

## ONLINE FIRST

# Biomedical Research in an Age of Austerity

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**T**HE 2011 BUDGET CONTROL ACT REQUIRES MOST US federal military and civilian spending to be reduced by 8% to 10% in January 2013 (“sequestration”) and will increase personal and corporate tax rates and revenues substantially. By creating draconian penalties, the act was intended to prod Congress to reduce the federal deficit. Unless Congress alters the bill, spending reductions will affect many areas of medicine, particularly medical research.

The National Institutes of Health (NIH) budget would be reduced by \$2.5 billion, or about 8.2%.<sup>1</sup> Given that three-fourths of the NIH budget is committed to previously awarded grants, sequestration could affect predominantly new applications and young researchers. These budget reductions at the NIH and at other research agencies, such as \$0.5 billion at the Centers for Disease Control and Prevention and \$0.6 billion at the National Science Foundation (TABLE), will exacerbate tensions between large infrastructure projects (such as those that maintain public databases in genomics, clinical trials, and bioinformatics) and small investigator-initiated grants, which historically have been the primary source of new clinical insights.

Government support of science and technology reached a peak of about 5.5% of the federal budget in the mid 1960s, when space exploration and medicine captured the public’s imagination. Today, government funding for research accounts for about 0.4% of the total federal budget.<sup>2</sup>

With or without sequestration, neither federal nor private support for research and development will return to the trend that produced a tripling in support between 1995 and 2005. As a portion of gross domestic product, research and development expenditures are declining in the United States and Europe, whereas they are increasing at an accelerated rate in China, South Korea, and India. In 1980, US private investment in research and development in all fields eclipsed government spending. Today, privately funded biomedical research comprises \$70 billion (65%) of the \$110 billion total.<sup>3</sup>

Moreover, spending by pharmaceutical and device companies on preclinical research has declined from approximately 55% in 1998 to approximately 25% in 2010 as the cost of late-stage development has increased, especially clinical trials aimed at obtaining Food and Drug Administra-

tion approval.<sup>4</sup> Likewise, the NIH budget has not kept pace with inflation. The result is justified concern over the support of institutions and researchers who must conduct critical early-stage investigations to validate new approaches to diseases of high prevalence and high morbidity, such as common cancers, autism, and dementia, for which the public health burden (and costs) are increasing and effective prevention or treatment are elusive.

Some observers see research as a source of added cost without commensurate clinical value. Drug and device charges and service fees are borne by insurers and patients, whereas benefits accrue to companies, hospitals, and physicians. Those with this view hold that proven, existing, low-cost preventive and public health measures, such as ensuring treatment of hypertension, smoking cessation, or weight loss, are preferable in an age of austerity.<sup>5</sup> Overuse and lack of reliable evidence for effectiveness of many common technologies bolsters this skepticism, as the Institute of Medicine has recently recognized.<sup>6</sup>

Another factor is the increasing tension between traditional, biologically based research (predominantly through the NIH) and that related to health service delivery, information technology, and clinical effectiveness. The conflict over research goals has become more pointed since the 2010 Affordable Care Act, when dissemination of best practices was made a priority, with \$3.5 billion of funding allowed for the new Patient-Centered Outcomes Research Institute. Tension is certain to increase as the nation struggles with aging, cost, deficits, and taxation.

The decline in real federal support for biomedical research also affects many universities with substantial research portfolios, in which federal dollars support two-thirds of all research (and approximately 90% in science and engineering). Research universities, which benefitted during the decade of the doubling of the NIH budget, are now confronted with underfunded researchers and potentially underused research space. This comes at a time when income from clinical fees may decline, requiring reevaluation of the cross-subsidies that have been used to support biomedical research.

For would-be researchers, declines and uncertainty in research funding drive talent away from a career in the laboratory. Despite an increase in the number and types of NIH-funded career development (“K”) awards, the number of applicants for these awards has decreased by 15% from its peak in 2007. Although the United States still attracts trainees from

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See also p 2343.

**Table.** Estimated Reduction in Budget Attributable to Sequestration for Select Health and Science Agencies<sup>a</sup>

Agency	Sequester Amount, \$ in Billions	Sequester Percentage Range <sup>b</sup>
Centers for Medicare & Medicaid Services <sup>c</sup>	11.9	2.0-8.2
National Institutes of Health	2.5	7.6-8.2
National Aeronautics and Space Administration	1.5	7.6-8.2
Environmental Protection Agency	0.7	7.6-8.2
Health Resources and Services Administration <sup>d</sup>	0.6	2.0-8.2
National Science Foundation	0.6	7.6-9.4
Centers for Disease Control and Prevention	0.5	7.6-10.0
National Oceanic and Atmospheric Administration	0.4	7.6-8.2
Food and Drug Administration	0.3	7.6-8.2
Substance Abuse and Mental Health Services Administration	0.3	8.2
United States Geological Survey	0.1	8.2
Department of Veterans Affairs <sup>e</sup>	0	0

<sup>a</sup>Adapted from OMB Report Pursuant to the Sequestration Transparency Act of 2012 (Pub L No. 112-155).<sup>1</sup>

<sup>b</sup>The resulting sequestration percentage is expressed as a range because each agency's budget varies in the amount of defense vs nondefense spending and discretionary vs mandatory spending.

<sup>c</sup>Most of the Medicare nonadministrative budget is limited to 2% sequestration.

<sup>d</sup>Sequestration on a small proportion of Health Resources and Services Administration spending is limited to 2.0%.

<sup>e</sup>The Department of Veterans Affairs was generally exempt from sequestration.

overseas because of its strong universities, the United States has difficulty retaining talent because of current immigration policy and new opportunities in developing countries.

Above all, the decline in funding for research hurts the public. Although the current political focus is on short-term economic stability and job creation, biomedical research has economic and health benefits that are easy to overlook. But research is a long-term investment, with discoveries requiring 15 to 25 years to mature to clinical application, an interval that has been stable for a century. Physicians and biomedical scientists must do a better job of making explicit the connection between health and new discovery while simultaneously improving success, speed, and productivity.

Regardless of the political outcome of the sequestration, federal funding for biomedical research is unlikely to increase significantly in the near term. Although this will trouble key stakeholders, the reduction in federal funding, which is now approaching a decade in duration, presents an opportunity to reshape biomedical research.

New private sources of research support are needed. One solution involves forming new types of mutual funds and creating new bonds (Biomedical Research Bonds).<sup>7</sup> These measures are analogous to those used to build sports arenas, ports, bridges, or highways, thereby lessening the financial burden on government. They also have the potential to lower barriers, such as conflicting patent claims, that

prevent collaboration between competing universities, companies, and researchers.<sup>8</sup>

Public charities and private foundations are also vital, both for their financial sponsorship and for their ability to organize new approaches. Individuals affected by serious medical conditions are impatient with the pace of discovery. Recent examples of approaches aimed at increasing speed and lowering cost include patient-initiated clinical trials, social media as an aid to trial recruitment, tablet-computer monitoring technology, and novel ways to validate self-reported outcome measures.<sup>9</sup> In addition, freestanding private research institutes (supported by private philanthropy) are discarding the tripartite mission of academic medical centers by focusing only on research in basic biology (especially genomics, structural biology, and neuroscience) or specific diseases (such as cancer or dementia).

Although the long-term success of such approaches remains to be determined, these changes will surely alter government's role, destabilize universities and teaching hospitals, and disrupt the technology cycle of the past 60 years.

Churchill emphasized the importance of seeing every crisis as an opportunity in disguise. Sequestration could provide the impetus for changes that would reduce uncertainty and bolster investment. Regardless of what happens in the next few months, biomedical research must look to the private sector and not the federal government as the source of new funds. The paradox—and reason for optimism—is that the science has never been more promising.

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