Gulf Separates Funding Levels in House, Senate Appropriations Bills

As this extremely challenging appropriations process continues, two very different budgets have emerged. The Senate has a top-line budget that is $91 billion higher than the House and assumes that sequestration is replaced. The House, on the other hand, is working at a level below the spending caps mandated by the Budget Control Act. The House budget also factors in sequestration. The end result is that the two chambers are producing individual appropriation bills with very different spending levels.

At the time of this writing, the House Labor-HHS appropriations subcommittee has not marked up a bill, but we know

New Polling Examines Attitudes Toward Clinical Trials

New polling, commissioned by Research!America, examined public opinion toward clinical trials, with a deeper analysis of the views of minorities. The poll, conducted by Zogby Analytics, was supported by the Association of Clinical Research Organizations, the Clinical Research Forum, the Clinical Trials Transformation Initiative and Friends of the National Library of Medicine.

All groups said they would participate to improve the health of others—more than 60% of African-Americans, for instance, identified this as a very important reason, compared to 57% of Hispanics, 50% of Asians and 47% of non-Hispanic whites—but the poll found that only 16% said they or a family member had ever enrolled in a clinical trial. A lack of trust, a lack of awareness, and concerns about risk were the most cited barriers to participation.

Among racial groups, 17% of Hispanics, 15% of African-Americans, 15% of non-Hispanic whites and 11% of Asians said they or a family member had enrolled in a clinical trial. Lack of trust was the main concern among African-Americans (61%) and Hispanics (52%), while Asians identified risk and non-Hispanic whites said a lack of awareness. Overall, respondents said that, assuming appropriate privacy protections were in place, they would be willing to share their health information for a number of reasons, most notably to aid researchers and to advance medical research.


Seven in 10 Say Doctors Don’t Talk About Medical Research

Has your doctor or other health care professional ever talked to you about medical research?

AdvaMed—short for Advanced Medical Technology Association—has represented the medical technology sector. Today, the organization has more than 300 members of all sizes, representing medical devices, diagnostic products and health information systems.

The idea of a medical device may conjure images of a cutting-edge machine using breakthrough technology or perhaps the latest diagnostics or genetics test; indeed, that would certainly qualify. But items such as tongue depressors and hospital gowns also fall under the umbrella of AdvaMed’s membership.

“In a sort of broad-brush way, it’s everything that’s used in medicine that’s not a drug,” explains David Nexon, AdvaMed’s senior executive vice president.

The medical device tax that was enacted with the Affordable Care Act is a key policy concern for AdvaMed at the moment. “It’s such a drain on our U.S. competitiveness and our companies’ ability to fund research and development,” Nexon said.

Other policy concerns include keeping America’s taxes competitive globally as part of any tax reform movement; changing the incentives in the reimbursement system to focus on sustaining medical progress while reducing costs; helping AdvaMed’s members navigate the regulatory and payment structures outside the U.S.; and continually working with the Food and Drug Administration to improve the agency’s efficiency at reviewing new technology. Like pharmaceutical companies, medical device companies pay user fees to FDA in order to speed up the approval process; sequestration has affected FDA’s ability to use those fees for their intended purposes.

“The sequester, with the way it’s set up, it keeps you paying the user fees but then doesn’t let FDA use a portion of the money,” Nexon said, “and that’s clearly wrong.”

Nexon said that Research!America’s focus on advocating for all research, with the eventual end goal of better treatments for patients, is a key reason why AdvaMed is a member.

“I think Research!America is a very powerful voice for the importance of both public investment in research, but also creating a climate in the United States that’s friendly to medical progress and developing innovation, whether that comes out of the private sector or the public sector,” Nexon said.

To learn more, visit http://advamed.org.
Porter Op-Ed Warns of Dangers of Budget Cuts
Research!America’s chair, The Honorable John Edward Porter, penned an op-ed that ran in several McClatchy-Tribune newspapers across the country highlighting the dangers that indiscriminate budget cuts pose to our medical and health research ecosystem. “This is not the time to allow our nation’s research enterprise to falter,” he wrote.

Sigal Op-Ed Notes Sequestration’s Impact to FDA
Former Research!America Board member and Friends of Cancer Research Chairperson and Founder Ellen Sigal, PhD, calls attention to sequestration’s damage to the Food and Drug Administration and patients in a Reuters op-ed. “This is government malpractice—every bit as deadly as the medical kind.”

Advocates Continue to Speak Out About Sequestration
Research!America Board member John R. Seffrin, PhD, chief executive officer of the American Cancer Society Cancer Action Network (ACS CAN), and Michael A. Caligiuri, MD, of the Ohio State University Comprehensive Cancer Center, wrote an op-ed in U.S. News & World Report about how the sequester is hurting cancer patients.

Clinical Trial National Public Opinion Poll
Research!America’s national poll on clinical trials received significant media coverage in The Atlanta Journal-Constitution, Bloomberg BNA, EHR Intelligence, FDAWeek, GenomeWeb, LiveScience, MedcityNews, Pharma Times and Pharmalot.

July Fourth Congressional Recess
Research!America President and CEO Mary Woolley and VP of Policy and Programs Ellie Dehoney were interviewed by radio stations in key congressional districts during the recess about the impact of sequestration to research.

Developing Drugs for Rare Diseases
In a letter to the editor published in The New York Times, Ellie Dehoney makes the case that, when only a small subset of patients benefit from medicine that doesn’t lead to a commercially viable product, there should still be an effort to embrace it.

NIH and FY14 Budget
Mary Woolley was interviewed for a profile piece about National Institutes of Health Director Francis Collins, MD, PhD, in Government Executive and spoke with MedPage Today about funding for research and health programs in FY14.

Statement on Appropriations Subcommittee Markup
Research!America’s statement on the Senate Labor-HHS-Education Appropriations Subcommittee markup of FY14 bill was featured in Bloomberg BNA. “[The bill] goes a step in the right direction in softening the blow sequestration has dealt to the hopes and expectations of patients and their families,” Mary Woolley said.

Media Matters

President’s Message
Stakeholders in research have never been as concerned as we all are right now. We see a confluence of opportunity in science, along with urgent patient need and heightened expectations, but see it checked by a push for smaller government that is allowing only the most limited prioritization of funding needs. It’s agonizingly counterintuitive. We sometimes hear that more evidence is needed that research is worth the cost; I think that what we need as much or more of is broader awareness of the existing evidence. That’s a communication task, one that every stakeholder, including every researcher, can take on—and take it on we must. It is time to drive past excuses like “wait until the economy recovers,” to which our response is: By investing in a more robust research ecosystem, through stronger funding and innovation-driving policies, we can turbocharge the economy. And patients are waiting.

Congress will be in recess in the month of August. Many Members have town halls planned. There will surely be discussion of the Affordable Care Act; there should also be discussion of how we can assure a healthier future through the delivery of better health care and prevention based on evidence whether for better diagnostics, drugs and devices, for better prevention strategies (including vaccines), or for better health care systems. But our topics of concern won’t be discussed without your engagement. Tell your representatives that we want #curesnotcuts. Do it in person as well as via social media. Check our website regularly for tips and then tell us your advocacy story.

Mary Woolley
Policy Update

Gulf Separates Funding Levels
Continued from page 1

the subcommittee’s allocation is 18.6% lower than FY13 and nearly 26% lower than the Senate’s. If this reduction is applied evenly to all accounts under the subcommittee’s jurisdiction, the funding level put forward by the House for the National Institutes of Health, for instance, would be approximately $23.5 billion; the Senate markup budgeted $30.96 billion for NIH. If the House and the Senate compromise by agreeing on numbers that are somewhere between the two, then the federal health research agencies are bound to sustain another round of dramatic cuts.

The Food and Drug Administration appears to be faring better: Both the House and Senate proposed increases for FDA, with the Senate increasing funding by $174 million and the House $96 million. In addition, the Senate bill exempts user fees from sequestration, and there is bipartisan legislation in the two chambers that would apply evenly to all accounts under the subcommittee’s jurisdiction, the fund-

2013 FEDERAL RESEARCH BUDGET

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<th>Agency</th>
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* CDC core budget
** Excludes funding from transfers
NIH Releases Fact Sheet on the Impact of Sequestration

The National Institutes of Health recently released an online fact sheet which outlines the negative impact that sequestration will have on both the NIH and medical innovation as a whole in FY13. The fact sheet defines sequestration as it applies specifically to the NIH and provides some details which illustrate how research will be negatively affected. Among the most indicative examples of this effect: There will be approximately 700 fewer competitive research project grants issued, as well as approximately 750 fewer new patients admitted to the NIH Clinical Center, the world’s largest hospital dedicated to clinical research. The fact sheet further outlines the impact of delays to medical progress, as well as the risks to the scientific workforce.

The fact sheet is available at http://1.usa.gov/16VpXkE.

Mikulski, Collins Warn of Sequestration’s Dire Effects

Sen. Barbara Mikulski (D-MD) and National Institutes of Health Director Francis Collins, MD, PhD, warned of the bleak future for biomedical research in the U.S. if sequestration continues to be the law of the land.

“We’re going to lose generations of talent,” Mikulski told an audience of researchers at Johns Hopkins Hospital, according to CQ HealthBeat. Collins said a “remarkably talented” student in his lab was reconsidering her career choice, since she’d seen so many of her role models unable to secure funding.

The cuts are of a more immediate concern as well: Officials at Johns Hopkins told CQ that the institution is facing $70 million in cuts for FY13; $38 million of those cuts are from NIH funding alone.

“Sequester is not a one-time deal for the current fiscal year,” CQ quoted Collins as saying. “If nothing is done, this will persist, leading to a nearly $19 billion loss to NIH-supported research over the next 10 years, with major negative consequences for [U.S.] leadership.”

Cantor, Collins Speak at FasterCures Hill Event

House Majority Leader Eric Cantor (R-VA) reiterated his support for publicly funded biomedical research at a recent event on Capitol Hill hosted by FasterCures.

“If there is anything I believe can bring this nation together for a cause, it is finding cures for disease,” Cantor said in his opening remarks. “We ought to be about research regardless of political leaning, because it is an investment that yields tangible returns for our country.”

The event focused on the importance of translational research at the National Institutes of Health. NIH Director Francis Collins, MD, PhD, and Christopher Austin, MD, director of the National Center for Advancing Translational Sciences, spoke at the event as well. They were joined by Simeon Taylor, PhD, MD, of Bristol-Myers Squibb and Sharon Terry of Genetic Alliance. FasterCures Executive Director Margaret Anderson moderated the discussion.
In May, initial public offerings for life sciences companies reached their highest level since 2000, according to a report from Thomson Reuters and the National Venture Capital Association.

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Research!America Board members Nancy Brown, CEO of the American Heart Association, and John Seffrin, PhD, CEO of the American Cancer Society, were among the 16 people named to the Bipartisan Policy Center’s CEO Council Health Care Advisory Board.

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The United States rejoined the top five most innovative nations in the Global Innovation Index 2013, published by Cornell University, INSEAD and the World Intellectual Property Organization.

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**NEOMED Receives Grant to Study Schizophrenia Treatment**

The Margaret Clark Morgan Foundation has awarded a $5.5 million grant to the Northeast Ohio Medical University’s Best Practices in Schizophrenia Treatment (BeST) Center. The grant is the largest foundation grant in the school’s history.

The grant announcement featured officials from the foundation and the school, as well as The Honorable Patrick Kennedy, a Research!America Board member and a noted mental health advocate.

NEOMED President Jay Gershen, DDS, PhD, is also a Research!America Board member.

In February 2009, the Margaret Clark Morgan Foundation provided a $5 million grant that established the BeST Center.

“This is a momentous day for NEOMED,” Gershen said.

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**Research!America to Host Communications Workshop**

Research!America and its partners are hosting a communications workshop designed to enable young scientists to better communicate the importance of their work to the media and policy makers. The workshop will be held October 9 at The George Washington University and will include the chance to participate in meetings on Capitol Hill.

To learn more or register, visit www.researchamerica.org/communicationsworkshop.

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**Battelle, UMR Release Report on the Impact of Genomics to the U.S. Economy**

United for Medical Research has released a study by Battelle which highlights the nearly $1 trillion impact that the genetics and genomics industry has had on the U.S. economy. Researchers analyzed data collected over the past two years in order to update the 2011 Battelle report, which established a link between the federally funded Human Genome Project and the growth of this frontier-pushing industry.

Carrie Wolinetz, PhD, president of UMR, said in a press release that “this report illustrates the vital role that key federal research funding plays in growing the U.S. economy, creating new industries and innovative technologies and producing the diagnostics and treatments that can save lives.”

The full report can be found at http://bit.ly/1cpiRL3.

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**Research!America Extends Special Thanks to Our Principal Partners**

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- Investment in Research Saves Lives and Money Fact Sheet National Multiple Sclerosis Society
- Visit www.researchamerica.org/partnership_opportunities for ways to support Research!America.

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**AMERICA SPEAKS**

Do you believe that the health care services you receive are based on the best and most recent research available?

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SOURCE: A RESEARCH!AMERICA POLL OF U.S. ADULTS CONDUCTED IN PARTNERSHIP WITH ZOGBY ANALYTICS IN MAY 2013
IOM Report Praises CTSA, Offers Recommendations  
A report by the Institute of Medicine has found that the Clinical and Translational Science Awards Program at the National Institutes of Health is “a worthwhile investment” but that revisions were necessary to maximize the program’s efficiency and effectiveness.

The report’s four “opportunities for action” centered on leadership, collaboration, resource development and maintaining program strengths. Six other recommendations offered more specific tips, ranging from strengthening leadership from the National Center for Advancing Translational Sciences—the NIH institute that funds CTSA—to ensuring community engagement at all phases of research.

The committee that produced the report was chaired by Alan Leshner, PhD, CEO of the American Association for the Advancement of Science and a Research!America Board member. Sharon Terry, president and CEO of Genetic Alliance, was the vice chair.

Surgeon General Regina Benjamin Steps Down  
After announcing her resignation earlier in the summer, Surgeon General Regina Benjamin, MD, left the position July 16.

“She has been a remarkable advocate in promoting the value of prevention as a national health priority. She forged the way as leader of the National Prevention Council, created under the Affordable Care Act, to help transform our nation’s health system from one that focuses on treating disease to one that focuses on prevention and staying well,” said Research!America Board member and American Public Health Association Executive Director Georges Benjamin, MD, in a press release.

Deputy Surgeon General Boris Lushniak, MD, MPH, is serving as acting Surgeon General while a permanent replacement is sought.

U.S. Health Improved Since 1990 but Lags Peer Nations  
Research published in the Journal of the American Medical Association has found that American population health in the U.S. has improved since 1990. But high rates of chronic illness and disability mean that, compared with other wealthy nations, the U.S. ranked 27th out of the 34 nations studied.

“Individuals in the United States are living longer but are not necessarily in good health,” the authors wrote.

The U.S. fell in a number of categories, including early deaths, life expectancy from birth and healthy life expectancy.

Read the full report at http://bit.ly/14Qg3VO.

Nearly Half Say Participants are Treated Fairly and with Respect  
SOURCE: A RESEARCH!AMERICA POLL OF U.S. ADULTS CONDUCTED IN PARTNERSHIP WITH ZOGBY ANALYTICS IN MAY 2013. (TOTALS DO NOT ADD TO 100% DUE TO ROUNDING.)
We Need Cures, Not Cuts!

Sequestration’s arbitrary, across-the-board budget cuts to defense and non-defense spending have ravaged (and will continue to ravage) our research enterprise. Funding cuts are stopping highly promising research in its tracks, squandering exciting new potential for treatments and cures for millions of Americans who are waiting for them. We can’t let this continue. Tell Congress: WE NEED CURES, NOT CUTS!

During the August congressional recess, Research!America and our partners will continue a social media campaign on Facebook and Twitter using the hashtag #curesnotcuts. We encourage you and your organization to join us! More information can be found at http://bit.ly/1ckGXXj.
Join us for Research! America’s 10th Annual National Health Research Forum:

**Straight Talk about the Future of Medical and Health Research**

**Thursday, Sept. 12, 2013**

**Newseum Knight Conference Center**

555 Pennsylvania Ave. NW

Washington, DC

Confirmed moderators and panelists include:

- Eleanor Clift, *Newsweek* (moderator)
- Michelle Miller, CBS News (moderator)
- Norm Ornstein, PhD, American Enterprise Institute (moderator)
- Patrick Conway, MD, Centers for Medicare & Medicaid Services
- Francis Collins, MD, PhD, National Institutes of Health
- N. Anthony Coles, MD, Onyx Pharmaceuticals
- Thomas Frieden, MD, MPH, Centers for Disease Control and Prevention
- William Hait, MD, PhD, Janssen Pharmaceuticals
- Robert Hariri, MD, PhD, Celgene Cellular Therapeutics
- Margaret Hamburg, MD, Food and Drug Administration
- E. Albert Reece, MD, PhD, Univ. of Maryland School of Medicine
- Lisa Simpson, MB, BCh, MPH, AcademyHealth

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