Healthy Funding

Ensuring a Predictable and Growing Budget for the National Institutes of Health

A Report by UNITED FOR MEDICAL RESEARCH and
THE INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION

Joseph V. Kennedy and Robert D. Atkinson

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Executive Summary

As a new Pew Research Center poll confirms, a majority of the American public agrees on the benefits of federal investment in scientific research.[1] Fully seven-in-ten adults believe government investment in engineering and technology (72 percent) and basic science research (71 percent) pays off in the long run, according to the poll. At the same time, the United States faces a difficult budget environment with rising national debt and annual spending that is expected to grow rapidly over the next two decades. And while members of Congress from both sides of the aisle and the President's Council of Advisors on Science and Technology agree that the National Institutes of Health and the scientists it supports deserve robust federal investment, funding has declined 22 percent in real terms over the past decade.

The innovative approaches to increase and sustain federal support for NIH might include:

- Learning from international competitors ranging from strategic investments in China to innovative financing in Australia to public-private partnerships in Singapore;
- Adjusting discretionary spending caps;
- Multi-year budgeting and appropriations;
- Advance appropriations and forward funding; and,
- Approaches encompassing changes in mandatory programs, trust funds, dedicated funding streams, or mandatory spending.

The current budget and appropriations process coupled with lack of consensus among policymakers on how to address our long-term fiscal challenges makes it seemingly impossible to deliver the level of funding for biomedical research that the American public overwhelmingly supports. This report will first review the implications of reduced federal commitment to NIH-funded research (including a look beyond our shores) and then examine possible options for altering the budget process so that Congress can continue to invest in the nation's biomedical leadership even as it makes progress on addressing broader fiscal challenges.

Members on both sides of the aisle understand that the federal government has an essential role in funding biomedical research and often point with pride to the advances made and lives saved or improved on account of research undertaken by scientists in their home states. There also seems to be a growing awareness that the failure to provide both growing resources and increased predictability has negative effects on both the pace of medical breakthroughs and the strength of the U.S. biomedical industry.

Unfortunately, political battles over the broader federal budget have prevented legislators from translating this support into rising, or even stable, budgets. This has resulted in tremendous uncertainty about what NIH's budget will be from year to year. Although there is a general willingness to increase the agency's budget, members differ over whether any increases should be offset by cuts to other programs. As a result, policymakers should consider separating NIH's budget from the broader deficit battles.

Introduction

Members of Congress from both sides of the aisle consistently voice strong support for the National Institutes of Health (NIH) and the scientists it supports across the country. At the same time, the United States clearly faces a difficult budget environment with rising national debt and annual spending that is expected to grow rapidly over the next two decades. The current budget and appropriations process coupled with a lack of consensus among policymakers on how to address our long-term fiscal challenges makes it seemingly impossible to deliver the level of funding for biomedical research that the American public overwhelmingly supports.

But it hasn't always been this way. Between 1998 and 2003, a bipartisan, bicameral effort doubled the amount of federal funding for NIH. This increase was motivated by a strong belief that medical research benefitted the country in a number of ways. Although the fiscal landscape changed mid-way through the doubling, policymakers in both Congress and the White House continued to honor this commitment and increase funding for NIH. Since then, NIH's budget has been much tighter. After growing moderately between 2003 and 2010, it has actually fallen in nominal terms since 2010. And when measured against the rising cost of conducting medical research (known as the biomedical research and development price index or BRDPI), NIH funding decreased by 22 percent between 2003 and 2013. (see Figure 1)[2]

This decline threatens not only research but the innovation ecosystem it supports. Funding provided by NIH plays a critical role in the nation's biomedical ecosystem. The agency funds basic research conducted by the nation's best scientists, supporting the world's premier biomedical education system. Its peer review process for selecting the most important and promising research is highly regarded. NIH-funded research results in better knowledge of the classification of diseases and the development of drugs and other therapies. Ample research shows that NIH funding delivers large benefits for

"NIH funding decreased by 22 percent between 2003 and 2013"

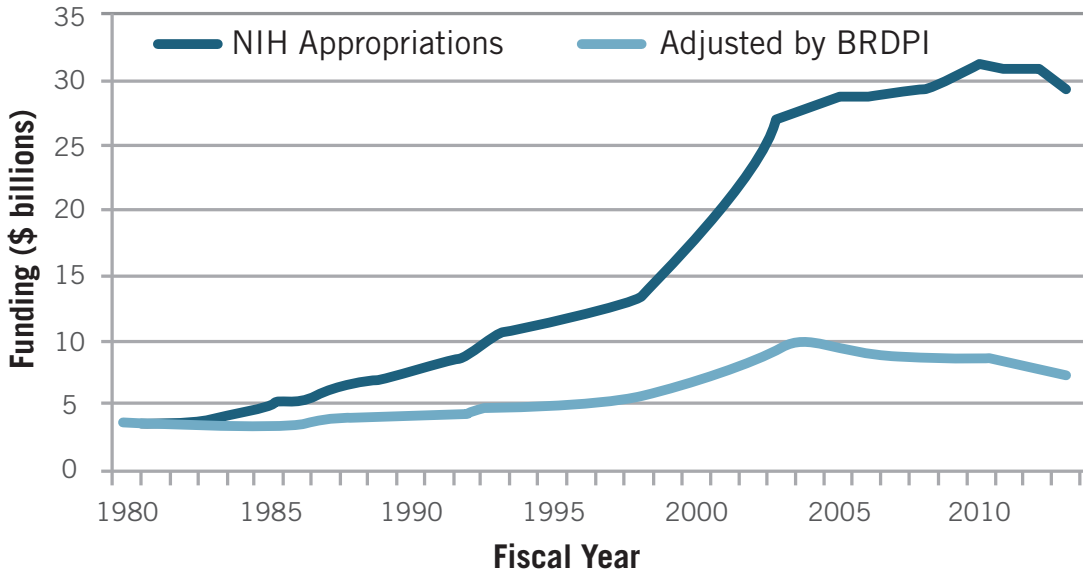

Figure 1: NIH Funding Erodes Over Time (Source: NIH, Office of the Budget, https://officeofbudget.od.nih.gov/approp_hist.html, and https://officeofbudget.od.nih.gov/gbipriceindexes.html.)

the federal budget (through reduced health care spending and higher tax revenues) as well as the nation's health. Although the nation benefits from discoveries elsewhere, NIH funding is also critical to convincing the best researchers and companies to keep and commercialize their research in the United States.

Fortunately, the broad mission of NIH continues to enjoy strong bipartisan support in Congress. Members on both sides of the aisle understand that the federal government has an essential role in funding biomedical research and often point with pride to the advances made and lives saved or improved on account of research undertaken by scientists in their home states. There also seems to be a growing awareness that the failure to provide growing resources and increased predictability has negative effects on both the pace of medical breakthroughs and the strength of the U.S. biomedical industry.

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Unfortunately, political battles over the broader federal budget have prevented legislators from translating this support into rising, or even stable, budgets—resulting in tremendous uncertainty about what NIH's budget will be from year to year. Although there is a general willingness to increase the agency's budget, members differ over whether any increases should be offset by cuts to other programs. As a result, policymakers should consider separating NIH's budget from the broader deficit battles.

Why Biomedical Research Matters

Reduced and inconsistent spending at NIH has broad implications for our health and the economy. There is a growing body of literature on the value of federally funded research in general and of funding for NIH and biomedical research specifically. Part of this literature looks at the cost of disease on the economy. Although in some ways human disease adds to the economy by creating a demand for doctors, hospitals, and other health providers, these resources essentially go toward mitigating or preventing harm. Society would be better off if the harm never existed so that the resources could instead be used for other productive purposes. Moreover, illness and early mortality impose a large cost on the productivity of individual workers—to say nothing of their quality of life—and, therefore, reduce the nation's potential wealth. *The positive impact of federal support for biomedical research lies first and foremost in its effect on speeding the delivery of better health and medical cures.*

Illness imposes tremendous costs on society. A recent study estimated the value of past and future progress on human health.[3] It found that the increase in longevity by about 30 years per person since 1900 was roughly worth the equivalent of over $1.2 million to the average American in 2000. Overall, progress against various diseases since 1970 had increased national wealth by $3.2 trillion per year, or about half of GDP. Looking forward, a 1 percent reduction in mortality from cancer would deliver roughly $500 billion in net present benefits, while a cure would deliver $50 trillion in present and future benefits.

Even aside from its health effects, federal spending on basic research has an important impact on the life sciences. This is certainly true of NIH spending, which is central to the nation's biomedical ecosystem (see Figure 2). Federal support for biomedical research improves the environment for private investment, encourages more students to enter the field, and flows through the economy as the recipients of federal grants spend the money on salaries and equipment. A 2012 report by the Milken Institute found that a dollar of NIH funding boosted the size of the bioscience industry by $1.70 and that the long-term impact may be as high as $3.20 for every dollar spent.[4] This estimate did not include the direct effects of NIH spending on other medical industries or the indirect effects of spending by those who received grants.

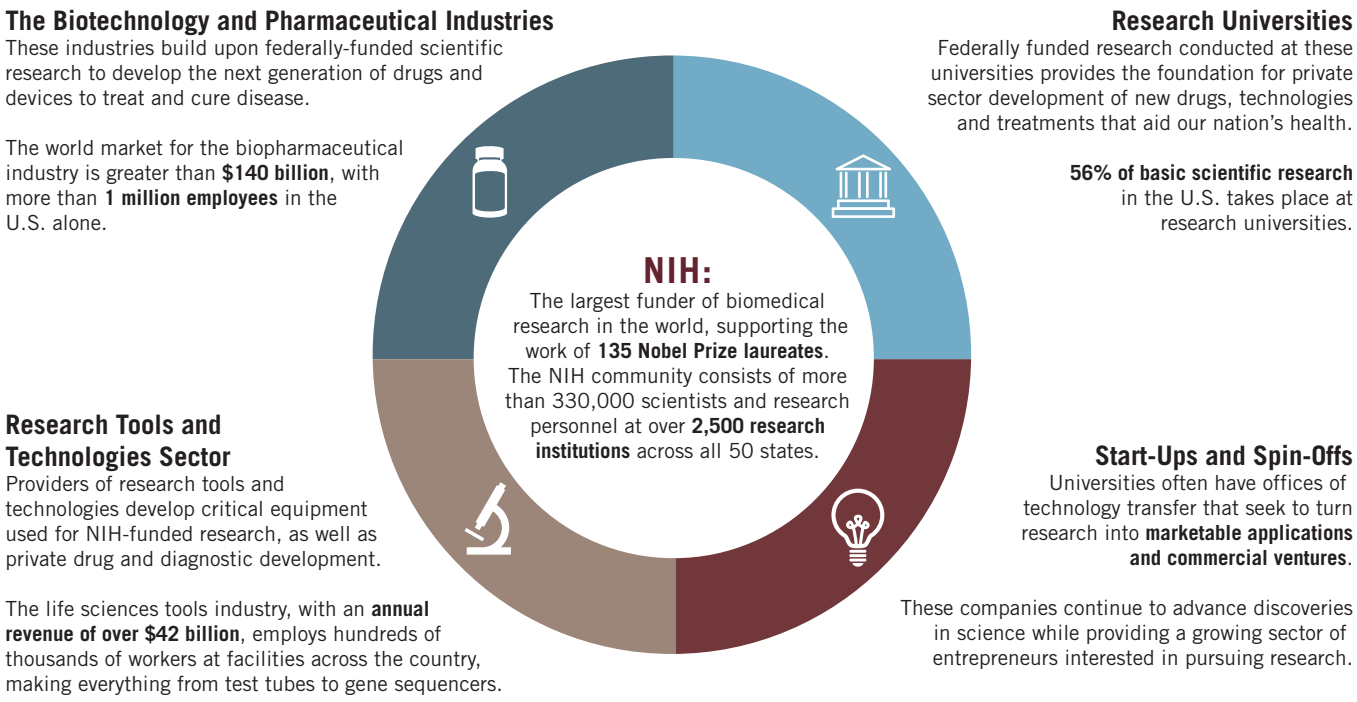

Figure 2: The NIH Medical Innovation Ecosystem (Source: United for Medical Research)

Analysis done by United for Medical Research (UMR) suggests that in 2013, NIH-sponsored research supported over 405,000 jobs. NIH funding has fostered medical breakthroughs and supported the creation of innovative companies.[5] For example, a 2013 report by Battelle and funded by UMR found that, looking solely at federal support for the Human Genome Project between 1988 and 2012, every dollar of federal funding helped generate an additional $65 dollars in genetics-related private activity.[6] This activity in turn produced nearly $3.9 billion in federal taxes and $2.1 billion in U.S. state and local taxes in 2012 alone.

The decline in real funds available to NIH has had serious consequences: fewer jobs and less science. In 2013 the American Society for Biochemistry and Molecular Biology conducted an online survey of 3,700 scientists across America.[7] Of those responding, 46 percent had laid off scientists or expected to soon, while 55 percent knew of a colleague who lost his or her job. In addition to cutting existing staff, 53 percent had to turn away promising young researchers because of a lack of funds. A more recent survey of researchers holding NIH or National Science Foundation grants found that nearly half had abandoned an area of investigation they considered central to their lab's mission, and that more than 75 percent had reduced their recruitment of graduate students and research fellows.[8]

Decreases in funding to NIH also have dire consequences for industry-funded research. In 2012, private industry spent over $69 billion in health and medical research—more than double the current NIH budget. Other sources, including universities and state and local governments, spent another $20 billion.[9] However, this critical investment is intrinsically tied to the foundational investment made by the U.S. government in medical research. A recent study found that total biomedical research and development (R&D) spending in the United States declined by $12 billion from 2007 to 2012, largely the consequence of a reduction in domestic industry investment.[10] Declines in federal funding can therefore have large multiplier effects in the private sector.

Constrained funding creates imbalance. In a recent article, four prominent biologists argue that America's biomedical research ecosystem contains systemic flaws that threaten its future.[11] According to the authors, despite the tremendous promise of new technologies, a severe imbalance between available research funding and the growing number of capable researchers threatens to drive away many participants. They suggest that the rapid doubling of federal dollars ending in 2003 might have perpetuated an assumption that research funding would grow indefinitely at a substantial rate. This attracted a growing number of researchers and investment into the field. As a result, scientists are spending more time seeking funds from an ever-smaller pool of resources and less time doing the vital research the country needs. The authors stressed the importance of predictable budgets for funding agencies, advocating that appropriators consider adding a five-year projected fiscal plan to the current process.

The current funding environment also places stress on the peer review process for awarding research grants. Although it can make tentative plans, NIH cannot make awards until Congress appropriates the money for a given fiscal year. Given the protracted nature of recent budget debates, this often occurs well into the fiscal year, creating uncertainty for investigators and their home institutions.

Challengers to U.S. Leadership in Biomedical Research

Democracies face a constant need to balance being responsive to ever-changing political and social dynamics with upholding long-term public policy commitments. They must be responsive to public opinion—even if this opinion changes suddenly or is inconsistent—while also being responsive to new facts regarding the effectiveness of public programs and the ranking of public priorities. This balancing act is made more complicated by the fact that many public investments take years to pay off. Every government struggles with the difficulty of making binding commitments to the future. Yet at one point in our recent past, Congress did make a commitment to double NIH funding over five years. Although this commitment was not legally binding, it was honored over the next four years and the goal was achieved. Unless governments can make a credible commitment to increase research investments over the long term, their ability to attract additional private research dollars and the best scientists will be compromised. Uncertainty itself imposes a cost.

While NIH spending has basically stagnated in the U.S. since 2003, a number of other countries have attempted to move forward and have made long-term commitments to increase their support of biomedical sciences. The difference has resulted in an erosion of America's preeminence in biomedicine. A recent report by the Information Technology and Innovation Foundation and UMR concluded that: "the competitive position of the U.S. life sciences industry has been eroding over the past decade."[12] In part, this has been because competitor countries improved their institutional framework surrounding biomedical research through innovations such as patent boxes and regulatory reforms.[13] But a large factor has been increased public funding for basic research. This report looks at how and why four other countries have made a commitment to increase funding for basic biomedical research and then tried to sustain it over the following years.

China: Biotechnology is a Strategic Industry

China has committed itself to developing a globally competitive life sciences industry by the end of the decade.[14] As part of this commitment, the current five-year plan (covering 2011–2015) designates biotechnology as one of the nation's strategic industries and pledges to invest 2 trillion yuan ($308.5 billion) over the next five years.

"Unless governments can make a credible commitment to increase research investments over the long term, their ability to attract additional private research dollars and the best scientists will be compromised."

This investment was partially premised on the belief that a major increase in government funding would attract significant private investment to take advantage of research findings. Rather than crowding out private funding, this support has attracted a large amount of private finance, making China the second-largest source of venture capital for medical technology.

With the world's largest population and a rapidly growing economy, the size of China's domestic market was certain to attract private investment irrespective of government funding, at least as long as China offers a stable legal environment. As a highly centralized one-party state, decision-making in China is streamlined and is not subject to inter-party differences. Additionally, because of its status as a large creditor nation without built-in future government deficits, China's budget does not face the same fiscal constraints as the United States. Although China faces serious economic and demographic challenges in the future, these have not impinged on its budget situation so far.

United Kingdom: Decreased Public Research Erodes Private Industry

Support for biomedical research funding in the United Kingdom stems from a determination to reverse the sudden erosion of the private biomedical industry, in part the result of previous declines in public spending.[15] When the Cameron government took power in 2010 in the midst of the Great Recession and Eurozone crisis, it initially focused on cutting spending in order to reduce budget deficits. Although funding for some agencies was reduced as much as 25 percent, funding for scientific research was held constant in nominal terms. This meant that in real terms, funding fell and the private sector did not take up the slack. Instead, the pharmaceutical industry, which had been one of the country's economic strengths, went into a decline. Pfizer closed its research and development operation in Sandwich, Kent, and the number of U.K. biotech firms fell by 3 percent between 2009 and 2011. The result was that small savings in the public budget had large negative effects on private industry, leading to a loss of jobs, lower taxes, and a decline in competitiveness.

In December 2011, the Cameron government responded by pursuing a new commitment to the life sciences.[16] The government's "Strategy for UK Life Sciences" identifies a number of institutional initiatives to enhance the competitiveness of the biomedical industry, including the creation of a "patent box" to lower the tax rate on income from new patents, faster regulatory approval for new drugs, and institutional reforms. With a parliamentary system, the government can be

confident of enacting its main funding priorities as long as it is in power. However, the United Kingdom continues to suffer from large budget deficits, so it will be difficult to maintain spending increases. Nevertheless, the negative consequences of previous cuts in biomedical funding seem to have convinced the government that the costs of cutting spending can be great.

Singapore: Public-Private Collaboration is Critical to Success in Biomedical Research

Over the past decade, Singapore has moved aggressively to increase its share of global life sciences research.[17] In 2003 the government created Biopolis, which provides dedicated research and residential facilities and places public research institutes next to corporate laboratories in an effort to foster collaboration. Singapore has also provided direct funding to support research and development by the pharmaceutical industry, devoting five times the percentage of its economy to this effort as the United States. Its efforts are further aided by a business-friendly environment. On average it takes only three weeks to receive approval for clinical trials, and a manufacturing facility can become operational within two to three years. As a result, the country is now the regional headquarters of eight of the top ten global pharmaceutical firms. These efforts have had positive results. Singapore's share of global pharmaceutical output has more than tripled since 1995 (although it declined slightly since 2006), and its trade surplus in pharmaceutical goods has shifted from a deficit of 0.01 percent of GDP in 2003 to a surplus of 3.86 percent in 2012.[18]

A report by Singapore's Agency for Science, Technology and Research, which includes a separate Biomedical Research Council, is explicit about the government's goal of using a collaborative and integrated research and development system to become an attractive investment location for high value-added manufacturing by global companies.[19] A new Technology Adoption Programme is intended to increase the ability of small- and medium-sized companies to access technology and upgrade their capabilities. Nevertheless, the government has not been able to maintain the very high level of public funding that existed in 2006. The government has also worked to incorporate university research into its efforts, attracting outposts from leading research institutions including MIT, Duke, Johns Hopkins, Chicago, and Carnegie Mellon, and recruiting leading scientists.[20]

Australia: Innovative Financing Can Ensure Continued Investment and Growth

Earlier this year, the Australian government announced the creation of a new Medical Research Future Fund. The Fund is to begin operations in January 2015 with $A1.1 billion and has a target size of $A20 billion by 2020.[21] Initial capital will come from an existing Health and Hospitals Fund, but future funds are supposed to come from reforms in the government health programs, including a $A7 co-payment for general practitioner and other visits. The purpose of the Fund is to finance medical research through competitive grants. Current government funding for medical research is through the National Health and Medical Research Council (NHMRC). If the Fund reaches its goals, it will roughly double government funding for medical research.

The creation of a large endowment fund to underwrite medical research should provide stability in funding. Its intended operation seems similar to the Wellcome Trust in the United Kingdom, which had an endowment of £16.4 billion in 2013, and the Howard Hughes Medical Institute in the United States, with an endowment of $17 billion. However, as long as the Fund is a government entity, its assets are subject to repurposing. Perhaps more likely, in tough times future governments may be tempted to cut or at least hold constant annual spending on the NHMRC. In this case the Fund's resources would replace, rather than add to, the traditional means

of financing research. As an example of this threat, while it was creating the Fund the government also cut $A265 million in other research funding.[22]

Innovative Ways to Increase Federal Support for NIH

Despite the prevalence of the annual appropriations cycle, Congress has already made a number of modifications for specific programs. Each of these precedents serves as a possible model for delivering increased, predictable funding to NIH that will ensure America's scientists can continue their work on life-saving therapies and interventions.

Mandatory Spending

At one end of the spectrum are mandatory programs. A few programs, such as student loans and agricultural crop subsidies, receive permanent appropriations. These mandatory programs are driven by authorization bills that set out what the agency is supposed to do. The money is automatically appropriated to the agency and/or its beneficiaries to be used for the purposes specified in law. NIH already receives $150 million in mandatory funds for research into Type I diabetes and diabetes through Indian health facilities, although this is due to expire in 2015.[23] For the past few years, Congress has extended the program an additional year at a time. For new programs, these extensions are normally subject to so-called PAYGO provisions that require Congress to offset their cost by cutting other mandatory programs or raising revenues.

What would a mandatory funding bill look like for NIH? One could imagine a statute that required NIH to enter into research contracts that met certain criteria. These criteria might encompass all the current activities of the Institutes or just a subset, as the diabetes programs do. Besides providing the authority for these contracts, the legislation would also provide the appropriations, either for several years or indefinitely. Such a program would transform NIH research into a mandatory program, excusing it from the need to go through the annual appropriations process. Of course, if the legislation expired every year, as the diabetes programs already do, NIH may not gain much stability from the process. In addition, under PAYGO provisions, Congress would have to find a way to pay for the increased spending every time the law is renewed. While providing multi-year appropriations might seem desirable, doing so would also increase the cost of the bill and therefore the offsets that Congress would need to find. Without an offset, any member of either chamber could attempt to block the bill by raising a point of order. While not fatal, such an objection would require broad support to overcome.

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In the past, appropriators, the Budget Committees, and the Office of Management and Budget at the White House have strongly discouraged using this as a model for other programs. However, legislation drafted by Senator Richard Durbin (D-IL) and Representative Anna Eshoo (D-CA) would essentially create a mandatory program on top of NIH's current appropriations.

Dedicated Funding Streams

The creation of a mandatory program and the designation of an offset would be easier if Congress could identify a dedicated stream of revenues to pay for NIH programs. Once the legislation is passed, the agency would be free to spend the money as authorized without going through the appropriations process. Again, the authorizing

legislation might expire after a number of years, but extending it would no longer require an offset. Congress could also place a limit on the agency's authority to obligate the funds, thus capping its overall budget.

"NIH research in genetics could lead to breakthroughs in areas as diverse as heart disease and oncology"

A number of programs use this model. For instance, the federal government requires companies requesting the review of certain chemicals to pay a pesticide registration fee. The revenue from these fees goes directly to the Environmental Protection Agency to help pay for government's necessary research and review of the chemicals. In this case pesticides produce an identifiable harm that Congress sought to reduce through a regulatory process that includes collecting research results specific to the issue. Similarly, the Food and Drug Administration charges a prescription drug user fee to help pay for the review and approval of pharmaceuticals, and the National Park Service charges an entrance fee that can be directly used to pay for the operation of the parks.

Under this model the agency is seen as performing a service for the industry or consumer, albeit one that industry is sometimes required to consume, and the legislation places the burden of paying for at least part of that service on the direct beneficiaries rather than the taxpayer.

As applied to NIH, there are challenges with such a model, however. Much of NIH research is basic science whose industry or consumer beneficiaries simply will not be known until a later stage of research. For example, NIH research in genetics could lead to breakthroughs in areas as diverse as heart disease and oncology.

Generally speaking, depending on the revenue stream, this funding method may not significantly increase agency budgets. The Highway Trust Fund, which is supposed to pay for the maintenance and construction of roads, is funded by a tax on gasoline. However, for several years these revenues have not been sufficient to pay for all of the projects that Congress thinks are necessary. As a result, Congress has had to provide additional money from general revenues, making the highway bill subject to PAYGO (offset) provisions and significantly complicating passage of any highway bill.

NIH already receives about $3.2 million in payments from other federal agencies for research that it conducts on their behalf. However, these funds do not increase the amount of free resources available to fund NIH priorities because they are offset by the cost of doing the research itself. Ideally, there would be a direct and logical connection between the entities that pay a fee (or are taxed) and the research funded. For instance, in 1997 Senators Tom Harkin (D-IA) and Arlen Specter (R-PA) proposed increasing NIH funding by as much as $6 billion per year by levying a 1 percent tax on health insurance premiums and devoting the revenues to NIH.[24] Yet, those providing the revenue, whether they are insurers, pharmaceutical drug manufacturers, health care consumers, or research institutions that benefit from patents derived from NIH-sponsored research, are likely to oppose any additional costs. In the case of NIH, paying the cost does not ensure that an individual or group will benefit from a specific government service.

Trust Funds

A related possibility would be to create a trust fund that remained subject to appropriations. NIH would still need to go through the annual process and would be subject to the budget caps, but it would have an advantage over other programs by claiming that money had already been set aside for its funding.

Legislation to clean up hazardous waste sites (so-called "Superfund" sites) was originally funded on this model. However, the tax created to fill the "Superfund" has since expired and the fund balance has gone to zero. The program is now funded like most other discretionary programs. Likewise,

Congress established a Harbor Maintenance Trust Fund that is funded by a tax on barge fuel. Money from this fund is appropriated to pay for the federal dredging of harbors and waterways. These resources are subject to appropriations but since the balance in the fund has now grown to approximately $8.5 billion, water infrastructure advocates have a strong argument that more funds should be appropriated for this use (what they call "full utilization"). [25] Finally, in a mix of the first model and the trust fund model, the Patent and Trademark Office (PTO) collects user fees from patent applicants. However, the use of these fees remains subject to spending limits established in appropriation bills. Critics of the approach have complained that Congress is not letting the PTO spend all of the fees collected. This dispute was only partially addressed by patent reform in 2011.[26]

CHIMPs

The offset for an increase in discretionary spending does not have to come from another discretionary program.[27] The budget rules allow changes in mandatory programs (CHIMPs) to be applied to discretionary programs. When these changes save money in a mandatory program, the savings can be used to offset increases in a discretionary program. For example, in 2014, the Labor, Health and Human Services, Education, and Related Agencies subcommittees used legislation reducing budget authority for the Children's Health Insurance Program (CHIP) in order to increase spending on other programs within its jurisdiction. However, because this money was not expected to be spent anyway, the Congressional Budget Office (CBO) estimated that it produced no reduction in actual outlays.[28] Obviously, if an offset can be identified that would not result in a real cut to the targeted program, the political opposition to enacting it is likely to be much lower. The past use of CHIMPs is likely to make future budgets tighter.

"If NIH funding cannot be substantially increased, there are some options that could provide the agency with more flexibility and stability."

Advance Appropriations and Forward Funding

Absent a dedicated (or semi-dedicated) source of revenue, NIH appropriations must continue to compete with all the other agencies and programs funded from the discretionary budget under the caps that exist at the time. But if NIH funding cannot be substantially increased, there are some options that could provide the agency with more flexibility and stability.

A few agencies receive what is called advance appropriations and forward or advanced funding.[29] Although these still have to go through the annual appropriations process, in these cases Congress makes appropriations commitments ahead of schedule. Whereas most agencies do not know what their budgets will be until that year's appropriation bill is passed, often well into the fiscal year, agencies that get advance appropriations receive their appropriation in previous years' bills.[30] These appropriations, however, must fit under the discretionary caps for the year in which they become available and are always subject to change in later legislation.

For example, since 1975 Congress has given two-year advances to the Corporation for Public Broadcasting (CPB). In 2015 Congress will debate the FY 2016 budget for most agencies. For CPB, it will debate the FY 2018 budget. This does not guarantee the agency any additional money, but it does provide it with an additional two years of relative certainty about what its budget will likely be. It also eliminates the possibility that CPB will temporarily have to shut down at the end of a fiscal year while Congress negotiates a broader agreement to keep the government funded. While advance appropriations do not necessarily yield higher funding overall, the main benefit of this budget device is some funding security and less disruption to the agency during times of temporary Continuing Resolutions or other incomplete appropriations actions, including a government shutdown.

"Multi-year appropriations would give the peer review process more time to operate by either extending or removing the date beyond which funds are no longer available."

Advanced appropriations can be a mixed blessing. As long as the budget caps are binding, legislators who want to increase funding for any program must offset the additional funding by identifying cuts in another agency. One of the easiest ways to do this is to find programs that have unobligated balances—in other words, they have not spent all of their money. Agencies receiving advanced appropriations often have large unobligated balances. This makes them attractive targets for offsets to pay for increases in other programs.

Multi-Year Appropriations and Budgeting

Another possible reform would be to remove the constraint that NIH must obligate most of its money before the end of the fiscal year. The vast majority of NIH's funds must be spent by September 31st or they revert back to the Treasury. Multi-year appropriations would give the peer review process more time to operate by either extending or removing the date beyond which funds are no longer available.[31] Congress might still want to set a time limit, but the deadline need not be September 31st. This, of course, would not increase the total funding available to the Institutes, but it might allow them to smooth funding between years, space the work load out more evenly over the year, and improve the quality of the peer review process.

Working within the current appropriations process, NIH could build support for additional funding by developing a multi-year budget that lays out a nexus between future funding and research results. The result might give Congress a better understanding of the long-term link between research and outcomes and build support for a long-run vision. During testimony related to the 21st Century Cures initiative, an effort to accelerate medical innovation led by the House Energy and Commerce Committee, NIH Director Francis Collins urged Committee Chairman Fred Upton (R-MI) to consider the possibility of multi-year budgeting for the agency.[31] Appropriators have tended to strongly resist multi-year budgeting, however.

Although not binding, an example of advance budgeting exists for the defense budget. In most years the Department of Defense prepares a five-year budget plan, called the Future Years Defense Program (FYDP) that supplements its annual budget request to Congress. Then CBO often does its own analysis of future defense spending, going out 15 years using both an extension of the estimates in the FYDP and CBO's own estimates of what programs will cost.[33]

As another example, in the research space, in an exercise largely removed from the budget process, every decade the nation's astrophysicists compile

a report on the state of the science and the outlook for the next 10 years, including, importantly, a prioritization of research areas. The latest report was released in 2010.[34] This report has provided an important and stable framework to federal agencies, such as the National Aeronautics and Space Administration and the National Science Foundation, that provide research grants to this community, and it may have been responsible for this community receiving a greater share of funds compared to other research areas that do not have such a plan. A similar effort by the biomedical research community might help proponents of greater NIH funding demonstrate a coherent and long-term plan as well as show the expected tangible benefits that an increased investment in medical research would bring. The 21st Century Cures Discussion Document released earlier this year would have NIH develop a five year biomedical research strategic investment plan that would be updated every year.

Adjusting the Caps on Discretionary Spending

A potentially promising strategy for NIH could be to amend the Budget Control Act to raise the cap on domestic discretionary spending in a way that ensures additional money flows to NIH. To ensure that the raised cap results in additional resources for NIH, the cap would only rise if the appropriators provided a specified level of appropriations to the agency under the normal caps. The extra money under the raised caps would also have to go to NIH.

"A potentially promising strategy for NIH could be to amend the Budget Control Act to raise the cap on domestic discretionary spending in a way that ensures additional money flows to NIH."

The Budget Control Act already contains two provisions that make additional funds available for disability reviews and determinations for the Social Security program and combating health care fraud and abuse, respectively.[35] Both of these programs share the advantage that additional funding might actually lower deficits by reducing the amount of fraud in the system. The amounts total less than $1.3 billion for FY 2014, and Congress only took advantage of the provision for disability insurance. However, for that program the additional funds represented over three times the amount that Congress was required to provide through normal appropriations.

Current Legislation to Increase NIH Funding

Over the last several years, lawmakers on both sides of the aisle in the House and Senate have introduced legislation to relieve pressure on the NIH budget and move toward a more predictable funding model. Many of the proposals are built upon existing federal funding models and options presented in this report. These and other methods to put NIH on a path toward predictable, increased funding deserve the full consideration of Congress.

Lawmakers should:

- Increase discretionary spending caps and ensure additional funding flow to NIH;
- Provide NIH with permanent appropriations, limiting the agency's exposure to annual budget battles;
- Establish a biomedical research fund to supplement annual appropriations;
- Remove NIH from the discretionary budget, making the program mandatory; and
- Streamline regulatory processes to ensure efficient use of existing funding.

Conclusion

A recent report by the National Academy of Sciences called for increasing total national R&D investment by all sources to at least 3.3 percent of GDP.[36] Such a goal would presume large increases in government funding for biomedical research. While NIH is fortunate to have broad support in Congress, and at times has fared well relative to other federal programs, significant funding increases are unlikely in FY 2016 and beyond within the current constraints of the Budget Control Act.

The case for the health and economic benefits of NIH is clear and further emphasized in this paper. This report points to research showing that science funded by NIH can be expected to reduce government spending on health care and increase future productivity by delivering cures to some of society's most pressing problems. The challenge for Congress is to find consensus and innovative means to provide the agency with predictable, sustainable, and increased funding to continue that mission. The options contained in this report provide a starting place for this important debate.

Endnotes

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Acknowledgements

The authors would like to thank Stephen Ezell, Erik Fatemi, Adrienne Hallett, G. William Hoagland, Erin Katzelnik-Wise, Adams Nager, Marcus Peacock, and Bettilou Taylor for their help in developing the ideas in this report. Although each of these individuals provided useful ideas, any statements of fact and recommendations are the sole responsibility of the authors.

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