

National Institutes of Health in the FY 2004 Budget

*Jonathan Fishburn,
Association of American Medical Colleges*

HIGHLIGHTS

- The **National Institutes of Health (NIH)** would receive **\$27.9 billion for its total budget in FY 2004**, an increase of \$726 million (2.7 percent) over the FY 2003 estimate. NIH R&D would increase 2.7 percent to \$26.9 billion (see Table II-9).
- As a result of converting approximately \$1.4 billion of one-time non-recurring costs in FY 2003 for facilities construction and anthrax vaccine procurement to research, NIH research programs and support would have a more robust increase of \$1.9 billion (7.5 percent). This breaks down into a 4.3 percent increase for non-defense research, and a 117 percent increase for bioterrorism research.
- **The largest increases within the NIH go to the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)**, with increases of 17.0 percent and 5.6 percent, respectively. These increases are due to specific initiatives in the areas of biodefense research at NIAID and diabetes and obesity at NIDDK. Funding at the National Center for Research Resources would decrease 7.5 percent, due to reductions in the amount of construction proposed. Most of the other institutes and centers would receive increases of between 1.5 and 4 percent (see Table II-9).
- The FY 2004 budget projects the awarding of 10,509 competing research project grants (RPGs), an increase of 344 RPGs over FY 2003, and increasing the average aggregate cost of

Jonathan Fishburn

competing and non-competing grants by 2.7 percent (see Table II-10). NIH also proposes to fully fund 322 competing grants and undertake a study to determine whether other categories of grants could also be considered for full funding in the future.

- Stipend levels for the Ruth L. Kirschstein National Research Service Awards would increase by 4 percent for predoctoral fellows and on a decreasing scale from 4 to 1 percent for postdoctoral fellows with the larger increases given to less experienced individuals.

BACKGROUND

The National Institutes of Health (NIH) is the world's premier medical research institution, supporting more than 50,000 scientists at over 2,000 research universities, medical schools, teaching hospitals, independent research institutes and industrial organizations throughout the United States and the world. NIH is the second largest supporter of R&D in the federal government, after the Department of Defense (DOD). Located within the Department of Health and Human Services (HHS), the NIH is comprised of 27 distinct institutes and centers, each of which has an explicit mission directed to the advancement of an aspect of biomedical and behavioral sciences. An institute's focal point may be a particular disease, organ system, stage of development, or have a cross-cutting mission such as developing research tools and other resources.

FY 2003 was a landmark year for the NIH, with Congress appropriating \$27.2 billion, which completes the five-year doubling of the agency's budget from FY 1998 to FY 2003. The campaign to double the NIH budget received strong support in both chambers of Congress, particularly from the chairmen and ranking members of the House and Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittees. Additionally, doubling the NIH budget has been a goal of the Bush Administration and was included in the President's budget request in each of the last two years.

The recent unprecedented rate of growth has allowed NIH to significantly expand its efforts in both basic and clinical research. FY 2003 witnessed the completion of the sequencing of the human genome, and extraordinary advances in research technologies such as DNA arrays have altered the way that scientists conduct research. However, there is

NATIONAL INSTITUTES OF HEALTH IN THE FY 2004 BUDGET

concern that many policy makers see the completion of the doubling as a time to devote scarce resources to other agencies and provide inflationary future increases for the NIH, potentially impeding the NIH's ability to take full advantage of the recent investments. While the NIH maintains broad support in the Congress, evidenced by Senate Labor-HHS Appropriations Subcommittee Chairman Arlen Specter's (R-PA) introduction late in the 107th Congress of a resolution to triple the NIH budget over 10 years beginning in FY 1999 (which works out to an average increase of 8.5 percent per year), future increases are expected to be more difficult to attain.

FY 2004 FUNDING REQUEST

The FY 2004 budget request of \$27.9 billion for the NIH is an increase of \$726 million (2.7 percent; see Table II-9). Of this total, 97 percent or \$26.9 billion is classified as R&D; the remainder is for training and research, management and support (RMS). This reflects an increase in R&D of \$700 million (2.7 percent). The FY 2004 budget also proposes outyear funding increases for the NIH ranging from 1.9 percent to 2.5 percent annually for FYs 2005-2008. NIH estimates the Biomedical Research and Development Price Index (BRDPI) for FY 2004 at 3.3 percent. When discussing the total NIH budget, it is also important to keep in mind that the FY 2003 figures do not reflect the 2.1 percent Public Health Service Evaluation transfer tap (which was raised from the FY 2002 level of 1.25 percent).

The largest segment of the NIH budget is devoted to research project grants (RPGs). In FY 2004, the NIH proposes to allocate \$14.6 billion to RPGs, an increase of 7.5 percent, for a total of 37,467 RPGs, an increase of 1,107 over the FY 2003 estimate (see Table II-10). RPGs are generally investigator-initiated awards that are peer-reviewed and awarded competitively based on the peer review score. The total number of grants includes 26,958 non-competing continuation grants and 10,509 new competing awards (an increase of 344 or 3.4 percent). The NIH also plans to award 2,053 SBIR/STTR (Small Business Innovation Research and Small Business Technology Transfer) grants at a cost of \$602 million for a total of 39,520 grants. NIH expects a success rate of 29 percent, a slight decrease from 30 percent in FY 2003 and a high point of 31 percent in FY 2002. The average cost of an RPG would increase by 2.7 percent, down from 3.7 percent in FY 2003, and 5.7 percent in FY 2002.

Jonathan Fishburn

The budget request proposes to fully fund 322 grants in FY 2004. This means that the NIH would fund the entire cost of multi-year projects from the FY 2004 appropriation rather than the typical year-to-year arrangement. For FY 2004, NIH is proposing only certain Academic Research Enhancement Awards, Shannon Awards and challenge grants for full funding; however, the agency will undertake a study to determine what other types of grants can be fully funded.

In addition to RPGs, NIH also funds research through its intramural program, R&D contracts, and research centers. The NIH intramural program, which is conducted mostly at the Bethesda, Maryland campus by NIH's world-class scientists, accounts for 9.4 percent of the agency's total budget. R&D contracts comprise approximately 10 percent of the agency's budget, an increase of 15.7 percent over FY 2003. This increase would be due in large part to the increase in biodefense research, much of which is conducted through this mechanism, and to fund studies arising from the Best Pharmaceuticals for Children Act. NIH estimates non-biodefense R&D contracts would increase 7.7 percent. Research centers would be allocated \$2.6 billion. This increase of \$195 million (8.2 percent) would include four new Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases funded through the NIAID.

The agency also provides significant training opportunities for young researchers, and proposes an increase of 80 new awards under the Ruth L. Kirschstein National Research Service Awards (NRSA) program, with 74 of the awards slated for biodefense. The budget proposes pre-doctoral stipends of \$19,632, which is 4 percent about the President's FY 2003 budget proposal but \$536 (2.7 percent) below the FY 2003 final level announced by the NIH of \$19,968. The budget would provide for post-doctoral stipends ranging from \$33,624 to \$49,584, an increase of between 1 and 4 percent over the FY 2003 President's budget, but below the FY 2003 range of \$34,200 to \$50,808 announced by the NIH. Stipend increases have strong support in Congress; the FY 2003 omnibus appropriations bill includes a recommendation that stipends be increased by 10 percent.

The NIH classifies 54.9 percent (\$14.8 billion) of the total spending on R&D as basic research, an increase of \$713 million (5.1 percent), making NIH the largest federal supporter of basic research with over 55 percent

NATIONAL INSTITUTES OF HEALTH IN THE FY 2004 BUDGET

of the nation's overall federal investment in basic research (see Table II-1). The agency is also the largest federal supporter of applied research with 45.3 percent of the total federal investment. Applied research comprises 44.8 percent of the NIH's R&D budget, an increase of \$1.03 billion (9.4 percent). NIH does not classify any of its work as development.

The remaining \$80 million of R&D funds is classified as R&D facilities and would address the routine maintenance costs of NIH's existing R&D facilities. Given the tight budget situation, this decrease of \$1.1 billion (92.9 percent; see Table II-1) in R&D facilities funding reflects a conscious decision to devote scarce resources to research grants rather than additional construction projects; **there would be no funding for extramural or intramural facilities construction in FY 2004.** FY 2003 saw funding completed for the Mark O. Hatfield Clinical Research Center and the John Edward Porter National Neurosciences Research Center, as well as construction of several extramural biosafety level 3 and 4 labs. The budget also proposes to eliminate funding for the extramural construction program, which was appropriated \$120 million in FY 2003.

FY 2004 PRIORITIES

The NIH budget mechanism table also reflects a significant increase (19.4 percent) for the Office of the Director (see Table II-9). **A large portion of this increase would be targeted for the NIH Roadmap proposal,** the hallmark of new NIH Director Elias Zerhouni, M.D.'s vision for the agency. The \$35 million slated for this initiative would be distributed to the Institutes and Centers to address "critical roadblocks and knowledge gaps that currently constrain rapid progress in biomedical research." Divided into three broad initiatives, the NIH Roadmap will address new pathways to discovery, which includes both new approaches and enabling technologies, such as a comprehensive parts list for biology, pathways and networks in health and disease, regenerative medicine, structural biology, molecular libraries, nanotechnology, computational biology and bioinformatics and molecular imaging; multidisciplinary research teams of the future; and re-engineering the clinical research process.

The NIH's number one priority in the area of biodefense is to support research needed in the war on terrorism. This includes basic

Jonathan Fishburn

research into the biology of microbial agents with bioterrorism potential, and applied research in the development of new vaccines, diagnostics and therapeutics. The FY 2004 budget request includes approximately \$1.6 billion for NIH biodefense efforts, an increase of \$121 million. However, when the one-time, non-recurring biodefense expenditures from FY 2003 (construction of biosafety level 3 and 4 laboratories and anthrax vaccine procurement) are backed out of the calculation, the NIH's biodefense research efforts would increase by \$875 million (117 percent) in FY 2004. Primarily administered through the NIAID, biodefense funds would be used to expand basic research to provide and maintain the R&D capacity necessary for identifying and responding to emerging diseases and bioterrorism events; increase the number of candidate drugs and vaccines under research; and expand clinical research projects to support Phase I and II clinical trials of candidate drugs and vaccines.

The FY 2004 budget continues to support investment in the **Institutional Development Award (IDeA) program**, administered by the National Center for Research Resources (NCRR). The IDeA program is an example of the agency's continuing efforts to develop a critical mass of competitive biomedical researchers in states that have been historically underrepresented in NIH research funding. The budget proposes \$210 million in FY 2004, the same level appropriated in FY 2003.

The NIH is also highlighting specific examples in the areas of **diabetes and obesity** in the FY 2004 budget request. Specifically, the budget provides \$150 million in mandatory funds (an increase of \$50 million over FY 2003) for research on the prevention and cure of Type I diabetes. In addition, there is an increase of \$14 million for expanded trans-NIH research programs in obesity and diabetes.

OTHER HEALTH RESEARCH IN THE FEDERAL BUDGET

Although 97 percent of total R&D funding at the Department of Health and Human Services comes from the NIH, there is also significant research conducted by several other agencies (see Table II-8).

Under the President's budget request, the **Agency for Healthcare Research and Quality (AHRQ)** would receive \$279 million; however, the agency's entire budget would be funded through transfers from the Public Health Service Evaluation Fund. This represents a decrease of

NATIONAL INSTITUTES OF HEALTH IN THE FY 2004 BUDGET

\$24.5 million from the FY 2003 level. AHRQ conducts and sponsors health services research to inform decision-making and improve clinical care and the organization and financing of health care.

Funding at the **Centers for Disease Control and Prevention (CDC)** is primarily aimed at non-R&D activities such as public health and health promotion activities, and more recently in biodefense for programs such as increasing state and local preparedness and improving security. The FY 2004 budget request does provide for \$521 million in R&D activities, a decrease of \$36 million (6.4 percent) from the latest estimate of FY 2003 appropriations. The majority of the R&D conducted at the CDC is in the National Institute for Occupational Safety and Health (NIOSH); however, the budget would also provide for \$18 million for applied anthrax research.

The **Department of Veterans Affairs (VA)** also conducts a significant biomedical research program. The VA Medical and Prosthetics Research Program was established to improve health care for veterans and to stress research into injuries and illnesses specifically relevant to the veteran population. The VA research program is an intramural program and requires all grantees to be VA employees (meaning VA principal investigators must hold at least a 5/8 appointment from the VA. Many grantees also hold joint faculty appointments at affiliated universities and medical schools.) Research funding is allocated to VA field facilities to support research in seventeen designated research areas that address diseases and conditions prevalent in the veteran population. Unlike other federal research agencies, VA does not make grants to colleges and universities, cities and states, or any other non-VA entity.

The FY 2004 budget request provides \$822 million for the VA research program, an increase of \$22 million (2.8 percent; see Table II-19). Basic research comprises \$495 million (60 percent) of this total, with \$302 million (37 percent) going toward applied research, and \$25 million (3 percent) for development. VA scientists are also successful in competing for, and leveraging, research support from other federal agencies (such as NIH and DOD), foundations and industry. In FY 2004, VA estimates its total research enterprise would be \$1.5 billion, an increase of \$55 million (3.8 percent) over FY 2003.

The FY 2004 request proposes a restructuring of the VA budget to include both the direct costs of research, which have traditionally been

Jonathan Fishburn

part of the research line item, and the indirect costs such as clinician and investigator salaries, which traditionally have been paid out of the Medical Care account. The FY 2004 proposal would direct \$408 million to the portion of the line item dedicated to the direct cost of research, an increase of \$8 million (2 percent) over the comparable FY 2003 figure. While the change does not affect the total level of R&D funding, VA officials hope the change will better account for the actual costs of research.