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109TH CONGRESS, 2d Session | HOUSE OF REPRESENTATIVES | REPORT 109–687

NATIONAL INSTITUTES OF HEALTH REFORM ACT OF 2006

SEPTEMBER 26, 2006.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 6164]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6164) to amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

The purpose of H.R. 6164 is to reauthorize the National Institutes of Health.

BACKGROUND AND NEED FOR LEGISLATION

The National Institutes of Health (NIH) is the Federal government's principal medical research agency. Its mission is to advance research in pursuit of fundamental knowledge that will lead to better health outcomes for all. Funding for the NIH represents nearly half of the discretionary budget of the Department of Health and Human Services.

The last reauthorization of the NIH occurred 13 years ago, when the "National Institutes of Health Revitalization Act of 1993" was signed into law (P.L. 103–43), authorizing several NIH research programs for fiscal years 1994–1996. In 1996, the Senate passed S. 1897, the "National Institutes of Health Revitalization Act of 1996," but the House did not take action. Beginning in fiscal year 1999, Congress committed to doubling the budget of the NIH over a five-year period in the absence of an existing authorization.

In the 108th Congress, more than 100 bills were introduced in the House of Representatives to change some function of the NIH. Many of the bills introduced focused on a specific disease, disorder, or adverse health condition. Often the bill sponsors indicated that the need for such legislation was to direct NIH to do more in the respective area of research. However, without a comprehensive reporting system to accurately evaluate the level and degree of effort in these areas at NIH, the Committee on Energy and Commerce was left with an impossible task of determining how to prioritize research activities throughout the 27 research institutes and centers. Furthermore, several of the proposals demanded that NIH establish research programs that promoted multidisciplinary research and greater collaboration between the 27 institutes and centers. However, the current budget allocations for the NIH, determined largely by institute and center status, do not accurately reflect the level of trans-NIH research that is currently underway at the agency. Trans-NIH research activities are generally referred to as important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that would benefit from additional research where such research involves the responsibilities of more than one institute or center.

The diverse research portfolios of the 27 research institutes and centers that make up the NIH are designed both to meet public health needs and to embrace scientific opportunities. Although the Administration has authority to establish and abolish research institutes and centers, Congress is largely responsible for the creation of new institutes and centers. For more than two decades, evaluations of the NIH have highlighted that the proliferation of institutes and centers is a problematic trend for the agency. In 1984, when the NIH consisted of 17 research institutes (which included research bureaus), the Institute of Medicine (IOM) was asked to review the organizational structure of the NIH ("Responding to Health Needs and Scientific Opportunity: The Organizational Structure of the National Institutes of Health," Institute of Medicine Report, October 16, 1984).

The IOM reported the following:

> The [IOM] committee believes that NIH is now at a stage where there should be a presumption against additions at the institute level because such changes:
>
> (1) fragment the scientific effort and diminish effective communication with key scientists in other institutes;
>
> (2) add to the burden and difficulty of effective program coordination by the NIH Director and his top staff, and
>
> (3) add to the administrative costs without ensuring increased appropriations.

Dr. Harold Varmus, Director of the NIH from 1993 through 1999, wrote the following in an article published in Science magazine in March 2001 ("Proliferation of National Institutes of Health," Science, Volume 291, March 9, 2001):

> Many people with influence in Washington view the National Institutes of Health as "the jewel in the crown of the federal government." Such praise has helped to enhance the value—the number of carats—in this jewel, especially over the past few years. But considerably less attention has been given to its shape than its price. New facets are being added without much thought to overall design, providing a superficial sparkle that may be pleasing to the few, but threatening to the functional integrity of the entire gem. With too many surfaces of different sizes, the organization may soon become less able to take advantage of its extraordinary budget increase and more difficult to manage responsibly. Those who care about the NIH need to think about its form and propose some solutions before the structure becomes even more fragmented and harder to fix.

In an interview published in the January 2004 edition of Health Affairs, Current NIH Director Dr. Zerhouni discusses the difficulties of managing the vast research portfolio of the NIH ("Twenty-Seven Fingers Without A Palm Is Not A Hand: A Conversation With Elias Zerhouni," Health Affairs, January 8, 2004).

He stated as follows:

> Over the years the NIH has had what I call a structural approach to portfolio management. Anytime there was a need and a vocal constituency, and Congress agrees, a structure was added to the NIH. That structure would get an appropriation that would grow in lockstep with all of the other structures. The problem here is that no one cares for the entire institution except the director . . . at the end of the day we need a new way to manage the portfolio, and that's what I call functional portfolio management. The director needs the ability to merge the fourteen different tracking systems that have developed to record and code what the NIH does . . . We need to be able to plan across NIH. We need some funds in common. If you have twenty-seven fingers out there with no palm, you don't have a hand.

The National Academy of Sciences in July 2003 once again reported on the organizational design of the National Institutes of Health. In the report, "Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges," the IOM committee recommended a series of changes at the NIH, including strengthening the Office of the Director, expanding trans-NIH strategic planning and funding, and improving data collection systems. These changes require authorizing legislation.

In response to the IOM suggestion that there is need for public process when considering proposed changes in the number of NIH institutes and centers, the National Institutes of Health Reform Act of 2006 creates a formal, public process to review the structural organizational design of the agency every seven years. A "scientific management review" group comprised of institute and center directors and other scientific experts would evaluate the structural design of the existing institutes and centers at the NIH, and proposed new institutes, and recommend necessary restructuring plans. After a series of statutorily required public meetings, the scientific management review board is to issue its first report to Congress within 18 months of the date of enactment of the National Institutes of Health Reform Act of 2006. If a recommendation is made regarding organizational authorities, the NIH official responsible for overseeing the change must initiate the public process toward making the change within 100 days, and the change is to be fully implemented within a three-year period. Should the Director of NIH object to a recommendation, he may submit within 90 days a report to Congress outlining the reasons for not implementing the recommendation.

The National Institutes of Health Reform Act of 2006 responds to the IOM recommendation to enhance and increase trans-NIH strategic planning and funding by requiring the Director, through the Division of Program Coordination, Planning, and Strategic Initiatives, to identify research that is important to the advancement of biomedical science and involves the responsibilities of more than one institute or center. The National Institutes of Health Reform Act of 2006 establishes a "common fund" to provide a permanent funding mechanism for trans-NIH research projects identified through the Division. The common fund would be a reserve account that may be competitively drawn down by institutes, centers, and independent investigators to advance trans-NIH research.

The IOM report clearly stated the need to strengthen the Office of the Director and create a Director's special project program. Additionally, in response to the IOM's recommendation to establish a process for creating new Office of the Director offices and programs, the National Institutes of Health Reform Act of 2006 would permit the Director, with the approval of the Secretary of Health and Human Services, to reorganize the offices within the Office of the Director. The Division of Program Coordination, Planning, and Strategic Initiatives would house the existing offices to better coordinate trans-NIH research activities. The Director of NIH would also be able to establish demonstration programs that award grants, contracts, or engage in other transactions for high-impact, cutting edge research.

The IOM report includes strong recommendations to standardize data and information management systems. The National Insti-

tutes of Health Reform Act of 2006 achieves that goal by creating a new, comprehensive electronic reporting system that would, for the first time, catalogue all of the research activities of the NIH in a standardized format. Instead of thousands of pages of reports from each of the individual research institutes and centers, the NIH Director will compile biennially a report that comprehensively lays out the strategic plans and research activities of the agency. Increased transparency of NIH research activities would highlight areas of ongoing research to improve research portfolio management, provide greater accountability of research dollars, and spur creative thinking about new scientific approaches.

The National Institutes of Health Reform Act of 2006 provides NIH with the management tools to better evaluate the research portfolio of the agency, encourage greater research collaboration between national research institutes and centers, and make necessary changes, including structural changes, to ensure that NIH research addresses current scientific opportunities and public health burdens.

HEARINGS

The Subcommittee on Health held a hearing on "Setting the Path for Reauthorization: Improving Portfolio management at the NIH" on March 17, 2005. The Subcommittee received testimony from: Elias A. Zerhouni, M.D., Director, National Institutes of Health.

The House Energy and Commerce Committee held a hearing on "Legislation to Reauthorize the National Institutes of Health" on July 19, 2005. The Committee received testimony from: Elias A. Zerhouni, M.D., Director, National Institutes of Health.

The Subcommittee on Oversight and Investigations held a hearing on "Human Tissue Samples: NIH Research Policies and Practices" on June 13, 2006. The Subcommittee received testimony from: Dr. Susan Molchan, Program Director, AD Neuroimaging Initiative, Neuroscience and Neuropsychology of Aging Program, National Institute on Aging.

The Subcommittee on Oversight and Investigations held a hearing on "Human Tissue Samples: NIH Research Policies and Practices" on June 14, 2006. The Subcommittee received testimony from: Dr. Thomas Insel, Director of the National Institute of Mental Health (NIMH), accompanied by (1) Dr. Donald Rosenstein, Acting Clinical Director, National Institute of Mental Health, National Institutes of Health; (2) William Fitzsimmons, Executive Officer; National Institute of Mental Health, National Institutes of Health; and (3) Suzanne Winfeld, Technology Transfer Officer, National Institute of Mental Health, National Institutes of Health; Dr. David L. Friedman, formerly with Pfizer, Inc.; Dr. Trey Sunderland, Chief of the Geriatric Psychiatry Branch, National Institute of Mental Health, National Institutes of Health; Karen Putnam, formerly with the Geriatric Psychiatry Branch, National Institute of Mental Health, National Institutes of Health; and Dr. Michael Gottesman, Deputy Director for Intramural Research, National Institutes of Health.

The Subcommittee on Oversight and Investigations held a hearing on "Continuing Ethics and Mangement Concerns at NIH and the Public Health Service Commissioned Corps" on September 13, 2006. The Subcommittee received testimony from: The Honorable

John Agwunobi, Assistant Secretary for Health, U.S. Department of Health and Human Services; Dr. Raynard Kington, Deputy Director, National Institutes of Health; Dr. John Niederhuber, Director, National Cancer Institute; Dr. Thomas R. Insel, Director, National Institute of Mental Health, National Institutes of Health; and Mr. William Fitzsimmons, Executive Officer, National Institute of Mental Health, National Institutes of Health.

The House Energy and Commerce Committee held a hearing on "Improving NIH Management and Operation: A Legislative Hearing on the NIH Reform Act of 2006" on September 19, 2006. The Committee received testimony from: Dr. Edward D. Miller, Chief Executive Officer, Johns Hopkins Medicine; Dr. Robert H. Eckel, Professor, Department of Physiology and Biophysics, University of Colorado Health Sciences Center, on behalf of the American Heart Association; Dr. Leo T. Furcht, President, Federation of American Societies for Experimental Biology (FASEB); Dr. Darrell G. Kirch, President, Association of American Medical Colleges (AAMC); and Dr. Elias A. Zerhouni, Director, National Institutes of Health.

COMMITTEE CONSIDERATION

On Wednesday, September 20, 2006, the Full Committee met in open markup session and ordered a Committee Print entitled the National Institutes of Health Reform Act of 2006 favorably reported to the House, amended, by a record vote of 42 yeas and 1 nay, a quorum being present. A request by Mr. Barton to allow a report to be filed on a bill to be introduced by Mr. Barton, and that the actions of the Committee be deemed as actions on that bill, was agreed to by unanimous consent.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following are the recorded votes taken on amendments offered to the measure, including the names of those Members voting for and against. A motion by Mr. Barton to order the Committee Print entitled the National Institutes of Health Reform Act of 2006 favorably reported to the House, amended, was agreed to by a record vote of 42 yeas and 1 nay.

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 137

Bill: Committee Print, the National Institutes of Health Reform Act of 2006

AMENDMENT: An amendment by Mr. Markey, No. 2, to amend the authorization levels to an increase of five percent plus Biomedical Research and Development Price Index over the previous year's baseline.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 15 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns		X		Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown			
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson				Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn			
Mr. Pickering		X		Mr. Green			
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt		X		Ms. DeGette			
Mr. Buyer				Ms. Capps			
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen	X		
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis			
Mr. Terry		X		Mr. Gonzalez			
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers		X		Ms. Baldwin	X		
Mr. Otter		X		Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan		X					
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 138

Bill: Committee Print, the National Institutes of Health Reform Act of 2006

AMENDMENT: An amendment by Mr. Markey, No. 3, to prohibit money from going to the common fund until appropriated funding equals the FY06 baseline plus the most recent Biomedical Research and Development Price Index percentage.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 17 yeas to 26 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown			
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood				Mr. Rush	X		
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak			
Ms. Wilson		X		Mr. Engel			
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer				Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen	X		
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis			
Mr. Terry		X		Mr. Gonzalez			
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers		X		Ms. Baldwin	X		
Mr. Otter		X		Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan		X					
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn							

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COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 139

Bill: Committee Print, the National Institutes of Health Reform Act of 2006

AMENDMENT: An amendment by Ms. Capps, No. 5, to require statutory approval for organizational changes at the National Institutes of Health.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 17 yeas to 22 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown			
Mr. Whitfield		X		Mr. Gordon	X		
Mr. Norwood				Mr. Rush	X		
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus				Mr. Stupak			
Ms. Wilson				Mr. Engel			
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer				Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen			
Mr. Pitts				Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden				Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez			
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers		X		Ms. Baldwin	X		
Mr. Otter		X		Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan		X					
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 140

Bill: Committee Print, the National Institutes of Health Reform Act of 2006

AMENDMENT: An amendment by Ms. Capps, No. 6, to direct the National Institutes of Health to conduct research specific to breast cancer and environment factors.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 20 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor				Mr. Pallone	X		
Mr. Deal		X		Mr. Brown			
Mr. Whitfield		X		Mr. Gordon	X		
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson				Mr. Engel			
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer				Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass	X			Mr. Allen	X		
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden				Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez			
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers		X		Ms. Baldwin	X		
Mr. Otter		X		Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan		X					
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn		X					

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COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 141

Bill: Committee Print, the National Institutes of Health Reform Act of 2006

MOTION: A motion by Mr. Barton to order the Committee Print reported, as amended.

DISPOSITION: **AGREED TO**, by a roll call vote of 42 yeas to 1 nay.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton	X			Mr. Dingell	X		
Mr. Hall	X			Mr. Waxman			
Mr. Bilirakis	X			Mr. Markey		X	
Mr. Upton	X			Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor				Mr. Pallone	X		
Mr. Deal	X			Mr. Brown			
Mr. Whitfield	X			Mr. Gordon	X		
Mr. Norwood	X			Mr. Rush	X		
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Stupak	X		
Ms. Wilson				Mr. Engel	X		
Mr. Shadegg	X			Mr. Wynn	X		
Mr. Pickering	X			Mr. Green	X		
Mr. Fossella	X			Mr. Strickland			
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer				Ms. Capps			
Mr. Radanovich	X			Mr. Doyle	X		
Mr. Bass	X			Mr. Allen	X		
Mr. Pitts	X			Mr. Davis			
Ms. Bono	X			Ms. Schakowsky	X		
Mr. Walden	X			Ms. Solis	X		
Mr. Terry	X			Mr. Gonzalez			
Mr. Ferguson	X			Mr. Inslee	X		
Mr. Rogers	X			Ms. Baldwin	X		
Mr. Otter	X			Mr. Ross	X		
Ms. Myrick	X						
Mr. Sullivan	X						
Mr. Murphy	X						
Mr. Burgess							
Ms. Blackburn	X						

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COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held legislative and oversight hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The National Institutes of Health Reform Act of 2006 amends Title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6164, the National Institutes of Health Reform Act of 2006, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK

In compliance with H. Res. 1000 as passed the House of Representatives on September 14, 2006, the Committee finds that H.R. 6164, the National Institutes of Health Reform Act of 2006, contains no earmarks.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

SEPTEMBER 25, 2006.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for the National Institutes of Health Reform Act of 2006.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

DONALD B. MARRON,
Acting Director.

Enclosure.

National Institutes of Health Reform Act of 2006

Summary: The National Institutes of Health Reform Act would authorize appropriations for the activities of the National Institutes

of Health (NIH) of $29.7 billion for fiscal year 2007, $31.2 billion for fiscal year 2008, and $32.8 billion for fiscal year 2009. Assuming appropriation of the specified amounts, CBO estimates that implementing the bill would cost about $8.6 billion in 2007 and about $90 billion over the 2007–2011 period. Enacting the bill would not affect direct spending or receipts.

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of the bill is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2006	2007	2008	2009	2010	2011
SPENDING SUBJECT TO APPROPRIATION						
NIH Spending Under Current Law:						
Budget Authority [1]	28,310	0	0	0	0	0
Estimated Outlays	27,549	19,927	5,122	1,841	404	11
Proposed Changes:						
Authorization Level	0	29,748	31,235	32,797	0	0
Estimated Outlays	0	8,574	24,561	29,117	22,007	5,455
NIH Spending Under the Bill:						
Authorization Level [1]	28,310	29,748	31,235	32,797	0	0
Estimated Outlays	27,549	28,501	29,683	30,958	22,411	5,466

[1] The 2006 level is the amount appropriated for that year.

Basis of Estimate: Title IV of the Public Health Service Act contains nearly 50 provisions that established the responsibilities of the National Institutes of Health and authorized the appropriation of funds to carry out those responsibilities. Nearly all of those authorizations have expired. The bill would:

- Strike all of those authorizations of appropriations (without terminating the authority of the NIH to conduct the activities funded by those appropriations);
- Authorize all of the national research institutes and national centers that currently make up the the NIH; and
- Authorize the appropriation of specified amounts for fiscal years 2007 through 2009 to conduct the activities of the NIH ($29.7 billion for 2007, rising to $32.8 billion for 2009).

Assuming the appropriation of the specified amounts, and based on historical patterns of spending by the NIH, CBO estimates that implementing the bill would cost about $8.6 billion in fiscal year 2007 and about $90 billion over the 2007–2011 period.

The bill would require the Secretary of Health and Human Services to establish a board that would review the organizational structure of the NIH and recommend modifications to that structure. NIH would be required to implement the board's recommendations unless the Director of NIH submits to the Congress a report objecting to a change.

The bill would require the allocation of part of the appropriated amounts to a "common fund" for research that involves the collaboration of two or more institutes of the NIH. In 2007, the allocation to the common fund would be 5 percent of the amount appropriated for NIH (about $1.5 billion, assuming appropriation of the authorized amount). By comparison, 1.2 percent (about $330 million) of the appropriation for 2006 is earmarked for similar collaborative

research activities. That allocation would increase in subsequent years by half of any increase in the amount appropriated for NIH. CBO expects that change would not have a significant effect on the average rate of spending by the NIH.

The bill also would require the Director of NIH to submit biennial reports to the Congress on the state of biomedical research and on the activities supported by NIH and to establish an electronic database to track research activities and grants.

Intergovernmental and private-sector impact: The bill contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal Costs: Tom Bradley. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Paige Shevlin.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; table of contents

This section provides the short title of the bill, the "National Institutes of Health Reform Act of 2006," and a table of contents.

Section 2. Organization of the National Institutes of Health

Section 2 strikes and replaces Section 401 of the Public Health Service Act (PHSA), which describes the organizational structure of the National Institutes of Health (NIH). The list includes the names of the 24 national research institutes and centers in existence. In addition, the section recognizes any other national center that, as an agency separate from any national research institutes, was established within the NIH as of the day before the date of en-

actment of the Act. The Committee recognizes these centers to include the Center for Scientific Review, the Center for Information Technology, and the NIH Clinical Center, thereby totaling 27 national research institutes and centers.

Section 2 establishes within the Office of the Director, a Division of Program Coordination, Planning, and Strategic Initiatives (Division). The Division includes the Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, the Office of Rare Diseases, and any other office designated by the Director. The section clarifies that each office included in the Division shall continue to carry out the authorities that were in effect for the office before the date of enactment of the Act, and as determined appropriate by the Director of NIH, to support the work of the Division with respect to its authorities.

Section 2 states that the total number of national research institutes and centers at the NIH may not exceed 27. The Committee intends for this number to include the 24 national research institutes and centers listed by name in the Act, as well as the Center for Scientific Review, the Center for Information Technology, and the NIH Clinical Center at the NIH. The Committee recognizes that changes in scientific opportunities and public health burdens may necessitate the addition of a new institute or center to manage research activities at the agency properly. However, for nearly two decades, evaluations of the NIH by the Institute of Medicine and others have highlighted that the proliferation of institutes and centers is a problematic trend for the agency. The Committee expects that if the Director of the NIH, or the Scientific Management Review Board (as described below) determines that a new national research institute or center is needed, that existing research institute and center structures will be consolidated or eliminated, to comply with this provision.

Section 2 also clarifies when and what notification requirements that must occur before structural reforms can be implemented at the NIH. Under current law, Section 401 of the PHSA permits the Secretary to reorganize the institutes and centers with notice to Congress. Section 2 authorizes the Director to makes organizational changes if the overall mission of the NIH, or the management and operation of programs and activities conducted or supported by NIH would be more efficiently carried out under the reorganization. Section 2 authorizes the Director to reorganize the institutes and centers subject to three requirements: (1) approval of the Secretary; (2) a public process, carried out by regulations; and (3) notice to Congress. The Director, with the approval of the Secretary, and after a series of public hearings, may reorganize the offices within the Office of the Director. In addition, the director of an institute or center may, with the approval of the Director of NIH, and after a series of public hearings, reorganize the divisions, centers, or other administrative units within an institute or center. A reorganization of a national research institute or center, an office within the Office of the Director, or a division or other unit located within a national research institute or center, may not be implemented before the expiration of 90 days after the Secretary submits written notice of the reorganization to the Committee on Energy

and Commerce of the House of Representative and the Committee on Health, Education, Labor, and Pensions of the Senate.

Section 2 establishes a new advisory council, to be known as the "Scientific Management Review Board," to review the organizational design of the NIH periodically. The Scientific Management Review Board (Board) must convene at least once every seven years to determine whether and to what extent the organizational authorities provided to the Secretary, Director of NIH, and national research institute and center directors should be used; and issue a report providing recommendations for changes that should be made to the organizational design of the agency. In fulfilling these responsibilities, the Board must: (1) review all programs of the NIH to determine their progress and cost-effectiveness, and allocation of resources with respect to the programs; (2) determine what are pending scientific opportunities and public health needs that the NIH should focus on; and (3) include proposals for organizational change. With respect to proposals for organizational change, the Board must analyze the budgetary and operational consequences of the proposed changes, estimate the level of resources needed to implement the proposed changes, and make a recommendation for the allocation of resources throughout NIH if the change were to be fully implemented. The Committee notes several Congressional proposals for organizational changes to NIH, including, for example, the possible creation of an institute for arthritis, rehabilitation research, and a center for translating NIH research into new products. The Scientific Management Review Board should carefully consider all of these proposals as part of its deliberations.

To fulfill its responsibilities, the Board must consult with the directors of the national research institutes and centers, other scientific leaders within NIH, advisory councils of the national research institutes and centers, organizations representing the scientific community, and organizations representing patients.

The membership of the Board may not exceed 21 individuals, all of whom shall be voting members with equal weight. The board will include the Director of NIH, at least 9 officials representing national research institutes and centers, individuals representing the interest of public or private institutes of higher education that have historically received funds from NIH, and individuals representing the interest of private entities that have received funds from NIH or that have broad expertise regarding how the NIH functions. With the exception of the Director of NIH, the Secretary makes appointments for the remaining 20 individuals who will serve on the Board. The Secretary also selects who will chair the Board, and may select the Director of NIH to serve in this capacity.

The Board must meet at the call of the chair or upon the request of the Director of NIH, but may not meet fewer than five times before issuing a report required at least once every seven years. The Board must also hold a series of forums, involving both the scientific community and patient advocate organizations, to seek input and suggestions on changes to the structure of NIH. The Director must post a summary of the meetings on the Internet site of the NIH to inform the public of the discussions. Members of the Board may be compensated in the same manner as other NIH advisory councils, as outlined in section 406 of the PHSA.

The Board must submit a report to the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, the Secretary, and officials with organizational authorities within the NIH. The report must be posted on the Internet site of the NIH. The first report must be completed no later than 18 months after the date of enactment of the Act.

Once the Board has submitted its report, an official who has organizational authorities must begin to execute the change no later than 100 days after the report is submitted, and shall fully implement the change within a three-year period. The Director of NIH may object to the entirety of a recommended organizational change or to an aspect of the recommended change. A change does not have to be implemented if the Director of NIH submits a subsequent report to Congress within 90 days after the Board submits its report on recommendations.

Section 2 makes technical and conforming changes to reflect that the National Center for Human Genome Research is now the National Human Genome Research Institute.

Section 3. Authority of Director of NIH

Section 3 amends Section 402 of the PHSA, which outlines the authorities of the Director of NIH. In addition to existing authorities, Section 3 delineates several new authorities to improve agency coordination and collaboration. Specifically, the Director, in consultation with the heads of the national research institutes and centers, is responsible for program coordination, including conducting priority setting reviews, to ensure that the research portfolio of the NIH is balanced and free of unnecessary, duplicative research. The Committee is concerned that the NIH cannot track accurately the research activities between the national research institutes and centers. For example, both the National Cancer Institute and the National Heart, Lung, and Blood Institute conduct research on lung cancer. There is nothing in current law that prohibits the two research institutes from conducting and supporting the unnecessarily redundant or duplicative research experiments. The Committee recognizes that science demands duplication to verify results. However, the Committee is concerned that at some point, duplication may be counterproductive and an inefficient use of taxpayer dollars given the numerous research opportunities that demand attention. When evaluating the research portfolio of the NIH, the Director of NIH should work with the national research institute and center directors to ensure that all of the priorities of the NIH can be accomplished as efficiently as possible with the resources available.

Section 3 requires the Director of NIH to assemble accurate data to be used to assess research priorities, including information to evaluate scientific opportunity, public health burdens, and progress in reducing health disparities. For example, the Committee believes that all research conducted or supported by NIH should include both males and females, except when it is scientifically inappropriate, using sex as a variable when appropriate. This includes research on human or animal subjects and material derived from the research, clinical research, and publications resulting from such research. With respect to reducing health disparities, the Director

of NIH, when evaluating the research portfolio, must identify the activities conducted by NIH that make progress in reducing health disparities, so that this information may be used to assess the research priorities of the agency better. Compiling accurate data with respect to health disparities should be a critical function that the Director of NIH fulfills in coordination with the Director for the National Center for Minority Health and Health Disparities.

The Director shall also ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the institutes and centers. The Director shall also ensure that the resources of NIH are sufficiently allocated for research projects identified in strategic plans.

Section 3 outlines the authorities of the Division of Program Coordination, Planning, and Strategic Initiatives (Division) as established in Section 2 of the Act. The Director, acting through the Division, must identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from research that involves collaboration between two or more national research institutes and centers, or would otherwise benefit from strategic coordination and planning. The Committee recognizes research resources, such as the databases and research networks for training translational and clinical researchers, as an activity that may be supported by the common fund.

The Director may allocate funds set aside in a "common fund," under Section 4 of the Act, to the national research institutes and centers for conducting and supporting research that is identified. The Committee expects that research conducted or supported through the common fund will be subject to the same peer review standards as research conducted or supported through the national research institutes and centers. The Director of NIH may assign additional functions to the Division. The Division must report on its activities in the biennial report required in Section 5 of the Act.

With respect to research supported through the common fund, the Director must require that proposals include milestones and goals for the research and timeframes for funding of the research. The Director must also ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the NIH. The Committee is concerned that young investigators are given a fair opportunity to make significant contributions within their areas of expertise and that they are provided with the incentive to be the future driving force of innovation and new discoveries. The Committee recognizes the existing Clinical Transformation Science Awards program as an activity that may receive common fund support, especially as it may assist first time young investigator applicants.

To reflect the growing trend in interdisciplinary science, the Committee expects that the common fund will provide an avenue to fund meritorious research that requires the collaboration of several national research institutes and centers. For example, the Institute of Medicine reported in 2006 that to better understand premature birth, a multidisciplinary research approach is needed. Several other areas of public health concern, such as spinal cord injuries and rehabilitation, mental health, Parkinson's disease, and au-

tism, also require multidisciplinary research approaches that involve the responsibilities of several research institutes and centers.

Section 3 requires the Director of NIH, in coordination with the heads of the national research institutes and centers, to ensure that the institutes and centers preserve an emphasis on investigator-initiated research project grants, including projects funded by the common fund; and, when appropriate, maximize investigator-initiated research project grants in the annual research portfolios. The Committee encourages NIH to consider taking the steps necessary to allow principal investigators the opportunity to communicate to the agency whether their research involves trans-NIH research in order to possibly allow the respective investigators' research to be considered for funding through the common fund.

Section 3 requires that the Director of NIH ensure that research conducted or supported by the NIH is subject to review in accordance with Section 492 of the PHSA, and specifically Section 492(a)(2) of the PHSA, which requires appropriate advisory council review before research proposals are funded. The Committee is concerned that some national research institutes and centers may not be complying fully with statutory requirements that demand advisory council review of grant applications.

Section 3 requires that the Director approve the establishment of all centers of excellence recommended by the national research institutes, other than the centers already recognized under Section 414. The Committee is concerned that, over the past decade, the number of centers of excellence to conduct research on specific diseases, disorders, or other adverse health conditions, has grown without proper evaluation to determine if indeed these centers are the most efficient use of taxpayer dollars to accomplish the research priorities of the NIH. The Institute of Medicine reported in 2004 that centers of excellence represent nearly 9 percent of the overall NIH budget. The Committee is requiring the Director of NIH to approve any new center of excellence so that NIH may accurately track the number of centers of excellence it funds and the research activities completed.

Section 3 also refines the authorities of the Director of NIH to establish a Director's Discretionary Fund to reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority. The Committee expects that the Director's transfer authority may be used to augment this account, in addition to any funds appropriated in a fiscal year, to be used at the Director's discretion.

The Director may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences.

Section 3 establishes a new advisory council to be known as the Council of Councils (Council) for the purpose of advising the Director on matter related to the responsibilities of the Division, including making recommendations with respect to the conduct and support of research identified by the Division through the common fund. The Committee designed the Council to be similar to the existing advisory councils in the national research institutes and centers that provide recommendations regarding what research to con-

duct and support and help set priorities for the national research institutes and centers.

The membership of the Council may not exceed 27 members selected by the Director of NIH, with approval by the Secretary. In selecting the members of the Council, the Director must ensure that the members represent a broad range of disciplines and perspectives, and must include at all times at least one representative from each national research institute whose budget is substantial relative to a majority of the other institutes. The Committee recognizes at this time these institutes to be the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute of Allergy and Infectious Diseases. The Director must maintain an updated list of individuals who have been nominated to serve on the Council. With respect to nominations from each national research institute and center, three individuals shall be nominated by the head of the institute or center; at least two must be scientists, and one other representing the general public; four shall be a leader in the field of public policy, law, health policy, economics, or management. In addition, each office within the Division of Program Coordination, Planning, and Strategic Initiatives shall nominate one person.

The Committee expects the Council to be a rotating body that will grant representation to every institute and center that comprises the NIH at some point in time. The Committee expects that national research institutes and centers with budgets that are substantially less than the majority of others will have an opportunity to serve on the Council of Councils. The Act requires that a term of service is six years for a member of the Council. The initial terms of service are: nine members serving for six years, nine members for four years, and nine members for two years. The Director may appoint a member to fill a position if there is a vacancy, but only for the remainder of the term or until a successor is replaced.

Section 3 amends Section 492A(a)(2) of the PHSA by requiring that a majority of the voting members of the appropriate advisory council within the national research institutes and centers recommend approval of a research proposal before it may receive funding. The Committee is very concerned that the two-tier peer review system is followed completely, given that NIH leaders consistently note that the peer review system is the hallmark of NIH success. It has been brought to the Committee's attention that past Cancer Center Support Grant (CCSG) recipients receiving a National Cancer Institute (NCI) "priority score" were not awarded funds consistent with NCI recommended levels. The Committee would like information on whether or not appropriate consideration has been given to the scores received by potential grant applications through the CCSG program, and the respective budgetary allocations that correspond with this program.

Section 3 clarifies that the new authorities of the Director may not be construed as affecting the specific authorities of the institutes and centers that were in effect on the date of enactment of the bill.

Section 4. Authorization of appropriations

Section 4 creates a new section 402A of the PHSA.

"Section 402A. Authorization of Appropriations."

New Section 402A authorizes appropriations for the overall NIH budget for the fiscal year 2007 through fiscal year 2009 period. For fiscal year 2007, $29,747,874,000 is authorized; for fiscal year 2008, $31,235,268,000; and for fiscal year 2009, $32,797,032,000.

New Section 402A also authorizes appropriations for the Office of the Director for the fiscal year 2007 through 2009 period, within the overall appropriation for the NIH. For fiscal year 2007, $1 billion; for fiscal year 2008, $1,050,000,000; and for fiscal year 2009, $1,102,500,000.

New Section 402A establishes a "common fund" to provide a permanent funding mechanism for trans-NIH research projects identified through the Division of Program Coordination, Planning, and Strategic Initiatives. The amount reserved in the common fund for a fiscal year is equal to the sum of the base amount and any additional allocation as determined through appropriations. The amount reserved by the Director of NIH for a fiscal year may not exceed 5 percent of the total NIH budget. This restriction does not apply after an evaluation and recommendations are submitted to Congress in the first year that the common fund represents 5 percent of the total NIH budget. The percentage reservation for the common fund may not be less than the previous fiscal year, and may not fall below 5 percent after the first fiscal year that the common fund represents 5 percent of the total amount appropriated.

The base amount for the common fund for fiscal year 2007 is the amount reserved by the Director of NIH for fiscal year 2006 for trans-NIH research. The Committee has identified several initiatives at NIH that meet this criteria, including, but not limited to, the Director's Roadmap initiative, the neurosciences blueprint, and the obesity initiative. In addition, the Committee recognizes Clinical Transformation Science Awards as an important use of common fund dollars. The base amount for the common fund in fiscal year 2008 and each subsequent fiscal year is the amount of the common fund reserved for the preceding fiscal year.

The additional amount that is reserved in the common fund represents 50 percent of the amount appropriated that exceeds the appropriation for the preceding fiscal year. The new funding percentage set aside may be adjusted for a fiscal year after the submission of an evaluation and recommendations to Congress with respect to the common fund.

An evaluation of the common fund must be conducted during the six month period following the end of the first fiscal year when the common fund equals 5 percent of the total NIH budget. The Director of NIH, in consultation with the Council of Councils, must submit recommendations to Congress for changes to the amount of the reservation for the common fund. The Committee strongly recommends that when the Director and the Council of Councils evaluate the program, the Director include in the report to Congress an evaluation of various levels of funding for the common fund. This report should discuss whether or not the common fund should be less than 5 percent of the total NIH budget at any point in time, and how the common fund could potentially grow to the level recommended by the Institute of Medicine of 10 to 15 percent of the total NIH budget. The evaluation should include information

on research activities funded by the common fund, as is required in the biennial report as described in Section 5 of the Act.

New Section 402A, beginning in fiscal year 2008, national research institutes and centers may only receive funding increases above the fiscal year 2006 baseline if they report on the level of trans-NIH activities that the Institute or Center has engaged in during the previous fiscal year. This amount may include projects funded through the common fund. Not later than January 1, 2008, and each subsequent January 1st thereafter, the head of each national research institute or center must submit to the Director a report, which the Director of NIH is required to verify the accuracy. The Secretary of HHS will then submit a report to Congress identifying the percentage of funds made available by each national research institute or center for the previous fiscal year for conducting trans-NIH research. At the request of a national research institute or center, the Director of NIH may waive this requirement if the Director of NIH determines that the condition is inconsistent with the mission of the institute or center. The Committee also recognizes that there may be collaborative work between national research institutes and centers that may not be fully demonstrated in budgetary data, such as planning meetings, conferences, and casual communication. The heads of national research institutes and centers should highlight the major time-consuming activities that fall under this category.

New Section 402A authorizes transfer authority for the Director of NIH at 1 percent, however, the Director may not decrease any appropriation account by more than 1 percent. The Committee notes that this is the same level that is currently permitted in annual appropriations legislation.

New Section 402A strikes statutory authorization of appropriations line items that are expired or have never received a direct appropriation. The elimination of other authorizations of appropriations, however, may not be construed as terminating the authority of the Federal Agency involved to carry out the program. The Committee notes that Title III of the PHSA grants the Secretary of HHS broad authority to conduct research on a variety of issues, regardless of disease-specific research directives that Congress has approved over the years. The Committee firmly believes that, in order to avoid political micromanagement of the agency, NIH needs to improve the transparency of research activities and findings.

Section 5. Reports

Section 5 amends the PHSA to create a new Section 402B.

"Section 402B. Electronic Coding of Grants and Activities."

New Section 402B requires the Secretary of HHS, acting through the Director of NIH, to establish an electronic system to uniformly code research grants and activities throughout the NIH. The electronic coding system must be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area interest. When permissible, the Director must provide information on relevant literature and patents that are associated with research activities of the NIH. The Committee has listened to stakeholder concerns about NIH's current open access policy with respect to making published literature

available online. The Committee will continue to monitor the open access policies adopted by the NIH, including the management of the program and the participation levels of scientific journals.

Section 5 amends Section 403 of PHSA to require the Director of NIH to submit biennially a report to Congress. The report must include an assessment of the state of biomedical research, a description of the activities conducted or supported by the NIH, classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out by the Division of Program Coordination, Planning, and Strategic Initiatives.

The report must include a catalogue of all the research activities of the agencies. The catalogue must include (1) epidemiological studies and longitudinal studies; (2) disease registries, information clearinghouses, and other data systems; (3) public education and information campaigns; (4) training activities; (5) clinical trials, including a breakdown by demographic variables and other appropriate categories; and (6) translational research activities. The Committee directs the NIH to create a new, comprehensive electronic reporting system that will, for the first time, catalogue all of the research activities of the NIH in a standardized format. The Committee expects to receive from the NIH Director a report that comprehensively lays out the strategic plans and research activities of the agency, instead of thousands of pages of reports from each of the individual research Institutes and Centers. The Committee strongly believes that increased transparency of NIH research activities will highlight areas of ongoing research to improve research portfolio management, provide greater accountability of research dollars, and spur creative thinking about new scientific approaches. The Committee does not expect, nor does it encourage, the NIH to submit a 1,000+ page report; however, the Committee does expect that the research activities are catalogued in an electronically accessible database, searchable by the variety of new codes to meet the criteria outlined in the Act.

With respect to reporting on training activities, the Committee requests that the Director accurately identify the institutions that receive training awards, as well as provide a breakdown of appropriate variables to analyze the disbursement of awards, including, but not limited to, race, ethnicity, and gender.

The catalogue must also identify the agency or agencies involved, state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved, and identify whether the specific activity was carried out through a center of excellence. The Committee believes this information is critical in determining the overall level of intramural and extramural activities supported through the NIH. It has been brought to the Committee's attention that centers of excellence may shelter researchers who may not be as competitive if they were applying for research support through another avenue, or unduly emphasize research that should not be a high priority for NIH based on current scientific opportunities and public health burdens. Information on the type of research supported by centers of excellence will highlight the efficiency of these programs.

The report must also include a summary of the research activities throughout NIH, organized by the following categories: cancer;

neurosciences; life stages, human development, and rehabilitation; organ systems and autoimmune diseases; genomics; molecular biology and basic science; technology development; chronic diseases, including pain and palliative care; infectious diseases and bioterrorism; health disparities; and any other additional categories as the Director determines to be appropriate. For example, the Director may choose to include a separate subsection under the category of neurosciences for stroke, and a separate subsection under organ systems for heart disease, two of the leading causes of death in America.

With respect to research activities on specific diseases, disorders, or other adverse health conditions, the Director must present information in a standardized format, identify the actual dollar amounts obligated for such activities, and include plans for research on specific diseases, disorders, and conditions, including statements of objectives regarding the research, the means for achieving the objectives, and a date by which the objectives are expected to be achieved, and justifications for revisions to the plans. The Committee does not expect that the NIH develop all at once a report on 3,000+ diseases, disorders, and adverse health conditions in the same standardized format. The Committee does demand, however, that from this point forward, when NIH disseminates information regarding research activities with respect to a disease, disorder, or adverse health condition, that the information be formatted in a standardized format. For example, the Committee is interested in learning more about the research activities with respect to diseases such as Cystic Fibrosis, rare diseases, arthritis, Chronic Obstructive Pulmonary Disease, Idiopathic Pulmonary Fibrosis, chronic kidney diseases, and Charcot Marie Tooth disease. The Committee is also interested in learning more about prevention methods using microbicides and studies of routine scheduled Cesarean delivery procedures versus attempted vaginal childbirth. The Committee is interested in better understanding what research is underway at NIH to address the adverse health conditions of those impacted by the terrorist attacks on September 11, 2001. The Committee would like to know more about the research underway at NIH with respect to prosthetics for soldiers whose limbs have been amputated as a result of combat, and related illnesses experienced by those individuals due to amputations. The Director should also include in the report information about population research activities and advances.

Section 5 permits the Director to submit additional reports to Congress as he determines appropriate.

Section 5 amends the PHSA by creating a new Section 403A.

"Section 403A. Annual Reporting to Increase Interagency Collaboration and Coordination."

New Section 403A requires the Director of NIH to submit a report on an annual basis to the Secretary of HHS describing the activities involving collaboration between NIH and the other agencies of the Department of Health and Human Services. This information is important to better tracking not only patient safety initiatives, but also agency efforts to reduce health disparities. Specifically, the Committee recognizes the positive impact that the NIH can have by collaborating across the institutes and centers and

with the Centers for Disease Control, Agency for Healthcare Research and Quality, and other HHS agencies to improve the delivery of care for the nation's patients by increasing quality, eliminating duplication, and reducing the unnecessary costs caused by infections, medical, and medication errors. The Committee encourages NIH to include detailed information that describes how long the agency has collaborated on the projects listed in the report, the total level of funding to date, the total contribution of NIH funding to the project, and a list of all major meetings between the agencies. It is also critically important for NIH and the Food and Drug Administration to collaborate on new research initiatives to help speed the development and approval of lifesaving drugs and biologics. Other agency collaborations, such as the provision included in the Medicare Prescription Drug and Modernization Act of 2003 that directed the Agency for Healthcare Research and Quality to conduct systematic reviews of existing evidence on drugs and other treatments that treat the same condition should be included in the report. The Committee requests that the report include public education campaigns, epidemiological studies and longitudinal studies, disease registries, and information clearinghouses that the NIH coordinates with the Centers for Disease Control and Prevention, including detailed information about NIH funding for the activities.

New Section 403A requires the Director of NIH to submit to the Commissioner of the Food and Drug Administration on an annual basis a report that identifies each clinical trial that is registered during the calendar year in the databank of information established under Section 402(j) of the PHSA.

Section 5 amends the PHSA by creating a new Section 403B.

"Section 403B. Annual Reporting to Prevent Fraud and Abuse."

New Section 403B requires the Director of NIH submit to Congress on an annual basis a report that describes how the NIH stores and tracks human tissue samples.

New Section 403B requires the Director of NIH to submit to the Inspector General of the Department of HHS, the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report summarizing the activities of the NIH relating to whistleblower complaints, including the agency involved, the status of the complaint, and the resolution of the complaint to date. The Director of NIH is also required to submit a report that identifies the number of experts and consultants whose services are obtained by the NIH.

New Section 403B strikes all other statutory reporting requirements that are either expired or are duplicative given the new comprehensive reporting system. The Committee, however, expects NIH to submit reports that are already underway, and near completion, such as the report required by Section 4923 of Public Law 105–33.

Section 6. Certain demonstration projects

Section 6 authorizes the Director of NIH to conduct two distinct demonstration programs with funds appropriated through the Office of the Director.

The first demonstration program, "Bridging the Sciences," permits the Secretary of HHS, acting through the Director of NIH, in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agencies, to award grants for demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences with the physical, chemical, mathematical, and computational sciences. The Secretary must establish goals, priorities, and methods of evaluation for the research. A grant must be peer reviewed, as required under Section 492 of the PHSA, and an advisory council must complete the review. The Committee recognizes that research projects eligible under this demonstration program may require a more diverse group of peer reviewers than are currently available through NIH's traditional peer review process, and encourages the agencies involved to organize appropriate advisory councils to properly review the applicants.

The second demonstration program, "High Risk, High Reward Research," permits the Director of NIH to allocate funds for the national research institutes and centers to award grants, contracts, or engage in other transactions, for high-impact, cutting edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. In addition to funds allocated by the Director, the head of a national research institute or center may conduct or support similar research with funds appropriated to the institute or center, if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis regarding the activities.

The Director of NIH must give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes. The Committee recognizes that high risk, high reward research, similar to the Defense Advanced Research Projects Agency initiatives at the Department of Defense, could be quite expensive to conduct. Therefore the Committee encourages the Director of NIH to maximize funds for this demonstration project by coordinating with institutes and centers with substantial budgets. In addition, the Director of NIH or the head of a national research or institute should seek to facilitate partnerships between public and private entities. The Director of NIH or the head of a national research institute or center must also coordinate with the Foundation for the National Institutes of Health. The Committee expects coordination with the Foundation for the National Institutes of Health for the sole purpose of drawing down additional research dollars to operate the demonstration program. All grants must be peer reviewed.

The Director of NIH must conduct an evaluation of both demonstration projects and submit a report to Congress on the results no later than the end of fiscal year 2009.

Section 7. Foundation for the National Institutes of Health

Section 7 amends Section 499 of the Public Health Service Act, the statute governing the National Foundation for the National Institutes of Health (Foundation), and makes technical corrections and grants increased flexibility in the amounts of Federal funding and support services. Most significantly, these corrections clarify

membership in the Foundation's board of directors and assure that the Foundation receives funds from the National Institutes of Health (NIH) to support the Foundation's administrative and operating expenses.

Section 8. Applicability

Section 8 clarifies that the amendments made by the bill apply only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

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SEC. 399E. STUDY IN CERTAIN STATES TO DETERMINE THE FACTORS CONTRIBUTING TO THE ELEVATED BREAST CANCER MORTALITY RATES.

(a) * * *

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[(e) REPORT.—Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of -the Senate, a report describing the findings and recommendations made as a result of the study.]

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

[ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

[SEC. 401. (a) The National Institutes of Health is an agency of the Service.

[(b)(1) The following national research institutes are agencies of the National Institutes of Health:

[(A) The National Cancer Institute.

[(B) The National Heart, Lung, and Blood Institute.

[(C) The National Institute of Diabetes and Digestive and Kidney Diseases.

[(D) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

[(E) The National Institute on Aging.

[(F) The National Institute of Allergy and Infectious Diseases.

[(G) The National Institute of Child Health and Human Development.

[(H) The National Institute of Dental and Craniofacial Research.

[(I) The National Eye Institute.

[(J) The National Institute of Neurological Disorders and Stroke.

[(K) The National Institute of General Medical Sciences.

[(L) The National Institute of Environmental Health Sciences.

[(M) The National Institute on Deafness and Other Communication Disorders.

[(N) The National Institute on Alcohol Abuse and Alcoholism.

[(O) The National Institute on Drug Abuse.

[(P) The National Institute of Mental Health.

[(Q) The National Institute of Nursing Research.

[(R) The National Institute of Biomedical Imaging and Bioengineering.

[(2) The following entities are agencies of the National Institutes of Health:

[(A) The National Library of Medicine.

[(B) The National Center for Research Resources.

[(C) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

[(D) The National Center for Human Genome Research.

[(E) The Office of Dietary Supplements.

[(F) The National Center for Complementary and Alternative Medicine.

[(G) The National Center on Minority Health and Health Disparities.

[(c)(1) The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

[(A) the Secretary determines that an additional institute is necessary to carry out such activities; and

[(B) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate written notice of the determination made under subparagraph (A) with respect to the institute.

[(2) The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of

Representatives and the Committee on Labor and Human Resources of the Senate written notice of the reorganization or abolition.

[(d) For purposes of this title, the term "national research institute" means a national research institute listed in subsection (b) or established under subsection (c). A reference to the National Institutes of Health includes its agencies.]

SEC. 401. ORGANIZATION OF NATIONAL INSTITUTES OF HEALTH.

(a) RELATION TO PUBLIC HEALTH SERVICE.—The National Institutes of Health is an agency of the Service.

(b) NATIONAL RESEARCH INSTITUTES AND NATIONAL CENTERS.—The following agencies of the National Institutes of Health are national research institutes or national centers:

(1) The National Cancer Institute.

(2) The National Heart, Lung, and Blood Institute.

(3) The National Institute of Diabetes and Digestive and Kidney Diseases.

(4) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(5) The National Institute on Aging.

(6) The National Institute of Allergy and Infectious Diseases.

(7) The National Institute of Child Health and Human Development.

(8) The National Institute of Dental and Craniofacial Research.

(9) The National Eye Institute.

(10) The National Institute of Neurological Disorders and Stroke.

(11) The National Institute on Deafness and Other Communication Disorders.

(12) The National Institute on Alcohol Abuse and Alcoholism.

(13) The National Institute on Drug Abuse.

(14) The National Institute of Mental Health.

(15) The National Institute of General Medical Sciences.

(16) The National Institute of Environmental Health Sciences.

(17) The National Institute of Nursing Research.

(18) The National Institute of Biomedical Imaging and Bioengineering.

(19) The National Human Genome Research Institute.

(20) The National Library of Medicine.

(21) The National Center for Research Resources.

(22) The John E. Fogarty International Center for Advanced Study in the Health Sciences.

(23) The National Center for Complementary and Alternative Medicine.

(24) The National Center on Minority Health and Health Disparities.

(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006.

(c) DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES.—

(1) IN GENERAL.—Within the Office of the Director of the National Institutes of Health, there shall be a Division of Program Coordination, Planning, and Strategic Initiatives (referred to in this subsection as the "Division").

(2) OFFICES WITHIN DIVISION.—

(A) OFFICES.—The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, the Office of Rare Diseases, and any other office located within the Office of the Director of NIH as of the day before the date of the enactment of the National Institutes of Health Reform Act of 2006. In addition to such offices, the Director of NIH may establish within the Division such additional offices or other administrative units as the Director determines to be appropriate.

(B) AUTHORITIES.—Each office in the Division—

(i) shall continue to carry out the authorities that were in effect for the office before the date of enactment referred to in subparagraph (A); and

(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 402(b)(7).

(d) ORGANIZATION.—

(1) NUMBER OF INSTITUTES AND CENTERS.—In the National Institutes of Health, the number of national research institutes and national centers may not exceed a total of 27, including any such institutes or centers established under authority of paragraph (2) or under authority of this title as in effect on the day before the date of the enactment ofthe National Institutes of Health Reform Act of 2006.

(2) REORGANIZATION OF INSTITUTES AND CENTERS.—

(A) IN GENERAL.—Notwithstanding subsection (b), and subject to paragraph (1), the Director of NIH may, with the approval of the Secretary, reorganize the national research institutes and the national centers, including the addition, removal, or transfer of functions of such institutes and centers, and the establishment or termination of such institutes and centers, if the Director determines that the overall mission of the National Institutes of Health, or the management and operation of programs and activities conducted or supported by the National Institutes of Health, would be more efficiently carried out under such a reorganization.

(B) ADMINISTRATIVE UNIT.—For purposes of paragraph (1), an administrative unit within the National Institutes of Health that is established under authority of subparagraph (A) shall be considered a national research institute or a national center, without regard to whether the administrative unit is designated by the Director of NIH as such an institute or center.

(C) PUBLIC PROCESS.—Any reorganization under subparagraph (A) shall be carried out by regulation in accordance with the procedures for substantive rules under section 553 of title 5, United States Code.

(3) REORGANIZATION OF OFFICE OF DIRECTOR.—Notwithstanding subsection (c), the Director of NIH may, after a series of public hearings, and with the approval of the Secretary, reorganize the offices within the Office of the Director, including the addition, removal, or transfer of functions of such offices, and the establishment or termination of such offices, if the Director determines that the overall management and operation of programs and activities conducted or supported by such offices would be more efficiently carried out under such a reorganization.

(4) INTERNAL REORGANIZATION OF INSTITUTES AND CENTERS.—Notwithstanding any conflicting provisions of this title, the director of a national research institute or a national center may, after a series of public hearings and with the approval of the Director of NIH, reorganize the divisions, centers, or other administrative units within such institute or center, including the addition, removal, or transfer of functions of such units, and the establishment or termination of such units, if the director of such institute or center determines that the overall management and operation of programs and activities conducted or supported by such divisions, centers, or other units would be more efficiently carried out under such a reorganization.

(5) NOTICE TO CONGRESS; EFFECTIVE DATE.—A reorganization under paragraph (2), (3), or (4) may not take effect before the expiration of 90 days after the Secretary submits to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the reorganization.

(e) SCIENTIFIC MANAGEMENT REVIEW BOARD FOR PERIODIC ORGANIZATIONAL REVIEWS.—

(1) IN GENERAL.—Not later than 60 days after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the "Board").

(2) DUTIES.—

(A) REPORTS ON ORGANIZATIONAL ISSUES.—The Board shall provide advice to the appropriate officials under subsection (d) regarding the use of the authorities established in paragraphs (2), (3), and (4) of such subsection to reorganize the National Institutes of Health (referred to in this subsection as "organizational authorities"). Not less frequently than once each 7 years, the Board shall—

(i) determine whether and to what extent the organizational authorities should be used; and

(ii) issue a report providing the recommendations of the Board regarding the use of the authorities and the reasons underlying the recommendations.

(B) CERTAIN RESPONSIBILITIES REGARDING REPORTS.—The activities of the Board with respect to a report under subparagraph (A) shall include the following:

(i) Reviewing all programs of the National Institutes of Health (referred to in this subsection as "NIH") in order to determine the progress and cost-effectiveness of

such programs and the allocation among the programs of the resources of NIH.

(ii) Determining pending scientific opportunities, and public health needs, with respect to research within the jurisdiction of NIH.

(iii) For any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation in such report—

(I) analyzing the budgetary and operational consequences of the proposed changes;

(II) estimating the level of resources needed to implement the proposed changes; and

(III) assuming the proposed changes will be made and making a recommendation for the allocation of the resources of NIH among the national research institutes and national centers.

(C) CONSULTATION.—In carrying out subparagraph (A), the Board shall consult with—

(i) the heads of national research institutes and national centers whose directors are not members of the Board;

(ii) other scientific leaders who are officers or employees of NIH and are not members of the Board;

(iii) advisory councils of the national research institutes and national centers;

(iv) organizations representing the scientific community; and

(v) organizations representing patients.

(3) COMPOSITION OF BOARD.—The membership of the Board may not exceed 21 individuals, all of whom shall be voting members. The Board shall be composed of the following:

(A) The Director of NIH, who shall be a permanent member on an ex officio basis.

(B) Not fewer than 9 officials who are directors of national research institutes or national centers. The Secretary shall designate such officials for membership and shall ensure that the group of officials so designated includes directors of—

(i) national research institutes whose budgets are substantial relative to a majority of the other institutes;

(ii) national research institutes whose budgets are small relative to a majority of the other institutes;

(iii) national research institutes that have been in existence for a substantial period of time without significant organizational change under subsection (d);

(iv) as applicable, national research institutes that have undergone significant organization changes under such subsection, or that have been established under such subsection, other than national research institutes for which such changes have been in place for a substantial period of time; and

(v) national centers.

(C) Members appointed by the Secretary from among individuals who are not officers or employees of the United States. Such members shall include—

(i) individuals representing the interests of public or private institutions of higher education that have historically received funds from NIH to conduct research; and

(ii) individuals representing the interests of private entities that have received funds from NIH to conduct research or that have broad expertise regarding how the National Institutes of Health functions, exclusive of private entities to which clause (i) applies.

(4) CHAIR.—The Chair of the Board shall be selected by the Secretary from among the appointed members of the Board, except that the Secretary may select the Director of NIH as the Chair. The term of office of the Chair shall be 2 years.

(5) MEETINGS.—

(A) IN GENERAL.—The Board shall meet at the call of the Chair or upon the request of the Director of NIH, but not fewer than 5 times with respect to issuing any particular report under paragraph (2)(A). The location of the meetings of the Board is subject to the approval of the Director of NIH.

(B) PARTICULAR FORUMS.—Of the meetings held under subparagraph (A) with respect to a report under paragraph (2)(A)—

(i) one or more shall be directed toward the scientific community to address scientific needs and opportunities related to proposals for organizational changes under subsection (d), or as the case may be, related to a proposal that no such changes be made; and

(ii) one or more shall be directed toward consumer organizations to address the needs and opportunities of patients and their families with respect to proposals referred to in clause (i).

(C) AVAILABILITY OF INFORMATION FROM FORUMS.—For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

(6) COMPENSATION; TERM OF OFFICE.—The provisions of subsections (b)(4) and (c) of section 406 apply with respect to the Board to the same extent and in the same manner as such provisions apply with respect to an advisory council referred to in such subsections, except that the reference in such subsection (c) to 4 years regarding the term of an appointed member is deemed to be a reference to 5 years.

(7) REPORTS.—

(A) RECOMMENDATIONS FOR CHANGES.—Each report under paragraph (2)(A) shall be submitted to—

(i) the Committee on Energy and Commerce within the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions within the Senate;

(iii) the Secretary; and

(iv) officials with organizational authorities, other than any such official who served as a member of the Board with respect to the report involved.

(B) AVAILABILITY TO PUBLIC.—The Director of NIH shall post each report under paragraph (2) on the Internet site of the National Institutes of Health.

(C) REPORT ON BOARD ACTIVITIES.—Not later than 18 months after the date of the enactment of the National Institutes of Health Reform Act of 2006, the Board shall submit to the committees specified in subparagraph (A) a report describing the activities of the Board.

(f) ORGANIZATIONAL CHANGES PER RECOMMENDATION OF SCIENTIFIC MANAGEMENT REVIEW BOARD.—

(1) IN GENERAL.—With respect to an official who has organizational authorities within the meaning of subsection (e)(2)(A), if a recommendation to the official for an organizational change is made in a report under such subsection, the official shall, except as provided in paragraph (2) of this subsection, make the change in accordance with the following:

(A) Not later than 100 days after the report is submitted under subsection (e)(7)(A), the official shall initiate the applicable public process required in subsection (d) toward making the change.

(B) The change shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

(2) OBJECTION BY DIRECTOR OF NIH.—

(A) IN GENERAL.—Paragraph (1) does not apply to a recommendation for an organizational change made in a report under subsection (e)(2)(A) if, not later than 90 days after the report is submitted under subsection (e)(7)(A), the Director of NIH submits to the committees specified in such subsection a report providing that the Director objects to the change, which report includes the reasons underlying the objection.

(B) SCOPE OF OBJECTION.—For purposes of subparagraph (A), an objection by the Director of NIH may be made to the entirety of a recommended organizational change or to 1 or more aspects of the change. Any aspect of a change not objected to by the Director in a report under subparagraph (A) shall be implemented in accordance with paragraph (1).

(g) DEFINITIONS.—For purposes of this title:

(1) The term "Director of NIH" means the Director of the National Institutes of Health.

(2) The terms "national research institute" and "national center" mean an agency of the National Institutes of Health that is—

(A) listed in subsection (b) and not terminated under subsection (d)(2)(A); or

(B) established by the Director of NIH under such subsection.

(h) REFERENCES TO NIH.—For purposes of this title, a reference to the National Institutes of Health includes its agencies.

APPOINTMENT AND AUTHORITY OF DIRECTOR OF NIH

SEC. 402. (a) The National Institutes of Health shall be headed by the ❙Director of the National Institutes of Health (hereafter in this title referred to as the "Director of NIH") who shall❙ *Director*

of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) In carrying out the purposes of section 301, the Secretary, acting through the Director of NIH—

[(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

[(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

[(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 492;]

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary, duplicative research, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health;

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 403; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B) may, with respect to funds reserved under section 402A(c)(1) for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers; and

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 492 and that, after such review, the research is reviewed in accordance with section 492A(a)(2) by the appropriate advisory council under section 406 before the research proposals are approved for funding;

(10) shall approve the establishment of all centers of excellence recommended by the national research institutes, other than centers recognized under section 414;

(11) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 487;

(12) may, from funds appropriated under section 402A(b), reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

[(4)**]** *(14)* for the national research institutes and administrative entities within the National Institutes of Health—

(A) * * *

* * * * * * *

[(5)**]** *(15)* may secure resources for research conducted by or through the National Institutes of Health;

[(6)] *(16)* may, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this title and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

[(7)] *(17)* may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

[(8)] *(18)* may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

[(9)] *(19)* may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

[(10)] *(20)* may accept voluntary and uncompensated services;

[(11)] *(21)* may perform such other administrative functions as the Secretary determines are needed to effectively carry out this title; *and*

[(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 486(b);

[(13) may conduct and support research training—

[(A) for which fellowship support is not provided under section 487; and

[(B) which does not consist of residency training of physicians or other health professionals; and]

[(14)] *(22)* may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5, United States Code, relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38, United States Code.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under [paragraph (6)] *paragraph (16)*. The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

* * * * * * *

[(i)(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this Act for the National Institutes of Health. The purposes for which such fund may be expended include—

[(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

[(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

[(C) purchasing or renting equipment and quarters for activities of such Institutes.

[(2) Not later than February 10 of each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

[(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.]

[(j)] *(i)*(1)(A) [The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank").] The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.

[(k)**]** *(j)*(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(k) COUNCIL OF COUNCILS.—

(1) ESTABLISHMENT.—The Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

(B) CERTAIN REQUIREMENTS.—In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) NOMINATION.—The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(3) TERMS.—

(A) IN GENERAL.—The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) TERMS OF INITIAL APPOINTEES.—Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) VACANCIES.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

[(l) The Director of NIH shall carry out the program established in part F of title XII (relating to interagency research on trauma).**]**

SEC. 402A. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this title, there are authorized to be appropriated—

(1) $29,747,874,000 for fiscal year 2007;

(2) $31,235,268,000 for fiscal year 2008; and

(3) $32,797,032,000 for fiscal year 2009.

(b) OFFICE OF THE DIRECTOR.—Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this title carried out through the Office of the Director of NIH the following amount, as applicable to the fiscal year:

(1) $1,000,000,000 for fiscal year 2007.

(2) $1,050,000,000 for fiscal year 2008.

(3) $1,102,500,000 for fiscal year 2009.

(c) TRANS-NIH RESEARCH.—

(1) COMMON FUND.—

(A) ANNUAL RESERVATION OF AMOUNTS.—Of the total amount appropriated under subsection (a) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH

shall reserve the applicable amount under subparagraph (B) for allocations under section 402(b)(7)(B) (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), which reservations shall constitute an account to be known as the Common Fund.

(B) AMOUNT OF RESERVATION.—Subject to subparagraph (C), the amount reserved by the Director of NIH under subparagraph (A) for a fiscal year shall be the sum of—

(i) the base amount determined under subparagraph (D); and

(ii) any additional amount determined under subparagraph (E).

Amounts reserved under the preceding sentence shall remain available until expended.

(C) MAXIMUM RESERVATION.—

(i) IN GENERAL.—The amount reserved by the Director of NIH under subparagraph (A) for a fiscal year shall not exceed 5 percent of the total amount appropriated under subsection (a) for such fiscal year, subject to clause (ii).

(ii) APPLICABILITY.—Clause (i) may not apply with respect to any fiscal year beginning after the submission of recommendations under subparagraph (F).

(iii) PRESERVATION OF RESERVATION.—For any fiscal year following the first fiscal year for which the percentage that applies for purposes of clause (i) is 5 percent, the reservation under subparagraph (A) for the fiscal year involved may not be less than 5 percent of the total amount appropriated under subsection (a) for such fiscal year. For fiscal year 2008 and each subsequent fiscal year, the percentage constituted by the reservation under subparagraph (A) relative to the total amount appropriated under subsection (a) for the fiscal year involved may not be less than the percentage constituted by the reservation under such subparagraph for the preceding fiscal year relative to the total amount appropriated under subsection (a) for such preceding fiscal year.

(D) BASE AMOUNT.—The base amount referred to in subparagraph (B)(i) for a fiscal year is—

(i) for fiscal year 2007, the amount reserved by the Director of NIH for fiscal year 2006 for research described in section 402(b)(7)(A)(i); and

(ii) for fiscal year 2008 and each subsequent fiscal year, the amount reserved under subparagraph (A) for the preceding fiscal year.

(E) ADDITIONAL AMOUNT CORRESPONDING TO INCREASES IN APPROPRIATIONS.—The additional amount referred to in subparagraph (B)(ii) is 50 percent of the amount by which the total amount appropriated under subsection (a) for the fiscal year involved exceeds the total amount appropriated under such subsection for the preceding fiscal year, except that for any fiscal year beginning after the submission of recommendations under subparagraph (F), such percentage

may be adjusted by the Director of NIH, and such percentage shall be adjusted by the Director to the extent necessary for compliance with subparagraph (C)(iii).

(F) EVALUATION.—During the 6-month period following the end of the first fiscal year for which the amount reserved by the Director of NIH under subparagraph (A) is equal to 5 percent of the total amount appropriated under subsection (a) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 402(k), shall submit recommendations to the Congress for changes to the amount of the reservation under subparagraph (A).

(2) TRANS-NIH RESEARCH REPORTING.—

(A) LIMITATION.—With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) REPORTING.—Not later than January 1, 2008, and each January 1st thereafter—

(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).

(C) DETERMINATION.—For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 402(b)(7)(B) shall be included.

(D) VERIFICATION OF AMOUNTS.—Upon receipt of each report submitted under subparagraph (B)(i), the Director of NIH shall review and verify the accuracy of the amounts specified in the report.

(E) WAIVER.—At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B)(i) is inconsistent with the mission of such institute or center.

(d) TRANSFER AUTHORITY.—Of the total amount appropriated under subsection (a) for a fiscal year, the Director of NIH may (in addition to the reservation under (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this title and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not

decrease any appropriation account under subsection (a) by more than 1 percent.

(e) RULE OF CONSTRUCTION.—This section may not be construed as affecting the authorities of the Director of NIH under section 401.

[REPORT OF DIRECTOR OF NIH

[SEC. 403. The Secretary shall transmit to the President and to the Congress a biennial report which shall be prepared by the Director of NIH and which shall consist of—

[(1) a description of the activities carried out by and through the National Institutes of Health and the policies respecting the programs of the National Institutes of Health and such recommendations respecting such policies as the Secretary considers appropriate;

[(2) a description of the activities undertaken to improve grants and contracting accountability and technical and scientific peer review procedures of the National Institutes of Health and the national research institutes;

[(3) the reports made by the Associate Director for Prevention under section 402(f) during the period for which the biennial report is prepared;

[(4) a description of the health related behavioral research that has been supported by the National Institutes of Health in the preceding 2-year period, and a description of any plans for future activity in such area; and

[(5) the biennial reports of the Directors of each of the national research institutes, the Director of the Division of Research Resources, and the Director of the National Center for Nursing Research.

The first report under this section shall be submitted not later than July 1, 1986, and shall relate to the fiscal year ending September 30, 1985. The next report shall be submitted not later than December 30, 1988, and shall relate to the two-fiscal-year period ending on the preceding September 30. Each subsequent report shall be submitted not later than 90 days after the end of the two-fiscal-year period for which the report is to be submitted.]

SEC. 402B. ELECTRONIC CODING OF GRANTS AND ACTIVITIES.

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

SEC. 403. BIENNIAL REPORTS OF DIRECTOR OF NIH.

(a) IN GENERAL.—The Director of NIH shall submit directly to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

(1) An assessment of the state of biomedical and behavioral research.

(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

(3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 402(b)(7) through the Division of Program Coordination, Planning, and Strategic Initiatives.

(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

(A) The catalog shall, for each such activity—

(i) identify the agency or agencies involved;

(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

(iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on health disparities.

(C) Research activities listed in the catalog shall include the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clearinghouses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including National Research Service Awards and a breakdown by demographic variables and other appropriate categories.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 492B (regarding inclusion of women and minorities in clinical research).

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories:

(A) Cancer.

(B) Neurosciences.

(C) Life stages, human development, and rehabilitation.

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

(I) Chronic diseases, including pain and palliative care.

(J) Infectious diseases and bioterrorism.

(K) Health disparities.

(L) Such additional categories as the Director determines to be appropriate.

(b) REQUIREMENT REGARDING DISEASE-SPECIFIC RESEARCH ACTIVITIES.—In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

(1) present information in a standardized format;

(2) identify the actual dollar amounts obligated for such activities; and

(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

(c) ADDITIONAL REPORTS.—In addition to reports required by subsections (a) and (b), the Director of NIH may submit to the Congress such additional reports as the Director determines to be appropriate.

SEC. 403A. ANNUAL REPORTING TO INCREASE INTERAGENCY COLLABORATION AND COORDINATION.

(a) COLLABORATION WITH OTHER HHS AGENCIES.—On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

(b) CLINICAL TRIALS.—Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 402(j).

(c) HUMAN TISSUE SAMPLES.—On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

(d) FIRST REPORT.—The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

SEC. 403B. ANNUAL REPORTING TO PREVENT FRAUD AND ABUSE.

(a) WHISTLEBLOWER COMPLAINTS.—

(1) IN GENERAL.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

(2) CONTENTS.—For each whistleblower complaint pending during the year for which a report is submitted under this subsection, the report shall identify the following:

(A) Each agency of the National Institutes of Health involved.

(B) The status of the complaint.

(C) The resolution of the complaint to date.

(b) EXPERTS AND CONSULTANTS.—On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report that—

(1) identifies the number of experts and consultants, including any special consultants, whose services are obtained by the National Institutes of Health or its agencies;

(2) specifies whether such services were obtained under section 207(f), section 402(d), or other authority;

(3) describes the qualifications of such experts and consultants;

(4) describes the need for hiring such experts and consultants; and

(5) if such experts and consultants make financial disclosures to the National Institutes of Health or any of its agencies, specifies the income, gifts, assets, and liabilities so disclosed.

(c) FIRST REPORT.—The first report under subsections (a) and (b) shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006.

DES

SEC. [403A] *403C*. (a) * * *

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[(e) In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 2003.]

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CHILDREN'S VACCINE INITIATIVE

SEC. 404B. (a) * * *

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[(c) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section $20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.]

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SEC. 404E. MUSCULAR DYSTROPHY; INITIATIVE THROUGH DIRECTOR OF NATIONAL INSTITUTES OF HEALTH.

(a) * * *

(b) CENTERS OF EXCELLENCE.—

(1) * * *

* * * * * * *

[(3) COORDINATION OF CENTERS; REPORTS.—The Director of NIH—

[(A) shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers; and

[(B) shall require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.]

(3) COORDINATION OF CENTERS.—The Director of NIH shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers.

* * * * * * *

[(f) REPORTS TO CONGRESS.—The Coordinating Committee shall biennially submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that describes the research, education, and other activities on muscular dystrophy being conducted or supported through the Department of Health and Human Services. Each such report shall include the following:

[(1) The plan under subsection (e)(1) (or revisions to the plan, as the case may be).

[(2) Provisions specifying the amounts expended by the Department of Health and Human Services with respect to various forms of muscular dystrophy, including Duchenne, myotonic, FSHD and other forms of muscular dystrophy.

[(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on all muscular dystrophies.]

[(g)] *(f)* PUBLIC INPUT.—The Secretary shall, under subsection (a)(1), provide for a means through which the public can obtain information on the existing and planned programs and activities of the Department of Health and Human Services with respect to various forms of muscular dystrophy and through which the Secretary can receive comments from the public regarding such programs and activities.

[(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2002 through 2006. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to muscular dystrophy.]

OFFICE OF RARE DISEASES

SEC. 404F. (a) * * *

(b) DUTIES.—

(1) IN GENERAL.—The Director of the Office shall carry out the following:

(A) * * *

* * * * * * *

[(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research

institutes and centers or other entities in the field of research on rare diseases.

[(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.]

* * * * * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006.]

RARE DISEASE REGIONAL CENTERS OF EXCELLENCE

SEC. 404G. (a) * * *

[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006.]

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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[BIENNIAL REPORT

[SEC. 407. The Director of each national research institute, after consultation with the advisory council for the institute, shall prepare for inclusion in the biennial report made under section 403 a biennial report which shall consist of a description of the activities of the institute and program policies of the Director of the institute in the fiscal years respecting which the report is prepared. The Director of each national research institute may prepare such additional reports as the Director determines appropriate. The Director of each national research institute shall provide the advisory council for the institute an opportunity for the submission of the written comments referred to in section 406(g).]

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RESEARCH ON OSTEOPOROSIS, PAGET'S DISEASE, AND RELATED BONE DISORDERS

SEC. 409A. (a) * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.]

* * * * * * *

PARKINSON'S DISEASE

SEC. 409B. (a) IN GENERAL.—The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of

amounts appropriated [under subsection (e)] *to carry out this section*).

* * * * * * *

[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section and section 301 and title IV of the Public Health Service Act with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to $100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000.]

EXPANSION, INTENSIFICATION, AND COORDINATION OF ACTIVITIES OF NATIONAL INSTITUTES OF HEALTH WITH RESPECT TO RESEARCH ON AUTISM

SEC. 409C. (a) * * *

(b) CENTERS OF EXCELLENCE.—

(1) * * *

* * * * * * *

[(4) COORDINATION OF CENTERS; REPORTS.—The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director.]

[(5)] *(4)* ORGANIZATION OF CENTERS.—Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

[(6)] *(5)* NUMBER OF CENTERS; DURATION OF SUPPORT.—

(A) * * *

* * * * * * *

[(e) FUNDING.—There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose.]

PEDIATRIC RESEARCH INITIATIVE

SEC. 409D. (a) * * *

* * * * * * *

[(d) AUTHORIZATION.—For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.]

[(e)] *(d)* TRANSFER OF FUNDS.—The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

SEC. 409E. AUTOIMMUNE DISEASES.

(a) * * *

* * * * * * *

[(d) REPORTS TO CONGRESS.—The Coordinating Committee under subsection (b)(1) shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on

Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the national research institutes, and that in addition includes the following:

[(1) The plan under subsection (c)(1) (or revisions to the plan, as the case may be).

[(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

[(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases.

[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases.]

MUSCULAR DYSTROPHY RESEARCH

SEC. 409F. (a) * * *

* * * * * * *

[(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for each of the fiscal years 2001 through 2005. Amounts appropriated under this subsection shall be in addition to any other amounts appropriated for such purpose.]

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SEC. 409H. ENHANCEMENT AWARDS.

(a) MENTORED PATIENT-ORIENTED RESEARCH CAREER DEVELOPMENT AWARDS.—

(1) * * *

* * * * * * *

[(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.]

(b) MID-CAREER INVESTIGATOR AWARDS IN PATIENT-ORIENTED RESEARCH.—

(1) * * *

* * * * * * *

[(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.]

(c) GRADUATE TRAINING IN CLINICAL INVESTIGATION AWARD.—

(1) * * *

* * * * * * *

[(5) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.]

(d) CLINICAL RESEARCH CURRICULUM AWARDS.—

(1) * * *

* * * * * * *

[(4) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year.]

SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

(a) * * *

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[(d) AUTHORIZATION OF APPROPRIATIONS.—

[(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

[(A) $200,000,000 for fiscal year 2002; and

[(B) such sums as are necessary for each of the five succeeding fiscal years.

[(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.]

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

Subpart 1—National Cancer Institute

* * * * * * *

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 417B. (a) ACTIVITIES GENERALLY.—For the purpose of carrying out this subpart, there are authorized to be appropriated $2,728,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

[(b) BREAST CANCER AND GYNECOLOGICAL CANCERS.—

[(1) BREAST CANCER.—

[(A) For the purpose of carrying out subparagraph (A) of section 417(c)(1), there are authorized to be appropriated $225,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

[(B) For the purpose of carrying out subparagraphs (B) through (E) of section 417(c)(1), there are authorized to be appropriated $100,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

[(2) OTHER CANCERS.—For the purpose of carrying out subsection (d) of section 417, there are authorized to be appropriated $75,000,000 for fiscal year 1994, and such sums as are

necessary for each of the fiscal years 1995 through 2003. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

[(c) PROSTATE CANCER.—For the purpose of carrying out section 417A, there are authorized to be appropriated $72,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2004. Such authorizations of appropriations are in addition to the authorizations of appropriations established in subsection (a) with respect to such purpose.

[(d) ALLOCATION REGARDING CANCER CONTROL.—

[(1) IN GENERAL.—Of the amounts appropriated for the National Cancer Institute for a fiscal year, the Director of the Institute shall make available not less than the applicable percentage specified in paragraph (2) for carrying out the cancer control activities authorized in section 412 and for which budget estimates are made under section 413(b)(9) for the fiscal year.

[(2) APPLICABLE PERCENTAGE.—The percentage referred to in paragraph (1) is—

[(A) 7 percent, in the case of fiscal year 1994;

[(B) 9 percent, in the case of fiscal year 1995; and

[(C) 10 percent, in the case of fiscal year 1996 and each subsequent fiscal year.]

SEC. 417C. GRANTS FOR EDUCATION, PREVENTION, AND EARLY DETECTION OF RADIOGENIC CANCERS AND DISEASES.

(a) * * *

* * * * * * *

[(f) REPORT TO CONGRESS.—Beginning on October 1 of the year following the date on which amounts are first appropriated to carry out this section and annually on each October 1 thereafter, the Secretary shall submit a report to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on the Judiciary and the Committee on Commerce of the House of Representatives. Each report shall summarize the expenditures and programs funded under this section as the Secretary determines to be appropriate.

[(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for the purpose of carrying out this section $20,000,000 for fiscal year 1999 and such sums as may be necessary for each of the fiscal years 2000 through 2009.]

SEC. 417D. RESEARCH, INFORMATION, AND EDUCATION WITH RESPECT TO BLOOD CANCER.

(a) JOE MOAKLEY RESEARCH EXCELLENCE PROGRAM.—

(1) * * *

* * * * * * *

[(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.]

(b) GERALDINE FERRARO CANCER EDUCATION PROGRAM.—

(1) * * *

* * * * * * *

[(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose.]

Subpart 2—National Heart, Lung, and Blood Institute

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HEART ATTACK, STROKE, AND OTHER CARDIOVASCULAR DISEASES IN WOMEN

SEC. 424A. (a) * * *

* * * * * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose.]

COORDINATION OF FEDERAL ASTHMA ACTIVITIES

SEC. 424B (a) IN GENERAL.—The Director of Institute shall, through the National Asthma Education Prevention Program Coordinating Committee—

(1) identify all Federal programs that carry out asthma-related activities; *and*

(2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma[; and].

[(3) not later than 12 months after the date of the enactment of the Children's Health Act of 2000, submit recommendations to the appropriate committees of the Congress on ways to strengthen and improve the coordination of asthma-related activities of the Federal Government.]

* * * * * * *

[(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 425. For the purpose of carrying out this subpart, there are authorized to be appropriated $1,500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.]

Subpart 3—National Institute of Diabetes and Digestive and Kidney Diseases

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INTERAGENCY COORDINATING COMMITTEES

SEC. 429. (a) * * *

* * * * * * *

[(c) Each Committee shall prepare an annual report for—

[(1) the Secretary;

[(2) the Director of NIH; and

[(3) the Advisory Board established under section 430 for the diseases for which the Committee was established,

detailing the work of the Committee in carrying out paragraphs (1) and (2) of subsection (a) in the fiscal year for which the report was prepared. Such report shall be submitted not later than 120 days after the end of each fiscal year.

[(d) In each annual report prepared by the Diabetes Mellitus Interagency Coordinating Committee pursuant to subsection (c), the Committee shall include an assessment of the Federal activities and programs related to pancreatic islet cell transplantation. Such assessment shall, at a minimum, address the following:

[(1) The adequacy of Federal funding for taking advantage of scientific opportunities relating to pancreatic islet cell transplantation.

[(2) Current policies and regulations affecting the supply of pancreata for islet cell transplantation.

[(3) The effect of xenotransplantation on advancing pancreatic islet cell transplantation.

[(4) The effect of United Network for Organ Sharing policies regarding pancreas retrieval and islet cell transplantation.

[(5) The existing mechanisms to collect and coordinate outcomes data from existing islet cell transplantation trials.

[(6) Implementation of multiagency clinical investigations of pancreatic islet cell transplantation.

[(7) Recommendations for such legislation and administrative actions as the Committee considers appropriate to increase the supply of pancreata available for islet cell transplantation.]

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JUVENILE DIABETES

SEC. 434A. (a) * * *

* * * * * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

Subpart 4—National Institute of Arthritis and Musculoskeletal and Skin Diseases

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LUPUS

SEC. 441A. (a) * * *

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[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.]

ADVISORY BOARD

SEC. 442. (a) * * *

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[(j) The Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to arthritis, musculoskeletal diseases, and skin diseases;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year for which the report is made;

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 436(a); and

[(5) contains recommendations for expanding the Institute's funding of research directly applicable to the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.]

[(k)] *(j)* The National Arthritis Advisory Board in existence on the date of enactment of the Health Research Extension Act of 1985 shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after such date. The members of the Board in existence on such date may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

JUVENILE ARTHRITIS AND RELATED CONDITIONS

SEC. 442A. (a) * * *

* * * * * * *

[(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

Subpart 5—National Institute on Aging

* * * * * * *

AGING PROCESSES REGARDING WOMEN

SEC. 445H. [(a)] The Director of the Institute, in addition to other special functions specified in section 444 and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behav-

ioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

[(b) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose.]

SEC. 445I. ALZHEIMER'S CLINICAL RESEARCH AND TRAINING AWARDS.

(a) * * *

* * * * * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 445J. For the purpose of carrying out this subpart, there are authorized to be appropriated $500,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.]

Subpart 6—National Institute of Allergy and Infectious Diseases

* * * * * * *

RESEARCH AND RESEARCH TRAINING REGARDING TUBERCULOSIS

SEC. 447A. [(a)] In carrying out section 446, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

[(b) For the purpose of carrying out subsection (a), there are authorized to be appropriated $50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.]

SEC. 447B. SEXUALLY TRANSMITTED DISEASE CLINICAL RESEARCH AND TRAINING AWARDS.

(a) * * *

* * * * * * *

[(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005.]

Subpart 7—National Institute of Child Health and Human Development

* * * * * * *

RESEARCH CENTERS WITH RESPECT TO CONTRACEPTION AND INFERTILITY

SEC. 452A. (a) * * *

* * * * * * *

[(g) For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.]

* * * * * * *

FRAGILE X

SEC. 452E. (a) * * *

(b) RESEARCH CENTERS.—

(1) * * *

* * * * * * *

[(7) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

INVESTMENT IN TOMORROW'S PEDIATRIC RESEARCHERS

SEC. 452G. [(a) ENHANCED SUPPORT.—]In order to ensure the future supply of researchers dedicated to the care and research needs of children, the Director of the Institute, after consultation with the Administrator of the Health Resources and Services Administration, shall support activities to provide for—

(1) an increase in the number and size of institutional training grants to institutions supporting pediatric training; and

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research.

[(b) AUTHORIZATION.—For the purpose of carrying out subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

* * * * * * *

Subpart 12—National Institute of Environmental Health Sciences

* * * * * * *

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY BOARD

SEC. 464D. (a) * * *

* * * * * * *

[(j) The Advisory Board shall prepare an annual report for the Secretary which—

[(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

[(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

[(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

[(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 464A(a).]

INTERAGENCY COORDINATING COMMITTEE

SEC. 464E. (a) * * *

* * * * * * *

[(e) Not later than 120 days after the end of each fiscal year, the Coordinating Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out subsection (b).]

* * * * * * *

Subpart 14—National Institute on Alcohol Abuse and Alcoholism

PURPOSE OF INSTITUTE

SEC. 464H. (a) * * *

* * * * * * *

[(d) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $300,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

[(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to alcohol abuse and alcoholism.]

* * * * * * *

Subpart 15—National Institute on Drug Abuse

PURPOSE OF INSTITUTE

SEC. 464L. (a) * * *

* * * * * * *

[(d) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, other than section 464P, there are authorized to be appropriated $440,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

[(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to drug abuse.]

* * * * * * *

DRUG ABUSE RESEARCH CENTERS

SEC. 464N. (a) * * *

* * * * * * *

(c) DRUG ABUSE AND ADDICTION RESEARCH.—

(1) * * *

* * * * * * *

[(4) AUTHORIZATION OF APPROPRIATIONS.—

[(A) IN GENERAL.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each fiscal year.

[(B) SUPPLEMENT NOT SUPPLANT.—Amounts appropriated pursuant to the authorization of appropriations in subparagraph (A) for a fiscal year shall supplement and not supplant any other amounts appropriated in such fiscal year for research on drug abuse and addiction.]

* * * * * * *

MEDICATION DEVELOPMENT PROGRAM

SEC. 464P. (a) * * *

* * * * * * *

[(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $85,000,000 for fiscal year 1993, and $95,000,000 for fiscal year 1994.]

Subpart 16—National Institute of Mental Health

PURPOSE OF INSTITUTE

SEC. 464R. (a) * * *

* * * * * * *

[(f) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $675,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994.

[(2) ALLOCATION FOR HEALTH SERVICES RESEARCH.—Of the amounts appropriated under paragraph (1) for a fiscal year, the Director shall obligate not less than 15 percent to carry out health services research relating to mental health.]

* * * * * * *

OFFICE OF RURAL MENTAL HEALTH RESEARCH

SEC. 464T. (a) * * *

* * * * * * *

[(e) REPORT TO CONGRESS.—Not later than February 1, 1993, and each fiscal year thereafter, the Director shall submit to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce (of the House of Representatives), and to the Committee on Labor and Human Resources (of the Senate), a report describing the activities of the Office during the preceding

fiscal year, including a summary of the activities of demonstration projects and a summary of evaluations of the projects.]

* * * * * * *

Subpart 17—National Institute of Nursing Research

* * * * * * *

PURPOSE OF THE INSTITUTE

SEC. 464z. (a) * * *

* * * * * * *

[(d)(1) Subject to paragraph (2), for the purpose of carrying out this section:

[(A) For fiscal year 2001, there is authorized to be appropriated an amount equal to the amount obligated by the National Institutes of Health during fiscal year 2000 for biomedical imaging and bioengineering, except that such amount shall be adjusted to offset any inflation occurring after October 1, 1999.

[(B) For each of the fiscal years 2002 and 2003, there is authorized to be appropriated an amount equal to the amount appropriated under subparagraph (A) for fiscal year 2001, except that such amount shall be adjusted for the fiscal year involved to offset any inflation occurring after October 1, 2000.

[(2) The authorization of appropriations for a fiscal year under paragraph (1) is hereby reduced by the amount of any appropriation made for such year for the conduct or support by any other national research institute of any program with respect to biomedical imaging and bioengineering.]

Subpart [3—National Center for Human Genome Research] *19—National Human Genome Research Institute*

PURPOSE OF THE [CENTER] *INSTITUTE*

SEC. [485B] *464z–1.* (a) The general purpose of the [National Center for Human Genome Research] *National Human Genome Research Institute* (in this subpart referred to as the "[Center] *Institute*") is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) * * *

* * * * * * *

(b) The Director of the [Center] *Institute* may conduct and support research training—

(1) * * *

* * * * * * *

(c)(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the [Center] *Institute* shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Direc-

tor of the [Center] *Institute* certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 491 and 492.

PART D—NATIONAL LIBRARY OF MEDICINE

Subpart 1—General Provisions

* * * * * * *

LIBRARY FACILITIES

SEC. 467. [There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library.] The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for [such buildings and facilities] *suitable and adequate buildings and facilities for use of the Library* and to erect thereon, furnish, and equip such buildings and facilities. [The amounts authorized to be appropriated by this section include] *Amounts appropriated to carry out this section may be used for* the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

[AUTHORIZATION OF APPROPRIATIONS

[SEC. 468. (a) For the purpose of carrying out this part, there are authorized to be appropriated $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

[(b) Amounts appropriated under subsection (a) and made available for grants or contracts under any of sections 472 through 476 shall remain available until the end of the fiscal year following the fiscal year for which the amounts were appropriated.]

* * * * * * *

PART E—OTHER AGENCIES OF NIH

Subpart 1—National Center for Research Resources

SEC. 481A. BIOMEDICAL AND BEHAVIORAL RESEARCH FACILITIES.

(a) * * *

* * * * * * *

(c) REQUIREMENTS FOR GRANTS.—

(1) * * *

(2) INSTITUTIONS OF EMERGING EXCELLENCE.—From the amount appropriated [under subsection (i)(1)] *to carry out this section* for a fiscal year up to $50,000,000, the Director of the Center shall make available 25 percent of such amount, and from the amount appropriated [under such subsection] *to carry out this section* for a fiscal year that is over $50,000,000,

the Director of the Center shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) * * *

* * * * * * *

[(h) REPORT TO CONGRESS.—The Director of the Center shall prepare and submit to the appropriate committees of Congress a biennial report concerning the status of the biomedical and behavioral research facilities and the availability and condition of technologically sophisticated laboratory equipment in the United States. Such reports shall be developed in concert with the report prepared by the National Science Foundation on the needs of research facilities of universities as required under section 108 of the National Science Foundation Authorization Act for Fiscal Year 1986 (42 U.S.C. 1886).

[(i) AUTHORIZATION OF APPROPRIATIONS.—

[(1) CENTER.—For the purpose of carrying out this section with respect to the Center, there are authorized to be appropriated $250,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

[(2) NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.—For the purpose of carrying out this section with respect to the National Institute of Allergy and Infectious Diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.]

CONSTRUCTION OF REGIONAL CENTERS FOR RESEARCH ON PRIMATES

SEC. 481B. (a) With respect to activities carried out by the National Center for Research Resources to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 1994 through 1996, reserve from the amounts appropriated [under section 481A(h)] *to carry out section 481A* up to $2,500,000 for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

* * * * * * *

[SEC. 481C. GENERAL CLINICAL RESEARCH CENTERS.

[(a) GRANTS.—The Director of the National Center for Research Resources shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

[(b) ACTIVITIES.—In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

[(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.]

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Subpart 4—Office of Dietary Supplements

SEC. 485C. DIETARY SUPPLEMENTS.

(a) * * *

* * * * * * *

[(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year.]

* * * * * * *

Subpart 6—National Center on Minority Health and Health Disparities

SEC. 485E. PURPOSE OF CENTER.

(a) * * *

* * * * * * *

[(k) ANNUAL REPORT.—The Director of the Center shall prepare an annual report on the activities carried out or to be carried out by the Center, and shall submit each such report to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Commerce of the House of Representatives, the Secretary, and the Director of NIH. With respect to the fiscal year involved, the report shall—

[(1) describe and evaluate the progress made in health disparities research conducted or supported by the national research institutes;

[(2) summarize and analyze expenditures made for activities with respect to health disparities research conducted or supported by the National Institutes of Health;

[(3) include a separate statement applying the requirements of paragraphs (1) and (2) specifically to minority health disparities research; and

[(4) contain such recommendations as the Director considers appropriate.

[(l) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subpart, there are authorized to be appropriated $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for the conduct and support of minority health disparities research or other health disparities research by the agencies of the National Institutes of Health.]

SEC. 485F. CENTERS OF EXCELLENCE FOR RESEARCH EDUCATION AND TRAINING.

(a) * * *

* * * * * * *

[(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.]

SEC. 485G. LOAN REPAYMENT PROGRAM FOR MINORITY HEALTH DISPARITIES RESEARCH.

(a) * * *

* * * * * * *

[(e) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

[(2) AVAILABILITY OF APPROPRIATIONS.—Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.]

SEC. 485H. GENERAL PROVISIONS REGARDING THE CENTER.

[(a) ADMINISTRATIVE SUPPORT FOR CENTER.—The Secretary,] *The Secretary,* acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Center and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

[(b) EVALUATION AND REPORT.—

[(1) EVALUATION.—Not later than 5 years after the date of the enactment of this subpart, the Secretary shall conduct an evaluation to—

[(A) determine the effect of this subpart on the planning and coordination of health disparities research programs at the agencies of the National Institutes of Health;

[(B) evaluate the extent to which this subpart has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

[(C) provide, to the extent determined by the Secretary to be appropriate, recommendations concerning future legislative modifications with respect to this subpart, for both minority health disparities research and other health disparities research.

[(2) MINORITY HEALTH DISPARITIES RESEARCH.—The evaluation under paragraph (1) shall include a separate statement that applies subparagraphs (A) and (B) of such paragraph to minority health disparities research.

[(3) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Commerce of the House of Representatives, a report concerning the results of such evaluation.]

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PART G—AWARDS AND TRAINING

Ruth L. Kirschstein National Research Service Awards

SEC. 487. (a) * * *

* * * * * * *

[(d) For the purpose of carrying out this section, there are authorized to be appropriated $400,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996. Of the amounts appropriated under this subsection—

[(1) not less than 15 percent shall be made available for payments under Ruth L. Kirschstein National Research Service Awards provided by the Secretary under subsection (a)(1)(A);

[(2) not less than 50 percent shall be made available for grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards;

[(3) 1 percent shall be made available to the Secretary, acting through the Administrator of the Health Resources and Services Administration, for payments under Ruth L. Kirschstein National Research Service Awards which (A) are made to individuals affiliated with entities which have received grants or contracts under section 747, 748, or 749, and (B) are for research in primary medical care; and 1 percent shall be made available for payments under Ruth L. Kirschstein National Research Service Awards made for health services research by the Agency for Health Care Policy and Research under section 304(a); and

[(4) not more than 4 percent may be obligated for Ruth L. Kirschstein National Research Service Awards for periods of three months or less.]

LOAN REPAYMENT PROGRAM FOR RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

SEC. 487A. (a) * * *

* * * * * * *

[(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2001.]

* * * * * * *

SEC. 487F. LOAN REPAYMENT PROGRAM REGARDING CLINICAL RESEARCHERS.

(a) * * *

* * * * * * *

[(c) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

[(2) AVAILABILITY.—Amounts appropriated for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.]

* * * * * * *

PART H—GENERAL PROVISIONS

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CERTAIN PROVISIONS REGARDING REVIEW AND APPROVAL OF PROPOSALS FOR RESEARCH

SEC. 492A. (a) REVIEW AS PRECONDITION TO RESEARCH.—

(1) * * *

(2) PEER REVIEW.—In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 492 unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review*, and unless a majority of the voting members of the appropriate advisory council under section 406, or as applicable, of the advisory council under section 402(k), has recommended the proposal for approval*.

* * * * * * *

RESEARCH ON PUBLIC HEALTH EMERGENCIES

SEC. 494. ❚(a) If the Secretary❚ *If the Secretary* determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) * * *

* * * * * * *

❚(b) Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) in such fiscal year.❚

* * * * * * *

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

SEC. 499. ESTABLISHMENT AND DUTIES OF FOUNDATION.

(a) * * *

* * * * * * *

(d) BOARD OF DIRECTORS.—

(1) COMPOSITION.—

(A) * * *

* * * * * * *

(D)(i) * * *

❚(ii) Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate.❚

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

* * * * * * *

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of *appointed* members of the Board shall be greater than the number specified in subparagraph (C).

* * * * * * *

(3) TERMS AND VACANCIES.—

(A) * * *

[(B) Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board.]

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

* * * * * * *

(5) MEETINGS AND QUORUM.—A majority of the *appointed* members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

* * * * * * *

(j) GENERAL PROVISIONS.—

(1) * * *

(2) FINANCIAL CONFLICTS OF INTEREST.—Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection [(d)(2)(B)(i)(II)] *(d)(6)*) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 109(16) of the Ethics in Government Act of 1978) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

* * * * * * *

(4) REPORTS.—

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments

of the Foundation*, including an accounting of the use of amounts transferred under subsection (l).*

* * * * * * *

[(C) The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.]

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

* * * * * * *

(10) TRANSFER OF FUNDS.—The Foundation may transfer funds to the National Institutes [of Health.] *of Health and the National Institutes of Health may accept transfers of funds from the Foundation.* Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

* * * * * * *

[(l) FUNDING.—

[(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this part, there is authorized to be appropriated an aggregate $500,000 for each fiscal year.

[(2) LIMITATION REGARDING OTHER FUNDS.—Amounts appropriated under any provision of law other than paragraph (1) may not be expended to establish or operate the Foundation.]

* * * * * * *

TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

* * * * * * *

PART B—SUDDEN INFANT DEATH SYNDROME

SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS

SEC. 1122. [(a) From the sums] *From the sums* appropriated to the National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

[(b)(1) Not later than ninety days after the close of the fiscal year ending September 30, 1979, and of each fiscal year thereafter, the Secretary shall report to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on

Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives specific information for such fiscal year on—

[(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this Act for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

[(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this Act for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds.

[(2) Each report submitted under paragraph (1) of this subsection shall—

[(A) contain a summary of the findings of intramural and extramural research supported by the National Institute of Child Health and Human Development relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of such paragraph (1), and the plan of such Institute for taking maximum advantage of such research leads and findings; and

[(B) provide an estimate of the need for additional funds over each of the next five fiscal years for grants and contracts under this Act for research activities described in such subparagraphs.

[(c) Within five days after the Budget is transmitted by the President to the Congress for each fiscal year after fiscal year 1980, the Secretary shall transmit to the Committees on Appropriations of the Senate and the House of Representatives, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives an estimate of the amounts requested for the National Institute of Child Health and Human Development and any other Institutes of the National Institutes of Health, respectively, for research relating to sudden infant death syndrome as described in subparagraphs (A) and (B) of subsection (b)(1) of this section, and a comparison of such amounts with the amounts requested for the preceding fiscal year.]

TITLE XXIII—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

PART A—ADMINISTRATION OF RESEARCH PROGRAMS

[SEC. 2301. REQUIREMENT OF ANNUAL COMPREHENSIVE REPORT ON ALL EXPENDITURES BY SECRETARY WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME.

[(a) IN GENERAL.—Not later than December 1 of each fiscal year, the Secretary shall prepare and submit to the Congress a report on the expenditures by the Secretary of amounts appropriated for the

preceding fiscal year with respect to acquired immune deficiency syndrome.

[(b) INCLUSION OF CERTAIN INFORMATION.—The report required in subsection (a) shall, with respect to acquired immune deficiency syndrome, include—

[(1) for each program, project, or activity with respect to such syndrome, a specification of the amount obligated by each office and agency of the Department of Health and Human Services;

[(2) a summary description of each such program, project, or activity;

[(3) a list of such programs, projects, or activities that are directed towards members of minority groups;

[(4) a description of the extent to which programs, projects, and activities described in paragraph (3) have been coordinated between the Director of the Office of Minority Health and the Director of the Centers for Disease Control and Prevention;

[(5) a summary of the progress made by each such program, project, or activity with respect to the prevention and control of acquired immune deficiency syndrome;

[(6) a summary of the evaluations conducted under this title; and

[(7) any report required in this Act to be submitted to the Secretary for inclusion in the report required in subsection (a).]

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PART D—OFFICE OF AIDS RESEARCH

Subpart I—Interagency Coordination of Activities

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SEC. 2354. ADDITIONAL AUTHORITIES.

(a) * * *

[(b) REPORT TO SECRETARY.—The Director of the Office shall each fiscal year prepare and submit to the Secretary, for inclusion in the comprehensive report required in section 2301(a), a report—

[(1) describing and evaluating the progress made in such fiscal year in research, treatment, and training with respect to acquired immune deficiency syndrome conducted or supported by the Institutes;

[(2) summarizing and analyzing expenditures made in such fiscal year for activities with respect to acquired immune deficiency syndrome conducted or supported by the National Institutes of Health; and

[(3) containing such recommendations as the Director considers appropriate.]

[(c)] *(b)* PROJECTS FOR COOPERATION AMONG PUBLIC AND PRIVATE HEALTH ENTITIES.—In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

Subpart II—Emergency Discretionary Fund

SEC. 2356. EMERGENCY DISCRETIONARY FUND.

(a) * * *

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[(e) REPORT TO CONGRESS.—Not later than February 1 of each fiscal year, the Director of the Office shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report on the identified sets of AIDS activities carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such set of activities and an explanation of the reasons underlying the use of the Fund for the set.]

[(f)] *(e)* DEFINITIONS.—For purposes of this section:

(1) * * *

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[(g)] *(f)* FUNDING.—

(1) * * *

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Subpart III—General Provisions

SEC. 2359. GENERAL PROVISIONS REGARDING THE OFFICE.

(a) * * *

[(b) EVALUATION AND REPORT.—

[(1) EVALUATION.—Not later than 5 years] *(b) EVALUATION.—Not later than 5 years* after the date of the enactment of National Institutes of Health Revitalization Act of 1993, the Secretary shall conduct an evaluation to—

[(A)] *(1)* determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

[(B)] *(2)* evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

[(C)] *(3)* provide recommendations concerning future alterations with respect to this part.

[(2) REPORT.—Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of such evaluation.]

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SECTION 7 OF THE ORPHAN DRUG ACT

ANALYSIS OF THYROID CANCER; ACTIONS BY THE SECRETARY

SEC. 7. (a) In carrying out section 301 of the Public Health Service Act, the Secretary of Health and Human Services shall—

(1) * * *

(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; *and*

(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests[; and].

[(4) prepare and transmit to the Congress within one year after the date of enactment of this Act a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).]

(b)(1) * * *

(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. [The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.]

HOME HEALTH CARE AND ALZHEIMER'S DISEASE AMENDMENTS OF 1990

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TITLE III—TASK FORCE ON AGING RESEARCH

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[SEC. 304. REPORTS.

[(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter, the Task Force shall prepare and submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report providing the recommendations required in section 301(b).

[(b) AVAILABILITY TO PUBLIC.—The Task Force may make available to the public copies of the reports required in subsection (a).]

SEC. [305] *304*. DEFINITIONS.

For purposes of this title:

(1) * * *

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SEC. [306] *305*. AUTHORIZATION OF APPROPRIATIONS.

For the purpose of carrying out this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

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SECTION 4923 OF THE BALANCED BUDGET ACT OF 1997

SEC. 4923. REPORT ON DIABETES GRANT PROGRAMS.

(a) * * *

[(b) REPORTS.—The Secretary shall submit to the appropriate committees of Congress—

[(1) an interim report on the evaluation conducted under subsection (a) not later than January 1, 2000, and

[(2) a final report on such evaluation not later than January 1, 2007.]

CHILDREN'S HEALTH ACT OF 2000

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DIVISION A—CHILDREN'S HEALTH

TITLE I—AUTISM

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[SEC. 105. REPORT TO CONGRESS.

[Not later than January 1, 2001, and each January 1 thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress, a report concerning the implementation of this title and the amendments made by this title.]

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TITLE X—PEDIATRIC RESEARCH INITIATIVE

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SEC. 1004. LONG-TERM CHILD DEVELOPMENT STUDY.

(a) * * *

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[(d) REPORT.—Beginning not later than 3 years after the date of the enactment of this Act, and periodically thereafter for the duration of the study under this section, the Director of the National Institute of Child Health and Human Development shall prepare and submit to the appropriate committees of Congress a report on the implementation and findings made under the planning and feasibility study conducted under this section.]

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DIVISION B—YOUTH DRUG AND MENTAL HEALTH SERVICES

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TITLE XXXVI—METHAMPHETAMINE AND OTHER CONTROLLED SUBSTANCES

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PART III—ABUSE PREVENTION AND TREATMENT

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[SEC. 3633. STUDY OF METHAMPHETAMINE TREATMENT.

[(a) STUDY.—

[(1) REQUIREMENT.—The Secretary of Health and Human Services shall, in consultation with the National Institute on Drug Abuse, conduct a study on the development of medications for the treatment of addiction to amphetamine and methamphetamine.

[(2) REPORT.—Not later than 9 months after the date of the enactment of this Act, the Secretary shall submit to the Committees on the Judiciary of the Senate and House of Representatives a report on the results of the study conducted under paragraph (1).

[(b) AUTHORIZATION OF APPROPRIATIONS.—There are hereby authorized to be appropriated for the Department of Health and Human Services for fiscal year 2000 such sums as may be necessary to meet the requirements of subsection (a).]

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SECTION 105 OF THE MINORITY HEALTH AND HEALTH DISPARITIES RESEARCH AND EDUCATION ACT OF 2000

[SEC. 105. REPORT REGARDING RESOURCES OF NATIONAL INSTITUTES OF HEALTH DEDICATED TO MINORITY AND OTHER HEALTH DISPARITIES RESEARCH.

[Not later than December 1, 2003, the Director of the National Center on Minority Health and Health Disparities (established by the amendment made by section 101(a)), after consultation with the advisory council for such Center, shall submit to the Congress, the Secretary of Health and Human Services, and the Director of the National Institutes of Health a report that provides the following:

[(1) Recommendations for the methodology that should be used to determine the extent of the resources of the National Institutes of Health that are dedicated to minority health disparities research and other health disparities research, including determining the amount of funds that are used to conduct and support such research. With respect to such methodology, the report shall address any discrepancies between the methodology used by such Institutes as of the date of the enactment of this Act and the methodology used by the Institute of Medicine as of such date.

[(2) A determination of whether and to what extent, relative to fiscal year 1999, there has been an increase in the level of resources of the National Institutes of Health that are dedicated to minority health disparities research, including the amount of funds used to conduct and support such research. The report shall include provisions describing whether and to what extent there have been increases in the number and amount of awards to minority serving institutions.]

SECTION 6 OF THE MUSCULAR DYSTROPHY COMMUNITY ASSISTANCE, RESEARCH AND EDUCATION AMENDMENTS OF 2001

[SEC. 6. REPORT TO CONGRESS.

[Not later than January 1, 2003, and each January 1 thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress, a report concerning the implementation of this Act and the amendments made by this Act.]

RESEARCH REVIEW ACT OF 2004

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[SEC. 3. EPIDEMIOLOGICAL STUDY REPORT.

[(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall prepare a report outlining the epidemiological studies currently under way at such Centers, future planned studies, the criteria involved in determining what epidemiological studies to conduct, defer, or suspend, and the scope of those studies, including with respect to the inflammatory bowel disease epidemiological study. The report shall include a description of the activities the Centers for Disease Control and Prevention undertakes to establish partnerships with research and patient advocacy communities to expand epidemiological studies.

[(b) REPORT.—Not later than May 1, 2005, the Secretary shall submit the report under subsection (a) to the Committee on Energy and Commerce of the House of Representatives and to the Committee on Health, Education, Labor, and Pensions of the Senate.]

SEC. [4] *3.* STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE ON MEDICARE AND MEDICAID COVERAGE STANDARDS.

(a) * * *

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SEC. [5] *4.* STUDY BY GOVERNMENT ACCOUNTABILITY OFFICE INVOLVING DISABILITY INSURANCE.

(a) * * *

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ADDITIONAL VIEWS OF REPRESENTATIVES EDWARD MARKEY, JOHN DINGELL, HENRY WAXMAN, RICK BOUCHER, EDOLPHUS TOWNS, FRANK PALLONE, SHERROD BROWN, ANNA ESHOO, BART STUPAK, ELIOT ENGEL, ALBERT WYNN, GENE GREEN, DIANA DE GETTE, LOIS CAPPS, THOMAS ALLEN, JAN SCHAKOWSKY, HILDA SOLIS, JAY INSLEE, TAMMY BALDWIN

The National Institutes of Health is our country's premier research institution. It embodies our hopes for treating or curing debilitating diseases like heart disease, Alzheimer's, cystic fibrosis, diabetes, cancer and so many other illnesses that American families battle every day. It also our best hope for containing the health care costs of the Baby Boomers. If we don't act now, the chronic disease epidemic and its economic costs will skyrocket over the next 25 years. We must invest in research today that will yield the cures tomorrow.

We are concerned that the 5% authorization level included in this legislation sets a cap on the funding available for NIH for the duration of the authorization. Further this 5% increase will barely keep up with the high rate of inflation. Biomedical inflation, as measured by the Biomedical Research and Development Price Index (BRDPI), is generally 3–4 percent per year. In some years it is even as high as 5–10%. In a year in which biomedical inflation is over 5%, this bill would authorize a real cut to NIH.

We have already seen the impact on research when the NIH budget fails to account for increases in inflation. Since 2003, NIH has lost 11 percent of its research funding when adjusted for inflation. Already this has done significant damage to NIH's ability to support cutting edge research and encourage new investigators. The impact has been so significant that even top-tier researchers with established track records of publishing in top journals are struggling to get funding for their research.

In committee, we supported an amendment offered by Mr. Markey to ensure that the bill authorized a real 5% increase in NIH funding above the rate of inflation. This amendment was endorsed by numerous research and patient advocacy organizations including, AIDS Action, The AIDS Institute, AIDS Vaccine Advocacy Coalition (AVAC), The Alliance for Aging Research, The Alliance for Microbicide Development, The Alzheimer's Foundation of America, American Psychological Association, amfAR, The Foundation for AIDS Research, Beth Israel Deaconess Medical Center, Boston Medical Center, Boston University School of Medicine, Brigham and Women's Hospital, Cambridge Health Alliance, Caritas Carney Hospital, Caritas St. Elizabeth's Medical Center, Children's Hospital Boston, Consortium of Social Science Associations, The Cystic Fibrosis Foundation, Dana Farber Cancer Institute, Drug Development Committee of the AIDS Treatment Advocacy Campaign

(ATAC), Elizabeth Glaser Pediatric AIDS foundation, Faulkner Hospital, The Friends of the National Institute on Aging, Harvard University, Lahey Clinic Medical Center, Massachusetts Eye and Ear Infirmary, Massachusetts General Hospital, National AIDS Treatment Advocacy Project (NATAP), The New England Council, The Schepens Eye Research Institute, Treatment Action Group (TAG), Tufts New England Medical Center.

Although the amendment was rejected on a party-line vote, we continue to believe that Congress should provide at least 5 percent annual increases in NIH funding above the level of biomedical inflation, so that NIH can maintain and expand its life-saving research.

EDWARD J. MARKEY.
RICK BOUCHER.
HENRY A. WAXMAN.
EDOLPHUS TOWNS.
GENE GREEN.
SHERROD BROWN.
ELIOT L. ENGEL.
BART STUPAK.
TAMMY BALDWIN.
JAN SCHAKOWSKY.
TOM ALLEN.
DIANA DEGETTE.
HILDA L. SOLIS.
LOIS CAPPS.
ANNA ESHOO.
JAY INSLEE.
FRANK PALLONE, Jr.
JOHN D. DINGELL.
ALBERT R. WYNN.

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