

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

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.

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 Medications for
5 Moms and Babies Act of 2016”.

1 **SEC. 2. TASK FORCE ON RESEARCH SPECIFIC TO PREG-**
2 **NANT WOMEN AND LACTATING WOMEN.**

3 (a) TASK FORCE.—

4 (1) ESTABLISHMENT.—Not later than 90 days
5 after the date of enactment of this Act, the Sec-
6 retary of Health and Human Services (in this sec-
7 tion referred to as the “Secretary”) shall establish
8 a task force, in accordance with the Federal Advi-
9 sory Committee Act (5 U.S.C. App.), to be known
10 as the Task Force on Research Specific to Pregnant
11 Women and Lactating Women (in this section re-
12 ferred to as the “Task Force”).

13 (2) DUTIES.—The Task Force shall provide ad-
14 vice and guidance to the Secretary regarding Fed-
15 eral activities related to identifying and addressing
16 gaps in knowledge and research regarding safe and
17 effective therapies for pregnant women and lactating
18 women, including the development of such therapies
19 and the collaboration on and coordination of such
20 activities.

21 (3) MEMBERSHIP.—

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

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

1 (ii) The Director of the National In-
2 stitutes of Health, the Director of the Eu-
3 nice Kennedy Shriver National Institute of
4 Child Health and Human Development,
5 and the directors of such other national re-
6 search institutes as the Secretary deter-
7 mines appropriate.

8 (iii) The Commissioner of Food and
9 Drugs.

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

12 (v) The Director of the National Vac-
13 cine Program Office.

14 (vi) The head of any other research-
15 related agency or department not described
16 in clauses (i) through (v) that the Sec-
17 retary determines appropriate, which may
18 include the Department of Veterans Af-
19 fairs and the Department of Defense.

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

23 (i) Representatives from relevant med-
24 ical 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-

1 riod described in subparagraph (A), if the Sec-
2 retary determines that the extension is appro-
3 priate for carrying out the purpose of this sec-
4 tion.

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

9 (6) TASK FORCE REPORT TO CONGRESS.—Not
10 later than 18 months after the date on which the
11 Task Force is established under paragraph (1), and
12 not later than 36 and 48 months after such date if
13 the Secretary extends the operation of the Task
14 Force pursuant to paragraph (4)(B), the Task Force
15 shall prepare and submit to the Secretary, the Com-
16 mittee on Health, Education, Labor, and Pensions
17 of the Senate, and the Committee on Energy and
18 Commerce of the House of Representatives a report
19 on gaps in knowledge and research regarding safe
20 and effective therapies for pregnant women and lac-
21 tating women. Each such report shall, at a min-
22 imum, include each of the following:

23 (A) A plan to identify and address gaps in
24 knowledge and research regarding safe and ef-
25 fective 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

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

4 (E) Recommendations to improve the de-
5 velopment of safe and effective therapies for
6 pregnant women and lactating women.

7 (b) CONFIDENTIALITY.—Nothing in this section au-
8 thorizes the Secretary to disclose any information that is
9 a trade secret, or other privileged or confidential informa-
10 tion, described in section 552(b)(4) of title 5, United
11 States Code, or section 1905 of title 18, United States
12 Code.

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

15 (1) IN GENERAL.—Not later than 2 years after
16 the date of enactment of this Act, and not later than
17 3 and 4 years after such date if the Secretary ex-
18 tends the operation of the Task Force pursuant to
19 subsection (a)(4)(B), the Secretary, taking into con-
20 sideration any recommendations of the Task Force
21 available at such time and in consultation with the
22 heads of relevant agencies of the Department of
23 Health and Human Services, shall, as appropriate,
24 update regulations and guidance, as applicable, re-

1 garding the inclusion of pregnant women and lac-
2 tating women in clinical research.

3 (2) CRITERIA FOR EXCLUDING PREGNANT OR
4 LACTATING WOMEN.—In updating any regulations or
5 guidance described in paragraph (1), the Secretary
6 shall consider any appropriate criteria to be used by
7 institutional review boards and individuals reviewing
8 grant proposals for excluding from participating in
9 human subject research pregnant women or lac-
10 tating women as a study population requiring addi-
11 tional protections.

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

15 Not later than 1 year after the date of enactment
16 of this Act, and not less than annually for the succeeding
17 9 years, the Commissioner of Food and Drugs shall sub-
18 mit to the appropriate committees of the Congress a re-
19 port on—

20 (1) the number of new drug applications and
21 supplements to such applications approved or li-
22 censed by the Food and Drug Administration under
23 section 505(c) of the Federal Food, Drug, and Cos-
24 metic Act or section 351(a) of the Public Health
25 Services Act (42 U.S.C. 262(a)) based on research

1 that included pregnant women or lactating women in
2 trials;

3 (2) the number of new drug applications and
4 supplements to such applications so approved or li-
5 censed that included data on the excretion of the
6 drug in breast milk;

7 (3) the number of new drug applications and
8 supplements to such applications so approved or li-
9 censed with required postmarket studies in pregnant
10 or breastfeeding women; and

11 (4) the number of drugs with respect to which
12 a labeling change is made to include new informa-
13 tion regarding use in pregnant or breastfeeding
14 women.

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