

Union Calendar No. 371

107TH CONGRESS
2^D SESSION

H. R. 1784

[Report No. 107-616]

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

IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2001

Mrs. MORELLA (for herself, Mrs. MALONEY of New York, Mr. WAXMAN, Mr. TOM DAVIS of Virginia, Ms. SLAUGHTER, Mr. McNULTY, Mr. HONDA, Ms. BROWN of Florida, Mrs. THURMAN, Ms. ESHOO, Mr. LANTOS, Ms. LEE, Mr. WYNN, Mr. FROST, Ms. NORTON, Ms. MCCARTHY of Missouri, Mr. HILLIARD, Mr. HORN, Ms. BALDWIN, Ms. MILLENDER-McDONALD, Mrs. CHRISTENSEN, Ms. DELAURO, Ms. JACKSON-LEE of Texas, Mr. WEXLER, Ms. SOLIS, Mrs. ROUKEMA, Mr. KILDEE, Ms. KAPTUR, Ms. HARMAN, Ms. SCHAKOWSKY, Mr. BENTSEN, and Mrs. JONES of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 25, 2002

Additional sponsors: Mr. BONIOR, Ms. PELOSI, Mr. JACKSON of Illinois, Ms. McCOLLUM, Mr. MCINTYRE, Ms. RIVERS, Mr. JEFFERSON, Mr. MCGOVERN, Mr. NADLER, Mrs. DAVIS of California, Mrs. CLAYTON, Mrs. LOWEY, Mr. SANDERS, Mr. PAYNE, Mr. REYES, Mr. CUNNINGHAM, Mr. BERMAN, Mrs. CAPPS, Mr. FILNER, Mr. LAHOOD, Mr. NETHERCUTT, Mr. GREENWOOD, Mr. BLAGOJEVICH, Mr. CUMMINGS, Mr. RANGEL, Ms. ROYBAL-ALLARD, Mr. PRICE of North Carolina, Mr. GEORGE MILLER of California, Mr. OLVER, Mr. FARR of California, Mrs. NAPOLITANO, Mr. GUTIERREZ, Ms. HOOLEY of Oregon, Mr. ISRAEL, Mr. RUSH, Mr. DOYLE, Ms. LOFGREN, Mr. BORSKI, Mr. GANSKE, Mr. BRADY of Pennsylvania, Mr. BLUMENAUER, Ms. CARSON of Indiana, Mr. PALLONE, Mr. HOLT, Mr. ANDREWS, Mrs. MINK of Hawaii, Mr. STARK, Mr. BALDACCI, Mr. OWENS, Ms. WOOLSEY, Ms. WATSON, Mr. DEFazio, Mr. BOUCHER, Mr. DINGELL, Mr. FOLEY, Mr. BISHOP, Mr. SHERMAN, Mr. McDERMOTT, Mr. CASTLE, Mr. WHITFIELD, Mr. STRICKLAND, Mr.

1 *Office of the Secretary, an Office on Women’s Health (re-*
2 *ferred to in this section as the ‘Office’). The Office shall*
3 *be headed by a Deputy Assistant Secretary for Women’s*
4 *Health.*

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

7 “(1) *establish short-range and long-range goals*
8 *and objectives within the Department of Health and*
9 *Human Services and, as relevant and appropriate,*
10 *coordinate with other appropriate offices on activities*
11 *within the Department that relate to disease preven-*
12 *tion, health promotion, service delivery, research, and*
13 *public and health care professional education, for*
14 *issues of particular concern to women;*

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

18 “(3) *monitor the Department of Health and*
19 *Human Services’ offices, agencies, and regional ac-*
20 *tivities regarding women’s health and stimulate ac-*
21 *tivities and facilitate coordination of such depart-*
22 *mental and agency offices on women’s health;*

23 “(4) *establish a Department of Health and*
24 *Human Services Coordinating Committee on Wom-*
25 *en’s Health, which shall be chaired by the Deputy As-*

1 *stant Secretary for Women’s Health and composed*
2 *of senior level representatives from each of the agen-*
3 *cies and offices of the Department of Health and*
4 *Human Services;*

5 *“(5) establish a National Women’s Health Infor-*
6 *mation Center to—*

7 *“(A) facilitate the exchange of information*
8 *regarding matters relating to health information,*
9 *health promotion, preventive health services, re-*
10 *search advances, and education in the appro-*
11 *priate 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 this*
15 *paragraph; and*

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

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

22 *“(7) through publications and any other means*
23 *appropriate, provide for the exchange of information*
24 *between the Office and recipients of grants, contracts,*

1 *and agreements under subsection (c), and between the*
2 *Office and health professionals and the general public.*

3 “(c) *GRANTS AND CONTRACTS REGARDING DUTIES.—*

4 “(1) *AUTHORITY.—In carrying out subsection*
5 *(b), the Secretary may make grants to, and enter into*
6 *cooperative agreements, contracts, and interagency*
7 *agreements with, public and private entities, agencies,*
8 *and organizations.*

9 “(2) *EVALUATION AND DISSEMINATION.—The*
10 *Secretary shall directly or through contracts with*
11 *public and private entities, agencies, and organiza-*
12 *tions, provide for evaluations of projects carried out*
13 *with financial assistance provided under paragraph*
14 *(1) and for the dissemination of information devel-*
15 *oped as a result of such projects.*

16 “(d) *REPORTS.—Not later than January 31, 2003,*
17 *and January 31 of each second year thereafter, the Sec-*
18 *retary shall prepare and submit to the appropriate commit-*
19 *tees of Congress a report describing the activities carried*
20 *out under this section during the period for which the report*
21 *is being prepared.*

22 “(e) *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 each*
25 *of the fiscal years 2003 through 2007.”.*

1 (b) *TRANSFER OF FUNCTIONS.*—*There are transferred*
2 *to the Office on Women’s Health (established under section*
3 *229 of the Public Health Service Act, as added by this sec-*
4 *tion), all functions exercised by the Office on Women’s*
5 *Health of the Public Health Service prior to the date of*
6 *enactment of this section, including all personnel and com-*
7 *pensation authority, all delegation and assignment author-*
8 *ity, and all remaining appropriations. All orders, deter-*
9 *minations, rules, regulations, permits, agreements, grants,*
10 *contracts, certificates, licenses, registrations, privileges, and*
11 *other administrative actions that—*

12 (1) *have been issued, made, granted, or allowed*
13 *to become effective by the President, any Federal*
14 *agency or official thereof, or by a court of competent*
15 *jurisdiction, in the performance of functions trans-*
16 *ferred under this subsection; and*

17 (2) *are in effect at the time this section takes ef-*
18 *fect, or were final before the date of enactment of this*
19 *section and are to become effective on or after such*
20 *date;*

21 *shall continue in effect according to their terms until modi-*
22 *fied, terminated, superseded, set aside, or revoked in accord-*
23 *ance with law by the President, the Secretary, or other au-*
24 *thorized official, a court of competent jurisdiction, or by*
25 *operation of law.*

1 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVENTION**

2 **OFFICE OF WOMEN'S HEALTH.**

3 *Part A of title III of the Public Health Service Act*
4 *(42 U.S.C. 241 et seq.) is amended by adding at the end*
5 *the following:*

6 “CENTERS FOR DISEASE CONTROL AND PREVENTION

7 OFFICE OF WOMEN'S HEALTH

8 “SEC. 310A. (a) ESTABLISHMENT.—*The Secretary*
9 *shall establish through the last date for which appropri-*
10 *tions are authorized under subsection (f), within the Office*
11 *of the Director of the Centers for Disease Control and Pre-*
12 *vention, an office to be known as the Office of Women's*
13 *Health (referred to in this section as the 'Office'). The Office*
14 *shall be headed by a director who shall be appointed by*
15 *the Director of such Centers.*

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

17 “(1) *report to the Director of the Centers for Dis-*
18 *ease Control and Prevention on the current level of*
19 *the Centers' activity regarding women's health condi-*
20 *tions across, where appropriate, age, biological, and*
21 *sociocultural contexts, in all aspects of the Centers'*
22 *work, including prevention programs, public and pro-*
23 *fessional education, services, and treatment;*

24 “(2) *establish short-range and long-range goals*
25 *and objectives within the Centers for women's health*
26 *and, as relevant and appropriate, coordinate with*

1 *other appropriate offices on activities within the Cen-*
2 *ters that relate to prevention, research, education and*
3 *training, service delivery, and policy development, for*
4 *issues of particular concern to women;*

5 *“(3) identify projects in women’s health that*
6 *should be conducted or supported by the 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) serve as a member of the Department of*
13 *Health and Human Services Coordinating Committee*
14 *on Women’s Health (established under section*
15 *229(b)(4)).*

16 *“(c) COORDINATING COMMITTEE.—*

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

22 *“(2) COMPOSITION.—The Coordinating Com-*
23 *mittee shall be composed of the directors of the na-*
24 *tional centers and other appropriate officials of the*
25 *Centers for Disease Control and Prevention.*

1 “(3) *CHAIRPERSON.*—*The Director of the Office*
2 *shall serve as the Chairperson of the Coordinating*
3 *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 coordi-*
10 *nation of activities, including intramural and*
11 *extramural multidisciplinary activities; and*

12 “(C) *making recommendations to the Direc-*
13 *tor of the Centers for Disease Control and Pre-*
14 *vention concerning findings made under sub-*
15 *paragraphs (A) and (B).*

16 “(d) *REPORTS.*—*Not later than January 31, 2003,*
17 *and January 31 of each second year thereafter, the Director*
18 *of the Office shall prepare and submit to the appropriate*
19 *committees of Congress a report describing the activities*
20 *carried out under this section during the period for which*
21 *the report is being prepared.*

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 diseases, disorders,*
25 *and conditions—*

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

3 “(2) *for which the factors of medical risk or type*
4 *of medical intervention are different for women.*

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

9 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
10 **ITY ACTIVITIES REGARDING WOMEN’S**
11 **HEALTH.**

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

14 (1) *by redesignating sections 927 and 928 as sec-*
15 *tions 928 and 929, respectively;*

16 (2) *by inserting after section 926 the following:*

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

18 “(a) *ESTABLISHMENT.—The Director shall designate*
19 *an official of the Office of Priority Populations to carry*
20 *out, through the last date for which appropriations are au-*
21 *thorized under section 928(e), the responsibilities described*
22 *in this section for such official.*

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

1 “(1) report to the Director on the current Agency
2 level of activity regarding women’s health, across,
3 where appropriate, age, biological, and sociocultural
4 contexts, in all aspects of Agency work, including the
5 development of evidence reports and clinical practice
6 protocols and the conduct of research into patient out-
7 comes, delivery of health care services, quality of care,
8 and access to health care;

9 “(2) establish short-range and long-range goals
10 and objectives within the Agency for research impor-
11 tant to women’s health and, as relevant and appro-
12 priate, coordinate with other appropriate offices on
13 activities within the Agency that relate to health serv-
14 ices and medical effectiveness research, for issues of
15 particular concern to women;

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) serve as a member of the Department of
24 Health and Human Services Coordinating Committee

1 *on Women’s Health (established under section*
2 *229(b)(4)).*

3 “(c) *COORDINATING COMMITTEE.*—

4 “(1) *ESTABLISHMENT.*—*In carrying out sub-*
5 *section (b), the official designated under subsection*
6 *(a) shall establish a committee to be known as the Co-*
7 *ordinating Committee on Research on Women’s*
8 *Health (referred to in this subsection as the ‘Coordi-*
9 *nating Committee’).*

10 “(2) *COMPOSITION.*—*The Coordinating Com-*
11 *mittee shall be composed of the official designated*
12 *under subsection (a) and the directors of the centers*
13 *and offices of the Agency.*

14 “(3) *CHAIRPERSON.*—*The official designated*
15 *under subsection (a) shall serve as the Chairperson of*
16 *the Coordinating Committee.*

17 “(4) *DUTIES.*—*With respect to research on wom-*
18 *en’s health, the Coordinating Committee shall assist*
19 *the official designated under subsection (a) in—*

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

23 “(B) *identifying needs regarding the coordi-*
24 *nation of research activities, including intra-*

1 *tration, an office to be known as the Office of Women’s*
2 *Health. The Office shall be headed by a director who shall*
3 *be appointed by the Administrator.*

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

5 “(1) *report to the Administrator on the current*
6 *Administration level of activity regarding women’s*
7 *health across, where appropriate, age, biological, and*
8 *sociocultural contexts;*

9 “(2) *establish short-range and long-range goals*
10 *and objectives within the Health Resources and Serv-*
11 *ices Administration for women’s health and, as rel-*
12 *evant and appropriate, coordinate with other appro-*
13 *priate offices on activities within the Administration*
14 *that relate to health care provider training, health*
15 *service delivery, research, and demonstration projects,*
16 *for issues of particular concern to women;*

17 “(3) *identify projects in women’s health that*
18 *should be conducted or supported by the bureaus of*
19 *the Administration;*

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 Administration policy*
24 *with regard to women; and*

1 “(5) *serve as a member of the Department of*
2 *Health and Human Services Coordinating Committee*
3 *on Women’s Health (established under section*
4 *229(b)(4) of the Public Health Service Act).*

5 “(c) *COORDINATING COMMITTEE.—*

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

11 “(2) *COMPOSITION.—The Coordinating Com-*
12 *mittee shall be composed of the directors of the bu-*
13 *reaus of the Administration.*

14 “(3) *CHAIRPERSON.—The Director of the Office*
15 *shall serve as the Chairperson of the Coordinating*
16 *Committee.*

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

20 “(A) *identifying the need for programs and*
21 *activities that focus on women’s health;*

22 “(B) *identifying needs regarding the coordi-*
23 *nation of activities, including intramural and*
24 *extramural multidisciplinary activities; and*

1 “(C) *making recommendations to the Ad-*
2 *ministrator concerning findings made under sub-*
3 *paragraphs (A) and (B).*

4 “(d) *REPORTS.—Not later than January 31, 2003,*
5 *and January 31 of each second year thereafter, the Director*
6 *of the Office shall prepare and submit to the appropriate*
7 *committees of Congress a report describing the activities*
8 *carried out under this section during the period for which*
9 *the report is being prepared.*

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

11 “(1) *ADMINISTRATION.—The term ‘Administra-*
12 *tion’ means the Health Resources and Services Ad-*
13 *ministration.*

14 “(2) *ADMINISTRATOR.—The term ‘Adminis-*
15 *trator’ means the Administrator of the Health Re-*
16 *sources and Services Administration.*

17 “(3) *OFFICE.—The term ‘Office’ means the Office*
18 *of Women’s Health established under this section in*
19 *the Administration.*

20 “(f) *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 each*
23 *of the fiscal years 2003 through 2007.”.*

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. 908. OFFICE OF WOMEN'S HEALTH.**

7 *“(a) ESTABLISHMENT.—The Secretary shall establish*
8 *through the last date for which appropriations are author-*
9 *ized under subsection (e), within the Office of the Commis-*
10 *sioner, an office to be known as the Office of Women's*
11 *Health (referred to in this section as the ‘Office’). The Office*
12 *shall be headed by a director who shall be appointed by*
13 *the Commissioner of Food and Drugs.*

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

15 *“(1) report to the Commissioner of Food and*
16 *Drugs on current Food and Drug Administration (re-*
17 *ferred to in this section as the ‘Administration’) levels*
18 *of activity regarding women's participation in clin-*
19 *ical trials and the analysis of data by sex in the test-*
20 *ing of drugs, medical devices, and biological products*
21 *across, where appropriate, age, biological, and*
22 *sociocultural contexts;*

23 *“(2) establish short-range and long-range goals*
24 *and objectives within the Administration for issues of*
25 *particular concern to women's health within the juris-*
26 *isdiction of the Administration, including, where rel-*

1 *evant and appropriate, adequate inclusion of women*
2 *and analysis of data by sex in Administration proto-*
3 *cols and policies;*

4 *“(3) provide information to women and health*
5 *care providers on those areas in which differences be-*
6 *tween men and women exist;*

7 *“(4) consult with pharmaceutical, biologics, and*
8 *device manufacturers, health professionals with exper-*
9 *tise in women’s issues, consumer organizations, and*
10 *women’s health professionals on Administration pol-*
11 *icy with regard to women;*

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

15 *“(6) serve as a member of the Department of*
16 *Health and Human Services Coordinating Committee*
17 *on Women’s Health (established under section*
18 *229(b)(4) of the Public Health Service Act).*

19 *“(c) COORDINATING COMMITTEE.—*

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

1 “(2) *COMPOSITION.*—*The Coordinating Com-*
2 *mittee shall be composed of the directors of the centers*
3 *of the Administration.*

4 “(3) *CHAIRPERSON.*—*The Director of the Office*
5 *shall serve as the Chairperson of the Coordinating*
6 *Committee.*

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

10 “(A) *identifying whether there is a need for*
11 *further studies and, if so, developing strategies to*
12 *foster such studies;*

13 “(B) *identifying issues in specific areas of*
14 *women’s health that fall within the mission of*
15 *the Administration;*

16 “(C) *identifying whether any need exists for*
17 *the coordination of Administration activities, in-*
18 *cluding internal and external activities;*

19 “(D) *maintaining the Administration’s*
20 *focus in areas of importance to women;*

21 “(E) *supporting the development of meth-*
22 *odologies to determine how to obtain data spe-*
23 *cific to women (including data relating to the*
24 *age of women and the membership of women in*
25 *ethnic or racial groups); and*

1 “(F) supporting the development and ex-
2 pansion of clinical trials of treatments and
3 therapies for which obtaining such data has been
4 determined to be an appropriate function.

5 “(d) *REPORTS.*—Not later than January 31, 2003,
6 and January 31 of each second year thereafter, the Director
7 of the Office shall prepare and submit to the appropriate
8 committees of Congress a report describing the activities
9 carried out under this section during the period for which
10 the report is being prepared.

11 “(e) *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 each
14 of the fiscal years 2003 through 2007.”.

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

16 *Nothing in this Act and the amendments made by this*
17 *Act may be construed as establishing regulatory authority*
18 *or modifying any existing regulatory authority.*

Union Calendar No. 371

107TH CONGRESS
2^D SESSION

H. R. 1784

[Report No. 107-616]

A BILL

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

JULY 25, 2002

Reported with an amendment, committed to the Com-
mittee of the Whole House on the State of the Union,
and ordered to be printed