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114TH CONGRESS
2D SESSION

H. R. 5219

To provide for the establishment of the Task Force on Research Specific to Pregnant Women and Lactating Women, to require an annual report to Congress on approved new drug applications with information on pregnancy and lactation, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 12, 2016

Ms. HERRERA BEUTLER (for herself and Ms. CASTOR of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide for the establishment of the Task Force on Research Specific to Pregnant Women and Lactating Women, to require an annual report to Congress on approved new drug applications with information on pregnancy and lactation, and for other purposes.

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 Medications for Moms and Babies Act of 2016''.

SEC. 2. TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.

(a) TASK FORCE.—

(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall establish a task force, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the Task Force on Research Specific to Pregnant Women and Lactating Women (in this section referred to as the ''Task Force'').

(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

(3) MEMBERSHIP.—

(A) FEDERAL MEMBERS.—The Federal members of the Task Force shall be composed of the following members (or their designees):

(i) The Director of the Centers for Disease Control and Prevention.

(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other national research institutes as the Secretary determines appropriate.

(iii) The Commissioner of Food and Drugs.

(iv) The Director of the Office on Women's Health.

(v) The Director of the National Vaccine Program Office.

(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

(B) NON-FEDERAL MEMBERS.—The non-Federal members of the Task Force shall be composed of the following members:

(i) Representatives from relevant medical societies with subject matter expertise

on pregnant women, lactating women, or children.

(ii) Nonprofit organizations with expertise related to the health of women and children.

(iii) Relevant industry representatives.

(iv) Representatives of patient or consumer advocacy organizations.

(v) Other representatives, as appropriate.

(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

(ii) be appointed by the Secretary.

(4) TERMINATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year pe-

riod described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), and not later than 36 and 48 months after such date if the Secretary extends the operation of the Task Force pursuant to paragraph (4)(B), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report on gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women. Each such report shall, at a minimum, include each of the following:

(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lac-

tating women, including the development of such therapies.

(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

(D) Identification of Federal activities, including—

(i) the state of research involving pregnant and lactating women;

(ii) recommendations for the coordination of, and collaboration on, research related to pregnant women and lactating women;

(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts of therapies on pregnant women and lactating women

and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

(b) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, and not later than 3 and 4 years after such date if the Secretary extends the operation of the Task Force pursuant to subsection (a)(4)(B), the Secretary, taking into consideration any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, re-

garding the inclusion of pregnant women and lactating women in clinical research.

(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding from participating in human subject research pregnant women or lactating women as a study population requiring additional protections.

SEC. 3. ANNUAL REPORT FROM FDA ON APPROVED NEW DRUG APPLICATIONS WITH INFORMATION ON PREGNANCY AND LACTATION.

Not later than 1 year after the date of enactment of this Act, and not less than annually for the succeeding 9 years, the Commissioner of Food and Drugs shall submit to the appropriate committees of the Congress a report on—

(1) the number of new drug applications and supplements to such applications approved or licensed by the Food and Drug Administration under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Services Act (42 U.S.C. 262(a)) based on research

that included pregnant women or lactating women in trials;

(2) the number of new drug applications and supplements to such applications so approved or licensed that included data on the excretion of the drug in breast milk;

(3) the number of new drug applications and supplements to such applications so approved or licensed with required postmarket studies in pregnant or breastfeeding women; and

(4) the number of drugs with respect to which a labeling change is made to include new information regarding use in pregnant or breastfeeding women.

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