CRS Report for Congress

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The National Institutes of Health: An Overview

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Summary

The National Institutes of Health (NIH) is the focal point for federal health research. An agency of the Department of Health and Human Services, it uses its \$17.8 billion budget to support more than 50,000 scientists working at 2,000 institutions across the United States, as well as to conduct biomedical and behavioral research and research training at its own facilities. Components of the agency include 25 institutes and centers, each with a focus on particular diseases or research areas in human health. Recent budget growth has been significant despite caps on discretionary spending. For FY2000, Congress gave NIH an increase of \$2.2 billion, its second consecutive increase of over 14%. The President requested a \$1 billion (5.6%) increase for FY2001, and Congress is poised to approve a \$2.7 billion (15.2%) increase. Several bills relating to authorization issues are pending in the 106th Congress. NIH's Internet home page is at [http://www.nih.gov]. This report will be updated periodically.

Background

NIH is the primary agency of the federal government charged with the conduct and support of biomedical and behavioral research. It also has major roles in research training and health information dissemination. In both budget and personnel, it is the largest of the eight health-related agencies that make up the Public Health Service (PHS) within the Department of Health and Human Services (DHHS).¹ For FY2000, it has a total budget of \$17.8 billion and total employment of about 17,000 people.

NIH derives its statutory authority from the Public Health Service Act of 1944, as amended numerous times in the last half century (42 U.S.C. 201-300gg). Section 301 of the PHS Act grants the Secretary of DHHS broad permanent authority to conduct and

¹ The Public Health Service also includes the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Indian Health Service (IHS), and the Agency for Toxic Substances and Disease Registry (ATSDR).

sponsor research. In addition, Title IV authorizes in greater detail various responsibilities, activities, and functions of the NIH Director and the institutes. Several of the NIH institutes have specific time-and-dollar authorizations that require periodic renewal by Congress, as do such other programs as training grants and facilities construction awards. Authorizing committees with jurisdiction over NIH are the Senate Health, Education, Labor and Pensions Committee and the House Commerce Committee. Appropriations are handled by the House and Senate Appropriations Subcommittees on Departments of Labor, Health and Human Services, and Education and Related Agencies.

Organization

Begun in 1887 as a one-room Marine Hospital laboratory, NIH spent its first half century operating as an intramural research lab for the Public Health Service. It became the National Institute of Health in 1930, and the National Institutes of Health in 1948. Today, NIH comprises 18 institutes, 3 centers, and the National Library of Medicine (see **Table 1**). Each has a specialized focus on particular diseases, areas of human health and development, or aspects of research support, and each receives a separate appropriation.² NIH has 78 buildings on a 300-acre main campus in Bethesda, Maryland, and also occupies off-campus sites in Maryland, North Carolina, Montana, and other locations.

Activities

Two categories of research are sponsored by the institutes and centers (ICs): extramural research, performed by scientists working in universities, academic health centers, hospitals, and independent research institutions using NIH grant or contract money; and intramural research, performed in the NIH laboratories and Clinical Center by NIH scientists. In both programs, the research projects are largely investigator-initiated, and span all fields of basic and clinical medical research. (Basic research is research in the fundamental medical sciences, sometimes called lab or bench research, while clinical research involves patients.) NIH also supports both extramural and intramural research training programs to prepare young investigators for research careers.

About 82% of the overall NIH budget goes for extramural awards in the form of research grants, research and development contracts, training awards, and a few smaller categories such as construction grants, facilities renovation grants, and medical library grants.³ The "research grants" category, by far the largest, includes traditional research project grants to individual investigators, as well as grants to groups of researchers who work in collaborative programs or in multidisciplinary centers that focus on particular

² Three other centers are also components of NIH: the Center for Scientific Review, which receives, reviews, and refers research and training grant applications; the Center for Information Technology, which coordinates NIH's information technology services; and the Clinical Center, NIH's hospital and outpatient clinic. These centers do not receive their own appropriations, but are funded through the NIH Management Fund, financed by taps on other NIH appropriations. For further information on each component, see the NIH Almanac, 1999 (NIH Pub. No. 99-5), [http://www.nih.gov/welcome/almanac/index.html].

³ The intramural research program accounts for about 10% of the budget, with the remaining 8% for management costs, buildings and facilities, interagency agreements, etc.

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Table 1. Components of the National Institutes of Health (NIH)with year of establishment and major research focus

INSTITUTES AND CENTERS (ICs) National Cancer Institute (NCI) (1937). All aspects of cancer. National Heart, Lung, and Blood Institute (NHLBI) (1948). Diseases of the heart, blood vessels, blood, lungs, and the use of blood and the management of blood resources. National Institute of Dental and Craniofacial Research (NIDCR) (1948). Craniofacial, oral and dental diseases and disorders. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (1950). Diabetes, endocrinology, metabolic diseases; digestive diseases, nutrition; kidney, urologic, hematologic diseases. National Institute of Neurological Disorders and Stroke (NINDS) (1950). Convulsive, neuromuscular, demvelinating, and dementing disorders: fundamental neurosciences: stroke, trauma. National Institute of Allergy and Infectious Diseases (NIAID) (1955). Allergic, immunologic, and infectious diseases; research on the immune system. National Institute of General Medical Sciences (NIGMS) (1963). Research and research training in basic medical sciences, such as cellular and molecular biology, genetics, pharmacology, and physiology. Special focus on minority biomedical researchers. National Institute of Child Health and Human Development (NICHD) (1963). Reproductive biology; population issues; embryonic development; maternal, child, family health; medical rehabilitation. National Eye Institute (NEI) (1968). Diseases of the retina, cornea, and lens; cataract, glaucoma, visual processing, low vision. National Institute of Environmental Health Sciences (NIEHS) (1969) (Research Triangle Park, NC). Interrelationships of environmental factors, individual genetic susceptibility, and age in affecting health. National Institute on Aging (NIA) (1974). Biomedical, social, and behavioral research on the aging process; diseases, problems, and needs of the aged. National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) (1986). Arthritis: bone, joint, connective tissue and muscle disorders: skin diseases. National Institute on Deafness and Other Communication Disorders (NIDCD) (1988). Disorders of hearing, balance, smell, taste, voice, speech and language. National Institute of Nursing Research (NINR) (center status, 1986; became an institute in 1993). Acute and chronic illness, health promotion/disease prevention, nursing systems, clinical therapeutics. National Institute on Alcohol Abuse and Alcoholism (NIAAA) (first created in PHS in 1970; moved to NIH in 1992). Causes of alcoholism, how alcohol damages the body, prevention and treatment strategies. National Institute on Drug Abuse (NIDA) (first created in PHS, 1974; moved to NIH, 1992). Social, biological, behavioral, and neuroscientific bases of drug abuse; causes, prevention, and treatment strategies. National Institute of Mental Health (NIMH) (originally established in 1949; transferred out of NIH in 1967; transferred back in 1992) Brain research, mental illness, and mental health. National Human Genome Research Institute (NHGRI) (center, 1989; institute, 1997). Chromosome mapping, DNA sequencing, database development, ethical/legal/social implications of genetics research. National Center for Research Resources (NCRR) (1990, merged two research resources divisions). Extramural and intramural research resources and technologies: general clinical research centers, computers, instrument systems, animal resources and facilities, nonmammalian research models. John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) (1968). Focal point for NIH's international collaboration activities and scientific exchanges. National Center for Complementary and Alternative Medicine (NCCAM) (Office created in OD in 1992; became a separate center, 1999). Identifies, evaluates, and researches unconventional health care practices. National Library of Medicine (NLM) (established 1836; moved to NIH in 1968). Collects, organizes, and makes available biomedical information; sponsors programs to improve U.S. medical library services. **OTHER** Office of the Director (OD). Overall NIH leadership, liaison with DHHS. Includes special offices for AIDS (acquired immune deficiency syndrome) research (see OAR), women's health, minority health, recombinant DNA activities, rare diseases, behavioral research, dietary supplements, and bioimaging/bioengineering (new in FY2000).

Office of AIDS Research (OAR) (established in OD in 1988). Coordinates NIH's AIDS activities, prepares comprehensive AIDS research plan; distributes funds to research institutes and centers according to the plan. Buildings and Facilities (B&F). Provides for the design, construction, improvement and repair of NIH clinical and laboratory buildings.

diseases or areas of research. Nearly three-fourths of NIH's extramural funds go to researchers working in institutions of higher education, with 50% going to the nation's 125 medical schools.⁴ All applications for extramural research support are considered under a two-tiered system of peer review. First, they are reviewed for scientific merit by "study sections" of nongovernment experts and given priority scores. Second, they are considered for program relevance by the appropriate National Advisory Councils or Boards of the ICs. IC staff make the final funding decisions among the top priority proposals. In FY1999, about 26,400 applications for research project grants were reviewed and about 8,550 received funding, for a "success rate" of 32.4%.⁵

The NIH intramural research program includes more than 9,000 scientists and technical support staff. Each of the institutes has an intramural research program, but the structure and activities of the programs vary greatly. Many intramural scientists work in the Clinical Center, which facilitates interdisciplinary collaboration and the direct clinical application of new knowledge derived from basic research.

NIH has important roles in translating the knowledge gained from biomedical research into medical practice and useful health information for the general public. The individual institutes and centers sponsor seminars, meetings, and consensus development conferences to inform health professionals of new findings; answer thousands of telephone and mail inquiries; publish physician and patient education materials (many of them available on the Internet); support information clearinghouses and run public information campaigns on various diseases; and make specialized databases available. Free searching of Medline citations and other NLM databases, together with resources for health questions, is available at [http://www.nlm.nih.gov/medlineplus].

Budget

At \$17.8 billion for FY2000, NIH's budget (see **Table 2**) represents over 40% of federal civilian (i.e., nondefense) spending for research and development (R&D). The agency has enjoyed strong bipartisan support from Congress, reflecting the interest of the American public in promoting medical research. Even in the face of pressure to reduce the deficit, Congress approximately doubled NIH's appropriation over the last decade, with the budget staying well ahead of inflation in real terms. With the FY1999 and FY2000 appropriations, Congress started increasing NIH's budget at an even faster rate, approaching a pace to double in 5 years. From the FY1998 level of \$13.6 billion, the budget increased by \$2 billion or 14.5% to a total of \$15.6 billion in FY1999. For FY2000, the increase was \$2.2 billion or 14.2% to a total of \$17.8 billion. The President requested a \$1 billion (5.6%) increase to \$18.8 billion for FY2001. The House and Senate have passed their respective versions of H.R. 4577, the Labor-HHS-Education Appropriations bill for FY2001, which is awaiting final conference action. Included in both versions is a total of \$20.5 billion for NIH, \$2.7 billion or 15.2% over the FY2000 level. Although the House bill contains a provision limiting FY2001 obligations to the level of the President's request, the tentative conference agreement described on the House Appropriations Committee website accepts the \$20.5 billion figure. For further details, see

⁴ NIH Office of Extramural Research. *NIH Extramural Awards: Characteristics of Awardee Organizations*. [http://silk.nih.gov/public/cbz2zoz.@www.awards.instchar.htm]

⁵ NIH Office of Extramural Research. *NIH Extramural Awards: Competing Research Projects Success Rates.* [http://silk.nih.gov/public/cbz2zoz.@www.awards.projsucc.htm]

the NIH section of CRS Issue Brief IB10051, *Research and Development Funding: Fiscal Year 2001*.

Issues for Congress

Congressional attention to NIH in the 106th Congress has focused on budgetary and appropriations issues, accompanied by some authorizing and oversight activity. In appropriations activity for FY1999, FY2000, and thus far for FY2001, Congress has pushed forward with an agenda to double the agency's budget in 5 years from the FY1998 level of \$13.6 billion to approximately \$27 billion in FY2003. That pace is about twice as fast as the Clinton Administration has recommended. The Administration has sought to balance the substantial increases received by health research with support for its other priorities within the Labor-HHS-Education appropriations bill, and also with funding for other areas of science. Since progress in health research relies in part on advances in chemistry, physics, mathematics, and computational sciences, the biomedical research community acknowledges the need for adequate support of these other fields. It warns, however, against large fluctuations in NIH's grants budget because of the detrimental effects to new investigators.

As the NIH budget has increased, concerns have been raised in and out of Congress about the agency's continued ability to spend the money responsibly in support of good science and the ability of the research community to absorb additional large increases. In addition, as disease advocacy groups continue to pressure Congress to direct funds to their areas of research interest, NIH's processes for priority setting and resource allocation have come under scrutiny. (See CRS Report RL30483, *Medical Research Funding: Summary of a CRS Seminar on Challenges and Opportunities of Proposed Large Increases for the National Institutes of Health.*) A July 1998 congressionally-mandated study by the Institute of Medicine, *Scientific Opportunities and Public Needs: Improving Priority Setting and Public Input at NIH* [http://www.nap.edu/readingroom/books/nih/], generally supported the criteria that NIH uses for priority setting. It recommended additional mechanisms for public involvement, including a Council of Public Representatives, which NIH has created, and also recommended that Congress provide more funding for research management and support so NIH can implement additional improvements in the priority-setting process, including stronger analytical, planning, and public interface capacities.

Reauthorization legislation for various NIH programs was last enacted in 1993 (P.L. 103-43), with authorizations expiring in FY1996. A few of the expired authorities were extended in health bills passed at the end of the 105th Congress, and two new authorizations, for Parkinson's disease research and for complementary/alternative medicine, were attached to 105th Congress appropriations bills. No new authorizations have been enacted by the 106th Congress. Several bills addressing authorization issues have been introduced this Congress, but few have received action. Senate-passed bills include S. 1243, to extend prostate cancer preventive health programs; S. 1268, to support construction of biomedical and behavioral research facilities; and S. 1813, to expand clinical research programs. The House has passed H.R. 4365, expanding a number of children's health programs. Pending bills to increase research on domestic and global health disparities among minorities and on biomedical imaging and engineering suggest creation of new institutes or centers at NIH. Dr. Harold Varmus, former NIH director, has recommended that Congress commission an in-depth study of the agency's organization and the role of the director, because of concerns over the proliferation of institutes and centers. Other research-related topics that have received committee attention include stem cell research (see CRS Report RS20523), women's health, various specific diseases, geographic disparities in receipt of NIH awards, and oversight of gene therapy research and human subjects protection.

Institute or Center	FY2000 comp ^{a,b}	FY2001 request ^a	FY2001 House ^{a,c}	FY2001 Senate ^a
Cancer (NCI)	\$3,311.7	\$3,505.1	\$3,793.6	\$3,804.1
Heart/Lung/Blood (NHLBI)	2,026.4	2,136.8	2,321.3	2,328.1
Dental/Craniofacial Research (NIDCR)	269.2	284.2	309.0	309.9
Diabetes/Digestive/Kidney (NIDDK)	1,141.4	1,209.2	1,315.5	1,318.1
Neurological Disorders/Stroke (NINDS)	1,029.7	1,084.8	1,185.8	1,189.4
Allergy/Infectious Diseases (NIAID)	1,796.6	1,906.2	2,062.1	2,066.5
General Medical Sciences (NIGMS)	1,353.9	1,428.2	1,548.3	1,554.2
Child Health/Human Develop't (NICHD)	859.3	904.7	984.3	986.1
Eye (NEI)	450.1	474.0	514.7	516.6
Environmental Health Sciences (NIEHS)	442.7	468.6	506.7	508.3
Aging (NIA)	687.9	725.9	790.3	794.6
Arthritis/Musculoskeletal/Skin (NIAMS)	349.5	368.7	400.0	401.2
Deafness/Communication Dis. (NIDCD)	263.7	278.0	301.8	303.5
Nursing Research (NINR)	89.5	92.5	102.3	106.8
Alcohol Abuse/Alcoholism (NIAAA)	293.2	308.7	349.2	336.8
Drug Abuse (NIDA)	687.4	725.5	788.2	790.0
Mental Health (NIMH)	974.7	1,031.4	1,114.6	1,117.9
Human Genome Research (NHGRI)	335.9	357.7	386.4	385.9
Research Resources (NCRR)	675.1	714.2	832.0	775.2
Compl/Alternative Medicine (NCCAM)	69.0	72.4	78.9	100.1
Fogarty International Center (FIC)	43.3	48.0	50.3	61.3
National Library of Medicine (NLM)	215.2	230.1	256.3	257.0
Office of Director (OD)	282.0	309.0	342.3	352.2
Buildings & Facilities (B&F) ^d	165.4	148.9	178.7	148.9
[AIDS/Office of AIDS Research (non-add)] ^e	[2,006.2]	[2,111.2]	[NA]	[NA]
Total, NIH Budget Authority	\$17,812.7	\$18,812.7	\$20,512.7	\$20,512.7

Table 2. National Institutes of Health Appropriations

(dollars in millions)

Source: H.Rept. 106-645 on H.R. 4577 and S.Rept. 106-293 on S. 2553.

a. All years do not include these transfers: \$27 million to NIDDK for diabetes research (funding from the Balanced Budget Act of 1997 for FY1998-FY2002), and \$9.5 million to NIDA from Office of National Drug Control Policy.

- b. FY2000 reflects rescission of \$100 million, transfer of \$20 million from NIAID to Centers for Disease Control, and transfer to NIAID of \$19.883 million for NIH Challenge Grants appropriated to the Public Health and Social Services Emergency Fund in the Office of the Secretary. Comparable for Central Services formula adjustments.
- c. Amounts shown for FY2001 are those provided in the House bill. The bill also includes language limiting the amount NIH can obligate in FY2001 to the budget request level, but the tentative conference agreement as of July 27, 2000 drops that language and accepts the \$20.5 billion figure.
- d. FY2000 amount includes \$40 million advance appropriation from FY1999 appropriation. A proposal in the FY2001 request for an advance appropriation of \$26 million for FY2002 for the new Neurosciences Center is not shown. Neither bill includes this advance funding.
- e. All AIDS funding is shown distributed to the individual institutes and centers, although the FY2001 request placed the money in a consolidated OAR account. Total AIDS spending, as reported by NIH, is shown in brackets. The FY2000 appropriations act did not specify an amount for AIDS, nor do the House or Senate reports for FY2001.

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