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118TH CONGRESS
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H. R. 1117

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

FEBRUARY 21, 2023

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

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A BILL

To implement certain recommendations to promote the inclusion of pregnant and lactating women in clinical research, 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 ''Advancing Safe Medications for Moms and Babies Act of 2023''.

SEC. 2. UPDATING FDA REGULATIONS TO REMOVE PREGNANT WOMEN AS A VULNERABLE RESEARCH POPULATION.

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

(1) to facilitate compliance with applicable Federal regulations relating to the protection of pregnant women participating in research as subjects; and

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

(b) HARMONIZATION.—For the purposes specified in subsection (a), the Secretary of Health and Human Services (in this Act referred to as the ''Secretary'') shall, to the extent practicable and consistent with other applicable statutes, issue such regulations as may be appropriate to harmonize the regulations of the Food and Drug Administration relating to the protection of human subjects, including parts 50 and 56 of title 21, Code of Federal Regulations, with the latest regulations of the Department of Health and Human Services relating to the inclusion of pregnant women as subjects in clinical research.

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

SEC. 3. CLEARINGHOUSE OF CLINICAL TRIALS AND REGISTRIES.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, and in con-

sultation with the Commissioner of Food and Drugs and the heads of other relevant Federal departments and agencies, shall establish and maintain a national clearinghouse of educational materials and current information on registries and clinical trials that enroll pregnant and lactating women in order to—

(1) enable pregnant and lactating women, their families, and health care professionals to easily identify and enroll in registries and clinical trials;

(2) educate pregnant and lactating women, their families, and health care professionals on the importance of enrolling in registries and clinical trials; and

(3) inform pregnant and lactating women, their families, and health care professionals about the general requirements, commitments, and benefits associated with participating in a registry or clinical trial.

(b) REQUIREMENTS.—The Secretary, acting through the Director of the National Institutes of Health, and in consultation with the Commissioner of Food and Drugs and the heads of other relevant Federal departments and agencies, shall ensure that the clearinghouse under subsection (a)—

(1) is accessible by means of the internet;

(2) is updated on a regular basis, not less than quarterly;

(3) is designed for consumers, incorporates a user-friendly interface, and is searchable;

(4) includes links to related public and private sector resources on registries and clinical trials described in subsection (a); and

(5) is available to the public by October 1, 2025.

(c) PLANNING.—

(1) IN GENERAL.—In establishing the clearinghouse under subsection (a), the Secretary, shall—

(A) develop criteria for which registries and clinical trials are eligible for listing in the clearinghouse under subsection (a);

(B) establish a procedure for archiving closed registries and clinical trials; and

(C) identify educational resources needed for the clearinghouse.

(2) PUBLIC INPUT.—The Secretary shall solicit public input on content to be included in the clearinghouse under subsection (a).

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated—

(1) $4,000,000 for the period of fiscal years 2024 through 2025; and

(2) $3,000,000 for the period of fiscal years 2026 through 2028.

SEC. 4. COORDINATING COMMITTEE ON RESEARCH SPECIFIC TO PREGNANT AND LACTATING WOMEN.

(a) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act, the Secretary shall establish a committee, in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), to be known as the Committee on Research Specific to Pregnant and Lactating Women or the PRGLAC Committee (in this section referred to as the ''Committee'') to advise on coordinating Federal activities to address gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women.

(b) DUTIES.—The Committee shall—

(1) advise on coordinating Federal activities to promote the inclusion of pregnant and lactating women in clinical research;

(2) promote opportunities for Federal agencies and private actors to advance the inclusion of pregnant and lactating women in clinical research;

(3) develop and annually update a summary of Federal agency progress toward implementing recommendations included in the September 2018 Report to the Secretary of Health and Human Services, and the August 2020 Report Implementation Plan to the Secretary of Health and Human Services, prepared by the Task Force on Research Specific to Pregnant Women and Lactating Women;

(4) identify new recommendations for the Secretary regarding Federal activities to address gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women; and

(5) receive updates on private sector and international efforts to include pregnant and lactating women in clinical research.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Committee shall be composed of—

(A) the Federal members listed in paragraph (2); and

(B) the non-Federal members appointed pursuant to paragraph (3).

(2) FEDERAL MEMBERS.—The Federal members of the Committee shall consist of the following Federal officials (or their designees):

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

(B) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Director of the Office of Research on Women's Health of the National Institutes of Health, and the directors of such other national research institutes and national centers of the National Institutes of Health as the Secretary determines appropriate.

(C) The Commissioner of Food and Drugs.

(D) The Director of the Agency for Healthcare Research and Quality.

(E) The Director of the Office on Women's Health of the Department of Health and Human Services.

(F) The Director of the National Vaccine Program.

(G) The Director of the Office for Human Research Protections of the Department of Health and Human Services.

(H) The Administrator of Health Resources and Services Administration.

(I) The head of any other research-related agency or department not described in subparagraphs (A) through (H) as the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

(3) NON-FEDERAL MEMBERS.—

(A) IN GENERAL.—The non-Federal members of the Committee shall consist of—

(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(ii) representatives from nonprofit organizations with expertise related to the health of women and children;

(iii) relevant industry representatives;

(iv) individuals with ethical and legal expertise in clinical trials and research;

(v) representatives from relevant nonprofit organizations with expertise in clinical research; and

(vi) other representatives, as the Secretary determines appropriate.

(B) LIMITATIONS.—The non-Federal members of the Committee shall compose not more than one-half, and not less than one-third, of the total membership of the Committee.

(C) APPOINTMENT.—The Secretary shall appoint the non-Federal members of the Committee.

(D) TERMS.—The non-Federal members of the Committee shall serve for a term of 4 years, and may be reappointed for 1 additional 4-year term. Any non-Federal member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A non-Federal member may serve after the expiration of the member's term until a successor has taken office.

(d) ADMINISTRATIVE SUPPORT.—The Secretary shall provide the Committee such administrative support as the Secretary determines to be necessary for carrying out this section.

(e) MEETINGS.—The Committee shall meet at least 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under subsection (b).

(f) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and every other year thereafter, the Committee 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—

(A) the progress of Federal agencies in implementing the recommendations and implementation plan described in subsection (b)(3);

(B) Federal activities undertaken to advance the inclusion of pregnant and lactating women in clinical research; and

(C) additional recommendations for the Secretary regarding Federal activities to address gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women.

(2) PUBLIC AVAILABILITY.—The Secretary shall make the reports required by paragraph (1) available on a public website of the Department of Health and Human Services.

(g) SUPPLEMENTAL REPORT ON DEPARTMENT GUIDANCE.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Committee 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 to inform guidance of the Department of Health and Human Services to facilitate the conduct of clinical research involving pregnant and lactating women.

(2) CONTENTS.—The report under paragraph (1) shall include—

(A) information on which clinical studies require consent from both biological parents, including information quantifying how requiring consent from both biological parents limits participation in such clinical studies;

(B) best practices and recommendations for institutional review boards related to the inclusion of pregnant and lactating women in clinical research, including information on successes and challenges of using a centralized institutional review board; and

(C) an evaluation of statutory programs enacted to spur pediatric-specific information in Food and Drug Administration-approved thera-

pies, such as the Best Pharmaceuticals for Children Act (Public Law 107–109) and the Pediatric Research Equity Act of 2008 (Public Law 108–155), and how approaches taken in such programs can be applied to clinical research including pregnant and lactating women.

(3) PUBLIC AVAILABILITY.—The Secretary shall make the report required by paragraph (1) available on a public website of the Department of Health and Human Services.

(h) TERMINATION.—

(1) IN GENERAL.—The Committee shall terminate on the date that is 5 years after the date on which the Committee is established under subsection (a).

(2) EXTENSION.—The Secretary may extend the operation of the Committee for up to 3 additional 2-year periods following the 5-year period described in paragraph (1) if the Secretary determines that the extension is appropriate to monitor the implementation of the recommendations and implementation plan described in subsection (b)(3) or any additional recommendations made by the Committee.

SEC. 5. RAISING AWARENESS OF RESEARCH THAT INCLUDES PREGNANT AND LACTATING WOMEN IN CLINICAL RESEARCH.

(a) IN GENERAL.—The Secretary, acting through the Director of the National Institutes of Health, in consultation with the heads of other relevant Federal agencies, shall establish and implement an education campaign designed to—

(1) educate the public on the importance of—

(A) including pregnant and lactating women in clinical research to better inform health care decisions on the safety and effectiveness of medications for pregnant and lactating women before, during, and after pregnancy;

(B) registries and clinical trials that include pregnant and lactating women;

(2) encourage and facilitate participation by pregnant and lactating women in clinical research;

(3) improve the general understanding of the critical role registries and other postmarket surveillance activities have in collecting data related to the use of medications by pregnant and lactating women;

(4) improve the understanding of available clinical trials and registries that enroll pregnant and lactating women;

(5) encourage pregnant and lactating women to seek additional information about such opportunities to participate in clinical research;

(6) encourage health care providers to make information on clinical research available to pregnant and lactating women; and

(7) facilitate access to and enrollment in such research by pregnant and lactating women.

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

(1) nonprofit organizations with expertise related to the health of women and children, including those representing populations with high rates of maternal mortality and morbidity;

(2) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

(3) relevant industry representatives; and

(4) other representatives, as appropriate.

(c) PLANNING.—In establishing the campaign under subsection (a), the Secretary, acting through the Director

of the National Institutes of Health, in consultation with the heads of other relevant Federal agencies, shall—

(1) conduct a needs assessment to—

(A) evaluate existing resources; and

(B) identify barriers to awareness and opportunities to fill gaps and address barriers;

(2) identify target audiences for the campaign;

(3) identify best practices to reach each such target audience;

(4) test appropriate messaging strategies, including risk communication messaging, for each target audience; and

(5) coordinate with the clearinghouse established under section 3.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2024 through 2028.

SEC. 6. RESEARCH PRIORITIZATION PROCESS FOR PREGNANT AND LACTATING WOMEN AT THE EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT.

(a) IN GENERAL.—The Director of the National Institutes of Health, acting through the Director of the Eu-

nice Kennedy Shriver National Institute of Child Health and Human Development (referred to in this section as ''NICHD''), shall carry out priority research projects on existing and new medications prescribed for pregnant and lactating women.

(b) RESEARCH PRIORITIZATION PROCESS.—The Director of the National Institutes of Health shall establish a research prioritization process to determine which proposed research projects should receive priority funding under this section. Such research prioritization process shall take into account the following factors:

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

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

(3) The potential impact of research, including the severity of the disease or condition in pregnant and lactating women, the current cost of treating the disease or condition in pregnant and lactating women, the frequency of use of the drug in pregnant and lactating women, and the availability of alter-

native treatments for the disease or condition in pregnant and lactating women.

(c) CONSULTATION.—In developing the research prioritization process described in subsection (b), the Director of the National Institutes of Health shall seek feedback from—

(1) the existing research networks of the National Institute of Child Health and Human Development with expertise in clinical research involving pregnant and lactating women;

(2) relevant medical societies with subject matter expertise on pregnant women, lactating women, or children; and

(3) nonprofit organizations with expertise related to the health of pregnant women, lactating women, or children, including those representing populations with high rates of maternal mortality and morbidity.

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

(e) ACCOUNTABILITY AND OVERSIGHT.—

(1) WORK PLAN.—Not later than 180 days after the date of enactment of this Act, the Director of the National Institutes of Health shall submit to

the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a work plan for—

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

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

(2) REPORTS.—Not later than October 1 of each of fiscal years 2024 through 2028, the Director of the National Institutes of Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the program under this section, including—

(A) the amount of money obligated or expended in the prior fiscal year for each priority research project under subsection (a);

(B) a description of each such project; and

(C) the rationale for prioritizing each such project according to the process under subsection (b).

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $50,000,000 for the period of fiscals year 2024 through 2028.

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