

November 21st, 2024

The Honorable Patty Murray
Chair, Senate Appropriations
S-128, The Capitol
Washington, D.C. 20515

The Honorable Susan Collins
Vice Chair, Senate Appropriations
S-128, The Capitol
Washington, D.C. 20515

The Honorable Tom Cole
Chairman, House Appropriations
H-307, The Capitol
Washington, D.C. 20515

The Honorable Rosa DeLauro
Ranking Member, House Appropriations
H-307, The Capitol
Washington, D.C. 20515

Dear Chair Murray, Chairman Cole, Vice Chair Collins, and Ranking Member DeLauro:

On behalf of the 20 undersigned organizations, we thank you for your continued support to improve the lives and safety of pregnant mothers and their infants within the fiscal year (FY) 2025 appropriations process. **As you move toward final passage of FY 2025 appropriations legislation, we respectfully request that you provide level funding for the Pregnant Women and Lactating Women Advisory Committee. We also ask that you prioritize language from the House Labor, Health and Human Services, Education, and Related Agencies Appropriations (LHHS) Act report “*Pregnant and Lactating Women*” research at the National Institutes of Child Health and Human Development (NICHD), as well as language from the and Senate Agriculture, Rural Development, Food and Drug Administration (Ag-FDA) report for the “*Women in Clinical Research*” at the Food and Drug Administration (FDA) to improve health outcomes for both mothers and babies.**

Pregnant and lactating women have historically been excluded from clinical trials, leading to significant evidence gaps impacting the health outcomes of both mothers and infants. Of the more than 3.5 million women (about twice the population of Nebraska) 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 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 babies at risk.

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

I. LHHS: Pregnant Women and Lactating Women Advisory Committee

Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) recommendation #15 focuses on creating an advisory committee to oversee the implementation of the Task Force’s recommendations.³ We thank you for providing level funding of \$200,000 for the Advisory Committee in past appropriations cycles and in the House & Senate FY 2025 LHHS bills for FY 2025

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 List of Recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). (2019). <https://www.nichd.nih.gov/>. <https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations>

and urge you to continue this funding as well as include the House report language ([page 205](#)) that requests an update on the progress within the Fiscal Year 2026 Congressional Justification.

II. LHHS: National Institute of Child Health and Human Development

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 Pregnant and Lactating Women .⁴ For these reasons, we respectfully request that you include the House LHHS report language under NICHD ([page 106](#)) in the FY25 end of year package:

***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 pregnant women taking prescription medication, only 5 percent of medications have data on the impact of the medications during pregnancy. The Committee urges NICHD to conduct priority research projects on existing medications and therapeutics prescribed to pregnant and lactating women. NICHD is urged to prioritize research applications in the following areas 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 justification on this effort.*

III. Ag-FDA Women in Clinical Research

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. For these reasons, we respectfully request that you include the House Ag-FDA report language ([page 92](#)) in the FY25 end of year package:

***Women in Clinical Research.** —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 (P.L. 114–255). Despite, 90 percent of pregnant women taking 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 urges the agency to issue final regulations.*

On behalf of the more than 3.5 million women who give birth each year and their babies, 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,

Academy of Breastfeeding Medicine (ABM)

American Academy of Pediatrics

American College of Nurse-Midwives

American College of Obstetricians and Gynecologists

Association of Maternal & Child Health Programs

Association of Women's Health, Obstetric and Neonatal Nurses

Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society

Epilepsy Foundation of America

HealthyWomen

March of Dimes

Maternal Mental Health Leadership Alliance

National Women's Health Network

Organization of Teratology Information Specialists

Shades of Blue Project

Society for Birth Defects Research and Prevention

Society for Maternal-Fetal Medicine

Society for Women's Health Research

Treatment Action Group

Wake Up Narcolepsy

CC: Chairwoman Baldwin, Ranking Member Capito, Chairman Aderholt, Chairman Heinrich, Ranking Member Hoeven, Chairman Harris, Ranking Member Bishop