

104TH CONGRESS
1ST SESSION

H. R. 1736

To amend various Acts to establish offices of women's health within certain agencies, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 25, 1995

Mrs. MORELLA (for herself, Mrs. LOWEY, Mrs. JOHNSON of Connecticut, Ms. NORTON, Ms. SLAUGHTER, Ms. EDDIE BERNICE JOHNSON of Texas, Mrs. KENNELLY, Mrs. SCHROEDER, Mrs. MINK of Hawaii, Ms. PELOSI, Ms. WOOLSEY, Mrs. MALONEY, Ms. MCKINNEY, Ms. LOFGREN, Ms. VELÁZQUEZ, Ms. JACKSON-LEE, and Miss COLLINS of Michigan) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend various Acts to establish offices of women's health within certain agencies, 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 1995".

1 **SEC. 2. PUBLIC HEALTH SERVICE OFFICE ON WOMEN'S**
2 **HEALTH.**

3 Title XVII of the Public Health Service Act (42
4 U.S.C. 300u et seq.) is amended by adding at the end
5 the following section:

6 "OFFICE ON WOMEN'S HEALTH

7 "SEC. 1710. (a) ESTABLISHMENT OF OFFICE.—

8 There is established an Office on Women's Health (here-
9 after referred to in this section as the 'Office') within the
10 Office of the Assistant Secretary for Health.

11 "(b) ASSISTANT SECRETARY.—There shall be in the
12 Department of Health and Human Services a Deputy As-
13 sistant Secretary for Women's Health, who shall be the
14 head of the Office. The Secretary, acting through such
15 Deputy Assistant Secretary, shall carry out this section.

16 "(c) DUTIES.—The Secretary, acting through the Of-
17 fice, shall, with respect to women's health conditions—

18 "(1) advise the Assistant Secretary for Health
19 concerning scientific, legal, ethical, and policy issues
20 relating to women's health;

21 "(2) establish short-range and long-range goals
22 and objectives and coordinate all other activities
23 within the Department of Health and Human Serv-
24 ices that relate to disease prevention, health pro-
25 motion, service delivery, and research concerning
26 women;

1 “(3) enter into interagency agreements with
2 other agencies of the Service to increase the partici-
3 pation of women in health service and promotion
4 programs;

5 “(4) support research, demonstrations and eval-
6 uations to test new and innovative models, to in-
7 crease knowledge and understanding of health risk
8 factors, to develop mechanisms that support better
9 information dissemination, education, prevention,
10 and service delivery for women, and to support ini-
11 tiatives for the promotion of women with respect to
12 careers in the health professions and research;

13 “(5) monitor Public Health Service agency and
14 regional activities regarding women’s health, and co-
15 ordinate activities of such agency Offices of Wom-
16 en’s Health;

17 “(6) establish a women’s health resource center
18 to facilitate the exchange of information regarding
19 matters relating to health information and health
20 promotion, preventive health services, and education
21 in the appropriate use of health care, to facilitate ac-
22 cess to such information, to assist in the analysis of
23 issues and problems relating to such matters, and to
24 provide technical assistance with respect to the ex-
25 change of such information (including facilitating

1 the development of materials for such technical as-
2 sistance); and

3 “(7) coordinate efforts to promote women’s
4 health programs and policies in the voluntary and
5 corporate sectors.

6 “(d) COORDINATING COMMITTEE.—The Secretary
7 shall provide for the operation of a committee composed
8 of the heads of the agencies of the Public Health Service
9 (or the designees of the agency heads), which committee
10 shall be chaired by the Deputy Assistant Secretary for
11 Women’s Health. With respect to women’s health condi-
12 tions, such committee shall assist the Deputy Assistant
13 Secretary in identifying the needs for programs regarding
14 the conditions, and in making an estimate each fiscal year
15 of the funds needed to adequately support the programs;
16 identifying needs regarding the coordination of programs;
17 and encouraging the agencies of the Public Health Service
18 to conduct and support programs.

19 “(e) ADVISORY COMMITTEE.—The Secretary shall
20 provide for the operation of an advisory committee regard-
21 ing the duties of the Office. Such committee shall be com-
22 posed of 15 voting members, appointed from among indi-
23 viduals who have expertise in women’s health and who are
24 not officers or employees of the Federal Government, and
25 the term of office for such members shall be four years.

1 The membership of the committee shall include as
2 nonvoting members each of the individuals serving as
3 nonvoting members of the Coordinating Committee under
4 subsection (d), and shall include such other Federal offi-
5 cials or employees as the Secretary determines to be ap-
6 propriate. The committee shall be chaired by the Deputy
7 Assistant Secretary for Women’s Health, and shall meet
8 at the call of the Chair, but not less than once each fiscal
9 year.

10 “(f) REPORTS.—Not later than January 31, 1996,
11 and January 31 of each second year thereafter, the Sec-
12 retary shall prepare and submit to the appropriate com-
13 mittees of Congress a report describing the activities car-
14 ried out under this section during the preceding 2 fiscal
15 years.

16 “(g) DEFINITION.—For purposes of this section, the
17 term ‘women’s health conditions’, with respect to women
18 of all age, ethnic, and racial groups, means all diseases,
19 disorders, and conditions—

20 “(1) unique to, more serious, or more prevalent
21 in women; and

22 “(2) for which the factors of medical risk or
23 type of medical intervention are different for women,
24 or for which it is unknown whether such factors or
25 types are different for women.

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

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

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

14 “(5) coordinate agency activities on women’s
15 health with the Public Health Service Office on
16 Women’s Health established under section 1710.

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 National Centers.

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 women’s health,
8 the Coordinating Committee shall assist the Director
9 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, 1996,
20 and January 31 of each second year thereafter, the Direc-
21 tor shall prepare and submit to the Director of the Public
22 Health Service Office of Women’s Health, a report de-
23 scribing the activities carried out under this section during
24 the preceding 2 fiscal years.

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

5 “(1) unique to, more serious, or more prevalent
6 in women; and

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

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

13 Part C of title IX of the Public Health Service Act
14 (42 U.S.C. 299c et seq.) is amended—

15 (1) by redesignating section 927 as section 928;
16 and

17 (2) by inserting after section 926 the following
18 section:

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

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

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

2 “(1) determine the current Agency level of ac-
3 tivity regarding women’s health, across age, biologi-
4 cal, and sociocultural contexts, in all aspects of
5 Agency work, including drafting clinical practice
6 guidelines, and conducting research into patient out-
7 comes, delivery of health care services, and access to
8 health care;

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

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

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

21 “(5) coordinate agency activities on women’s
22 health with the Public Health Service Office on
23 Women’s Health established under section 1710.

24 “(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 Research on Women’s Health (hereafter
5 referred to in this subsection as the ‘Coordinating
6 Committee’).

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

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

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

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

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

24 “(C) making recommendations to the Di-
25 rector of the Agency for Health Care Policy and

1 Research concerning findings made under sub-
2 paragraphs (A) and (B).

3 “(d) REPORTS.—Not later than January 31, 1996,
4 and January 31 of each second year thereafter, the Direc-
5 tor shall prepare and submit to the Director of the Public
6 Health Service Office of Women’s Health, a report de-
7 scribing the activities carried out under this section during
8 the preceding 2 fiscal years.”.

9 **SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
10 **TION OFFICE OF WOMEN’S HEALTH.**

11 Part D of title III of the Public Health Service Act
12 (42 U.S.C. 254b et seq.) is amended—

13 (1) by redesignating section 340D as section
14 340E; and

15 (2) by inserting before section 340E (as so re-
16 designated) the following:

17 “Subpart IX—Miscellaneous Provisions

18 “OFFICE OF WOMEN’S HEALTH

19 “SEC. 340D. (a) ESTABLISHMENT.—There is estab-
20 lished within the Office of the Administrator of the Health
21 Resources and Services Administration an office to be
22 known as the Office of Women’s Health (hereafter re-
23 ferred to in this section as the ‘Office’). The Office shall
24 be headed by a director who shall be appointed by the Di-
25 rector of the Administration.

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

2 “(1) determine the current agency level of activ-
3 ity regarding women’s health across age, biological,
4 and sociocultural contexts;

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

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

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

17 “(5) coordinate agency activities on women’s
18 health with the Public Health Service Office on
19 Women’s Health established under section 1710.

20 “(c) COORDINATING COMMITTEE.—

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

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 research on
10 women’s health, the Coordinating Committee shall
11 assist the Director 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, 1996,
22 and January 31 of each second year thereafter, the Direc-
23 tor of the Office shall prepare and submit to the Director
24 of the Public Health Service Office of Women’s Health,

1 a report describing the activities carried out under this
2 section during the preceding 2 fiscal years.”.

3 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
4 **WOMEN’S HEALTH.**

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

8 **“SEC. 906. OFFICE OF WOMEN’S HEALTH.**

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

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

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

23 “(2) establish short-range and long-range goals
24 and objectives for adequate inclusion of women in all
25 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 Public Health Service Office on
15 Women’s Health established under section 1710 of
16 the Public Health Service 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, 1996,
7 and January 31 of each second year thereafter, the Direc-
8 tor shall prepare and submit to the Director of the Public
9 Health Service Office of Women’s Health, a report de-
10 scribing the activities carried out under this section during
11 the preceding 2 fiscal years.”.

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