National Institutes of Health

MISSION

The National Institutes of Health (NIH) supports more biomedical research than any other single entity in the world. NIH plays a key role in advancing knowledge, shaping future research directions and generating growth in U.S.-based medical and pharmaceutical industries. Leading the way toward important medical discoveries that improve people’s health and save lives, NIH-supported scientists investigate ways to prevent disease as well as to discover their causes, treatments, and cures.

TODAY’S OPPORTUNITY

Medical science is entering a revolutionary period marked by a shift in focus from acute to chronic diseases (e.g., diabetes, Alzheimer’s disease, Parkinson’s disease and hypertension), rapidly escalating health care costs, a torrent of biological data generated by the sequencing of the human genome, and the development of advanced high-throughput technologies that allow for the study of vast molecular networks in health and disease. This unique period offers the unprecedented opportunity to identify individuals at risk of disease based on precise molecular knowledge, and the chance to intervene to preempt disease before it strikes.

The momentum generated from NIH’s five-year growth cycle has energized biomedical science at every level and is bridging the gap between basic research and clinical practice. Basic research supported by NIH is providing the fundamental knowledge, information and tools necessary to discover new and affordable treatments for numerous diseases. The clinical research supported by NIH ensures that such discoveries and treatments will extend our productive years and reduce the burden of disease.

NIH’S SCIENTIFIC ENTERPRISE

NIH provides leadership and financial support to researchers throughout the United States. The extent of NIH’s reach and influence is evident from the following:

- More than 82% of NIH funding is targeted to extramural research (research conducted in areas outside NIH’s campus), which involves more than 200,000 scientists and other research personnel affiliated with more than 3,100 organizations nationally and internationally.¹
- NIH seeks input annually from more than 30,000 scientists and members of the public who serve on NIH advisory boards, review groups, and expert panels.²

NIH grantees win 2005 Nobel Prize in Chemistry

The 2005 Nobel Prize in chemistry is shared by two long-time NIH grantees, Robert H. Grubbs, Ph.D., and Richard R. Schrock, Ph.D., along with Yves Chauvin, Ph.D. Grubbs and Schrock were honored for developing metal-containing molecules that are now used daily in the chemical and pharmaceutical industries to make important compounds for the drug discovery process, as well as for other purposes.

The NIH's National Institute of General Medical Sciences (NIGMS) supported the research of each scientist since 1983, spanning the period in which their award-winning work was conducted and published. The Institute also helped support the training of the scientists before they launched their independent research careers. Early and sustained support of investigator-initiated ideas yield significant discovery.

How NIH support improves human health and saves lives

Many important health and medical discoveries of the last century resulted from research supported by NIH. The NIH translates research results into interventions and communicates research findings to patients and their families, health care providers, and the general public. In part because of NIH research, our citizens are living longer and better. Life expectancy at birth was only 47 years in 1900; by 2003, it was almost 78 years.³

In the past several decades, NIH-supported research and its national programs to communicate the results of research played a major role in health achievements, such as:

- Death rates from heart disease and stroke fell by 51% and 62%, respectively, between 1970 and 2002.⁴
- The overall five-year survival rate for childhood cancers rose to nearly 80% by 2000 from under 60% in the 1970s.⁵
- The number of AIDS-related deaths fell by 73% between 1995 and 2004.⁶
- Sudden infant death syndrome rates fell by more than 52% between 1994 and 2002.⁷
- Infectious diseases — such as rubella, whooping cough, and pneumococcal pneumonia — that once killed and disabled millions of people are now prevented by vaccines.
- Quality of life for more than 20 million Americans suffering with depression has improved as a result of more effective medication and psychotherapy.

NIH AT THE CROSSROADS

As the 21st century began, the pace of discoveries in the life sciences accelerated at an unprecedented rate. The completion of NIH’s five-year growth campaign (in 2003) provided NIH with the resources to support remarkable, life-saving research. Biomedical researchers understood that there would be a gradual easing into slower growth rates. However, it was not expected that NIH’s budget increases would slow as dramatically as they have. NIH’s budget increase slowed to 3.2% in 2004, and further dropped to just 2% in 2005. NIH’s FY2006 budget will be $80 million less than its FY2005 level (a 0.3% reduction). Thus, this marks the third year in a row that the NIH R&D portfolio failed to keep pace with the Biomedical Research and Development Price Index (BRDPI), a Department of Commerce index that attempts to calculate the inflation rate for goods and services purchased by the NIH budget. BRDPI projections for the past three years (2004-2006) were 3.5%, 3.3% and 3.2%, respectively. As a result, the positive effects from NIH’s five-year growth period are being eroded at an accelerating rate. Now is not the time to step back from the research momentum currently underway.

As you can see from the chart below, should NIH’s budget remain relatively flat in FY2007 and FY2008, the gains from NIH’s five-year growth campaign will essentially be eliminated.
NIH’S RESEARCH PORTFOLIO INTEGRATES PUBLIC HEALTH NEEDS AND OPTIMIZES SCIENTIFIC OPPORTUNITIES

**Heart Disease**

The Problem: Heart disease kills more than 600,000 people each year in the U.S., more deaths than by any other cause. As an indicator of heart disease risk, blood cholesterol level has proven invaluable in preventive medicine. According to NIH’s National Heart, Lung, and Blood Institute (NHLBI), 99.5 million adults in the U.S. – about half of the adult population – have elevated total cholesterol levels.

The Research Successes: Decades of NIH-supported fundamental research on the mysterious and ubiquitous molecule cholesterol led scientists to understand its role in causing atherosclerosis and heart disease. This basic understanding allowed development of the statin drugs, which lower cholesterol production by inhibiting the biochemical process that produces it.

Statin medications are now taken by millions of patients worldwide, and more recent research shows they may be useful in treatment of inflammatory and other disorders as well. Clinical studies reveal that statins lower the risk of heart disease by as much as 40% and help explain, along with other new treatment and prevention strategies, why the number of deaths from heart disease has been slashed by close to 60% since 1950. By uncovering the intricate mechanisms involved in the production of cholesterol and its deposition in the walls of arteries, basic scientists have given us the medical tools to stave off coronary heart disease.

The creation of cholesterol-lowering drugs is an excellent example of how biochemists, endocrinologists, and physiologists were able to solve a basic scientific puzzle and bring that knowledge to bedside application. Thanks to their efforts, more than 25 million people worldwide now take statins and will have many more years added on to their lives as a result. These drugs prevent more than 125,000 people in this country of dying from heart attacks each year. In fact, between 1970 and 2000, life expectancy in the United States increased by six years and nearly two-thirds of that increase can be attributed to the reduction in mortality due to heart disease and stroke.

**Obesity**

The Problem: Being overweight increases the likelihood of developing diabetes, high blood pressure and heart disease, stroke, breathing problems such as asthma and sleep apnea, some cancers, osteoarthritis, and gall bladder disease. The most recent figures show that 65% of U.S. adults – or 130 million people – are either overweight or obese. In fact, a large, community-based study supported by NHLBI suggests that the United States could have an even more serious problem regarding people’s propensity for becoming overweight or obese and may be underestimating the risk for some ethnic groups.

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The Research Successes: The obesity epidemic represents a complex interplay of behavioral, sociocultural, economic, and environmental factors against a backdrop of genetic and other biological factors. The NIH Strategic Plan for Obesity Research exploits the breadth of expertise available from a wide range of disciplines at the NIH, engaging 19 Institutes and Centers to set an agenda for this research.

NIH-supported scientists are continuing to make significant progress in obesity research. For example, recent studies by nutritional epidemiologists have suggested that the body mass index of women at the time of conception and excessive weight gain during pregnancy are important risk factors for delivering premature infants and for setting in place a pattern for being overweight during childhood leading to the complications of adult obesity in the offspring. Furthermore, female infants born to overweight/obese mothers themselves produce babies at risk for obesity, thus propagating the obesity epidemic into future generations. Addressing these early preventable issues can save costs and suffering for future health problems related to obesity complications.

In addition, investigators have identified an elaborate network of hormones and other molecules that connect the brain, gastrointestinal tract, fat cells, and other parts of the body to achieve energy balance. An increased level of one of the appetite-induced hormones was found in obese people following diet-induced weight loss. It may explain why some people may have difficulty “keeping it off” after dieting. Such hormones are now “targets” for drug design. New drugs now in development might affect appetite, food absorption, and/or energy expenditure. During the last several years as new discoveries have been reported regarding the basic mechanism of appetite and satiety, particularly neuropeptides, and their central nervous system receptors and nuclear receptors, obesity cohorts have been studied for mutations in these important hormones and their receptors to identify individuals at risk for developing obesity. Using basic research data obtained during NIH’s five-year growth period, these “translational” researchers are poised to deal with obesity before it actually develops. The important discoveries of sub populations of obesity-prone individuals can be dealt with by rigorous environmental intervention to prevent obesity, a much more successful approach than obesity intervention. To accomplish these ongoing investigations, which can potentially save billions of dollars in health care costs and can potentially lead to new therapeutic interventions by pharmaceutical companies, NIH must continue to grow at a healthy rate.

Cancer

The Problem: Cancer kills more than 500,000 people each year in the U.S., more deaths than by any other cause except for heart disease.9 The fact that cancer occurs primarily in individuals over the age of 50 means that more of our citizens will suffer the terrible burden of this disease in the next 10-20 years due to the aging and changing demographics of our population. However, today more people are living with cancer than dying from it. In 1976, half of all cancer patients survived more than five years after diagnosis. Today, closer to two-thirds (63%) are alive five years after they learn they have cancer.10

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The Research Successes: In early 2003, the Director of the National Cancer Institute (NCI) announced a goal to eliminate the suffering and deaths due to cancer by 2015. Since that time, NCI has worked with the national scientific, medical and lay community to identify the critical elements required to reach this goal.

NIH–supported scientists are making exponential advances to define with ever increasing specificity the many genetic, molecular, and cellular events that influence the cancer process. For example, when Gleevec was approved with great fanfare in 2001 for two hard-to-treat cancers, scientists promised the start of a new era in cancer treatment—a time when therapies are so specifically designed that they can precisely stop the disease with fewer harmful side effects. Gleevec was named one of the first of many potent, safer, targeted anticancer drugs whose designs resulted from new understanding of cancer at its molecular level.

Additional amazing breakthroughs have been made against cancer in recent years and we are poised to make even more progress. For example, the prevention of cervical cancer has the potential to become a major public health success story in the early twenty-first century. At the center of this story is the NCI-supported researchers who unraveled the etiology of the disease, presented epidemiologic proof of the causal link between the sexually transmitted human papillomavirus (HPV) and cancer, and are now well on their way to developing the means to prevent cervical cancer in a majority of women. In fact, this past year, NCI-supported researchers, in collaboration with industry, successfully developed a vaccine that will prevent HPV infection and, by extension, HPV-related cervical cancers.

Success in controlling cervical cancer has important implications for women around the world. Despite advances in the detection of cervical cancer (most notably the Pap smear) and its treatment, this disease remains the second leading cause of cancer death worldwide, and exacts a devastating toll in developing nations. In the United States, an estimated 14,500 cases of invasive cervical cancer were diagnosed in 1997, and approximately 4,800 women died. However, a safe and effective HPV vaccine will have an enormous public health impact; such a vaccine has the potential to save thousands of lives and millions of dollars in screening and health care costs each year.

**Infectious Diseases, including the Avian Flu**

The Problem: Like HIV/AIDS, Ebola, West Nile Virus, and SARS, the avian flu reminds us that emerging and reemerging infectious diseases are constant threats to national and international public health. The lethal H5N1 variant of avian flu is responsible for the death of 140 million birds (including those intentionally destroyed to stop its spread) and 68 people (as of October 27, 2005). The U.S. government is concerned that the avian flu could become a global pandemic that, in a worst-case extrapolation from the toll of the 1918 Spanish flu, could kill 150 million people, 2.5% of the world’s population—in a matter of months. While bird flu has a high fatality rate, it rarely spreads between people. However, this could change with a few simple mutations.

The Research Successes: The possibility of emerging and reemerging infectious diseases strongly reminds us that the ability of NIH (and the CDC) to marshal resources to combat these diseases relies on a very strong knowledge in the basic sciences of immunology, virology, molecular, and cellular biology.
NIH played a crucial role in our fight against the SARS outbreak and in the coordinated public health response to the West Nile virus. NIH-supported researchers advanced our understanding of the genetic blueprints of these viruses and devised and tested ways to combat them. This same kind of coordinated effort is currently underway to combat avian flu concerns.

The National Institute of Allergy and Infectious Diseases (NIAID), an NIH Institute with the mission to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases, is currently supporting numerous basic research projects intended to increase our understanding of how animal and human influenza viruses replicate, interact with their hosts, stimulate the immune response and evolve into new strains. These studies lay the foundation for the design of new antiviral drugs, diagnostics, and vaccines, and are applicable to seasonal epidemic and pandemic strains alike.

Two teams of NIAID-supported scientists used such earlier generated knowledge to reconstruct the 1918 influenza virus and determine that it was a bird flu that jumped directly to humans. This finding was announced in October, 2005. The discovery was the culmination of work that began a decade ago and involved tiny fragments of the 1918 virus from snippets of lung tissue from two soldiers and an Alaskan woman who had died in the 1918 pandemic.

In addition, the Models for Infectious Disease Agent Study (MIDAS), funded by the National Institute of General Medical Sciences (NIGMS), an NIH Institute with a mission to support basic biomedical research that is not targeted to specific diseases, developed sophisticated mathematical models to predict how the avian flu virus might spread throughout rural villages in South East Asia, and simulated a variety of possible responses by the public health community. Their results provide a foundation for public health officials who have the daunting task of planning a response to an emerging infection that they have never before faced. The NIGMS-supported researchers utilize computational biology and bioinformatics tools to examine how to contain pandemic influenza. Their work was published in the August 2005 issue of the journal *Science*.

**Aging Population**

**The Problem:** Today, our nation has a growing population of senior citizens who will live for decades with chronic diseases and place an ever greater burden on health budgets. In fact, chronic diseases now account for 70% of all deaths and 75% of our health care costs. One example of a chronic disease is Alzheimer’s disease. Alzheimer’s disease, the most common form of dementia, gradually destroys a person’s memory and ability to reason and carry out daily activities. Ultimately, the disease is fatal. Alzheimer’s disease kills more than 50,000 people die each year. An estimated 4.5 million U.S. residents have Alzheimer’s; that number is projected to double in the next twenty years.

12Hebert, LE; Scherr, PA; Bienias, JL; Bennett, DA; Evans, DA. “Alzheimer Disease in the U.S. Population: Prevalence Estimates Using the 2000 Census.” *Archives of Neurology* August 2003; 60 (8): 1119 – 1122.
The Research Successes: The research that NIH-supported scientists are conducting in molecular biology and molecular genetics to identify disease early and intervene before irrevocable damage occurs will provide substantial payoffs in this century. The goal is to thwart diseases years before they strike, at potentially greatly reduced costs.

For example, by measuring two proteins in cerebrospinal fluid, researchers at the National Institute of Mental Health (NIMH) found that, with high sensitivity, they could distinguish patients with Alzheimer’s disease from healthy individuals. The hope is that these disease indicators will be able to identify young people who have Alzheimer’s disease with no outward symptoms. Such early diagnosis might some day allow doctors to begin early treatment for the disease before considerable damage to the brain occurs.

In addition, a long-term study has found that diabetes mellitus was linked to a 65% increased risk of developing Alzheimer’s disease. Current research underway will tell us whether therapies for diabetes may play a role in lowering the risk of Alzheimer’s disease or cognitive decline.

**Arthritis**

The Problem: The number of Americans with arthritis is increasing. In 1985, 35 million people were affected. Twenty years later, that number has soared to an estimated 66 million Americans – nearly one in three adults. This is worrisome since arthritis is the leading cause of disability among Americans over age 15.13

The Research Successes: Only a decade ago, people who had been diagnosed with arthritis had few options for controlling pain. But thanks to advances in physical therapy, medication, and other treatments, millions of arthritis sufferers are now able to manage their pain and lead relatively normal lives.

Advances in understanding osteoarthritis, a chronic condition that afflicts 21 million Americans each year and is caused by the breakdown of cartilage, the connective tissue that cushions the ends of bones within the joint, are providing hope that prevention and control are within reach. For example, researchers are attempting to come up with new laboratory tests to detect osteoarthritis early. If such a test were made available, medical professionals would be able to intervene early and prevent damage to the joint so that fewer people would require joint replacement surgery.

In addition, two components of NIH, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Center for Complementary and Alternative Medicine (NCCAM) are responsible for initiating a study to evaluate the impact of two dietary supplements—glucosamine and chondroitin—on reducing pain in a large number of patients with knee osteoarthritis. The Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) was initiated in response to a real and urgent health need to test these agents in a rigorous way.

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13 Arthritis Foundation web site, www.arthritisfoundation.org
In addition, NIAMS partnered with the National Institute on Aging (NIA), several other NIH components, and three pharmaceutical companies in establishing the Osteoarthritis Initiative, a public-private partnership aimed at developing clinical research resources that support the discovery and evaluation of biomarkers and surrogate endpoints for osteoarthritis clinical trials. For the first time, a public-private partnership is bringing together new resources and commitment to help find biological markers for the progression of osteoarthritis.

**Competitive Peer Review**

Part of the success of American science derives directly from the system for awarding research grants. The majority of NIH funding comes in response to investigator-initiated research proposals that are evaluated by a committee of experts in each scientific field. Elaborate care is taken to ensure that conflicts of interest are minimized and each research proposal is evaluated on its merit. Over many years this competitive system has promoted the highest quality research, and it is a shining example of a program based on “reward for excellence.” No scientist can afford to rest on his or her previous accomplishments. As opposed to an entitlement system of funding found in some other countries, the American system rewards productivity, innovation, and impact. While FASEB welcomes new ideas to make the system function even better, we support the concept of peer review as practiced by NIH.

**Young Investigators – The Pipeline for Biomedical Research**

Training initiatives supported by NIH’s twenty-seven Institutes and Centers have encouraged talented students to choose a career in academic medicine. These highly talented and motivated individuals spend ten years or more after college in graduate school and postdoctoral appointments. In 2003, only 16.6% of new investigators obtained funding within their first three years of applying for these critical grants, thereby making it very difficult for these young scientists to establish their new innovative research programs. In fact, the average age for a scientist to receive his/her first NIH grant is now 42 years old.¹⁴

It is impossible to predict exactly which cures and therapies will be lost if funds for medical research are curtailed. What is certain is that inconsistent NIH funding sends a chilling message to young scientists in training and those just entering the research field. Scientific competition will always be intense, but exceptionally talented scientists must be assured that sufficient research funding will be available or they will choose to pursue alternative careers.

**Medical Research: The U.S. Economy and our Quality of Life**

While the principal benefit of medical research is better health and longer life, our economy is also directly affected by the cost of medical care and the success of our high-tech medical industries. We need to maintain the quality of our research infrastructure to find new cures and new technologies, capitalize on our recent investment, and preserve our leadership position in the world.

¹⁴ National Academy of Sciences Bridges to Independence Report
As our population ages and our culture changes, we are being confronted by the rising incidence of chronic diseases such as Alzheimer’s disease, Parkinson’s disease, and diabetes. These conditions are costly to treat and require years of care. NIH has attempted to quantify the economic costs associated with these and many other diseases. In FY2000, NIH prepared a congressionally mandated report titled, “Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support.” [http://ospp.od.nih.gov/ecostudies/COIreportweb.htm]. The report contains sixty cost estimates: for fourteen of the top fifteen killers (no cost estimate is available for conditions originating in the perinatal period) and for forty-six other diseases and conditions identified by various NIH Institutes. For example, NIH calculates that Alzheimer’s disease and other dementia cost $100 billion annually, while annual spending on diabetes totals $98 billion. If we are to avoid the economic consequences of rising health care costs and/or draconian and morally undesirable choices associated with rationing health care, we must find new ways to understand the causes of these diseases and methods to prevent them. “Without research, there is no hope.”

Our leadership in biomedical research gave rise to the biotechnology industry in the 1990s. This source of state-of-the-art therapies and life science products was a leading generator of economic growth, as biotechnology hubs sprung up in areas adjacent to universities and research institutes conducting federally funded research. Biotech employment doubled between 1992 and 2002, and sales of biotech products more than tripled during the same time period. The subsequent collaboration between industry, academia, and government that occurred has resulted in numerous successes. For example, the biotech drug Gleevec represents a new class of anti-cancer drugs with minimal side effects. The basic scientific concepts and the cancer-causing molecule that Gleevec targets were discovered 20 years ago by scientists funded by NIH.

Other nations were inspired by our success in biomedical research and biotechnology and are now starting to imitate us. Western Europe has increased its training of scientists and the European Union is taking action to attract many of the scientists that used to flock to our shores. Asian nations are challenging us in many high-tech fields, and high quality jobs are being moved overseas like manufacturing jobs were a generation before.

Our biomedical research infrastructure, which gave rise to the biotech industry, must be preserved—not only to protect our economy, but to maintain our ability to defend our citizens against new and emerging diseases. As a result of the research capacity built-up during the 1998-2003 period of strong growth in the NIH budget, scientists in the U.S. and around the world have been able to move rapidly in response to the SARS and avian flu threats. We must not allow the recently expanded research infrastructure to decline and leave us without adequate defenses.

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**Recommendation**

We need to maintain the pace of discovery to provide the new cures that the public demands. Every indicator, from public opinion polls\(^{20}\) to consumer behavior,\(^{21}\) demonstrates that Americans want better health care and are willing to pay the price to obtain it.

Fundamental research and large-scale studies, the keys to providing better health care, are only possible with public funding. Private investors are unwilling and ill-suited to support the broadly focused and high risk research needed to provide the knowledge that will give rise to the next generation of drugs and diagnostic tools.

Our investment in research has paid substantial dividends, and our research institutions are the envy of the rest of the world. In the last three years, however, the NIH budget has failed to keep up with inflation, and we are in danger of sacrificing our nation’s dominance in biomedical research and biotechnology. New opportunities for pathbreaking research are going unfunded; we risk that the number of new therapies under development will begin to decrease.

Even more threatening are the proposed decreases in future funding for medical research. This forecast sends the wrong message to aspiring young scientists. We run the risk of discouraging our most talented young people from pursuing careers in biomedical research and diminishing our ability to generate new cures and improve health.

The United States has been and will always be a nation with competing priorities. While FASEB understands that the FY2007 budget for discretionary spending is projected to be constrained in light of the large deficit, the expenditures for hurricane relief, defense and homeland security, and the growth in entitlement obligations, our organization strongly believes that the scientific opportunities for progress in medical research have never been greater. In addition, during the past few years, NIH’s budget has fallen behind its own calculations of biomedical research inflation. Therefore, the more than 84,000 FASEB society member scientists call on Congress to make NIH a priority in the FY2007 budget and respectfully request a 5% increase. This increase will allow NIH to maintain its purchasing power and take advantage of scientific opportunities. The enormous promise of medical and scientific research — in both lifesaving and economic terms — will not be realized without such support.

**FASEB’s Recommendation:**

- FASEB recommends that the National Institutes of Health receive $30 billion in FY 2007, an increase of 5% ($1.43 billion) over the level for the previous fiscal year ($28.57 billion).

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