CONSERVATIVE REFORM NETWORK

The Case for Increasing American Investment in Medical Research

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"Healing is a matter of time, but it is sometimes also a matter of opportunity."

—Hippocrates

Executive Summary

This November the American people will elect a new president. Soon after his or her inauguration, the next president will submit the new administration's first budget plan to Congress. A president's first budget is not only an opportunity to lay out funding levels and policies for the next year, but also a chance to outline a vision for the nation's finances over the next decade. Where will the federal government spend more, where will it spend less? In the context of finite resources, what investments offer the American people the greatest return in terms of security and future prosperity?

Since the presidency of John Adams, the federal government has been involved in halting the spread of disease. And with good reason, medical advances further one of the most basic functions of government: the protection of its citizens. There is a broad and compelling case for increasing the federal government's investment in medical research, including:

- Moral: Prior medical advances have cured once incurable diseases and saved millions of lives. It is imperative that we build on those successes to treat and cure today's afflictions.
- Economic: Medical research not only contributes to the economy, but medical advances generate savings in health care and improve overall longevity, adding to economic growth.
- National Security: The ability to confront highly infectious natural diseases and bioterrorism is key to preserving order and advancing America's national security.
- Global Leadership: Stagnant investment in medical research in the U.S. coupled with growing investments abroad threaten America's position as the global leader in medical research.

Further, the federal government has a unique and essential role in promoting and supporting basic research.

As Congress and the president complete the fiscal year 2017 budget process and as the next president and Congress prepare their budgets, there are near- and medium-term opportunities to make significant investments in medical research. Policymakers should seize these opportunities, but they should also avoid a repeat of the problems created between 1998 and 2013 when funding for the National Institutes of Health was quickly doubled, then flat-lined, and then reduced. The lack of sustainable, predictable funding has made it difficult to invest in new research and new researchers.

It is crucial that new investments in medical research be accompanied by reforms that reduce waste, and improve the efficiency and rate of return of taxpayers' funds. Reforms should improve the accountability of senior officials, increase transparency, break down the silos that dominate much of the existing research infrastructure, and utilize funding mechanisms that incentive high-risk, high-reward research.

This white paper, which explores these issues and policies, is divided into three sections: (1) The Case for Investing in Medical Research, (2) Background and Outlook for Federal Investments in Medical Research, and (3) Reforms that Enhance Investments in Medical Research.

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The Case for Investing in Medical Research

The Moral Case

Diphtheria, a bacterial infection easily spread through coughs, sneezes, and touching infected objects, can cause difficulty breathing and even death. Hippocrates, the Greek physician and author of the Hippocratic Oath, first described the disease in the fifth century BC. One hundred years ago – 24 centuries after Hippocrates first description – diphtheria was a leading cause of illness and death among American children, with 206,000 cases and 15,520 deaths recorded in 1921 alone. But what was once a leading cause of death, especially among young children, is now so rare that in the last 15 years there have been less than five reported cases in the U.S.[1]

As Table 1 illustrates, what is true of diphtheria today is also true of many other once fatal or debilitating afflictions. In each case, medical research led to a better understanding of the disease and ultimately a vaccine or cure.

Table 1. Disease Cases and Deaths, Pre- and Post-Vaccine

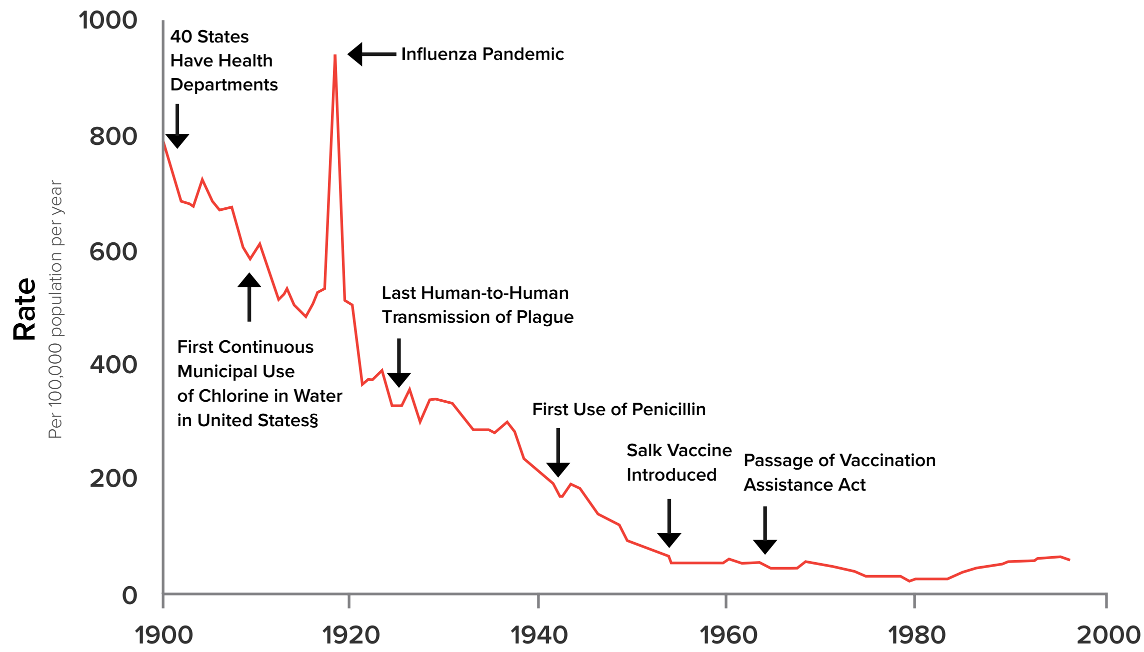
	Pre-vaccine Estimated Annual Average		Most Recent	
	U.S. Cases	**U.S. Deaths**	**U.S. Cases**	**U.S. Deaths**
Diphtheria	21,053 (1936–45)	1,822 (1936–45)	0 (2010)	0 (2010)
Smallpox	29,005 (1900–49)	337 (1900–49)	0 (2015)	0 (2015)
Polio, paralytic	16,316 (1951–54)	1,879 (1951–54)	26 (2010)	0 (2010)
Measles	530,217 (1953–62)	440 (1953–62)	140 (2008)	0 (2008)
Mumps	162,344 (1963–68)	39 (1963–68)	2,612 (2010)	2 (2010)
Rubella	47,745 (1966–68)	17 (1966–68)	5 (2010)	2 (2010)
Tetanus	580 (1947–49)	472 (1947–49)	26 (2010)	3 (2010)

Sources: Roush SW, Murphy TV, Vaccine-Preventable Disease Table Working Group a. Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States. JAMA. 2007;298(18):2155-2163. doi:10.1001/jama.298.18.2155. http://jama.jamanetwork.com/article.aspx?articleid=209448#REF-JOC70121-59

Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition." Centers for Disease Control and Prevention. April 2015. http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/dip.pdf

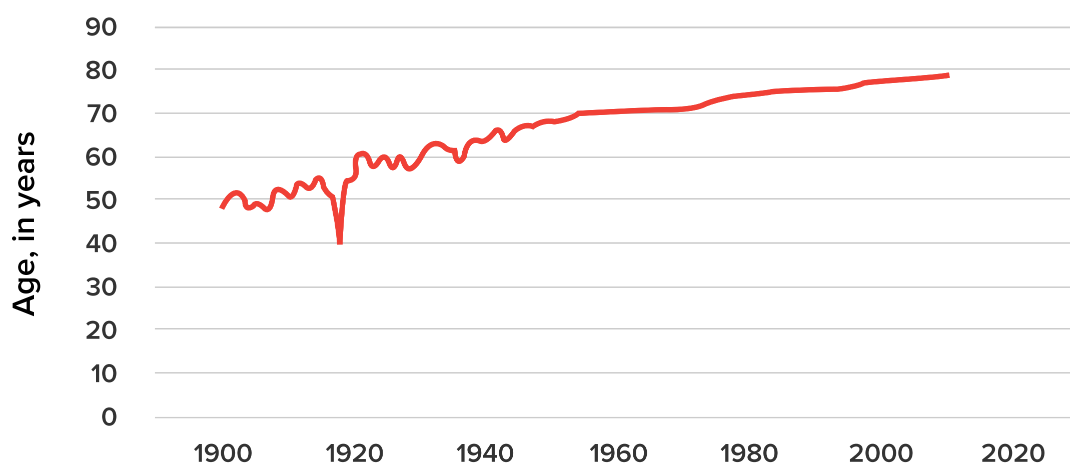
The combined result of these and many other medical and public health advances is illustrated in the two graphs below. The first graph (Figure 1) illustrates the decline in deaths from infectious diseases in the U.S. The second graph (Figure 2) details the increase in life expectancy at birth since 1900.

Figure 1. Crude Death Rate for Infectious Diseases – United States, 1900–1996



Source: "Achievements in Public Heath, 1900-1999: Control of Infectious Diseases." Centers for Disease Control and Prevention. MMWR Weekly. July 30, 1999. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm

Figure 2. Life Expectancy from Birth, 1900 – 2011



Source: Arias E. United States life tables, 2011. National vital statistics reports; vol 64 no 11. Hyattsville, MD: National Center for Health Statistics. 2015. http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_11.pdf

Behind all the data in these charts are literally millions of lives – sons and daughters, mothers and fathers – who lived because medical science cured the once incurable. Since the days of Hippocrates, we have thought of medicine and the duty to heal in moral terms. Today, the duty to heal is a moral responsibility born not just by front-line physicians but also by researchers in the lab who spend years, even decades, searching for treatments and cures.

In the U.S., these researchers work for universities, hospitals, foundations, charities, biopharmaceutical and medical device companies, and the government. As of 2012, about one-third of overall medical research spending came directly from the federal government, principally through the National Institutes of Health.[2]

As part of its Fiscal Year 2016 budget submission, the National Institutes of Health (NIH) noted some of its many accomplishments:[3]

> As a result of long-term national investments, scientific and technological breakthroughs generated by NIH-supported research are behind much of the gains in health and longevity that the nation has enjoyed. For example:
>
> NIH research has generated effective drugs for lowering cholesterol, controlling blood pressure, and dissolving artery-clogging blood clots, as well as new techniques for heart attack prevention, including helping people make lifestyle changes that promote cardiovascular health. As a result, the death rate today for coronary heart disease is 60 percent lower – and for stroke, more than 70 percent lower – than during the World War II era in which cardiovascular disease caused half of U.S. deaths and claimed the lives of many people in their 50s or 60s.
>
> Over the past 15 years, cancer death rates in the U.S. have dropped about one percent annually, due in large measure to NIH's success in improving the basic understanding of the causes and mechanisms of cancer, improving early detection and diagnosis, developing effective treatments, and expanding knowledge of cancer prevention strategies.
>
> NIH has led the global research effort against HIV/AIDS over the past 34 years, enabling the development of rapid HIV tests and the identification of a new class of HIV-fighting drugs that could be combined in life-saving ways in the clinic. As a result, HIV infection has changed from a virtual death sentence into a manageable chronic disease. Today, HIV-infected people in their 20s who receive combination therapy may expect to live to age 70 or beyond.

The Economic Case

> *"[W]e don't spend money on polio anymore, not because we streamlined treatment or because we are heartless, but because we eliminated the disease itself."*
>
> —James Pinkerton

It is fairly easy to identify the economic costs of medical research. For the cost to taxpayers, a simple turn to the relevant page in the annual budget reveals the total amount appropriated. It is, however, much more difficult to quantify the economic returns of medical research. The return on investment in medical research takes on many forms, including savings to the health care system from preventing a disease, curing a disease, and substituting lower cost, more effective treatments for higher cost, less effective treatments, and greater economic output as people live and work longer.

In 2000, Congress's Joint Economic Committee attempted to quantify the economic value of medical research. The committee's report notes:

> U.S. longevity has increased as the overall U.S. death rate has dropped by one-third since 1970. A recent study found that these longevity increases have created net "value of life" gains to Americans of about $2.4 trillion every year. Such estimates place a value on a year of life based on the typical person's "willingness to pay" to avoid various safety risks.
>
> A portion of the $2.4 trillion in annual longevity gains stem from medical research, and NIH-funded research in particular. If just 10 percent of the value of longevity increases ($240 billion) resulted from NIH-funded research, it indicates a payoff of about 15 times the annual NIH investment of $16 billion.[4]

The committee's report also states:

> Measuring the economy-wide rate of return to publicly funded research involves difficult problems of quantification. However, direct estimates that have been made in econometric studies place the economy-wide rate of return on publicly funded research on the order of 25 to 40 percent a year.

The Human Genome Project offers a concrete example on how federally funded research can impact the overall the economy. In 1990, the federal government set out to map the human genome and gain a fundamental understanding about how our DNA works. By the time the project was completed in 2003, the federal government had invested nearly $3.8 billion.

The initial investment in this basic research by the federal government, allowed for a literal explosion of private sector activity.

Leah Eisenstadt of the Broad Institute noted in 2010:

> Once upon a time, sequencing the human genome took tens of millions of dollars and a warehouse full of DNA sequencing machines that analyzed samples throughout the day, and year after year. Now, less than a decade later, the same human genome sequence — the order of nucleotides or "letters" — can be generated using a single machine that analyzes samples for a few days, and for about 100-fold lower cost. The ability to sequence DNA faster and more cheaply comes from recent technological advancements, representing the most significant technological metamorphosis in the history of modern genetics."[5]

In article for the journal *Nature*, Eric Lander explained the impact on medicine:

> In medicine, genomics has provided the first systematic approaches to discover the genes and cellular pathways underlying disease. Whereas candidate gene studies yielded slow progress, comprehensive approaches have resulted in the identification of ~2,850 genes underlying rare Mendelian diseases, ~1,100

loci affecting common polygenic disorders and ~150 new recurrent targets of somatic mutation in cancer. These discoveries are propelling research throughout academia and industry.[6]

All of this activity has broad economic impact. Batelle attempted to quantify the economic impact of the initial federal investment in the human genome project finding that:

> In 2012 alone, the research, development, and commercial activities that continue to leverage the federal investment in the human genome sequencing projects directly and indirectly generated: $65 billion in U.S. economic output, $31 billion toward 2012 U.S. GDP, 152,000 genomics and supplier jobs and supporting more than 125,000 additional jobs in the economy.[7]

Curing certain high-cost diseases could also produce economically significant benefits.

Table 2 shows government estimates of the direct (expenditures for health care services including hospital and professional services as well as prescribed medications) and indirect costs (economic value of life) of certain diseases for the year 2009. The table also includes an estimate of the share of the direct costs taxpayers paid through the Medicare and Medicaid programs.

Table 2. Direct and Indirect Costs of Diseases, 2009 (in billions)

	Direct Costs (in billions)	Indirect Costs (in billions)	Total (in billions)	Approximate Share of Direct Costs Paid by Medicare	Approximate Share of Direct Costs Paid by Medicaid
Cardiovascular Diseases	$192.1	$120.5	$312.6	41.9%	14.2%
Cancer	$86.6	$130.0	$216.6	33.0%	6.9%
Respiratory Diseases	$97.7	$31.7	$129.4	28.7%*	12.0%*
Mental Disorders	$79.8	$8.1	$87.9	20.9%	24.6%

*COPD and asthma only

Sources: "Total Expenses and Percent Distribution for Selected Conditions by Source of Payment: United States, 2009." Medical Expenditure Panel Survey (MEPS). Agency for Healthcare Research and Quality, Rockville, MD. https://meps.ahrq.gov/mepsweb/data_stats/tables_compendia_hh_interactive.jsp?_SERVICE=MEPSSocket0&_PROGRAM=MEPSPGM.TC.SAS&File=HCFY2009&Table=HCFY2009%5FCNDXP%5FD&_Debug=
"NHLBI Fact Book, Fiscal Year 2012." National Heart, Lung, and Blood Institute, NIH. February 2013. https://www.nhlbi.nih.gov/files/docs/factbook/FactBook2012.pdf

Often, various organizations will commission their own studies, which include other expenses and estimation methodologies that result in alternative cost estimates (Table 3).

Table 3. Alternative Cost Estimates of Diseases

	Estimated Cost	Year of Estimate	Note	Source
Cardiovascular Diseases	$317 Billion	2011	Projected to increase to $1.2 trillion by	American Heart Association
Alzheimer's	$236 Billion	2016	Projected to increase to $1 trillion by 2050	Alzheimer's Association
Diabetes	$245 Billion	2012	A 41% increase since 2007	American Diabetes Association

Whatever estimate of costs one uses, what is clear is that developing prevention measures and/or low-cost treatments (or preferably cures) for afflictions like Alzheimer's disease, cancer, and heart disease will result in significant overall health care savings.

For example, the Alzheimer's Association estimates that the introduction of a treatment that simply delays the onset of Alzheimer's by five years would result in $219 billion in savings in the first five years, with over half the savings accruing to Medicare and Medicaid. Over 10 years, the savings would total $935 billion, with $534 billion in savings for Medicare and Medicaid.[8]

Recent breakthroughs to cure Hepatitis C offer a concrete example of the savings that can be generated by new cures. While the press focuses on the overall cost of the new cure – up to $1,000 a day or $86,000 for a full treatment – research demonstrates how cost-effective the new cure is even at that price. As PricewaterhouseCoopers Health Research Institute notes:

> …[L]ong-term savings for chronic treatments, liver transplants, and lost productivity may ultimately offset the cost of these specialty drugs for the most seriously ill patients.
>
> Compare the average $86,000 for a course of the new therapy to medical costs for treating those with varying severity of liver disease. For instance, patients with no scarring of the liver can incur average annual costs of $17,000. Patients with compensated cirrhosis, a scarred but functional liver, can incur $270,000 in treatment over a decade. At the most severe side of the spectrum, patients who require a liver transplant could expect to be billed an average of $580,000.[9]

The National Security Case

During the little less than two years that America fought in World War I (1917-1918), 116,000 Americans soldiers died. By comparison, the 1918-1919 Spanish flu pandemic claimed nearly 675,000 American lives. The flu was so powerful that some people reportedly felt fine in the morning, but died by nightfall.[10] As a result of the flu, life expectancy suddenly dropped by about 12 years (see Figure 2).

Highly infectious, deadly diseases not only can claim hundreds of thousands or millions of lives, but also destabilize societies and threaten U.S. national security.

In 2002, the National Intelligence Council released a report regarding the rising HIV/AIDS epidemic in five countries of strategic importance to the United States.[11] Its findings were part of a series of reports and analyses that focused on the national security implications of the epidemic that was ravaging Africa. The U.S. government responded in 2003 with the President's Emergency Plan for AIDS Relief (PEPFAR).

The U.S. investment in PEPFAR has produced tremendous dividends in terms of both lives saved and countries stabilized. As the 2016 PEPFAR Report to Congress notes,

> ...PEPFAR has helped to halt the relentless escalation of new HIV infections and mortality rates across the globe. PEPFAR has saved millions of lives and prevented millions more HIV infections by providing core HIV prevention and treatment services, changing the very course of the HIV pandemic. Our investments have resulted in more than 1.5 million babies who would have otherwise been infected being born HIV-free, and have provided compassionate care and support for millions of AIDS orphans and vulnerable children (OVC). PEPFAR has built and strengthened the capacity of country-specific and country-led responses in both government and civil society, and brought key partners to the table.
>
> ...PEPFAR's impact extends well beyond the health sector, also strengthening economic development, stability and communities.[12]

Disease continues to threaten U.S. national security interests. In his 2016 assessment of worldwide threats, the Director of National Intelligence included the following:

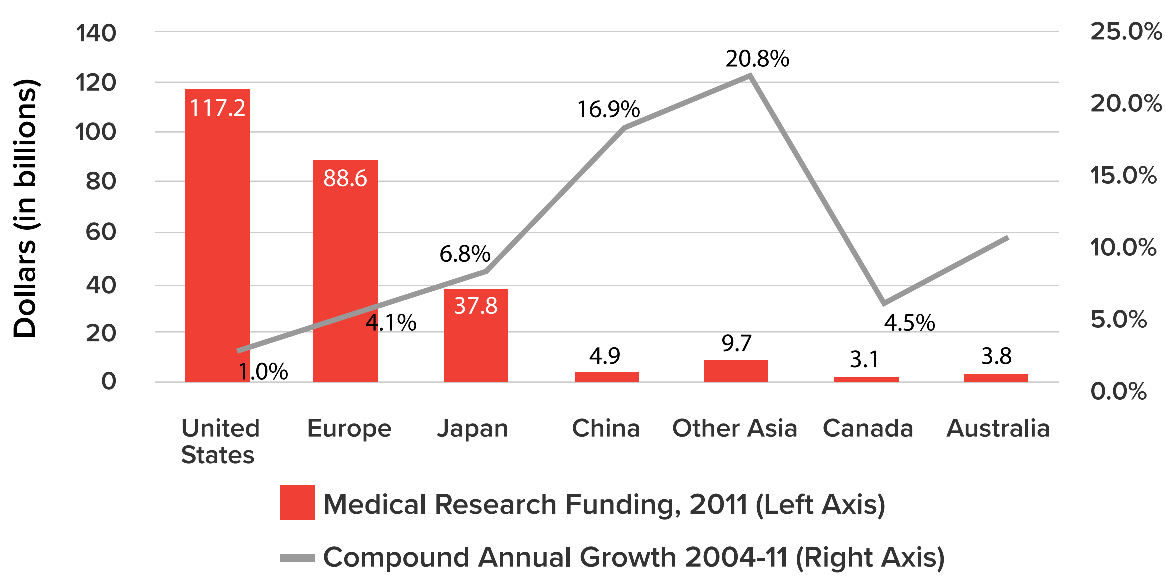
> Infectious diseases and vulnerabilities in the global supply chain for medical countermeasures will continue to pose a danger to US national security in 2016. Land-use changes will increase animal-to-human interactions and globalization will raise the potential for rapid cross-regional spread of disease, while the international community remains ill prepared to collectively coordinate and respond to disease threats. Influenza viruses, coronaviruses such as the one causing Middle Eastern Respiratory Syndrome (MERS), and hemorrhagic fever viruses such as Ebola are examples of infectious disease agents that are passed from animals to humans and can quickly pose regional or global threats. Zika virus, an emerging infectious disease threat first detected in the Western Hemisphere in 2014, is projected to cause up to 4 million cases in 2016; it will probably spread to virtually every country in the hemisphere. Although the virus is predominantly a mild illness, and no vaccine or treatment is available, the Zika virus might be linked to devastating birth defects in children whose mothers were infected during pregnancy. Many developed and developing nations remain unable to implement coordinated plans of action to prevent infectious disease outbreaks, strengthen global disease surveillance and response, rapidly share information, develop diagnostic tools and countermeasures, or maintain the safe transit of personnel and materials.[13]

In addition to natural diseases, bioterrorism is also a significant security threat. Medical research plays a critical role in our ability to prepare for and respond with medical interventions to any attack. In 2014, Congress heard expert testimony about the need to strengthen our efforts to prepare for and respond to bioterror attack, including through sustained research.[14] This is a role that really only the government can play. There is little incentive for private companies to invest in the development of biologic countermeasures for an attack that may never occur. Yet, once an attack does occur, we can hardly wait for researchers to then begin work on development of vaccines or treatments. Recognizing this threat, in 2006 Congress created the Biomedical Advanced Research and Development Authority (BARDA) to focus on the development, manufacturing, and acquisition of countermeasures against chemical, biological, radiological and other similar threats. Key to BARDA's success is the ability to build on the basic and preclinical research conducted by others, like the National Institutes of Health.

The Global Leadership Case

While the U.S. remains the world leader in terms of both total funding and share of funding for medical research, recent slow growth in the U.S. has resulted in the U.S. losing ground to our global competitors (Figure 3). A 2014 study published in the Journal of the American Medical Association (JAMA) compares medical research spending and outputs across various countries. The research finds that the U.S. share of total global investment in medical research declined approximately 13 percent between 2004 and 2012.[15]

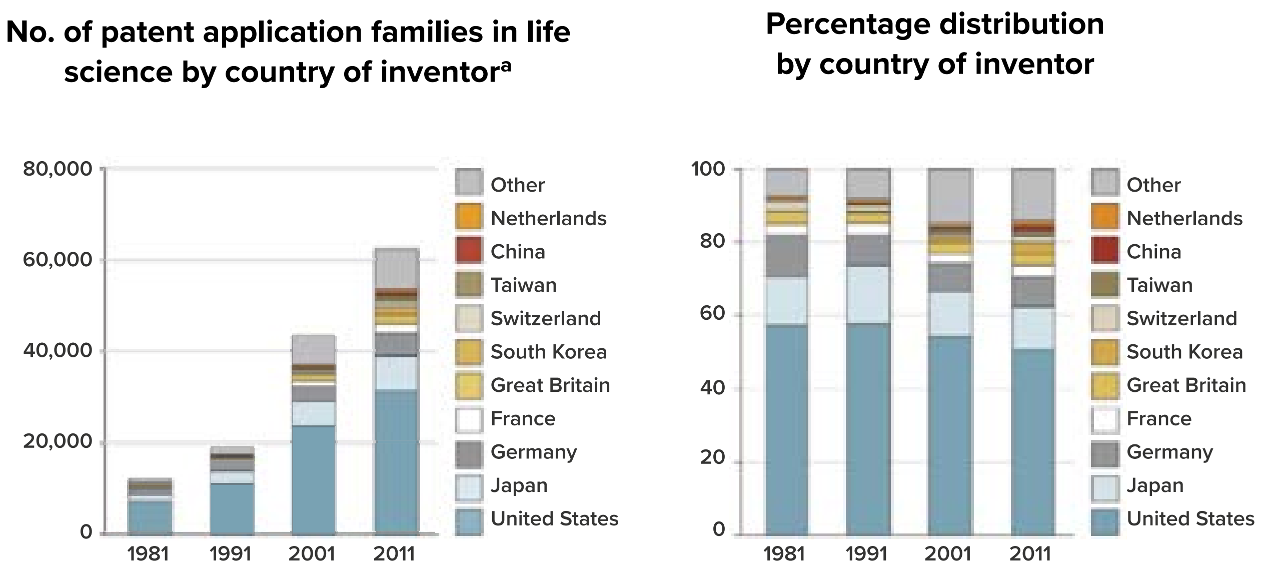
Figure 3. Overall Medical Research Funding & Growth Rate



Source: Moses H, III, Matheson DM, Cairns-Smith S, George BP, Palisch C, Dorsey E. The Anatomy of Medical Research: US and International Comparisons. JAMA. 2015;313(2):174-189. doi:10.1001/jama.2014.15939. http://jama.jamanetwork.com/article.aspx?articleid=2089358

As the U.S. share of global medical research funding has fallen, so has the U.S. share of some of the measurable outputs of medical research, such as life science patents, as illustrated by the nearby chart included in the JAMA study (Figure 4).

Figure 4. Life Science Patent Applications by Country



Source: Moses H, III, Matheson DM, Cairns-Smith S, George BP, Palisch C, Dorsey E. The Anatomy of Medical Research: US and International Comparisons. JAMA. 2015;313(2):174-189. doi:10.1001/jama.2014.15939. http://jama.jamanetwork.com/article.aspx?articleid=2089358

The Federal Role

Some have argued that additional investments in medical research should come from the private sector rather than the federal government. But the two are not mutually exclusive, and focusing just on one sector or the other ignores the important and complementary roles played by the federal government and private industry.

Modern medical research can be roughly divided into three sectors: basic, applied, and clinical research. Basic research focuses on base knowledge, while applied or translational research takes base knowledge and applies it to specific problems. Finally, clinical research generally involves researching how treatments affect patients. See Table 4 for examples of each.

While the federal government and private industry conduct all three types of research, the federal government principally focuses on basic research and areas of applied and clinical research where there is little prospect for a return on investment. Private industry generally focuses on applied and clinical research where there is the prospect for a return on their investment. If there were no return on investment, privately funded research would cease to exist outside of the charitable realm. That is why government support for the most speculative types of basic research is critical.

Table 4. Examples of Modern Medical Research by Type

Research Type	Example
Basic	Mapping the human genome
Applied / Translational	What drugs or treatments might correct a genetic defect
Clinical	How do patients react to the treatment

Of course, applied research would be nearly impossible without the building blocks of basic research. In 2008, a Rutgers University professor released a study on the relationship between basic research conducted by the National Institutes of Health and the development of new drug treatments. He found a 1 percent increase in the stock of public basic research is associated with a 1.8 percent increase in the number of new drug applications. The average lag between the public investment and industry application is 17 to 24 years, which comports with the concept that basic research and the applied research that builds upon it takes considerable time.[16]

Background and Outlook for Federal Investments in Medical Research

Background

In July 1798, the Fifth Congress passed and President John Adams signed into law "An Act for the relief of sick and disabled Seamen" which established the Marine Hospital Service to care for sick seamen.

In August, September, and October of that year, the yellow fever struck numerous cities in the U.S., including the then-seat of the federal government, Philadelphia. That December, President Adams began his State of the Union message with the following:

> While with reverence and resignation we contemplate the dispensations of Divine Providence in the alarming and destructive pestilence with which several of our cities and towns have been visited, there is cause for gratitude and mutual congratulations that the malady has disappeared and that we are again permitted to assemble in safety at the seat of Government for the discharge of our important duties.
> But when we reflect that this fatal disorder has within a few years made repeated ravages in some of our principal sea ports, and with increased malignancy, and when we consider the magnitude of the evils arising from the interruption of public and private business, whereby the national interests are deeply affected, I think it my duty to invite the Legislature of the Union to examine the expediency of establishing suitable regulations in aid of the health laws of the respective States; for these being formed on the idea that contagious sickness may be communicated through the channels of commerce, there seems to be a necessity that Congress, who alone can regulate trade, should frame a system which, while it may tend to preserve the general health, may be compatible with the interests of commerce and the safety of the revenue.[17]

By 1887, the Marine Health Service had established a bacteriological laboratory, a precursor to today's NIH.

In 1930, Congress redesignated the Hygienic Laboratory as the National Institute of Health (NIH). Since that time, NIH has been the principal federal agency responsible for medical research.[18]

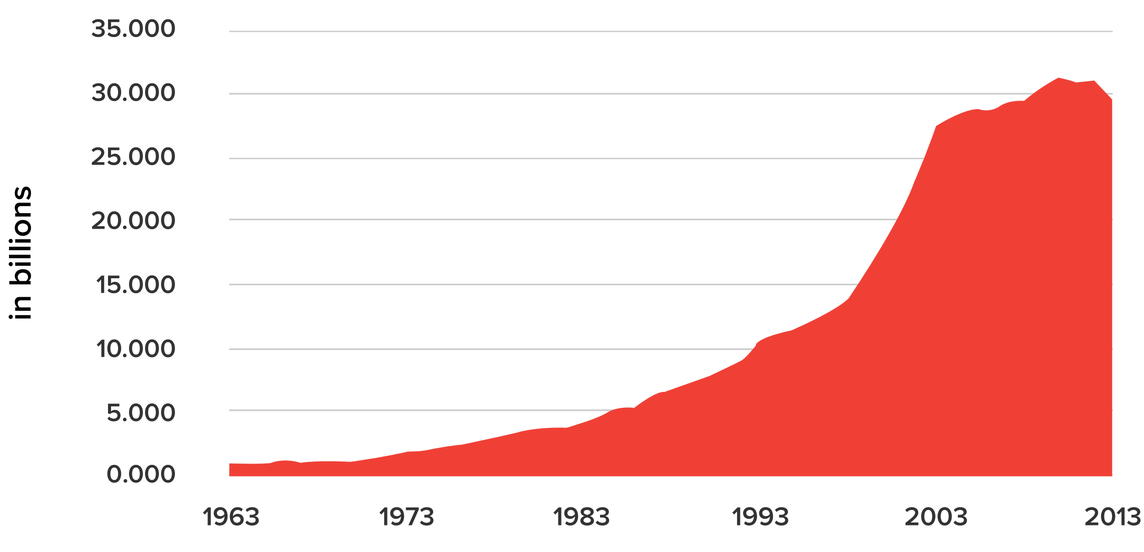
Direct federal support for medical research has always been complementary of private sector efforts. For example, privately owned hospitals that served seamen outnumbered hospitals operated by the Marine Health Service.[19] And since the founding of the Republic, the Constitution's patent provisions have served as an important tool to encourage private medical innovation. The first patent for a medicine in the U.S. was awarded to Samuel Lee of Connecticut in April 1796.[20]

The NIH Budget

From the early 1960s to late 1990s, the NIH's budget doubled in nominal dollars about every nine years. In 1998, Republicans and Democrats in Congress championed a plan to double the NIH's budget in five years.

Doubling spending over five years required annual increases of approximately 15 percent a year. After the doubling was complete, NIH funding essentially flat-lined, and over the next nine years, the budget increased by only 14 percent – compared to about 14 percent annually during the five-year doubling. In 2013, budget sequestration resulted in a 5 percent cut in funding.

Figure 5. Funding for the National Institutes of Health



Source: History of Congressional Appropriations. Office of Budget, National Institutes of Health. https://officeofbudget.od.nih.gov/approp_hist.html

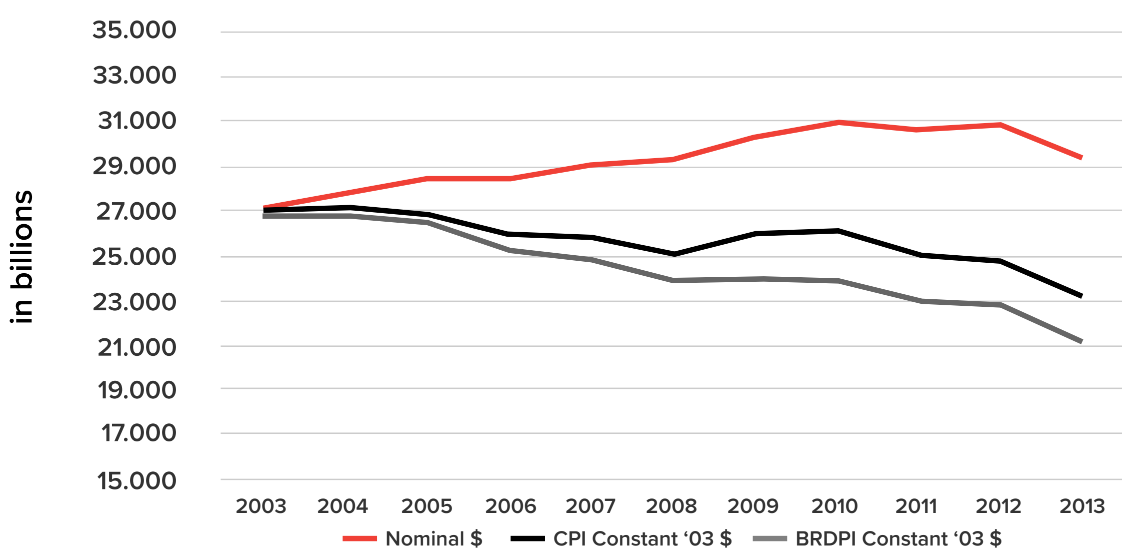
The quick doubling followed by essentially flat budgets created a perverse scenario, in which the NIH had to quickly ramp up spending, thus increasing the number and size of grants, investing more in laboratories, etc. But when funding flattened out, the NIH then grappled with sustaining the newly inflated budget while still trying to fund new research.

Research published in 2012 highlights some of the problems of the yo-yo funding:

> …the number of competing R01 grants increased in the doubling period (+15%), which then was followed by a marked drop at the end of the doubling period (−20% in three years). The effect on the number of grants could have been much worse if NIH had not reacted by changing the size of grants.
>
> The rise and fall in competing grants were reflected in the grant application success rate… After an early euphoria sends a positive signal encouraging researchers to submit grant applications, the latter hangover negatively affects the success rate of already increased grant applications. The combination of more applications and less money worsens the magnitude of the effect at the end of the doubling period.
>
> Finally, effects were also reflected in the average age of first-time R01 recipients. More and larger grants encouraged more established researchers to submit grant proposals, and in the competitive environment, established scholars benefited from their experience and won more grants, leaving fewer opportunities for young scholars. The result was a two-year jump in the average age of first-time R01 recipients…. Interestingly, after the doubling period, the effect remained in the system.[21]

When evaluating the NIH budget, it is important to consider not just the nominal amount of funding, but also the purchasing power of those funds. The chart below adjusts the nominal dollars for both changes in the consumer price index (CPI), a typical measure of inflation, and the Biomedical Research and Development Price Index (BRDPI), an inflation index which is unique to medical research (a greater discussion of the BRDPI follows later in this white paper). In terms of actual purchasing power, funding for NIH has fallen significantly since the conclusion of the doubling period in 2003.

Figure 6. NIH Funding Adjusted for Inflation



Source: Judith A. Johnson. “Brief History of NIH Funding: Fact Sheet.” Congressional Research Service. December 3, 2013. and Author calculations. https://www.fas.org/sgp/crs/misc/R43341.pdf

Near-Term Opportunity

The 2015 budget agreement between President Obama and congressional Republicans resulted in a 5 percent year-over-year increase in nondefense discretionary spending for 2016. Congress used a significant portion of that increase to fund a $2 billion (or 6.5 percent) increase in funding for NIH.[22]

For the upcoming fiscal year 2017, the Senate Appropriations Committee has proposed another $2 billion or 6.2 percent increase.[23] The Appropriations Committee in the House of Representatives has proposed a $1.25 billion or 3.9 percent increase.[24]

In addition to the funding increases proposed by the Appropriations committees, the House of Representatives has passed the 21st Century Cures Act, the result of a multiyear, bipartisan effort by the House Energy and Commerce Committee to invest in and improve the regulatory environment for medical innovation and cures. The House-passed bill would invest an additional $1.75 billion a year for five years in an "Innovation Fund" for the NIH. The Innovation Fund would finance discreet projects at the NIH, including a new Accelerating Advancement Program that leverages matching funds from current NIH resources and nine other specific activities authorized by law.[25]

As policymakers conclude the fiscal year 2017 budget process and wrap up legislation for the current Congress, they should seek to build on the additional funding provided to NIH in last year's appropriations process. This should include additional funding along with the reforms and project priorities included in the 21st Century Cures Act.

Medium-Term Opportunity

The transition to the next administration provides an opportunity to consider the more medium-term goals relating to supporting medical research. The next president should include in his or her first budget a ten-year plan for NIH funding. In contrast to the "double in five" approach of 1998, the new plan should seek to first restore and then increase the purchasing power of the NIH, but do so with steady, predictable, and sustainable increases. The plan must avoid the boom and bust cycle of the last 18 years.

As policymakers consider the appropriate level of sustainable increases, they may wish to consider various inflators of expenses. Measuring future budget changes against the appropriate inflation adjustment is critical to understanding the potential return on the resources being invested.

While we typically think of inflation in terms of the CPI, the government often uses the GDP price index, which includes changes in prices to businesses and government as well as consumers, to project future funding needs.

We know, however, that costs in some segments of the economy routinely outpace overall inflation – one such area is health care. For that reason, NIH and the Bureau of Economic Analyses (BEA) produce an inflation index called the Biomedical Research and Development Price Index (BRDPI), which measures the cost increase of all inputs purchased by NIH. As the nearby chart shows the annual average growth in BRDPI significantly outpaced both traditional inflation and the GDP price index from 1985 to 2015 (Figure 7). This trend is expected to continue with BRDPI outpacing both the GDP Price Index and CPI each year through 2020 (Figure 8).[26]

Figure 7. Historical Comparison of Different Measures of Inflation

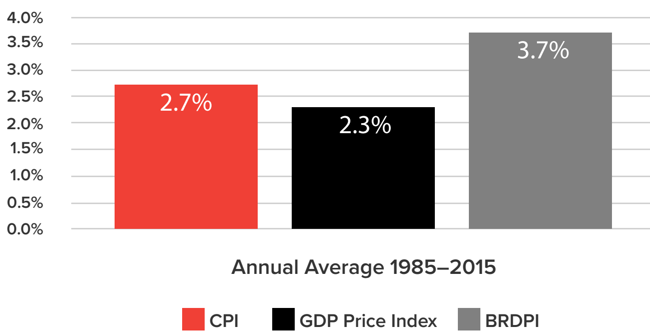
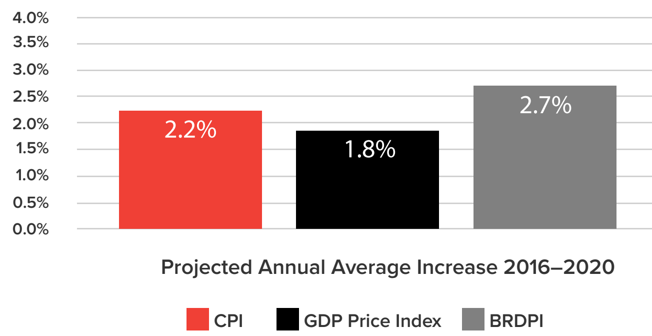


Figure 8. Projections of Different Measures of Inflation



Sources: "Biomedical Research and Development Price Index (BRDPI): Fiscal Year 2015 Update and Projections for FY 2016-FY 2021." National Institutes of Health. January 19, 2016. https://officeofbudget.od.nih.gov/pdfs/FY17/BRDPI_final_memo_02092016.pdf "The Budget and Economic Outlook: 2016 to 2026." Congressional Budget Office. January 2016. https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51129-2016Outlook.pdf

Reforms That Enhance Investments in Medical Research

NIH Reforms

Increases in funding for medical research must be combined with reforms that ensure that scarce taxpayer dollars are put to the best use and maximize the return on the taxpayer's investment. At a minimum, reforms should include those recently passed by the House of Representatives as part of the 21st Century Cures Act, including:

- **Improving Accountability**
  - Require the NIH Director to develop ongoing 5-year strategic plans to ensure proper planning.
  - Require the directors of the various NIH centers to be appointed by the NIH Director and subject to five-year terms.
  - Require directors of NIH centers to approve new grants taking into consideration the individual center's mission and priorities.
- **Improving Efficiency**
  - Identify and eliminate areas of research duplication between various federal agencies.
  - Reduce the paperwork and administrative burdens imposed on research grantees.
  - Facilitate collaborative research by requiring standardized data and the sharing of data from certain federally funded research projects.
  - Provide greater flexibility in the type of transactions NIH can enter into similar to what is permitted for the Defense Advanced Research Projects Agency (DARPA).
- **Improving Research Programs**
  - Authorize "prize" competitions to encourage interest in certain difficult-to-solve problems.

- Authorize the establishment of "high-risk, high-reward" programs in NIH centers to focus on cutting edge research.
- Create a capstone program to facilitate the transition or conclusion of research funded by the NIH.

In addition to the reforms passed by the House of Representatives, policymakers should consider additional reforms, including:

- **Improving Accountability**
    - Utilize objective metrics like patent references and citations in scholarly journals to evaluate past research as part of conducting performance reviews for individual NIH centers and programs. Such performance reviews should guide not only future strategic plans, but also funding allocations within NIH.

- **Improving Efficiency and Research Programs**
    - Significant portions of any additional funding should be directed into a common fund (created by the NIH Reform Act of 2006), innovation fund, or other similar mechanism rather than the 27 individual NIH institutes. The current framework of 27 separate centers (see Table 5) silos research efforts and discourages the kind of cross-center collaboration that can improve efficiency and result in scientific breakthroughs. Additionally, directing funding into a common fund would provide the NIH director with greater flexibility to respond to emerging health threats or direct additional resources to areas of research that are showing particular promise.
    - As noted earlier, one effect of the relatively flat funding period after the doubling of the NIH budget was that the average age of first time grantees increased by almost two years. This compounded an overall trend where the average age for a first time research grantee has increased from 38 years of age in 1980 to more than 45 years as of 2013.[27] This trend can result both in a braindrain as young scientists leave research for other fields and in a type of uniformity in researchers that discourages innovation through disruption. The NIH director has launched a number of programs to focus on young scientists. Policymakers should evaluate whether these efforts are sufficient or whether more needs be done to attract and retain promising young scientists.

Table 5. NIH Institutes & Centers

National Cancer Institute (NCI) — Est. 1937

National Eye Institute (NEI) — Est. 1968

National Heart, Lung, and Blood Institute (NHLBI) — Est. 1948

National Human Genome Research Institute (NHGRI) — Est. 1989

National Institute on Aging (NIA) — Est. 1974

National Institute on Alcohol Abuse and Alcoholism (NIAAA) — Est. 1970

National Institute of Allergy and Infectious Diseases (NIAID) — Est. 1948

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) — Est. 1986

National Institute of Biomedical Imaging and Bioengineering (NIBIB) — Est. 2000

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) — Est. 1962

National Institute on Deafness and Other Communication Disorders (NIDCD) — Est. 1988

National Institute of Dental and Craniofacial Research (NIDCR) — Est. 1948

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) — Est. 1950

National Institute on Drug Abuse (NIDA) — Est. 1974

National Institute of Environmental Health Sciences (NIEHS) — Est. 1969

National Institute of General Medical Sciences (NIGMS) — Est. 1962

National Institute of Mental Health (NIMH) — Est. 1949

National Institute on Minority Health and Health Disparities (NIMHD) — Est. 1993

National Institute of Neurological Disorders and Stroke (NINDS) — Est. 1950

National Institute of Nursing Research (NINR) — Est. 1986

National Library of Medicine (NLM) — Est. 1956

NIH Clinical Center (CC) — Est. 1953

Center for Information Technology (CIT) — Est. 1964

Center for Scientific Review (CSR) — Est. 1946

Fogarty International Center (FIC) — Est. 1968

National Center for Advancing Translational Sciences (NCATS) — Est. 2011

National Center for Complementary and Integrative Health (NCCIH) — Est. 1999

Congressional Budget Reforms

Congress should also consider reforms to its own budget process to take into account long-term savings and costs associated with medical research and preventive health programs. Current congressional scoring of investments in medical research and preventive care only records the costs of the direct outlays that will occur over the subsequent 10 years. As discussed earlier, however, investments in preventive care and in research that lead to more economical treatments and cures can reduce future health care spending. Similar to dynamic scoring of tax measures, attempting to quantify long-term savings from preventive care and medical cures would provide policymakers greater information on which to evaluate spending proposals. For example, knowing that a cure to Alzheimer's would reduce future federal health expenditures by X amount over Y years, could be extremely useful in evaluating whether to invest Z dollars for research or an innovation prize today.

At least two bipartisan measures, the Preventive Health Savings Act of 2015 and the Long-Term Studies of Comprehensive Outcomes and Returns for the Economy Act (Long-Term SCORE Act), have been introduced in Congress to update how Congress scores investments in health care.

Conclusion

As Hippocrates said, healing takes both time and opportunity. This applies as much to the treatment of a patient as it does to the research that makes new and better treatments possible. Since our nation's founding, policymakers have recognized that the federal government has a unique and critical role to play in helping to maintain the nation's health. Principally, that role includes activities that individuals and local communities cannot do for themselves. In the time of John Adams, that included fighting infectious diseases rapidly spread by commerce. Today, a significant part of both that fight and the federal government's role is the financing of the basic research that is necessary for the follow-on research that results in so many treatments and cures.

While we have successfully cured many of the diseases of the past, we face new diseases today that threaten the well-being and longevity of millions of Americans, the finances of our health care system, and even our national security. Confronting these new challenges requires that policymakers rightsize and reform the government's investment in medical research. There is no better opportunity to do just that than the beginning of new presidential administration. And as Francis Collins, the Director of the National Institutes of Health, noted in recent testimony before Congress, "This investment could not come at a better time. We are in the midst of a remarkable stream of scientific advances spurred by dramatic advances in biotechnology."[28] Policymakers should seize this moment.

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