

107TH CONGRESS
2^D SESSION

H. R. 4602

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 HOUSE OF REPRESENTATIVES

APRIL 25, 2002

Mr. DINGELL (for himself and Mrs. LOWEY) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

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pand 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
16 conditions. Two to 3 lives are lost each day due to
17 pregnancy-related mortality.

18 (4) Racial and ethnic minority women suffer a
19 significantly higher risk of pregnancy-related mor-
20 tality than non-Hispanic white women. African
21 American women are almost 4 times more likely to
22 die from pregnancy-related illnesses or conditions
23 than white women. Hispanic, Asian immigrant, and

1 American Indian women are twice as likely to die
2 from pregnancy-related illnesses or conditions as
3 their non-Hispanic counterparts.

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

8 (6) There has been no decline in pregnancy-re-
9 lated deaths in the United States over the last 20
10 years. In 1987 the United States set goals as part
11 of Healthy People 2000: National Health Promotion
12 and Disease Prevention Objectives, to reduce mater-
13 nal deaths from 7.5 deaths per 100,000 to 3.3 per
14 100,000 for live births and no more than 5.0 mater-
15 nal deaths per 100,000 births among African Amer-
16 ican women. Again in 2000, as part of Health Peo-
17 ple 2010, new goals have been set. These goals have
18 not been met.

19 (7) In the United States, 30 percent of women,
20 or 1 out of every 3 pregnant women, experience a
21 major medical complication at some point during
22 their pregnancy. The most common complications
23 are miscarriage, ectopic pregnancy, excessive vom-
24 iting, diabetes, hemorrhage, infection, pre-eclampsia,

1 premature labor, and the need for a surgical (cae-
2 sarian) delivery.

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

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

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

13 (11) There is a lack of knowledge regarding the
14 causes of these complications, as well as effective
15 preventative and therapeutic interventions. Perinatal
16 diseases rank as the second lowest National Institute
17 of Health-funded group of diseases in the whole field
18 of medicine when comparisons take into account dis-
19 ability adjusted life years (DALYs) lost due to each
20 disease.

21 (12) Most drugs women take during pregnancy
22 are necessary to maintain health. However, 80 per-
23 cent of approved drugs lack adequate scientific evi-
24 dence about their use in pregnancy. Only 1 percent

1 of drugs have been shown in controlled studies to
2 pose no risk to pregnant women.

3 (13) Women under age 35 take an average of
4 3 prescription drugs during pregnancy. For women
5 over the age of 35 the number of prescription drugs
6 increases to 5.

7 (14) Pregnancy is a critical time in a women's
8 life with far ranging implications for her short- and
9 long-term health and for the health of her family.
10 The United States must devote the resources and
11 have the will of the nation to ensure a safe preg-
12 nancy and good health throughout the lives of Amer-
13 ican women.

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

15 (1) develop a national effort to achieve a
16 healthy and safe pregnancy for all women in the
17 United States;

18 (2) reduce the risk of pregnancy-related deaths
19 and complications due to pregnancy;

20 (3) eliminate racial and ethnic disparities in the
21 rates of maternal mortality and morbidity;

22 (4) improve the treatment and clinical care of
23 pregnant women;

24 (5) reduce pre-term labor;

1 (6) examine the impact of pregnancy on the
2 short- and long-term health of women;

3 (7) work toward an evidence-based standard of
4 care with respect to pregnant women;

5 (8) expand knowledge about the safety and dos-
6 ing of drugs and devices used to treat pregnant
7 women with chronic conditions and women who be-
8 come sick during pregnancy;

9 (9) expand public health prevention, education
10 and outreach; and

11 (10) develop improved and more accurate data
12 collection relating to maternal morbidity and mor-
13 tality.

14 **TITLE I—AMENDMENTS TO THE**
15 **PUBLIC HEALTH SERVICE ACT**

16 **Subtitle A—Reducing Maternal**
17 **Morbidity and Mortality**
18 **Through Coordinated Federal**
19 **Action**

20 **SEC. 101. INTERAGENCY COORDINATING COMMITTEE ON**
21 **SAFE MOTHERHOOD.**

22 Part P of title III of the Public Health Service Act
23 (42 U.S.C. 280g et seq.) is amended by adding at the end
24 the following:

1 **“SEC. 3990. INTERAGENCY COORDINATING COMMITTEE ON**
2 **SAFE MOTHERHOOD.**

3 “(a) ESTABLISHMENT.—The Secretary, acting
4 through the Director of the Office of Women’s Health,
5 shall establish a committee to be known as the ‘Inter-
6 agency Coordinating Committee on Safe Motherhood’ (re-
7 ferred to in this section as the ‘Coordinating Committee’).

8 “(b) COMPOSITION.—The Coordinating Committee
9 shall be composed of—

10 “(1) the Director of the Centers for Disease
11 Control and Prevention (and the heads of such insti-
12 tutes, centers and offices as the Director determines
13 appropriate);

14 “(2) the Director of the National Institutes of
15 Health (and the heads of such institutes, centers
16 and offices as the Director determines appropriate);

17 “(3) the Director of the Health Resources and
18 Services Administration (and the heads of such in-
19 stitutes, centers and offices as the Director deter-
20 mines appropriate);

21 “(4) the Commissioner of Food and Drugs (and
22 the heads of such institutes, centers and offices as
23 the Commissioner determines appropriate);

24 “(5) the Director of the Agency for Healthcare
25 Research and Quality (and the heads of such insti-

1 tutes, centers and offices as the Director determines
2 appropriate);

3 “(6) the Secretary of Labor (and the heads of
4 such institutes, centers and offices as the Secretary
5 determines appropriate);

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

8 “(8) representatives of women’s health care ad-
9 vocacy and grassroots organizations, health care pro-
10 viders including providers of specialty care, and re-
11 searchers to be appointed by the Director of the Of-
12 fice.

13 “(c) ADMINISTRATIVE SUPPORT.—The Secretary
14 shall make available to the Coordinating Committee nec-
15 essary and appropriate administrative support.

16 “(d) DUTIES.—

17 “(1) EVALUATION.—The Coordinating Com-
18 mittee shall assess health promotion campaigns that
19 are administered by the Federal Government (in-
20 cluding smoking cessation programs, alcohol and
21 substance abuse treatment programs, and domestic
22 violence prevention programs), evaluate the effect
23 that such campaigns have on health during preg-
24 nancy if pregnancy was a focus, and assess whether

1 such programs may be adapted to emphasize the im-
2 portance of maternal health.

3 “(2) FEDERAL RESEARCH PLAN.—

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

9 “(B) CONTENTS.—The plan developed
10 under subparagraph (A) shall define the areas
11 of research that are necessary to carry out the
12 purposes of the SMART Mom Act and include
13 recommendations for the implementation and
14 funding of activities under the plan. Such plan
15 shall take into consideration any programs and
16 plans existing on the date of enactment of this
17 section as well as research opportunities that
18 arise during the 5-year period beginning on
19 such date of enactment and shall at a minimum
20 include—

21 “(i) recommendations for research on
22 pregnancy-related conditions;

23 “(ii) recommendations for research on
24 the impact of chronic conditions, physical

1 impairments, or mental health conditions
2 on pregnant women;

3 “(iii) recommendations for research
4 on medical complications that occur during
5 delivery;

6 “(iv) recommendations for research on
7 post-partum conditions (such as depres-
8 sion, hemorrhage, and fever);

9 “(v) recommendations for research on
10 racial, ethnic, social, behavioral, and eco-
11 nomic factors effecting pregnancy;

12 “(vi) recommendations for research to
13 improve outreach efforts, education pro-
14 grams, and prevention and health pro-
15 motion strategies for pregnant women; and

16 “(vii) a recommended plan and re-
17 search agenda to improve knowledge about
18 the safety of drugs, devices, cosmetics, and
19 food with respect to pregnancy.

20 “(C) REPORT.—Not later than 18 months
21 after the date of enactment of this section, the
22 Coordinating Committee shall prepare and sub-
23 mit to the Secretary and the appropriate com-
24 mittees of Congress, a report concerning the
25 plan developed under this paragraph and the

1 results of the evaluation conducted under para-
2 graph (1).

3 “(3) KEY INDICATORS OF WELL BEING.—

4 “(A) IN GENERAL.—The Coordinating
5 Committee, in consultation with the Centers for
6 Disease Control and Prevention, the Director of
7 the National Institute of Child Health and
8 Human Development, the Director of the Agen-
9 cy for Healthcare Research and Quality, and
10 the heads of other relevant Federal agencies,
11 shall determine the key indicators of maternal
12 health and the sources of data to be included in
13 the report under subparagraph (B), and shall
14 update such indicators as new data becomes
15 available.

16 “(B) REPORT.—Not later than October 1,
17 2003, and biannually thereafter, the Coordi-
18 nating Committee shall prepare and submit to
19 the appropriate committees of Congress, a re-
20 port, to be known as ‘America’s Mothers: Key
21 National Indicators of Well Being’ (referred to
22 in this section as the ‘Report’), that contains
23 the indicators of maternal health described in
24 subparagraph (A).

1 “(C) AVAILABILITY.—The Report shall be
2 made available to the public through the Inter-
3 net website established under paragraph (4).

4 “(4) SAFE MOTHERHOOD CAMPAIGN.—The Co-
5 ordinating Committee shall establish and implement
6 a national public education and health promotion
7 campaign on safe motherhood, including developing
8 and maintaining an Internet website as provided for
9 in section 399P, promoting the establishment of
10 community partnerships, supporting community-
11 based programs, promoting the establishment of
12 partnerships with State and local health providers
13 and educators, and promoting the establishment of
14 partnerships with private non-profit organizations.

15 “(e) NONAPPLICABILITY OF FACCA.—The provisions
16 of the Federal Advisory Committee Act (5 U.S.C. App.)
17 shall not apply to the Coordinating Committee.

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

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

4 **SEC. 111. EXPAND AND INTENSIFY RESEARCH ACTIVITIES**
5 **AT THE NATIONAL INSTITUTE OF HEALTH.**

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

17 (b) SAFE MOTHERHOOD AS A PRIORITY AREA.—Sub-
18 part 7 of part C of title IV of the Public Health Service
19 Act (42 U.S.C. 285g et seq.) is amended by adding at
20 the end the following:

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

22 “The Director of the Institute shall annually report
23 to Congress and the public on the extent of the total funds
24 obligated to conduct or support research on safe mother-
25 hood across the National Institutes of Health, including

1 the specific support and research awards allocated through
2 the 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
6 (b), 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
11 better treatments and care for women throughout their
12 pregnancy, and to prevent pregnancy-related illnesses, in-
13 jury and death whenever possible, the Director of NIH,
14 acting through the Director of the Institute, shall enhance
15 and expand research into the leading causes of pregnancy-
16 related death and complications of pregnancy.

17 “(b) REDUCING PRE-TERM LABOR AND DELIV-
18 ERY.—In order to reduce the rates of pre-term labor and
19 delivery, the Director of NIH shall expand and intensify
20 research on pre-term labor and delivery.

21 “(c) POST-PARTUM HEALTH CONDITIONS.—The Di-
22 rector of NIH shall expand and enhance research con-
23 cerning the post-partum health conditions and illness that
24 affect women.

1 “(d) REDUCTIONS IN RACIAL AND ETHNIC DISPARI-
2 TIES.—The Director of NIH shall provide for the conduct
3 of research to investigate the mechanisms contributing to
4 the disparities in maternal and perinatal outcomes of ra-
5 cial and ethnic populations and immigrant groups.

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

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

14 **“SEC. 494B. IMPROVING THE UNDERSTANDING AND TREAT-**
15 **MENT OF CHRONIC CONDITIONS OF WOMEN**
16 **DURING PREGNANCY.**

17 “(a) IN GENERAL.—The Director of NIH shall ex-
18 pand research concerning the impact of chronic conditions,
19 physical impairments, and mental health problems on the
20 health of women during their pregnancy.

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

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

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

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

10 “(a) IN GENERAL.—The Director of the Institute
11 shall establish a Maternal Fetal Medicine Units Network.
12 In carrying out this subsection, the Director may enter
13 into agreements to utilize the existing Maternal Fetal
14 Medicine Units Network.

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

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

1 **SEC. 112. EXPAND AND INTENSIFY RESEARCH ACTIVITIES**
2 **AT THE CENTERS FOR DISEASE CONTROL**
3 **AND PREVENTION.**

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

8 (1) by redesignating subsection (d) as sub-
9 section (f); and

10 (2) by inserting after subsection (c), the fol-
11 lowing:

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

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

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

4 (b) PREVENTION RESEARCH CENTERS.—Section
5 317K of the Public Health Service Act (42 U.S.C. 247b–
6 12) is amended by inserting after subsection (d), as added
7 by subsection (a) of this section, the following:

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

19 **SEC. 113. IMPROVE QUALITY HEALTH CARE FOR PREG-**
20 **NANT WOMEN THROUGH AGENCY FOR**
21 **HEALTHCARE RESEARCH AND QUALITY.**

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

25 “(c) MATERNAL HEALTH CARE.—

1 “(1) IN GENERAL.—The Director shall provide
2 for the conduct of research concerning the quality of
3 maternal health care from a patient-centered per-
4 spective, including—

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

7 “(B) an examination of all types of care
8 and interventions, both medical and non-med-
9 ical, as well as barriers women face in gaining
10 access to recommended treatments; and

11 “(C) recommendations for the minimum
12 care needed to be considered as having received
13 quality care.

14 “(2) REPORT.—The results of the research con-
15 ducted under paragraph (1) shall be provided by the
16 Director to Congress as part of the annual report
17 submitted under subsection (b)(2).”.

18 **Subtitle C—Data Collection and** 19 **Surveillance**

20 **SEC. 121. EXPAND AND INTENSIFY DATA COLLECTION AC-** 21 **TIVITIES AT THE CENTERS FOR DISEASE** 22 **CONTROL AND PREVENTION.**

23 Part B of title III of the Public Health Service Act
24 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
25 tion 317K the following:

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

3 “(a) STANDARD DEFINITIONS FOR PREGNANCY-RE-
4 LATED MORTALITY AND MORBIDITY.—The Secretary,
5 acting through the Director of the Centers for Disease
6 Control and Prevention and in cooperation with State offi-
7 cials, professional medical experts, medical organizations,
8 and health care advocacy groups, shall develop a standard
9 definition of ‘maternal mortality’ and ‘maternal mor-
10 bidity’.

11 “(b) GRANTS FOR SURVEILLANCE OF PREGNANCY-
12 RELATED MORTALITY AND MORBIDITY DATA.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through the Director of the Centers for Disease
15 Control and Prevention, shall establish a program to
16 award grants to States, counties, and cities for the
17 development of surveillance systems, that use the
18 standard definitions established under subsection
19 (a), to gather data on maternal mortality and mater-
20 nal morbidity.

21 “(2) ELIGIBILITY.—To be eligible to receive a
22 grant under paragraph (1), a State, county, or city
23 shall—

24 “(A) prepare and submit to the Secretary
25 an application, at such time, in such manner,

1 and containing such information as the Sec-
2 retary may require;

3 “(B) provide an assurance that the appli-
4 cant will work with the Centers for Disease
5 Control and Prevention to adopt standard pro-
6 cedures for the identification, collection, and
7 analysis of the data that is to be collected under
8 the grant; and

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

13 “(3) TECHNICAL ASSISTANCE.—The Centers
14 for Disease Control and Prevention shall provide
15 technical assistance to grantees under this sub-
16 section.

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

22 “(c) PREVALENCE OF PRE-TERM LABOR AND DELIV-
23 ERY.—The Secretary, acting through the Director of the
24 Centers for Disease Control and Prevention, shall work
25 with States and other entities to improve knowledge re-

1 guarding the incidence and prevalence of symptoms and
2 risk factors for pre-term births.

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

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

7 Section 1004 of the Children’s Health Act of 2000
8 (42 U.S.C. 285g note) is amended—

9 (1) by redesignating subsections (d) and (e) as
10 subsections (e) and (f), respectively; and

11 (2) by inserting after subsection (c), the fol-
12 lowing:

13 “(d) STUDY ON EFFECTS OF PREGNANCY ON
14 WOMEN.—As part of the study conducted under this sec-
15 tion, the Director of the National Institute of Child Health
16 and Human Development, in collaboration with the Direc-
17 tor of the Centers for Disease Control and Prevention, the
18 Commission on Food and Drugs, and other appropriate
19 Federal officials, shall plan, develop, and implement a pro-
20 spective cohort study of mothers to determine the effects
21 of pregnancy on the health of women. Such study shall
22 evaluate—

23 “(A) the effects of pregnancy on women’s
24 health;

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

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

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

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

14 “(2) COMMUNITY PARTNERSHIPS.—The provi-
15 sion of support for community-based programs to
16 provide outreach, education, information and health
17 promotion services and information to give women
18 the tools they need to achieve a safe and healthy
19 pregnancy.

20 “(3) STATE AND LOCAL PARTNERSHIPS.—The
21 facilitation of consultations with State and local pub-
22 lic health officials to gain access to the broadest
23 number of women in an effort to provide outreach
24 and education assistance and information to help
25 women succeed in having a safe and healthy preg-
26 nancy.

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

6 “(c) INTERNET WEBSITE.—

7 “(1) ESTABLISHMENT.—The Secretary, acting
8 through the Office of Women’s Health and the Co-
9 ordinating Committee, shall develop and maintain a
10 single Internet website to provide pregnant women,
11 and research and health practitioners with the most
12 up-to-date and accurate information on pregnancy,
13 in a manner designed to carry out the purpose de-
14 scribed in paragraph (2).

15 “(2) PURPOSE.—It is the purpose of the
16 website established under paragraph (1) to consoli-
17 date information, research, and data related to preg-
18 nancy (prenatal, intrapartum, and postpartum) to-
19 gether in one place and to provide links for women
20 to other critical websites (Federal agencies, commu-
21 nity health programs, State and tribal health pro-
22 grams, and self-help professional and advocacy orga-
23 nizations).

24 “(3) ADDRESS.—The Secretary shall ensure
25 that the uniform resource locator for the website es-

1 established under paragraph (1) is
2 www.pregnancy.gov. If such locator is not available,
3 the Secretary shall select another similar locator.

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

6 “(A) educational materials for how to suc-
7 ceed in having the safest pregnancy possible, in-
8 cluding a description of chronic conditions,
9 pregnancy-related illnesses, and other health
10 problems that could pose risks to the mother or
11 fetus;

12 “(B) information concerning the safety
13 and risk of prescription and over-the-counter
14 medications and other products that women
15 might use during pregnancy;

16 “(C) information concerning standards for
17 clinical care throughout pregnancy;

18 “(D) information on trends in labor inter-
19 vention, such as induction, epidural, and cae-
20 sarean sections, and alternative approaches;

21 “(E) information concerning the issue of
22 domestic violence during pregnancy, including
23 how women can obtain assistance;

24 “(F) information concerning infertility and
25 maternal health; and

1 “(G) information concerning pregnancy-re-
2 lated workplace laws and policies, such as the
3 Family and Medical Leave Act of 1993.

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

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

11 **TITLE II—PREGNANT AND** 12 **LACTATING WOMEN**

13 **SEC. 201. AMENDMENTS TO FEDERAL FOOD, DRUG, AND** 14 **COSMETIC ACT.**

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

18 **“SEC. 564. SAFE DRUGS AND DEVICES FOR PREGNANT AND** 19 **LACTATING WOMEN.**

20 “(a) IMPROVING THE QUALITY OF INFORMATION ON
21 DRUGS AND BIOLOGICAL PRODUCTS FOR WOMEN WHO
22 ARE PREGNANT OR LACTATING.—

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

1 “(A) IDENTIFYING DRUGS TO BE STUD-
2 IED.—The Secretary, acting through the Direc-
3 tor of the National Institutes of Health and in
4 consultation with the Commissioner of Food
5 and Drugs and experts in maternal and fetal
6 health, shall—

7 “(i) identify marketed drugs and bio-
8 logical products that were not approved or
9 licensed based on studies in pregnant
10 women for which studies are needed—

11 “(I) to establish appropriate dos-
12 ing for women who are pregnant or
13 lactating; and

14 “(II) to investigate the marketed
15 drugs and biological products’ safe
16 use for pregnant women and fetuses
17 through the use of pregnancy reg-
18 istries and pharmacoepidemiological
19 databases; and

20 “(ii) design protocols for the needed
21 studies described in clause (i).

22 “(B) STUDYING MARKETED DRUGS.—The
23 Director of the National Institutes of Health
24 shall award grants, enter into contracts, or use
25 other appropriate mechanisms to aid in prompt-

1 ly completing the studies designed under sub-
2 paragraph (A), as the National Institutes of
3 Health’s resources allow.

4 “(2) POSTMARKETING STUDIES.—As a condi-
5 tion of approval of an application submitted under
6 section 505(b)(1) or of a biologics license application
7 under section 351 of the Public Health Service Act
8 (42 U.S.C. 262), the Secretary may require that the
9 holder of the application conduct postmarketing
10 studies, to be completed and submitted to the Sec-
11 retary by a date specified by the Secretary, to—

12 “(A) establish dosing recommendations for
13 such drug or biological product for women who
14 are pregnant or lactating; and

15 “(B) investigate the safe use of such drug
16 or biological product for pregnant women and
17 fetuses through the use of pregnancy registries
18 and pharmacoepidemiological databases.

19 “(3) PREGNANCY REGISTRIES AND
20 PHARMACOEPIDEMOLOGICAL DATABASES.—

21 “(A) REGISTRIES.—The Secretary shall
22 issue guidances on the use and evaluation of
23 data from pregnancy registries, including data
24 from centralized registries for drugs and bio-
25 logical products.

1 “(B) DATABASES.—

2 “(i) ESTABLISHMENT.—The Secretary
3 shall establish or award grants, enter into
4 contracts and cooperative agreements, and
5 use other appropriate mechanisms to pro-
6 vide for pharmacoepidemiological databases
7 (including a teratogen surveillance system)
8 to study safety issues related to drugs and
9 biological products, including safety issues
10 for pregnant women and fetuses.

11 “(ii) STUDY AND USE OF DATA.—The
12 Secretary shall hold workshops and issue
13 guidances on how to study and use the
14 data from the pharmacoepidemiological
15 databases established or provided for under
16 clause (i).

17 “(4) CLARIFICATION REGARDING MARKET EX-
18 CLUSIVITY INTERACTIONS.—A clinical investigation
19 involved in any study conducted under this sub-
20 section shall not be considered to be a new clinical
21 investigation for purposes of clauses (iii) and (iv) of
22 section 505(j)(5(D).

23 “(b) IMPROVING COMMUNICATION OF INFORMATION
24 TO PREGNANT AND LACTATING WOMEN AND THEIR

1 HEALTH CARE PROVIDERS THROUGH DRUG LABEL-
2 ING.—

3 “(1) REGULATIONS.—

4 “(A) PROPOSED REGULATION.—Not later
5 than 6 months after the date of enactment of
6 this section, the Secretary shall promulgate a
7 proposed regulation requiring enhanced commu-
8 nication of safety and dosage information for
9 women who are pregnant or lactating in the la-
10 beling of drugs, including drugs licensed under
11 section 351 of the Public Health Service Act
12 (42 U.S.C. 262).

13 “(B) FINAL RULE.—Not later than 2
14 years after the date of enactment of this sec-
15 tion, the Secretary shall promulgate a final reg-
16 ulation requiring enhanced communication of
17 safety and dosage information for women who
18 are pregnant or lactating in the labeling of
19 drugs, including drugs licensed under section
20 351 of the Public Health Service Act (42
21 U.S.C. 262).

22 “(2) BIENNIAL REVIEW OF CERTAIN DRUGS.—
23 Not later than 32 months after the date of enact-
24 ment of this section, and biennially thereafter, each
25 person who holds an approved application for a drug

1 under section 505(b) that was not approved based
2 on studies of pregnant women or who holds an ap-
3 proved biologics license application for a drug under
4 section 351 of the Public Health Service Act (42
5 U.S.C. 262) that was not licensed based on studies
6 of pregnant women, shall—

7 “(A) review any newly available data or in-
8 formation for such drug, including data or in-
9 formation from the studies completed under
10 subsection (a), to determine whether such data
11 or information, and all other relevant data and
12 information, warrants a labeling change for
13 women who are pregnant or lactating; and

14 “(B) submit to the Secretary—

15 “(i) a supplement to the holders’ new
16 drug application or biologics license appli-
17 cation that includes—

18 “(I) a summary of the data or
19 information reviewed under subpara-
20 graph (A);

21 “(II) an analysis of why such
22 data or information warrants a label-
23 ing change for women who are preg-
24 nant or lactating;

1 “(III) a proposal for the labeling
2 change; and

3 “(IV) a certification that the re-
4 view, summary, and analysis is com-
5 plete and accurate; or

6 “(ii) a letter that includes—

7 “(I) a summary of the data or
8 information, if any, reviewed under
9 subparagraph (A);

10 “(II) an analysis of why such
11 data or information does not warrant
12 a labeling change for women who are
13 pregnant or lactating; and

14 “(III) a certification that the re-
15 view, summary, and analysis is com-
16 plete and accurate.

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

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

22 “(B) the analysis of why such data or in-
23 formation does or does not warrant a labeling
24 change required to be submitted to the Sec-

1 retary in a supplement or in a letter under
2 paragraph (2)(B).

3 “(4) PERIODIC REVIEW OF DRUGS.—

4 “(A) PRIORITY.—Not later than 2 years
5 after the date of enactment of this section, the
6 Secretary shall prioritize marketed drugs that
7 were not approved or licensed based on studies
8 in pregnant women, considering—

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

11 “(ii) whether new information avail-
12 able about such drugs may warrant a la-
13 beling change for such women; and

14 “(iii) which of such drugs have label-
15 ing for such women that is most in need
16 of revision.

17 “(B) REGULATIONS AND ORDERS.—

18 “(i) INITIAL REGULATIONS AND OR-
19 DERS.—Based on the prioritization of
20 drugs under subparagraph (A), the Sec-
21 retary shall, as resources allow—

22 “(I) promulgate regulations for
23 such drugs that meet the conditions
24 contained in any applicable mono-
25 graph to revise safety and dosage in-

1 formation required in labeling for
2 women who are pregnant or lactating;
3 and

4 “(II) issue orders for other such
5 drugs to require revised safety and
6 dosage information required in label-
7 ing for women who are pregnant or
8 lactating.

9 “(ii) SUBSEQUENT REGULATIONS AND
10 ORDERS.—The Secretary shall periodically
11 review new data or information as it be-
12 comes available on the drugs described in
13 subparagraph (A), and shall promulgate
14 regulations or issue orders, as appropriate,
15 to revise safety and dosage information re-
16 quired in labeling for such drugs for
17 women who are pregnant or lactating.

18 “(c) IMPROVING COMMUNICATION AND INFORMATION
19 ABOUT FETAL RISK FROM DEVICES.—

20 “(1) RESEARCH ON MATERIALS USED IN DE-
21 VICES.—

22 “(A) IDENTIFYING MATERIALS TO BE
23 STUDIED.—The Secretary, acting through the
24 Director of the National Institutes of Health

1 and in consultation with the Commissioner of
2 Food and Drugs, shall—

3 “(i) periodically review all available
4 data and information about the safety for
5 persons and fetuses of materials used in
6 devices that may come into contact with,
7 or be absorbed into, the body;

8 “(ii) identify materials for which addi-
9 tional data or information is needed to as-
10 sess the safety for persons and fetuses of
11 such materials; and

12 “(iii) design protocols for studies to
13 collect data or information described in
14 clause (ii).

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

22 “(C) SAFETY STUDIES.—The Secretary
23 may require a person that manufactures a de-
24 vice that bears or contains a material for which
25 the Secretary has designed studies under sub-

1 paragraph (A), to complete and submit such
2 studies to the Secretary, by a date specified by
3 the Secretary.

4 “(2) REVIEW OF DEVICE MATERIAL AND LA-
5 BELING.—Considering all available data and infor-
6 mation about the safety for persons and fetuses of
7 a material that may come into contact with, or be
8 absorbed into, the body when used in a device, in-
9 cluding data and information from studies conducted
10 under paragraph (1), the Secretary shall—

11 “(A) require appropriate statements dis-
12 closing any risks to persons or fetuses from the
13 material in the labeling of a device that bears
14 or contains such material; or

15 “(B) if use of the material in a device pre-
16 sents an unreasonable and substantial risk of
17 illness or injury to persons or fetuses, ban the
18 use of such material in such device.

19 “(d) LIMITATIONS ON INJUNCTIVE RELIEF TO EN-
20 SURE PROMPT REVISION OF DRUG AND DEVICE LABEL-
21 ING.—In an action under section 302 with respect to a
22 drug or a device deemed to be misbranded under section
23 502(k) or section 502(l), such misbranding shall not be
24 the sole basis for any judicial order that requires a person

1 to cease the manufacturing, distribution, or sale of such
2 drug or device.

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

6 “(1) women who are pregnant or lactating to
7 inform such women about the safety issues involved
8 in taking prescription and over-the-counter drugs,
9 and using medical devices, while such women are
10 pregnant or breast feeding; and

11 “(2) health care providers and the public to
12 provide information about the safety issues involved
13 when women, who are pregnant or breast feeding,
14 take prescription and over-the-counter drugs or use
15 medical devices.

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this section,
18 such sums as are necessary.”.

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

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

5 “(k)(1) If it is a drug; and—

6 “(2)(A) a study required under section 564(a)(2)
7 with respect to such drug is not completed and submitted
8 to the Secretary by the date specified by the Secretary;

9 “(B) a supplement or letter required to be submitted
10 to the Secretary under section 564(b)(2)(B) with respect
11 to such drug is not submitted to the Secretary;

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

16 “(D) its labeling does not include safety or dosage
17 information for pregnant or lactating women required by
18 the Secretary by regulation or order under section
19 564(b)(4)(B).

20 “(l) If it is a device and its labeling does not include
21 statements required by the Secretary under section
22 564(c)(2)(A).”.

23 (d) AMENDMENT TO CIVIL PENALTIES.—Section
24 307(a) of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 335b(a)) is amended—

1 (1) in paragraph (6)(B), by striking “or”; and

2 (2) by inserting after paragraph (7) the fol-
3 lowing:

4 “(8) has failed to complete and submit to the
5 Secretary, by the date specified by the Secretary, a
6 study required by the Secretary under section
7 564(a)(2);

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

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

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

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

23 “(13) has distributed in interstate commerce a
24 device whose labeling does not include statements re-

1 quired by the Secretary under section 564(c)(2)(A);

2 or

3 “(14) has distributed in interstate commerce a

4 device that bears or contains a material whose use

5 in such device has been banned under section

6 564(c)(2)(B).”.

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