June 20, 2024

The Honorable Tammy Baldwin
Chair, Senate Appropriations Committee
Subcommittee on Labor, Health and Human Services, Education, & Related Agencies
S-128, The Capitol
Washington, D.C. 20510

The Honorable Shelley Moore Capito
Ranking Member, Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, Education, & Related Agencies
S-128, The Capitol
Washington, D.C. 20510

The Honorable Robert Aderholt
Chair, House Appropriations Committee
Subcommittee on Labor, Health and Human Services, Education, & Related Agencies
2358-B Rayburn House Office Building
Washington, D.C. 20510

The Honorable Rosa DeLauro
Ranking Member, House Appropriations Committee Subcommittee on Labor, Health and Human Services, Education, & Related Agencies
2358-B Rayburn House Office Building
Washington, D.C. 20510

The Honorable Martin Heinrich
Chair, Senate Appropriations Committee
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, & Related Agencies
S-128, The Capitol
Washington, D.C. 20510

The Honorable John Hoeven
Ranking Member, Senate Appropriations Committee Subcommittee on Agriculture, Rural Development, Food and Drug Administration, & Related Agencies
S-128, The Capitol
Washington, D.C. 20510

The Honorable Andy Harris
Chair, House Appropriations Committee
Subcommittee on Agriculture, Rural Development, Food and Drug Administration, & Related Agencies
2362-A Rayburn House Office Building
Washington, D.C. 20510

The Honorable Sanford Bishop
Ranking Member, House Appropriations Committee Subcommittee on Agriculture, Rural Development, Food and Drug Administration, & Related Agencies
2358-B Rayburn House Office Building
Washington, D.C. 20510

Dear Chair Baldwin, Ranking Member Capito, Chair Aderholt, Ranking Member DeLauro, Chair Heinrich, Ranking Member Hoeven, Chair Harris, and Ranking Member Bishop,

The 16 undersigned 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, urge you to prioritize maternal and infant health through the inclusion of pregnant and lactating populations in clinical trials within the Labor, Health and Human Services, Education and Related Agencies (LHHS) and the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (FDA-Ag) appropriations bills for fiscal year (FY) 2025.

We are grateful that in recent years, final spending bills have included key provisions that will advance our understanding of the safety and efficacy of medications used during pregnancy and while breastfeeding. To build upon those efforts, we respectfully request the inclusion of report and programmatic requests in the FY 2025 LHHS and FDA-Ag appropriations bills.

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 over-the-counter or prescription medication during their pregnancy.[1] Despite these high rates of usage, 70% of medications approved by the Food and Drug Administration (FDA) have no human pregnancy data, and 98% have insufficient data to determine risk to the infant.[2] For women who live with chronic conditions like diabetes, narcolepsy, epilepsy, lupus, mental health conditions, and hypertension, this lack of data creates serious challenges for management of their conditions during pregnancy, putting both mothers and infants at risk.

In 2016, Congress took bipartisan, bicameral action within the *21st Century Cures Act* to address the lack of pregnant and lactating women in clinical trials and research, establishing the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) Task Force. In 2018, under Secretary Azar, the Task Force made 15 recommendations for the federal government to support the safe and ethical inclusion of pregnant and lactating women in clinical trials and research.[3] In the wake of our growing maternal health crisis, the implementation of these bipartisan recommendations is paramount. We must now work to implement them to ensure all mothers and infants are able to experience a healthy pregnancy and postpartum period.

With these considerations in mind, we urge you to include the following requests:

National Institutes of Health (NIH)

The United States spends approximately $4 trillion on health care annually, but we remain behind every high-income country on preventing maternal mortality, which could be addressed through health care interventions.[5] Priority research funding would begin to fix the current lack of knowledge about the effect of therapeutics and medications currently being prescribed to pregnant and lactating women, rectifying the lack of a reliable evidence base. This request would fulfill recommendation #8 from PRGLAC.[4]

> **Priority Research for Pregnant and Lactating Women** – *The Committee remains concerned about the lack of pregnant and lactating women in clinical research. Women with chronic health conditions lack access to appropriate treatments during pregnancy, putting both them and their infants at risk. Despite, 90 percent of women taking at least one medication during pregnancy, only 5 percent of medications have data on the impact of the medications during pregnancy. The Committee provides $2,000,000 for the Director to conduct priority research projects on existing medications, and therapeutics prescribed to pregnant and lactating women. The Secretary shall give preference to research applications demonstrating the following as it relates to pregnant and lactating women: an unmet medical need or gap in treatment, severity and prevalence of a specific disease or condition, and cost and availability of treatment or alternate treatments. The Committee requests an update in the fiscal year 2026 Congressional Budget Justification on the amount of money obligated to priority research projects for pregnant and lactating women, a description of each project and rationale for prioritization, institutes at the NIH that can contribute to this research, and the existing medications and therapeutics that will be prioritized for study.*

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[1] 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

[2] Ibid

[3] 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

[4] List of Recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). (June 7, 2019). Https://Www.nichd.nih.gov/. https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations

Office on Women's Health (OWH)

PRGLAC recommendation #15 focuses on creating an advisory committee to oversee the implementation of the Task Force's recommendations.[5] We thank appropriators for providing $200,000 for the Advisory Committee in past appropriations cycles and urge you to continue this support.

PRGLAC recommendation #5 calls for increased public awareness to better inform patients and clinicians about opportunities to participate in clinical research.[6] Enrolling sufficient pregnant or lactating women in trials and registries is a significant barrier to research in these populations, and this education campaign would seek to make it easier for clinicians, patients, and families to identify research opportunities.

> **Pregnant Women and Lactating Women Advisory Committee** – *The Committee provides $200,000 for the Advisory Committee to continue activities within the 2020 Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) Implementation Plan. The Committee directs the agency to provide an update in the fiscal year 2026 Congressional Budget Justification on progress and federal activities undertaken to implement the PRGLAC recommendations and recommendations for further implementation of all PRGLAC recommendations, including policy needs and resources.*

> **Pregnant and Lactating Women in Clinical Trials Public Awareness Campaign** – *The Committee provides $1,000,000 for public awareness campaign to educate maternal and child health providers, patients, and their families on opportunities to enroll pregnant and lactating women into clinical trials and registries following the recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The campaign shall include information on registries and clinical trials that enroll pregnant and lactating women, how patients can enroll, and address common questions for clinicians and patients. The public awareness campaign shall have a public-facing website where providers and patients can access information from the public awareness campaign and registries and clinical trials that enroll pregnant and lactating women. In designing the public awareness campaign, the Secretary shall consult with outside organizations with subject matter expertise in pregnant women, lactating women, and infants. No later than 180 days after enactment of this Act, the Secretary shall provide the Committee with a report on the public awareness campaign and the public website including information to be included as part of the public awareness campaign, the launch date of the campaign and website, and outside organizations that have been engaged as part of the campaign.*

Food and Drug Administration (FDA)

With the bipartisan *21st Century CURES Act*, Congress requested that the FDA harmonize its regulations with the Common Rule to improve the inclusion of pregnant and lactating women in clinical research. The harmonization was supposed to be completed in 2019, but it is still only in draft form. With worsening maternal health and infant outcomes across the United States, the finalization of this guidance is critical. Therefore, we urge you to include the following report language:

> **Pregnant Women in Clinical Research**. — *The Committee remains concerned about FDA's failure to issue final regulations 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, as required by 21st Century Cures Act (PL 114-255). Despite, 90 percent of pregnant*

[5] List of Recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). (June 7, 2019). Https://Www.nichd.nih.gov/. https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations

[6] Ibid.

women taking over the counter or prescription medication during their pregnancy, 70 percent of medications approved by the FDA have no human pregnancy data, and 98 percent have insufficient data to determine the risk to the infant, leaving both the mother and infant at risk to adverse health events. Following recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women, the Committee directs the agency to issue final regulations. The agency shall provide further guidance about ethical issues to be considered and strategies for designing ethical studies, to inform the inclusion of pregnant and lactating women in a clinical trial and facilitate their participation. No later than 90 days after the enactment of this Act, FDA shall submit a report to the Committee on the status for final regulations and steps taken by the agency to include pregnant and lactating women in clinical trials.

On behalf of the more than 3.5 million women who give birth each year and their infants, we thank you for your attention to this critical matter. A strong commitment to fund and prioritize the safe and ethical inclusion of pregnant and lactating women in clinical trials and research will not only improve maternal and infant health outcomes, but most importantly, will save lives.

Sincerely,

American Academy of Pediatrics
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
Association of Maternal & Child Health Programs
Elizabeth Glaser Pediatric AIDS Foundation
Endocrine Society
Epilepsy Foundation
HealthyWomen
March of Dimes
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
Treatment Action Group