U.S. Representative
KATHY CASTOR

SECTION-BY-SECTION SUMMARY:
Bipartisan Advancing Safe Medications for Moms and Babies Act of 2022

Legislation introduced by Reps. Kathy Castor, Brian Fitzpatrick, and Lauren Underwood

Sec. 1 – SHORT TITLE
Advancing Safe Medications for Moms and Babies Act of 2022

Sec. 2 – UPDATING FDA REGULATIONS TO REMOVE PREGNANT WOMEN AS A VULNERABLE RESEARCH POPULATION
This section calls for the Food and Drug Administration (FDA) to harmonize its regulations relating to the protection of human subjects —specifically parts 50 and 56 of title 21, Code of Federal Regulations—with the latest regulations of the Department of Health and Human Services (HHS). The current FDA regulations still contain provisions citing "pregnant women" as a vulnerable category of subjects. These criteria may hinder the participation of these populations in research.

The HHS Secretary is to finalize these regulations no later than 180 days after the enactment of the bill.

Sec. 3 – ESTABLISHING AND MAINTAINING FEDERAL CLEARINGHOUSE
This section calls for the Secretary, acting through the NIH Director and in consultation with the FDA Commissioner and heads of other relevant Federal departments and agencies, to establish and maintain a national clearinghouse of educational materials and current information on registries and clinical trials that enroll pregnant and lactating women. This would allow women, their families, and health professionals to easily identify registries and clinical trials that enroll these populations and facilitate enrollment. The Clearinghouse would also educate stakeholders on the importance of participating in clinical research and the general requirements, commitments, and benefits associated with participation.

The clearinghouse should be accessible by internet, updated no less than on a quarterly basis, user-friendly and searchable, and should include links to related public and private sector resources. The clearinghouse is to be available to the public by October 1, 2025.

In establishing the clearinghouse, the bill calls on the Secretary to develop criteria to determine which registries and clinical trials are eligible for listing in the clearinghouse, establish a procedure for archiving closed registries and clinical trials, identify educational resources needed for the clearinghouse, and solicit public input on content for the clearinghouse.

The authorization level provided for this section is $4,000,000 for the period of fiscal years 2023 – 2024 and $3,000,000 for the period of fiscal years 2025 – 2027.

Sec. 4 – CREATING COORDINATING COMMITTEE

This section calls for the Secretary to establish a Committee on Research Specific to Pregnant and Lactating Women, or PRGLAC Committee, to advise on coordinating Federal activities to address gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women.

In addition to coordinating Federal activities, the Committee will promote opportunities to advance the inclusion of pregnant and lactating women in research; develop and annually update a summary of Federal agency progress toward implementing recommendations laid out in previous PRGLAC reports—namely, the 2018 Report and the August 2020 Report Implementation Plan; identify additional Federal activities to address gaps in knowledge and research; and receive updates on private sector and international efforts to include pregnant and lactating women in clinical research.

The Committee shall include Federal members from the NIH, FDA, HRSA, CDC, and the Office of the HHS Secretary, as well as non-Federal members, consisting of representatives from relevant medical societies, nonprofit organizations, and industry representatives, as well as individuals with ethical and legal expertise in clinical trials and research.

Sec. 5 – EDUCATION CAMPAIGN

This section calls for the HHS Secretary, acting through the NIH Director and in consultation with other relevant Federal agencies, to establish and implement an campaign that would educate the public on the importance of including pregnant and lactating women in clinical research and which registries and clinical trials include such populations; encourage and facilitate participation by these populations; improve understanding of the role of registries and post-market surveillance activities; encourage pregnant and lactating women to seek additional information about opportunities to participate in clinical research; and encourage providers to make information on clinical research available to pregnant and lactating women.

The campaign should be developed in consultation with relevant nonprofit organizations, medical societies, industry representatives, and other representatives, as appropriate.

The authorization level provided for this section is $5,000,000 for the period of fiscal years 2023 – 2027.

Sec. 6 – PRIORITIZING PREGNANT AND LACTATING WOMEN RESEARCH PROCESS

This section calls for the NIH Director to carry out priority research projects on existing and new medications prescribed for pregnant and lactating women. The section requires the Director to establish a research prioritization process to determine which of the proposed research projects related to this population should receive priority funding. That process could consider available evidence, the feasibility of research, and the potential impact of the research. The

process should be developed after soliciting feedback from NIH's existing research networks, relevant medical societies, and relevant nonprofit organizations.

Within 180 days of the legislation's enactment, the NIH Director is required to develop a work plan for funding such priority research projects and developing the research prioritization process. Further, the bill calls for annual reports from the NIH Director for fiscal years 2023 to 2027 detailing the amount of money obligated or expended in the prior fiscal year for each priority research project, including a description of each project and the rationale for prioritizing each project.

This section calls for an authorization level of $50,000,000 for the period of fiscal years 2023 – 2027.