Advancing Safe Medications for Moms and Babies Act

(H.R. 1117)

Lead Sponsors

Rep. Kathy Castor
(D-FL)

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Background

Pregnant and lactating people have been excluded from drug safety and effectiveness trials due to the perceived risks to moms and babies. Pregnant and lactating people are often taking drugs with limited data to inform safety, dosing, and efficacy, which may lead to increased risk of injury or death for them or their baby.

Approximately 4 million persons in the U.S. give birth annually and **over 3 million** of those will breastfeed their child.[1]

More than 90% of women take one or more prescription medications during their pregnancy with **almost one-third of** women using four medications. **More than 70% of women** were taking medications that were potentially unsafe or had unknown safety profiles while breastfeeding.[2,3]

Only 1% of clinical trials mention the word *pregnancy* or *pregnant* and **only 0.5%** mention *breastfeeding* or *lactation*.[4]

As a high-risk population, pregnant people urgently needed access to vaccines and treatments for COVID-19. Pregnant and lactating women were excluded from COVID-19 trials which delayed timely access to critical interventions due to safety concerns.

One study reported **47% of adverse outcomes** in the neonates as "possibly" linked, **53% as "probably" linked,** to medication exposure during breast-feeding.[5]

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Bill summary

The Advancing Safe Medications for Moms and Babies Act will improve our understanding of the effects of medications on pregnant and lactating women and their infants.

This bill builds on the work of the Safe Medications for Moms and Babies Act of 2016, which established the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC).

PRGLAC was tasked with advising the U.S. Secretary of Health and Human Services (HHS) about gaps in knowledge and research on safe and effective therapies for pregnant and lactating women. This bill includes recommendations from both reports released by PRGLAC.

Key provisions include:

- Updating FDA's regulations to remove pregnant women as a vulnerable research population.
- Establishing a national clearinghouse of educational materials and current information on registries and clinical trials that enroll pregnant and lactating women.
- Raising awareness of clinical research that includes pregnant and lactating women through an educational campaign for the public, health care providers, and other stakeholders.
- Directing the NIH to prioritize research on existing and new medications prescribed for pregnant and lactating women.

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3. *Mitchell, A. A., Gilboa, S. M., Werler, M. M., Kelley, K. E., Louik, C., Hernández-Díaz, S., & National Birth Defects Prevention Study. (2011, July). Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008. American journal of obstetrics and gynecology. Retrieved March 13, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3793635/*
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5. *Riley, L. E., Cahill, A. G., Beigi, R., Savich, R., & Saade, G. (2017, July). Improving safe and effective use of drugs in pregnancy and lactation: Workshop summary. American journal of perinatology. Retrieved March 13, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6193221/*

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