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WOMEN'S HEALTH OFFICE ACT OF 2002

JULY 25, 2002.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. TAUZIN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1784]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1784) to establish an Office on Women's Health within the Department of Health and Human Services, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Women's Health Office Act of 2002".

SEC. 2. HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.

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

"HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH

"SEC. 229. (a) ESTABLISHMENT OF OFFICE.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (e), within the Office of the Secretary, an Office on Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a Deputy Assistant Secretary for Women's Health.

"(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

"(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women;

"(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health;

"(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and stimulate activities and facilitate coordination of such departmental and agency offices on women's health;

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

"(5) establish a National Women's Health Information Center to—

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

"(B) facilitate access to such information;

"(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

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

"(6) coordinate efforts to promote women's health programs and policies with the private sector; and

"(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

"(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

"(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

"(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

"(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried 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 2003 through 2007.".

(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 this section and are to become effective on or after such date;

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

SEC. 3. CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.

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

"CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH

"SEC. 310A. (a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (f), within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

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

"(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

"(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the Centers;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

"(c) COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the 'Coordinating Committee').

"(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the national centers and other appropriate officials of the Centers for Disease Control and Prevention.

"(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

"(4) DUTIES.—With respect to women's health, the Coordinating Committee shall assist the Director of the Office in—

"(A) identifying the need for programs and activities that focus on women's health;

"(B) identifying needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities; and

"(C) making recommendations to the Director of the Centers for Disease Control and Prevention concerning findings made under subparagraphs (A) and (B).

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

"(e) DEFINITION.—As used in this section, the term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

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

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

"(f) 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 2003 through 2007.".

SEC. 4. AGENCY FOR HEALTHCARE RESEARCH AND QUALITY ACTIVITIES REGARDING WOMEN'S HEALTH.

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

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

(2) by inserting after section 926 the following:

"SEC. 927. ACTIVITIES REGARDING WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—The Director shall designate an official of the Office of Priority Populations to carry out, through the last date for which appropriations are authorized under section 928(e), the responsibilities described in this section for such official.

"(b) PURPOSE.—The official designated under subsection (a) shall—

"(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

"(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the Agency;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

"(c) COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—In carrying out subsection (b), the official designated under subsection (a) shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the 'Coordinating Committee').

"(2) COMPOSITION.—The Coordinating Committee shall be composed of the official designated under subsection (a) and the directors of the centers and offices of the Agency.

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

"(4) DUTIES.—With respect to research on women's health, the Coordinating Committee shall assist the official designated under subsection (a) in—

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

"(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities; and

"(C) making recommendations to the Director of the Agency concerning findings made under subparagraphs (A) and (B).

"(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the official designated under subsection (a) shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared."; and

(3) by adding at the end of section 928 (as redesignated by paragraph (1)) the following:

"(e) WOMEN'S HEALTH.—For the purpose of carrying out section 927 regarding women's health, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007.".

SEC. 5. HEALTH RESOURCES AND SERVICES ADMINISTRATION OFFICE OF WOMEN'S HEALTH.

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

"OFFICE OF WOMEN'S HEALTH

"SEC. 713. (a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (f), within the Office of the Administrator of the Health Resources and Services Administration, an office to be known as the Office of Women's Health. The Office shall be headed by a director who shall be appointed by the Administrator.

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

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

"(2) establish short-range and long-range goals and objectives within the Health Resources and Services Administration for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Administration that relate to health care provider training, health service delivery, research, and demonstration projects, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the bureaus of the Administration;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Administration policy with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act).

"(c) COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the 'Coordinating Committee').

"(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the bureaus of the Administration.

"(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

"(4) DUTIES.—With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

"(A) identifying the need for programs and activities that focus on women's health;

"(B) identifying needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities; and

"(C) making recommendations to the Administrator concerning findings made under subparagraphs (A) and (B).

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

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

"(1) ADMINISTRATION.—The term 'Administration' means the Health Resources and Services Administration.

"(2) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

"(3) OFFICE.—The term 'Office' means the Office of Women's Health established under this section in the Administration.

"(f) 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 2003 through 2007.".

SEC. 6. FOOD AND DRUG ADMINISTRATION OFFICE OF WOMEN'S HEALTH.

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

"SEC. 908. OFFICE OF WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (e), within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to

in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

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

"(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the 'Administration') levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

"(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

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

"(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

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

"(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act).

"(c) COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Women's Health (referred to in this subsection as the 'Coordinating Committee').

"(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the centers of the Administration.

"(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

"(4) DUTIES.—With respect to studies on women's health, the Coordinating Committee shall assist the Director of the Office in—

"(A) identifying whether there is a need for further studies and, if so, developing strategies to foster such studies;

"(B) identifying issues in specific areas of women's health that fall within the mission of the Administration;

"(C) identifying whether any need exists for the coordination of Administration activities, including internal and external activities;

"(D) maintaining the Administration's focus in areas of importance to women;

"(E) supporting the development of methodologies to determine how to obtain data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups); and

"(F) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function.

"(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the Director of the Office shall prepare and submit to the appropriate committees of Congress a report describing the activities carried 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 2003 through 2007.".

SEC. 7. NO NEW REGULATORY AUTHORITY.

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

PURPOSE AND SUMMARY

The purpose of H.R. 1784 is to formally establish an Office on Women's Health at the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA), and coordinate women's

health activities at the Agency for Healthcare Research and Quality through its Office of Priority Populations.

BACKGROUND AND NEED FOR LEGISLATION

In 1991, President George H. Bush created the Office on Women's Health at HHS to improve the health of American women. The mission of the office is to direct, develop, coordinate, and advance women's health research, health care services, and public and health care professional education and training across the agencies and offices of the public health services. The office does this in conjunction with other government agencies, public and private organizations, and consumer and health care professional groups. The Office on Women's Health also advises the Secretary, and the Assistant Secretary for Health, on the scientific, medical, ethical, and policy issues related to the advancement of women's health in the United States and internationally.

In addition to the Office of Women's Health located in Washington, D.C., the ten HHS Regional Offices also have a women's health coordinator. The CDC, FDA, and HRSA also maintain separate offices to focus on women's health. In 1992, Congress mandated the establishment of an Associate Administrator for Women's Services at the Substance Abuse and Mental Health Services Administration (SAMSA) and, in 1993, an Office of Research on Women's Health at the National Institutes of Health (NIH).

Current statistical data show that certain health conditions have a disproportionate impact on women. For example, osteoporosis, asthma, diabetes, and lupus continue to plague women at a higher rate than men. Similar to the purpose of the Office on Women's Health, the National Women's Health Information Center was created by HHS to help share information with the public and medical community on new research advancements and health initiatives focused primarily on women's health.

The federal government currently spends almost $70 billion on cross-cutting programs to address women's health.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On June 11, the Subcommittee on Health met in open markup session and approved H.R. 1784 for Full Committee consideration, as amended, by a voice vote. On June 13, the Full Committee met in open markup session, and favorably ordered reported H.R. 1784, as amended, by a voice vote.

COMMITTEE VOTES

There were no record votes taken in connection with ordering H.R. 1784 reported. A motion by Mr. Tauzin to order H.R. 1784 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to establish an Office on Women's Health at HHS, CDC, FDA, and HRSA.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1784, the Women's Health Office Act of 2002, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

H.R. 1784—Women's Health Office Act of 2002

Summary: H.R. 1784 would provide explicit authorization for offices of women's health in four federal agencies: the Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC); the Health Resources and Services Administration (HRSA); and the Food and Drug Administration (FDA). In addition, the bill would designate an individual within the existing Office of Priority Populations within the Agency for Health Care Research and Quality (AHRQ) to lead the agency's research on women's health.

H.R. 1784 also would establish coordinating committees within the AHRQ and the CDC. Each of the agencies affected currently engages in research on women's health and executes many of the provisions of H.R. 1784, but those activities are not specifically authorized under the Public Health Service Act.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 1784 would cost $27 million in 2003 and $144 million over the 2003–2007 period, assuming annual adjustments for inflation for those activities without specified authorization levels. The five-year total would be $139 million if such inflation adjustments are not made. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 1784 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA)

and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1784 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars—					
	2002	2003	2004	2005	2006	2007
SPENDING SUBJECT TO APPROPRIATION						
Spending under Current Law for Offices of Women's Health:						
Estimated Budget Authority	24	0	0	0	0	0
Estimated Outlays	23	5	0	0	0	0
Proposed Changes:						
Estimated Authorization Level [1]	0	29	30	30	31	32
Estimated Outlays	0	27	26	30	31	31
Spending under H.R. 1784 for Offices of Women's Health:						
Estimated Authorization Level	24	29	30	30	31	32
Estimated Outlays	23	27	26	30	31	31

[1] The amounts shown reflect adjustments for anticipated inflation for those activities for which the bill would authorize such sums as necessary. Without such inflation adjustments, the five-year changes in authorization levels would total $142 million (instead of $151 million) and the changes in outlays would total $139 million (instead of $144 million).

Note.—Numbers may not sum to totals due to rounding.

Basis of estimate: H.R. 1784 would require the Secretary of HHS to establish an Office on Women's Health within the Office of the Secretary and to transfer to that office all functions and personnel of the current Office on Women's Health of the Public Health Service. The office would be headed by the Deputy Assistant Secretary for Women's Health, with the task of establishing both short-range and long-range goals and objectives regarding women's health at both the national and local levels. The office would coordinate with and monitor the activities of other women's health offices within HHS on issues that relate to disease prevention, health promotion, service delivery, research, and education of the public and health care professionals on women's health issues.

In addition, the bill would establish the HHS Coordinating Committee on Women's Health, which would be chaired by the Deputy Assistant Secretary and senior-level representatives from other agencies within the department. H.R. 1784 also would establish a National Women's Health Information Center to facilitate the exchange of women's health information and provide technical assistance in analyzing women's health issues and health problems. The bill would authorize the office to make grants and cooperative agreements with public and private entities, and would require the office to report progress annually to the Congress. CBO estimates that these activities would cost $18 million in 2003 and $94 million over the 2003–2007 period if the necessary amounts are appropriated.

H.R. 1784 would authorize appropriations of such sums as necessary for the CDC, HRSA, and the FDA to establish at each agency an Office on Women's Health. Each would be responsible for assessing the current level of agency activity in the area of women's health, and for setting short-range and long-range goals for women's health and for each agency's activities related to prevention, research, education and training, service delivery, and policy development. The bill would also establish a Coordinating Committee on Research on Women's Health within each agency. CBO estimates

these activities would cost $2 million in 2003 and $9 million over the 2003–2007 period for the CDC, $1 million in 2003 and $3 million over the 2003–2007 period for HRSA, and $6 million in 2003 and $37 million over the 2003–2007 period for the FDA, if the necessary amounts are appropriated.

The bill would direct the director of AHRQ to designate an individual within the Office of Priority Populations to report to the director on the current level of activity within AHRQ on women's health issues, establish short-term and long-term research goals, identify opportunities for agency projects on women's health, serve as AHRQ's main point of contact on women's health issues for public and private stakeholders, and serve as a member of HHS's Coordinating Committee on Women's Health. In addition, H.R. 1784 would establish a Coordinating Committee on Research on Women's Health within the AHRQ to identify areas of research on women's health, estimate funds needed to fund this research, identify areas where coordination of research is needed, and make recommendations to the director of AHRQ based on the findings of the committee. CBO estimates these activities would cost less than $500,000 in 2003 and $2 million over the 2003–2007 period if the necessary amounts are appropriated.

For this estimate, CBO assumes that the bill would have an effective date of October 1, 2002, and that outlays would follow historical spending rates for the relevant agencies for the authorized activities. For most agencies, CBO based its estimates on amounts spent in the past for similar activities of the affected agencies. In the case of the FDA, CBO estimates that based on information obtained from the agency, the FDA would require an additional $4 million in appropriations over the 2002 appropriations level to carry out the requirements of the bill.

Pay-as-you-go considerations: None.

Intergovernmental and private-sector mandates: H.R. 1784 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal Costs: Alexis Ahlstrom, Julia Christenson, Jeanne De Sa, Hallie Torrell, and Christopher Topoleski. Impact on state, local, and tribal governments: Leo Lex. Impact on the private sector: Jennifer Bowman.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional au-

thority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides the short title of the bill, the "Women's Health Office Act of 2002."

Section 2. Health and Human Services Office on Women's Health

Section 2 requires the Secretary of HHS to establish, within the Office of the Secretary, an Office on Women's Health. A Deputy Assistant Secretary for Women's Health will head the office. The duties of the office include (1) establishing short-range and long-range goals and objectives within HHS and the coordination of activities that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women; (2) providing expert advice and consultation concerning scientific, legal, ethical, and policy issues relating to women's health; (3) monitoring the offices, agencies, and regional activities regarding women's health and stimulate activities and facilitate coordination of these activities; (4) establishing a Coordinating Committee on Women's Health composed of senior level representatives from each of the agencies and offices of HHS; (5) establishing a National Women's Health Information Center to facilitate the exchange of information; (6) coordinating efforts to promote women's health programs and policies with the private sector; and, (7) providing for the exchange of information through publications and other means. The Secretary may also make grants and enter into contracts and interagency agreements with public and private entities, agencies, and organizations. The Secretary must evaluate projects, and submit a report to Congress describing the activities carried out. This section also establishes the Office on Women's Health for fiscal years 2003 through 2007 and authorizes such sums as may be necessary for the same period.

Section 3. Centers for Disease Control and Prevention Office on Women's Health

Section 3 requires the Secretary to establish an Office on Women's Health within the Office of the Director of the CDC. The purpose of the new office will be to (1) report to the Director of the CDC on the current level of the Centers activity regarding women's health conditions; (2) establish short-range and long-range goals and objectives for issues of particular concern to women; (3) identify projects in women's health; (4) consult with health professionals, and other individuals; and, (5) serve as a member of the HHS Coordinating Committee on Women's Health. The office must also establish a Coordinating Committee on Research on Women's

Health. The Director of the Office must report to Congress on the activities of the office one year following enactment of the legislation, and each second year thereafter. This section also establishes the office for fiscal years 2003 through 2007 and authorizes such sums as may be necessary for the same period.

Section 4. Agency for Healthcare Research and Quality Activities Regarding Women's Health

Section 4 requires the Director of the Agency for Healthcare Research and Quality to designate an official of the Office of Priority Populations to report to the Director on the current Agency level of activity regarding women's health. The Official will (1) report to the Director on the current Agency level of activity regarding women's health; (2) establish short-range and long-range goals and objectives within the Agency for research important to women's health; (3) identify projects in women's health that should be conducted or supported by the Agency; (4) consult with health professionals and others on Agency policy with regard to women; and, (5) serve as a member of the HHS Coordinating Committee on Women's Health. The Official designated by this section must also establish a Coordinating Committee on Research on Women's Health, and report to Congress on the activities carried out by the Office of Priority Populations one year following enactment of the legislation, and each second year thereafter. This section also establishes the office for fiscal years 2003 through 2007 and authorizes such sums as may be necessary for the same period.

Section 5. Health Resources and Services Administration Office of Women's Health

Section 5 requires the Secretary to establish an Office of Women's Health within the Office of the Administrator of HRSA. The Director of the Office will (1) report to the Administrator on the current level of activity regarding women's health; (2) establish short-range and long-range goals for issues of particular concern to women; (3) identify projects in women's health that should be conducted; (4) consult with health professionals and others on Administration policy with regard to women; and, (5) serve as a member of the HHS Coordinating Committee on Women's Health. This section also requires that the office establish a Coordinating Committee on Research on Women's Health. The Director of the Office is required to report to Congress on the activities of the office one year following enactment of the legislation, and each second year thereafter. There are authorized to be appropriated such sums as may be necessary for fiscal years 2003 through 2007. This section also establishes the office for fiscal years 2003 through 2007 and authorizes such sums as may be necessary for the same period.

Section 6. Food and Drug Administration Office of Women's Health

Section 6 requires the Secretary to establish an Office of Women's Health within the Office of the Commissioner at FDA. The Director of the Office must (1) report to the FDA Commissioner on current FDA levels of activities regarding women's participation in clinical trials and the analysis of data, by sex, in the testing of drugs, medical devices, and biological products; (2) establish short-range and long-range goals and objectives for issues of particular

concern to women's health; (3) provide information to women and health care providers on those areas in which differences between men and women exist; (4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women; (5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex; and, (6) serve as a member of the HHS Coordinating Committee on Women's Health. In addition, the office must establish a Coordinating Committee on Women's Health, and the Director must report to Congress on the activities of the office one year following enactment of the legislation, and each second year thereafter. This section also establishes the office for fiscal years 2003 through 2007 and authorizes such sums as may be necessary for the same period.

Section 7. No New Regulatory Authority

Section 7 states that nothing in this legislation may be construed as establishing new regulatory authority or modifying existing regulatory authority.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

PART A—ADMINISTRATION

* * * * * * *

HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH

SEC. 229. (a) ESTABLISHMENT OF OFFICE.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (e), within the Office of the Secretary, an Office on Women's Health (referred to in this section as the "Office"). The Office shall be headed by a Deputy Assistant Secretary for Women's Health.

(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women;

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

(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and stimulate activities and facilitate coordination of such departmental and agency offices on women's health;

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

(5) establish a National Women's Health Information Center to—

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

(B) facilitate access to such information;

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

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

(6) coordinate efforts to promote women's health programs and policies with the private sector; and

(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

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

(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried 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 2003 through 2007.

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

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CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH

SEC. 310A. (a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (f), within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

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

(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Centers;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the "Coordinating Committee").

(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the national centers and other appropriate officials of the Centers for Disease Control and Prevention.

(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

(4) DUTIES.—With respect to women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for programs and activities that focus on women's health;

(B) identifying needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities; and

(C) making recommendations to the Director of the Centers for Disease Control and Prevention concerning findings made under subparagraphs (A) and (B).

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

(e) DEFINITION.—As used in this section, the term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

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

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

(f) 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 2003 through 2007.

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TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

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PART C—GENERAL PROVISIONS

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SEC. 927. ACTIVITIES REGARDING WOMEN'S HEALTH.

(a) ESTABLISHMENT.—The Director shall designate an official of the Office of Priority Populations to carry out, through the last date for which appropriations are authorized under section 928(e), the responsibilities described in this section for such official.

(b) PURPOSE.—The official designated under subsection (a) shall—

(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Agency;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

(c) COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out subsection (b), the official designated under subsection (a) shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the "Coordinating Committee").

(2) COMPOSITION.—The Coordinating Committee shall be composed of the official designated under subsection (a) and the directors of the centers and offices of the Agency.

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

(4) DUTIES.—With respect to research on women's health, the Coordinating Committee shall assist the official designated under subsection (a) in—

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

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities; and

(C) making recommendations to the Director of the Agency concerning findings made under subparagraphs (A) and (B).

(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the official designated under subsection (a) shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.

SEC. [927.] *928.* FUNDING.

(a) * * *

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(e) WOMEN'S HEALTH.—For the purpose of carrying out section 927 regarding women's health, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007.

SEC. [928.] *929.* DEFINITIONS.

In this title:

(1) * * *

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SOCIAL SECURITY ACT

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TITLE VII—ADMINISTRATION

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OFFICE OF WOMEN'S HEALTH

SEC. 713. (a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (f), within the Office of the Administrator of the Health Resources and Services Administration, an office to be known as the Office of Women's Health. The Office shall be headed by a director who shall be appointed by the Administrator.

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

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

(2) establish short-range and long-range goals and objectives within the Health Resources and Services Administration for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Administration that relate to health care provider training, health service delivery, research, and demonstration projects, for issues of particular concern to women;

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

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Administration policy with regard to women; and

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

(c) COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (referred to in this subsection as the "Coordinating Committee").

(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the bureaus of the Administration.

(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

(4) DUTIES.—With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for programs and activities that focus on women's health;

(B) identifying needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities; and

(C) making recommendations to the Administrator concerning findings made under subparagraphs (A) and (B).

(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the Director of the Office shall prepare and submit to the appropriate committees of Congress a report

describing the activities carried out under this section during the period for which the report is being prepared.

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

(1) ADMINISTRATION.—The term "Administration" means the Health Resources and Services Administration.

(2) ADMINISTRATOR.—The term "Administrator" means the Administrator of the Health Resources and Services Administration.

(3) OFFICE.—The term "Office" means the Office of Women's Health established under this section in the Administration.

(f) 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 2003 through 2007.

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FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER IX—MISCELLANEOUS

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SEC. 908. OFFICE OF WOMEN'S HEALTH.

(a) ESTABLISHMENT.—The Secretary shall establish through the last date for which appropriations are authorized under subsection (e), within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

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

(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the "Administration") levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

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

(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

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

(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act).

(c) COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Women's Health (referred to in this subsection as the "Coordinating Committee").

(2) COMPOSITION.—The Coordinating Committee shall be composed of the directors of the centers of the Administration.

(3) CHAIRPERSON.—The Director of the Office shall serve as the Chairperson of the Coordinating Committee.

(4) DUTIES.—With respect to studies on women's health, the Coordinating Committee shall assist the Director of the Office in—

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

(B) identifying issues in specific areas of women's health that fall within the mission of the Administration;

(C) identifying whether any need exists for the coordination of Administration activities, including internal and external activities;

(D) maintaining the Administration's focus in areas of importance to women;

(E) supporting the development of methodologies to determine how to obtain data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups); and

(F) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function.

(d) REPORTS.—Not later than January 31, 2003, and January 31 of each second year thereafter, the Director of the Office shall prepare and submit to the appropriate committees of Congress a report describing the activities carried 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 2003 through 2007.

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