



November 21, 2023

The Honorable Tammy Baldwin  
Chairwoman, Senate Labor, Health and Human  
Services, Education, and Related Agencies  
Appropriations Subcommittee  
Washington, DC 20510

The Honorable Shelly Moore Capito  
Ranking Member, Senate Labor, Health and Human  
Services, Education, and Related Agencies  
Appropriations Subcommittee  
Washington, DC 20510

The Honorable Robert Aderholt  
Chairman, House Labor, Health and Human  
Services, Education, and Related Agencies  
Appropriations Subcommittee  
Washington, DC 20515

The Honorable Rosa DeLauro  
Ranking Member, House Labor, Health and Human  
Services, Education, and Related Agencies  
Appropriations Subcommittee  
Washington, DC 20515

Dear Chairwoman Baldwin, Ranking Member Capito, Chairman Aderholt, and Ranking Member DeLauro,

On behalf of the undersigned 16 organizations of the Coalition to Advance Maternal Therapeutics (CAMT), a coalition of nonprofits, patients, providers, and industry groups committed to improving maternal health in the United States, we would like to thank you for your continued support of vital maternal and infant health programs. We respectfully request **\$200,000 for the Advisory Committee to implement the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) recommendations, the same as fiscal year (FY) 2023**, within the FY 2024 Labor, Health and Human Services, Education, and Related Agencies (LHHS) appropriations package.

Pregnant and lactating women have historically been excluded from clinical trials, leading to significant evidence gaps impacting the health outcomes of mothers and infants. Of the more than 3.5 million women in the United States who give birth each year, 89% take at least one prescription medication during their pregnancy.<sup>1</sup> Yet, 70% of medications approved in the United States by the Food and Drug Administration (FDA) have no human pregnancy data, and 98% have insufficient data to determine risk to the infant.<sup>2</sup> For women who live with chronic conditions like type 2 diabetes, narcolepsy, epilepsy, lupus, or hypertension, the lack of data creates challenges for management of their conditions during pregnancy, putting both moms and infants at risk.

---

<sup>1</sup> Ke, A. B., Greupink, R., & Abduljalil, K. (2018). Drug Dosing in Pregnant Women: Challenges and Opportunities in Using Physiologically Based Pharmacokinetic Modeling and Simulations. *CPT: pharmacometrics & systems pharmacology*, 7(2), 103–110. <https://doi.org/10.1002/psp4.12274>

<sup>2</sup> Ibid.

In 2016, Congress took bipartisan, bicameral action within the *21<sup>st</sup> Century Cures Act* to address the lack of pregnant and lactating women in clinical trials and research by creating the PRGLAC Task Force. In 2018, under Secretary Azar, the Task Force identified 15 recommendations for the federal government to support the safe and ethical inclusion of pregnant and lactating women in clinical trials and research.<sup>3</sup> Considering the United States is experiencing worsening maternal health outcomes, the implementation of these recommendations is paramount.

We thank you for including \$200,000 in the *Consolidated Appropriations Act of 2023 (PL 117-328)* to establish of an Advisory Committee to oversee the implementation of the Task Force recommendations.<sup>4</sup> This Advisory Committee, which meet for the first time this month, is vital to continue work across the federal government to implement the PRGLAC recommendations to ensure more moms and health care providers have the information they need to create the best possible conditions for healthy pregnancies and healthy babies. **For these reasons, we respectfully request that you again include \$200,000 to support the Advisory Committee in the FY 2024 LHHS appropriations package.**

This modest funding will ensure that the federal government is working to support the inclusion of this critical population in clinical trials to improve maternal and infant outcomes. There are numerous independent studies and multi-center trials that are successfully completing research in pregnant women, and we need to continue to build on this effort to support women and infants. These include trials of drugs (e.g., pravastatin); interventions (pessary, labor induction); and other therapies (CPAP, and Vitamins C). This funding is an important step to improve maternal health outcomes across the United States.

On behalf of the more than 3.5 million moms who give birth each year and their babies, we thank you for your attention to this critical matter. Please contact Rebecca Abbott at rabbott@smfm.org, 202-644-9296 should you have any questions.

Sincerely,

American Academy of Allergy, Asthma & Immunology / Vaccines and Medications in Pregnancy Surveillance System (VAMPSS)

American College of Obstetricians and Gynecologists

Association of Maternal & Child Health Programs

Elizabeth Glaser Pediatric AIDS Foundation

---

<sup>3</sup> U.S. Department of Health and Human Services. (n.d.). List of recommendations from the Task Force on research specific to pregnant women and lactating women (PRGLAC). Eunice Kennedy Shriver National Institute of Child Health and Human Development. <https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendation>

<sup>4</sup> Ibid.

Epilepsy Foundation

HealthyWomen

March of Dimes

Maternal Mental Health Leadership Alliance

National Women's Health Network

Organization of Teratology Information Specialists

Preeclampsia Foundation

Society for Birth Defects Research and Prevention

Society for Maternal-Fetal Medicine

Society for Women's Health Research

UCB

Wake Up Narcolepsy