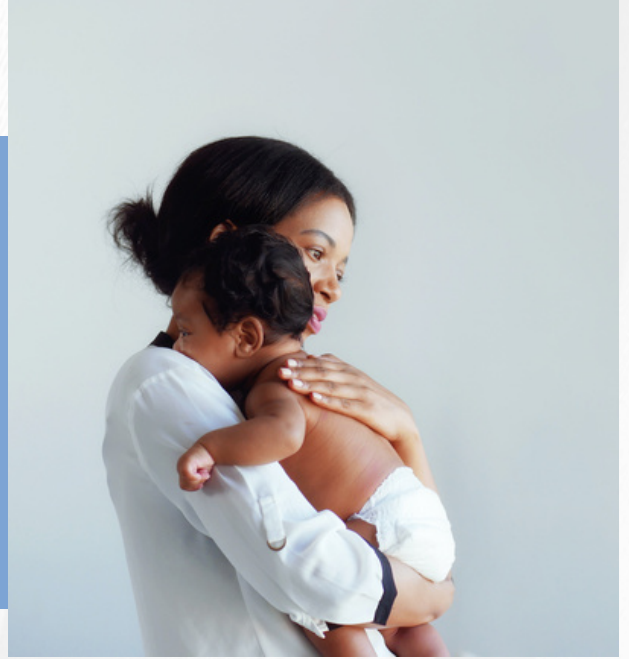


ADVANCING SAFE MEDICATIONS FOR MOMS AND BABIES ACT OF 2023 (H.R.1117)

Building off the Federal Investment from the bipartisan 21st Century Cures Act to include pregnant and lactating women in clinical trials.



THE NEED

Of the 4 million women in the United States who give birth each year, 70% take at least one prescription medication during their pregnancy. Yet, the National Institutes of Health (NIH) and U.S. Food and Drug Administration (FDA) have historically excluded pregnant and breastfeeding women from clinical trials, which has led to critical evidence gaps that can affect health outcomes for both mother and baby and has left women, their families, and health care providers to make health decisions without reliable data.

A lack of data can affect the health of mom and baby in a time when maternal mortality is at an all time high.



Gambling with Dosing: Doses that are too low could expose women to disease and too high, to toxicity. During the 2009 H1N1 flu pandemic, the CDC recommended using standard adult dosing of the flu medication Tamiflu due to the flu's severe impact on pregnant women. However, a 2011 study revealed that the standard dose of the medication was potentially too weak for pregnant women to benefit from the medication. ***Pregnant women were prescribed a drug that was potentially ineffective in combatting the flu and protecting women and their babies.***



Baby Safety: Without data, the baby may be exposed to unacceptable risk. The drug thalidomide was developed for treatment of morning sickness in the 1950s, but by 1962 the drug was linked to severe birth defects. ***Researchers have argued that a well-controlled clinical trial could have prevented the widespread effects of thalidomide.***



Preventing Maternal Mortality: Women may lack access to beneficial drugs for their diseases or conditions, which puts them at higher risk for complications during pregnancy or after birth. For women with severe epilepsy who become pregnant, stopping treatment is not a "reasonable or safe option." ***Seizures during pregnancy can affect the mother's cardiovascular health, which can cause risk for both mother and baby.***

Source: Anne Drapkin Lyerly, MD, MA, Presentation, CAMT Virtual Congressional Briefing (2023)

THE SOLUTION

Within the 21st Century Cures Act (P.L. 114-255 sec. 2041), Congress created the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). After years of federal investment to identify solutions, one of the primary recommendations was to improve the research and systems to integrate pregnant and breastfeeding mothers to keep mother and baby healthy. This legislation seeks to implement some of these recommendations as follows:

- Removing pregnant women as a vulnerable research population under the FDA
- Prioritizing pregnant and lactating women in NIH research projects on existing and new medications designed to improve the health of both mother and baby
- Establishing a federal clearinghouse and increase public awareness and transparency for clinical trials enrolling pregnant and lactating women
- Continuing the federal coordination to identify gaps, opportunities, and track the Federal agency progress towards implementing PRGLAC reports

ABOUT THE COALITION TO ADVANCE MATERNAL THERAPEUTICS

The Coalition to Advance Maternal Therapeutics (CAMT) was founded in 2014 to advocate for policy changes and raise awareness of the need for greater inclusion of pregnant and lactating populations in clinical research. Through the CAMT's efforts, the Common Rule was revised to declassify pregnant people as a vulnerable population, PRGLAC was established, and additional programs and support for the inclusion of this population in research have been promoted.

Coalition Membership

Nonprofit Members

- Academy of Breastfeeding Medicine
- American Academy of Allergy, Asthma & Immunology, Vaccines and Medications in Pregnancy Surveillance System
- American College of Nurse-Midwives
- American Association of Colleges of Pharmacy
- American College of Obstetricians and Gynecologists*
- American Heart Association
- Association of Maternal & Child Health Programs
- Association of Women's Health, Obstetric, and Neonatal Nurses
- Elizabeth Glaser Pediatric AIDS Foundation
- Endocrine Society
- Epilepsy Foundation
- Genetic Alliance
- HealthyWomen
- March of Dimes*
- Maternal Mental Health Leadership Alliance
- National Association of Nurse Practitioners in Women's Health
- North American Society for Psychosocial Obstetrics & Gynecology
- Organization of Teratology Information Specialists
- Society for Birth Defects Research and Prevention
- Society for Obstetric Anesthesia and Perinatology
- Society for Maternal-Fetal Medicine*
- Society of OB/GYN Hospitalists
- Society for Women's Health Research*
- Treatment Action Group
- United States Breastfeeding Committee
- WomenHeart: National Coalition for Women with Heart Disease

*Steering Committee Member

Corporate Advisory Committee

- Biogen
- Covis Pharma
- Janssen
- UCB

Select Sources

National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Forum on Drug Discovery, Development, and Translation; Shore C, March A, Wizemann T, editors. Inclusion of Pregnant and Lactating Persons in Clinical Trials: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2022 Dec 15. <https://www.ncbi.nlm.nih.gov/books/NBK587623/> doi: 10.17226/26790
Centers for Disease Control and Prevention. (2022, August 31). Breastfeeding Report Card. Centers for Disease Control and Prevention. Accessed May 17, 2023. <https://www.cdc.gov/breastfeeding/data/reportcard.htm>



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