

107TH CONGRESS
1ST SESSION

S. 946

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

IN THE SENATE OF THE UNITED STATES

MAY 24, 2001

Ms. SNOWE (for herself, Ms. MIKULSKI, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2001".

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 (referred to in this section as the ‘Of-
6 fice’). The Office on Women’s Health shall be headed by
7 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 stimulate ac-
22 tivities and facilitate coordination of such depart-
23 mental and agency 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
25 between the Office and recipients of grants, con-

1 tracts, and agreements under subsection (c), and be-
2 tween the Office and health professionals and the
3 general public.

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

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

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

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

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

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

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

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

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

1 accordance with law by the President, the Deputy Assist-
 2 ant Secretary for Women’s Health or other authorized of-
 3 ficial, a court of competent jurisdiction, or by operation
 4 of law.”.

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

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

10 **“SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVEN-**
 11 **TION OFFICE OF WOMEN’S HEALTH.**

12 “(a) **ESTABLISHMENT.**—There is established within
 13 the Office of the Director of the Centers for Disease Con-
 14 trol and Prevention an office to be known as the Office
 15 of Women’s Health (referred to in this section as the ‘Of-
 16 fice’). The Office shall be headed by a director who shall
 17 be appointed by the Director of such 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;

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-
10 governmental 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) serve as a member of the Department of
15 Health and Human Services Coordinating Com-
16 mittee on Women’s Health (established under sec-
17 tion 229(b)(4)).

18 “(c) COORDINATING COMMITTEE.—

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

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

4 “(3) CHAIRPERSON.—The Director of the Of-
5 fice shall serve as the chairperson of the Coordi-
6 nating 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, 2003,
20 and January 31 of each second year thereafter, the Direc-
21 tor of the Office shall prepare and submit to the appro-
22 priate committees of Congress a report describing the ac-
23 tivities carried out under this section during the period
24 for which the report is being prepared.

1 of Women’s Health (referred to in this section as the ‘Of-
2 fice’). The Office shall be headed by a director who shall
3 be appointed by the Director of the Agency.

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

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

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

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

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

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

5 “(c) COORDINATING COMMITTEE.—

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

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

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

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

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

24 “(B) identifying needs regarding the co-
25 ordination of research activities, including in-

1 the ‘Office’). The Office shall be headed by a director who
2 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,
22 and the analysis of data by sex in the testing of
23 drugs, medical devices, biological products, and
24 foods, across age, sociocultural, and where deemed
25 appropriate, 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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