

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 1784
OFFERED BY MR. BILIRAKIS

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

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

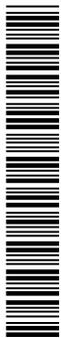
4 **SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOM-**
5 **EN’S HEALTH.**

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

11 “(a) ESTABLISHMENT OF OFFICE.—The Secretary
12 shall establish through the last date for which appropria-
13 tions are authorized under subsection (e), within the Of-
14 fice of the Secretary, an Office on Women’s Health (re-
15 ferred 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—



1 “(1) establish short-range and long-range goals
2 and objectives within the Department of Health and
3 Human Services and, as relevant and appropriate,
4 coordinate with other appropriate offices on activi-
5 ties within the Department that relate to disease
6 prevention, health promotion, service delivery, re-
7 search, and public and health care professional edu-
8 cation, for issues of particular concern to women;

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

12 “(3) monitor the Department of Health and
13 Human Services’ offices, agencies, and regional ac-
14 tivities regarding women’s health and stimulate ac-
15 tivities and facilitate coordination of such depart-
16 mental and agency offices on women’s health;

17 “(4) establish a Department of Health and
18 Human Services Coordinating Committee on Wom-
19 en’s Health, which shall be chaired by the Deputy
20 Assistant Secretary for Women’s Health and com-
21 posed of senior level representatives from each of the
22 agencies and offices of the Department of Health
23 and Human Services;

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



1 “(A) facilitate the exchange of information
2 regarding matters relating to health informa-
3 tion, health promotion, preventive health serv-
4 ices, research advances, and education in the
5 appropriate use of health care;

6 “(B) facilitate access to such information;

7 “(C) assist in the analysis of issues and
8 problems relating to the matters described in
9 this paragraph; and

10 “(D) provide technical assistance with re-
11 spect to the exchange of information (including
12 facilitating the development of materials for
13 such technical assistance);

14 “(6) coordinate efforts to promote women’s
15 health programs and policies with the private sector;
16 and

17 “(7) through publications and any other means
18 appropriate, provide for the exchange of information
19 between the Office and recipients of grants, con-
20 tracts, and agreements under subsection (c), and be-
21 tween the Office and health professionals and the
22 general public.

23 “(c) GRANTS AND CONTRACTS REGARDING DU-
24 TIES.—



1 “(1) AUTHORITY.—In carrying out subsection
2 (b), the Secretary may make grants to, and enter
3 into cooperative agreements, contracts, and inter-
4 agency agreements with, public and private entities,
5 agencies, and organizations.

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

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

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

23 (b) TRANSFER OF FUNCTIONS.—There are trans-
24 ferred to the Office on Women’s Health (established under
25 section 229 of the Public Health Service Act, as added



1 by this section), all functions exercised by the Office on
2 Women's Health of the Public Health Service prior to the
3 date of enactment of this section, including all personnel
4 and compensation authority, all delegation and assign-
5 ment authority, and all remaining appropriations. All or-
6 ders, determinations, rules, regulations, permits, agree-
7 ments, grants, contracts, certificates, licenses, registra-
8 tions, privileges, and other administrative actions that—

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

14 (2) are in effect at the time this section takes
15 effect, or were final before the date of enactment of
16 this section and are to become effective on or after
17 such date;

18 shall continue in effect according to their terms until
19 modified, terminated, superseded, set aside, or revoked in
20 accordance with law by the President, the Secretary, or
21 other authorized official, a court of competent jurisdiction,
22 or by operation of law.



1 **SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVEN-**
2 **TION 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 appropria-
10 tions are authorized under subsection (f), within the Office
11 of the Director of the Centers for Disease Control and
12 Prevention, an office to be known as the Office of Wom-
13 en’s Health (referred to in this section as the ‘Office’).
14 The Office shall be headed by a director who shall be ap-
15 pointed by the Director of such Centers.

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

17 “(1) report to the Director of the Centers for
18 Disease Control and Prevention on the current level
19 of the Centers’ activity regarding women’s health
20 conditions across, where appropriate, age, biological,
21 and sociocultural contexts, in all aspects of the Cen-
22 ters’ work, including prevention programs, public
23 and professional 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
2 Centers that relate to prevention, research, edu-
3 cation and training, service delivery, and policy de-
4 velopment, for issues of particular concern to
5 women;

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

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 the policy of the Cen-
12 ters with 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 Director of the Office shall establish
20 a committee to be known as the Coordinating Com-
21 mittee on Research on Women’s Health (referred to
22 in this subsection as the ‘Coordinating Committee’).

23 “(2) COMPOSITION.—The Coordinating Com-
24 mittee shall be composed of the directors of the na-



1 tional centers and other appropriate officials of the
2 Centers for Disease Control and Prevention.

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

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

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

11 “(B) identifying needs regarding the co-
12 ordination of activities, including intramural
13 and extramural multidisciplinary activities; and

14 “(C) making recommendations to the Di-
15 rector of the Centers for Disease Control and
16 Prevention concerning findings made under
17 subparagraphs (A) and (B).

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

24 “(e) DEFINITION.—As used in this section, the term
25 ‘women’s health conditions’, with respect to women of all



1 age, ethnic, and racial groups, means diseases, disorders,
2 and conditions—

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

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

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

11 **SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
12 **ITY ACTIVITIES REGARDING WOMEN'S**
13 **HEALTH.**

14 Part C of title IX of the Public Health Service Act
15 (42 U.S.C. 299e et seq.) is amended—

16 (1) by redesignating sections 927 and 928 as
17 sections 928 and 929, respectively;

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

19 **“SEC. 927. ACTIVITIES REGARDING WOMEN'S HEALTH.**

20 “(a) ESTABLISHMENT.—The Director shall designate
21 an official of the Office of Priority Populations to carry
22 out, through the last date for which appropriations are
23 authorized under section 928(e), the responsibilities de-
24 scribed in this section for such official.



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

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

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

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 official designated under subsection
8 (a) shall establish a committee to be known as the
9 Coordinating Committee on Research on Women’s
10 Health (referred to in this subsection as the ‘Coordi-
11 nating Committee’).

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

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

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

23 “(A) identifying the need for such re-
24 search, and making an estimate each fiscal year



1 of the funds needed to adequately support the
2 research;

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

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

10 “(d) REPORTS.—Not later than January 31, 2003,
11 and January 31 of each second year thereafter, the official
12 designated under subsection (a) shall prepare and submit
13 to the appropriate committees of Congress a report de-
14 scribing the activities carried out under this section during
15 the period for which the report is being prepared.”; and

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

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

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

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



1 “OFFICE OF WOMEN’S HEALTH

2 “SEC. 713. (a) ESTABLISHMENT.—The Secretary
3 shall establish through the last date for which appropria-
4 tions are authorized under subsection (f), within the Office
5 of the Administrator of the Health Resources and Services
6 Administration, an office to be known as the Office of
7 Women’s Health. The Office shall be headed by a director
8 who shall be appointed by the Administrator.

9 “(b) PURPOSE.—The Director of the Office shall—
10 “(1) report to the Administrator on the current
11 Administration level of activity regarding women’s
12 health across, where appropriate, age, biological, and
13 sociocultural contexts;

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

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



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

6 “(5) 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 Research on Women’s Health (referred to
15 in this subsection as the ‘Coordinating Committee’).

16 “(2) COMPOSITION.—The Coordinating Com-
17 mittee shall be composed of the directors of the bu-
18 reaus 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 research on
23 women’s health, the Coordinating Committee shall
24 assist the Director of the Office in—



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

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

6 “(C) making recommendations to the Ad-
7 ministrators concerning findings made under
8 subparagraphs (A) and (B).

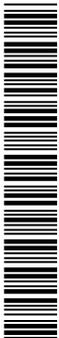
9 “(d) REPORTS.—Not later than January 31, 2003,
10 and January 31 of each second year thereafter, the Direc-
11 tor of the Office shall prepare and submit to the appro-
12 priate committees of Congress a report describing the ac-
13 tivities carried out under this section during the period
14 for which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

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

16 “(1) ADMINISTRATION.—The term ‘Administra-
17 tion’ means the Health Resources and Services Ad-
18 ministration.

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

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



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 2003 through 2007.”.

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

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

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

11 “(a) ESTABLISHMENT.—The Secretary shall estab-
12 lish through the last date for which appropriations are au-
13 thorized under subsection (e), within the Office of the
14 Commissioner, an office to be known as the Office of
15 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 Commissioner of Food and Drugs.

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

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



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

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

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

13 “(4) consult with pharmaceutical, biologics, and
14 device manufacturers, health professionals with ex-
15 pertise in women’s issues, consumer organizations,
16 and women’s health professionals on Administration
17 policy with regard to 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 cen-
8 ters of the Administration.

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 whether there is a need
16 for further studies and, if so, developing strate-
17 gies to foster such studies;

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

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

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



1 “(E) 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); and

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

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

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

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

