

105TH CONGRESS
1ST SESSION

S. 91

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

IN THE SENATE OF THE UNITED STATES

JANUARY 21, 1997

Ms. SNOWE introduced the following bill; which was read twice and referred
to the Committee on Labor and Human Resources

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”.

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

8 Part A of title II of the Public Health Service Act
9 (42 U.S.C. 202 et seq.) is amended by adding at the end
10 the following:

1 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**
 2 **WOMEN’S HEALTH.**

3 “(a) **ESTABLISHMENT OF OFFICE.**—There is estab-
 4 lished within the Office of the Secretary an Office on
 5 Women’s Health (hereafter referred to in this section as
 6 the ‘Office’). The Office on Women’s Health shall be head-
 7 ed by a Deputy Assistant Secretary for Women’s Health.

8 “(b) **DUTIES.**—The Office shall, with respect to the
 9 health concerns of women—

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

16 “(2) provide expert advice and consultation to
 17 the Secretary concerning scientific, legal ethical, and
 18 policy issues relating to women’s health;

19 “(3) monitor the Department of Health and
 20 Human Services offices, agencies, and regional ac-
 21 tivities regarding women’s health and coordinate and
 22 stimulate activities of such departmental and agency
 23 offices on women’s health;

24 “(4) establish a Department of Health and
 25 Human Services Coordinating Committee on Wom-
 26 en’s Health to be chaired by the Deputy Assistant

1 Secretary for Women’s Health which shall be com-
2 posed of senior level representatives from each of the
3 agencies and offices of the Department of Health
4 and Human Services;

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

7 “(A) facilitate the exchange of information
8 regarding matters relating to health informa-
9 tion and health promotion, preventive health
10 services, research advances, and education in
11 the appropriate use of health care;

12 “(B) facilitate access to such information;

13 “(C) assist in the analysis of issues and
14 problems relating to the matters described in
15 this paragraph; and

16 “(D) provide technical assistance with re-
17 spect to the exchange of information (including
18 facilitating the development of materials for
19 such technical assistance);

20 “(6) coordinate efforts to promote women’s
21 health programs and policies in the private sector;
22 and

23 “(7) through publications and any other means
24 appropriate, provide for the exchange of information

1 between members of the Office, grantees of the Of-
2 fice, and the general public.

3 “(c) GRANTS AND CONTRACTS REGARDING DU-
4 TIES.—

5 “(1) AUTHORITY.—In carrying out subsection
6 (b), the Secretary, acting through the Office, may
7 make grants to, and enter into cooperative agree-
8 ments, contracts, and interagency agreements with
9 public and nonprofit private entities, agencies, and
10 organizations.

11 “(2) EVALUATION AND DISSEMINATION.—The
12 Office shall directly or through contracts with public
13 and private entities, agencies, and organization, pro-
14 vide for evaluations of projects carried out with fi-
15 nancial assistance provided under paragraph (1) and
16 for the dissemination of information developed as a
17 result of such projects.

18 “(d) REPORTS.—Not later than January 31, 1998,
19 and January 31 of each second year thereafter, the Sec-
20 retary shall prepare and submit to the appropriate com-
21 mittees of Congress a report describing the activities car-
22 ried out under this section during the period for which
23 the report is being prepared.

24 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
25 purpose of carrying out this section, there are authorized

1 to be appropriated such sums as may be necessary for
2 each of the fiscal years 1998 through 2001.

3 “(f) TRANSFER.—There are transferred to the Office,
4 all functions exercised by the Office on Women’s Health
5 of the Public Health Service prior to the date of enactment
6 of this section, including all personnel and compensation
7 authority, all delegation and assignment authority, and all
8 remaining appropriations. All orders, determinations,
9 rules, regulations, permits, agreements, grants, contracts,
10 certificates, licenses, registrations, privileges, and other
11 administrative actions—

12 “(1) which have been issued, made, granted, or
13 allowed to become effective by the President, any
14 Federal agency or official thereof, or by a court of
15 competent jurisdiction, in the performance of func-
16 tions which are transferred under this subsection;
17 and

18 “(2) which are in effect at the time this section
19 takes effect, or were final before the date of enact-
20 ment of this section and are to become effective on
21 or after such date;

22 shall continue in effect according to their terms until
23 modified, terminated, superseded, set aside, or revoked in

1 accordance with law by the President, the Assistant Sec-
 2 retary for Women’s Health or other authorized official, a
 3 court of competent jurisdiction, or by operation of law.”.

4 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
 5 **TION OFFICE OF WOMEN’S HEALTH.**

6 Part A of title III of the Public Health Service Act
 7 (42 U.S.C. 241 et seq.) is amended by adding at the end
 8 the following:

9 “CENTERS FOR DISEASE CONTROL AND PREVENTION
 10 OFFICE OF WOMEN’S HEALTH

11 “SEC. 310A. (a) ESTABLISHMENT.—There is estab-
 12 lished within the Office of the Director of the Centers for
 13 Disease Control and Prevention an office to be known as
 14 the Office of Women’s Health (hereafter referred to in this
 15 section as the ‘Office’). The Office shall be headed by a
 16 director who shall be appointed by the Director of the
 17 Centers.

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

19 “(1) determine the current level of the Centers
 20 activity regarding women’s health conditions, across
 21 age, biological, and sociocultural contexts, in all as-
 22 pects of the Centers work, including prevention pro-
 23 grams, public and professional education, services,
 24 and treatment;

25 “(2) establish short-range and long-range goals
 26 and objectives for women’s health and coordinate all

1 other activities within the Centers that relate to pre-
 2 vention, research, education and training, service de-
 3 livery, and policy development;

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

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

12 “(5) coordinate agency activities on women’s
 13 health with the Office on Women’s Health estab-
 14 lished under section 229.

15 “(c) COORDINATING COMMITTEE.—

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

22 “(2) COMPOSITION.—The Coordinating Com-
 23 mittee shall be composed of the Directors of the
 24 National 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 women’s health,
 5 the Coordinating Committee shall assist the Director
 6 of the Office in—

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

9 “(B) identifying needs regarding the co-
 10 ordination of activities, including intramural
 11 and extramural multidisciplinary activities; and

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

16 “(d) REPORTS.—Not later than January 31, 1998,
 17 and January 31 of each second year thereafter, the Direc-
 18 tor shall prepare and submit to the Director of the Office
 19 on Women’s Health established under section 229, a re-
 20 port describing the activities carried out under this section
 21 during the preceding 2 fiscal years.

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

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

3 “(2) for which the factors of medical risk or
4 type of medical intervention are different for women,
5 or for which it is unknown whether such factors or
6 types are different for women.”.

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

9 Part C of title IX of the Public Health Service Act
10 (42 U.S.C. 299c et seq.) is amended—

11 (1) by redesignating section 927 as section 928;
12 and

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

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

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

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

22 “(1) determine the current Agency level of ac-
23 tivity regarding women’s health, across age, biologi-
24 cal, and sociocultural contexts, in all aspects of
25 Agency work, including drafting clinical practice

1 guidelines, and conducting research into patient out-
2 comes, delivery of health care services, and access to
3 health care;

4 “(2) establish short-range and long-range goals
5 and objectives for research important to women’s
6 health and coordinate all other activities within the
7 Agency that relate to health services and medical
8 effectiveness research;

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

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

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

19 “(c) COORDINATING COMMITTEE.—

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

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

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 such re-
11 search, and making an estimate each fiscal year
12 of the funds needed to adequately support the
13 research;

14 “(B) identifying needs regarding the co-
15 ordination of research activities, including in-
16 tramural and extramural multidisciplinary ac-
17 tivities; and

18 “(C) making recommendations to the Di-
19 rector of the Agency for Health Care Policy and
20 Research concerning findings made under sub-
21 paragraphs (A) and (B).

22 “(d) REPORTS.—Not later than January 31, 1998,
23 and January 31 of each second year thereafter, the Direc-
24 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 **SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
 5 **TION OFFICE OF WOMEN’S HEALTH.**

6 Title VII of the Social Security Act (42 U.S.C. 901
 7 et seq.) is amended by adding at the end the following:

8 “OFFICE OF WOMEN’S HEALTH

9 “SEC. 713. (a) ESTABLISHMENT.—There is estab-
 10 lished within the Office of the Administrator of the Health
 11 Resources and Services Administration an office to be
 12 known as the Office of Women’s Health (hereafter re-
 13 ferred to in this section as the ‘Office’). The Office shall
 14 be headed by a director who shall be appointed by the Di-
 15 rector of the Administration.

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

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

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

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

1 “(4) consult with health professionals, non-gov-
 2 ernmental organizations, consumer organizations,
 3 women’s health professionals, and other individuals
 4 and groups, as appropriate, on agency policy with
 5 regard to women; and

6 “(5) coordinate agency activities on women’s
 7 health with the Office of Women’s Health estab-
 8 lished under section 310A of the Public Health Serv-
 9 ice Act.

10 “(c) COORDINATING COMMITTEE.—

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

17 “(2) COMPOSITION.—The Coordinating Com-
 18 mittee shall be composed of the Directors of the
 19 Bureaus.

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

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

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

3 “(B) identifying needs regarding the co-
4 ordination of activities, including intramural
5 and extramural multidisciplinary activities; and

6 “(C) making recommendations to the Di-
7 rector of the Centers for Disease Control and
8 Prevention concerning findings made under
9 subparagraphs (A) and (B).

10 “(d) REPORTS.—Not later than January 31, 1998,
11 and January 31 of each second year thereafter, the Direc-
12 tor of the Office shall prepare and submit to the Director
13 of the Office on Women’s Health established under section
14 229 of the Public Health Service Act, a report describing
15 the activities carried out under this section during the pre-
16 ceding 2 fiscal years.”.

17 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
18 **WOMEN’S HEALTH.**

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

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

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

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

10 “(1) determine current Commission levels of ac-
11 tivity regarding women’s participation in clinical
12 trials the study of gender differences in the testing
13 of drugs, medical devices, and biological products,
14 across, age, sociocultural, and, where deemed appro-
15 priate, biological contexts;

16 “(2) establish short-range and long-range goals
17 and objectives for adequate inclusion of women in all
18 Commission protocols and policies;

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

23 “(4) consult with pharmaceutical manufactur-
24 ers, health professionals with expertise in women’s
25 issues, consumer organizations, and women’s health

1 professionals on Commission policy with regard to
2 women;

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

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

10 “(c) COORDINATING COMMITTEE.—

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

16 “(2) COMPOSITION.—The Coordinating Com-
17 mittee shall be composed of the Directors of the
18 Food and Drug Administration Centers.

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

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

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

5 “(B) identifying needs regarding the co-
6 ordination of Commission activities, including
7 intramural and extramural studies;

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

10 “(D) supporting the development of meth-
11 odologies to determine the circumstances in
12 which obtaining data specific to women (includ-
13 ing data relating to the age of women and the
14 membership of women in ethnic or racial
15 groups) is an appropriate function of clinical
16 trials of treatments and therapies;

17 “(E) supporting the development and ex-
18 pansion of clinical trials of treatments and
19 therapies for which obtaining such data has
20 been determined to be an appropriate function;
21 and

22 “(F) encouraging the Food and Drug Ad-
23 ministration Centers to conduct and support
24 such studies, including such clinical trials.

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

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