How the current Congressional budget debate could affect cancer research funding

Addressing the cancer community at a town hall meeting in January 2011, Harold Varmus revealed that one thing he never anticipated the previous summer when he took the reins of the National Cancer Institute (NCI) was the dire financial circumstances NCI and the NIH are now facing. At a time when the science behind cancer treatment and prevention is accelerating, budgetary disputes in Washington, DC, are forcing him to cut back on key programs and research grants that could yield innovative and potentially game-changing discoveries.

Congressional budget battles are nothing new to Varmus, who served as NIH director during the Clinton administration, but the severity of the proposals currently being considered in Congress appears to have him, and certainly the entire biomedical research advocacy community, exceptionally alarmed. With NIH on the chopping block, along with almost every other federal agency and program, stakeholders are uniting and intensifying their efforts to convince lawmakers about the value of public investment in NIH- and NCI-supported research.

Whereas, in the past, the countless life-improving discoveries that arise from NIH research have been justification enough to secure support, there is now a growing recognition that it will take something more to convince fiscally conservative legislators, who are flexing more clout than before on spending matters.

Having wrested control of the House of Representatives from the Democrats and increased their numbers in the Senate as a result of the 2010 midterm elections, Republicans swept into office in January touting a voter mandate to shrink the role of government and roll back federal spending. In the latest round over the FY2011 budget, where party leaders pushed for more than $60 billion in spending cuts, including a drastic $1.6 billion cut from the NIH, they’ve shown they mean business. After a long and rancorous showdown with Democrats, a last-minute compromise resulted in cuts totaling about $38 billion, including $320 million from NIH, representing a 1% reduction, and roughly $45 million from NCI. Other federal agencies fared much worse; the Centers for Disease Control and Prevention (CDC) suffered a staggering $730 million (11%) cut, reducing its budget to below 2006 levels, and the Environmental Protection Agency’s budget was reduced by $1.6 billion (16%) for the remainder of the current fiscal year. Ultimately, the final package represented the largest reduction in non-defense spending in history, yet it is considered only a small taste of what is to come in FY2012.

As part of the $30.7-billion NIH, NCI runs the nation’s cancer enterprise with about $5 billion a year. Nearly 80% of NCI’s annual funding is distributed across the country to support research at laboratories, clinics, universities, and medical centers in all 50 states. NCI also supports a national network of 65 leading cancer centers, cutting-edge clinical trials needed to translate basic scientific findings into cancer treatments, and programs to train the next generation of cancer scientists.

After a considerable expansion between 1998 and 2003, the budget for the entire NIH, including NCI, has remained essentially flat. Factoring in the rate of biomedical inflation, NIH has actually lost about 13% of its purchasing power during this time.

While the American Recovery and Reinvestment Act of 2009 provided a welcome and timely stimulus for the community, the infusion of temporary funds also, in a way, exacerbated the fiscal predicament that the research entities are now facing.

The $862 billion stimulus package invested an unprecedented $10.4 billion in the NIH, of which about $1.3 billion was allocated to the NCI, with the stipulation that all funds be obligated during a brief 2-year window. This windfall was distributed to individual investigators with innovative proposals and helped launch new initiatives that allowed researchers to dive into the study of the human genome and the genetics of cancer, pursue the development of novel targeted therapies, and streamline approaches to clinical research and clinical trials.

Unfortunately, now that the Recovery Act funds are largely exhausted, and without a commitment from Congress to provide anywhere close to a sustained level of funding, many of those projects may be left in the lurch when the scientific momentum outruns NIH resources.

As it stands today, only about 17% of scientists applying for NCI research grants have a chance of receiving funding to pursue novel ideas. This number has fallen steadily; a decade ago the success rate hovered at around 27%. The worsened odds partly reflect the groundswell of applications that NCI received from scientists competing for the Recovery Act funds, and the odds are expected to fall further during the next 2 years as investigators who were unable to secure stimulus dollars resubmit their applications while at the same time successful recipients attempt to extend support for their projects.

The response in applications for Challenge Grants, for example, which were new awards using Recovery Act funds, was so overwhelming that at the end of the day, less than 5% of the approximately 20,000 applications were successful. According to NIH, this was the largest response in history, equal to the total number of applications the Institute receives in one of the agency’s three major review rounds each year.

NIH and NCI have taken pains to soften the blow, but the Institutes are fast approaching the cliff that has been looming on the horizon, and there will be a long way to fall if House Republicans succeed in their attempts to vastly reduce federal spending. Cancer and biomedical research was largely spared from deep budget cuts for this year, but judging by the FY2012 budget plan recently passed in the House, NIH will likely be a target once again. The nonbinding budget resolution, introduced by House Budget Committee Chairman Paul Ryan (R-Wis.), proposes to decrease federal spending by $6.2 trillion over the next decade by,
among other things, cutting discretionary health spending 13.5% from current levels and subsequently freezing funding at that level through FY2016.

At this point in the budget process, funding levels for individual agencies and programs have not yet been specified, as lawmakers are focused on establishing a broad framework for federal spending to guide the next steps in the debate, but the research community is bracing for an uphill battle to stave off NIH and NCI cuts.

Even in this environment, turning away promising research applications is the last thing NCI wants to do. With funds becoming increasingly scarce, Varmus has let it be known that one of his three top priorities will be to sustain the same number of new grant awards as has been awarded in the recent past. Ensuring that cancer genomics programs are running at full speed and paying for an imperative restructuring of the clinical trials program will also receive protected status. With little room to maneuver in the Institute’s tightening budget, continued progress in these key areas will inevitably come at the expense of other important areas. Varmus has disclosed that he is “unabashedly” considering reductions to budget items such as cancer center awards and inflationary increases for noncompetitive awards, and he has told the cancer community to brace for potentially more tough decisions ahead.

Larger NIH-wide initiatives that would likely benefit cancer research may also run into a wall due to lack of resources, including a new endeavor to open a translational research center this fall. The National Center for Advancing Translational Sciences, championed by NIH Director Francis Collins, is envisioned as a vehicle to advance promising products through the development pipeline and pioneer new approaches to therapeutics development. The new center would also house the Cures Acceleration Network, a program authorized through the recent health care reform law that is intended to create a pathway to fund translational research conducted in academia or industry.

The possibility that all of this scientific promise could come to a standstill has research advocacy organizations and professional societies striving to find a message that will resonate with the budget hawks in Congress to show that cuts to the NIH are not only detrimental to scientific progress but also that they jeopardize American global competitiveness and threaten local economies that thrive on jobs and economic development generated by research. Families USA, for example, estimates that, in 2007, every dollar of NIH funding generated more than twice as much in state economic revenue and that NIH grants and contracts created and supported more than 350,000 jobs across the country.

With a number of lawmakers committed to decreasing the reach of the federal government, many of whom believe that Congress has been overly generous to the NIH in the past, there is also an imperative to explain that public investment in the NIH serves as an irreplaceable driving force in private sector medical innovation and drug development. While the historical role of NIH has been to uncover basic scientific discoveries that incentivize the private sector to take the required risk to pursue commercially viable drugs and products, the agency has become more and more proficient at helping to translate scientific breakthroughs into applications that benefit patients.

According to a recent study (N Engl J Med 2011;364:567–71), a surprising number of valuable new drugs and vaccines approved in the United States have arisen from research funded by the public sector. The authors showed that nearly one out of every five important medical advances approved by the FDA between 1990 and 2007 was invented in a federally funded laboratory; previous estimates had put the number as low as one in fifteen. Moreover, those inventions included 40 new drugs for cancer.

“Many lawmakers grasp the idea that NIH- and NCI-funded research is important for public health, but we need to take our case a step further to show that these taxpayer dollars are not only driving the development of new treatments and technologies for patients but also stimulating economic development and innovation in every state and Congressional district,” said William S. Dalton, PhD, MD, Chair of the American Association for Cancer Research (AACR) Science Policy and Legislative Affairs Committee. “This line of argument is concrete and should be very hard for legislators to ignore,” Dalton added.

The biomedical research advocacy community, both working independently and through broad coalitions of other like-minded organizations, such as the Ad Hoc Group for Medical Research, which represents nearly 300 patient groups, scientific and medical societies, research institutions and industry organizations, and One Voice Against Cancer, a collaboration of over 40 nonprofit organizations that represent cancer researchers, patients, and survivors, has stepped-up efforts to increase appreciation for biomedical research in Congress by reaching out to both sides of the aisle through letters, in-person meetings, and educational briefings. A Congressional members-only briefing organized by the AACR last fall, for instance, brought Varmus to Capitol Hill, where he had the opportunity to address lawmakers face to face about the latest advances in cancer research and the promising opportunities on the horizon.

This kind of outreach is viewed as essential in the effort to identify and cultivate new champions for cancer research. The loss of stalwart advocates like the late Edward M. Kennedy (D-Mass.) and Senator Arlen Specter (D-Penn.) continues to be intensely felt by the research community, which for decades relied on their leadership to inspire and build broad bipartisan coalitions of support within Congress for research funding and policy matters. Filling their shoes will not be easy, especially in the current political environment.

Of course bipartisan agreement has never been easily reached on Capitol Hill, but the existence of fewer moderates in Congress today, particularly in the House of Representatives, suggests that common ground will be more elusive than ever and that legislators will be less willing to put aside ideological differences.

In this bleak picture, there are some bright spots: the Obama White House has consistently made research and innovation a priority in the national agenda, and in Congress, there are still outspoken leaders committed to NIH research like Sen. Tom Harkin (D-Iowa), who chairs two key committees that wield significant control over the oversight, creation, and funding of health care programs and health research. Harkin said recently that providing researchers with the resources they need is a “moral responsibility.”

Ultimately, however, turning the tide may depend upon researchers themselves speaking out and sharing personal stories with the public and their federal representatives about how much their work and the whole field suffers when research is underfunded.

“If we just passively let things happen, then we can’t complain about the outcome,” said Dalton. “I think many researchers aren’t particularly comfortable advocating for their work. They feel that it’s self-serving, but this is about advocating for a greater good. Obviously, our members wouldn’t be dedicating their lives to research, doing what they were doing if they didn’t want to have a positive impact on people and society.”
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