NIH, CDC, AHRQ Await Funding Decisions

On June 12, the Senate subcommittee overseeing the National Institutes of Health, the Centers for Disease Control and Prevention, and the Agency for Healthcare Research and Quality will release its “mark-up” to allocate funding for FY13 for those and other Labor-HHS agencies. The House subcommittee dealing with these agencies has not yet made such an announcement. Final funding decisions will likely not occur until after the elections.

The House and Senate have released and reconciled their respective funding recommendations for the National Science Foundation, which is poised to receive an increase in FY13. The bill providing the increase in funding has been sent to President Barack Obama for his signature, but the White House has released a statement indicating that the president will not sign legislation that fails to comply with the Budget Control Act (BCA). This act had previously established funding levels, which were undercut in the House bill that sets funding for NSF. (While NSF received a slight increase, other agencies under the jurisdiction of the same subcommittee received deep cuts.) The House is basing their appropriations bills on an overall spending level that is $19 billion less than the levels agreed to in the BCA. As a result, it is unlikely that the president will sign any spending bill at this time.

Research!America Releases Report on the Potential Impact of Sequestration

If enacted, the effect of sequestration—or across-the-board cuts in funding—will have a devastating impact on research to improve health. To that end, Research!America’s most recent publication, “Sequestration: Health Research at the Breaking Point,” helps demonstrate what could be lost if sequestration takes effect in January 2013.

Assuming a conservative, 7.8% budget cut, the report identifies budget items that are equivalent to the cut across five government agencies: the National Institutes of Health, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Food and Drug Administration, and the National Science Foundation.

For example, each of the following is roughly equivalent to the amount due to be lost by sequester at their respective agencies:

- Nearly half the entire budget of the National Cancer Institute;
- Funding for the CDC’s Vaccines for Children program in 22 states and the District of Columbia;
- Funding for the Agency for Healthcare Research and Quality;
- Funding for the Food and Drug Administration; and
- Funding for the National Science Foundation.

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- Funding for the National Science Foundation.

Wide Majority Concerned About Effects of Stagnant Funding

Science and technology are responsible for about half of our economic growth since World War II. Flat and decreasing federal investment in research creates an uncertain future for scientists. As a result, scientists may leave their profession and move abroad and use their scientific training in countries with strong and stable investments in research.

In your judgment, what level of concern is this to the United States?

<table>
<thead>
<tr>
<th>Concern Level</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>A great concern</td>
<td>43%</td>
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<tr>
<td>Somewhat of a concern</td>
<td>42%</td>
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<tr>
<td>Somewhat unimportant</td>
<td>7%</td>
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<tr>
<td>Not much of a concern</td>
<td>2%</td>
</tr>
<tr>
<td>Not sure</td>
<td>6%</td>
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SOURCE: A RESEARCH!AMERICA POLL CONDUCTED IN PARTNERSHIP WITH JZ ANALYTICS IN MARCH 2012.
In 1912, leaders from three professional societies saw a need to “increase the efficiency of the societies as agencies for the promotion of research.” On the final day of that year, at the meeting of the American Society for Pharmacology and Experimental Therapeutics in the old Colonial Hotel in Cleveland, FASEB was born. A century on, FASEB represents 26 societies and more than 100,000 members.

Throughout 2012, FASEB is commemorating its centennial. Special activities include increased outreach to scientists, an expanded Capitol Hill Day, and a series of district initiatives (including new state and district-level fact sheets for the National Institutes of Health and National Science Foundation).

The society’s current president, Joseph LaManna, PhD, has a special celebration planned too: As a Cleveland resident—he is a professor at the Case Western Reserve University School of Medicine—he is trying to put together a December 31 gathering at the Residence Inn downtown, where the Colonial Hotel once stood, to mark FASEB’s birthday.

“If you look at scientific progress over the last 40, 50, 60 years or so,” LaManna said, “the way lifespan has changed, there were somewhere around 3,000 people who were 100 years old in 1912. By 2012, the number is 30 times that.”

LaManna said he recently was forced to miss the 100th birthday party of his aunt; her lifespan exceeds that of FASEB by less than a year. And, he believes, someone born today will be alive for FASEB’s 250th birthday.

All of the celebrations have not slowed down FASEB’s mission, however. LaManna said, even in a difficult fiscal environment, he’s been encouraged by his trips to Capitol Hill that elected officials on both sides are supportive of researchers and the work they do.

And though he won’t be FASEB president for his New Year’s Eve party—president-elect Judith S. Bond, PhD, of the Penn State College of Medicine takes over July 1—LaManna will remain involved with the organization.

For LaManna and FASEB, a membership with Research!America helps amplify FASEB’s messages.

“The general public knows more who [Research!America is] than they would know who FASEB is,” he said. “We go along with you, and they see us. And that helps us.”

To learn more, visit www.faseb.org and www.fasebcentennial.org.

Research!America Adds Value

Research!America stands on a reputation of innovative advocacy that generates results serving our mission and the interests of our members:

• Our publications demonstrate the critical role that research to improve health plays in both the health of all Americans and the U.S. economy. Most recently, our report on pending sequestration, or across-the-board cuts, linked the amount of federal funding under threat to current programs employed by federal research agencies.

• Research!America’s global health R&D advocacy has featured the health impact and the economic impact of global health research conducted in various states across the country.
Sequestration Report Shows Potential Threat to Research

Several media outlets wrote articles about Research!America’s report, “Sequestration: Health Research at the Breaking Point,” released in May, including Politico Pro, CQ HealthBeat and The Hill. The report demonstrates the damaging consequences of potential automatic spending cuts to medical research and public health and illustrates how these cuts could slow medical progress.

A More Efficient Drug Approval Process

An op-ed in The Hill and written by Research!America Board members Mark McClellan, MD, PhD, director of the Engelberg Center for Health Care Reform at the Brookings Institution, and Ellen Sigal, PhD, chairperson and founder of Friends of Cancer Research, focused on how the Food and Drug Administration could work more strategically in the release of new “breakthrough” treatments.

Letters to the Editor on Research and Prematurity

Research!America President and CEO Mary Woolley had a letter to the editor published in The New York Times on May 30. Woolley responded to an article about highly skilled workers training in the U.S. but leaving after college to pursue opportunities abroad. “It’s no surprise that expatriates are returning home to countries that are aggressively ramping up their investments in research and development as our nation’s commitment to the research enterprise continues to fall short,” she wrote.

The Charlotte (NC) News & Observer published a letter to the editor from Suzanne Wilkison, president of the North Carolina Association for Biomedical Research, urging congressional candidates to state their views on research.

A letter to the editor, written by Billie Lou Short, MD, chief of the Division of Neonatology at Children’s National Medical Center and researcher at the Children’s Research Institute in Washington, DC, appeared in USA Today in response to the newspaper’s article, “More than 1 in 10 babies born premature.”

Stimulating Research Advocacy at Universities

During Research!America President and CEO Mary Woolley’s visits to the University of Nebraska Medical Center, Nebraska Coalition for Lifesaving Cures and Oregon Health & Science University, the Omaha World-Herald and Portland Business Journal covered the visits and described the need for more advocacy from scientists and the possible consequences of sequestration.

Global Health Event in New York

Research!America’s global health event in New York City and new state poll were featured in Nature Medicine’s blog, Spoonful of Medicine; HIVe Vaccine Enterprise; Science Newline Medicine; Medical Xpress; Science Codex and The Center for Global Health Policy’s Science Speaks.

Research!America/ScienceDebate.org Poll Highlighted

Shawn Lawrence Otto, cofounder of ScienceDebate.org, described some of the findings in the Research!America national poll on Americans’ attitudes about faith and science in The Huffington Post. The article and the poll, cosponsored by ScienceDebate.org, showed that the overwhelming majority of American voters want candidates to talk about science.

With June upon us, media and political attention will be focused on the Supreme Court’s expected ruling on the Affordable Care Act. The court will not be weighing in on research for health per se; what it will do, by triggering the election-season debate on government’s role in health care, is give us our cue to talk about the real game-changer for the future of health: research.

Vaccines, tobacco cessation, heart disease prevention, the dramatic transformation of HIV/AIDS into a controllable illness, our ability to treat and cure childhood cancer, putting babies on their backs to sleep—all of these advances and more are the result of research; lives have been saved, health care costs reduced. Now consider the future: If we don’t find a way to prevent, treat and ultimately cure Alzheimer’s disease, the federal government will shoulder trillions of dollars in Medicare and Medicaid costs. And that’s just one example!

Importantly, let’s not forget that federally funded medical research lays the scientific groundwork for private sector medical innovation, fueling new businesses and jobs in the research and manufacturing sectors. A majority of respondents to the most recent poll we have commissioned say that research should be exempted from any across-the-board cuts in the federal budget. People realize that research is an indispensable investment in the future of our nation and the health of every American. We must all tell this story and tell it often. We can’t wait for the nation’s research infrastructure to crumble before standing up and fighting for it. Stay in touch with us as the weeks go by for suggestions on how to get the message out.
Agencies Await Funding Decisions

The Senate has released a funding recommendation for the Food and Drug Administration, providing a slight increase of about $50 million over FY12 levels. The House has not yet released a funding recommendation for FDA.

While these are encouraging signs for health research, any funding increases may be undone by across-the-board budget cuts—sequester—that will take effect in January 2013 unless legislation is passed to prevent them. In addition, the upcoming elections will likely complicate and delay the appropriations process. Many of the more controversial bills, such as those that provide funding for NIH, CDC and AHRQ, may not be decided upon until after the election. Finally, the president’s veto threat on appropriations bills that are below the BCA spending levels—while a positive step in terms of preserving critical funding—creates additional uncertainty regarding the timing of this year’s budget process.

Regardless of the timing, however, the bottom line is that health and medical research funding is at risk. There is no bad time to contact your federal representatives and let them know that federal investment in continued medical progress is important to you, your family and the nation as a whole. We can’t afford to be complacent as the incidence of Alzheimer’s grows, cancer takes more lives, and other disabling and deadly diseases bring pain and suffering to millions of Americans. Write your representatives now.

FDA User Fee Legislation

The Senate and the House have passed legislation that would reauthorize industry user fees that help expedite the review and approval process for brand and generic prescription drugs, biologics and biosimilars, and medical devices. These bills also include important changes to FDA policy, including avenues for better communication between industry and FDA to prevent unnecessary delays in the review and approval of new medical products and new incentives to help address the issue of microbial resistance by bolstering the antibiotic pipeline.

The bills will be subject to reconciliation efforts between the Senate and House. According to reports, leaders in both houses have said they would like to finalize and deliver a bill to the White House by early July.

CPH Foundation Update

The CPH Foundation recently released a video challenging the budget plan of Rep. Paul Ryan (R-WI). The Foundation’s “vlog” questions how increasing provider options alone will lower the cost of Medicare. They argue that Ryan’s failure to mention prevention is a huge missing piece and that lowering health care expenditures will require reducing the number of sick people entering the health care system.

Watch the video at www.youtube.com/TheCPHFoundation.

Policy UPDATE

2012 FEDERAL RESEARCH BUDGET

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<tr>
<th>Agency</th>
<th>FY12 Enacted</th>
<th>FY13 President’s Request</th>
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<tr>
<td>National Institutes of Health</td>
<td>$30.7 billion</td>
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<tr>
<td>Centers for Disease Control and Prevention*</td>
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<td>National Science Foundation</td>
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<tr>
<td>Agency for Healthcare Research and Quality**</td>
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<td>$334 million</td>
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</table>

* Reflects the CDC core program budget.  ** Excludes funding from transfers.
NCATS, Industry to Collaborate on New Therapies from Old Compounds

Three industry partners—AstraZeneca, Eli Lilly and Co., and Pfizer—will turn over a total of 24 compounds for the pilot phase of a new initiative with the National Institutes of Health’s National Center for Advancing Translational Sciences called Discovering New Therapeutic Uses for Existing Molecules.

Through grants from NCATS, those compounds will be tested by researchers for efficacy in other diseases and conditions. Each of the compounds has already undergone significant testing, including for safety in humans. The initiative aims to improve on current therapies more quickly.

“Clearly, we need to speed the pace at which we are turning discoveries into better health outcomes,” NIH Director Francis Collins, MD, PhD, said in a statement.

In the pilot program, companies will retain the ownership of their compounds. Researchers, meanwhile, own any intellectual property that arises from their work and the right to publish their work.

Members of Congress, Institutions Announce Golden Goose Awards

Instead of mocking odd-sounding research, three representatives—Reps. Jim Cooper (D-TN), Charlie Dent (R-PA) and Robert Dold (R-IL)—have banded together with seven organizations to announce the Golden Goose Awards. The awards will celebrate researchers whose projects, while sounding unusual, led to discoveries that benefited society.

“We’ve all seen reports that ridicule odd-sounding research projects as examples of government waste,” Cooper said. “The Golden Goose Award does the opposite. It recognizes that a valuable federally funded research project may sound funny, but its purpose is no laughing matter. I hope more of my colleagues will join us in supporting, not killing, the goose that lays the golden egg.”

“There is an urgent need to inform policy makers and the public about the nature of basic scientific research and about the relationship between that research and the economy—we can’t grow our economy if we don’t fund the scientific research that supports it,” said Alan Leshner, PhD, CEO of the American Association for the Advancement of Science and Research!America Board member. “This is why the message behind the Golden Goose Award is so important.”

Besides AAAS, the other founding organizations of the Golden Goose Awards are the Association of American Universities, the Association of Public and Land-grant Universities, the Breakthrough Institute, the Progressive Policy Institute, The Science Coalition, and the Task Force on American Innovation.
Research!America Releases Update to Fact Sheet on Prematurity

Research!America has released an update to one of its “Investment in Research Saves Lives and Money” fact sheets. The 19th in the series, focusing on prematurity, was updated this spring with support from the March of Dimes Foundation.

Research has led the way to a dramatic, fourfold decrease in infant death rates since 1950, and it has played a critical role in reducing the number of premature births as well. Besides lives saved, hydroxyprogesterone—a hormone that can reduce preterm birth—saved as much as $450 million per year and $2 billion over the lifetime of babies who would have otherwise been born premature by preventing major health problems associated with prematurity.

The Albert and Mary Lasker Foundation is a founding partner in the “Investment in Research Saves Lives and Money” fact sheet series.

Foege Receives Presidential Medal of Freedom

William Foege, MD, MPH, former director of the Centers for Disease Control and Prevention and a towering figure in public health, was one of 13 recipients of the Presidential Medal of Freedom. President Barack Obama cited the winners at a White House ceremony.

Foege, the 2008 winner of the Raymond and Beverly Sackler Award for Sustained National Leadership at Research!America’s Advocacy Awards, is a senior fellow in the Global Health Program at the Bill & Melinda Gates Foundation and holds professorships at Emory University and the University of Washington.

Other honorees included former Secretary of State Madeleine Albright, PhD; singer-songwriter Bob Dylan; astronaut and former Sen. John Glenn (D-OH); author Toni Morrison; president of Israel Shimon Peres; former Supreme Court Justice John Paul Stevens; and legendary women’s basketball coach and Alzheimer’s disease advocate Pat Summitt. The awards were presented May 29.

The report also features comments from the heads of the five agencies represented: AHRQ’s Carolyn Clancy, MD; NIH’s Francis Collins, MD, PhD; CDC’s Thomas Frieden, MD, MPH; FDA’s Margaret Hamburg, MD; and NSF’s Subra Suresh, MS, ScD. There are also testimonials on the potential impact of sequester from the perspectives of a patient advocate (Alex Silver of the Jackson Gabriel Silver Foundation), a researcher (Keith Yamamoto, PhD, of the University of California, San Francisco) and a Research!America Board member) and a representative from industry (Bob McNally, PhD, of GeoVax, Inc.).

To download the report, visit www.researchamerica.org/sequestrationreport.

Sequestration Report
Continued from page 1

• More than the total AHRQ spent on advancing health IT;
• Nearly all that the FDA spent on reviewing and approving biologics;
• And more than the NSF spent on all undergraduate educational support programs.

Over Half Skeptical that U.S. Will Be a Leader in Health Care

In your view, which of the following will be considered the No. 1 world leader in health care in the year 2020?

SOURCE: A RESEARCH!AMERICA POLL CONDUCTED IN PARTNERSHIP WITH JZ ANALYTICS IN MARCH 2012.
Research!America Hosts Global Health R&D Forum in New York City

“If we cannot protect the U.S. commitment to global health spending, every single program in global health is going to have to chop, chop, chop its budget.” With this statement, Laurie Garrett, senior fellow for global health at the Council on Foreign Relations and the moderator of Research!America’s forum, “Global Health Research and Development in New York: Fueling Innovation and Saving Lives,” set the tone of discussion and provided a call to action to the New York global health community.

Mary Woolley, president and CEO of Research!America, and Rep. Nita Lowey (D-NY), opened the forum—held in April at the New York Academy of Sciences—by acknowledging the remarkable progress made in global health R&D in the past decade and the significant impact that this work has had on New York’s economy.

Garrett then moderated a discussion among expert panelists Rachel Cohen, regional executive director, Drugs for Neglected Diseases initiative North America; Jack DeHovitz, MD, MPH, director, SUNY Downstate AIDS International Training and Research Program; Margaret McGlynn, president and CEO, International AIDS Vaccine Initiative; Mel Spigelman, MD, president and CEO, Global Alliance for TB Drug Development; and Pol Vandenbroucke, MD, vice president of development, emerging markets, Pfizer. In addition to discussing potential consequences of the proposed funding cuts to global health programs in the president’s FY13 budget request, panelists also talked about the role of public-private partnerships in sustaining the momentum of progress in global health R&D in New York.

AIDS Quilt Headed to DC This Summer

The AIDS Memorial Quilt will spend June and July in the nation’s capital to coincide with the XIX International AIDS Conference—also being held in Washington this summer.

The quilt’s 47,000 panels represent 94,000 individuals who have lost their battle with AIDS. Part of the quilt will appear on the National Mall, and other parts will appear at venues throughout the DC region.

AIDS 2012 will be held July 22-27 at the Walter E. Washington Convention Center. Registration remains open.

Majority Feels Medical Research Will Impact U.S. in the Future

On a scale from 1 to 5, please rate government investment in medical and health research relative to how seriously you believe each will impact the future of the United States.

- 5 (serious impact on the nation): 31%
- 4: 35%
- 3: 22%
- 2: 6%
- 1 (no serious impact on the nation): 1%
- Not sure: 5%

Source: A Research!America poll conducted in partnership with ZJ Analytics in March 2012.
Congress Could Cut Billions from Medical Research

In January 2013, all health research agencies could be subject to a multi-billion dollar budget cut! This budget cut, commonly referred to as the sequester, would have a devastating impact on patients and researchers. It could deprive the National Institutes of Health, the Centers for Disease Control and Prevention, the National Science Foundation, the Food and Drug Administration, and the Agency for Healthcare Research and Quality of the funding they need to support lifesaving research throughout the country. To download Research!America’s report on sequestration, visit www.researchamerica.org/sequestrationreport.

Contact your representatives right away and let them know that we cannot allow the sequester to occur. Like this alert on Facebook, and remember to share with your networks.

Visit www.researchamerica.org
Investment in research saves lives and money

facts about: Prematurity

Today:

- Each year, more than half a million babies are born premature (gestation period of less than 37 weeks) in the U.S. That’s one in every eight births.*
- Of the nearly 30,000 babies who die each year before their first birthday, 68% are born preterm.*
- Preterm infants (less than 37 weeks) are 15 times as likely to die as full-term babies during the first year of life, and very premature infants (less than 32 weeks) are 73 times as likely to die during this same period.*
- Preterm infants are at significantly higher risk for cognitive deficiencies, cerebral palsy, respiratory problems, vision and hearing loss, and feeding and digestive problems.**

*SOURCE: CENTERS FOR DISEASE CONTROL AND PREVENTION (WWW.CDC.GOV)
**SOURCE: MARCH OF DIMES (WWW.MARCHOFDIMES.COM)

The Cost:

- In 2005, preterm births in the United States cost more than $26 billion for medical care, delivery, early intervention services, special education and lost productivity.*
- First-year average medical costs totaled more than $32,000 for preterm infants compared to about $3,300 for term infants in 2005.**
- The cost of saving a life of a very low weight (less than 3 lbs., 5 oz.) preterm newborn is nearly $550,000.***

*SOURCE: INSTITUTE OF MEDICINE (WWW.IOM.EDU)
**SOURCE: MARCH OF DIMES (WWW.MARCHOFDIMES.COM)

Survivor:

NAME: LAUREN FLEMING
AGE: 7
CONDITION: BORN 3 MONTHS EARLY

Lauren Fleming was born in 2004 at just 26 weeks, weighing 2 pounds, 1 ounce, and doctors prepared her parents for the worst. During her 5-month stay in newborn intensive care, Lauren was treated for respiratory distress and underwent multiple surgeries related to a damaged vocal cord and a heart defect. Today, in many ways, she acts like a typical 7-year old, but because of her premature birth Lauren has asthma and ongoing gastrointestinal and receptive language issues. The cost of Lauren’s medical care is nearly $1 million and counting. Doctors prepared the Flemings for the worst, Densel says, but “Lauren did everything doctors said she wouldn’t be able to do — like cry and breathe on her own. I knew she was saying to me, if I’m willing to fight, then, Daddy, you better be man enough to fight as well.” Today, Lauren is a warm and loving 7-year old who makes friends easily and loves to dance, draw, create storybooks and read.

The Flemings are grateful for the March of Dimes research and treatment that helped Lauren beat the odds and helped their other two children, Erin and Corbin, be born healthy.

As the 2011 March of Dimes National Ambassador, Lauren and her family traveled the country, sharing her inspiring story to help raise awareness of premature birth and encourage families and companies to walk with them in March for Babies.*

*SOURCE: AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (WWW.AHRQ.GOV)
Hope for the Future:

- Research by the NIH and Wayne State University has found that a progesterone gel can reduce the risk for preterm birth for women with a short cervix.*
- Research has indicated that thyroid dysfunction during pregnancy puts mothers at risk for preterm pregnancy. Proper treatment of thyroid conditions may significantly reduce the risk of a premature birth.**

**SOURCE: NATIONAL INSTITUTES OF HEALTH (WWW.NIH.GOV)

The Bottom Line:

Medical research has identified effective strategies for the prevention of preterm births and the treatment of premature babies. These advances have made a remarkable difference, saving lives and preventing serious disabilities. However, the high incidence of preterm births and resulting complications remain a major health concern in the U.S. The complex nature of preterm birth requires additional research on the biological and psychosocial causes of, and treatments for, prematurity to address this serious medical problem.

Number of Premature Births 2009

SOURCE: NATIONAL CENTER FOR HEALTH STATISTICS 2009 NATALITY DATA PREPARED BY THE MARCH OF DIMES PERINATAL DATA CENTER, 2011