

The Hard Numbers

AGENCY	(-) 7.8% SEQUESTER
National Institutes of Health	\$2,393,820,000
Centers for Disease Control and Prevention	\$444,600,000
Agency for Healthcare Research and Quality	\$29,016,000
Food and Drug Administration	\$191,100,000
National Science Foundation	\$ 538,200,000

Total Estimated Effect of Sequester: \$3.6 billion*

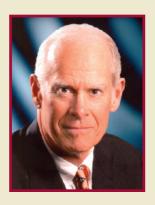
Message from Research!America Leadership

The prospect of automatic spending cuts, or sequestration, scheduled to take effect in January 2013, casts a pall over future U.S. leadership of research and development and would delay access to new medical treatments. Sequestration would slash federal investments in critical health, scientific, medical and biological research aimed at discovering treatments, moving safe and effective new medicines to market, and creating the innovations to grow our economy. More than 80% of these dollars are competitively awarded to universities, academic medical centers, small businesses and independent research institutes throughout the nation to ensure our leadership in a global marketplace. Sequestration would negatively impact job creation, scientific progress, the health of Americans and U.S. competitiveness just as other nations are aggressively boosting their investments in research and development.

Cutting health and medical research funding is the wrong strategy for reducing the federal deficit. Why?

- · Research and development fuels the economy by creating new businesses and new jobs
- It is our best weapon against the exploding health care costs of major diseases
- It reduces waste and inefficiencies in our health care system
- It saves lives

This report, "Sequestration: Health Research at the Breaking Point," illustrates the dire consequences of a 7.8% cut, which could reduce funding for research agencies by approximately \$3.6 billion in 2013 alone. The National Institutes of Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Agency for Healthcare Research and Quality, and the National Science Foundation would lose critical funding for innovative research and programs that save lives and drive economic growth. Examples demonstrating the impact of sequestration on these agencies and the nation can be found in this unique compilation of data, statements and testimonials from the heads of the federal health agencies and individuals from the patient community, academia and industry. Research!America and our member organizations, representing academic institutions, industry, foundations, and scientific and patient groups, urge Congress to preserve and increase funding for research to maintain American leadership in science and innovation in an increasingly competitive global environment.



John Edward Porter chair, Research! America



Mary Woolley

president & CEO, Research! America



What does \$2.39 billion mean to the National Institutes of Health?

- → The National Institute of Allergy and Infectious Diseases spent slightly more than \$2.7 billion in external grant funding in FY11.¹
- → In FY11, 50 states, three territories and the District of Columbia received grants from the NIH; the bottom half of that list, ranked by funding, totaled \$2.35 billion.²
- → All external grant funding related to training and Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs in FY11 equaled \$1.43 billion. These programs fuel job creation at research-intensive startups across the nation and foster the next generation of researchers.³
- → That amount of money is equal to nearly half of the entire budget of the National Cancer Institute, which itself is the largest of the NIH's 27 institutes and centers.⁴
- → That amount covered NIH funding in FY11 for hundreds of rare and common diseases and conditions, including: sickle cell disease, West Nile virus, childhood leukemia, hepatitis A and B, attention deficit disorder, ALS (Lou Gehrig's disease), neonatal respiratory distress syndrome, fetal alcohol syndrome, food allergies, Duchenne and Becker muscular dystrophy, cerebral palsy, frontotemporal dementia, sudden infant death syndrome, emphysema, Down syndrome, Hodgkin's disease, spina bifida, psoriasis, and chronic fatigue syndrome.⁵

What does **\$445** million mean to the Centers for Disease Control and Prevention?

- → CDC spent \$345 million on all cancer prevention and control in 2011.6
- → CDC spent \$467 million on Public Health Scientific Services. This is essential research on health statistics, surveillance, epidemiology, and informatics which helps track disease.⁷
- → In FY11, budget authority for CDC's Immunization grant program was \$426 million. Without this program, CDC would not be able to fund state immunization grants that support the reduction of vaccine-preventable disease. Grants fund both the purchase of immunizations themselves and the infrastructure necessary for wide dissemination, surveillance, and outbreak control.⁸
- → That amount is equivalent to FY11 funding for the Vaccines for Children program in Alaska, Connecticut, Delaware, Hawaii, Idaho, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, New Hampshire, Nevada, New Mexico, North Dakota, Oregon, Rhode Island, South Dakota, Utah, Vermont, West Virginia, Wyoming and the District of Columbia. 9
- → That amount equals FY11 funding for all chronic disease prevention and health promotion programs in every state except for California, Georgia, Michigan and New York.⁹
- → That amount is equivalent to all CDC funding to Louisiana, Missouri, Tennessee and Virginia in FY11.9



What does **\$29 million** mean to the Agency for Healthcare Research and Quality?

- → That amount equals 62% of AHRQ's total FY11 budget for investigator-initiated research grants for quality, effectiveness and efficiency research.¹⁰
- → In FY11, AHRQ spent \$27 million advancing health information technology.¹¹
- → AHRQ spent \$29 million to fund extramural grants in 23 states in FY11: Alaska, Alabama, Arizona, Colorado, Florida, Georgia, Hawaii,

- Maine, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, Oklahoma, Rhode Island, South Carolina, Tennessee, Utah, Washington, Wisconsin and Wyoming.¹²
- → The cut is equivalent to 95.3% of all FY11 AHRQ spending on its patient safety and Medical Expenditure Panel Survey, which is the country's most complete resource on the cost and use of health care and health insurance coverage.¹³

What does **\$191 million** mean to the Food and Drug Administration?

- → That amount is virtually the same amount FDA spent in FY11 to review and approve biologics, a new and complex class of medications that has revolutionized the treatment of arthritis, MS and other major diseases.¹⁴
- → In FY11, FDA spent \$213.6 million on the National Center for Toxicological Research and its Animal Drugs and Feeds Program. ¹⁵ ¹⁶
- → The amount is more than the agency's budget for pre-market review of medical devices ¹⁷
- → That amount is equivalent to the agency's FY11 laboratory analysis activities for domestic foods, drugs and other products under its purview.¹⁷

What does **\$538 million** mean to the National Science Foundation?

- → That's nearly 75% of NSF's entire budget for all biological sciences research in FY11.18
- Approximately 70% of that amount was spent in FY11 on homeland security research endeavors, which includes research into improving counterterrorism, cybersecurity, emergency planning and response, and research to combat bioterrorism.¹⁹
- → That amount is equivalent to FY11 funding for 13 of the top 50 NSF-funded universities: Florida State University, Harvard

- University, University of Southern California, Oregon State University, Virginia Tech, University of Florida, Iowa State University, Ohio State University, Indiana University, the University of Massachusetts Amherst, Johns Hopkins University, the University of Hawaii and the University of Tennessee.²⁰
- → A total of \$523 million supported all undergraduate educational support programs in FY11, including training, scholarships and novel research opportunities.²¹

CDC



"CDC works 24/7 to protect the health of all Americans. Each of us depends on public health agencies to protect our food supply, guard against deadly infectious diseases, improve our chances of avoiding deadly — and costly — chronic diseases, and improve our quality of life. Those of us who help address our health threats every day — and see the potential for

saving lives and money — think this is no time to let down our guard. An 8%-10% reduction, on top of 50,000 front-line public health professionals already lost at the state and local levels, will risk costly and deadly spread of disease and failures to prevent tragic and expensive health problems. Instead, this is the time for thoughtful, sustained, strategic investments in prevention and health protection that can save lives and help reduce future costs."

Thomas Frieden, MD, MPH

director, Centers for Disease Control and Prevention

NIH

"The estimate that has been put forward by an analysis would result in roughly 2,300 grants that we would not be able to award in FY13 that we otherwise would have expected to. That represents almost a quarter of our new and competing grants. That would result in success rates for applicants who come in with new applications, or competing ones, falling to



historically low levels and would be devastating for many investigators who are seeking to continue programs that they have had funded in the past and are back for their competing renewal, or who are starting things that are entirely new; and I think the burden would hit particularly heavily upon first-time investigators who are seeking to get their programs up and going, and upon learning of something of this sort, what is already a considerable sense of anxiety in that cohort, who are our future, would only go up."

Francis Collins, MD, PhD

director, National Institutes of Health

AHRQ



"AHRQ's relentless focus on making care safer has made measurable improvements in the quality of health care, for

example, as seen in our support of work to reduce central line bloodstream infections, which thus far has resulted in almost 500 lives saved and more than \$32 million in excess costs averted in a 2-year period. This success and others are the direct result of AHRQ's ongoing efforts to accelerate the application of science in the health care system to improve patient care. Further budget reductions, such as those envisioned by sequestration, will put initial successes at risk, slow further efforts to help health care providers reduce life-threatening infections, curtail work on other problems that can cause harm to patients, and greatly decrease efforts to help providers deliver patient-focused care."

Carolyn Clancy, MD

director, Agency for Healthcare Research and Quality

NSF



"The nation's well-being and global competitiveness depend, more than ever, on the steady stream of new ideas and the

highly skilled science, technology, engineering and mathematical talent supported by the National Science Foundation and other federal science agencies. A significant budget reduction would result in fewer awards and investigators supported with federal funding, and challenge the nation's future economic prosperity."

Subra Suresh, MS, ScD

director, National Science Foundation

FDA



"FDA's inspectors on the front lines of public health, its scientists and its medical professionals work tirelessly to protect Americans from

potentially risky food and medical products. Whether inspecting a facility that collects and processes human blood, ensuring that a life-saving medication is manufactured properly, or tracing the product that has caused an illness, FDA is there for the public. Every day, we are promoting medical product innovation and helping to bring safe and effective medical products to patients who need them, so they can benefit from the extraordinary scientific breakthroughs of our age. No other public health agency touches patients and consumers in as many important ways as the FDA. This protection is a bargain at approximately \$8.00 in taxpayer dollars per person per year. Now is not the time to reduce this modest amount that provides such comprehensive protection and peace of mind."

Margaret A. Hamburg, MD

commissioner, Food and Drug Administration

Patient



Alex Silver's 4-year-old son, Jackson, suffers from epidermolysis bullosa, or EB, a rare disorder in which a missing protein, which would bind layers of

skin together effectively, causes skin to separate from the body. EB is a debilitating and devastating genetic disorder that affects a child from birth. EB is extremely rare — approximately 25,000 people in the U.S. have EB.

"It's incurable but doesn't need to be incurable," said Silver who, along with his wife, founded the Jackson Gabriel Silver Foundation. "In fact one of the fascinating things about EB is that if you look at the history of EB research, some of the great strides came through National Institutes of Health funding." The National Institute of Arthritis and Musculoskeletal and Skin Diseases helped foster key EB breakthroughs.

Alex Silver notes sequestration would have a devastating impact on research to find new treatments for this disease. A 7.8% cut to the NIH budget would be shortsighted, he said. EB researchers "fight tooth and nail" for every research dollar, and a possible cut of that magnitude is "making the impossible even more impossible. It's not logical; it's not a good thing overall for anybody in this country in the long term.

"It's a question of prioritization," he said.
"... The notion of just cutting core programs that have both an economic and social value especially small dollars in the context of a budget ... is not the smart choice."

Researcher



On multiple levels, Keith Yamamoto, PhD, worries about the effects of sequestration. As a researcher with experience in policy and public atti-

tudes toward science, he sees the big picture of potential effects. But as vice chancellor for research at the University of California, San Francisco, the effects on the ground are also easy to imagine.

The National Institutes of Health, which has funded Yamamoto since 1986, has already seen its budget stagnate for the better part of a decade. UCSF has instituted bridge loans to support researchers who are between grants; and researchers who focus more on securing funding are focusing less on performing science.

An across-the-board cut of 7% to 9% would exacerbate the situation considerably.

"If applied across the board, we're talking about funding 2,100 fewer new and competing applications. And that will have very dire effects on the whole endeavor," Yamamoto said. Shuttering active labs and discouraging young investigators mean lost jobs and lost research progress; meanwhile, morale will likely suffer among the researchers that remain, he said, and students may be dissuaded from entering the profession at all. And that's to say nothing of the effects on American competitiveness.

"The United States has long enjoyed a real primacy, real leadership in research," he said. "And I think that we will be facing the potential end of that kind of leadership."

Industry



The 13 full-time employees at Atlanta-based GeoVax Labs, Inc. are developing multiple vaccines centered on HIV/AIDS. Two of these are currently being

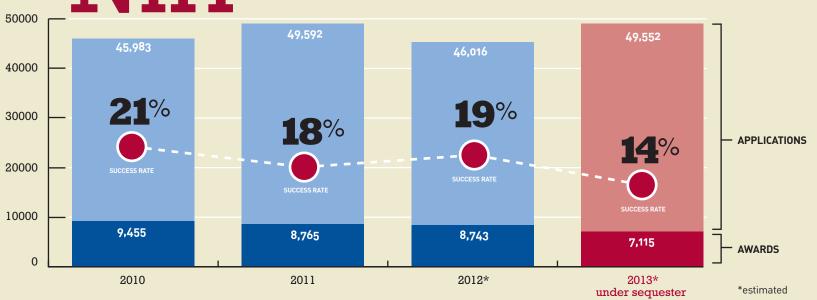
tested in clinical trials: one as a preventive vaccine for uninfected individuals and the other as a therapeutic to lessen HIV-infected individuals' need for drugs. From the therapies' earliest days, GeoVax and its founders have worked hand-in-hand with government agencies.

The technology, on which GeoVax is based, was collaborative research conducted at Emory University, the National Institutes of Health, and the Centers for Disease Control and Prevention. In addition to financial support received from an ongoing NIH grant, the company's most advanced vaccine is in a Phase 2a clinical trial sponsored by the HIV Vaccine Trials Network, which is a program of the NIH's National Institute for Allergy and Infectious Diseases. As the clinical trials advance, GeoVax continues its interaction with the Food and Drug Administration for approval.

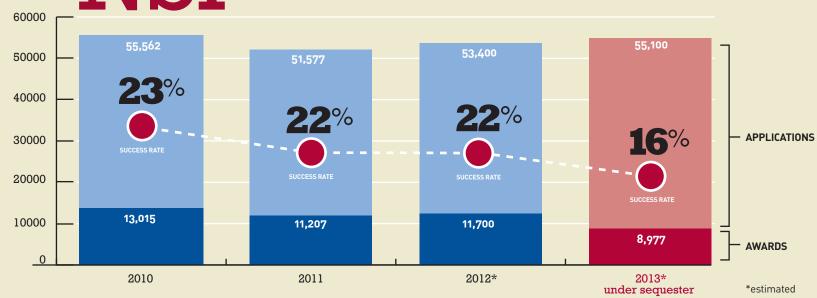
GeoVax President and CEO Bob McNally, PhD, noted, "The FDA must be fully equipped to keep pace with rapidly evolving technology; delays create tragic missed opportunities for patients and their families. Research at NIH is just as crucial, as it sets the stage for private sector development.

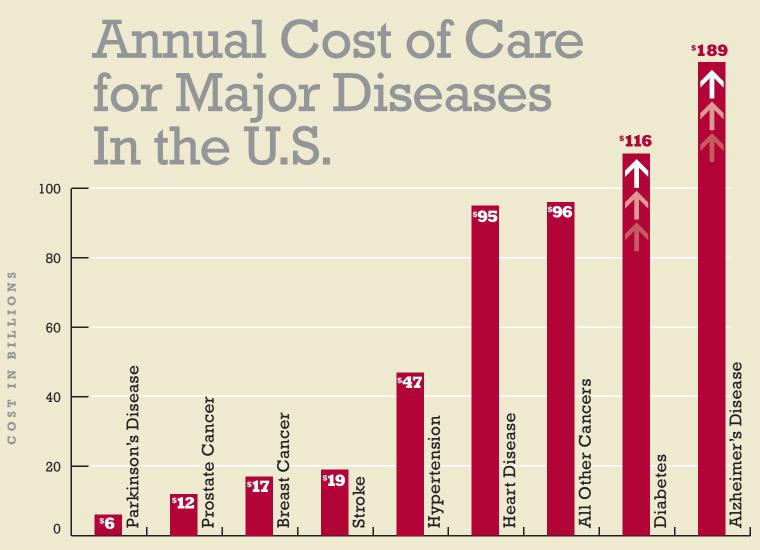
"As federal leaders consider the way forward toward a balanced budget," he said, "we hope they will support federal activities that complement and promote private sector innovation and continued medical progress."

GRANT SUCCESS RATES



ITS F GRANT SUCCESS RATES





Medical research can find cures for our nation's deadliest and costliest diseases.

This is not the time to cut funding.

Congress, it's time to reconsider.

Methodology

For the purposes of this report, we selected 7.8% as the across-the-board cut that would affect **NIH**, **NSF**, **AHRQ**, **FDA** and **CDC**. This percentage is the estimate put forward by the Congressional Budget Office

http://www.cbo.gov/publication/42754. FY11 budgets, which are approximations based on agency budget requests, were used as the baseline to determine the fiscal impact of a sequester, which would take effect on January 2, 2013. FY11 is the most recent year that comprehensive data on budgeting and grant rates are available.

Agency Budgets

NIH: National Institutes of Health, FY 2013 Congressional Justification, page ES-4

http://officeofbudget.od.nih.gov/pdfs/FY13/FY2013 Overview.pdf

CDC: Dept of Health and Human Services, Fiscal Year 2013, CDC, Justification of Estimates for Appropriation Committees, page 21

http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2013_CDC_CJ_Final.pdf
AHRQ: Dept of Health and Human Services, Fiscal Year 2013, AHRQ, Justification of Estimates for Appropriation
Committees page 4

http://www.ahrg.gov/about/cj2013/cj2013.pdf

FDA: Dept of Health and Human Services, Fiscal Year 2013, FDA, Justification of Estimates for Appropriation Committees, page 3 http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf

NSF: NSF, FY 2013 NSF Budget Request to Congress, Summary Table, page 3 http://www.nsf.gov/about/budget/fy2013/pdf/02-Summary_Tables_fy2013.pdf

Budget Comparisons

NIH extramural expenditures were calculated using the various features of NIH's Research Portfolio Online Reporting Tools (RePORT). CDC expenditures were calculated using the Funding Profiles tool and by comparing budget line items, using Dept of Health and Human Services, FY13, FDA, Justification of Estimates for Appropriation Committees as background.

AHRQ's line items are available in the Friends of AHRO Briefing materials, February 2012. FDA expenditures were determined from the FY13 congressional budget request. NSF funding data is available in FY 2012 Budget Request and the Budget Internet Information System, which was used to calculate too-funded NSF institutions.

Success Rate Graphs

Historical information and success rates for NIH are available on the NIH RePORT website:

http://report.nih.gov/NIHDatabook/Charts/Default.aspx?showm=Y&chartId=124&catId=13. **NIH** estimates, in its Summary of the FY 2013 President's Budget that 8,743 competing grants will be funded in 2012, and will be able to fund 9,415 grants in 2013. NIH estimated (page 28) a success rate of 18% in FY12 and 19% in FY13:

http://officeofbudget.od.nih.gov/pdfs/FY13/Vol%201%201ab%203%20-%20Supplementary%20Tables.pdf. Under the sequester scenario for 2013, grant applications were estimated using the numbers provided in the NIH FY13 Budget: http://officeofbudget.od.nih.gov/pdfs/FY13/FY2013_Overview.pdf. FY 2013 success rates were calculated based on the Senate testimony of Francis Collins, MD, PhD before the Senate Subcommittee on Labor, Health & Human Services, Education, and Related Agencies: http://www.appropriations.senate.gov/ht-labor.cfm?method=hearings.view&id=fb861787-a153-4ed0-9ba8-f483681fec2a. NSF reports and estimates statistics for competitive awards are available in the 2013 NSF Budget Request to Congress. FY 2013 sequester estimates were calculated data were estimated using the expected number of awards in 2013 based on the president's budget request. A 7.8% sequester would eliminate \$538.2 million in NSF funding, which could support over 3,000 grants at an average award size of \$167,000 according to the FY12 NSF Merit Review Report. For FY10, data was gathered from the NSF report on FY11 Performance and Financial Highlights.

Disease Chart

Cost of direct care for various diseases and sources:

Parkinson's: National Institutes of Health, National Institute of Neurological Disorders and Stroke, Parkinson's Disease. Hope Through Research, 2006:

http://www.ninds.nih.gov/disorders/parkinsons disease/detail parkinsons disease.htm

Cancer: National Institutes of Health, National Cancer Institute, Cancer Prevalence and Cost of Care Projections, National Expenditures for Cancer Care, 2010: http://costorojections.cancer.gov/expenditures.html

Stroke, Hypertension, Heart Disease: National Institutes of Health, National Heart, Lung, and Blood Institute, Disease Statistics, 2008: http://www.nhlbi.nih.gov/about/factbook/chapter4.htm#4 7

Diabetes: American Diabetes Association, The Cost of Diabetes, 2007:

http://www.diabetes.org/advocate/resources/cost-of-diabetes.html

Alzheimer's: Alzheimer's Association, Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 7, Issue 2, 2011; http://www.alz.org/downloads/facts_figures_2011.pdf

Sources:

NIH

- 1 National Institutes of Health (NIH), Office of Research Information Systems (ORIS), NIH Research Grants Table: http://report.nih.gov/FileLink.aspx?rid=544
- National Institutes of Health (NIH), RePORT, NIH Awards by Location & Organization: http://report.nih.gov/award/index.cfm?ot=&fy=2011&state= &ic=&fm=&orgid=
- 3 National Institutes of Health (NIH), RePORT, Funding Facts: http://report.nih.gov/fundingfacts/index.cfm
- 4 The National Institutes of Health (NIH) Almanac, Appropriations (Section 1): www.nih.gov/about/almanac/ appropriations/index.htm
- 5 National Institutes of Health (NIH), RePORT, Research, Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC): http://report.nih.gov/categorical_spending.aspx

CDC

- 6 Centers for Disease Control (CDC), Financial Management Office, Fiscal Year 2011 Operating Plan: www.cdc.gov/fmo/topic/Budget%20Information/ appropriations_budget_form_pdf/CDC_FY_2011_ Operating_Plan_Table.pdf
- 7 Centers for Disease Control (CDC), Financial Management Office, Fiscal Year 2013 Budget Request Summary: www.cdc.gov/fmo/topic/Budget%20Information/ appropriations_budget_form_pdf/FY2013_Budget_ Request_Summary.pdf
- 8 Centers for Disease Control (CDC), Financial Management Office, Fiscal Year 2013 Justification of Estimates for Appropriations Committees: www.cdc.gov/frmo/topic/ Budget%20Information/appropriations_budget_form_pdf/ FY2013 CDC CJ Final.pdf
- 9 Centers for Disease Control (CDC), Fiscal Year 2011 Grant Funding Profiles: http://wwwn.cdc.gov/fundingprofiles/FundingProfilesRIA/Re port_Docs/EXCELDocs/DataSet2011/2011%20Funding%20Pr offie%20Summany%20Data%20Download.xls

AHRQ

- 10 Agency for Health Research and Quality (AHRQ), Financial Management Office, Fiscal Year 2012 Justification of Estimates for Appropriations Committees: www.ahrq.gov/about/cj2012/cj2012.pdf
- 11 Agency for Health Research and Quality (AHRO), Financial Management Office, Fiscal Year 2012 Justification of Estimates for Appropriations Committees: www.ahrq.gov/about/cj2012/cj2012.pdf
- 12 Research!America, Research Funding by State: www.researchamerica.org/state_funding
- 13 Agency for Health Research and Quality (AHRQ), Financial Management Office, Fiscal Year 2012 Justification of Estimates for Appropriations Committees: www.ahrq.gov/about/ci2012/ci2012.pdf

FDA

- 14 Food and Drug Administration (FDA), About FDA, Reports, Budget Reports, Fiscal Year 2012: www.fda.gov/ downloads/AboutFDA/Reports/ManualsForms/Reports/ BudgetReports/UCM244195.pdf
- 15 Food and Drug Administration (FDA), Fiscal Year 2012 Congressional Budget Request: www.fda.gov/downloads/AboutFDA/ReportsManuals Forms/Reports/BudgetReports/UCM248624.pdf
- 16 Food and Drug Administration (FDA), Fiscal Year 2012 Congressional Budget Request: www.fda.gov/downloads/AboutFDA/ReportsManuals Forms/Reports/BudgetReports/UCM247868.pdf
- 17 Food and Drug Administration (FDA), Fiscal Year 2012 Congressional Budget Request: www.fda.gov/downloads/AboutFDA/ReportsManuals Forms/Reports/BudgetReports/UCM275325.pdf

NSF

- 18 National Science Foundation (NSF), Fiscal Year 2012 Budget Request, Biological Sciences: www.nsf.gov/about/budget/fy2012/pdf/16_fy2012.pdf
- 19 National Science Foundation (NSF), Fiscal Year 2012 Budget Request, NSF Homeland Security Activities: www.nsf.gov/about/budget/fy2012/pdf/09_fy2012.pdf
- 20 National Science Foundation, Budget Internet Information System, Award/Summary by Top Institutions: http://dellweb.bfa.nsf.gov/Top50Inst2/default.asp
- 21 National Science Foundation (NSF), Fiscal Year 2012 Budget Request, Education and Human Resources: www.nsf.gov/about/budget/fy2013/pdf/11_fy2013.pdf



1101 King Street, Suite 520 Alexandria, Virginia 22314 703.739.2577 Fax 703.739.2372 www.researchamerica.org









www.researchamerica.org/blog www.facebook.com/ResearchAmerica.org www.twitter.com/ResearchAmerica www.youtube.com/user/ResearchAmerica