

119TH CONGRESS
2D SESSION

H. R. 8651

To implement certain recommendations to promote the inclusion of pregnant and lactating women in clinical research, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 4, 2026

Ms. CASTOR of Florida (for herself, Mr. FITZPATRICK, and Ms. UNDERWOOD) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To implement certain recommendations to promote the inclusion of pregnant and lactating women in clinical research, 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 “Advancing Safe Medi-
5 cations for Moms and Babies Act of 2026”.

6 **SEC. 2. UPDATING FDA REGULATIONS TO INCLUDE PREG-**
7 **NANT WOMEN IN CLINICAL TRIALS.**

8 (a) PURPOSES.—The purposes of this section are—

1 (1) to facilitate compliance with applicable Fed-
2 eral regulations relating to the protection of preg-
3 nant women participating in research as subjects;
4 and

5 (2) to promote the inclusion of pregnant women
6 in clinical research.

7 (b) HARMONIZATION.—For the purposes specified in
8 subsection (a), the Secretary of Health and Human Serv-
9 ices (referred to in this Act as the “Secretary”), acting
10 through the Commissioner of Food and Drugs, shall, to
11 the extent practicable and consistent with other applicable
12 Federal statutory law, issue such regulations as may be
13 appropriate to harmonize the regulations of the Food and
14 Drug Administration relating to the protection of human
15 subjects, including parts 50 and 56 of title 21, Code of
16 Federal Regulations, with the regulations of the Depart-
17 ment of Health and Human Services relating to the inclu-
18 sion of pregnant women as subjects in clinical research.

19 (c) DEADLINE.—The Secretary of Health and
20 Human Services shall finalize the regulations required by
21 subsection (b) not later than 180 days after the date of
22 enactment of this Act.

1 **SEC. 3. RAISING AWARENESS OF RESEARCH THAT IN-**
2 **CLUDES PREGNANT AND LACTATING WOMEN.**

3 (a) IN GENERAL.—The Secretary of Health and
4 Human Services (referred to in this section as the “Sec-
5 retary”), in consultation with the heads of other relevant
6 Federal agencies, including the Director of the Centers for
7 Disease Control and Prevention and the Director of the
8 National Institutes of Health, shall establish and imple-
9 ment an education campaign designed to educate patients,
10 their families, health care providers, and other target audi-
11 ences on—

12 (1) how including pregnant and lactating
13 women in clinical research can benefit maternal and
14 infant health;

15 (2) available registries and clinical trials that
16 include pregnant and lactating women;

17 (3) the role registries and other postmarket
18 surveillance activities have in studying drugs used by
19 pregnant and lactating women; and

20 (4) how pregnant and lactating women can eas-
21 ily identify and enroll in clinical trials or registries.

22 (b) CONSULTATION.—In carrying out this section,
23 the Secretary shall consult with—

24 (1) organizations with expertise related to the
25 health of women and infants, including such organi-

1 zations representing populations with high rates of
2 maternal mortality and morbidity;

3 (2) representatives from relevant medical soci-
4 eties with subject matter expertise on pregnant
5 women, lactating women, or infants;

6 (3) relevant industry representatives; and

7 (4) other representatives, as appropriate.

8 (c) PLANNING.—In establishing the campaign under
9 subsection (a), the Secretary, in consultation with the
10 heads of other relevant Federal agencies, shall—

11 (1) conduct a needs assessment to—

12 (A) evaluate existing resources; and

13 (B) identify barriers to awareness and op-
14 portunities to fill gaps and address barriers;

15 (2) identify target audiences for the campaign;

16 (3) identify resource needs for each target audi-
17 ence and best practices to reach each such audience;
18 and

19 (4) test appropriate messaging strategies, in-
20 cluding risk communication messaging, for each tar-
21 get audience.

22 (d) DISSEMINATION.—The Secretary shall publish on
23 a public website, and regularly update, the campaign ma-
24 terials described in this section, and shall ensure that such
25 website—

1 (1) includes information on clinical trials and
2 registries enrolling pregnant and lactating women;
3 and

4 (2) provides a user-friendly interface for pa-
5 tients, their families, health care providers, and
6 other target audiences.

7 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
8 authorized to be appropriated to carry out this section
9 \$5,000,000 for each of fiscal years 2027 through 2031.

10 **SEC. 4. RESEARCH PRIORITIZATION PROCESS FOR PREG-**
11 **NANT AND LACTATING WOMEN AT THE EU-**
12 **NICE KENNEDY SHRIVER NATIONAL INSTI-**
13 **TUTE OF CHILD HEALTH AND HUMAN DEVEL-**
14 **OPMENT.**

15 (a) IN GENERAL.—The Director of the National In-
16 stitutes of Health, acting through the Director of the Eu-
17 nice Kennedy Shriver National Institute of Child Health
18 and Human Development (referred to in this section as
19 “NICHD”), shall carry out priority research projects on
20 existing and new drugs prescribed for pregnant and lac-
21 tating women.

22 (b) RESEARCH PRIORITIZATION PROCESS.—The Di-
23 rector of the National Institutes of Health shall establish
24 a research prioritization process to determine which pro-
25 posed research projects should receive priority funding

1 under this section. Such research prioritization process
2 shall take into account the following factors:

3 (1) The available evidence, including whether
4 there is an unmet medical need or gap in scientific
5 information relevant to treatment of pregnant and
6 lactating women with specific diseases or conditions.

7 (2) The feasibility of research, including the
8 prevalence of a disease or condition in pregnant and
9 lactating women and the availability of investigators
10 with expertise in studying such disease or condition.

11 (3) The potential impact of research, including
12 the severity of the disease or condition in pregnant
13 and lactating women, the current cost of treating
14 the disease or condition in pregnant and lactating
15 women, the frequency of use of the drug in pregnant
16 and lactating women, and the availability of alter-
17 native treatments for the disease or condition in
18 pregnant and lactating women.

19 (c) CONSULTATION.—In developing the research
20 prioritization process described in subsection (b), the Di-
21 rector of the National Institutes of Health shall seek feed-
22 back from—

23 (1) the existing research networks of the
24 NICHD with expertise in clinical research involving
25 pregnant and lactating women;

1 (2) relevant medical societies with subject mat-
2 ter expertise on pregnant women, lactating women,
3 or children; and

4 (3) organizations with expertise related to the
5 health of pregnant women, lactating women, or chil-
6 dren, including such organizations representing pop-
7 ulations with high rates of maternal mortality and
8 morbidity.

9 (d) RESEARCH REQUIREMENTS.—The Director of
10 the National Institutes of Health shall ensure that—

11 (1) research projects carried out under sub-
12 section (a) are conducted by individuals who have
13 the expertise to rigorously evaluate the best-available
14 scientific research; and

15 (2) the findings from such research projects are
16 based on a preponderance of the best-available, peer-
17 reviewed scientific evidence.

18 (e) PUBLIC COMMENT.—The Secretary shall provide
19 an opportunity for public comment on the program under
20 this section.

21 (f) ACCOUNTABILITY AND OVERSIGHT.—

22 (1) WORK PLAN.—Not later than 180 days
23 after the date of enactment of this Act, the Director
24 of the National Institutes of Health shall submit to
25 the Committee on Health, Education, Labor, and

1 Pensions and the Committee on Appropriations of
2 the Senate and the Committee on Energy and Com-
3 merce and the Committee on Appropriations of the
4 House of Representatives a work plan for—

5 (A) funding priority research projects
6 under subsection (a); and

7 (B) developing the research prioritization
8 process under subsection (b).

9 (2) REPORTS.—Not later than October 1 of
10 each fiscal year for the 5 fiscal years beginning im-
11 mediately after the date of enactment of this Act,
12 the Director of the National Institutes of Health
13 shall submit to the Committee on Health, Edu-
14 cation, Labor, and Pensions and the Committee on
15 Appropriations of the Senate and the Committee on
16 Energy and Commerce and the Committee on Ap-
17 propriations of the House of Representatives a re-
18 port on the program under this section, including—

19 (A) the amount of money obligated or ex-
20 pended in the prior fiscal year for each priority
21 research project under subsection (a);

22 (B) a description of each such project; and

23 (C) the rationale for prioritizing each such
24 project according to the process under sub-
25 section (b).

1 (g) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this section
3 such sums as may be necessary for each of fiscal years
4 2027 through 2031.

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