

108TH CONGRESS
2D SESSION

H. R. 4354

To improve the health of women through the establishment of Offices of Women's Health within the Department of Health and Human Services.

IN THE HOUSE OF REPRESENTATIVES

MAY 12, 2004

Mrs. MALONEY (for herself, Ms. PRYCE of Ohio, Mr. WAXMAN, Mr. GRIJALVA, Mr. SERRANO, Mrs. JONES of Ohio, Ms. MILLENDER-McDONALD, Ms. BALDWIN, Ms. CARSON of Indiana, Mr. GEORGE MILLER of California, Ms. ROYBAL-ALLARD, Ms. NORTON, Mrs. MCCARTHY of New York, Ms. BERKLEY, Ms. LOFGREN, Mr. FROST, Mr. GONZALEZ, Mr. KILDEE, Ms. SLAUGHTER, Ms. SCHAKOWSKY, Ms. DELAURO, Ms. LEE, Mr. HINCHEY, Mr. CASTLE, Mr. LANTOS, Mr. OWENS, Mrs. CAPITO, Ms. LINDA T. SÁNCHEZ of California, Mr. BRADY of Pennsylvania, Mr. VAN HOLLEN, Mr. SCHIFF, Mr. CROWLEY, Mr. NETHERCUTT, Mr. FORD, Mr. HASTINGS of Florida, Ms. ESHOO, Mr. STARK, Mr. CONYERS, Ms. WATERS, Mr. TOWNS, Ms. BORDALLO, and Ms. SOLIS) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To improve the health of women through the establishment of Offices of 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Women’s Health Office
3 Act of 2004”.

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

11 “(a) ESTABLISHMENT OF OFFICE.—The Secretary
12 shall establish within the Office of the Secretary, an Office
13 on Women’s Health (referred to in this section as the ‘Of-
14 fice’). The Office shall be headed by a Deputy Assistant
15 Secretary for Women’s Health.

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

18 “(1) establish short-range and long-range goals
19 and objectives within the Department of Health and
20 Human Services and, as relevant and appropriate,
21 coordinate with other appropriate offices on activi-
22 ties within the Department that relate to disease
23 prevention, health promotion, service delivery, re-
24 search, and public and health care professional edu-
25 cation, for issues of particular concern to women;

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

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

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

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

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

23 “(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, 2006,
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 2005 through 2009.”.

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 known as the Office of Women’s Health (referred to in
2 this section as the ‘Office’). The Office shall be headed
3 by a director who shall be appointed by the Director of
4 such Centers.

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

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

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

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

23 “(4) consult with health professionals, non-
24 governmental organizations, consumer organizations,
25 women’s health professionals, and other individuals

1 and groups, as appropriate, on the policy of the Cen-
2 ters with regard to women; and

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

7 “(c) COORDINATING COMMITTEE.—

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

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

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

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

23 “(A) identifying the need for programs and
24 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, 2006,
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 or for which there is reasonable evidence that indi-
23 cates that such factors or types may be different for
24 women.

1 “(f) 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 2005 through 2009.”.

5 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
6 **ITY ACTIVITIES REGARDING WOMEN’S**
7 **HEALTH.**

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

10 (1) by redesignating sections 927 and 928 as
11 sections 928 and 929, respectively;

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

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

14 “(a) ESTABLISHMENT.—The Director shall designate
15 an official of the Office of Priority Populations to carry
16 out the responsibilities described in this section for such
17 official.

18 “(b) PURPOSE.—The official designated under sub-
19 section (a) shall—

20 “(1) report to the Director on the current
21 Agency level of activity regarding women’s health,
22 across, where appropriate, age, biological, and
23 sociocultural contexts, in all aspects of Agency work,
24 including the development of evidence reports and
25 clinical practice protocols and the conduct of re-

1 search into patient outcomes, delivery of health care
2 services, quality of care, and access to health care;

3 “(2) establish short-range and long-range goals
4 and objectives within the Agency for research impor-
5 tant to women’s health and, as relevant and appro-
6 priate, coordinate with other appropriate offices on
7 activities within the Agency that relate to health
8 services and medical effectiveness research, for
9 issues of particular concern to women;

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

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 Agency policy with
16 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)).

21 “(c) COORDINATING COMMITTEE.—

22 “(1) ESTABLISHMENT.—In carrying out sub-
23 section (b), the official designated under subsection
24 (a) shall establish a committee to be known as the
25 Coordinating Committee on Women’s Health (re-

1 ferred to in this subsection as the ‘Coordinating
2 Committee’).

3 “(2) COMPOSITION.—The Coordinating Com-
4 mittee shall be composed of the official designated
5 under subsection (a) and the directors of the centers
6 and offices of the Agency.

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

10 “(4) DUTIES.—With respect to research on
11 women’s health, the Coordinating Committee shall
12 assist the official designated under subsection (a)
13 in—

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

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

22 “(C) making recommendations to the Di-
23 rector of the Agency concerning findings made
24 under subparagraphs (A) and (B).

1 “(d) REPORTS.—Not later than January 31, 2006,
 2 and January 31 of each second year thereafter, the official
 3 designated under subsection (a) shall prepare and submit
 4 to the appropriate committees of Congress a report de-
 5 scribing the activities carried out under this section during
 6 the period for which the report is being prepared.”; and

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

9 “(e) WOMEN’S HEALTH.—For the purpose of car-
 10 rying out section 927 regarding women’s health, there are
 11 authorized to be appropriated such sums as may be nec-
 12 essary for each of the fiscal years 2005 through 2009.”.

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

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

17 “OFFICE OF WOMEN’S HEALTH

18 “SEC. 713. (a) ESTABLISHMENT.—The Secretary
 19 shall establish within the Office of the Administrator of
 20 the Health Resources and Services Administration, an of-
 21 fice to be known as the Office of Women’s Health. The
 22 Office shall be headed by a director who shall be appointed
 23 by the Administrator.

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

25 “(1) report to the Administrator on the current
 26 Administration level of activity regarding women’s

1 health across, where appropriate, age, biological, and
2 sociocultural contexts;

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

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

14 “(4) consult with health professionals, non-
15 governmental organizations, consumer organizations,
16 women’s health professionals, and other individuals
17 and groups, as appropriate, on Administration policy
18 with 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 Women’s Health (referred to in this sub-
3 section as the ‘Coordinating Committee’).

4 “(2) COMPOSITION.—The Coordinating Com-
5 mittee shall be composed of the directors of the bu-
6 reaus of the Administration.

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 women’s health,
11 the Coordinating Committee shall assist the Director
12 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 concerning findings made under
20 subparagraphs (A) and (B).

21 “(d) REPORTS.—Not later than January 31, 2006,
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) DEFINITIONS.—For purposes of this section:

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

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

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

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purpose of carrying out this section, there are authorized
15 to be appropriated such sums as may be necessary for
16 each of the fiscal years 2005 through 2010.”.

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:

22 **“SEC. 910. OFFICE OF WOMEN’S HEALTH.**

23 “(a) ESTABLISHMENT.—The Secretary shall estab-
24 lish within the Office of the Commissioner, an office to
25 be known as the Office of Women’s Health (referred to

1 in this section as the ‘Office’). The Office shall be headed
2 by a director who shall be appointed by the Commissioner
3 of Food and Drugs.

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

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

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

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

23 “(4) consult with pharmaceutical, biologics, and
24 device manufacturers, health professionals with ex-
25 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 women’s health,
23 the Coordinating Committee shall assist the Director
24 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, 2006,
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 2005 through 2009.”.

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.

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