to emphasize the human health impacts and research needs to address them.

Led by Christopher Portier, from NIEHS, membership of the working group also includes representatives from the National Institutes of Health Fogarty International Center, the U.S. Department of Agriculture, the U.S. Department of State, the White House Office of Science and Technology Policy, and the U.S. Department of Health and Human Services, with support and input from the U.S. Global Change Research Program and others.

The report is available at www.niehs.nih.gov/climatereport.

Clinical Trials:

Consent Forms More Accurate, But Harder To Understand

The consent forms that people sign before participating in research are widely considered difficult to understand and sometimes inaccurate.

A review by researchers at the University of Pennsylvania Law School and Columbia University examined the changes over a quarter century in the accuracy and length of research consent forms used for 215 studies by one department in a major academic center. The study revealed two trends with potentially opposite effects on comprehensibility.

One trend is that the information in the consent forms became more accurate over time, as measured

by discrepancies in the description of risks in the consent forms compared with the descriptions in the study protocols themselves. In the early consent forms evaluated in the study, which dated back to 1978, more than 54 percent had such discrepancies, mainly with the consent forms understating the actual risk. But by 2002, there were no discrepancies.

On the other hand, the consent forms became much longer, growing from an average of a paragraph or two to more than four and a half pages. The increased length could interfere with comprehension: the authors cite data showing that consent forms that are longer than four pages “are unlikely to be read, perhaps in part because of the time involved.”

“Our findings highlight the inherent paradox in attempting to use consent forms to convey ever-more-complete information to potential research subjects,” the authors write. “Greater information is associated with increased length of consent forms, and studies have shown an inverse relationship between length and individuals’ comprehension of the information provided.” They conclude that innovative approaches are needed—possibly including supplementary booklets or computer-based disclosures—to achieve genuinely informed consent.

The study is available at <http://www.thehastingscenter.org/Publications/IRB/Detail.aspx?id=4673>.

In Brief:

SANOFI-AVENTIS has entered into a strategic alliance agreement with the Massachusetts Institute of Technology Center for Biomedical Innovation, which will be known as the sanofi-aventis Biomedical Innovation Programme (SABIP).

The goal of the strategic alliance is to advance knowledge in the area of human health through basic and applied research and to promote scientific exchange between MIT and sanofi-aventis. The alliance provides sanofi-aventis the opportunity to develop therapeutic, diagnostic and prognostic applications based on the discoveries made during the alliance.

Under the newly announced partnership, the SABIP will support a number of activities over the next 3 years through the granting of Biomedical Innovation Funding Awards. These financial awards will provide MIT researchers with focused, flexible and rapidly available support to enable innovative research projects for the development of potential healthcare solutions for patients.