

105TH CONGRESS  
1ST SESSION

# H. R. 920

To establish an Office on Women's Health within the Department of Health  
and Human Services.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 1997

Mrs. MORELLA (for herself, Mrs. LOWEY, Mrs. JOHNSON of Connecticut, Ms. NORTON, Mr. GREENWOOD, Ms. SLAUGHTER, Mr. WAXMAN, Mr. MCHUGH, Mrs. MALONEY of New York, Mr. FAZIO of California, Ms. SANCHEZ, Mr. ROMERO-BARCELÓ, Mrs. CARSON, Mrs. MEEK of Florida, Mr. OBERSTAR, Mr. DELLUMS, Mr. DELAHUNT, Mr. BALDACCI, Mr. EVANS, Mr. FROST, Ms. FURSE, and Mrs. KELLY) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To establish an Office on Women's Health within the  
Department of Health and Human Services.

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 1997".

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 (hereafter referred to in this section as  
11 the ‘Office’). The Office on Women's Health shall be head-  
12 ed by 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 coordinate and

1 stimulate activities of such departmental and agency  
2 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 organization, pro-  
21 vide for evaluations of projects carried out with fi-  
22 nancial assistance provided under paragraph (1) and  
23 for the dissemination of information developed as a  
24 result of such projects.

1       “(d) REPORTS.—Not later than January 31, 1998,  
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 1998 through 2001.

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) coordinate agency activities on women’s  
19 health with the Office on Women’s Health estab-  
20 lished under section 229.

21 “(c) COORDINATING COMMITTEE.—

22 “(1) ESTABLISHMENT.—In carrying out sub-  
23 section (b), the Director of the Office shall establish  
24 a committee to be known as the Coordinating Com-  
25 mittee on Research on Women’s Health (hereafter

1 referred to in this subsection as the ‘Coordinating  
2 Committee’).

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

6 “(3) CHAIRPERSON.—The Director of the Of-  
7 fice shall serve as the chairperson of the Coordinat-  
8 ing 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, 1998,  
22 and January 31 of each second year thereafter, the Direc-  
23 tor shall prepare and submit to the Director of the Office

1 on Women’s Health established under section 229, a re-  
2 port describing the activities carried out under this section  
3 during the preceding 2 fiscal years.

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

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

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

14 **SEC. 4. AGENCY FOR HEALTH CARE POLICY AND RE-**  
15 **SEARCH OFFICE OF WOMEN’S HEALTH.**

16 Part C of title IX of the Public Health Service Act  
17 (42 U.S.C. 299c et seq.) is amended—

18 (1) by redesignating section 927 as section 928;

19 and

20 (2) by inserting after section 926 the following:

21 **“SEC. 927. OFFICE OF WOMEN’S HEALTH.**

22 “(a) ESTABLISHMENT.—There is established within  
23 the Office of the Director of the Agency for Health Care  
24 Policy and Research an office to be known as the Office  
25 of Women’s Health (hereafter referred to in this section

1 as the ‘Office’). The Office shall be headed by a Director  
2 who shall be appointed by the Director of the Agency.

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, in all aspects of  
7 Agency work, including drafting clinical practice  
8 guidelines, and conducting research into patient out-  
9 comes, delivery of health care services, and access to  
10 health care;

11 “(2) establish short-range and long-range goals  
12 and objectives for research important to women’s  
13 health and coordinate all other activities within the  
14 Agency that relate to health services and medical  
15 effectiveness research;

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

18 “(4) consult with health professionals, non-  
19 governmental organizations, consumer organizations,  
20 women’s health professionals, and other individuals  
21 and groups, as appropriate, on Agency policy with  
22 regard to women; and

23 “(5) coordinate agency activities on women’s  
24 health with the Office of Women’s Health estab-  
25 lished under section 310A.

1 “(c) COORDINATING COMMITTEE.—

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

8 “(2) COMPOSITION.—The Coordinating Com-  
9 mittee shall be composed of the Directors of the  
10 Offices.

11 “(3) CHAIRPERSON.—The Director of the Of-  
12 fice shall serve as the chairperson of the Coordinat-  
13 ing Committee.

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

17 “(A) identifying the need for such re-  
18 search, and making an estimate each fiscal year  
19 of the funds needed to adequately support the  
20 research;

21 “(B) identifying needs regarding the co-  
22 ordination of research activities, including in-  
23 tramural and extramural multidisciplinary ac-  
24 tivities; and



1           “(2) establish short-range and long-range goals  
2           and objectives for women’s health and coordinate all  
3           other activities within the agency that relate to  
4           health care provider training, health service delivery,  
5           research, and demonstration projects;

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

8           “(4) consult with health professionals, non-gov-  
9           ernmental organizations, consumer organizations,  
10          women’s health professionals, and other individuals  
11          and groups, as appropriate, on agency policy with  
12          regard to women; and

13          “(5) coordinate agency activities on women’s  
14          health with the Office of Women’s Health estab-  
15          lished under section 310A of the Public Health Serv-  
16          ice Act.

17          “(c) COORDINATING COMMITTEE.—

18                 “(1) ESTABLISHMENT.—In carrying out sub-  
19                 section (b), the Director of the Office shall establish  
20                 a committee to be known as the Coordinating Com-  
21                 mittee on Research on Women’s Health (hereafter  
22                 referred to in this subsection as the ‘Coordinating  
23                 Committee’).

1           “(2) COMPOSITION.—The Coordinating Com-  
2           mittee shall be composed of the Directors of the  
3           Bureaus.

4           “(3) CHAIRPERSON.—The Director of the Of-  
5           fice shall serve as the Chairperson of the Coordinat-  
6           ing Committee.

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

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

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

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

19           “(d) REPORTS.—Not later than January 31, 1998,  
20           and January 31 of each second year thereafter, the Direc-  
21           tor of the Office shall prepare and submit to the Director  
22           of the Office on Women’s Health established under section  
23           229 of the Public Health Service Act, a report describing  
24           the activities carried out under this section during the pre-  
25           ceding 2 fiscal years.”.

1 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**  
2 **WOMEN'S HEALTH.**

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

6 **“SEC. 906. OFFICE OF WOMEN'S HEALTH.**

7 “(a) **ESTABLISHMENT.**—There is established within  
8 the Office of the Commissioner of the Food and Drug Ad-  
9 ministration an office to be known as the Office of Wom-  
10 en's Health (hereafter referred to in this section as the  
11 ‘Office’). The Office shall be headed by a Director who  
12 shall be appointed by the Commissioner of the Administra-  
13 tion.

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

15 “(1) determine current Commission levels of ac-  
16 tivity regarding women's participation in clinical  
17 trials the study of gender differences in the testing  
18 of drugs, medical devices, and biological products,  
19 across, age, sociocultural, and, where deemed appro-  
20 priate, biological contexts;

21 “(2) establish short-range and long-range goals  
22 and objectives for adequate inclusion of women in all  
23 Commission protocols and policies;

1           “(3) provide guidance or criteria for drug and  
2 device manufacturers to use in determining the ex-  
3 tent and sufficiency of female representation in clini-  
4 cal trials;

5           “(4) consult with pharmaceutical manufactur-  
6 ers, health professionals with expertise in women’s  
7 issues, consumer organizations, and women’s health  
8 professionals on Commission policy with regard to  
9 women;

10           “(5) make annual estimates of funds needed to  
11 monitor clinical trials in accordance with needs that  
12 are identified; and

13           “(6) coordinate Commission activities on wom-  
14 en’s health with the Office of Women’s Health estab-  
15 lished under section 310A of the Public Health Serv-  
16 ice Act.

17           “(c) COORDINATING COMMITTEE.—

18           “(1) ESTABLISHMENT.—In carrying out sub-  
19 section (b), the Director of the Office shall establish  
20 a committee to be known as the Coordinating Com-  
21 mittee on Women’s Health (hereafter referred to in  
22 this subsection as the ‘Coordinating Committee’).

23           “(2) COMPOSITION.—The Coordinating Com-  
24 mittee shall be composed of the Directors of the  
25 Food and Drug Administration Centers.

1           “(3) CHAIRPERSON.—The Director of the Of-  
2           fice shall serve as the Chairperson of the Coordinat-  
3           ing Committee.

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

7                   “(A) identifying the need for further stud-  
8                   ies in specific areas of women’s health that fall  
9                   within the mission of the Commission, and de-  
10                  veloping strategies to foster such studies;

11                  “(B) identifying needs regarding the co-  
12                  ordination of Commission activities, including  
13                  intramural and extramural studies;

14                  “(C) maintaining the Commission’s focus  
15                  in areas of importance to women;

16                  “(D) supporting the development of meth-  
17                  odologies to determine the circumstances in  
18                  which obtaining data specific to women (includ-  
19                  ing data relating to the age of women and the  
20                  membership of women in ethnic or racial  
21                  groups) is an appropriate function of clinical  
22                  trials of treatments and therapies;

23                  “(E) supporting the development and ex-  
24                  pansion of clinical trials of treatments and  
25                  therapies for which obtaining such data has

1           been determined to be an appropriate function;  
2           and

3                   “(F) encouraging the Food and Drug Ad-  
4           ministration Centers to conduct and support  
5           such studies, including such clinical trials.

6           “(d) REPORTS.—Not later than January 31, 1998,  
7   and January 31 of each second year thereafter, the Direc-  
8   tor shall prepare and submit to the Director of the Office  
9   on Women’s Health established under section 229 of the  
10   Public Health Service Act, a report describing the activi-  
11   ties carried out under this section during the preceding  
12   2 fiscal years.”.

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