

## ONLINE FIRST

# The Future of Biomedical Research

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**T**HE COMMUNITY OF BIOMEDICAL RESEARCHERS IS ANXIOUS, if not downright depressed, about the future, and there is good reason for this pessimism. For decades the importance of biomedical research was a reliable pillar of bipartisan agreement, as evidenced by the continuous high levels of funding that both parties have sustained during the last 3 presidential administrations. From the beginning of President Clinton's first term to the end of President George W. Bush's second term, the National Institutes of Health (NIH) budget more than tripled, increasing from \$8.9 billion to \$29.6 billion.<sup>1</sup> Cumulatively, over the last 15 years, the federal government has spent more than \$385 billion in funding for biomedical research through the NIH—despite 2 wars and a turbulent economy.

Yet to many observers, the future appears bleak. This coming year, there will almost certainly be no increase in NIH funding. Moreover, sequestration means that the NIH will actually lose approximately 5.1% of its current level of funding, or about \$1.55 billion.<sup>2</sup> Bipartisan support has all but evaporated, and biomedical research is quickly becoming just another partisan issue.

How did this reversal of fortunes occur? Is there anything the biomedical research community can do about it?

## Why Is Support for the NIH Disappearing?

Four factors contribute to the erosion of support for the NIH.

First, there is increasing politicization of science in general. Despite the massive explanatory power of science and the ability of scientific discovery to create amazing inventions that have positively transformed many lives—from computers and cell phones to vaccines and robotic prosthetics—there is an increasing uncertainty in the United States about the value of science. Recent polls show that 46% of Americans believe that human beings were created “pretty much in their present form at one time within the last 10,000 years or so.”<sup>3</sup> One researcher reported that while “public trust in science has not declined since the 1970s except among conservatives and those who frequently attend church,” there has still been a significant “politicization” of science.<sup>4</sup> Politicization of science means that federal funding of science is more contentious and can no longer be considered an area of bipartisan agreement.

Second, for decades there have been strong Congressional champions of the NIH. But such champions are quickly becoming an endangered species in Washington. John Porter, the former Illinois Republican Congressman who helped guide the legislation that doubled the NIH budget, retired from politics in 2001; Senator Arlen Specter, who almost single-handedly insisted on including a one-time \$10 billion appropriation for the NIH in the American Recovery and Reinvestment Act, recently died, as did the indefatigable defender of NIH funding, Senator Ted Kennedy. No other Congressional leaders have stepped forward to replace these individuals as the unyielding defenders of biomedical research—making NIH funding more precarious.

Third, although the doubling of the NIH budget appeared to be a blessing, it also may have been a curse. Once Congress doubled the budget in 2003, many members could be lulled into a sense that they had “taken care of the NIH” and that they did not have to do more to support biomedical science. In addition, as the NIH budget has surpassed \$30 billion per year, it has drawn much more critical oversight from lawmakers who expect to see evidence of increased accountability and return on investment. The burden of proof for the necessity of additional resources has shifted. Promised advances are no longer acceptable. Even though the NIH already has the largest biomedical research budget of any organization in the world, there are incessant requests for more funding. Complicating matters are the recurring episodes of well-paid scientists embroiled in financial conflicts of interest. The result is a depiction of the scientific establishment as just another interest group looking out for itself rather than the public good.

## Biomedical Research and Clinical Medicine

Fourth, the greatest threat to NIH funding may well be the increasingly difficult federal budget situation. In 2012, the federal deficit “declined” to \$1.1 trillion, or more than 7% of gross domestic product (GDP). This was the fourth year in a row in which deficits exceeded \$1 trillion. In this economic and fiscal environment, it seems difficult to justify increasing NIH funding when many other worthy priorities also need addi-

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tional resources—priorities like early childhood education, support for college tuition, and rebuilding the nation's roads, bridges, rail lines, electricity grid, and other infrastructure.

Although many factors contribute to these large deficits, the biggest threat to the federal budget is health care payments. In 2012, the federal outlays for Medicare (\$555 billion),<sup>5</sup> the federal portion of Medicaid and the Children's Health Insurance Program (\$260 billion),<sup>6</sup> the Federal Employee Health Benefits Fund (\$43 billion), and Veterans Affairs health benefits (\$52 billion) constituted \$910 billion—even excluding the Indian Health Service and Department of Defense health care programs.

To put these data into context, in 2012 the United States spent \$779 billion on Social Security and \$677 billion on national defense. More importantly, health care costs are increasing more rapidly than any other portion of the federal budget—even before the Affordable Care Act. Although scientists prefer to view the NIH budget as separate from health care spending, they are intimately linked.

Why are health care costs increasing much faster than GDP? About half of the increase is from technology, that is, advances in biomedical science.<sup>7</sup> And a main source—if not *the* main source—of advances in biomedical technology is the NIH.

This is the ultimate vicious cycle: the NIH conducts and funds research that develops new insights; those insights spawn new expensive clinical interventions that drive up the cost of health care; and the increasing cost of care raises Medicare and Medicaid expenditures, which increases the federal budgets and deficits, which in turn threatens biomedical research funding.

For example, the NIH has funded research into antiangiogenesis factors as anticancer agents. Bevacizumab, the best-known and most widely used antiangiogenesis factor, has not been shown to cure any patient. At best, this drug prolongs life a median of 3 to 5.3 months in metastatic colon cancer and 2 months in non-small-cell lung cancer.<sup>8</sup> The cost is approximately \$5000 per month for treatment, and the cost-effectiveness ratio is approximately \$140 000 per quality-adjusted life year for colorectal cancer<sup>9</sup> and exceeds \$500 000 for lung cancer.<sup>10</sup> Government expenditures increase as Medicare and Medicaid cover this expensive drug.

Researchers funded by the NIH may not perceive their role in contributing to increasing health care costs and thereby undermining NIH funding. Although NIH-spawned discoveries are certainly not the only factor driving up health care costs, they are nevertheless integral and inescapable.

### What Can Be Done?

There is no easy solution for improving the NIH funding environment. It will take at least 3 factors, only some of which are in the control of the biomedical research community. First, the future Porters, Specters, and Kennedys of Congress need to be identified, educated, and cultivated. Leaders willing to fight for funding of biomedical research are essential.

Second, researchers have to do a better job of explaining the value of biomedical research. For instance, the war on cancer was going to cure cancer. Stem cells were promised as a cure for numerous diseases, from Parkinson disease to diabetes. Today, it is proteomics and microbiomes that will unlock the mysteries of disease—and perhaps treatments. To the extent that these discoveries have led to new interventions, this research has generally failed to reduce costs. Researchers need to stop promising cost reductions and be more concrete.

Third, researchers have to hope for—and work for—health care cost control. The prospects for NIH funding are unlikely to improve unless the federal budget situation improves. This means that Medicare, Medicaid, and all the other health-related expenditures must stop increasing faster than GDP. Researchers who are part of academic health centers need to actively urge more focus on efficient delivery of care, not just increased clinical revenues. Reducing cost growth will ease the federal budget deficit and pressure to cut discretionary programs like the NIH.

Most importantly, the NIH and the larger biomedical research community need to direct their considerable talents and resources to developing biomedical technologies that are not just “incredibly exciting” but also cost lowering and value enhancing. Many tremendous triumphs of NIH research, such as the *Haemophilus influenzae* type B vaccine, did just that.

Focusing research on cost-lowering, quality-improving interventions has not been an NIH priority. This change in focus is vital to the future of both the country and the NIH.

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