Outside Witness Testimony for Rebecca Abbott, Coalition Chair, the Coalition to Advance Maternal Therapeutics, Fiscal Year 2025 Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee

On behalf 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, I write to provide our perspective on how the Department of Health and Human Services (HHS) can address the lack of research on medications and therapeutics for pregnant and lactating women and how the House Labor, Health and Human Services, Education, and Related Agencies (LHHS) Appropriations Subcommittee can support this work in Fiscal Year (FY) 2025 within the HHS Office of Women's Health and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The safe and ethical inclusion of these populations in clinical trials will lead to better outcomes for the more than 3.5 million women who give birth each year in the United States and their infants.[1]

Historically, pregnant and lactating women have been excluded from clinical trials, leading to significant evidence gaps that impact the health outcomes of mothers and infants today. Studies indicate that 90% of pregnant women take at least one prescription or over-the-counter medication during their pregnancy.[2] 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.[3] For women who live with chronic health conditions, such as type 2 diabetes, narcolepsy, epilepsy, mental health disorders, lupus, or hypertension, the lack of data creates challenges for management of their condition(s) during pregnancy, putting both mother and infant at risk.

To demonstrate the state impact, in Alabama, more than 52,000 women annually will take at least one medication during their pregnancies.[4] In Connecticut, more than 32,000 women annually will take at least one medication during their pregnancies.[5] Due to systematic exclusion of pregnant and lactating populations from clinical research, these

---

[1] Hamilton, BE, Martin, JA, Osterman, MJK. Births: Provisions Data for 2023. Vital Statistic Rapid Release, Report No. 35. National Center for Health Statistics. Centers for Disease Control and Prevention. April 2024. Available at https://www.cdc.gov/nchs/data/vsrr/vsrr035.pdf.

[2] 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

[3] Ibid.

[4] Centers for Disease Control and Prevention| National Center for Health Statistics . (2023, February 10). Fertility Rates by State. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/pressroom/sosmap/fertility_rate/fertility_rates.htm

[5] Ibid.

patients and their providers have little data on how to best treat chronic conditions or conditions that arise during pregnancy, with some patients forgoing treatment for their condition entirely.

The safe and ethical inclusion of pregnant and lactating women in research has received wide bipartisan support over the years. In 2016, Congress took action within the *21st Century Cures Act* to address the lack of pregnant and lactating women in clinical trials and research by creating the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC).[6] In 2018, under HHS Secretary Alex 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.[7] Still, many of these recommendations have yet to be implemented, despite worsening maternal and infant health outcomes in the United States.

For example, one of the requirements in the *21st Century Cures'* Act and a key recommendation of PRGLAC was to harmonize FDA regulations governing participation of human subjects in clinical trials with 2017 updates to the HHS Federal Policy for the Protection of Human Subjects, or the "Common Rule," which would remove barriers to the inclusion of pregnant women in clinical research. This harmonization was to be completed by 2019. However, five years later, the FDA has not updated its regulations. FDA inaction needlessly continues a significant barrier to the inclusion of pregnant women in research and prevents progress to improving the health of pregnant women and their infants.

Implementation of PRGLAC recommendations has never been more pressing. There are a greater number of women entering pregnancy with pre-existing conditions including hypertension, type II diabetes, substance use disorder, anxiety, and major depression.[8] Additionally, the number of women with postpartum depression increased by nearly 30% between 2014 to 2018.[9] The Centers for Disease Control has reported that suicide and overdose are the leading cause of maternal mortality.[10] The exclusion of pregnant and lactating populations from clinical trials and research has a direct impact on the lifelong health of a woman and her infant.

---

[6] Task Force on Research Specific to Pregnant Women and Lactating Women. - NICHD. National Institute of Health. (2020, August). https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Implement_Plan_083120.pdf

[7] Ibid.

[8] BlueCross BlueShield. (2020, June 17). Trends in Pregnancy and Childbirth Complications in the U.S. BlueCross BlueShield | The Health of America . https://www.bcbs.com/the-health-of-america/reports/trends-in-pregnancy-and-childbirth-complications-in-the-us

[9] Ibid.

[10] Centers for Disease Control and Prevention. (2022, September 19). Four in 5 pregnancy-related deaths in the U.S. are preventable. Centers for Disease Control and Prevention. https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html

Many of the PRGLAC recommendations can be implemented without additional authorization and the LHHS Subcommittee has historically supported implementation of PRGLAC recommendations. For example, in FY 2023 and FY 2024 the Committee provided $200,000 for an Advisory Committee to oversee steps the federal government has taken to include pregnant and lactating women in clinical research. This advances PRGLAC recommendation #15. Additionally, the FY 2024 Agriculture, Rural Development, FDA Senate Report included language urging the FDA to update regulations to better include pregnant women in research. This addresses PRGLAC recommendation #1**.** Finally, in FY 2022 appropriations legislation, Congress provided funding to examine the perceived and real liability risks that impede the inclusion of pregnant and lactating women in research, advancing PRGLAC recommendation #7.

Still, there is more to be done.

As you consider requests for FY 2025, I strongly urge the Committee to continue its support for the implementation of the PRGLAC recommendations. Below I have highlighted three requests for programmatic and report language supported by the Coalition that would have a profound impact as we work to include these populations in research and improve maternal and infant health outcomes for your constituents.

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. (PRGLAC Recommendation #8)

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. (PRGLAC Recommendation #5)

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. (PRGLAC Recommendation #15)

On behalf of the more than 3.5 million women who give birth each year and their infants, thank you for your attention to this critical matter as you consider the fiscal year LHHS Appropriations package. The entire Coalition and I stand ready to serve as a resource for your team if there are further questions.