

Outside Witness Testimony for Lillie Heyman, Coalition Vice Chair, Coalition to Advance Maternal Therapeutics
Fiscal Year 2027 Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, U.S. Senate Appropriations Committee

The Coalition to Advance Maternal Therapeutics (CAMT)—a coalition representing nonprofit organizations, professional societies, patients, health care providers, and industry—appreciates the opportunity to provide outside witness testimony to the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) for fiscal year (FY) 2027. Our testimony includes suggestions for how we believe the U.S. Department of Health and Human Services (HHS) can further promote the safe and ethical inclusion of pregnant and lactating women in research through the ***Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)***. Specifically, the Coalition supports the public health community’s request of **\$1.8917 billion for NICHD** and requests **\$200,000** in continued funding for the Pregnant Women and Lactating Women Advisory Committee for FY 2027.

Approximately 3.6 million women give birth in the United States every year,¹ and 84% of mothers breastfeed their babies after giving birth.² Yet, due to the historical exclusion of these populations from clinical trials, there is a dearth of evidence about how safe and effective different treatments and medications are for both mother and child. In fact, studies indicate that while 90% of pregnant women take at least one prescription or over-the-counter medication during their pregnancy,³ 70% of the medications approved by the U.S. Food and Drug Administration (FDA) have no human pregnancy data, and 98% have insufficient data to determine risk to the infant.⁴ In the absence of this data, women and their families and health care providers are left with limited evidence to guide their decisions, often forcing them to rely on clinical judgment and uncertainty when determining what may be best for the patient.

We know that pregnancy does not stop a woman from becoming sick. Similarly, pregnancy does not stop a woman from living with her chronic condition; it remains an active part of her health that must still be managed. Women and families deserve clear, evidence-based information about how medications may affect their own health as well as the health of their baby during pregnancy and lactation so they can make informed decisions about their

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. (2025). *Births: Final data for 2023* (National Vital Statistics Reports, Vol. 74, No. 1). U.S. Department of Health and Human Services. <https://www.cdc.gov/nchs/data/nvsr/nvsr74/nvsr74-1.pdf>

² U.S. Department of Agriculture, Food and Nutrition Service. (n.d.). *National breastfeeding rates*. WIC Breastfeeding Support. <https://wicbreastfeeding.fns.usda.gov/social-media-library/celebrate-moms/national-breastfeeding-rates>

³ 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>

⁴ Ibid.

health care. Without such data, women may proactively take themselves off a needed medication unnecessarily, or they may take a medication that is not the safest or most effective choice for her and her baby.

Given the worsening maternal and infant health outcomes in the United States, Congress should prioritize supporting research that will answer these questions.

The safe and ethical inclusion of pregnant and lactating women in research has received strong bipartisan support over the past decade. In 2016, Congress passed the *21st Century Cures Act*, which contained language establishing the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)⁵ to improve research and guidance on medications used during pregnancy and lactation. As part of that charge, under Secretary Azar, the Task Force in 2018 released a report outlining 15 recommendations on how the federal government could better support the safe and ethical inclusion of pregnant and lactating women in clinical trials and research.⁶

While this was a significant step in the right direction, work remains to ensure that the Task Force’s goals and full potential are realized. Thanks to the findings of the PRGLAC Implementation Working Group of Council, which was formed in 2023 in response to appropriations legislation, we know that many of these recommendations are still either only “in progress or planned” or “have not yet been implemented.”⁷ The Coalition is grateful that in both 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 research, advancing PRGLAC recommendation #15: “Establish an Advisory Committee to monitor and report on implementation of recommendations, updating regulations, and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.”⁸ As the Committee considers its funding requests for FY 2027, the CAMT strongly urges it to continue this funding to ensure that these critical recommendations are put into practice and prioritized. Below is report language supported by the Coalition:

Pregnant and Lactating Women’s Advisory Committee.—The Committee continues funding for the advisory committee to continue activities within the 2020 Task Force on Research Specific to Pregnant Women and Lactating Women

⁵ 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

⁶ Ibid.

⁷ Eunice Kennedy Shriver National Institute of Child Health and Human Development. (2024). *PRGLAC implementation progress report*. https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Progress_Report.pdf

⁸ Eunice Kennedy Shriver National Institute of Child Health and Human Development. (2019, June 7). *List of recommendations from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)*. <https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations>

(PRGLAC) Implementation Plan. The Committee urges NICHD to hold at least one public meeting of the Advisory Committee and federal agencies in fiscal year 2027 to review how each agency plans to renew their commitment to implementing PRGLAC recommendations over the next five years and publish a report outlining each agency's plan discussed at the meeting by the end of fiscal year 2027.

Prioritizing the implementation of the PRGLAC recommendations has never been more important. The historical and continued exclusion of pregnant and lactating women in research continues to affect clinical care. At the same time, more women are entering pregnancy with preexisting conditions, including hypertension, type 2 diabetes, substance use disorder, anxiety, and major depression,⁹ that require ongoing treatment. Implementing PRGLAC's recommendations helps ensure that research is more effective and informative, ultimately improving maternal and infant health outcomes, reducing disparities, and supporting informed decision-making for families across the country.

On behalf of the Coalition members and the more than 3.6 million U.S. women who give birth every year, thank you for your consideration of this funding request for FY 2027. The CAMT and its members stand ready to assist if you have questions or if there is additional information we can provide to be helpful.

For questions or to discuss this request further, please contact CAMT Vice Chair Lillie Heyman at lheyman@acog.org.

⁹ Blue Cross Blue Shield. (2020, June 17). *Trends in pregnancy and childbirth complications in the U.S.* The Health of America. <https://www.bcbs.com/the-health-of-america/reports/trends-in-pregnancy-and-childbirth-complications-in-the-us>