Outside Witness Testimony for Lindsey Miltenberger, Chair, Coalition to Advance Maternal Therapeutics: Fiscal Year 2026 Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee

On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), a coalition comprised of nonprofit medical, public health, and scientific societies, patient advocacy organizations, and industry, I appreciate the opportunity to provide outside witness testimony to the House Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) Appropriations Subcommittee for fiscal year (FY) 2026. This testimony addresses how appropriators can support the safe and ethical inclusion of pregnant and lactating women in research in FY 2026—leading to better outcomes for moms, babies, and their families—through activities within the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). The CAMT encourages members of Congress to **provide at least $1.891 billion for NICHD**. This investment is critical to supporting NICHD programs, such as the **Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative** and the **Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub**, which drive research aimed at improving health outcomes for pregnant women. Additionally, we encourage the inclusion of report language that promotes the participation of pregnant and lactating women in clinical trials—ensuring that these populations are no longer left behind in the advancement of evidence-based care.

While many research areas merit federal investment, medication use in pregnant and lactating women is critically understudied. Each year, more than 3.6 million women give birth in the United States,[1] and more than 90% take at least one prescription or over-the-counter medication during their pregnancy.[2] Yet 70% of Food and Drug Administration (FDA) approved medications lack human pregnancy data, and 98% have insufficient data to assess risk to the infant.[3] In a 2025 analysis published in the *American Journal of Obstetrics and Gynecology*, of 90,860 drug trials involving women ages 18-45 years of age from the past 15 years, only 0.8% included pregnant women.[4]

This data gap has serious consequences for pregnant and breastfeeding women nationwide. A woman who falls ill may be uncertain whether a medication is safe for her and her baby. Conversely, a woman managing a chronic condition may stop taking a necessary medication out of caution, unaware that it poses no risk to her child. Addressing this knowledge deficit is essential to ensuring the health and safety of both mothers and

---

[1] Osterman MJ, Hamilton BE, Martin JA, Driscoll AK, Valenzuela CP. Births: Final Data for 2022. Natl Vital Stat Rep. 2024 Apr 4;73(2):1–50.
[2] Ke AB, Rostami-Hodjegan A, Zhao P, Unadkat JD. Drug dosing in pregnant women: challenges and opportunities in using physiologically based pharmacokinetic modeling and simulations. CPT Pharmacometrics Syst Pharmacol. 2012 Dec;1:e10. doi: 10.1002/psp4.12274.
[3] Ibid.
[4] Bilinski A, Bateman BT, Hernandez-Diaz S, Zash R, Hehir MP, Smith LH, et al. Fewer than 1% of US clinical drug trials enroll pregnant participants. Am J Obstet Gynecol. 2025;232(3):000–000.

infants. Take hypertension as an example. An estimated 14.5% of reproductive age women in the United States have hypertension.[5] A drug called methyldopa is often used to treat high blood pressure in pregnancy. While it is considered safe, "published experience on first trimester exposure to methyldopa is still limited," according to a piece in the journal *Hypertension*.[6] This situation isn't isolated. Limited data also exist for medications used to treat and manage type 2 diabetes, epilepsy, narcolepsy, lupus, and more.

However, a clear path exists to close these knowledge gaps and equip health care providers, moms, and families with the information they need to make safe, informed health care decisions for both mother and baby. This "path" is a set of 15 recommendations made by the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) in its September 2018 report to the U.S. Secretary of Health and Human Services (HHS) and Congress.[7] Recommendations made by the Task Force included integrating pregnant and lactating women into the clinical research agenda; creating a public awareness campaign to engage the public and health care providers on information relevant to research on pregnant and lactating women; and optimizing registries for pregnancy and lactation, among others.

While these recommendations could alter the "cultural assumptions that have significantly limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women," many have yet to be implemented. In July 2024, the PRGLAC Implementation Working Group of Council released a Report on Implementation Progress,[8] outlining which PRGLAC recommendations have been implemented, are in progress or planned, or have not been implemented. Many of the recommendations were classified as not implemented, despite worsening maternal and infant health outcomes in the United States.

As you consider funding requests for FY 2026, we strongly urge the Committee to support the continued implementation of PRGLAC recommendations to support healthy moms and babies across the country. Included below is a report language request supported by the Coalition that would continue our path forward to improving knowledge on the safety and efficacy of medications in pregnant and lactating women.

---

[5] Weng X, Woodruff RC, Park S, He S, Thompson-Paul AM, Hayes D, et al. Hypertension prevalence and control among U.S. women of reproductive age. Am J Prev Med. 2023 Oct 23;[Epub ahead of print]. doi: 10.1016/j.amepre.2023.10.016.

[6] Hoeltzenbein M, Beck E, Fietz AK, Wernicke J, Zinke S, Kayser A, et al. Pregnancy outcome after first trimester use of methyldopa: a prospective cohort study. Hypertension. 2017;70(1):123–129. doi: 10.1161/HYPERTENSIONAHA.117.09110.

[7] Pregnancy and Lactation Research Recommendations Task Force (PRGLAC). PRGLAC Report to the HHS Secretary and Congress. Bethesda, MD: Eunice Kennedy Shriver National Institute of Child Health and Human Development; 2018 Sep.

[8] Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) Implementation Working Group of Council. PRGLAC Implementation Progress Report. Bethesda, MD: Eunice Kennedy Shriver National Institute of Child Health and Human Development; July 2024. Available from: https://www.nichd.nih.gov/about/advisory/council/PRGLAC-implementation-WG-of-council

Pregnant and Lactating Women in Clinical Research. – 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 continues to provide $200,000 to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development for activities related to the implementation of the Task Force on Research Specific to Pregnant Women and Lactating Women's recommendations to better integrate pregnant and lactating women in clinical research, placing emphasis on conducting priority research projects on existing medications and therapeutics prescribed to pregnant and lactating women. The Committee requests an update in the fiscal year 2027 congressional justification on this effort.

Additionally, the Coalition strongly supports sustained and robust investments in NICHD programs that fund research aimed at improving outcomes for pregnant and lactating women. Specifically, the Coalition urges Congress to continue funding the **IMPROVE Initiative** to advance critical maternal health research and care. A historically bipartisan initiative, the IMPROVE Initiative is dedicated to reducing maternal mortality and improving pregnancy-related outcomes. Among its funded programs, the IMPROVE Initiative supports Maternal Health Research Centers of Excellence, which are tasked with developing and evaluating innovative approaches to reduce pregnancy-related complications and deaths. IMPROVE received $53.4 million in FY 2024 appropriations legislation.

The **MPRINT Hub** within NICHD serves as a national resource compiling and sharing the available knowledge, tools, and expertise in maternal and pediatric therapeutics to benefit the research, regulatory science, and drug development communities. Within MPRINT is the Knowledge and Research Coordination Center, which maintains a web portal that houses knowledge of maternal and pediatric pharmacology and therapeutics, helping researchers access the latest information on medication safety and efficacy during pregnancy. MPRINT's Centers of Excellence in Therapeutics generate tools and approaches to advance research and regulatory science in this field, including studies on medication safety for pregnant women.

Together, these resources play a crucial role in advancing maternal health by addressing the urgent need to reduce maternal mortality and ensuring the safety and efficacy of medications during pregnancy, ultimately improving health outcomes for both mothers and their children.

We know that Congress is operating in a difficult fiscal environment with many competing priorities. However, this topic touches more than 3.6 million women across the United States and their families – and it is deserving of our attention.

Thank you for considering our requests as part of the FY 2026 Labor-HHS appropriations package. Please know that members of the CAMT are here to serve as a resource for your team. Should you have questions, or require additional information, please contact CAMT Chair Lindsey Miltenberger at lindsey@swhr.org.