

## Lifespan Respite Care Act of 2006 Becomes Law

The Lifespan Respite Care Act of 2006 (H.R. 3248) was signed into law Dec. 21 by President Bush. It's taken years of lobbying by a coalition of national, state, local and non-profit patient support groups during the past several Congressional sessions for this legislation to be enacted.

The new law will authorize \$289 million over five years for state grants to develop Lifespan Respite Programs to help families access quality, affordable respite care. Lifespan respite programs are defined in the Act "as coordinated systems of accessible, community-based respite care services for family caregivers of children and adults with special needs." Specifically, the law authorizes funds for:

- development of state and local lifespan respite programs;
- planned or emergency respite care services;
- training and recruitment of respite care workers and volunteers; and
- caregiver training.

## NIH Update

Funding for the National Institutes of Health (NIH) has declined in recent years which is negatively impacting all medical research, and is profoundly affecting funds available for research of rare diseases.

Elias A. Zerhouni, director of the NIH, wrote about the desperate state of funding in the Nov. 17, 2006, issue of *Science* magazine: "This has been a challenging year for the NIH and the biomedical research community. An extraordinarily tight federal budget is eroding the growth of the NIH at a time when opportunities for scientific progress and advances in human health have never been greater. As I talk to scientists and administrators throughout the country, the anxiety is palpable. I share these concerns. I am most deeply troubled about the impact of this difficult situation on junior scientists, and on the ability of established investigators to maintain their laboratories." Read more at: [www.sciencemag.org/cgi/content/full/314/5802/1088?ijkey=h./6MpMB/SDeM&keytype=ref&siteid=sci](http://www.sciencemag.org/cgi/content/full/314/5802/1088?ijkey=h./6MpMB/SDeM&keytype=ref&siteid=sci)

Understanding the way in which the NIH functions and is funded is vital to understanding how research is either advanced or hindered. The following excerpts are from an October 2006 Congressional Research Service report titled: *The National Institutes of Health (NIH): Organization, Funding and Congressional Issues*. The report provides background and analysis on the organization, mission, budget and history of NIH as an agency, outlines its major responsibilities and methods of fulfilling them, and discusses the issues facing Congress as it debates reauthorization legislation and works to guide and monitor the nation's investment in medical research. To read the full report go to: [www.nih.gov/about/director/crsrept.pdf](http://www.nih.gov/about/director/crsrept.pdf).

The NIH is the focal point for federal health research. An agency of the Department of Health and Human Services (DHHS), it uses its \$28.5 billion budget to support more than 200,000 scientists and research personnel working at more than 3,100 institutions across the United States and abroad, as well as to conduct biomedical and behavioral research and research training at its own facilities. The agency consists of the Office of the Director, in charge of overall policy and program coordination, and 27 institutes and centers, each of which focuses on particular diseases or research areas in human health. A range of basic and clinical research is funded through a highly competitive system of peer-reviewed grants and contracts.

The NIH appropriation in the past three years has shifted from marked growth to low or no increases. Congress doubled the budget in five years, from \$13.6 billion in FY1998 to \$27.1 billion in FY2003. Since then, growth has slowed to below the rate of inflation. The budget request for FY2007 is for \$28.5 billion, roughly the same as the FY2006 level and a decrease of 0.2 percent below FY2005. In inflation-adjusted (2006) dollars, the FY2007 request is 8.7 percent below the FY2003 level. The House Appropriations Committee matched the request for NIH, and the Senate bill provided \$200 million more (0.8 percent over FY2006). The only major increases in the proposals are for research related to pandemic influenza and to biodefense drugs and vaccines. The request would support some 650 fewer research project grants. The success rate for competing grant applications getting funded would be an

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estimated 19 percent, the same as FY2006, compared with 22 percent in FY2005 and 30–32 percent during the doubling years. Currently, FY2007 funding is continued at the FY2006 rate.

Appropriators and authorizers face many issues in working with the NIH to set research priorities in the face of tight budgets. Congress accepts, for the most part, the priorities established through the agency's complex process of weighing scientific opportunity and public health needs. While the Public Health Service Act (PHSA) provides the statutory basis for NIH programs, it is primarily through appropriations report language, not budget line items or earmarks, that Congress gives direction to the NIH and allows a voice for advocacy groups. Challenges facing the agency and the research enterprise, all aggravated by restrained budgets, include attracting and keeping young scientists in research careers; improving the translation of research results into useful medical interventions through more efficient clinical research; creating opportunities for transdisciplinary research that cuts across institute boundaries to exploit the newest scientific discoveries; and managing the portfolio of extramural and intramural research with strategic planning, openness and public accountability. A reauthorization bill addressing some of these issues (H.R. 6164) passed the House in September 2006. Congress also monitors ethics rules on conflicts of interest and tracks the efficacy of procedures intended to make results of NIH-sponsored research accessible to the public.

The 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 DHHS. For FY2006, it had a total budget of \$28.5 billion and total employment of more than 18,000 people. The President's FY2007 budget requests level funding.

Congress maintains a high level of interest in NIH for a variety of reasons:

- The NIH budget is by far the largest and most visible component of federal civilian research and development spending. It garners great interest during deliberations on the annual appropriations bill for the Departments of Labor, Health and Human Services, and Education and Related Agencies. NIH funds extramural researchers in every state, and widespread constituencies contact Congress about funding for particular diseases and levels of research support in general.
- NIH has increasingly come to the attention of Congress and the American people in the last decade, thanks to greater awareness of science advances (for example, the Human Genome Project and its potential for guiding more personalized medicine) and public policy debates (for instance, the use and regulation of embryonic stem cells). Special interest surrounded the five-year doubling of the agency's budget between FY1999 and FY2003. Since then, during three years of low or no growth, Congress has increasingly scrutinized how the NIH is using its expanded resources, how it can most efficiently adapt to budgetary constraints, and whether its current structure of 27 semi-autonomous institutes and centers may be too "stovepiped" to identify and respond nimbly to important public health challenges.
- The last major reauthorization of the NIH was in 1993, although a number of laws focusing on individual NIH-related topics have amended the Public Health Service Act since then. Most policy changes have come in the appropriations arena, or through agency initiatives under its broad research authority. Some in Congress feel that the authorizing committees (the House Committee on Energy and Commerce and Senate Committee on Health, Education, Labor, and Pensions) should reassert their role in shaping the agency's structure and policies. After many hearings, the Energy and Commerce Committee reported H.R. 6164, the NIH Reform Act of 2006, which the House passed on Sept. 26, 2006. Draft legislation had been circulated starting in the summer of 2005 to solicit comments and reactions from the disparate stakeholders of the medical research community, including those in academia, government, industry, the nonprofit sector, patient advocacy groups, and the general public. H.R. 6164 focuses on enhancing the authority and tools for the NIH director to do strategic planning, especially to facilitate and fund cross-institute research initiatives. (H.R. 6164 was signed into law in January, 2007).

## Issues for Congress

Congress has devoted considerable attention to the NIH for decades, spurred by constituents who have voiced their expectation that the federal government would take the lead in cutting-edge research on prevention and treatment of disease. Since the mid-1990s, the doubling of the NIH budget and big projects like the sequencing of the human genome have fired the public's imagination, generating much hope and anticipation of further advances. More recently, however, budgetary realities and various issues facing the research enterprise are challenging NIH and Congress to rethink some approaches to NIH's traditional mission. Congress is confronting those challenges in the three spheres of appropriations, authorizations, and oversight.

**Background on Agency Budget Formulation.** The NIH budget request that Congress receives from the President each February for the next fiscal year reflects both recent history and professional judgments about the future, because it needs to support both ongoing research commitments and new initiatives. The request is formulated through a lengthy process that starts more than a year before in the institutes and centers (ICs). The budget then evolves over a number of months as it progresses from the ICs to NIH, then to DHHS and finally to the Office of Management and Budget (OMB). At each stage, IC and NIH needs are weighed in the context of the larger budget of which they are a part. Eventually, Congress is called upon to make similar judgments.

As a continuing process, IC leaders, with input from the scientific community, define the most important and promising areas in their respective fields. They consider whether the research portfolio they are already supporting needs any rebalancing, and they decide on possible new initiatives for the coming budget year. An annual budget retreat in May brings together the IC leaders with top NIH management to discuss policies and priorities under various budget scenarios. They might consider, for example, what the different emphases in their programs would be if the appropriation turned out to be a certain percent decrease, a flat budget, or an increase. The presentations and discussions allow NIH management to develop the budget request they will submit to DHHS, taking into account the estimate of the amount of funding needed to support the "commitment base" of continuing awards, the funding desired for unsolicited new research proposals, the new initiatives that the Director wants to incorporate, and guidance from the department about the request (for example, there might be an instruction to pay no inflationary increases on grants). At the DHHS level, NIH's request is considered in the context of the overall department budget, resulting in a notice back to NIH on the department's allowance. There are usually appeals and adjustments made before the final HHS budget goes to OMB. The process of submission, passback, and appeals is repeated as OMB considers the entire federal budget and tells HHS what amounts and policy approaches are approved for incorporation into the President's final budget that will be sent to Congress. Once the budget is made public in early February, all agency comments about the request are expected to support the President's proposed levels.

**Setting Research Priorities.** Some people feel that the main role of the Congress in regard to NIH should be to provide money with as few strings attached as possible. They favor trusting the creativity of investigator-initiated research and the NIH priority-setting process (to the extent that "good science" is driving research priorities), with funding targeted toward the maximum exploitation of scientific opportunity, as defined by the peer review system. They object to influences that skew research priorities in directions they would judge not scientifically sound. In support of that general philosophy, appropriators have traditionally tried to minimize congressional micromanagement of NIH's budget, and have avoided specifying dollar amounts for particular fields of research or mechanisms of funding below the level of the Institute and Center accounts.

**Advocacy Groups.** In Congress, the annual appropriations process has always been a magnet for those seeking to bolster funding for biomedical research generally or to influence research priorities in favor of some disease or field of science. Every congressional district includes multiple parties with an interest in NIH. Patient advocacy organizations, sometimes termed "disease lobby groups," are active in sending information to their members by mail and over the Internet. Advocacy groups have become more organized, and more demanding of a role in setting research priorities. They educate their contacts and the interested public about the latest developments in research and new therapies in their disease area. They frequently track federal and state legislation pertaining to health research and health care,

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and urge their members to contact their representatives for action in their areas of interest, including support of funding for the NIH. Appropriators often use report language directing the NIH to pay more attention to research on particular diseases as a way of responding to the public's requests.

**Scarce Resources.** Congress's flexibility in helping the NIH respond to scientific opportunity and public health needs has been severely reduced since FY2004. The prior five years, when Congress provided for the doubling of the NIH budget, coincided with a time of economic expansion and federal budget surpluses. More recent years, on the other hand, have been characterized by a return to federal deficits and new commitments to spending on defense and homeland security. The result has been a tightening of funds available for domestic discretionary programs.

**Young Investigators.** The NIH is concerned that prospects for a lower number of grants and a lower success rate will further discourage young scientists from pursuing careers in medical research. New investigators with creative ideas are the lifeblood of the research enterprise, but the path to becoming an independent researcher is long and challenging. Many young doctoral students and postdoctoral scientists already observe that their more senior colleagues have had increasing trouble in getting funded. Especially if they are physicians with the option of going into clinical practice, they may wonder about the wisdom of devoting themselves to years of research training that may not lead to successful competition for independent grant support. Some may decide on other career paths, and some may choose to pursue research opportunities overseas. In January 2006, the NIH announced a new "Pathway to Independence" program that increases support of young investigators in order to address the ever-lengthening time that it has been taking them to get their first grants. The new program will support promising postdoctoral scientists through five-year awards that will have a two-year mentored phase and a three-year independent phase. The NIH planned to support 150 to 200 awards beginning in fall 2006, and a similar number in each of the following five years, for a total commitment of almost \$400 million.

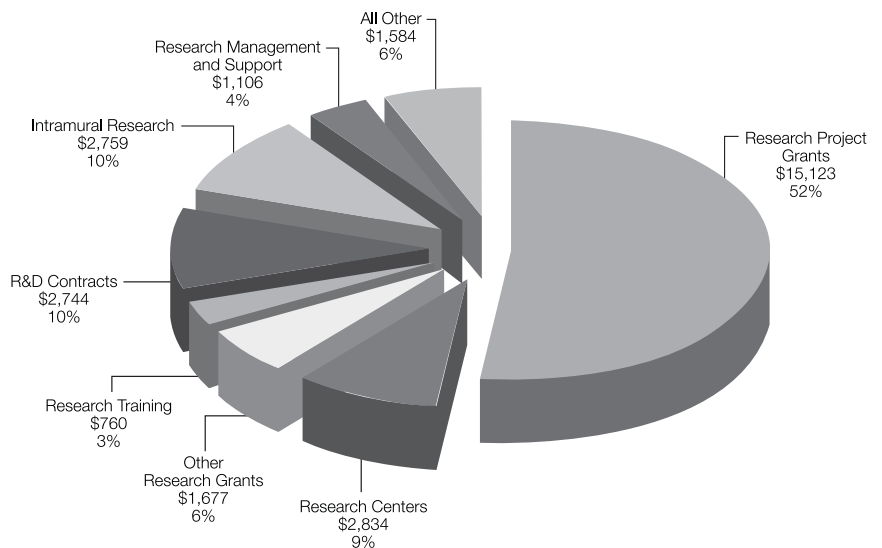
**Research Restrictions.** Also generating uncertainty for some researchers are congressional and/or administrative restrictions on types of research funded. The major recent examples are controls on federal funding of research on human embryonic stem cells, and congressional concerns over grant awards in certain areas of behavioral research.

**New Approaches?** While advocates warn that tight budgets will slow research advances on the major chronic conditions that burden American society, other commentators advise that coping with the reality of budget constraints will require the NIH and the research community to rethink some of their traditional approaches to planning and organizing research. As NIH Director Dr. Elias Zerhouni has noted in *The NIH Roadmap*, "As science grows more complex, it is also converging on a set of unifying principles that link apparently disparate diseases through common biological pathways and therapeutic approaches. Today, NIH research needs to reflect this new reality." Scientific leaders in and out of NIH urge critical examination of the best ways to transform knowledge into medical applications and allocate resources into the most critical priorities to maximize return on the public's investment.

*Please read the full report for much more information including: Addressing the organizational complexity of the NIH, Implementing the recommendations of the 2003 National Academies of Science study Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges, following the NIH Roadmap, Trans-NIH Initiatives, Oversight and transparency.*

#### FY2007 NIH Budget Request by Funding Mechanism

Total NIH Program Level = \$28,587 Million  
(Dollars in Millions)



**Source:** Adapted from *NIH: Summary of the FY2007 President's Budget*, Feb. 6, 2006, p. 6  
<http://officeofbudget.od.nih.gov/pdf/Press%20info%20final.pdf>