

Calendar No. 602107TH CONGRESS
2^D SESSION**S. 2328**

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to ensure a safe pregnancy for all women in the United States, to reduce the rate of maternal morbidity and mortality, to eliminate racial and ethnic disparities in maternal health outcomes, to reduce pre-term labor, to examine the impact of pregnancy on the short and long term health of women, to expand knowledge about the safety and dosing of drugs to treat pregnant women with chronic conditions and women who become sick during pregnancy, to expand public health prevention, education and outreach, and to develop improved and more accurate data collection related to maternal morbidity and mortality.

IN THE SENATE OF THE UNITED STATES

APRIL 25, 2002

Mr. HARKIN (for himself, Mr. KENNEDY, Ms. MIKULSKI, Mr. DODD, Mr. EDWARDS, Mrs. MURRAY, Mrs. CLINTON, Mr. GREGG, Mr. BINGAMAN, Mr. JOHNSON, Mr. FRIST, Mr. JEFFORDS, Ms. COLLINS, Mr. DEWINE, Ms. LANDRIEU, Mr. LEVIN, Ms. STABENOW, Mr. BIDEN, Mr. KERRY, Mr. INOUE, Mr. SARBANES, Mr. CLELAND, Mr. BAUCUS, Mr. GRAHAM, Ms. CANTWELL, and Mr. REID) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 17, 2002

Reported by Mr. KENNEDY, with an amendment and an amendment to the title

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Public Health Service Act and the Federal

Food, Drug, and Cosmetic Act to ensure a safe pregnancy for all women in the United States, to reduce the rate of maternal morbidity and mortality, to eliminate racial and ethnic disparities in maternal health outcomes, to reduce pre-term labor, to examine the impact of pregnancy on the short and long term health of women, to expand knowledge about the safety and dosing of drugs to treat pregnant women with chronic conditions and women who become sick during pregnancy, to expand public health prevention, education and outreach, and to develop improved and more accurate data collection related to maternal morbidity and mortality.

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 “Safe Motherhood Act
 5 for Research and Treatment” or the “SMART Mom Act”.

6 **SEC. 2. FINDINGS AND PURPOSES.**

7 (a) FINDINGS.—Congress makes the following find-
 8 ings:

9 (1) Pregnancy is a natural condition. Approxi-
 10 mately 6,000,000 women become pregnant each year
 11 and more than 10,000 give birth each day.

12 (2) The United States ranks 20th in maternal
 13 mortality out of 49 developed countries.

14 (3) In the United States about 1,000 women
 15 will die each year from pregnancy-related illnesses or

1 conditions. Two to 3 lives are lost each day due to
2 pregnancy-related mortality.

3 (4) Racial and ethnic minority women suffer a
4 significantly higher risk of pregnancy-related mor-
5 tality than non-Hispanic white women. African
6 American women are almost 4 times more likely to
7 die from pregnancy-related illnesses or conditions
8 than white women. Hispanic, Asian immigrant, and
9 American Indian women are twice as likely to die
10 from pregnancy-related illnesses or conditions as
11 their non-Hispanic counterparts.

12 (5) Women between the ages of 35 and 40 are
13 2 to 3 times more likely to experience a pregnancy-
14 related death compared to women between the ages
15 of 20 and 25.

16 (6) There has been no decline in pregnancy-re-
17 lated deaths in the United States over the last 20
18 years. In 1987 the United States set goals as part
19 of Healthy People 2000: National Health Promotion
20 and Disease Prevention Objectives, to reduce mater-
21 nal deaths from 7.5 deaths per 100,000 to 3.3 per
22 100,000 for live births and no more than 5.0 mater-
23 nal deaths per 100,000 births among African Amer-
24 ican women. Again in 2000, as part of Healthy Peo-

1 ple 2010, new goals have been set. These goals have
2 not been met.

3 (7) In the United States, 30 percent of women,
4 or 1 out of every 3 pregnant women, experience a
5 major medical complication at some point during
6 their pregnancy. The most common complications
7 are miscarriage, ectopic pregnancy, excessive vom-
8 iting, diabetes, hemorrhage, infection, pre-eclampsia,
9 premature labor, and the need for a surgical (cae-
10 sarian) delivery.

11 (8) Women who are at high-risk, who have a
12 chronic condition, or who do not have access to
13 health care face even more difficult pregnancies, de-
14 liveries, and risk to their long-term health.

15 (9) African American, Hispanic, and older
16 women, have a significantly increased risk of com-
17 plications.

18 (10) Pre-term infants were more than 14 times
19 more likely than infants that were not pre-term to
20 die before their first birthday.

21 (11) There is a lack of knowledge regarding the
22 causes of these complications, as well as effective
23 preventative and therapeutic interventions. Perinatal
24 diseases rank as the second lowest National Institute
25 of Health-funded group of diseases in the whole field

1 of medicine when comparisons take into account dis-
2 ability adjusted life years (DALYs) lost due to each
3 disease.

4 (12) Most drugs women take during pregnancy
5 are necessary to maintain health. However, 80 per-
6 cent of approved drugs lack adequate scientific evi-
7 dence about their use in pregnancy. Only 1 percent
8 of drugs have been shown in controlled studies to
9 pose no risk to pregnant women.

10 (13) Women under age 35 take an average of
11 3 prescription drugs during pregnancy. For women
12 over the age of 35 the number of prescription drugs
13 increases to 5.

14 (14) Pregnancy is a critical time in a women's
15 life with far ranging implications for her short- and
16 long-term health and for the health of her family.
17 The United States must devote the resources and
18 have the will of the nation to ensure a safe preg-
19 nancy and good health throughout the lives of Amer-
20 ican women.

21 (b) PURPOSES.—It is the purpose of this Act to—

22 (1) develop a national effort to achieve a
23 healthy and safe pregnancy for all women in the
24 United States;

- 1 (2) reduce the risk of pregnancy-related deaths
2 and complications due to pregnancy;
- 3 (3) eliminate racial and ethnic disparities in the
4 rates of maternal mortality and morbidity;
- 5 (4) improve the treatment and clinical care of
6 pregnant women;
- 7 (5) reduce pre-term labor;
- 8 (6) examine the impact of pregnancy on the
9 short- and long-term health of women;
- 10 (7) work toward an evidence-based standard of
11 care with respect to pregnant women;
- 12 (8) expand knowledge about the safety and dos-
13 ing of drugs and devices used to treat pregnant
14 women with chronic conditions and women who be-
15 come sick during pregnancy;
- 16 (9) expand public health prevention, education
17 and outreach; and
- 18 (10) develop improved and more accurate data
19 collection relating to maternal morbidity and mor-
20 tality.

1 **TITLE I—AMENDMENTS TO THE**
 2 **PUBLIC HEALTH SERVICE ACT**
 3 **Subtitle A—Reducing Maternal**
 4 **Morbidity and Mortality**
 5 **Through Coordinated Federal**
 6 **Action**

7 **SEC. 101. INTERAGENCY COORDINATING COMMITTEE ON**
 8 **SAFE MOTHERHOOD.**

9 Part P of title III of the Public Health Service Act
 10 (42 U.S.C. 280g et seq.) is amended by adding at the end
 11 the following:

12 **“SEC. 3990. INTERAGENCY COORDINATING COMMITTEE ON**
 13 **SAFE MOTHERHOOD.**

14 **“(a) ESTABLISHMENT.—**The Secretary, acting
 15 through the Director of the Office of Women’s Health,
 16 shall establish a committee to be known as the ‘Inter-
 17 agency Coordinating Committee on Safe Motherhood’ (re-
 18 ferred to in this section as the ‘Coordinating Committee’).

19 **“(b) COMPOSITION.—**The Coordinating Committee
 20 shall be composed of—

21 **“(1)** the Director of the Centers for Disease
 22 Control and Prevention (and the heads of such insti-
 23 tutes, centers and offices as the Director determines
 24 appropriate);

1 ~~“(2) the Director of the National Institutes of~~
2 ~~Health (and the heads of such institutes, centers~~
3 ~~and offices as the Director determines appropriate);~~

4 ~~“(3) the Director of the Health Resources and~~
5 ~~Services Administration (and the heads of such in-~~
6 ~~stitutes, centers and offices as the Director deter-~~
7 ~~mines appropriate);~~

8 ~~“(4) the Commissioner of Food and Drugs (and~~
9 ~~the heads of such institutes, centers and offices as~~
10 ~~the Commissioner determines appropriate);~~

11 ~~“(5) the Director of the Agency for Healthcare~~
12 ~~Research and Quality (and the heads of such insti-~~
13 ~~tutes, centers and offices as the Director determines~~
14 ~~appropriate);~~

15 ~~“(6) the Secretary of Labor (and the heads of~~
16 ~~such institutes, centers and offices as the Secretary~~
17 ~~determines appropriate);~~

18 ~~“(7) representatives of other Federal Govern-~~
19 ~~ment agencies that serve women; and~~

20 ~~“(8) representatives of women’s health care ad-~~
21 ~~vocacy and grassroots organizations; health care pro-~~
22 ~~viders including providers of specialty care; and re-~~
23 ~~searchers to be appointed by the Director of the Of-~~
24 ~~fice.~~

1 “(e) ADMINISTRATIVE SUPPORT.—The Secretary
2 shall make available to the Coordinating Committee nec-
3 essary and appropriate administrative support.

4 “(d) DUTIES.—

5 “(1) EVALUATION.—The Coordinating Com-
6 mittee shall assess health promotion campaigns that
7 are administered by the Federal Government (in-
8 cluding smoking cessation programs, alcohol and
9 substance abuse treatment programs, and domestic
10 violence prevention programs); evaluate the effect
11 that such campaigns have on health during preg-
12 nancy if pregnancy was a focus, and assess whether
13 such programs may be adapted to emphasize the im-
14 portance of maternal health.

15 “(2) FEDERAL RESEARCH PLAN.—

16 “(A) IN GENERAL.—Not later than 18
17 months after the date of enactment of this sec-
18 tion, the Coordinating Committee shall develop
19 a coordinated Federal research and strategic
20 action plan for safe motherhood.

21 “(B) CONTENTS.—The plan developed
22 under subparagraph (A) shall define the areas
23 of research that are necessary to carry out the
24 purposes of the SMART Mom Act and include
25 recommendations for the implementation and

1 funding of activities under the plan. Such plan
2 shall take into consideration any programs and
3 plans existing on the date of enactment of this
4 section as well as research opportunities that
5 arise during the 5-year period beginning on
6 such date of enactment and shall at a minimum
7 include—

8 “(i) recommendations for research on
9 pregnancy-related conditions;

10 “(ii) recommendations for research on
11 the impact of chronic conditions, physical
12 impairments, or mental health conditions
13 on pregnant women;

14 “(iii) recommendations for research
15 on medical complications that occur during
16 delivery;

17 “(iv) recommendations for research on
18 post-partum conditions (such as depres-
19 sion, hemorrhage, and fever);

20 “(v) recommendations for research on
21 racial, ethnic, social, behavioral, and eco-
22 nomic factors effecting pregnancy;

23 “(vi) recommendations for research to
24 improve outreach efforts, education pro-

1 grams, and prevention and health pro-
2 motion strategies for pregnant women; and

3 “(vii) a recommended plan and re-
4 search agenda to improve knowledge about
5 the safety of drugs, devices, cosmetics, and
6 food with respect to pregnancy.

7 “(C) REPORT.—Not later than 18 months
8 after the date of enactment of this section, the
9 Coordinating Committee shall prepare and sub-
10 mit to the Secretary and the appropriate com-
11 mittees of Congress, a report concerning the
12 plan developed under this paragraph and the
13 results of the evaluation conducted under para-
14 graph (1).

15 “(3) KEY INDICATORS OF WELL BEING.—

16 “(A) IN GENERAL.—The Coordinating
17 Committee, in consultation with the Centers for
18 Disease Control and Prevention, the Director of
19 the National Institute of Child Health and
20 Human Development, the Director of the Agen-
21 cy for Healthcare Research and Quality, and
22 the heads of other relevant Federal agencies,
23 shall determine the key indicators of maternal
24 health and the sources of data to be included in
25 the report under subparagraph (B), and shall

1 update such indicators as new data becomes
2 available.

3 “(B) REPORT.—Not later than October 1,
4 2002, and biannually thereafter, the Coordinating
5 Committee shall prepare and submit to
6 the appropriate committees of Congress, a report,
7 to be known as ‘America’s Mothers: Key
8 National Indicators of Well Being’ (referred to
9 in this section as the ‘Report’), that contains
10 the indicators of maternal health described in
11 subparagraph (A).

12 “(C) AVAILABILITY.—The Report shall be
13 made available to the public through the Internet
14 website established under paragraph (4).

15 “(4) SAFE MOTHERHOOD CAMPAIGN.—The Coordinating
16 Committee shall establish and implement
17 a national public education and health promotion
18 campaign on safe motherhood, including developing
19 and maintaining an Internet website as provided for
20 in section 399P, promoting the establishment of
21 community partnerships, supporting community-
22 based programs, promoting the establishment of
23 partnerships with State and local health providers
24 and educators, and promoting the establishment of
25 partnerships with private non-profit organizations.

1 “(e) NONAPPLICABILITY OF FACA.—The provisions
2 of the Federal Advisory Committee Act (5 U.S.C. App.)
3 shall not apply to the Coordinating Committee.

4 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
5 is authorized to be appropriated, such sums as may be
6 necessary to carry out this section.”.

7 **Subtitle B—Research and Data Col-**
8 **lection To Improve Maternal**
9 **Well-Being**

10 **SEC. 111. EXPAND AND INTENSIFY RESEARCH ACTIVITIES**

11 **AT THE NATIONAL INSTITUTE OF HEALTH.**

12 (a) PURPOSE.—It is the purpose of this section to
13 require the Director of the National Institutes of Health,
14 acting through the Director of the National Institute of
15 Child Health and Human Development and in collabora-
16 tion with the Directors of other appropriate Institutes and
17 Offices, to expand and intensify research activities with
18 respect to conditions that lead to pregnancy-related ill-
19 nesses, injury and death before, during, and after preg-
20 nancy and to expand research to improve understanding
21 and treatment of pregnant women who have chronic dis-
22 ease, physical impairment, or mental health conditions.

23 (b) SAFE MOTHERHOOD AS A PRIORITY AREA.—Sub-
24 part 7 of part C of title IV of the Public Health Service

1 Act (42 U.S.C. 285g et seq.) is amended by adding at
2 the end the following:

3 **“SEC. 452H. SAFE MOTHERHOOD REPORT.**

4 “The Director of the Institute shall annually report
5 to Congress and the public on the extent of the total funds
6 obligated to conduct or support research on safe mother-
7 hood across the National Institutes of Health, including
8 the specific support and research awards allocated through
9 the such Institutes.”.

10 (c) **EXPANDED RESEARCH INTO PREGNANCY.**—Sub-
11 part 7 of part C of title IV of the Public Health Service
12 Act (42 U.S.C. 285g et seq.), as amended by subsection
13 (b), is further amended by adding at the end the following:

14 **“SEC. 452I. EXPANDED RESEARCH ON PREGNANCY.**

15 “(a) **CONDITIONS AND COMPLICATIONS OF PREG-**
16 **NANCY.**—In order to improve the understanding of condi-
17 tions and complications related to pregnancy, to lead to
18 better treatments and care for women throughout their
19 pregnancy, and to prevent pregnancy-related illnesses, in-
20 jury and death whenever possible, the Director of NIH,
21 acting through the Director of the Institute, shall enhance
22 and expand research into the leading causes of pregnancy-
23 related death and complications of pregnancy.

24 “(b) **REDUCING PRE-TERM LABOR AND DELIV-**
25 **ERY.**—In order to reduce the rates of pre-term labor and

1 delivery, the Director of NIH shall expand and intensify
2 research on pre-term labor and delivery.

3 “(e) ~~POST-PARTUM HEALTH CONDITIONS.~~—The Di-
4 rector of NIH shall expand and enhance research con-
5 cerning the post-partum health conditions and illness that
6 affect women.

7 “(d) ~~REDUCTIONS IN RACIAL AND ETHNIC DISPARI-~~
8 ~~TIES.~~—The Director of NIH shall provide for the conduct
9 of research to investigate the mechanisms contributing to
10 the disparities in maternal and perinatal outcomes of ra-
11 cial and ethnic populations and immigrant groups.

12 “(e) ~~AUTHORIZATION OF APPROPRIATIONS.~~—There
13 is authorized to be appropriated, such sums as may be
14 necessary to carry out this section.”.

15 (d) ~~IMPROVING THE UNDERSTANDING AND TREAT-~~
16 ~~MENT OF CHRONIC CONDITIONS OF WOMEN DURING~~
17 ~~PREGNANCY.~~—Part H of title IV of the Public Health
18 Service Act (42 U.S.C. 289 et seq.) is amended by insert-
19 ing after section 494A, the following:

20 “**SEC. 494B. IMPROVING THE UNDERSTANDING AND TREAT-**
21 **MENT OF CHRONIC CONDITIONS OF WOMEN**
22 **DURING PREGNANCY.**”

23 “(a) ~~IN GENERAL.~~—The Director of NIH shall ex-
24 pand research concerning the impact of chronic conditions,

1 physical impairments, and mental health problems on the
2 health of women during their pregnancy.

3 “(b) COLLABORATION.—In carrying out subsection
4 (a), the Director of the Institute shall act in collaboration
5 with the Directors of other appropriate Institutes and Of-
6 fices of the National Institutes of Health.”.

7 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
8 is authorized to be appropriated, such sums as may be
9 necessary to carry out this section.”.

10 (e) MATERNAL FETAL MEDICINE UNITS NET-
11 WORK.—Subpart 7 of part C of title IV of the Public
12 Health Service Act (42 U.S.C. 285g et seq.), as amended
13 by subsection (c), is further amended by adding at the
14 end the following:

15 **“SEC. 452J. MATERNAL FETAL MEDICINE UNITS NETWORK.**

16 “(a) IN GENERAL.—The Director of the Institute
17 shall establish a Maternal Fetal Medicine Units Network.
18 In carrying out this subsection, the Director may enter
19 into agreements to utilize the existing Maternal Fetal
20 Medicine Units Network.

21 “(b) EXPANSION OF NETWORK.—The Director of the
22 Institute shall, through grants, contracts, or cooperative
23 agreements, expand the Maternal Fetal Medicine Units
24 Network established or utilized under subsection (a) to as-
25 sist in the implementation of sections 452I and 494B.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated, such sums as may be
3 necessary to carry out this section.”.

4 **SEC. 112. EXPAND AND INTENSIFY RESEARCH ACTIVITIES**
5 **AT THE CENTERS FOR DISEASE CONTROL**
6 **AND PREVENTION.**

7 (a) REDUCTION IN POOR PREGNANCY OUTCOMES OF
8 ETHNIC AND MINORITY WOMEN.—Section 317K of the
9 Public Health Service Act (42 U.S.C. 247b–12) is
10 amended—

11 (1) by redesignating subsection (d) as sub-
12 section (f); and

13 (2) by inserting after subsection (e), the fol-
14 lowing:

15 “(d) REDUCTION IN POOR PREGNANCY OUTCOMES
16 OF ETHNIC AND MINORITY WOMEN.—

17 “(1) IN GENERAL.—The Secretary, acting
18 through the Director of the Centers for Disease
19 Control and Prevention, shall award grants to States
20 to support community-based demonstration projects
21 in disease prevention and health promotion to reduce
22 disparities in pregnancy outcomes, with particular
23 emphasis on social, economic, and behavioral health
24 issues (including violence and obesity) affecting ra-
25 cial and ethnic populations and immigrant groups.

1 Where practicable, such demonstration projects shall
2 be based on relevant scientific studies.

3 “(2) TECHNICAL ASSISTANCE.—In carrying out
4 paragraph (1), the Secretary may provide technical
5 assistance to States.”.

6 (b) PREVENTION RESEARCH CENTERS.—Section
7 317K of the Public Health Service Act (42 U.S.C. 247b-
8 12) is amended by inserting after subsection (d), as added
9 by subsection (a) of this section, the following:

10 “(e) PREVENTION RESEARCH CENTERS.—The Direc-
11 tor of the Centers for Disease Control and Prevention, act-
12 ing through the National Center for Chronic Disease Pre-
13 vention and Health Promotion, shall award grants to uni-
14 versities and other non-profit research institutions and
15 centers to enable such entities to conduct research con-
16 cerning improving maternal outcomes and eliminating ra-
17 cial disparities in maternal morbidity and mortality, with
18 special emphasis provided to research concerning the role
19 of stress, violence, discrimination, access, nutrition, obe-
20 sity and literacy.”.

1 **SEC. 113. IMPROVE QUALITY HEALTH CARE FOR PREG-**
2 **NANT WOMEN THROUGH AGENCY FOR**
3 **HEALTHCARE RESEARCH AND QUALITY.**

4 Section 913 of the Public Health Service Act (42
5 U.S.C. 299b-2) is amended by adding at the end the fol-
6 lowing:

7 **“(e) MATERNAL HEALTH CARE.—**

8 **“(1) IN GENERAL.—**The Director shall provide
9 for the conduct of research concerning the quality of
10 maternal health care from a patient-centered per-
11 spective, including—

12 **“(A)** the type of care that is available and
13 provided prior to, during, and after pregnancy;

14 **“(B)** an examination of all types of care
15 and interventions, both medical and non-med-
16 ical, as well as barriers women face in gaining
17 access to recommended treatments; and

18 **“(C)** recommendations for the minimum
19 care needed to be considered as having received
20 quality care.

21 **“(2) REPORT.—**The results of the research con-
22 ducted under paragraph (1) shall be provided by the
23 Director to Congress as part of the annual report
24 submitted under subsection (b)(2).”.

1 **Subtitle C—Data Collection and**
 2 **Surveillance**

3 **SEC. 121. EXPAND AND INTENSIFY DATA COLLECTION AC-**
 4 **TIVITIES AT THE CENTERS FOR DISEASE**
 5 **CONTROL AND PREVENTION.**

6 Part B of title III of the Public Health Service Act
 7 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
 8 tion 317K the following:

9 **“SEC. 317K-1. DATA COLLECTION REGARDING SAFE MOTH-**
 10 **ERHOOD.**

11 “(a) **STANDARD DEFINITIONS FOR PREGNANCY-RE-**
 12 **LATED MORTALITY AND MORBIDITY.**—The Secretary,
 13 acting through the Director of the Centers for Disease
 14 Control and Prevention and in cooperation with State offi-
 15 cials, professional medical experts, medical organizations,
 16 and health care advocacy groups, shall develop a standard
 17 definition of ‘maternal mortality’ and ‘maternal mor-
 18 bidity’.

19 “(b) **GRANTS FOR SURVEILLANCE OF PREGNANCY-**
 20 **RELATED MORTALITY AND MORBIDITY DATA.**—

21 “(1) **IN GENERAL.**—The Secretary, acting
 22 through the Director of the Centers for Disease
 23 Control and Prevention, shall establish a program to
 24 award grants to States, counties, and cities for the
 25 development of surveillance systems, that use the

1 standard definitions established under subsection
2 (a), to gather data on maternal mortality and mater-
3 nal morbidity.

4 “(2) ELIGIBILITY.—To be eligible to receive a
5 grant under paragraph (1), a State, county, or city
6 shall—

7 “(A) prepare and submit to the Secretary
8 an application, at such time, in such manner,
9 and containing such information as the Sec-
10 retary may require;

11 “(B) provide an assurance that the appli-
12 cant will work with the Centers for Disease
13 Control and Prevention to adopt standard pro-
14 cedures for the identification, collection, and
15 analysis of the data that is to be collected under
16 the grant; and

17 “(C) provide an assurance that the appli-
18 cant will contribute \$1 (in cash or in kind) to
19 activities under the grant for every \$4 provided
20 by the Federal Government.

21 “(3) TECHNICAL ASSISTANCE.—The Centers
22 for Disease Control and Prevention shall provide
23 technical assistance to grantees under this sub-
24 section.

1 “(4) INCORPORATION OF DATA INTO REPORT.—

2 Where determined appropriate by the Secretary,
3 data collected by the surveillance systems established
4 under this subsection shall be incorporated into the
5 report submitted under section 3990(d)(3)(B).

6 “(e) PREVALENCE OF PRE-TERM LABOR AND DELIV-
7 ERY.—The Secretary, acting through the Director of the
8 Centers for Disease Control and Prevention, shall work
9 with States and other entities to improve knowledge re-
10 garding the incidence and prevalence of symptoms and
11 risk factors for pre-term births.

12 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated, such sums as may be
14 necessary to carry out this section.”.

15 **SEC. 122. STUDY ON EFFECTS OF PREGNANCY ON WOMEN.**

16 Section 1004 of the Children’s Health Act of 2000
17 (42 U.S.C. 285g note) is amended—

18 (1) by redesignating subsections (d) and (e) as
19 subsections (e) and (f), respectively; and

20 (2) by inserting after subsection (e), the fol-
21 lowing:

22 “(d) STUDY ON EFFECTS OF PREGNANCY ON
23 WOMEN.—As part of the study conducted under this sec-
24 tion, the Director of the National Institute of Child Health
25 and Human Development, in collaboration with the Direc-

1 (2) providing women and other interest parties
2 with the tools necessary to achieve safe and healthy
3 pregnancies.

4 **SEC. 132. SAFE MOTHERHOOD CAMPAIGN.**

5 Part P of title III of the Public Health Service Act
6 (42 U.S.C. 280g et seq.), as amended by section 101, is
7 further amended by adding at the end the following:

8 **“SEC. 399P. SAFE MOTHERHOOD CAMPAIGN.**

9 “(a) ESTABLISHMENT.—The Secretary, acting
10 through the Director of the Office of Women’s Health and
11 the Interagency Coordinating Committee on Safe Mother-
12 hood (referred to in this section as the ‘Coordinating Com-
13 mittee’) established under section 399O, shall develop and
14 implement a national public education and health pro-
15 motion campaign to be known as the Safe Motherhood
16 Campaign (referred to in this section as the ‘Campaign’).

17 “(b) ELEMENTS OF CAMPAIGN.—The Campaign
18 shall at a minimum include the following:

19 “(1) WEBSITE.—An Internet website to be es-
20 tablished in accordance with subsection (c).

21 “(2) COMMUNITY PARTNERSHIPS.—The provi-
22 sion of support for community-based programs to
23 provide outreach, education, information and health
24 promotion services and information to give women

1 the tools they need to achieve a safe and healthy
2 pregnancy.

3 “(3) STATE AND LOCAL PARTNERSHIPS.—The
4 facilitation of consultations with State and local pub-
5 lic health officials to gain access to the broadest
6 number of women in an effort to provide outreach
7 and education assistance and information to help
8 women succeed in having a safe and healthy preg-
9 nancy.

10 “(4) SPECIAL POPULATIONS.—The implementa-
11 tion of procedures to ensure that activities under the
12 Campaign are accessible to low-literate, non-English
13 speaking, and nonnative immigrant communities
14 where determined appropriate by the Secretary.

15 “(c) INTERNET WEBSITE.—

16 “(1) ESTABLISHMENT.—The Secretary, acting
17 through the Office of Women’s Health and the Co-
18 ordinating Committee, shall develop and maintain a
19 single Internet website to provide pregnant women,
20 and research and health practitioners with the most
21 up-to-date and accurate information on pregnancy,
22 in a manner designed to carry out the purpose de-
23 scribed in paragraph (2).

24 “(2) PURPOSE.—It is the purpose of the
25 website established under paragraph (1) to consoli-

1 date information, research, and data related to preg-
2 nancy (prenatal, intrapartum, and postpartum) to-
3 gether in one place and to provide links for women
4 to other critical websites (Federal agencies, commu-
5 nity health programs, State and tribal health pro-
6 grams, and self-help professional and advocacy orga-
7 nizations).

8 “(3) ADDRESS.—The Secretary shall ensure
9 that the uniform resource locator for the website es-
10 tablished under paragraph (1) is
11 www.pregnancy.gov. If such locator is not available,
12 the Secretary shall select another similar locator.

13 “(4) CONTENTS.—The website established
14 under paragraph (1) shall, at a minimum, contain—

15 “(A) educational materials for how to suc-
16 ceed in having the safest pregnancy possible, in-
17 cluding a description of chronic conditions,
18 pregnancy-related illnesses, and other health
19 problems that could pose risks to the mother or
20 fetus;

21 “(B) information concerning the safety
22 and risk of prescription and over-the-counter
23 medications and other products that women
24 might use during pregnancy;

1 ~~“(C) information concerning standards for~~
2 ~~clinical care throughout pregnancy;~~

3 ~~“(D) information on trends in labor inter-~~
4 ~~vention, such as induction, epidural, and cae-~~
5 ~~sarean sections, and alternative approaches;~~

6 ~~“(E) information concerning the issue of~~
7 ~~domestic violence during pregnancy, including~~
8 ~~how women can obtain assistance;~~

9 ~~“(F) information concerning infertility and~~
10 ~~maternal health; and~~

11 ~~“(G) information concerning pregnancy-re-~~
12 ~~lated workplace laws and policies, such as the~~
13 ~~Family and Medical Leave Act of 1993.~~

14 ~~“(5) APPROPRIATE FORM OF INFORMATION.—~~
15 ~~The information contained on the website estab-~~
16 ~~lished under paragraph (1) shall be maintained in a~~
17 ~~culturally sensitive and appropriate form.~~

18 ~~“(d) AUTHORIZATION OF APPROPRIATIONS.—There~~
19 ~~is authorized to be appropriated, such sums as may be~~
20 ~~necessary to carry out this section.”.~~

1 **TITLE II—PREGNANT AND**
2 **LACTATING WOMEN**

3 **SEC. 201. AMENDMENTS TO FEDERAL FOOD, DRUG, AND**
4 **COSMETIC ACT.**

5 (a) AMENDMENT TO CHAPTER V.—Chapter V of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
7 et seq.) is amended by adding at the end the following:

8 **“SEC. 564. SAFE DRUGS AND DEVICES FOR PREGNANT AND**
9 **LACTATING WOMEN.**

10 “(a) IMPROVING THE QUALITY OF INFORMATION ON
11 DRUGS AND BIOLOGICAL PRODUCTS FOR WOMEN WHO
12 ARE PREGNANT OR LACTATING.—

13 “(1) MARKETED DRUGS FOR WHICH ADDI-
14 TIONAL INFORMATION IS NEEDED.—

15 “(A) IDENTIFYING DRUGS TO BE STUD-
16 HED.—The Secretary, acting through the Direc-
17 tor of the National Institutes of Health and in
18 consultation with the Commissioner of Food
19 and Drugs and experts in maternal and fetal
20 health, shall—

21 “(i) identify marketed drugs and bio-
22 logical products that were not approved or
23 licensed based on studies in pregnant
24 women for which studies are needed—

1 “(I) to establish appropriate dos-
2 ing for women who are pregnant or
3 lactating; and

4 “(II) to investigate the marketed
5 drugs and biological products’ safe
6 use for pregnant women and fetuses
7 through the use of pregnancy reg-
8 istries and pharmacoepidemiological
9 databases; and

10 “(ii) design protocols for the needed
11 studies described in clause (i).

12 “(B) STUDYING MARKETED DRUGS.—The
13 Director of the National Institutes of Health
14 shall award grants, enter into contracts, or use
15 other appropriate mechanisms to aid in prompt-
16 ly completing the studies designed under sub-
17 paragraph (A), as the National Institutes of
18 Health’s resources allow.

19 “(2) POSTMARKETING STUDIES.—As a condi-
20 tion of approval of an application submitted under
21 section 505(b)(1) or of a biologics license application
22 under section 351 of the Public Health Service Act
23 (42 U.S.C. 262), the Secretary may require that the
24 holder of the application conduct postmarketing

1 studies, to be completed and submitted to the Sec-
2 retary by a date specified by the Secretary, to—

3 “(A) establish dosing recommendations for
4 such drug or biological product for women who
5 are pregnant or lactating; and

6 “(B) investigate the safe use of such drug
7 or biological product for pregnant women and
8 fetuses through the use of pregnancy registries
9 and pharmacoepidemiological databases.

10 “(3) PREGNANCY REGISTRIES AND
11 PHARMACOEPIDEMOLOGICAL DATABASES.—

12 “(A) REGISTRIES.—The Secretary shall
13 issue guidances on the use and evaluation of
14 data from pregnancy registries, including data
15 from centralized registries for drugs and bio-
16 logical products.

17 “(B) DATABASES.—

18 “(i) ESTABLISHMENT.—The Secretary
19 shall establish or award grants, enter into
20 contracts and cooperative agreements, and
21 use other appropriate mechanisms to pro-
22 vide for pharmacoepidemiological databases
23 (including a teratogen surveillance system)
24 to study safety issues related to drugs and

1 biological products, including safety issues
2 for pregnant women and fetuses.

3 “(ii) ~~STUDY AND USE OF DATA.~~—The
4 Secretary shall hold workshops and issue
5 guidances on how to study and use the
6 data from the pharmacoepidemiological
7 databases established or provided for under
8 clause (i).

9 “(4) ~~CLARIFICATION REGARDING MARKET EX-~~
10 ~~CLUSIVITY INTERACTIONS.~~—A clinical investigation
11 involved in any study conducted under this sub-
12 section shall not be considered to be a new clinical
13 investigation for purposes of clauses (iii) and (iv) of
14 section 505(j)(5)(D).

15 “(b) ~~IMPROVING COMMUNICATION OF INFORMATION~~
16 ~~TO PREGNANT AND LACTATING WOMEN AND THEIR~~
17 ~~HEALTH CARE PROVIDERS THROUGH DRUG LABEL-~~
18 ~~ING.~~—

19 “(1) ~~REGULATIONS.~~—

20 “(A) ~~PROPOSED REGULATION.~~—Not later
21 than 6 months after the date of enactment of
22 this section, the Secretary shall promulgate a
23 proposed regulation requiring enhanced commu-
24 nication of safety and dosage information for
25 women who are pregnant or lactating in the la-

1 beling of drugs, including drugs licensed under
2 section 351 of the Public Health Service Act
3 (42 U.S.C. 262).

4 “(B) FINAL RULE.—Not later than 2
5 years after the date of enactment of this sec-
6 tion, the Secretary shall promulgate a final reg-
7 ulation requiring enhanced communication of
8 safety and dosage information for women who
9 are pregnant or lactating in the labeling of
10 drugs, including drugs licensed under section
11 351 of the Public Health Service Act (42
12 U.S.C. 262).

13 “(2) BIENNIAL REVIEW OF CERTAIN DRUGS.—
14 Not later than 32 months after the date of enact-
15 ment of this section, and biennially thereafter, each
16 person who holds an approved application for a drug
17 under section 505(b) that was not approved based
18 on studies of pregnant women or who holds an ap-
19 proved biologics license application for a drug under
20 section 351 of the Public Health Service Act (42
21 U.S.C. 262) that was not licensed based on studies
22 of pregnant women, shall—

23 “(A) review any newly available data or in-
24 formation for such drug, including data or in-
25 formation from the studies completed under

1 subsection (a), to determine whether such data
2 or information, and all other relevant data and
3 information, warrants a labeling change for
4 women who are pregnant or lactating; and

5 “(B) submit to the Secretary—

6 “(i) a supplement to the holders’ new
7 drug application or biologics license appli-
8 cation that includes—

9 “(I) a summary of the data or
10 information reviewed under subpara-
11 graph (A);

12 “(II) an analysis of why such
13 data or information warrants a label-
14 ing change for women who are preg-
15 nant or lactating;

16 “(III) a proposal for the labeling
17 change; and

18 “(IV) a certification that the re-
19 view, summary, and analysis is com-
20 plete and accurate; or

21 “(ii) a letter that includes—

22 “(I) a summary of the data or
23 information, if any, reviewed under
24 subparagraph (A);

1 “(II) an analysis of why such
2 data or information does not warrant
3 a labeling change for women who are
4 pregnant or lactating; and

5 “(III) a certification that the re-
6 view, summary, and analysis is com-
7 plete and accurate.

8 “(3) BIENNIAL SUBMISSIONS.—In the regula-
9 tions promulgated under paragraph (1), the Sec-
10 retary shall prescribe requirements for—

11 “(A) the summary of data or information
12 reviewed under paragraph (2)(A); and

13 “(B) the analysis of why such data or in-
14 formation does or does not warrant a labeling
15 change required to be submitted to the Sec-
16 retary in a supplement or in a letter under
17 paragraph (2)(B).

18 “(4) PERIODIC REVIEW OF DRUGS.—

19 “(A) PRIORITY.—Not later than 2 years
20 after the date of enactment of this section, the
21 Secretary shall prioritize marketed drugs that
22 were not approved or licensed based on studies
23 in pregnant women, considering—

24 “(i) how widely such drugs are used
25 by women who are pregnant or lactating;

1 “(ii) whether new information avail-
2 able about such drugs may warrant a la-
3 beling change for such women; and

4 “(iii) which of such drugs have label-
5 ing for such women that is most in need
6 of revision.

7 “(B) REGULATIONS AND ORDERS.—

8 “(i) INITIAL REGULATIONS AND OR-
9 DERS.—Based on the prioritization of
10 drugs under subparagraph (A), the Sec-
11 retary shall, as resources allow—

12 “(I) promulgate regulations for
13 such drugs that meet the conditions
14 contained in any applicable mono-
15 graph to revise safety and dosage in-
16 formation required in labeling for
17 women who are pregnant or lactating;
18 and

19 “(II) issue orders for other such
20 drugs to require revised safety and
21 dosage information required in label-
22 ing for women who are pregnant or
23 lactating.

24 “(ii) SUBSEQUENT REGULATIONS AND
25 ORDERS.—The Secretary shall periodically

1 review new data or information as it be-
2 comes available on the drugs described in
3 subparagraph (A), and shall promulgate
4 regulations or issue orders, as appropriate,
5 to revise safety and dosage information re-
6 quired in labeling for such drugs for
7 women who are pregnant or lactating.

8 “(e) IMPROVING COMMUNICATION AND INFORMATION
9 ABOUT FETAL RISK FROM DEVICES.—

10 “(1) RESEARCH ON MATERIALS USED IN DE-
11 VICES.—

12 “(A) IDENTIFYING MATERIALS TO BE
13 STUDIED.—The Secretary, acting through the
14 Director of the National Institutes of Health
15 and in consultation with the Commissioner of
16 Food and Drugs, shall—

17 “(i) periodically review all available
18 data and information about the safety for
19 persons and fetuses of materials used in
20 devices that may come into contact with,
21 or be absorbed into, the body;

22 “(ii) identify materials for which addi-
23 tional data or information is needed to as-
24 sess the safety for persons and fetuses of
25 such materials; and

1 “(iii) design protocols for studies to
2 collect data or information described in
3 clause (ii).

4 “(B) STUDYING DEVICE MATERIALS.—The
5 Director of the National Institutes of Health
6 shall award grants, enter into contracts, or use
7 other appropriate mechanisms to aid in prompt-
8 ly completing the studies designed under sub-
9 paragraph (A), as the National Institutes of
10 Health’s resources allow.

11 “(C) SAFETY STUDIES.—The Secretary
12 may require a person that manufactures a de-
13 vice that bears or contains a material for which
14 the Secretary has designed studies under sub-
15 paragraph (A), to complete and submit such
16 studies to the Secretary, by a date specified by
17 the Secretary.

18 “(2) REVIEW OF DEVICE MATERIAL AND LA-
19 BELING.—Considering all available data and infor-
20 mation about the safety for persons and fetuses of
21 a material that may come into contact with, or be
22 absorbed into, the body when used in a device, in-
23 cluding data and information from studies conducted
24 under paragraph (1), the Secretary shall—

1 “(A) require appropriate statements dis-
 2 closing any risks to persons or fetuses from the
 3 material in the labeling of a device that bears
 4 or contains such material; or

5 “(B) if use of the material in a device pre-
 6 sents an unreasonable and substantial risk of
 7 illness or injury to persons or fetuses; ban the
 8 use of such material in such device.

9 “(d) LIMITATIONS ON INJUNCTIVE RELIEF TO EN-
 10 SURE PROMPT REVISION OF DRUG AND DEVICE LABEL-
 11 ING.—In an action under section 302 with respect to a
 12 drug or a device deemed to be misbranded under section
 13 502(k) or section 502(l), such misbranding shall not be
 14 the sole basis for any judicial order that requires a person
 15 to cease the manufacturing, distribution, or sale of such
 16 drug or device.

17 “(e) OUTREACH AND EDUCATION.—The Secretary
 18 shall expand the Women’s Health: Take Time to Care pro-
 19 gram or establish a new program that is directed at—

20 “(1) women who are pregnant or lactating to
 21 inform such women about the safety issues involved
 22 in taking prescription and over-the-counter drugs,
 23 and using medical devices, while such women are
 24 pregnant or breast feeding; and

1 ~~“(2) health care providers and the public to~~
2 ~~provide information about the safety issues involved~~
3 ~~when women, who are pregnant or breast feeding,~~
4 ~~take prescription and over-the-counter drugs or use~~
5 ~~medical devices.~~

6 ~~“(f) AUTHORIZATION OF APPROPRIATIONS.—There~~
7 ~~are authorized to be appropriated to carry out this section,~~
8 ~~such sums as are necessary.”.~~

9 ~~(b) AMENDMENT TO ADULTERATED DRUGS AND DE-~~
10 ~~VICES.—Section 501(g) of the Federal Food, Drug, and~~
11 ~~Cosmetic Act (21 U.S.C. 351(g)) is amended by striking~~
12 ~~“device” and inserting “device or it is a device that bears~~
13 ~~or contains a material whose use in such a device has been~~
14 ~~banned under section 564(e)(2)(B)”.~~

15 ~~(c) AMENDMENT TO MISBRANDED DRUGS AND DE-~~
16 ~~VICES.—Section 502 of the Federal Food, Drug, and Cos-~~
17 ~~metic Act (21 U.S.C. 352) is amended by inserting after~~
18 ~~subsection (j) the following:~~

19 ~~“(k)(1) If it is a drug, and—~~

20 ~~“(2)(A) a study required under section 564(a)(2)~~
21 ~~with respect to such drug is not completed and submitted~~
22 ~~to the Secretary by the date specified by the Secretary;~~

23 ~~“(B) a supplement or letter required to be submitted~~
24 ~~to the Secretary under section 564(b)(2)(B) with respect~~
25 ~~to such drug is not submitted to the Secretary;~~

1 “(C) a supplement or letter required to be submitted
2 to the Secretary under section 564(b)(2)(B) with respect
3 to such drug does not include an adequate summary or
4 analysis of relevant information or data; or

5 “(D) its labeling does not include safety or dosage
6 information for pregnant or lactating women required by
7 the Secretary by regulation or order under section
8 564(b)(4)(B).

9 “(1) If it is a device and its labeling does not include
10 statements required by the Secretary under section
11 564(e)(2)(A).”.

12 (d) AMENDMENT TO CIVIL PENALTIES.—Section
13 307(a) of the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 335b(a)) is amended—

15 (1) in paragraph (6)(B), by striking “or”; and
16 (2) by inserting after paragraph (7) the fol-
17 lowing:

18 “(8) has failed to complete and submit to the
19 Secretary, by the date specified by the Secretary, a
20 study required by the Secretary under section
21 564(a)(2);

22 “(9) has failed to submit to the Secretary a
23 supplement or letter required to be submitted to the
24 Secretary under section 564(b)(2)(B);

1 “(10) has failed to include an adequate sum-
 2 mary or analysis of relevant information or data in
 3 a supplement or letter required to be submitted to
 4 the Secretary under section 564(b)(2)(B);

5 “(11) has distributed in interstate commerce a
 6 drug whose labeling does not include safety or dos-
 7 age information for pregnant or lactating women re-
 8 quired by the Secretary by regulation or order under
 9 section 564(b)(4)(B);

10 “(12) has failed to complete and submit to the
 11 Secretary, by the date specified by the Secretary, a
 12 study required under section 564(c)(1)(C);

13 “(13) has distributed in interstate commerce a
 14 device whose labeling does not include statements re-
 15 quired by the Secretary under section 564(c)(2)(A);
 16 or

17 “(14) has distributed in interstate commerce a
 18 device that bears or contains a material whose use
 19 in such device has been banned under section
 20 564(e)(2)(B).”.

21 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

22 (a) *SHORT TITLE.*—*This Act may be cited as the*
 23 *“Women’s Health Act of 2002”.*

24 (b) *TABLE OF CONTENTS.*—*The table of contents of this*
 25 *Act is as follows:*

Sec. 1. Short title; table of contents.

TITLE I—HEALTHY MOMS

Sec. 101. Short title.

Subtitle A—Achieving Goals Set by the U.S. Preventive Task Force and Healthy People 2000 and Healthy People 2010 to Achieve a Healthy Pregnancy and Reduce Pregnancy Related Complications

Sec. 111. Interagency Committee on Healthy Moms.

Subtitle B—Research and Data Collection To Improve Maternal Well-Being

Sec. 121. Expand and intensify research activities at the National Institutes of Health.

Sec. 122. Improving pregnancy outcomes of high risk women.

Sec. 123. Improve quality health care for pregnant women through the Agency for Healthcare Research and Quality.

Subtitle C—Data Collection and Surveillance

Sec. 131. Expand and intensify data collection activities at the Centers for Disease Control and Prevention.

Sec. 132. Pregnancy and women’s health.

Subtitle D—Public Education and Outreach

Sec. 141. Purpose.

Sec. 142. Healthy moms campaign.

TITLE II—OFFICE ON WOMEN’S HEALTH

Sec. 201. Short title.

Sec. 202. Health and Human Services Office on Women’s Health.

Sec. 203. Centers for Disease Control and Prevention Office of Women’s Health.

Sec. 204. Agency for Healthcare Research and Quality activities regarding women’s health.

Sec. 205. Health Resources and Services Administration Office of Women’s Health.

Sec. 206. Food and Drug Administration Office of Women’s Health.

Sec. 207. No new regulatory authority.

TITLE III—WISEWOMAN EXPANSION

Sec. 301. Short title.

Sec. 302. Findings.

Sec. 303. Supplemental grants for additional preventive health services for women.

TITLE IV—SUBSTANCE ABUSE PREVENTION

Sec. 401. Short title.

Sec. 402. Amendment to the Public Health Service Act.

TITLE V—PERINATAL DENTAL HEALTH IMPROVEMENT

Sec. 501. Short title.

Sec. 502. Findings.

Sec. 503. Grants to conduct research and demonstration projects that apply new scientific evidence about maternal and child oral health linkages.

TITLE VI—EATING DISORDERS

Sec. 601. Short title.

Sec. 602. Findings.

Sec. 603. Purposes.

Sec. 604. Amendments.

1 **TITLE I—HEALTHY MOMS**

2 **SEC. 101. SHORT TITLE.**

3 *This title may be cited as the “Healthy Moms Act for*
 4 *Research and Treatment” or the “Healthy Moms Act”.*

5 **Subtitle A—Achieving Goals Set by**
 6 ***the U.S. Preventive Task Force***
 7 ***and Healthy People 2000 and***
 8 ***Healthy People 2010 to Achieve a***
 9 ***Healthy Pregnancy and Reduce***
 10 ***Pregnancy Related Complica-***
 11 ***tions***

12 **SEC. 111. INTERAGENCY COMMITTEE ON HEALTHY MOMS.**

13 *Part P of title III of the Public Health Service Act*
 14 *(42 U.S.C. 280g et seq.) is amended by adding at the end*
 15 *the following:*

16 **“SEC. 3990. INTERAGENCY COMMITTEE ON HEALTHY MOMS.**

17 **“(a) ESTABLISHMENT.—***The Secretary, acting through*
 18 *the Director of the Office of Women’s Health, shall establish*
 19 *a committee to be known as the ‘Interagency Committee on*
 20 *Healthy Moms’ (referred to in this section as the ‘Inter-*
 21 *agency Committee’).*

1 “(b) *COMPOSITION.*—*The Interagency Committee shall*
2 *be composed of—*

3 “(1) *the Director of the Centers for Disease Con-*
4 *trol and Prevention (and the heads of such institutes,*
5 *centers, and offices as the Director determines appro-*
6 *priate);*

7 “(2) *the Director of the National Institutes of*
8 *Health (and the heads of such institutes, centers, and*
9 *offices as the Director determines appropriate);*

10 “(3) *the Director of the Indian Health Service*
11 *(and the heads of such institutes, centers, and offices*
12 *as the Director determines appropriate);*

13 “(4) *the Director of the Health Resources and*
14 *Services Administration (and the heads of such insti-*
15 *tutes, centers, and offices as the Director determines*
16 *appropriate);*

17 “(5) *the Commissioner of Food and Drugs (and*
18 *the heads of such institutes, centers, and offices as the*
19 *Commissioner determines appropriate);*

20 “(6) *the Director of the Agency for Healthcare*
21 *Research and Quality (and the heads of such insti-*
22 *tutes, centers, and offices as the Director determines*
23 *appropriate);*

1 “(7) *the Secretary of Labor (and the heads of*
2 *such institutes, centers, and offices as the Secretary*
3 *determines appropriate);*

4 “(8) *representatives of other Federal Government*
5 *agencies that the Secretary determines appropriate;*
6 *and*

7 “(9) *representatives of women’s health care advo-*
8 *cacy and grassroots organizations, health care pro-*
9 *viders including providers of specialty care, pediatric*
10 *advocates, and researchers to be appointed by the Di-*
11 *rector of the Office.*

12 “(c) *ADMINISTRATIVE SUPPORT.—The Secretary shall*
13 *make available to the Interagency Committee necessary and*
14 *appropriate administrative support.*

15 “(d) *DUTIES.—*

16 “(1) *EVALUATION.—The Interagency Committee*
17 *shall assess health promotion campaigns that are ad-*
18 *ministered by the Federal Government, evaluate the*
19 *effect that such campaigns have on health during*
20 *pregnancy if pregnancy was a focus, and assess*
21 *whether such programs may be adapted to emphasize*
22 *the importance of maternal health.*

23 “(2) *FEDERAL RESEARCH PLAN.—*

24 “(A) *IN GENERAL.—Not later than 18*
25 *months after the date of enactment of this sec-*

1 *tion, the Secretary shall develop a coordinated*
2 *Federal research and strategic action plan for*
3 *women’s health (referred to in this paragraph as*
4 *the ‘plan’), that includes provisions developed by*
5 *the Secretary after review of the recommenda-*
6 *tions made by the Interagency Committee to im-*
7 *prove the pregnancy-related health of women be-*
8 *fore, during and after pregnancy and improve*
9 *pregnancy outcomes. In developing the plan, the*
10 *Secretary shall coordinate with the Coordinating*
11 *Committee of the Office of Women’s Health.*

12 *“(B) REPORT.—Not later than 18 months*
13 *after the date of enactment of this section, the*
14 *Interagency Committee shall prepare and submit*
15 *to the Secretary, a report concerning the plan*
16 *developed under this paragraph and the results*
17 *of the evaluation conducted under paragraph (1).*
18 *The Secretary shall transmit the report, with*
19 *such comments as the Secretary determines to be*
20 *appropriate, to the appropriate committees of*
21 *Congress.*

22 *“(3) KEY INDICATORS OF WELL-BEING.—*

23 *“(A) IN GENERAL.—The Interagency Com-*
24 *mittee shall identify the key indicators of mater-*
25 *nal health and pregnancy outcomes and the*

1 *sources of data to be included in the report under*
2 *subparagraph (B), and shall update such indica-*
3 *tors as new data become available.*

4 “(B) *REPORT.*—*Not later than October 1,*
5 *2003, and every 2 years thereafter, the Inter-*
6 *agency Committee shall prepare and submit to*
7 *the Secretary, a report, to be known as ‘Amer-*
8 *ica’s Mothers: Key National Indicators of Well*
9 *Being’ (referred to in this section as the ‘Re-*
10 *port’), that contains the indicators of maternal*
11 *health described in subparagraph (A). The Sec-*
12 *retary shall transmit the report, with such com-*
13 *ments as the Secretary determines to be appro-*
14 *priate, to the appropriate committees of Con-*
15 *gress.*

16 “(C) *AVAILABILITY.*—*The Report shall be*
17 *made available to the public through the Internet*
18 *website established under section 399P(c).*

19 “(e) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
20 *authorized to be appropriated, such sums as may be nec-*
21 *essary to carry out this section.”.*

1 ***Subtitle B—Research and Data Col-***
 2 ***lection to Improve Maternal***
 3 ***Well-Being***

4 **SEC. 121. EXPAND AND INTENSIFY RESEARCH ACTIVITIES**
 5 **AT THE NATIONAL INSTITUTES OF HEALTH.**

6 (a) *PURPOSE.*—*It is the purpose of this section to re-*
 7 *quire the Director of the National Institutes of Health, act-*
 8 *ing through the Director of the National Institute of Child*
 9 *Health and Human Development and in collaboration with*
 10 *the Directors of other appropriate Institutes and Offices, to*
 11 *expand and intensify research activities with respect to*
 12 *pregnancy and pregnancy-related conditions and complica-*
 13 *tions and to expand research to improve understanding and*
 14 *treatment of pregnant women who have chronic disease,*
 15 *physical impairment, or mental health conditions.*

16 (b) *HEALTHY MOMS AS A PRIORITY AREA.*—*Subpart*
 17 *7 of part C of title IV of the Public Health Service Act*
 18 *(42 U.S.C. 285g et seq.) is amended by adding at the end*
 19 *the following:*

20 **“SEC. 452H. HEALTHY MOMS REPORT.**

21 *“The Director of the Institute shall, as part of the an-*
 22 *nual report submitted by the Director under this part, re-*
 23 *port to Congress and the public on the extent of the total*
 24 *funds obligated to conduct or support research on healthy*
 25 *mothers across the National Institutes of Health, including*

1 *the specific support and research awards allocated through*
 2 *such Institutes.”.*

3 (c) *EXPANDED RESEARCH INTO PREGNANCY.—Sub-*
 4 *part 7 of part C of title IV of the Public Health Service*
 5 *Act (42 U.S.C. 285g et seq.), as amended by subsection (b),*
 6 *is further amended by adding at the end the following:*

7 **“SEC. 452I. EXPANDED RESEARCH ON PREGNANCY.**

8 “(a) *CONDITIONS AND COMPLICATIONS OF PREG-*
 9 *NANCY.—In order to improve the understanding of condi-*
 10 *tions and complications related to pregnancy, to lead to bet-*
 11 *ter treatments and care for women throughout their preg-*
 12 *nancy, and to prevent pregnancy-related complications*
 13 *whenever possible, the Director of the Institute shall enhance*
 14 *and expand research into the leading causes of pregnancy-*
 15 *related conditions and complications of pregnancy.*

16 “(b) *REDUCING PRE-TERM LABOR AND DELIVERY.—*
 17 *In order to reduce the rates of pre-term labor and delivery,*
 18 *the Director of the Institute shall expand and intensify re-*
 19 *search on pre-term labor and delivery.*

20 “(c) *REDUCTIONS IN HEALTH DISPARITIES IN PREG-*
 21 *NANT WOMEN AND NEW MOMS.—The Director of the Insti-*
 22 *tute shall provide for the conduct of research to investigate*
 23 *the mechanisms contributing to the disparities in maternal*
 24 *and perinatal outcomes among pregnant women and new*
 25 *mothers.*

1 “(d) *AUTHORIZATION OF APPROPRIATIONS.—There is*
2 *authorized to be appropriated, such sums as may be nec-*
3 *essary to carry out this section.*

4 **“SEC. 452J. IMPROVING THE UNDERSTANDING AND TREAT-**
5 **MENT OF CHRONIC CONDITIONS OF WOMEN**
6 **DURING PREGNANCY.**

7 “(a) *IN GENERAL.—The Director of the Institute shall*
8 *expand research concerning the impact of chronic condi-*
9 *tions, physical impairments, and mental health problems*
10 *on the health of women during their pregnancy.*

11 “(b) *COLLABORATION.—In carrying out subsection (a),*
12 *the Director of the Institute shall act in collaboration with*
13 *the Directors of other appropriate Institutes and Offices of*
14 *the National Institutes of Health.”.*

15 “(c) *AUTHORIZATION OF APPROPRIATIONS.—There is*
16 *authorized to be appropriated, such sums as may be nec-*
17 *essary to carry out this section.*

18 **“SEC. 452K. MATERNAL FETAL MEDICINE UNITS NETWORK.**

19 “(a) *IN GENERAL.—The Director of the Institute shall*
20 *establish a Maternal Fetal Medicine Units Network and*
21 *may, based on an evaluation of the activities of such Net-*
22 *work, expand such Network. In carrying out this subsection,*
23 *the Director may enter into agreements to utilize the exist-*
24 *ing Maternal Fetal Medicine Units Network.*

1 “(b) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
 2 *authorized to be appropriated, such sums as may be nec-*
 3 *essary to carry out this section.*”.

4 **SEC. 122. IMPROVING PREGNANCY OUTCOMES OF HIGH**
 5 **RISK WOMEN.**

6 *Title III of the Public Health Service Act (42 U.S.C.*
 7 *241 et seq.), as amended by section 1302, is further amend-*
 8 *ed by adding at the end the following:*

9 **“PART S—PREGNANCY OUTCOMES**
 10 **“SEC. 399BB. IMPROVING PREGNANCY OUTCOMES OF HIGH**
 11 **RISK WOMEN.**

12 “(a) *IN GENERAL.*—*The Secretary, after consultation*
 13 *with the Director of the Centers for Disease Control and*
 14 *Prevention and the Administrator of the Health Resources*
 15 *and Services Administration, shall award grants to States*
 16 *and Indian tribes to support community-based demonstra-*
 17 *tion projects in disease prevention and health promotion*
 18 *to improve maternal pregnancy outcomes, with particular*
 19 *emphasis on social, economic, and behavioral health issues*
 20 *affecting high risk populations. Where practicable, such*
 21 *demonstration projects shall be based on relevant scientific*
 22 *studies.*

23 “(b) *TECHNICAL ASSISTANCE.*—*In carrying out sub-*
 24 *section (a), the Secretary may provide technical assistance*
 25 *to States and Indian tribes.*

1 “(c) *DEFINITION.*—In this section, the term ‘Indian
2 tribe’ has the meaning given the term in section 317M.”.

3 **SEC. 123. IMPROVE QUALITY HEALTH CARE FOR PREGNANT**
4 **WOMEN THROUGH THE AGENCY FOR**
5 **HEALTHCARE RESEARCH AND QUALITY.**

6 *Part B of title IX of the Public Health Service Act*
7 *(42 U.S.C. 299b et seq.) is amended by adding at the end*
8 *the following:*

9 **“SEC. 918. MATERNAL HEALTH CARE.**

10 “(a) *RESEARCH.*—The Secretary, acting through the
11 Director, shall provide for the conduct of research con-
12 cerning the quality of maternal health care, including pro-
13 viding for—

14 “(1) *synthesis of effective health services related*
15 *to pregnancy for women before, during, and after*
16 *pregnancy; and*

17 “(2) *research concerning the barriers women face*
18 *in receiving health services consistent with effective*
19 *health services under paragraph (1) or equivalent*
20 *health services.*

21 “(b) *REPORT.*—The results of the research conducted
22 under subsection (a) shall be provided by the Director to
23 Congress as part of the annual report submitted under sec-
24 tion 913(b)(2).”.

1 **Subtitle C—Data Collection and**
 2 **Surveillance**

3 **SEC. 131. EXPAND AND INTENSIFY DATA COLLECTION AC-**
 4 **TIVITIES AT THE CENTERS FOR DISEASE CON-**
 5 **TROL AND PREVENTION.**

6 *Part B of title III of the Public Health Service Act*
 7 *(42 U.S.C. 243 et seq.) is amended by inserting after section*
 8 *317K the following:*

9 **“SEC. 317K-1. DATA COLLECTION REGARDING HEALTHY**
 10 **MOMS.**

11 “(a) *STANDARD DEFINITIONS FOR MATERNAL MOR-*
 12 *TALITY AND MORBIDITY.—The Secretary, acting through*
 13 *the Director of the Centers for Disease Control and Preven-*
 14 *tion and in cooperation with State officials, professional*
 15 *medical experts, medical organizations, and health care*
 16 *service researchers, shall develop a standard definition of*
 17 *‘maternal mortality’ and ‘maternal morbidity’.*

18 “(b) *GRANTS FOR SURVEILLANCE OF MATERNAL MOR-*
 19 *TALITY AND MORBIDITY DATA.—*

20 “(1) *IN GENERAL.—The Secretary, acting*
 21 *through the Director of the Centers for Disease Con-*
 22 *trol and Prevention, shall establish a program to*
 23 *award grants to States, Indian tribes, counties, and*
 24 *cities for the development of surveillance systems, that*
 25 *use the standard definitions established under sub-*

1 *section (a), to gather data on maternal mortality and*
2 *maternal morbidity.*

3 “(2) *ELIGIBILITY.—To be eligible to receive a*
4 *grant under paragraph (1), a State, Indian tribe,*
5 *county, or city shall—*

6 “(A) *prepare and submit to the Secretary*
7 *an application, at such time, in such manner,*
8 *and containing such information as the Sec-*
9 *retary may require; and*

10 “(B) *provide an assurance that the appli-*
11 *cant will work with the Centers for Disease Con-*
12 *trol and Prevention to adopt standard proce-*
13 *dures for the identification, collection, and anal-*
14 *ysis of the data that are to be collected under the*
15 *grant.*

16 “(3) *TECHNICAL ASSISTANCE.—The Centers for*
17 *Disease Control and Prevention shall provide tech-*
18 *nical assistance to grantees under this subsection.*

19 “(4) *INCORPORATION OF DATA INTO REPORT.—*
20 *Where determined appropriate by the Secretary, data*
21 *collected by the surveillance systems established under*
22 *this subsection shall be incorporated into the report*
23 *submitted under section 3990(d)(3)(B).*

1 “(5) *DEFINITION.*—*In this subsection, the term*
 2 *‘Indian tribe’ has the meaning given the term in sec-*
 3 *tion 317M.*

4 “(c) *PREVALENCE OF PRE-TERM LABOR AND DELIV-*
 5 *ERY.*—*The Secretary, acting through the Director of the*
 6 *Centers for Disease Control and Prevention, shall work with*
 7 *States and other entities to improve knowledge regarding*
 8 *the incidence and prevalence of symptoms and risk factors*
 9 *for pre-term births.*

10 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
 11 *authorized to be appropriated, such sums as may be nec-*
 12 *essary to carry out this section.”.*

13 **SEC. 132. PREGNANCY AND WOMEN’S HEALTH.**

14 *Section 1004 of the Children’s Health Act of 2000 (42*
 15 *U.S.C. 285g note) is amended—*

16 (1) *by redesignating subsections (d) and (e) as*
 17 *subsections (e) and (f), respectively; and*

18 (2) *by inserting after subsection (c), the fol-*
 19 *lowing:*

20 “(d) *STUDY ON EFFECTS OF PREGNANCY ON*
 21 *WOMEN.*—*As part of the study conducted under this section,*
 22 *the Secretary, acting through the Director of the National*
 23 *Institute of Child Health and Human Development, shall*
 24 *plan, develop, and implement a 2-year prospective cohort*

1 *study of mothers to determine the effects of pregnancy on*
 2 *the health of women. Such study shall evaluate—*

3 *“(1) the effects of pregnancy on women’s health;*

4 *“(2) the effects of both preexisting and chronic*
 5 *conditions, physical impairments, and mental health*
 6 *problems related to pregnancy;*

7 *“(3) the impact of stress and anxiety; and*

8 *“(4) environmental health factors that influence*
 9 *both the mother’s health and that of her child.”.*

10 ***Subtitle D—Public Education and***
 11 ***Outreach***

12 ***SEC. 141. PURPOSE.***

13 *It is the purpose of this subtitle to address the need*
 14 *for providing women with accurate and up-to-date informa-*
 15 *tion through a 21st century public education and outreach*
 16 *Campaign for Healthy Moms that shall raise the public*
 17 *awareness of the issues related to healthy mothers.*

18 ***SEC. 142. HEALTHY MOMS CAMPAIGN.***

19 *Part P of title III of the Public Health Service Act*
 20 *(42 U.S.C. 280g et seq.), as amended by section 111, is fur-*
 21 *ther amended by adding at the end the following:*

22 ***“SEC. 399P. HEALTHY MOMS CAMPAIGN.***

23 *“(a) ESTABLISHMENT.—The Secretary, acting through*
 24 *the Director of the Office of Women’s Health and the Inter-*
 25 *agency Committee on Healthy Moms (referred to in this sec-*

1 *tion as the ‘Interagency Committee’ established under sec-*
2 *tion 3990, shall develop and implement a national public*
3 *education and health promotion campaign to be known as*
4 *the Healthy Moms Campaign (referred to in this section*
5 *as the ‘Campaign’).*

6 “(b) *ELEMENTS OF CAMPAIGN.—The Campaign shall*
7 *at a minimum include the following:*

8 “(1) *WEBSITE.—An Internet website to be estab-*
9 *lished in accordance with subsection (c).*

10 “(2) *COMMUNITY PARTNERSHIPS.—The provision*
11 *of support for community-based programs to provide*
12 *outreach, education, information, and health pro-*
13 *motion services to pregnant women and new mothers.*

14 “(3) *STATE, TRIBAL, AND LOCAL PARTNER-*
15 *SHIPS.—The facilitation of consultations with State,*
16 *tribal, and local public health officials to gain access*
17 *to high risk women in an effort to provide outreach*
18 *and education assistance and information to help*
19 *women have a healthy pregnancy.*

20 “(4) *SPECIAL POPULATIONS.—The implementa-*
21 *tion of procedures to ensure that activities under the*
22 *Campaign are accessible to low-literate, non-English*
23 *speaking where determined appropriate by the Sec-*
24 *retary.*

25 “(c) *INTERNET WEBSITE.—*

1 “(1) *ESTABLISHMENT.*—*The Secretary, acting*
2 *through the Office of Women’s Health and in con-*
3 *sultation with the Interagency Committee, shall de-*
4 *velop and maintain a single Internet website to pro-*
5 *vide pregnant women, and research and health prac-*
6 *titioners with the most up-to-date and accurate infor-*
7 *mation on pregnancy, in a manner designed to carry*
8 *out the purpose described in paragraph (2).*

9 “(2) *PURPOSE.*—*It is the purpose of the website*
10 *established under paragraph (1) to consolidate infor-*
11 *mation, research, and data related to pregnancy (pre-*
12 *natal, intrapartum, and postpartum) together in one*
13 *place and to provide links for women to other critical*
14 *websites (such as websites of Federal agencies, com-*
15 *munity health programs, and State and tribal health*
16 *programs).*

17 “(3) *CONTENTS.*—*The website established under*
18 *paragraph (1) shall, at a minimum, contain edu-*
19 *cational materials for how to have the healthiest preg-*
20 *nancy possible.*

21 “(4) *APPROPRIATE FORM OF INFORMATION.*—*The*
22 *information contained on the website established*
23 *under paragraph (1) shall be maintained in a cul-*
24 *turally sensitive and appropriate form.*

1 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
 2 *authorized to be appropriated, such sums as may be nec-*
 3 *essary to carry out this section.*”.

4 ***TITLE II—OFFICE ON WOMEN’S***
 5 ***HEALTH***

6 ***SEC. 201. SHORT TITLE.***

7 *This title may be cited as the “Women’s Health Office*
 8 *Act of 2002”.*

9 ***SEC. 202. HEALTH AND HUMAN SERVICES OFFICE ON WOM-***
 10 ***EN’S HEALTH.***

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

14 ***“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON WOM-***
 15 ***EN’S HEALTH.***

16 *“(a) ESTABLISHMENT OF OFFICE.*—*The Secretary*
 17 *shall establish within the Office of the Secretary, an Office*
 18 *on Women’s Health (referred to in this section as the ‘Of-*
 19 *fice’). The Office shall be headed by a Deputy Assistant Sec-*
 20 *retary for Women’s Health.*

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

23 *“(1) establish short-range and long-range goals*
 24 *and objectives within the Department of Health and*
 25 *Human Services and, as relevant and appropriate,*

1 *coordinate with other appropriate offices on activities*
2 *within the Department that relate to disease preven-*
3 *tion, health promotion, service delivery, research, and*
4 *public and health care professional education, for*
5 *issues of particular concern to women;*

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

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

14 “(4) *establish a Department of Health and*
15 *Human Services Coordinating Committee on Wom-*
16 *en’s Health, which shall be chaired by the Deputy As-*
17 *istant Secretary for Women’s Health and composed*
18 *of senior level representatives from each of the agen-*
19 *cies and offices of the Department of Health and*
20 *Human Services;*

21 “(5) *establish a National Women’s Health Infor-*
22 *mation Center to—*

23 “(A) *facilitate the exchange of information*
24 *regarding matters relating to health information,*
25 *health promotion, preventive health services, re-*

1 *search advances, and education in the appro-*
2 *priate use of health care;*

3 “(B) *facilitate access to such information;*

4 “(C) *assist in the analysis of issues and*
5 *problems relating to the matters described in this*
6 *paragraph; and*

7 “(D) *provide technical assistance with re-*
8 *spect to the exchange of information (including*
9 *facilitating the development of materials for such*
10 *technical assistance);*

11 “(6) *coordinate efforts to promote women’s health*
12 *programs and policies with the private sector; and*

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

18 “(c) *GRANTS AND CONTRACTS REGARDING DUTIES.—*

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

24 “(2) *EVALUATION AND DISSEMINATION.—The*
25 *Secretary shall directly or through contracts with*

1 *public and private entities, agencies, and organiza-*
2 *tions, provide for evaluations of projects carried out*
3 *with financial assistance provided under paragraph*
4 *(1) and for the dissemination of information devel-*
5 *oped as a result of such projects.*

6 *“(d) REPORTS.—Not later than January 31, 2004,*
7 *and January 31 of each second year thereafter, the Sec-*
8 *retary shall prepare and submit to the appropriate commit-*
9 *tees of Congress a report describing the activities carried*
10 *out under this section during the period for which the report*
11 *is being prepared.*

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

16 *(b) TRANSFER OF FUNCTIONS.—There are transferred*
17 *to the Office on Women’s Health (established under section*
18 *229 of the Public Health Service Act, as added by this sec-*
19 *tion), all functions exercised by the Office on Women’s*
20 *Health of the Public Health Service prior to the date of*
21 *enactment of this section, including all personnel and com-*
22 *pensation authority, all delegation and assignment author-*
23 *ity, and all remaining appropriations. All orders, deter-*
24 *minations, rules, regulations, permits, agreements, grants,*

1 *contracts, certificates, licenses, registrations, privileges, and*
 2 *other administrative actions that—*

3 *(1) have been issued, made, granted, or allowed*
 4 *to become effective by the President, any Federal*
 5 *agency or official thereof, or by a court of competent*
 6 *jurisdiction, in the performance of functions trans-*
 7 *ferred under this subsection; and*

8 *(2) are in effect at the time this section takes ef-*
 9 *fect, or were final before the date of enactment of this*
 10 *section and are to become effective on or after such*
 11 *date;*

12 *shall continue in effect according to their terms until modi-*
 13 *fied, terminated, superseded, set aside, or revoked in accord-*
 14 *ance with law by the President, the Secretary, or other au-*
 15 *thorized official, a court of competent jurisdiction, or by*
 16 *operation of law.*

17 **SEC. 203. CENTERS FOR DISEASE CONTROL AND PREVEN-**
 18 **TION OFFICE OF WOMEN'S HEALTH.**

19 *Part A of title III of the Public Health Service Act*
 20 *(42 U.S.C. 241 et seq.) is amended by adding at the end*
 21 *the following:*

22 *“CENTERS FOR DISEASE CONTROL AND PREVENTION*
 23 *OFFICE OF WOMEN'S HEALTH*

24 *“SEC. 310A. (a) ESTABLISHMENT.—The Secretary*
 25 *shall establish within the Office of the Director of the Cen-*
 26 *ters for Disease Control and Prevention, an office to be*

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

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

5 “(1) *report to the Director of the Centers for Dis-*
6 *ease Control and Prevention on the current level of*
7 *the Centers’ activity regarding women’s health condi-*
8 *tions across, where appropriate, age, biological, and*
9 *sociocultural contexts, in all aspects of the Centers’*
10 *work, including prevention programs, public and pro-*
11 *fessional education, services, and treatment;*

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

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

21 “(4) *consult with health professionals, non-*
22 *governmental organizations, consumer organizations,*
23 *women’s health professionals, and other individuals*
24 *and groups, as appropriate, on the policy of the Cen-*
25 *ters with regard to women; and*

1 “(5) *serve as a member of the Department of*
2 *Health and Human Services Coordinating Committee*
3 *on Women’s Health (established under section*
4 *229(b)(4)).*

5 “(c) *COORDINATING COMMITTEE.—*

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

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

15 “(3) *CHAIRPERSON.—The Director of the Office*
16 *shall serve as the Chairperson of the Coordinating*
17 *Committee.*

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

21 “(A) *identifying the need for programs and*
22 *activities that focus on women’s health;*

23 “(B) *identifying needs regarding the coordi-*
24 *nation of activities, including intramural and*
25 *extramural multidisciplinary activities; and*

1 “(C) making recommendations to the Direc-
2 tor of the Centers for Disease Control and Pre-
3 vention concerning findings made under sub-
4 paragraphs (A) and (B).

5 “(d) *REPORTS.*—Not later than January 31, 2004,
6 and January 31 of each second year thereafter, the Director
7 of the Office shall prepare and submit to the appropriate
8 committees of Congress a report describing the activities
9 carried out under this section during the period for which
10 the report is being prepared.

11 “(e) *DEFINITION.*—As used in this section, the term
12 ‘women’s health conditions’, with respect to women of all
13 age, ethnic, and racial groups, means diseases, disorders,
14 and conditions—

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

17 “(2) for which the factors of medical risk or type
18 of medical intervention are different for women, or for
19 which there is reasonable evidence that indicates that
20 such factors or types may be different for women.

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

1 **SEC. 204. AGENCY FOR HEALTHCARE RESEARCH AND QUAL-**
 2 **ITY ACTIVITIES REGARDING WOMEN'S**
 3 **HEALTH.**

4 *Part C of title IX of the Public Health Service Act*
 5 *(42 U.S.C. 299c et seq.) is amended—*

6 *(1) by redesignating sections 927 and 928 as sec-*
 7 *tions 928 and 929, respectively;*

8 *(2) by inserting after section 926 the following:*

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

10 *“(a) ESTABLISHMENT.—The Director shall designate*
 11 *an official of the Office of Priority Populations to carry*
 12 *out the responsibilities described in this section for such offi-*
 13 *cial.*

14 *“(b) PURPOSE.—The official designated under sub-*
 15 *section (a) shall—*

16 *“(1) report to the Director on the current Agency*
 17 *level of activity regarding women’s health, across,*
 18 *where appropriate, age, biological, and sociocultural*
 19 *contexts, in all aspects of Agency work, including the*
 20 *development of evidence reports and clinical practice*
 21 *protocols and the conduct of research into patient out-*
 22 *comes, delivery of health care services, quality of care,*
 23 *and access to health care;*

24 *“(2) establish short-range and long-range goals*
 25 *and objectives within the Agency for research impor-*
 26 *tant to women’s health and, as relevant and appro-*

1 *appropriate, coordinate with other appropriate offices on*
2 *activities within the Agency that relate to health serv-*
3 *ices and medical effectiveness research, for issues of*
4 *particular concern to women;*

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

7 *“(4) consult with health professionals, non-*
8 *governmental organizations, consumer organizations,*
9 *women’s health professionals, and other individuals*
10 *and groups, as appropriate, on Agency policy with*
11 *regard to women; and*

12 *“(5) serve as a member of the Department of*
13 *Health and Human Services Coordinating Committee*
14 *on Women’s Health (established under section*
15 *229(b)(4)).*

16 *“(c) COORDINATING COMMITTEE.—*

17 *“(1) ESTABLISHMENT.—In carrying out sub-*
18 *section (b), the official designated under subsection*
19 *(a) shall establish a committee to be known as the Co-*
20 *ordinating Committee on Women’s Health (referred to*
21 *in this subsection as the ‘Coordinating Committee’).*

22 *“(2) COMPOSITION.—The Coordinating Com-*
23 *mittee shall be composed of the official designated*
24 *under subsection (a) and the directors of the centers*
25 *and offices of the Agency.*

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

4 “(4) *DUTIES.*—*With respect to research on wom-*
5 *en’s health, the Coordinating Committee shall assist*
6 *the official designated under subsection (a) in—*

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

10 “(B) *identifying needs regarding the coordi-*
11 *nation of research activities, including intra-*
12 *mural and extramural multidisciplinary activi-*
13 *ties; and*

14 “(C) *making recommendations to the Direc-*
15 *tor of the Agency concerning findings made*
16 *under subparagraphs (A) and (B).*

17 “(d) *REPORTS.*—*Not later than January 31, 2004,*
18 *and January 31 of each second year thereafter, the official*
19 *designated under subsection (a) shall prepare and submit*
20 *to the appropriate committees of Congress a report describ-*
21 *ing the activities carried out under this section during the*
22 *period for which the report is being prepared.”; and*

23 (3) *by adding at the end of section 928 (as reded-*
24 *icated by paragraph (1)) the following:*

1 “(e) *WOMEN’S HEALTH.*—*For the purpose of carrying*
 2 *out section 927 regarding women’s health, there are author-*
 3 *ized to be appropriated such sums as may be necessary for*
 4 *each of the fiscal years 2003 through 2007.*”.

5 **SEC. 205. HEALTH RESOURCES AND SERVICES ADMINISTRA-**
 6 **TION OFFICE OF WOMEN’S HEALTH.**

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

9 “*OFFICE OF WOMEN’S HEALTH*

10 “*SEC. 713. (a) ESTABLISHMENT.*—*The Secretary shall*
 11 *establish within the Office of the Administrator of the*
 12 *Health Resources and Services Administration, an office to*
 13 *be known as the Office of Women’s Health. The Office shall*
 14 *be headed by a director who shall be appointed by the Ad-*
 15 *ministrator.*

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

17 “(1) *report to the Administrator on the current*
 18 *Administration level of activity regarding women’s*
 19 *health across, where appropriate, age, biological, and*
 20 *sociocultural contexts;*

21 “(2) *establish short-range and long-range goals*
 22 *and objectives within the Health Resources and Serv-*
 23 *ices Administration for women’s health and, as rel-*
 24 *evant and appropriate, coordinate with other appro-*
 25 *priate offices on activities within the Administration*
 26 *that relate to health care provider training, health*

1 *service delivery, research, and demonstration projects,*
2 *for issues of particular concern to women;*

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

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

11 “(5) *serve as a member of the Department of*
12 *Health and Human Services Coordinating Committee*
13 *on Women’s Health (established under section*
14 *229(b)(4) of the Public Health Service Act).*

15 “(c) *COORDINATING COMMITTEE.—*

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

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

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

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

7 “(A) *identifying the need for programs and*
8 *activities that focus on women’s health;*

9 “(B) *identifying needs regarding the coordi-*
10 *nation of activities, including intramural and*
11 *extramural multidisciplinary activities; and*

12 “(C) *making recommendations to the Ad-*
13 *ministrator concerning findings made under sub-*
14 *paragraphs (A) and (B).*

15 “(d) *REPORTS.*—*Not later than January 31, 2004,*
16 *and January 31 of each second year thereafter, the Director*
17 *of the Office shall prepare and submit to the appropriate*
18 *committees of Congress a report describing the activities*
19 *carried out under this section during the period for which*
20 *the report is being prepared.*

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

22 “(1) *ADMINISTRATION.*—*The term ‘Administra-*
23 *tion’ means the Health Resources and Services Ad-*
24 *ministration.*

1 “(2) *ADMINISTRATOR.*—*The term ‘Adminis-*
 2 *trator’ means the Administrator of the Health Re-*
 3 *sources and Services Administration.*”

4 “(3) *OFFICE.*—*The term ‘Office’ means the Office*
 5 *of Women’s Health established under this section in*
 6 *the Administration.*”

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 each*
 10 *of the fiscal years 2003 through 2007.”.*

11 **SEC. 206. FOOD AND DRUG ADMINISTRATION OFFICE OF**
 12 **WOMEN’S HEALTH.**

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

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

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

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

23 “(1) *report to the Commissioner of Food and*
 24 *Drugs on current Food and Drug Administration (re-*
 25 *ferred to in this section as the ‘Administration’) levels*

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

4 “(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 “(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 “(6) *serve as a member of the Department of Health and Human Services Coordinating Committee*

1 *on Women’s Health (established under section*
2 *229(b)(4) of the Public Health Service Act).*

3 “(c) *COORDINATING COMMITTEE.*—

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

9 “(2) *COMPOSITION.*—*The Coordinating Com-*
10 *mittee shall be composed of the directors of the centers*
11 *of the Administration.*

12 “(3) *CHAIRPERSON.*—*The Director of the Office*
13 *shall serve as the Chairperson of the Coordinating*
14 *Committee.*

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

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

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

1 “(C) identifying whether any need exists for
2 the coordination of Administration activities, in-
3 cluding internal and external activities;

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

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

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

15 “(d) *REPORTS.*—Not later than January 31, 2004,
16 and January 31 of each second year thereafter, the Director
17 of the Office shall prepare and submit to the appropriate
18 committees of Congress a report describing the activities
19 carried out under this section during the period for which
20 the report is being prepared.

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

1 **SEC. 207. NO NEW REGULATORY AUTHORITY.**

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

5 **TITLE III—WISEWOMAN**
6 **EXPANSION**

7 **SEC. 301. SHORT TITLE.**

8 *This Act may be cited as the “WISEWOMAN Expan-*
9 *sion Act of 2002”.*

10 **SEC. 302. FINDINGS.**

11 *Congress makes the following findings:*

12 *(1) Cardiovascular disease, including heart dis-*
13 *ease and stroke, remains the leading cause of death*
14 *among females in the United States, killing more*
15 *than 500,006 women each year.*

16 *(2) About 1 in 5 females have some form of car-*
17 *diovascular disease.*

18 *(3) More American women die of cardiovascular*
19 *disease than the next 14 causes of death combined.*

20 *(4) In women, cardiovascular disease is fre-*
21 *quently undetected and untreated until the disease*
22 *has become severe, causing 38 percent of women who*
23 *have heart attacks to die within 1 year.*

24 *(5) Obesity increases women’s risk for some of*
25 *the leading causes of death, including heart disease,*
26 *stroke, diabetes, and certain cancers.*

1 (6) *Better nutrition and lifestyle changes can ef-*
2 *fectively prevent and treat obesity.*

3 (7) *Osteoporosis afflicts more than 20,000,000*
4 *American women.*

5 (8) *More than half of all American women over*
6 *65 have osteoporosis.*

7 (9) *One out of every 2 women over the age of 50*
8 *will have an osteoporosis-related fracture during her*
9 *lifetime.*

10 (10) *The national annual costs associated with*
11 *osteoporosis are estimated at approximately*
12 *\$14,000,000,000.*

13 (11) *Physical activity is necessary for bone ac-*
14 *quisition and maintenance throughout adulthood.*

15 (12) *Muscular strength and balance may be very*
16 *significant in future risk reduction for osteoporosis.*

17 (13) *There is consensus that adequate vitamin D*
18 *and calcium intakes are required for bone health.*

19 (14) *Research has demonstrated that—*

20 (A) *the uninsured often have significantly*
21 *poorer health than the insured; and*

22 (B) *being uninsured is an obstacle to receiv-*
23 *ing preventive health care services.*

24 (15) *The WISEWOMAN demonstration program,*
25 *which is currently operating in 12 States, has—*

1 (A) provided improved access for preventive
2 health services, such as cholesterol and blood
3 pressure screening, for over 11,000 women and
4 identified risk factors for heart disease such as
5 obesity, high cholesterol, high blood pressure, sed-
6 entary behavior and poor diet; and

7 (B) improved follow up and maintenance
8 care, resulting in improved weight management,
9 lower blood pressure and lower cholesterol.

10 (16) Expansion of the WISEWOMAN dem-
11 onstration model program to additional States would
12 help reduce women's risk of illness and death from
13 heart disease and other preventable diseases and pro-
14 vide further insights into the feasibility and effective-
15 ness of making comprehensive, integrated preventive
16 services, including enhanced case management serv-
17 ices, available to low-income and uninsured women
18 across the nation.

19 **SEC. 303. SUPPLEMENTAL GRANTS FOR ADDITIONAL PRE-**
20 **VENTIVE HEALTH SERVICES FOR WOMEN.**

21 Section 1509 of the Public Health Service Act (42
22 U.S.C. 300n-4a) is amended to read as follows:

1 **“SEC. 1509. ESTABLISHMENT OF PROGRAM FOR ADDI-**
2 **TIONAL PREVENTIVE HEALTH SERVICES.**

3 “(a) *IN GENERAL.*—*The Secretary, acting through the*
4 *Director of the Centers for Disease Control and Prevention,*
5 *may, through a competitive review process, award grants*
6 *to States that have received grants under section 1501 for*
7 *a fiscal year, to enable such State to carry out programs—*

8 “(1) *to provide preventive health services, in ad-*
9 *dition to the services authorized in such section 1501,*
10 *for diseases such as cardiovascular diseases,*
11 *osteoporosis, and obesity;*

12 “(2) *to provide screenings, such as screening for*
13 *blood pressure, cholesterol, and osteoporosis, and other*
14 *services that the Secretary, acting through the Direc-*
15 *tor of the Centers for Disease Control and Prevention,*
16 *determines to be appropriate and feasible;*

17 “(3) *for health education, counseling, and inter-*
18 *ventions for behavioral risk factors, such as physical*
19 *inactivity and poor nutrition, and diseases referred to*
20 *in paragraph (1);*

21 “(4) *to provide appropriate referrals for medical*
22 *treatment of women receiving services pursuant to*
23 *paragraph (1) through (3), and ensuring, to the ex-*
24 *tent practicable, the provision of appropriate follow-*
25 *up services; and*

1 “(5) to evaluate the activities conducted under
2 paragraphs (1) through (4) through appropriate sur-
3 veillance, research, or program monitoring activities.

4 “(b) *STATUS AS PARTICIPANT IN PROGRAM REGARD-*
5 *ING BREAST AND CERVICAL CANCER.*—*The Secretary may*
6 *not make a grant to a State under subsection (a) unless*
7 *the State involved agrees that services under the grant will*
8 *be provided in conjunction with entities that are screening*
9 *women for breast or cervical cancer pursuant to a grant*
10 *under section 1501.*

11 “(c) *APPLICABILITY OF PROVISIONS.*—*The provisions*
12 *of this title shall apply to a grant under subsection (a) to*
13 *the same extent and in the same manner as such provisions*
14 *apply to a grant under section 1501.*

15 “(d) *FUNDING.*—*There is authorized to be appro-*
16 *priated to carry out this section—*

17 “(1) \$20,000,000 for fiscal year 2003;

18 “(2) \$25,000,000 for fiscal year 2004; and

19 “(3) such sums as may be necessary for each of
20 *fiscal years 2005 through 2007.*

21 ***TITLE IV—SUBSTANCE ABUSE***
22 ***PREVENTION***

23 ***SEC. 401. SHORT TITLE.***

24 *This title may be cited as the “Substance Abuse Pre-*
25 *vention and Treatment for Safe Motherhood Act”.*

1 **SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

3 *Section 519A of the Public Health Service Act (42*
4 *U.S.C. 290bb–25a) is amended—*

5 *(1) in subsection (d)—*

6 *(A) in paragraph (1), by striking “and” at*
7 *the end;*

8 *(B) in paragraph (2), by striking the period*
9 *and inserting a semicolon; and*

10 *(C) by adding at the end the following:*

11 *“(3) identify women with children in the judi-*
12 *cial or child welfare system in the State or locality*
13 *who are in need of substance abuse services;*

14 *“(4) provide early referral for substance abuse*
15 *treatment for women with children;*

16 *“(5) develop a comprehensive treatment plan for*
17 *the women and children to address—*

18 *“(A) the substance abuse service needs of the*
19 *women in the State or locality;*

20 *“(B) the health services needs for the women*
21 *with children, including services for HIV, tuber-*
22 *culosis, or any sexually transmitted disease; and*

23 *“(C) the mental health needs of the women*
24 *and the children;*

25 *“(6) provide treatment that follows best practices*
26 *in addressing the needs of the women;*

1 “(7) provide services to the women to ensure sta-
2 ble housing, employment, health, and social support
3 for women who are transitioning from treatment;

4 “(8) monitor the progress of women in substance
5 abuse treatment;

6 “(9) provide prevention and early intervention
7 services for women who are at risk for substance
8 abuse;

9 “(10) provide prevention and early intervention
10 services for the children;

11 “(11) provide for the health and educational
12 needs of the children;

13 “(12) provide parenting classes for the women;
14 and

15 “(13) provide training for the staff of each of the
16 participating agencies in order that such staff may—

17 “(A) identify women with children in need
18 of substance abuse services;

19 “(B) provide referrals to agencies that pro-
20 vide services for such women and children; and

21 “(C) determine how to use the program to
22 the advantage of the women and children.”;

23 (2) in subsection (e)—

24 (A) in paragraph (2), by striking “and” at
25 the end;

1 (B) in paragraph (3), by striking the period
2 and inserting a semicolon; and

3 (C) by adding at the end the following:

4 “(4) provides assurances that the applicant has
5 established, or will establish, a network consisting of
6 a substance abuse service agency, a child welfare
7 agency, and an agency of a State judicial system that
8 proposes to work cooperatively to provide the sub-
9 stance abuse program described in subsection (a); and

10 “(5) identifies a State that will develop a cooper-
11 ative group as described in paragraph (4).”; and

12 (3) by striking subsection (i) and inserting the
13 following:

14 “(i) *HIGH-RISK FAMILIES*.—In this section, the term
15 “high-risk family” means—

16 “(1) a family in which the individuals of such
17 family are at a significant risk of using or abusing
18 alcohol or any illegal substance and

19 “(2) a woman with a minor child who is in-
20 volved with the State or local child welfare agency or
21 protective services, or who is involved with an agency
22 of the State or local judicial system.”.

1 **TITLE V—PERINATAL DENTAL**
2 **HEALTH IMPROVEMENT**

3 **SEC. 501. SHORT TITLE.**

4 *This title may be cited as the “Perinatal Dental*
5 *Health Improvement Act of 2002”.*

6 **SEC. 502. FINDINGS.**

7 *Congress makes the following findings:*

8 (1) *The National Institutes of Health reports*
9 *that “as many as 18 percent of the 250,000 pre-*
10 *mature low-weight infants born in the United States*
11 *each year may be attributable to infectious oral dis-*
12 *ease.”.*

13 (2) *Recent scientific studies suggest that the se-*
14 *vere consequences of premature delivery and associ-*
15 *ated low birth weight may be partially preventable*
16 *through improved oral health of pregnant women.*

17 (3) *Additionally, extensive laboratory, clinical*
18 *and epidemiologic studies show that a mother’s expe-*
19 *rience with tooth decay determines their young chil-*
20 *dren’s risk of developing cavities.*

21 (4) *Dental caries (tooth decay) is now under-*
22 *stood to be an infectious and transmissible disease ac-*
23 *quired by children primarily from their mothers.*

1 **SEC. 503. GRANTS TO CONDUCT RESEARCH AND DEM-**
 2 **ONSTRATION PROJECTS THAT APPLY NEW**
 3 **SCIENTIFIC EVIDENCE ABOUT MATERNAL**
 4 **AND CHILD ORAL HEALTH LINKAGES.**

5 *Part B of title III of the Public Health Service Act*
 6 *(42 U.S.C. 243 et seq.) is amended by inserting after section*
 7 *317M the following:*

8 **“SEC. 317M-1. GRANTS TO CONDUCT RESEARCH AND DEM-**
 9 **ONSTRATION PROJECTS THAT APPLY NEW**
 10 **SCIENTIFIC EVIDENCE ABOUT MATERNAL**
 11 **AND CHILD ORAL HEALTH LINKAGES.**

12 *“(a) AUTHORITY TO AWARD GRANTS.—The Secretary,*
 13 *acting through the Director of the Maternal and Child*
 14 *Health Bureau, shall award grants to eligible entities to*
 15 *conduct surveillance research and demonstration projects*
 16 *concerning possible maternal and child oral health linkages*
 17 *related to adverse pregnancy outcomes and maternal trans-*
 18 *mission of dental caries.*

19 *“(b) ELIGIBLE ENTITY.—In this section, the term ‘eli-*
 20 *gible entity’ means a nonprofit organization, accredited*
 21 *dental education and research institution, an Indian tribe*
 22 *(as defined in section 4 of the Indian Self-Determination*
 23 *and Education Assistance Act (25 U.S.C. 450b)), or tribal*
 24 *organization.*

25 *“(c) REQUIREMENT FOR NONPROFIT ORGANIZATIONS,*
 26 *ACCREDITED DENTAL EDUCATION AND RESEARCH INSTI-*

1 TUTIONS, AND INDIAN TRIBES AND TRIBAL ORGANIZA-
2 TIONS.—*In order to be eligible for a grant under this sec-*
3 *tion, an eligible entity shall provide the Secretary with an*
4 *assurance that it such entity is an eligible entity.*

5 “(d) *USE OF FUNDS.*—

6 “(1) *IN GENERAL.*—*Funds provided under this*
7 *section may be used to provide direct funding to sup-*
8 *port projects in the following areas:*

9 “(A) *PROFESSIONAL EDUCATION.*—*The de-*
10 *velopment of programs based on the most recent*
11 *research available as of the date of the conduct*
12 *of the program with respect to maternal and*
13 *child health to inform dentists, pediatricians,*
14 *family physicians, obstetricians, nurse practi-*
15 *tioners, and other primary care providers in*
16 *order to educate women of childbearing age on*
17 *the possible maternal-child health consequences of*
18 *poor oral health, and to conduct surveillance re-*
19 *search on the outcomes of such programs.*

20 “(B) *PUBLIC EDUCATION.*—*The develop-*
21 *ment of programs based on the most recent re-*
22 *search available as of the date of the conduct of*
23 *the program with respect to maternal and child*
24 *health to raise the public’s awareness of possible*
25 *maternal and child health consequences of poor*

1 *oral health, to improve the oral health practices*
 2 *of women of childbearing age, and to conduct*
 3 *surveillance research on the outcomes of such*
 4 *programs.*

5 “(2) *LIMITATION.—Funds provided under a*
 6 *grant awarded under this section may not be used for*
 7 *payment of direct dental, medical, or other services or*
 8 *to obtain Federal matching funds under any Federal*
 9 *program.*

10 “(e) *APPLICATION.—An eligible entity desiring a grant*
 11 *under this section shall submit an application to the Sec-*
 12 *retary in such form and manner and containing such infor-*
 13 *mation as the Secretary may require.*

14 “(f) *AUTHORIZATION OF APPROPRIATIONS.—There are*
 15 *authorized to be appropriated to make grants under this*
 16 *section \$7,500,000 for fiscal year 2003, and such sums as*
 17 *may be necessary for each of fiscal years 2004 through*
 18 *2007.”.*

19 ***TITLE VI—EATING DISORDERS***

20 ***SEC. 601. SHORT TITLE.***

21 *This title may be cited as the “Promoting Healthy*
 22 *Eating Behaviors in Youth Act”.*

23 ***SEC. 602. FINDINGS.***

24 *Congress makes the following findings:*

1 (1) *Anorexia Nervosa is an eating disorder char-*
2 *acterized by self-starvation and excessive weight loss.*

3 (2) *Anorexia Nervosa is common: an estimated*
4 *.5 to 3.7 percent of American women will suffer from*
5 *this disorder in their lifetime.*

6 (3) *Anorexia Nervosa is associated with serious*
7 *health consequences including heart failure, kidney*
8 *failure, osteoporosis, and death.*

9 (4) *Anorexia Nervosa has the highest mortality*
10 *rate of all psychiatric disorders. A young woman is*
11 *12 times more likely to die than other women her age*
12 *without Anorexia.*

13 (5) *Anorexia Nervosa usually appears in adoles-*
14 *cence.*

15 (6) *Bulimia Nervosa is an eating disorder char-*
16 *acterized by excessive food consumption followed by*
17 *inappropriate compensatory behaviors, such as self-*
18 *induced vomiting, misuse of laxatives, fasting, or ex-*
19 *cessive exercise.*

20 (7) *Bulimia Nervosa is common: an estimated*
21 *1.1 to 4.2 percent of American women will suffer from*
22 *this disorder in their lifetime.*

23 (8) *Bulimia Nervosa is associated with cardiac,*
24 *gastrointestinal, and dental problems including irreg-*

1 ular heartbeats, gastric rupture, peptic ulcer, and
2 tooth decay.

3 (9) *Bulimia Nervosa usually appears in adoles-*
4 *cence.*

5 (10) *On the 1999 Youth Risk Behavior Survey,*
6 *7.5 percent of high school girls reported recent use of*
7 *laxatives or vomiting to control their weight.*

8 (11) *Binge Eating Disorder is characterized by*
9 *frequent episodes of uncontrolled overeating.*

10 (12) *Binge Eating Disorder is common: an esti-*
11 *mated 2 to 5 percent of Americans experience this*
12 *disorder in a 6-month period.*

13 (13) *Binge Eating is associated with obesity,*
14 *heart disease, gall bladder disease, and diabetes.*

15 (14) *Eating disorders are commonly associated*
16 *with substantial psychological problems, including de-*
17 *pression, substance abuse, and suicide.*

18 (15) *Obesity is reaching epidemic proportions:*
19 *27 percent of United States adults are obese and 13*
20 *percent of children and 14 percent of adolescents are*
21 *seriously overweight.*

22 (16) *Poor eating habits have led to a “calcium*
23 *crisis” among American youth: only 13.5 percent of*
24 *adolescent girls get the recommended daily amount of*
25 *calcium, placing them at serious risk for osteoporosis*

1 *and other bone diseases. Because nearly 90 percent of*
2 *adult bone mass is established by the end of this age*
3 *range, the Nation's youth's insufficient calcium intake*
4 *is truly a calcium crisis.*

5 *(17) Eating disorders of all types are more com-*
6 *mon in women than men.*

7 *(18) Eating preferences and habits are estab-*
8 *lished in childhood.*

9 *(19) Poor eating habits are a risk factor for the*
10 *development of eating disorders, obesity and*
11 *osteoporosis.*

12 *(20) However, simply urging overweight youth to*
13 *be thin has not reduced the prevalence of obesity and*
14 *may result in other problems including body dis-*
15 *satisfaction, low self-esteem, and eating disorders.*

16 *(21) Therefore, effective interventions for pro-*
17 *moting healthy eating behaviors in youth should pro-*
18 *mote healthy lifestyle and not inadvertently promote*
19 *unhealthy weight management techniques.*

20 **SEC. 603. PURPOSES.**

21 *The purposes of this title are as follows:*

22 *(1) To increase preventive health activities de-*
23 *signed to promote the development of healthy eating*
24 *habits and behaviors in youth.*

1 (2) *To support research to develop and test edu-*
 2 *cational curricula and intervention programs aimed*
 3 *at promoting healthy eating habits and behaviors in*
 4 *youth.*

5 (3) *To identify and disseminate effective inter-*
 6 *vention programs aimed at promoting healthy eating*
 7 *habits and behaviors in youth.*

8 **SEC. 604. AMENDMENTS.**

9 (a) *USE OF ALLOTMENTS.*—Section 1904(a)(1) of the
 10 *Public Health Service Act (42 U.S.C. 300w–3) is amended*
 11 *by adding after subparagraph (G) the following:*

12 “(H) *Activities designed to address and prevent*
 13 *eating disorders, obesity, and osteoporosis through ef-*
 14 *fective programs to promote healthy eating and exer-*
 15 *cise habits and behaviors in youth.”.*

16 (b) *GRANTS.*—Section 399W of the *Public Health Serv-*
 17 *ice Act (42 U.S.C. 280h) is amended to read as follows:*

18 **“SEC. 399W. GRANTS TO PROMOTE CHILDHOOD NUTRITION**

19 **AND PHYSICAL ACTIVITY.**

20 “(a) *PROGRAM AUTHORIZED.*—*The Secretary, acting*
 21 *through the Director of the Centers for Disease Control and*
 22 *Prevention (hereafter the ‘Director’) and in coordination*
 23 *with the Office of Women’s Health and the National Insti-*
 24 *tutes of Health, shall award competitive grants to States,*
 25 *political subdivisions of States, accredited universities, col-*

1 *leges, or nonprofit organizations, for the implementation of*
2 *State and community-based intervention programs to pro-*
3 *mote good nutrition, including promoting healthy eating*
4 *behaviors and physical activity in children and adolescents.*
5 *Such grants may be awarded to target youth or specific*
6 *at-risk populations, such as adolescent girls.*

7 “(b) *ELIGIBILITY.*—*To be eligible to receive a grant*
8 *under this section a State, political subdivision of a State,*
9 *university, college, or nonprofit organization shall prepare*
10 *and submit to the Secretary an application at such time,*
11 *in such manner, and containing such information as the*
12 *Secretary may require, including a plan that describes—*

13 “(1) *how the applicant proposes to develop a*
14 *comprehensive program of school- and community-*
15 *based approaches to encourage and promote good nu-*
16 *trition and appropriate levels of physical activity*
17 *with respect to children or adolescents in local com-*
18 *munities;*

19 “(2) *the manner in which the applicant shall co-*
20 *ordinate with appropriate State and local authorities,*
21 *such as State and local school departments, State de-*
22 *partments of health, chronic disease directors, State*
23 *directors of programs under section 17 of the Child*
24 *Nutrition Act of 1966, 5-a-day coordinators, gov-*
25 *ernors councils for physical activity and good nutri-*

1 *tion, and State and local parks and recreation de-*
2 *partments; and*

3 *“(3) the manner in which the applicant will*
4 *evaluate the effectiveness of the program carried out*
5 *under this section.*

6 *“(c) USE OF FUNDS.—A State, political subdivision*
7 *of a State, university, college, or nonprofit organization*
8 *that receives a grant under this section shall use funds re-*
9 *ceived to—*

10 *“(1) develop and test educational curricula and*
11 *intervention programs designed to promote healthy*
12 *eating behaviors and habits in youth, including*
13 *science-based interventions with multiple components*
14 *such as—*

15 *“(A) nutritional content;*

16 *“(B) understanding and responding to hun-*
17 *ger and satiety;*

18 *“(C) positive body image development;*

19 *“(D) positive self-esteem development; and*

20 *“(E) learning life skills, such as stress man-*
21 *agement, communication skills, problem solving*
22 *and decision making skills, as well as consider-*
23 *ation of cultural and developmental issues, and*
24 *the role of family, school, and community;*

1 “(2) *develop, implement, disseminate, and evalu-*
2 *ate school and community-based strategies to reduce*
3 *inactivity and improve nutrition among children and*
4 *adolescents;*

5 “(3) *expand opportunities for physical activity*
6 *programs in school- and community-based settings;*
7 *and*

8 “(4) *develop, implement, and evaluate programs*
9 *that promote good eating habits and physical activity*
10 *including opportunities for children and adolescents*
11 *with cognitive and physical disabilities.*

12 “(d) *TECHNICAL ASSISTANCE.—The Secretary may*
13 *set-aside an amount not to exceed 10 percent of the amount*
14 *appropriated for a fiscal year under subsection (h) to per-*
15 *mit the Director of the Centers for Disease Control and Pre-*
16 *vention to—*

17 “(1) *provide States and political subdivisions of*
18 *States with technical support in the development and*
19 *implementation of programs under this section; and*

20 “(2) *disseminate information about effective*
21 *strategies and interventions in preventing and treat-*
22 *ing obesity through the promotion of good nutrition*
23 *and physical activity.*

24 “(e) *LIMITATION ON ADMINISTRATIVE COSTS.—Not to*
25 *exceed 10 percent of the amount of a grant awarded to the*

1 *State or political subdivision under subsection (a) for a fis-*
2 *cal year may be used by the State or political subdivision*
3 *for administrative expenses.*

4 “(f) *TERM.*—*A grant awarded under subsection (a)*
5 *shall be for a term of not to exceed 4 years.*

6 “(g) *DEFINITIONS.*—*In this section:*

7 “(1) *CHILDREN AND ADOLESCENTS.*—*The term*
8 *‘children and adolescents’ means individuals who do*
9 *not exceed 18 years of age.*

10 “(2) *HEALTHY EATING.*—*The term ‘healthy eat-*
11 *ing’ means having regular eating habits, such as eat-*
12 *ing 3 meals a day to satisfy hunger, eating for nour-*
13 *ishment, health, and energy, eating in such a manner*
14 *as to acknowledge internal signals of appetite and sa-*
15 *tiety, and eating in a healthy manner in ordinary so-*
16 *cial environments to promote healthy social relation-*
17 *ships with family, peers, and community.*

18 “(h) *REPORT.*—*The Director shall review the results*
19 *of the grants awarded under this section and other related*
20 *research and identify programs that have demonstrated ef-*
21 *fectiveness in promoting healthy eating behaviors and hab-*
22 *its in youth. Such programs shall be referred to as “Pro-*
23 *grams that Work”.* *Information about Programs that Work,*
24 *including program curricula, shall be made readily avail-*
25 *able to the public.*

1 “(i) *SUNSET.*—*The provisions of this section shall be*
2 *effective for 5 years after the date of enactment of this sec-*
3 *tion.*

4 “(j) *AUTHORIZATION OF APPROPRIATIONS.*—*There is*
5 *authorized to be appropriated to carry out this section,*
6 *\$5,000,000 for fiscal year 2003, \$5,500,000 for fiscal year*
7 *2004, \$6,000,000 for fiscal year 2005, \$6,500,000 for year*
8 *2006, and \$1,000,000 for year 2007.”.*

The title is amended so as to read: “A bill to enhance the health of women in the United States.”.

Calendar No. 602

107TH CONGRESS
2D SESSION

S. 2328

A BILL

To amend the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act to ensure a safe pregnancy for all women in the United States, to reduce the rate of maternal morbidity and mortality, to eliminate racial and ethnic disparities in maternal health outcomes, to reduce pre-term labor, to examine the impact of pregnancy on the short and long term health of women, to expand knowledge about the safety and dosing of drugs to treat pregnant women with chronic conditions and women who become sick during pregnancy, to expand public health prevention, education and outreach, and to develop improved and more accurate data collection related to maternal morbidity and mortality.

SEPTEMBER 17, 2002

Reported with an amendment and an amendment to the
title