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2^D SESSION

H. R. 1784

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 18, 2002

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Women’s Health Office
3 Act of 2002”.

4 **SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOM-**
5 **EN’S HEALTH.**

6 (a) ESTABLISHMENT.—Part A of title II of the Pub-
7 lic Health Service Act (42 U.S.C. 202 et seq.) is amended
8 by adding at the end the following:

9 “HEALTH AND HUMAN SERVICES OFFICE ON WOMEN’S
10 HEALTH

11 “SEC. 229. (a) ESTABLISHMENT OF OFFICE.—The
12 Secretary shall establish through the last date for which
13 appropriations are authorized under subsection (e), within
14 the Office of the Secretary, an Office on Women’s Health
15 (referred to in this section as the ‘Office’). The Office shall
16 be headed by a Deputy Assistant Secretary for Women’s
17 Health.

18 “(b) DUTIES.—The Secretary, acting through the Of-
19 fice, with respect to the health concerns of women, shall—

20 “(1) establish short-range and long-range goals
21 and objectives within the Department of Health and
22 Human Services and, as relevant and appropriate,
23 coordinate with other appropriate offices on activi-
24 ties within the Department that relate to disease
25 prevention, health promotion, service delivery, re-

1 search, and public and health care professional edu-
2 cation, for issues of particular concern to women;

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

6 “(3) monitor the Department of Health and
7 Human Services’ offices, agencies, and regional ac-
8 tivities regarding women’s health and stimulate ac-
9 tivities and facilitate coordination of such depart-
10 mental and agency offices on women’s health;

11 “(4) establish a Department of Health and
12 Human Services Coordinating Committee on Wom-
13 en’s Health, which shall be chaired by the Deputy
14 Assistant Secretary for Women’s Health and com-
15 posed of senior level representatives from each of the
16 agencies and offices of the Department of Health
17 and Human Services;

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

20 “(A) facilitate the exchange of information
21 regarding matters relating to health informa-
22 tion, health promotion, preventive health serv-
23 ices, research advances, and education in the
24 appropriate use of health care;

25 “(B) facilitate access to such information;

1 “(C) assist in the analysis of issues and
2 problems relating to the matters described in
3 this paragraph; and

4 “(D) provide technical assistance with re-
5 spect to the exchange of information (including
6 facilitating the development of materials for
7 such technical assistance);

8 “(6) coordinate efforts to promote women’s
9 health programs and policies with the private sector;
10 and

11 “(7) through publications and any other means
12 appropriate, provide for the exchange of information
13 between the Office and recipients of grants, con-
14 tracts, and agreements under subsection (c), and be-
15 tween the Office and health professionals and the
16 general public.

17 “(c) GRANTS AND CONTRACTS REGARDING DU-
18 TIES.—

19 “(1) AUTHORITY.—In carrying out subsection
20 (b), the Secretary may make grants to, and enter
21 into cooperative agreements, contracts, and inter-
22 agency agreements with, public and private entities,
23 agencies, and organizations.

24 “(2) EVALUATION AND DISSEMINATION.—The
25 Secretary shall directly or through contracts with

1 public and private entities, agencies, and organiza-
2 tions, provide for evaluations of projects carried out
3 with financial assistance provided under paragraph
4 (1) and for the dissemination of information devel-
5 oped as a result of such projects.

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

12 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
13 purpose of carrying out this section, there are authorized
14 to be appropriated such sums as may be necessary for
15 each of the fiscal years 2003 through 2007.”.

16 (b) TRANSFER OF FUNCTIONS.—There are trans-
17 ferred to the Office on Women’s Health (established under
18 section 229 of the Public Health Service Act, as added
19 by this section), all functions exercised by the Office on
20 Women’s Health of the Public Health Service prior to the
21 date of enactment of this section, including all personnel
22 and compensation authority, all delegation and assign-
23 ment authority, and all remaining appropriations. All or-
24 ders, determinations, rules, regulations, permits, agree-

1 ments, grants, contracts, certificates, licenses, registra-
2 tions, privileges, and other administrative actions that—

3 (1) have been issued, made, granted, or allowed
4 to become effective by the President, any Federal
5 agency or official thereof, or by a court of competent
6 jurisdiction, in the performance of functions trans-
7 ferred under this subsection; and

8 (2) are in effect at the time this section takes
9 effect, or were final before the date of enactment of
10 this section and are to become effective on or after
11 such date;

12 shall continue in effect according to their terms until
13 modified, terminated, superseded, set aside, or revoked in
14 accordance with law by the President, the Secretary, or
15 other authorized official, a court of competent jurisdiction,
16 or by operation of law.

17 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
18 **TION OFFICE OF WOMEN'S HEALTH.**

19 Part A of title III of the Public Health Service Act
20 (42 U.S.C. 241 et seq.) is amended by adding at the end
21 the following:

22 “CENTERS FOR DISEASE CONTROL AND PREVENTION
23 OFFICE OF WOMEN’S HEALTH

24 “SEC. 310A. (a) ESTABLISHMENT.—The Secretary
25 shall establish through the last date for which appropria-
26 tions are authorized under subsection (f), within the Office

1 of the Director of the Centers for Disease Control and
2 Prevention, an office to be known as the Office of Wom-
3 en’s Health (referred to in this section as the ‘Office’).
4 The Office shall be headed by a director who shall be ap-
5 pointed by the Director of such Centers.

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

7 “(1) report to the Director of the Centers for
8 Disease Control and Prevention on the current level
9 of the Centers’ activity regarding women’s health
10 conditions across, where appropriate, age, biological,
11 and sociocultural contexts, in all aspects of the Cen-
12 ters’ work, including prevention programs, public
13 and professional education, services, and treatment;

14 “(2) establish short-range and long-range goals
15 and objectives within the Centers for women’s health
16 and, as relevant and appropriate, coordinate with
17 other appropriate offices on activities within the
18 Centers that relate to prevention, research, edu-
19 cation and training, service delivery, and policy de-
20 velopment, for issues of particular concern to
21 women;

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

24 “(4) consult with health professionals, non-
25 governmental organizations, consumer organizations,

1 women’s health professionals, and other individuals
2 and groups, as appropriate, on the policy of the Cen-
3 ters with regard to women; and

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

8 “(c) COORDINATING COMMITTEE.—

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

14 “(2) COMPOSITION.—The Coordinating Com-
15 mittee shall be composed of the directors of the na-
16 tional centers and other appropriate officials of the
17 Centers for Disease Control and Prevention.

18 “(3) CHAIRPERSON.—The Director of the Of-
19 fice shall serve as the Chairperson of the Coordi-
20 nating Committee.

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

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

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

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

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

14 “(e) DEFINITION.—As used in this section, the term
15 ‘women’s health conditions’, with respect to women of all
16 age, ethnic, and racial groups, means diseases, disorders,
17 and conditions—

18 “(1) unique to, significantly more serious for,
19 or significantly more prevalent in women; and

20 “(2) for which the factors of medical risk or
21 type of medical intervention are different for women.

22 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
23 purpose of carrying out this section, there are authorized
24 to be appropriated such sums as may be necessary for
25 each of the fiscal years 2003 through 2007.”.

1 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
2 **ITY ACTIVITIES REGARDING WOMEN'S**
3 **HEALTH.**

4 Part C of title IX of the Public Health Service Act
5 (42 U.S.C. 299e et seq.) is amended—

6 (1) by redesignating sections 927 and 928 as
7 sections 928 and 929, respectively;

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

9 **“SEC. 927. ACTIVITIES REGARDING WOMEN’S HEALTH.**

10 **“(a) ESTABLISHMENT.—**The Director shall designate
11 an official of the Office of Priority Populations to carry
12 out, through the last date for which appropriations are
13 authorized under section 928(e), the responsibilities de-
14 scribed in this section for such official.

15 **“(b) PURPOSE.—**The official designated under sub-
16 section (a) shall—

17 **“(1) report to the Director on the current**
18 **Agency level of activity regarding women’s health,**
19 **across, where appropriate, age, biological, and**
20 **sociocultural contexts, in all aspects of Agency work,**
21 **including the development of evidence reports and**
22 **clinical practice protocols and the conduct of re-**
23 **search into patient outcomes, delivery of health care**
24 **services, quality of care, and access to health care;**

25 **“(2) establish short-range and long-range goals**
26 **and objectives within the Agency for research impor-**

1 tant to women’s health and, as relevant and appro-
2 priate, coordinate with other appropriate offices on
3 activities within the Agency that relate to health
4 services and medical effectiveness research, for
5 issues of particular concern to women;

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

8 “(4) consult with health professionals, non-
9 governmental 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) serve as a member of the Department of
14 Health and Human Services Coordinating Com-
15 mittee on Women’s Health (established under sec-
16 tion 229(b)(4)).

17 “(c) COORDINATING COMMITTEE.—

18 “(1) ESTABLISHMENT.—In carrying out sub-
19 section (b), the official designated under subsection
20 (a) shall establish a committee to be known as the
21 Coordinating Committee on Research on Women’s
22 Health (referred to in this subsection as the ‘Coordi-
23 nating Committee’).

24 “(2) COMPOSITION.—The Coordinating Com-
25 mittee shall be composed of the official designated

1 under subsection (a) and the directors of the centers
2 and offices of the Agency.

3 “(3) CHAIRPERSON.—The official designated
4 under subsection (a) shall serve as the Chairperson
5 of the Coordinating Committee.

6 “(4) DUTIES.—With respect to research on
7 women’s health, the Coordinating Committee shall
8 assist the official designated under subsection (a)
9 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 concerning findings made
20 under subparagraphs (A) and (B).

21 “(d) REPORTS.—Not later than January 31, 2003,
22 and January 31 of each second year thereafter, the official
23 designated under subsection (a) shall prepare and submit
24 to the appropriate committees of Congress a report de-

1 scribing the activities carried out under this section during
 2 the period for which the report is being prepared.”; and

3 (3) by adding at the end of section 928 (as re-
 4 designated by paragraph (1)) the following:

5 “(e) WOMEN’S HEALTH.—For the purpose of car-
 6 rying out section 927 regarding women’s health, there are
 7 authorized to be appropriated such sums as may be nec-
 8 essary for each of the fiscal years 2003 through 2007.”.

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

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

13 “OFFICE OF WOMEN’S HEALTH

14 “SEC. 713. (a) ESTABLISHMENT.—The Secretary
 15 shall establish through the last date for which appropria-
 16 tions are authorized under subsection (f), within the Office
 17 of the Administrator of the Health Resources and Services
 18 Administration, an office to be known as the Office of
 19 Women’s Health. The Office shall be headed by a director
 20 who shall be appointed by the Administrator.

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

22 “(1) report to the Administrator on the current
 23 Administration level of activity regarding women’s
 24 health across, where appropriate, age, biological, and
 25 sociocultural contexts;

1 “(2) establish short-range and long-range goals
2 and objectives within the Health Resources and
3 Services Administration for women’s health and, as
4 relevant and appropriate, coordinate with other ap-
5 propriate offices on activities within the Administra-
6 tion that relate to health care provider training,
7 health service delivery, research, and demonstration
8 projects, for issues of particular concern to women;

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

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

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

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-

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 bu-
5 reaus of the Administration.

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 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 Ad-
18 ministrator concerning findings made under
19 subparagraphs (A) and (B).

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

1 “(e) DEFINITIONS.—For purposes of this section:

2 “(1) ADMINISTRATION.—The term ‘Administra-
3 tion’ means the Health Resources and Services Ad-
4 ministration.

5 “(2) ADMINISTRATOR.—The term ‘Adminis-
6 trator’ means the Administrator of the Health Re-
7 sources and Services Administration.

8 “(3) OFFICE.—The term ‘Office’ means the Of-
9 fice of Women’s Health established under this sec-
10 tion in the Administration.

11 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
12 purpose of carrying out this section, there are authorized
13 to be appropriated such sums as may be necessary for
14 each of the fiscal years 2003 through 2007.”.

15 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
16 **WOMEN’S HEALTH.**

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

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

21 “(a) ESTABLISHMENT.—The Secretary shall estab-
22 lish through the last date for which appropriations are au-
23 thorized under subsection (e), within the Office of the
24 Commissioner, an office to be known as the Office of
25 Women’s Health (referred to in this section as the ‘Of-

1 fice'). The Office shall be headed by a director who shall
2 be appointed by the Commissioner of Food and Drugs.

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

4 “(1) report to the Commissioner of Food and
5 Drugs on current Food and Drug Administration
6 (referred to in this section as the ‘Administration’)
7 levels of activity regarding women’s participation in
8 clinical trials and the analysis of data by sex in the
9 testing of drugs, medical devices, and biological
10 products across, where appropriate, age, biological,
11 and sociocultural contexts;

12 “(2) establish short-range and long-range goals
13 and objectives within the Administration for issues
14 of particular concern to women’s health within the
15 jurisdiction of the Administration, including, where
16 relevant and appropriate, adequate inclusion of
17 women and analysis of data by sex in Administration
18 protocols and policies;

19 “(3) provide information to women and health
20 care providers on those areas in which differences
21 between men and women exist;

22 “(4) consult with pharmaceutical, biologics, and
23 device manufacturers, health professionals with ex-
24 pertise in women’s issues, consumer organizations,

1 and women’s health professionals on Administration
2 policy with regard to women;

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

6 “(6) serve as a member of the Department of
7 Health and Human Services Coordinating Com-
8 mittee on Women’s Health (established under sec-
9 tion 229(b)(4) of the Public Health Service 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 (referred to in this sub-
15 section as the ‘Coordinating Committee’).

16 “(2) COMPOSITION.—The Coordinating Com-
17 mittee shall be composed of the directors of the cen-
18 ters of the Administration.

19 “(3) CHAIRPERSON.—The Director of the Of-
20 fice shall serve as the Chairperson of the Coordi-
21 nating 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 whether there is a need
2 for further studies and, if so, developing strate-
3 gies to foster such studies;

4 “(B) identifying issues in specific areas of
5 women’s health that fall within the mission of
6 the Administration;

7 “(C) identifying whether any need exists
8 for the coordination of Administration activi-
9 ties, including internal and external activities;

10 “(D) maintaining the Administration’s
11 focus in areas of importance to women;

12 “(E) supporting the development of meth-
13 odologies to determine how to obtain data spe-
14 cific to women (including data relating to the
15 age of women and the membership of women in
16 ethnic or racial groups); and

17 “(F) 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 “(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) 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 2003 through 2007.”.

7 **SEC. 7. NO NEW REGULATORY AUTHORITY.**

8 Nothing in this Act and the amendments made by
9 this Act may be construed as establishing regulatory au-
10 thority or modifying any existing regulatory authority.

Passed the House of Representatives September 17,
2002.

Attest:

JEFF TRANDAHL,

Clerk.