

107TH CONGRESS  
1ST SESSION

# H. R. 1784

To establish an Office on Women’s Health within the Department of Health and Human Services, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2001

Mrs. MORELLA (for herself, Mrs. MALONEY of New York, Mr. WAXMAN, Mr. TOM DAVIS of Virginia, Ms. SLAUGHTER, Mr. McNULTY, Mr. HONDA, Ms. BROWN of Florida, Mrs. THURMAN, Ms. ESHOO, Mr. LANTOS, Ms. LEE, Mr. WYNN, Mr. FROST, Ms. NORTON, Ms. MCCARTHY of Missouri, Mr. HILLIARD, Mr. HORN, Ms. BALDWIN, Ms. MILLENDER-McDONALD, Mrs. CHRISTENSEN, Ms. DELAURO, Ms. JACKSON-LEE of Texas, Mr. WEXLER, Ms. SOLIS, Mrs. ROUKEMA, Mr. KILDEE, Ms. KAPTUR, Ms. HARMAN, Ms. SCHAKOWSKY, Mr. BENTSEN, and Mrs. JONES of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To establish an Office on Women’s Health within the Department of Health and Human Services, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Women’s Health Office  
5 Act of 2001”.

1 **SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOM-**  
2 **EN'S HEALTH.**

3 Part A of title II of the Public Health Service Act  
4 (42 U.S.C. 202 et seq.) is amended by adding at the end  
5 the following:

6 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**  
7 **WOMEN'S HEALTH.**

8 “(a) ESTABLISHMENT OF OFFICE.—There is estab-  
9 lished within the Office of the Secretary an Office on  
10 Women's Health (referred to in this section as the ‘Of-  
11 fice’). The Office on Women's Health shall be headed by  
12 a Deputy Assistant Secretary for Women's Health.

13 “(b) DUTIES.—The Office shall, with respect to the  
14 health concerns of women—

15 “(1) establish short-range and long-range goals  
16 and objectives and coordinate all activities within the  
17 Department of Health and Human Services that re-  
18 late to disease prevention, health promotion, service  
19 delivery, research, and public and health care profes-  
20 sional education concerning women;

21 “(2) provide expert advice and consultation to  
22 the Secretary concerning scientific, legal ethical, and  
23 policy issues relating to women's health;

24 “(3) monitor the Department of Health and  
25 Human Services offices, agencies, and regional ac-  
26 tivities regarding women's health and stimulate ac-

1       activities and facilitate coordination of such depart-  
2       mental and agency offices on women’s health;

3               “(4) establish a Department of Health and  
4       Human Services Coordinating Committee on Wom-  
5       en’s Health to be chaired by the Deputy Assistant  
6       Secretary for Women’s Health which shall be com-  
7       posed of senior level representatives from each of the  
8       agencies and offices of the Department of Health  
9       and Human Services;

10              “(5) establish a National Women’s Health In-  
11      formation Center to—

12                      “(A) facilitate the exchange of information  
13      regarding matters relating to health informa-  
14      tion and health promotion, preventive health  
15      services, research advances, and education in  
16      the appropriate use of health care;

17                      “(B) facilitate access to such information;

18                      “(C) assist in the analysis of issues and  
19      problems relating to the matters described in  
20      this paragraph; and

21                      “(D) provide technical assistance with re-  
22      spect to the exchange of information (including  
23      facilitating the development of materials for  
24      such technical assistance);

1           “(6) coordinate efforts to promote women’s  
2 health programs and policies in the private sector;  
3 and

4           “(7) through publications and any other means  
5 appropriate, provide for the exchange of information  
6 between the Office and recipients of grants, con-  
7 tracts, and agreements under subsection (c), and be-  
8 tween the Office and health professionals and the  
9 general public.

10       “(c) GRANTS AND CONTRACTS REGARDING DU-  
11 TIES.—

12           “(1) AUTHORITY.—In carrying out subsection  
13 (b), the Secretary, acting through the Office, may  
14 make grants to, and enter into cooperative agree-  
15 ments, contracts, and interagency agreements with  
16 public and nonprofit private entities, agencies, and  
17 organizations.

18           “(2) EVALUATION AND DISSEMINATION.—The  
19 Office shall directly or through contracts with public  
20 and private entities, agencies, and organizations,  
21 provide for evaluations of projects carried out with  
22 financial assistance provided under paragraph (1)  
23 and for the dissemination of information developed  
24 as a result of such projects.

1       “(d) REPORTS.—Not later than January 31, 2003,  
2 and January 31 of each second year thereafter, the Sec-  
3 retary shall prepare and submit to the appropriate com-  
4 mittees of Congress a report describing the activities car-  
5 ried out under this section during the period for which  
6 the report is being prepared.

7       “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
8 purpose of carrying out this section, there are authorized  
9 to be appropriated such sums as may be necessary for  
10 each of the fiscal years 2002 through 2006.

11       “(f) TRANSFER.—There are transferred to the Office,  
12 all functions exercised by the Office on Women’s Health  
13 of the Public Health Service prior to the date of enactment  
14 of this section, including all personnel and compensation  
15 authority, all delegation and assignment authority, and all  
16 remaining appropriations. All orders, determinations,  
17 rules, regulations, permits, agreements, grants, contracts,  
18 certificates, licenses, registrations, privileges, and other  
19 administrative actions—

20               “(1) which have been issued, made, granted, or  
21 allowed to become effective by the President, any  
22 Federal agency or official thereof, or by a court of  
23 competent jurisdiction, in the performance of func-  
24 tions which are transferred under this subsection;  
25 and



1 age, biological, and sociocultural contexts, in all as-  
2 pects of the Centers work, including prevention pro-  
3 grams, public and professional education, services,  
4 and treatment;

5 “(2) establish short-range and long-range goals  
6 and objectives for women’s health and coordinate all  
7 other activities within the Centers that relate to pre-  
8 vention, research, education and training, service de-  
9 livery, and policy development;

10 “(3) identify projects in women’s health that  
11 should be conducted or supported by the National  
12 Centers;

13 “(4) consult with health professionals, non-  
14 governmental organizations, consumer organizations,  
15 women’s health professionals, and other individuals  
16 and groups, as appropriate, on the policy of the Cen-  
17 ters with regard to women; and

18 “(5) serve as a member of the Department of  
19 Health and Human Services Coordinating Com-  
20 mittee on Women’s Health (established under sec-  
21 tion 229(b)(4)).

22 “(c) COORDINATING COMMITTEE.—

23 “(1) ESTABLISHMENT.—In carrying out sub-  
24 section (b), the Director of the Office shall establish  
25 a committee to be known as the Coordinating Com-

1       mittee on Research on Women’s Health (referred to  
2       in this subsection as the ‘Coordinating Committee’).

3           “(2) COMPOSITION.—The Coordinating Com-  
4       mittee shall be composed of the Directors of the Na-  
5       tional Centers.

6           “(3) CHAIRPERSON.—The Director of the Of-  
7       fice shall serve as the chairperson of the Coordi-  
8       nating Committee.

9           “(4) DUTIES.—With respect to women’s health,  
10      the Coordinating Committee shall assist the Director  
11      of the Office in—

12           “(A) identifying the need for programs and  
13      activities that focus on women’s health;

14           “(B) identifying needs regarding the co-  
15      ordination of activities, including intramural  
16      and extramural multidisciplinary activities; and

17           “(C) making recommendations to the Di-  
18      rector of the Centers for Disease Control and  
19      Prevention concerning findings made under  
20      subparagraphs (A) and (B).

21           “(d) REPORTS.—Not later than January 31, 2003,  
22      and January 31 of each second year thereafter, the Direc-  
23      tor of the Office shall prepare and submit to the appro-  
24      priate committees of Congress a report describing the ac-



1 tivities carried out under this section during the period  
2 for which the report is being prepared.

3 “(e) DEFINITION.—As used in this section the term  
4 ‘women’s health conditions’, with respect to women of all  
5 age, ethnic, and racial groups, means all diseases, dis-  
6 orders, and conditions—

7 “(1) unique to, more serious, or more prevalent  
8 in women; and

9 “(2) for which the factors of medical risk or  
10 type of medical intervention are different for women,  
11 or for which it is unknown whether such factors or  
12 types are different for women.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the  
14 purpose of carrying out this section, there are authorized  
15 to be appropriated such sums as may be necessary for  
16 each of the fiscal years 2002 through 2006.”.

17 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**  
18 **ITY OFFICE OF WOMEN’S HEALTH.**

19 Part C of title IX of the Public Health Service Act  
20 (42 U.S.C. 299c et seq.) is amended—

21 (1) by redesignating section 928 as section 929;

22 and

23 (2) by inserting after section 927 the following:

1 **“SEC. 928. OFFICE OF WOMEN’S HEALTH.**

2       “(a) ESTABLISHMENT.—There is established within  
3 the Office of the Director of the Agency for Healthcare  
4 Research and Quality an office to be known as the Office  
5 of Women’s Health (referred to in this section as the ‘Of-  
6 fice’). The Office shall be headed by a director who shall  
7 be appointed by the Director of the Agency.

8       “(b) PURPOSE.—The Director of the Office shall—

9           “(1) determine the current Agency level of ac-  
10 tivity regarding women’s health, across age, biologi-  
11 cal, and sociocultural contexts, in all aspects of  
12 Agency work, including development of evidence re-  
13 ports and clinical practice protocols, and conducting  
14 research into patient outcomes, delivery of health  
15 care services, quality of care, and access to health  
16 care;

17           “(2) establish short-range and long-range goals  
18 and objectives for research important to women’s  
19 health and coordinate all other activities within the  
20 Agency that relate to health services and medical ef-  
21 fectiveness research;

22           “(3) identify projects in women’s health that  
23 should be conducted or supported by the Agency;

24           “(4) consult with health professionals, non-  
25 governmental organizations, consumer organizations,  
26 women’s health professionals, and other individuals

1 and groups, as appropriate, on Agency policy with  
2 regard to women; and

3 “(5) serve as a member of the Department of  
4 Health and Human Services Coordinating Com-  
5 mittee on Women’s Health (established under sec-  
6 tion 229(b)(4)).

7 “(c) COORDINATING COMMITTEE.—

8 “(1) ESTABLISHMENT.—In carrying out sub-  
9 section (b), the Director of the Office shall establish  
10 a committee to be known as the Coordinating Com-  
11 mittee on Research on Women’s Health (referred to  
12 in this subsection as the ‘Coordinating Committee’).

13 “(2) COMPOSITION.—The Coordinating Com-  
14 mittee shall be composed of the Directors of the  
15 Centers and Offices.

16 “(3) CHAIRPERSON.—The Director of the Of-  
17 fice shall serve as the chairperson of the Coordi-  
18 nating Committee.

19 “(4) DUTIES.—With respect to research on  
20 women’s health, the Coordinating Committee shall  
21 assist the Director of the Office in—

22 “(A) identifying the need for such re-  
23 search, and making an estimate each fiscal year  
24 of the funds needed to adequately support the  
25 research;



1 this section as the ‘Office’). The Office shall be headed  
2 by a director who shall be appointed by the Administrator.

3 “(b) PURPOSE.—The Director of the Office shall—

4 “(1) determine the current Agency level of ac-  
5 tivity regarding women’s health across age, biologi-  
6 cal, and sociocultural contexts;

7 “(2) establish short-range and long-range goals  
8 and objectives for women’s health and coordinate all  
9 other activities within the Agency that relate to  
10 health care provider training, health service delivery,  
11 research, and demonstration projects;

12 “(3) identify projects in women’s health that  
13 should be conducted or supported by the Bureaus;

14 “(4) consult with health professionals, non-gov-  
15 ernmental organizations, consumer organizations,  
16 women’s health professionals, and other individuals  
17 and groups, as appropriate, on Agency policy with  
18 regard to women; and

19 “(5) serve as a member of the Department of  
20 Health and Human Services Coordinating Com-  
21 mittee on Women’s Health (established under sec-  
22 tion 229(b)(4) of the Public Health Service Act).

23 “(c) COORDINATING COMMITTEE.—

24 “(1) ESTABLISHMENT.—In carrying out sub-  
25 section (b), the Director of the Office shall establish

1 a committee to be known as the Coordinating Com-  
2 mittee on Research on Women’s Health (referred to  
3 in this subsection as the ‘Coordinating Committee’).

4 “(2) COMPOSITION.—The Coordinating Com-  
5 mittee shall be composed of the Directors of the Bu-  
6 reaus.

7 “(3) CHAIRPERSON.—The Director of the Of-  
8 fice shall serve as the Chairperson of the Coordi-  
9 nating Committee.

10 “(4) DUTIES.—With respect to research on  
11 women’s health, the Coordinating Committee shall  
12 assist the Director of the Office in—

13 “(A) identifying the need for programs and  
14 activities that focus on women’s health;

15 “(B) identifying needs regarding the co-  
16 ordination of activities, including intramural  
17 and extramural multidisciplinary activities; and

18 “(C) making recommendations to the Ad-  
19 ministrator of the Health Resources and Serv-  
20 ices Administration concerning findings made  
21 under subparagraphs (A) and (B).

22 “(d) REPORTS.—Not later than January 31, 2003,  
23 and January 31 of each second year thereafter, the Direc-  
24 tor of the Office shall prepare and submit to the appro-  
25 priate committees of Congress a report describing the ac-

1 tivities carried out under this section during the period  
2 for which the report is being prepared.

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
4 purpose of carrying out this section, there are authorized  
5 to be appropriated such sums as may be necessary for  
6 each of the fiscal years 2002 through 2006.”.

7 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**  
8 **WOMEN’S HEALTH.**

9 Chapter IX of the Federal Food, Drug, and Cosmetic  
10 Act (21 U.S.C. 391 et seq.) is amended by adding at the  
11 end the following:

12 **“SEC. 908. OFFICE OF WOMEN’S HEALTH.**

13 “(a) ESTABLISHMENT.—There is established within  
14 the Office of the Commissioner of the Food and Drug Ad-  
15 ministration an office to be known as the Office of Wom-  
16 en’s Health (referred to in this section as the ‘Office’).  
17 The Office shall be headed by a director who shall be ap-  
18 pointed by the Commissioner.

19 “(b) PURPOSE.—The Director of the Office shall—

20 “(1) determine current Agency levels of activity  
21 regarding women’s participation in clinical trials and  
22 the analysis of data by sex in the testing of drugs,  
23 medical devices, biological products, and foods across  
24 age, socio-cultural, and where deemed appropriate,  
25 biological contexts;

1           “(2) establish short-range and long-range goals  
2           and objectives for all issues of women’s health within  
3           the jurisdiction of the Food and Drug Administra-  
4           tion, including adequate inclusion of women and  
5           analysis of data by sex in all Agency protocols and  
6           policies;

7           “(3) provide guidance or criteria for drug, bio-  
8           logics, and device manufacturers to use in deter-  
9           mining the extent and sufficiency of female rep-  
10          resentation in clinical trials and provide information  
11          to women and health care providers on those areas  
12          in which differences between men and women exist;

13          “(4) consult with pharmaceutical manufactur-  
14          ers, health professionals with expertise in women’s  
15          issues, consumer organizations, and women’s health  
16          professionals on Agency policy with regard to  
17          women;

18          “(5) make annual estimates of funds needed to  
19          monitor clinical trials and analysis of data by sex in  
20          accordance with needs that are identified; and

21          “(6) serve as a member of the Department of  
22          Health and Human Services Coordinating Com-  
23          mittee on Women’s Health (established under sec-  
24          tion 229(b)(4) of the Public Health Service Act).

25          “(c) COORDINATING COMMITTEE.—



1           “(1) ESTABLISHMENT.—In carrying out sub-  
2           section (b), the Director of the Office shall establish  
3           a committee to be known as the Coordinating Com-  
4           mittee on Women’s Health (referred to in this sub-  
5           section as the ‘Coordinating Committee’).

6           “(2) COMPOSITION.—The Coordinating Com-  
7           mittee shall be composed of the Directors of the  
8           Food and Drug Administration Centers.

9           “(3) CHAIRPERSON.—The Director of the Of-  
10          fice shall serve as the Chairperson of the Coordi-  
11          nating Committee.

12          “(4) DUTIES.—With respect to studies on wom-  
13          en’s health, the Coordinating Committee shall assist  
14          the Director of the Office in—

15                 “(A) identifying the need for further stud-  
16                 ies and issues in specific areas of women’s  
17                 health that fall within the mission of the Agen-  
18                 cy, and developing strategies to foster such  
19                 studies;

20                 “(B) identifying needs regarding the co-  
21                 ordination of Agency activities, including inter-  
22                 nal and external activities;

23                 “(C) maintaining the Agency’s focus in  
24                 areas of importance to women;

1           “(D) supporting the development of meth-  
2           odologies to determine how to obtain data spe-  
3           cific to women (including data relating to the  
4           age of women and the membership of women in  
5           ethnic or racial groups);

6           “(E) supporting the development and ex-  
7           pansion of clinical trials of treatments and  
8           therapies for which obtaining such data has  
9           been determined to be an appropriate function;  
10          and

11          “(F) encouraging the Food and Drug Ad-  
12          ministration Centers to conduct and support  
13          such studies, including such clinical trials.

14          “(d) REPORTS.—Not later than January 31, 2003,  
15          and January 31 of each second year thereafter, the Direc-  
16          tor of the Office shall prepare and submit to the appro-  
17          priate committees of Congress a report describing the ac-  
18          tivities carried out under this section during the period  
19          for which the report is being prepared.

20          “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
21          purpose of carrying out this section, there are authorized  
22          to be appropriated such sums as may be necessary for  
23          each of the fiscal years 2002 through 2006.”.

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