107TH CONGRESS
2D 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, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safe Motherhood Act for Research and Treatment'' or the ''SMART Mom Act''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

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

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

(3) In the United States about 1,000 women will die each year from pregnancy-related illnesses or conditions. Two to 3 lives are lost each day due to pregnancy-related mortality.

(4) Racial and ethnic minority women suffer a significantly higher risk of pregnancy-related mortality than non-Hispanic white women. African American women are almost 4 times more likely to die from pregnancy-related illnesses or conditions

than white women. Hispanic, Asian immigrant, and American Indian women are twice as likely to die from pregnancy-related illnesses or conditions as their non-Hispanic counterparts.

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

(6) There has been no decline in pregnancy-related deaths in the United States over the last 20 years. In 1987 the United States set goals as part of Healthy People 2000: National Health Promotion and Disease Prevention Objectives, to reduce maternal deaths from 7.5 deaths per 100,000 to 3.3 per 100,000 for live births and no more than 5.0 maternal deaths per 100,000 births among African American women. Again in 2000, as part of Healthy People 2010, new goals have been set. These goals have not been met.

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

premature labor, and the need for a surgical (caesarean) delivery.

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

(9) African American, Hispanic, and older women, have a significantly increased risk of complications.

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

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

(12) Most drugs women take during pregnancy are necessary to maintain health. However, 80 percent of approved drugs lack adequate scientific evidence about their use in pregnancy. Only 1 percent

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

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

(14) Pregnancy is a critical time in a women's life with far ranging implications for her short- and long-term health and for the health of her family. The United States must devote the resources and have the will of the nation to ensure a safe pregnancy and good health throughout the lives of American women.

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

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

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

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

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

(5) reduce pre-term labor;

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

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

(8) expand knowledge about the safety and dosing of drugs and devices used to treat pregnant women with chronic conditions and women who become sick during pregnancy;

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

(10) develop improved and more accurate data collection relating to maternal morbidity and mortality.

TITLE I—AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT

Subtitle A—Reducing Maternal Morbidity and Mortality Through Coordinated Federal Action

SEC. 101. INTERAGENCY COORDINATING COMMITTEE ON SAFE MOTHERHOOD.

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

"SEC. 399O. INTERAGENCY COORDINATING COMMITTEE ON SAFE MOTHERHOOD.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Office of Women's Health, shall establish a committee to be known as the 'Interagency Coordinating Committee on Safe Motherhood' (referred to in this section as the 'Coordinating Committee').

''(b) COMPOSITION.—The Coordinating Committee shall be composed of—

''(1) the Director of the Centers for Disease Control and Prevention (and the heads of such institutes, centers and offices as the Director determines appropriate);

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

''(3) the Director of the Health Resources and Services Administration (and the heads of such institutes, centers and offices as the Director determines appropriate);

''(4) the Commissioner of Food and Drugs (and the heads of such institutes, centers and offices as the Commissioner determines appropriate);

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

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

''(6) the Secretary of Labor (and the heads of such institutes, centers and offices as the Secretary determines appropriate);

''(7) representatives of other Federal Government agencies that serve women; and

''(8) representatives of women's health care advocacy and grassroots organizations, health care providers including providers of specialty care, and researchers to be appointed by the Director of the Office.

''(c) ADMINISTRATIVE SUPPORT.—The Secretary shall make available to the Coordinating Committee necessary and appropriate administrative support.

''(d) DUTIES.—

''(1) EVALUATION.—The Coordinating Committee shall assess health promotion campaigns that are administered by the Federal Government (including smoking cessation programs, alcohol and substance abuse treatment programs, and domestic violence prevention programs), evaluate the effect that such campaigns have on health during pregnancy if pregnancy was a focus, and assess whether

such programs may be adapted to emphasize the importance of maternal health.

"(2) FEDERAL RESEARCH PLAN.—

"(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Coordinating Committee shall develop a coordinated Federal research and strategic action plan for safe motherhood.

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

"(i) recommendations for research on pregnancy-related conditions;

"(ii) recommendations for research on the impact of chronic conditions, physical

impairments, or mental health conditions on pregnant women;

''(iii) recommendations for research on medical complications that occur during delivery;

''(iv) recommendations for research on post-partum conditions (such as depression, hemorrhage, and fever);

''(v) recommendations for research on racial, ethnic, social, behavioral, and economic factors effecting pregnancy;

''(vi) recommendations for research to improve outreach efforts, education programs, and prevention and health promotion strategies for pregnant women; and

''(vii) a recommended plan and research agenda to improve knowledge about the safety of drugs, devices, cosmetics, and food with respect to pregnancy.

''(C) REPORT.—Not later than 18 months after the date of enactment of this section, the Coordinating Committee shall prepare and submit to the Secretary and the appropriate committees of Congress, a report concerning the plan developed under this paragraph and the

results of the evaluation conducted under paragraph (1).

''(3) KEY INDICATORS OF WELL BEING.—

''(A) IN GENERAL.—The Coordinating Committee, in consultation with the Centers for Disease Control and Prevention, the Director of the National Institute of Child Health and Human Development, the Director of the Agency for Healthcare Research and Quality, and the heads of other relevant Federal agencies, shall determine the key indicators of maternal health and the sources of data to be included in the report under subparagraph (B), and shall update such indicators as new data becomes available.

''(B) REPORT.—Not later than October 1, 2003, and biannually thereafter, the Coordinating Committee shall prepare and submit to the appropriate committees of Congress, a report, to be known as 'America's Mothers: Key National Indicators of Well Being' (referred to in this section as the 'Report'), that contains the indicators of maternal health described in subparagraph (A).

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

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

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

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

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

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

(a) PURPOSE.—It is the purpose of this section to require the Director of the National Institutes of Health, acting through the Director of the National Institute of Child Health and Human Development and in collaboration with the Directors of other appropriate Institutes and Offices, to expand and intensify research activities with respect to conditions that lead to pregnancy-related illnesses, injury and death before, during, and after pregnancy and to expand research to improve understanding and treatment of pregnant women who have chronic disease, physical impairment, or mental health conditions.

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

"SEC. 452H. SAFE MOTHERHOOD REPORT.

''The Director of the Institute shall annually report to Congress and the public on the extent of the total funds obligated to conduct or support research on safe motherhood across the National Institutes of Health, including

the specific support and research awards allocated through the such Institutes.''.

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

''SEC. 452I. EXPANDED RESEARCH ON PREGNANCY.

''(a) CONDITIONS AND COMPLICATIONS OF PREGNANCY.—In order to improve the understanding of conditions and complications related to pregnancy, to lead to better treatments and care for women throughout their pregnancy, and to prevent pregnancy-related illnesses, injury and death whenever possible, the Director of NIH, acting through the Director of the Institute, shall enhance and expand research into the leading causes of pregnancy-related death and complications of pregnancy.

''(b) REDUCING PRE-TERM LABOR AND DELIVERY.—In order to reduce the rates of pre-term labor and delivery, the Director of NIH shall expand and intensify research on pre-term labor and delivery.

''(c) POST-PARTUM HEALTH CONDITIONS.—The Director of NIH shall expand and enhance research concerning the post-partum health conditions and illness that affect women.

''(d) REDUCTIONS IN RACIAL AND ETHNIC DISPARITIES.—The Director of NIH shall provide for the conduct of research to investigate the mechanisms contributing to the disparities in maternal and perinatal outcomes of racial and ethnic populations and immigrant groups.

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

(d) IMPROVING THE UNDERSTANDING AND TREATMENT OF CHRONIC CONDITIONS OF WOMEN DURING PREGNANCY.—Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 494A, the following:

''SEC. 494B. IMPROVING THE UNDERSTANDING AND TREATMENT OF CHRONIC CONDITIONS OF WOMEN DURING PREGNANCY.

''(a) IN GENERAL.—The Director of NIH shall expand research concerning the impact of chronic conditions, physical impairments, and mental health problems on the health of women during their pregnancy.

''(b) COLLABORATION.—In carrying out subsection (a), the Director of the Institute shall act in collaboration with the Directors of other appropriate Institutes and Offices of the National Institutes of Health.''.

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

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

''SEC. 452J. MATERNAL FETAL MEDICINE UNITS NETWORK.

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

''(b) EXPANSION OF NETWORK.—The Director of the Institute shall, through grants, contracts, or cooperative agreements, expand the Maternal Fetal Medicine Units Network established or utilized under subsection (a) to assist in the implementation of sections 452I and 494B.

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

SEC. 112. EXPAND AND INTENSIFY RESEARCH ACTIVITIES AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

(1) by redesignating subsection (d) as subsection (f); and

(2) by inserting after subsection (c), the following:

''(d) REDUCTION IN POOR PREGNANCY OUTCOMES OF ETHNIC AND MINORITY WOMEN.—

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

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

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

''(e) PREVENTION RESEARCH CENTERS.—The Director of the Centers for Disease Control and Prevention, acting through the National Center for Chronic Disease Prevention and Health Promotion, shall award grants to universities and other non-profit research institutions and centers to enable such entities to conduct research concerning improving maternal outcomes and eliminating racial disparities in maternal morbidity and mortality, with special emphasis provided to research concerning the role of stress, violence, discrimination, access, nutrition, obesity and literacy.''.

SEC. 113. IMPROVE QUALITY HEALTH CARE FOR PREGNANT WOMEN THROUGH AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

Section 913 of the Public Health Service Act (42 U.S.C. 299b–2) is amended by adding at the end the following:

''(c) MATERNAL HEALTH CARE.—

''(1) IN GENERAL.—The Director shall provide for the conduct of research concerning the quality of maternal health care from a patient-centered perspective, including—

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

''(B) an examination of all types of care and interventions, both medical and non-medical, as well as barriers women face in gaining access to recommended treatments; and

''(C) recommendations for the minimum care needed to be considered as having received quality care.

''(2) REPORT.—The results of the research conducted under paragraph (1) shall be provided by the Director to Congress as part of the annual report submitted under subsection (b)(2).''.

Subtitle C—Data Collection and Surveillance

SEC. 121. EXPAND AND INTENSIFY DATA COLLECTION ACTIVITIES AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION.

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

"SEC. 317K–1. DATA COLLECTION REGARDING SAFE MOTHERHOOD.

"(a) STANDARD DEFINITIONS FOR PREGNANCY-RELATED MORTALITY AND MORBIDITY.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in cooperation with State officials, professional medical experts, medical organizations, and health care advocacy groups, shall develop a standard definition of 'maternal mortality' and 'maternal morbidity'.

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

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a program to award grants to States, counties, and cities for the development of surveillance systems, that use the standard definitions established under subsection (a), to gather data on maternal mortality and maternal morbidity.

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

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

and containing such information as the Secretary may require;

"(B) provide an assurance that the applicant will work with the Centers for Disease Control and Prevention to adopt standard procedures for the identification, collection, and analysis of the data that is to be collected under the grant; and

"(C) provide an assurance that the applicant will contribute $1 (in cash or in kind) to activities under the grant for every $4 provided by the Federal Government.

"(3) TECHNICAL ASSISTANCE.—The Centers for Disease Control and Prevention shall provide technical assistance to grantees under this subsection.

"(4) INCORPORATION OF DATA INTO REPORT.—Where determined appropriate by the Secretary, data collected by the surveillance systems established under this subsection shall be incorporated into the report submitted under section 399O(d)(3)(B).

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

garding the incidence and prevalence of symptoms and risk factors for pre-term births.

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

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

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

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

(2) by inserting after subsection (c), the following:

''(d) STUDY ON EFFECTS OF PREGNANCY ON WOMEN.—As part of the study conducted under this section, the Director of the National Institute of Child Health and Human Development, in collaboration with the Director of the Centers for Disease Control and Prevention, the Commission on Food and Drugs, and other appropriate Federal officials, shall plan, develop, and implement a prospective cohort study of mothers to determine the effects of pregnancy on the health of women. Such study shall evaluate—

''(1) the effects of pregnancy on women's health;

''(2) the effects of both preexisting and chronic conditions, physical impairments, and mental health problems related to pregnancy;

''(3) the impact of stress and anxiety; and

''(4) environmental health factors that influence both the mother's health and that of her child.''.

Subtitle D—Public Education and Outreach

SEC. 131. PURPOSE.

It is the purpose of this subtitle to address the need for providing women with accurate and up-to-date information through a 21st century public education and outreach Campaign for Safe Motherhood that shall raise the public awareness of the issues related to safe motherhood, including—

(1) preventing pregnancy-related illnesses, injury, and death; and

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

SEC. 132. SAFE MOTHERHOOD CAMPAIGN.

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

"SEC. 399P. SAFE MOTHERHOOD CAMPAIGN.

''(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Office of Women's Health and the Interagency Coordinating Committee on Safe Motherhood (referred to in this section as the 'Coordinating Committee') established under section 399O, shall develop and implement a national public education and health promotion campaign to be known as the Safe Motherhood Campaign (referred to in this section as the 'Campaign').

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

''(1) WEBSITE.—An Internet website to be established in accordance with subsection (c).

''(2) COMMUNITY PARTNERSHIPS.—The provision of support for community-based programs to provide outreach, education, information and health promotion services and information to give women the tools they need to achieve a safe and healthy pregnancy.

''(3) STATE AND LOCAL PARTNERSHIPS.—The facilitation of consultations with State and local public health officials to gain access to the broadest number of women in an effort to provide outreach and education assistance and information to help women succeed in having a safe and healthy pregnancy.

''(4) SPECIAL POPULATIONS.—The implementation of procedures to ensure that activities under the Campaign are accessible to low-literate, non-English speaking, and nonnative immigrant communities where determined appropriate by the Secretary.

''(c) INTERNET WEBSITE.—

''(1) ESTABLISHMENT.—The Secretary, acting through the Office of Women's Health and the Coordinating Committee, shall develop and maintain a single Internet website to provide pregnant women, and research and health practitioners with the most up-to-date and accurate information on pregnancy, in a manner designed to carry out the purpose described in paragraph (2).

''(2) PURPOSE.—It is the purpose of the website established under paragraph (1) to consolidate information, research, and data related to pregnancy (prenatal, intrapartum, and postpartum) together in one place and to provide links for women to other critical websites (Federal agencies, community health programs, State and tribal health programs, and self-help professional and advocacy organizations).

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

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

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

''(A) educational materials for how to succeed in having the safest pregnancy possible, including a description of chronic conditions, pregnancy-related illnesses, and other health problems that could pose risks to the mother or fetus;

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

''(C) information concerning standards for clinical care throughout pregnancy;

''(D) information on trends in labor intervention, such as induction, epidural, and caesarean sections, and alternative approaches;

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

''(F) information concerning infertility and maternal health; and

''(G) information concerning pregnancy-related workplace laws and policies, such as the Family and Medical Leave Act of 1993.

''(5) APPROPRIATE FORM OF INFORMATION.—The information contained on the website established under paragraph (1) shall be maintained in a culturally sensitive and appropriate form.

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

TITLE II—PREGNANT AND LACTATING WOMEN

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

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

''SEC. 564. SAFE DRUGS AND DEVICES FOR PREGNANT AND LACTATING WOMEN.

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

''(1) MARKETED DRUGS FOR WHICH ADDITIONAL INFORMATION IS NEEDED.—

''(A) IDENTIFYING DRUGS TO BE STUDIED.—The Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in maternal and fetal health, shall—

''(i) identify marketed drugs and biological products that were not approved or licensed based on studies in pregnant women for which studies are needed—

''(I) to establish appropriate dosing for women who are pregnant or lactating; and

''(II) to investigate the marketed drugs and biological products' safe use for pregnant women and fetuses through the use of pregnancy registries and pharmacoepidemiological databases; and

''(ii) design protocols for the needed studies described in clause (i).

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

ly completing the studies designed under subparagraph (A), as the National Institutes of Health's resources allow.

''(2) POSTMARKETING STUDIES.—As a condition of approval of an application submitted under section 505(b)(1) or of a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262), the Secretary may require that the holder of the application conduct postmarketing studies, to be completed and submitted to the Secretary by a date specified by the Secretary, to—

''(A) establish dosing recommendations for such drug or biological product for women who are pregnant or lactating; and

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

''(3) PREGNANCY REGISTRIES AND PHARMACOEPIDEMIOLOGICAL DATABASES.—

''(A) REGISTRIES.—The Secretary shall issue guidances on the use and evaluation of data from pregnancy registries, including data from centralized registries for drugs and biological products.

''(B) DATABASES.—

''(i) ESTABLISHMENT.—The Secretary shall establish or award grants, enter into contracts and cooperative agreements, and use other appropriate mechanisms to provide for pharmacoepidemiological databases (including a teratogen surveillance system) to study safety issues related to drugs and biological products, including safety issues for pregnant women and fetuses.

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

''(4) CLARIFICATION REGARDING MARKET EXCLUSIVITY INTERACTIONS.—A clinical investigation involved in any study conducted under this subsection shall not be considered to be a new clinical investigation for purposes of clauses (iii) and (iv) of section 505(j)(5(D).

''(b) IMPROVING COMMUNICATION OF INFORMATION TO PREGNANT AND LACTATING WOMEN AND THEIR

HEALTH CARE PROVIDERS THROUGH DRUG LABELING.—

"(1) REGULATIONS.—

"(A) PROPOSED REGULATION.—Not later than 6 months after the date of enactment of this section, the Secretary shall promulgate a proposed regulation requiring enhanced communication of safety and dosage information for women who are pregnant or lactating in the labeling of drugs, including drugs licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(B) FINAL RULE.—Not later than 2 years after the date of enactment of this section, the Secretary shall promulgate a final regulation requiring enhanced communication of safety and dosage information for women who are pregnant or lactating in the labeling of drugs, including drugs licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

"(2) BIENNIAL REVIEW OF CERTAIN DRUGS.—Not later than 32 months after the date of enactment of this section, and biennially thereafter, each person who holds an approved application for a drug

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

''(A) review any newly available data or information for such drug, including data or information from the studies completed under subsection (a), to determine whether such data or information, and all other relevant data and information, warrants a labeling change for women who are pregnant or lactating; and

''(B) submit to the Secretary—

''(i) a supplement to the holders' new drug application or biologics license application that includes—

''(I) a summary of the data or information reviewed under subparagraph (A);

''(II) an analysis of why such data or information warrants a labeling change for women who are pregnant or lactating;

"(III) a proposal for the labeling change; and

"(IV) a certification that the review, summary, and analysis is complete and accurate; or

"(ii) a letter that includes—

"(I) a summary of the data or information, if any, reviewed under subparagraph (A);

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

"(III) a certification that the review, summary, and analysis is complete and accurate.

"(3) BIENNIAL SUBMISSIONS.—In the regulations promulgated under paragraph (1), the Secretary shall prescribe requirements for—

"(A) the summary of data or information reviewed under paragraph (2)(A); and

"(B) the analysis of why such data or information does or does not warrant a labeling change required to be submitted to the Sec-

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

''(4) PERIODIC REVIEW OF DRUGS.—

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

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

''(ii) whether new information available about such drugs may warrant a labeling change for such women; and

''(iii) which of such drugs have labeling for such women that is most in need of revision.

''(B) REGULATIONS AND ORDERS.—

''(i) INITIAL REGULATIONS AND ORDERS.—Based on the prioritization of drugs under subparagraph (A), the Secretary shall, as resources allow—

''(I) promulgate regulations for such drugs that meet the conditions contained in any applicable monograph to revise safety and dosage in-

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

"(II) issue orders for other such drugs to require revised safety and dosage information required in labeling for women who are pregnant or lactating.

"(ii) SUBSEQUENT REGULATIONS AND ORDERS.—The Secretary shall periodically review new data or information as it becomes available on the drugs described in subparagraph (A), and shall promulgate regulations or issue orders, as appropriate, to revise safety and dosage information required in labeling for such drugs for women who are pregnant or lactating.

"(c) IMPROVING COMMUNICATION AND INFORMATION ABOUT FETAL RISK FROM DEVICES.—

"(1) RESEARCH ON MATERIALS USED IN DEVICES.—

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

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

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

"(ii) identify materials for which additional data or information is needed to assess the safety for persons and fetuses of such materials; and

"(iii) design protocols for studies to collect data or information described in clause (ii).

"(B) STUDYING DEVICE MATERIALS.—The Director of the National Institutes of Health shall award grants, enter into contracts, or use other appropriate mechanisms to aid in promptly completing the studies designed under subparagraph (A), as the National Institutes of Health's resources allow.

"(C) SAFETY STUDIES.—The Secretary may require a person that manufactures a device that bears or contains a material for which the Secretary has designed studies under sub-

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

''(2) REVIEW OF DEVICE MATERIAL AND LABELING.—Considering all available data and information about the safety for persons and fetuses of a material that may come into contact with, or be absorbed into, the body when used in a device, including data and information from studies conducted under paragraph (1), the Secretary shall—

''(A) require appropriate statements disclosing any risks to persons or fetuses from the material in the labeling of a device that bears or contains such material; or

''(B) if use of the material in a device presents an unreasonable and substantial risk of illness or injury to persons or fetuses, ban the use of such material in such device.

''(d) LIMITATIONS ON INJUNCTIVE RELIEF TO ENSURE PROMPT REVISION OF DRUG AND DEVICE LABELING.—In an action under section 302 with respect to a drug or a device deemed to be misbranded under section 502(k) or section 502(l), such misbranding shall not be the sole basis for any judicial order that requires a person

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

''(e) OUTREACH AND EDUCATION.—The Secretary shall expand the Women's Health: Take Time to Care program or establish a new program that is directed at—

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

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

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as are necessary.''.

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

(c) AMENDMENT TO MISBRANDED DRUGS AND DEVICES.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by inserting after subsection (j) the following:

''(k)(1) If it is a drug; and—

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

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

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

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

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

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

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

(2) by inserting after paragraph (7) the following:

''(8) has failed to complete and submit to the Secretary, by the date specified by the Secretary, a study required by the Secretary under section 564(a)(2);

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

''(10) has failed to include an adequate summary or analysis of relevant information or data in a supplement or letter required to be submitted to the Secretary under section 564(b)(2)(B);

''(11) has distributed in interstate commerce a drug whose labeling does not include safety or dosage information for pregnant or lactating women required by the Secretary by regulation or order under section 564(b)(4)(B);

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

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

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

''(14) has distributed in interstate commerce a device that bears or contains a material whose use in such device has been banned under section 564(c)(2)(B).''.

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