

Supporting Statement A  
Attachment 1  
Legislative Authority

# House of Representatives/Senate Reports

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATION BILL, 1992

JUNE 20, 1991.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. NATCHER, from the Committee on Appropriations, submitted the following

REPORT

[To accompany H.R. 2707]

The Committee on Appropriations submits the following report in explanation of the accompanying bill making appropriations for the Departments of Labor, Health and Human Services (except the Food and Drug Administration, Indian Health Service, and the Office of Consumer Affairs), and Education (except Indian Education), Action, the Corporation for Public Broadcasting, the Federal Mediation and Conciliation Service, the Federal Mine Safety and Health Review Commission, the National Commission on Acquired Immune Deficiency Syndrome, the National Commission on Libraries and Information Science, the National Commission to Prevent Infant Mortality, the National Council on Disability, the National Labor Relations Board, the National Mediation Board, the Occupational Safety and Health Review Commission, the Prospective Payment Assessment Commission, the Physician Payment Review Commission, the Railroad Retirement Board, the United States Soldiers' and Airmen's Home, the United States Institute of Peace and the United States Naval Home for the fiscal year ending September 30, 1992 and for other purposes.

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science and its applications. NLM's role is to provide applications for this advanced technology and to help the biomedical research and medical practice communities prepare for the major changes it will introduce to the health sciences. Under this initiative, NLM will award grants to connect medical institutions to a high-speed network and to train scientists in the use of new computer capabilities. NLM's National Center for Biotechnology Information will expand its development of advanced software and retrieval methods to make molecular biology databases, including data resulting from the Human Genome Project, widely available to scientists. Programs under way at NLM's Lister Hill National Center for Biomedical Communications will advance the digital, 3-dimensional display of complicated images of the human body and accelerate the development of a unifying language to establish links and facilitate access to numerous sources of computerized information.

*Cost recovery.*—NLM continues to use appropriated funds to build and maintain the MEDLARS databases, while recovering from the biomedical community the full cost of access.

*Environmental health information.*—As a result of growing concerns on the impact of the environment on human health and as part of its long range planning process, the NLM Board of Regents has requested that a planning panel be convened to determine an appropriate role for NLM in toxicology and environmental health information.

#### OFFICE OF THE DIRECTOR

The bill includes \$149,176,000, an increase of \$54,000,000 over the amount requested and \$51,525,000 over the comparable 1991 appropriation.

*Mission.*—The Office of the Director (OD) provides leadership and direction to the NIH research community, and coordinates and directs initiatives which cut across the Institutes, Centers and Divisions of NIH. The OD is responsible for the development and management of intramural and extramural research and research training policy, the review of program quality and effectiveness, the coordination of selected NIH-wide program activities, and the administration of centralized support activities necessary to operations of the NIH.

*Women's health study.*—The OD will coordinate a major new clinical trial in women's health. The Committee has provided \$25,000,000 above the President's request to support the first year of this multi-year effort. The leading causes of death and disability among America's women are cancer, cardiovascular disease, and osteoporosis. Although distinctly different problems, these diseases are linked through specific potential preventive measures. The women's health study will address each of these areas, the impact preventive measures may have on these diseases, and the effects of such preventive measures in combination. The study will look at the effects on disease risk of: changes in diet and exercise patterns, the use of hormones, and smoking cessation. The study will have three components, including a large surveillance program, a nationally based community prevention and intervention study, and randomized clinical trials. The Committee would like a report prior

to the 1993 appropriation hearing providing more details on the design, implementation schedule, and cost estimates for the women's health study.

*Office of Research on Women's Health.*—The Office of Research on Women's Health was established to strengthen the efforts of NIH to improve the prevention, diagnosis, and treatment of illness in women and to enhance research related to diseases and conditions that primarily affect women. The Committee has increased funding for the Office by \$10,000,000 above the requested level of \$2,500,000. Plans are underway to conduct the following reviews: NIH funding of research in areas of women's health; barriers to the study of conditions that are unique to either gender; and identification of activities supported for any disease, disorder or condition deemed to have gender as a material concern. Results from these studies will provide insight into ways in which to enhance the overall status of women's health.

The Committee has provided additional funding to the Office of Research on Women's Health to enhance research in several areas. The Committee intends that the Office determine the allocation of the funds among the Institutes and Centers of the NIH, giving priority to the following research areas: uterine fibroids, endometriosis, pelvic inflammatory disease (PID), the relationship between breast cancer and oral contraceptive use, women and AIDS and health effects on those exposed to the synthetic estrogen drug, DES.

*Office of Minority Programs.*—The Office of Minority Programs (OMP) was established to give minority research and training higher visibility, thereby enabling NIH to increase the number of minority individuals participating in biomedical research. To respond to the Committee's directive to NIH to increase the funding and resources devoted to minority health during the next four years, OMP is developing a four-year plan to carry out that directive. In addition, OMP has established an NIH Minority Program Advisory Board, and is supporting pilot projects to develop new approaches to recruiting and retaining minority students and supporting demonstration projects that utilize new strategies to improve the health of targeted minority populations. The Committee has added \$10,000,000 to the budget request for this office to advance this work. As with the Office of Women's Health Research, the Committee expects the bulk of these funds to be reallocated among the Institutes for research in areas which disproportionately affect minorities. This includes but is not limited to research project grants. The amount added for OMP is in addition to amounts added at the various Institutes and Centers.

*Director's Discretionary Fund.*—The Committee has increased the \$20,000,000 request for the discretionary fund by \$9,000,000 for a total of \$29,000,000. Of this amount, the Committee intends that not less than \$14,500,000 be allocated for the James A. Shannon Director's Award program instituted in 1991. These research grants provide up to \$100,000 for a two-year period, with a 20 percent cap on indirect costs, for investigators whose priority scores fall just above the cut-off for funding. The discretionary fund allows the Director of NIH to respond to high priority needs, to react more effectively to unforeseen changes in research direction and to maximize

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES,  
AND EDUCATION AND RELATED AGENCIES AP-  
PROPRIATION BILL, 1992

JULY 11 (legislative day, JULY 8), 1991.—Ordered to be printed

Mr. HARKIN, from the Committee on Appropriations,  
submitted the following

REPORT

[To accompany H.R. 2707]

The Committee on Appropriations, to which was referred the bill (H.R. 2707) making appropriations for the Departments of Labor, Health and Human Services, and Education and related agencies for the fiscal year ending September 30, 1992, and for other purposes, reports the same to the Senate with various amendments and presents herewith information relative to the changes recommended.

<i>Amount of budget authority</i>	
Amount of House bill .....	\$203,998,247,000
Amount of Senate bill over House bill .....	+ 322,768,000
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Total bill as reported to Senate.....	-204,321,015,000
Amount of adjusted appropriations, 1991 .....	183,040,909,000
Budget estimates, 1992 .....	200,611,414,000
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The bill as reported to the Senate:	
Over the adjusted appropriations for 1991 .....	+ 21,280,106,000
Over the budget estimates for 1992.....	+ 3,709,601,000

The Committee is concerned that the average indirect cost between 1966 when we first adopted the system of negotiated indirect cost has increased from an average of 20 percent to an average of 54 percent. The Committee directs that the inspector general examine the weaknesses in the current negotiated process that have permitted this continuing escalation of the average rate and to recommend the changes needed in the system to better protect the public's money. The Committee requests that the inspector general also examine the differences that exist in the treatment by the various cognizant agencies in the negotiating process and identify the reasons for different treatment of these matters by the various cognizant agencies.

The Committee is aware that prior to 1966 the NIH and all other Federal agencies had fixed indirect cost rates that were not negotiated. These rates ranged from 8 percent to 20 percent. The Committee further directs the inspector general to examine whether returning to the system that existed prior to 1966 would be more cost effective. The Committee requests an analysis of the savings that would result from various levels of governmentwide caps returning to the 8 percent cap that existed in 1956 and for various higher levels.

During the Committee's regular hearings on the President's budget for fiscal year 1992, testimony was received concerning the tremendous opportunities for advances in the fields of the biomedical sciences. In order to take advantage of these opportunities, the Committee believes it essential that funds appropriated to support research be used to their maximum potential. Therefore, the Committee requests that the inspector general also examine whether the current funding methods for research grants fosters, or inhibits, the leveraging of non-Federal resources.

#### *Office of Research on Women's Health*

The Office of Research on Women's Health develops NIH policy to ensure that research pertinent to women's health is identified and addressed through research activities supported by NIH. In fiscal year 1992 the OD will initiate a grant program to support research on health issues of concern to women. Current efforts include the organization of a workshop that will bring together scientists, clinicians, and representatives of women's health organizations to develop a trans-NIH agenda for women's health research for the 1990's including the development of a strategic plan for rehabilitative research.

Cancer, cardiovascular disease, and osteoporosis are three of the leading causes of death and disability among America's women. Although distinctly different problems these diseases are now linked through potential preventive regimens. While menopause and reduced ovarian function are increasingly believed to play a significant role in the etiology of these diseases, diet modification along with a number of dietary supplements hormone replacement therapy, and exercise, as well as cessation of smoking offer hope for reducing the toll of these diseases. Such regimens however may not be reinforcing and may even work at cross purposes to one an-

A major study is needed to address each of these regimens the full range of impacts that each may have, and the effects of such preventive regimens in combination. Such a study clearly transcends the categorical structure of the National Institutes of Health [NIH]. In addition the findings must lead to recommendations which are couched in practical terms and are generalizable to all the Nation's women, including all racial and socioeconomic groups. Research and development of preventive strategies must consider risks as well as benefits of any specific therapy in an effort to address the whole person.

The National Institutes of Health proposes to address these issues by a study of the effects on disease risk of: changes in diet and exercise patterns, the use of hormones, and smoking cessation. This study will be coordinated by the NIH Office of Research on Women's Health and conducted by the research institutes and centers. The various components of the study will be performed by scientists in medical schools, universities and other components of the extramural community. Thus, the study will have an ecumenical approach—one that allows all of the categorical Institutes to contribute their knowledge, expertise, and wisdom to a coordinated research program.

The study will have three components, including a large prospective surveillance program, a nationally based community prevention and intervention study, as well as randomized clinical trials. This study will be the largest of its kind ever to take place in the United States, and thus will require careful planning and design over the next 6 to 9 months by scientific experts representing each of the NIH units named above. The Committee has included \$20,000,000 to begin this initiative as well as other priorities such as the effects of oral contraceptives on breast cancer, fibroid tumors, and endometriosis. The Committee has also increased funding for the Office by \$5,000,000 above the regulated level of \$2,500,000. Not only is this funding intended for office operations but for additional research on important issues of women's health.

The Committee is extremely concerned that the NIH has not contracted with the Institute of Medicine to conduct a study focusing on women's health research and strongly urges the NIH to comply with this request. As cited in last year's report, this study reviews NIH funding of research in areas of women's health, resource allocation to women's health, and barriers to this research. The study also includes review of nongovernmental support for women's research, as well as recommendations on how women's health issues may be better addressed by the NIH and the U.S. Public Health Service. As clarified in the chairman's letter to Acting Director Raub earlier this year, the Committee expects the NIH to complete this contract. Further, the Committee requests notification by July 31, 1991, that the contract has been completed.

Additionally, the Committee is concerned, however, that the health women's trial not supplant other important studies and research on women that needs to be done. The General Accounting Office reported to Congress that the lack of attention to women's health issues resulted not simply with the fact that specific research on women was not being accomplished, but that too little attention was being focused on studying gender difference across the board.



The Committee requests a report from the Director of NIH as to the timing and implementation of this large-scale, multicenter trial.

Further, the Committee directs the NIH to consider the role of diet in the prevention of cancer and coronary heart disease. This study should evaluate whether or not a simple dietary intervention, emphasizing total fat reduction, will prevent disease among postmenopausal women. The Committee requests a report from the Director of NIH regarding the timing and implementation of this study and how it will be accomplished by October 30, 1991.

*Director's discretionary funding authority*

The Committee has provided the \$20,000,000, as requested, for the Director's discretionary fund and the 1-percent transfer authority that has been provided to the Director in the past. The Committee has favorably reviewed a recent report entitled, "A National Institutes of Health Plan to Strengthen the Competitiveness of Selected States for Research Funding," which proposes a program to enhance the competitiveness of academic investigators in the lower rank of States through the NIH peer review system and to increase the probability of long-term growth of NIH competitive funding of investigators in those States. The Committee urges the Director to use her discretionary funds to initiate a NIH-CPSCOR program at the level of \$2,000,000. The Committee expects this program to be managed by the National Center for Research Resources [NCRR]. The Committee directs that all States designated by the EPSCoR program in the National Science Foundation be included in the NIH program, with the Director having discretion to include other States. In addition, because the State based improvement mechanism is viewed as essential, the Committee directs that all planning proposals and institutional development award applications be submitted by State based EPSCoR committees. The Director is encouraged to consult with the Director of the NSF to assure coordination of the overall program on a statewide basis. The NCRR is urged to expedite the planning phase, so that the full program may begin early in the next fiscal year. Additionally, consideration should be given to enhancing the Biomedical Research Support Grant Program and the shared institutional grant programs which have been funded, but at levels below those provided in fiscal year 1991.

*Office of Minority Programs*

The Office of Minority Programs [OMP] develops NIH-wide goals for minority research and training, directs and coordinates these programs and administers grant awards that increase minority participation in research. To increase funding and resources devoted to minority health, OMP is in the process of implementing the following: developing a 4-year plan to increase support for minority health and training, establishing an NIH Minority Program Advisory Board, supporting pilot projects to develop new approaches to recruiting and retaining minority students and supporting demonstration projects to improve the health of targeted minority populations.

# Public Health Service Act

103<sup>d</sup> CONGRESS  
1<sup>st</sup> Session

COMMITTEE PRINT

COMMITTEE  
PRINT 103-0

COMPILATION OF SELECTED ACTS WITHIN  
THE JURISDICTION OF THE COMMITTEE  
ON ENERGY AND COMMERCE

HEALTH LAW

As Amended Through September 30, 1993

INCLUDING

PUBLIC HEALTH SERVICE ACT

DEVELOPMENTAL DISABILITIES ASSISTANCE AND BILL OF  
RIGHTS ACT

MENTAL HEALTH SYSTEMS ACT

CONSUMER-PATIENT RADIATION HEALTH AND SAFETY ACT  
OF 1981

DRUG ABUSE PREVENTION, TREATMENT, AND REHABILITA-  
TION ACT

PROTECTION AND ADVOCACY FOR MENTALLY ILL INDIVID-  
UALS ACT OF 1986

HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986

ALZHEIMER'S DISEASE AND RELATED DEMENTIAS  
RESEARCH ACT OF 1992

ABANDONED INFANTS ASSISTANCE ACT OF 1988

MISCELLANEOUS PROVISIONS

PREPARED FOR THE USE OF THE

COMMITTEE ON ENERGY AND COMMERCE  
U.S. HOUSE OF REPRESENTATIVES



SEPTEMBER 1993

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC  
HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. [241] (a) The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under title 10, United States Code, sections 2353 and 2354, except that determination, approval, and certification required there- by shall be by the Secretary of Health, Education, and Welfare; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b)(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health; and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health, Education, and Welfare and shall consult with entities of the Federal Government, outside of the Department of Health, Education, and Welfare, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient,

or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health, Education, and Welfare for the Secretary, or

(II) from an entity within the Department of Health, Education, and Welfare to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in Appropriation Acts.

(c) The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

#### NARCOTICS

SEC. 302. [242] (a) In carrying out the purposes of section 301 with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act and Controlled Substances Import and Export Act, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary