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 lie 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 Wom-
3	en's Health, which shall be chaired by the Deputy
4	Assistant Secretary for Women's Health and com-
5	posed of senior level representatives from each of the
6	agencies and offices of the Department of Health
7	and Human Services;
8	"(5) establish a National Women's Health In-
9	formation Center to—
10	"(A) facilitate the exchange of information
11	regarding matters relating to health informa-
12	tion, health promotion, preventive health serv-
13	ices, research advances, and education in the
14	appropriate use of health care;
15	"(B) facilitate access to such information;
16	"(C) assist in the analysis of issues and
17	problems relating to the matters described in
18	this paragraph; and
19	"(D) provide technical assistance with re-
20	spect to the exchange of information (including
21	facilitating the development of materials for
22	such technical assistance);
23	"(6) coordinate efforts to promote women's
24	health programs and policies with the private sector;
25	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
- 7 "(c) Grants and Contracts Regarding Du-
- 8 TIES.—

general public.

- 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.
- "(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, 2007, and January 31 of each second year thereafter, the Secretary shall prepare and submit to the appropriate com-

- 1 ried out under this section during the period for which
- 2 the report is being prepared.
- 3 "(e) AUTHORIZATION OF APPROPRIATIONS.—For the
- 4 purpose of carrying out this section, there are authorized
- 5 to be appropriated such sums as may be necessary for
- 6 each of the fiscal years 2006 through 2010.".
- 7 (b) Transfer of Functions.—There are trans-
- 8 ferred to the Office on Women's Health (established under
- 9 section 229 of the Public Health Service Act, as added
- 10 by this section), all functions exercised by the Office on
- 11 Women's Health of the Public Health Service prior to the
- 12 date of enactment of this section, including all personnel
- 13 and compensation authority, all delegation and assign-
- 14 ment authority, and all remaining appropriations. All or-
- 15 ders, determinations, rules, regulations, permits, agree-
- 16 ments, grants, contracts, certificates, licenses, registra-
- 17 tions, privileges, and other administrative actions that—
- 18 (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 trans-
- ferred under this subsection; and
- 23 (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
- of the Centers' activity regarding women's health
- 24 conditions across, where appropriate, age, biological,
- and sociocultural contexts, in all aspects of the Cen-

- ters' work, including prevention programs, public
 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;
 - "(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)).
- 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-

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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
- type of medical intervention are different for women,
- or for which there is reasonable evidence that indi-
- cates that such factors or types may be different for
- 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
- 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-

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 "(5) serve as a member of the Department of 4 5 Health and Human Services Coordinating Com-6 mittee on Women's Health (established under sec-7 tion 229(b)(4). "(c) COORDINATING COMMITTEE.— 8 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 Coordinating Committee on Women's Health (re-12 13 ferred to in this subsection as the 'Coordinating' 14 Committee'). "(2) Composition.—The Coordinating Com-15 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.
 - "(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—

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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;

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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-

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	ministrator 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
- (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).

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.

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