

Ensuring Progress in the Fight against Disease through Sustained Biomedical Research Funding

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Executive Summary

The doubling of the National Institutes of Health (NIH) budget between 1998 and 2003 contributed to major advances in the nation's health through the strengthening of the biomedical research enterprise, greater understanding of disease mechanisms, and the emergence of new diagnostic and therapeutic approaches for many disorders. In contrast, flat funding for the NIH since 2004 has slowed the pace of progress in biomedical research.

A re-invigorated federal commitment to the biomedical research enterprise is an essential component of a 21st Century Intelligent Health System – a system that saves lives and saves money – and is warranted for the following reasons:

- Every day, the benefits of past medical innovations help millions of Americans across the nation, in every state and every district. Federal policymakers should view investment in biomedical research as an opportunity to deliver longer and more productive lives to Americans, rather than a mere fiscal obligation or cost to be scored. Investment in biomedical research saves and improves lives, as seen in examples such as the elimination of polio, great progress against heart disease and stroke and, more recently, the rapid acceleration of drugs to fight HIV/AIDS.
- The recent "start-stop" funding approach has hindered efficient research planning and slowed the rate of progress. Since it requires years to take biomedical advances from basic research conception through clinical trials to completion, our best scientists must have confidence that excellent projects will be funded through their conclusion. Without this certainty, researchers are less likely to engage in projects that may be risky but hold the potential for dramatic advances.
- The Federal Government under-invests in biomedical research. As noted below, the best economic analysis indicates that Americans value the resulting benefits of biomedical progress many times more than the amount the Federal Government invests to support this work. Coupled with the analysis of specific cases, this body of evidence indicates that a steady increase in funding for the NIH is a wise investment on behalf of the American people.
- Investments in basic biomedical research also benefit America by stimulating the biotech industry, one of the most important components of the nation's economy. Not only is the biomedical industry critically important for its own sake, but it is also tightly linked to many other growing fields. Basic

biomedical research investment benefits the economy by creating good jobs in the biotechnology, pharmaceutical and scientific instrument industries which, in turn, generate more jobs in other sectors.

Conclusion: Steadily growing investments in biomedical research are vital. To ensure the continued innovation that will safeguard, enhance, and extend the lives of Americans, the federal government should recommit to increasing the NIH budget at a steady, predictable pace that significantly outpaces the rate of biomedical inflation.

A Sound Investment with Profound Returns

America enjoyed dramatic medical advances over the past century, leading to more than a 50 percent increase in life expectancy. All told, the life expectancy of Americans expanded by three decades over the course of the 20th century, from 47 to 77 years of age.¹ Between 1974 and 2004, the average NIH investment per American was \$44.46. This has produced a 60 percent drop in mortality from heart disease and stroke, and a 30 percent drop in chronic disability among older Americans during the last two decades.²

Federal funding of basic biomedical research has consistently yielded outstanding returns to the American taxpayer, as measured by better health, more efficient care, and economic growth.



Chart 1: Increases in longevity within the United States during 20th Century³

http://209.217.72.34/aging/TableViewer/tableView.aspx?ReportId=357.

¹ National Center for Health Statistics. Available at

² Elias Zerhouni, MD, "FY 2008 Director's Budget Request Statement, "National Institutes of Health March 19, 2007. Available at

http://www.nih.gov/about/director/budgetrequest/fy2008directorssenatebudgetrequest.htm.

³ Annual Summary of Vital Statistics, PEDIATRICS Vol. 106 No. 6, December 2000, 1307-1317.

Whether we will enjoy comparable – or even greater – gains over the course of the 21st century may significantly depend on sustained, robust U.S. support for basic biomedical research.

The longer lives captured by these statistics represent an outstanding return to the American taxpayer from their investment in the federal funding of basic biomedical research. Yale economist William Nordhaus used established, peer-reviewed methods to conclude that "over the last half century, improvements in health have been as valuable [to Americans] as all other sources of economic growth combined."⁴

Using alternate but complementary methods, University of Chicago economists Kevin Murphy and Robert Topel calculated that "from 1970 to 2000, gains in life expectancy added about \$3.2 *trillion* per year to national wealth, with half of these gains due to progress against heart disease alone."^{5 6} This is equal to about half of the country's GDP gains over this same period.

We can use Murphy and Topel's findings to contrast: (1) the annual federal investment in the National Institutes of Health to increase Americans' health and longevity; with (2) the national wealth generated annually for Americans from these longevity increases, as recounted above.

The results are stark:



⁴ As summarized by Murphy and Topel, in Kevin M. Murphy and Robert H. Topel, Eds., *Measuring the Gains from Medical Research*, The University of Chicago Press, 2003, p. 4. These figures, like those from Murphy and Topel in the following paragraphs, are not captured in current national income accounts, such as GDP and GNP, because of the way they were designed. These models are built on sophisticated techniques used to measure the value Americans actually place on longer lives, measured in dollars.

⁵ Kevin M. Murphy and Robert H. Topel, "The Value of Health and Longevity." *Journal of Political Economy*, volume 114 (2006), 871–904. Emphasis added.

⁶ This three-decade period at the close of the 20th Century comes after many of the rapid gains from better infectious disease control and the use of antibiotics had already occurred. As such, this value is derived from progress made against the challenging chronic conditions associated with aging.

Of course, NIH investments are responsible only for a share of these longevity increases. Private corporations make substantial investments of their own to translate basic biomedical advances into commercially available therapies. And longevity increases also arise from public health advances ranging from using seatbelts to smoking reduction.

Yet even under the conservative assumption that NIH investments – the primary investments our nation makes to lay the foundation for medical advances – only account for 10 percent of these longevity gains, that still amounts to more than a ten-to-one return on investment. Very few investments, in either the public or private sectors, offer anything close to this consistent level of return.

Based on these recent economic analyses, evidence suggests that enhanced federal support for NIH would yield major wealth-creating benefits for the country.

The gains we now see in life expectancy stem from investments made many years before. But there is every reason to believe that the investments made through the NIH in FY2008 and beyond will be every bit as productive as those of the past. Competition to win federal grants is as intense as ever, driving researchers to design projects that will produce significant, measurable results. The NIH anticipates it will be able to fund only one in five grant applications in the coming fiscal year, meaning many promising proposals will go unfunded.

Moreover, biomedical researchers continue to unlock promising new research directions at the molecular level – in fields such as genomics, proteomics, and metabolomics – that already generate powerful new therapies and diagnostics, while enhancing the effectiveness of existing treatments by enabling truly personalized regimens.

This progress is particularly notable in the neurosciences. Researchers are learning much about the brain and the central role it plays in regulating almost all aspects of health. But the discoveries made to date, and the treatments they have yielded, are likely to prove to be only of the first glimmerings of the revelations that lie ahead – and with them, the potential for entirely new treatment strategies for many diseases and conditions.

So long as scientific investigators remain on the frontier of so many promising lines of research, there is little reason to fear that science has exhausted the largest potential gains from biomedical research. To the contrary, with steady federal support, more dramatic advances may very well arrive within the coming generation of research work.

A Sound Investment – Specific Examples

The return on these investments through the NIH is also apparent from examples that illustrate its impact in improving and extending life across a wide variety of cases.

Polio: The Dramatic Breakthrough. Fifty years ago, much of our nation's healthcare sector was focused on the construction of hospital polio wards and incremental improvements in iron lung technology. These were important responses to the growing epidemic but provided little comfort to any of 21,269 Americans paralyzed in 1952.

That same year, however, Jonas Salk first tested his polio vaccine. Wide-scale inoculations several years later quickly preempted further spread of the virus within the United States, reducing its impact from as many as 50,000 new U.S. cases per year to almost none within a decade.





⁷ http://www.post-polio.org/ipn/pnn15-4.html#incid.

It is estimated that this preemptive solution has saved the U.S. about \$3 billion per year in today's dollars over the course of the past 50 years.⁸

HIV/AIDS: Aggressive Commitment Yields Mounting Returns. Recently, NIH Director Elias Zerhouni recalled his experience as a doctor at Johns Hopkins during the mid-1980s, a time when there was not yet an effective treatment available for HIV/AIDS.⁹ Half of all beds were being used to care for terminally ill AIDS patients, and Dr. Zerhouni and his colleagues projected that within a decade, 80 percent of the Johns Hopkins beds would be used to care for those dying from HIV/AIDS.

However, through a combination of strong public and private research funding and accelerated FDA review, an aggressive federal response to the epidemic yielded dramatic results. In just five years, between 1995 and 2000, deaths fell 70 percent and survival rates increased by ten years. Results continue to improve in this decade. While much more remains to be done, within the U.S. an HIV/AIDS diagnosis is increasingly regarded for many as a chronic disease rather than a death sentence.

The fiscal impact of these new therapies has been equally dramatic. In his testimony before both the U.S. House and Senate last year, Dr. Zerhouni stated that \$10 billion invested in basic research between 1985 and 1995 saved \$1.4 trillion in healthcare expenditures; a return on investment of 140 to one.¹⁰

Promising new developments in the battle against HIV/AIDS continue to emerge from our biomedical laboratories, and many of the insights into the human immune system that we have gained in the battle against HIV/AIDS are now successfully informing our progress against other conditions as well.¹¹

Heart Disease and Stroke: The Steady Accumulation of Incremental Progress. Since 1970, death rates from cardiovascular diseases have fallen by almost 50 percent, and the death rates from stroke have fallen by 60 percent. Yet these diseases remain the number one cause of death and remain a research priority. The NIH-sponsored Framingham Heart Study identified smoking, high cholesterol, and high blood pressure as high-risk factors. Awareness of these risk factors has contributed significantly to decreases in heart disease and stroke. Years of productivity gained through prevention and treatment are estimated by Murphy and Topel to contribute \$1.5 trillion to the nation's economy each year

⁸ "The Economic Returns to Investment in Biomedical Research." Report prepared by the Policy Economics Group of KPMG Peat Marwick, April 14, 1993.

⁹ Health Affairs, 25, no. 3 (2006): w94-w103.

¹⁰ http://olpa.od.nih.gov/hearings/109/session2/testimonies/nihbudget.asp

¹¹ Elias Zerhouni, MD, "FY 2008 Director's Budget Request Statement, "National Institutes of Health March 19, 2007. (http://www.nih.gov/about/director/budgetrequest/fy2008directorssenatebudgetrequest.htm).

from 1970 to 1990. The clot-busting drug t-PA saves \$4,400 for each patient in healthcare costs, and the NIH predicts that \$100 million a year could be saved if this drug were used more widely. Still, stroke strikes some 700,000 people in the U.S. each year and many of the 4.7 million stroke survivors suffer significant disabilities. Stroke costs \$51 billion annually for medical care and disability.¹²

Biomedical Investment as an Economic Engine

Although second in importance to saving the lives and enhancing the health of Americans, investments in basic biomedical research also benefit America by stimulating one of the most strategic segments of the nation's economy. Not only is the biomedical industry critical for its own sake, but it is also tightly linked to other growing fields such as advanced imaging, high-performance computing, and nanotechnology.

Composed of 8,500 firms (mostly employing fewer than 50 people), the U.S. medical technology industry already sustains 350,000 high-value manufacturing jobs paying an average of 49 percent more than those in other manufacturing sectors. The industry also accounts for roughly half of the \$175 billion generated by global production of medical products and supplies. A 2003 New England Health Care Institute study showed that every job in the medical technology sector generates another 2.5 jobs elsewhere in the economy.

In every decade since World War II, America has lost jobs as entire sectors of the economy have declined in size. But in each of those same decades, America has created millions more new and different jobs in emerging industries to replace those that were lost. Focusing on the future, such as the job creation potential represented by the biomedical industry, will help ensure that America's children and grandchildren will have the best, highest-paying jobs in the world, with the large wealth creation that allows our seniors the opportunity of a prosperous retirement.

However, while the U.S. has long been the leader of almost every facet of biomedical research, that lead is eroding as each year sees a greater share of the world's research dollar invested outside the U.S. While it is laudable that scientists in other countries are joining in the search for cures for devastating conditions, it is in America's interest to ensure that our country remains the most attractive place to conduct this research. A key way to do that is to ensure that key research is conducted on our shores, as is the case through NIH funding.

¹² *Facts About: Heart Disease & Stroke*, Research!America (http://www.researchamerica.org/publications/ra-cardiovasc_f.pdf).

Recommendations to Strengthen U.S. Policy toward Medical Research

The National Institutes of Health Reform Act, approved by Congress in 2006, contained significant, widely-welcomed reforms, including enhancing the NIH director's ability to coordinate efforts, encouraging trans-NIH research, and authorizing higher funding levels over the next several years. But more remains to be done. While the legislation is a strong contribution to strengthening NIH, key aspects of U.S. funding policy for medical research remain broken; without follow-through, the reauthorizing legislation will not fix these problems.

Between 1998 and 2003, government leaders from both parties worked together to double the NIH budget, lifting it from a starting point of \$13.6 billion to a budget of \$27.1 billion. This goal was reached through increases of 15 percent annually.

After the completion of the doubling, a common assumption in Washington was that the NIH had "been taken care of." Yet the history of past budget decisions, in itself, tells us nothing about the adequacy of current budget decisions, let alone the appropriate levels for the future. This doubling was a great policy achievement, but it's time for policymakers to once again look forward instead of gazing backward.

Based on the evidence outlined above, policymakers should return to a path of steady increases in NIH funding, at a rate significantly above the pace of biomedical inflation. Investing in basic biomedical research is an investment in people, an investment in opportunity, and an investment in the future.

After the doubling of the NIH budget between 1998 and 2003, funding has essentially been flat-lined – leading to a real drop in purchasing power.



Chart 3: NIH fiscal year appropriations in nominal billions of dollars and in real billions of dollars (as adjusted for biomedical inflation)¹³

Because a substantial portion of the NIH budget is fixed to meet long-term obligations and continuing grants, funding fluctuations hit discretionary projects, such as new grant applications for promising new research directions, with magnified force.

This sudden deceleration in funding, following immediately after the rapid increases of the doubling period, has made efficient research planning extremely difficult. Ultimately it has led to a slower rate of research progress than if the same funds had been allocated over the same period at a steady pace. The full potential benefit of these appropriations has not been realized because of the uneven and unpredictable flow of funding.

The simple fact is that the pressing needs Americans have for medical advances vary little from year to year; there is no sound policy justification for allowing the funding required to address these needs to fluctuate unpredictably from year to year.

¹³ The appropriated amounts are as reported or estimated by the Office of the Budget at the National Institutes of Health (http://officeofbudget.od.nih.gov/UI/AppropriationsHistoryByIC.htm). The biomedical deflator data (Biomedical Research and Development Price Index) used to calculate the real dollar amounts are as reported by the Bureau of Economic Analysis (BEA), Department of Commerce (http://officeofbudget.od.nih.gov/UI/GDP_FromGenBudget.htm).

Basic research projects require years to complete the journey from conception to completion. Because of this, investigators are hesitant to launch their most creative and ambitious projects when they lack confidence that sustained funding will be available to see them through to conclusion. The most successful American corporations in the biopharmaceutical, medical device, and other R&D-intensive industries take a more consistent approach to R&D funding. The federal government would do well to emulate these best practices.

The "start-stop" funding syndrome does not save money in the long run, and it may reduce the impact of those investments the government does make in medical research. The U.S. government should have a consistent, long-term vision of increasing the longevity and health of Americans. And just as this vision should not fluctuate from year to year, neither should the funding required to reach that goal.

When changes are proposed to the prevailing level of funding increases, government leaders should ensure that they be gradually phased in over a longer term – such as ten years – to allow America's research community to methodically and efficiently adjust their own project plans accordingly.

Conclusion: Steady, Increasing NIH Funding Needed Now

Due to the careful work of several of America's most distinguished economists, we have recently gained a more complete understanding of the value we have delivered to the nation through the investment in biomedical research. A range of specific cases convincingly substantiate these general conclusions. Together, this evidence indicates that we continue to significantly under-invest in this research through the NIH.

The NIH Reform Act wisely authorized an increase of 8 percent for the agency in FY2008. This was an encouraging step in the wake of recent declines. However, to be meaningful policymakers must now follow through on the commitments embodied in this legislation.

Ensuring Americans continue to live longer, healthier lives will require that the federal government make long-term, steady, and significantly increased investments in the NIH. Doing so will bring continued progress against America's most deadly and debilitating diseases.