

109TH CONGRESS
1ST SESSION

H. R. 949

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

FEBRUARY 17, 2005

Mrs. MALONEY (for herself and Ms. PRYCE of Ohio) 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Women’s Health Office
5 Act of 2005”.

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

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

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

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

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

10 “(1) establish short-range and long-range goals
11 and objectives within the Department of Health and
12 Human Services and, as relevant and appropriate,
13 coordinate with other appropriate offices on activi-
14 ties within the Department that relate to disease
15 prevention, health promotion, service delivery, re-
16 search, and public and health care professional edu-
17 cation, for issues of particular concern to women;

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

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

1 “(4) establish a Department of Health and
2 Human Services Coordinating Committee on Women’s Health, which shall be chaired by the Deputy
3 Assistant Secretary for Women’s Health and composed of senior level representatives from each of the
4 agencies and offices of the Department of Health
5 and Human Services;

6 “(5) establish a National Women’s Health Information Center to—

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

11 “(B) facilitate access to such information;

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

15 “(D) provide technical assistance with respect to the exchange of information (including
16 facilitating the development of materials for
17 such technical assistance);

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

1 “(7) through publications and any other means
2 appropriate, provide for the exchange of information
3 between the Office and recipients of grants, con-
4 tracts, and agreements under subsection (c), and be-
5 tween the Office and health professionals and the
6 general public.

7 “(c) GRANTS AND CONTRACTS REGARDING DU-
8 TIES.—

9 “(1) AUTHORITY.—In carrying out subsection
10 (b), the Secretary may make grants to, and enter
11 into cooperative agreements, contracts, and inter-
12 agency agreements with, public and private entities,
13 agencies, and organizations.

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

21 “(d) REPORTS.—Not later than January 31, 2007,
22 and January 31 of each second year thereafter, the Sec-
23 retary shall prepare and submit to the appropriate com-
24 mittees of Congress a report describing the activities car-

ried out under this section during the period for which the report is being prepared.

“(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.”.

(b) TRANSFER OF FUNCTIONS.—There are transferred to the Office on Women’s Health (established under section 229 of the Public Health Service Act, as added by this section), all functions exercised by the Office on Women’s Health of the Public Health Service prior to the date of enactment of this section, including all personnel and compensation authority, all delegation and assignment authority, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

(1) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this subsection; and

(2) are in effect at the time this section takes effect, or were final before the date of enactment of

1 this section and are to become effective on or after
2 such date;
3 shall continue in effect according to their terms until
4 modified, terminated, superseded, set aside, or revoked in
5 accordance with law by the President, the Secretary, or
6 other authorized official, a court of competent jurisdiction,
7 or by operation of law.

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

10 Part A of title III of the Public Health Service Act
11 (42 U.S.C. 241 et seq.) is amended by adding at the end
12 the following:

13 “SEC. 310A. (a) ESTABLISHMENT.—The Secretary
14 shall establish within the Office of the Director of the Cen-
15 ters for Disease Control and Prevention, an office to be
16 known as the Office of Women’s Health (referred to in
17 this section as the ‘Office’). The Office shall be headed
18 by a director who shall be appointed by the Director of
19 such Centers.

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

21 “(1) report to the Director of the Centers for
22 Disease Control and Prevention on the current level
23 of the Centers’ activity regarding women’s health
24 conditions across, where appropriate, age, biological,
25 and sociocultural contexts, in all aspects of the Cen-

1 ters’ work, including prevention programs, public
2 and professional education, services, and treatment;

3 “(2) establish short-range and long-range goals
4 and objectives within the Centers for women’s health
5 and, as relevant and appropriate, coordinate with
6 other appropriate offices on activities within the
7 Centers that relate to prevention, research, edu-
8 cation and training, service delivery, and policy de-
9 velopment, for issues of particular concern to
10 women;

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

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

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

22 “(c) COORDINATING COMMITTEE.—

23 “(1) ESTABLISHMENT.—In carrying out sub-
24 section (b), the Director of the Office shall establish
25 a committee to be known as the Coordinating Com-

1 mittee on Women’s Health (referred to in this sub-
2 section as the ‘Coordinating Committee’).

3 “(2) COMPOSITION.—The Coordinating Com-
4 mittee shall be composed of the directors of the na-
5 tional centers and other appropriate officials of the
6 Centers for Disease Control and Prevention.

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 Di-
19 rector of the Centers for Disease Control and
20 Prevention concerning findings made under
21 subparagraphs (A) and (B).

22 “(d) REPORTS.—Not later than January 31, 2007,
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) DEFINITION.—As used in this section, the term
 4 ‘women’s health conditions’, with respect to women of all
 5 age, ethnic, and racial groups, means diseases, disorders,
 6 and conditions—

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

9 “(2) for which the factors of medical risk or
 10 type of medical intervention are different for women,
 11 or for which there is reasonable evidence that indi-
 12 cates that such factors or types may be different for
 13 women.

14 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
 15 purpose of carrying out this section, there are authorized
 16 to be appropriated such sums as may be necessary for
 17 each of the fiscal years 2006 through 2010.”.

18 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
 19 **ITY ACTIVITIES REGARDING WOMEN’S**
 20 **HEALTH.**

21 Part C of title IX of the Public Health Service Act
 22 (42 U.S.C. 299c et seq.) is amended—

23 (1) by redesignating sections 927 and 928 as
 24 sections 928 and 929, respectively;

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

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

2 “(a) ESTABLISHMENT.—The Director shall designate
3 an official of the Office of Priority Populations to carry
4 out the responsibilities described in this section for such
5 official.

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

8 “(1) report to the Director on the current
9 Agency level of activity regarding women’s health,
10 across, where appropriate, age, biological, and
11 sociocultural contexts, in all aspects of Agency work,
12 including the development of evidence reports and
13 clinical practice protocols and the conduct of re-
14 search into patient outcomes, delivery of health care
15 services, quality of care, and access to health care;

16 “(2) establish short-range and long-range goals
17 and objectives within the Agency for research impor-
18 tant to women’s health and, as relevant and appro-
19 priate, coordinate with other appropriate offices on
20 activities within the Agency that relate to health
21 services and medical effectiveness research, for
22 issues of particular concern to women;

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

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

1 women’s health professionals, and other individuals
2 and groups, as appropriate, on Agency policy with
3 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 official designated under subsection
11 (a) shall establish a committee to be known as the
12 Coordinating Committee on Women’s Health (re-
13 ferred to in this subsection as the ‘Coordinating
14 Committee’).

15 “(2) COMPOSITION.—The Coordinating Com-
16 mittee shall be composed of the official designated
17 under subsection (a) and the directors of the centers
18 and offices of the Agency.

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

22 “(4) DUTIES.—With respect to research on
23 women’s health, the Coordinating Committee shall
24 assist the official designated under subsection (a)
25 in—

1 “(A) identifying the need for such re-
2 search, and making an estimate each fiscal year
3 of the funds needed to adequately support the
4 research;

5 “(B) identifying needs regarding the co-
6 ordination of research activities, including in-
7 tramural and extramural multidisciplinary ac-
8 tivities; and

9 “(C) making recommendations to the Di-
10 rector of the Agency concerning findings made
11 under subparagraphs (A) and (B).

12 “(d) REPORTS.—Not later than January 31, 2007,
13 and January 31 of each second year thereafter, the official
14 designated under subsection (a) shall prepare and submit
15 to the appropriate committees of Congress a report de-
16 scribing the activities carried out under this section during
17 the period for which the report is being prepared.”; and

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

20 “(e) WOMEN’S HEALTH.—For the purpose of car-
21 rying out section 927 regarding women’s health, there are
22 authorized to be appropriated such sums as may be nec-
23 essary for each of the fiscal years 2006 through 2010.”.

1 **SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
2 **TION OFFICE OF WOMEN'S HEALTH.**

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

5 **“SEC. 713. OFFICE OF WOMEN'S HEALTH.**

6 “(a) ESTABLISHMENT.—The Secretary shall estab-
7 lish within the Office of the Administrator of the Health
8 Resources and Services Administration, an office to be
9 known as the Office of Women's Health. The Office shall
10 be headed by a director who shall be appointed by the Ad-
11 ministrator.

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

13 “(1) report to the Administrator on the current
14 Administration level of activity regarding women's
15 health across, where appropriate, age, biological, and
16 sociocultural contexts;

17 “(2) establish short-range and long-range goals
18 and objectives within the Health Resources and
19 Services Administration for women's health and, as
20 relevant and appropriate, coordinate with other ap-
21 propriate offices on activities within the Administra-
22 tion that relate to health care provider training,
23 health service delivery, research, and demonstration
24 projects, for issues of particular concern to women;

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

4 “(4) consult with health professionals, non-
5 governmental organizations, consumer organizations,
6 women’s health professionals, and other individuals
7 and groups, as appropriate, on Administration policy
8 with regard to women; and

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

13 “(c) COORDINATING COMMITTEE.—

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

19 “(2) COMPOSITION.—The Coordinating Com-
20 mittee shall be composed of the directors of the bu-
21 reaus of the Administration.

22 “(3) CHAIRPERSON.—The Director of the Of-
23 fice shall serve as the Chairperson of the Coordi-
24 nating Committee.

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

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

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

9 “(C) making recommendations to the Ad-
10 ministrators concerning findings made under
11 subparagraphs (A) and (B).

12 “(d) REPORTS.—Not later than January 31, 2007,
13 and January 31 of each second year thereafter, the Direc-
14 tor of the Office shall prepare and submit to the appro-
15 priate committees of Congress a report describing the ac-
16 tivities carried out under this section during the period
17 for which the report is being prepared.

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

19 “(1) ADMINISTRATION.—The term ‘Administra-
20 tion’ means the Health Resources and Services Ad-
21 ministration.

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

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

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
 5 purpose of carrying out this section, there are authorized
 6 to be appropriated such sums as may be necessary for
 7 each of the fiscal years 2006 through 2011.”.

8 **SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF**
 9 **WOMEN’S HEALTH.**

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

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

14 “(a) ESTABLISHMENT.—The Secretary shall estab-
 15 lish within the Office of the Commissioner, an office to
 16 be known as the Office of Women’s Health (referred to
 17 in this section as the ‘Office’). The Office shall be headed
 18 by a director who shall be appointed by the Commissioner
 19 of Food and Drugs.

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

21 “(1) report to the Commissioner of Food and
 22 Drugs on current Food and Drug Administration
 23 (referred to in this section as the ‘Administration’)
 24 levels of activity regarding women’s participation in
 25 clinical trials and the analysis of data by sex in the

1 testing of drugs, medical devices, and biological
2 products across, where appropriate, age, biological,
3 and sociocultural contexts;

4 “(2) establish short-range and long-range goals
5 and objectives within the Administration for issues
6 of particular concern to women’s health within the
7 jurisdiction of the Administration, including, where
8 relevant and appropriate, adequate inclusion of
9 women and analysis of data by sex in Administration
10 protocols and policies;

11 “(3) provide information to women and health
12 care providers on those areas in which differences
13 between men and women exist;

14 “(4) consult with pharmaceutical, biologics, and
15 device manufacturers, health professionals with ex-
16 pertise in women’s issues, consumer organizations,
17 and women’s health professionals on Administration
18 policy with regard to women;

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

22 “(6) serve as a member of the Department of
23 Health and Human Services Coordinating Com-
24 mittee on Women’s Health (established under sec-
25 tion 229(b)(4) of the Public Health Service Act).

1 “(c) COORDINATING COMMITTEE.—

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

7 “(2) COMPOSITION.—The Coordinating Com-
8 mittee shall be composed of the directors of the cen-
9 ters of the Administration.

10 “(3) CHAIRPERSON.—The Director of the Of-
11 fice shall serve as the Chairperson of the Coordi-
12 nating Committee.

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

16 “(A) identifying whether there is a need
17 for further studies and, if so, developing strate-
18 gies to foster such studies;

19 “(B) identifying issues in specific areas of
20 women’s health that fall within the mission of
21 the Administration;

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

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

3 “(E) supporting the development of meth-
4 odologies to determine how to obtain data spe-
5 cific to women (including data relating to the
6 age of women and the membership of women in
7 ethnic or racial groups); and

8 “(F) supporting the development and ex-
9 pansion of clinical trials of treatments and
10 therapies for which obtaining such data has
11 been determined to be an appropriate function.

12 “(d) REPORTS.—Not later than January 31, 2007,
13 and January 31 of each second year thereafter, the Direc-
14 tor of the Office shall prepare and submit to the appro-
15 priate committees of Congress a report describing the ac-
16 tivities carried out under this section during the period
17 for which the report is being prepared.

18 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there are authorized
20 to be appropriated such sums as may be necessary for
21 each of the fiscal years 2006 through 2010.”.

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

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

