CAMT
Coalition to Advance Maternal Therapeutics

July 30, 2024

The Honorable Diana DeGette
Committee on Energy and Commerce
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Larry Bucshon
Committee on Energy and Commerce
U.S. House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Bucshon:

The Coalition to Advance Maternal Therapeutics (CAMT), which represents medical and scientific societies, public health groups, patient advocacy organizations, and entities dedicated to the inclusion of pregnant and lactating populations in research, appreciates the opportunity to provide input on how we can fully realize the goals of the *21st Century Cures Act* and *Cures 2.0*. The Coalition recognizes the important foundation that the *21st Century Cures Act* laid in seeking to advance medical research and health care delivery in the United States and applauds you for soliciting stakeholder feedback both on whether the goals of this legislation have been met and where they could be built upon to improve health outcomes for people across the country.

Of great importance to the CAMT, the *21st Century Cures Act* called for the establishment of the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) to identify and address "gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities."[1] The Task Force's work culminated in a 2018 report to the Secretary of the U.S. Department of Health and Human Services (HHS)[2] that made 15 recommendations to improve knowledge and research on safe and effective therapeutics for pregnant and lactating populations and improve the inclusion of these populations in clinical research.

Implementation of the Task Force's recommendations will have a lasting impact on the current and future generations of pregnant and lactating women. Despite there being more than 3.5 million births in United States each year, of the 213 drugs approved by the U.S. Food and Drug Administration (FDA) from 2003-2012, just 5% included human data in the pregnancy section of their label and almost half did not contain information about medication use for lactating women.[3] This leads to situations where women, their families, and health care providers are

[1] 114th Congress. 21st Century Cures Act. Congressional Record. 2016; 130 Stat, PL 114-255. https://www.congress.gov/bill/114th-congress/house-bill/34/text. Accessed July 18, 2024.
[2] Task Force on Research Specific to Pregnant Women and Lactating Women. Report to Secretary, Health and Human Services, Congress. Bethesda, MD: NICHD; 2018. Available from: https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf. Accessed July 18, 2024.
[3] Moore K L, Persaud T VN, Torchia M G.The Developing Human: Clinically Oriented Embryology10th ed. Philadelphia, PA: Elsevier; 2015

having to make medical decisions without knowing enough about the effect of a given treatment on a woman and her infant.

Since the passage of the *21st Century Cures Act* and the release of the PRGLAC recommendations, Congress has continued to support bipartisan efforts to better include pregnant and lactating populations in research, including through the introduction of the *Advancing Safe Medications for Moms and Babies Act*. Despite these efforts, most of the PRGLAC recommendations have yet to be implemented. The Next-Generation Cures bill is a critical opportunity to move forward policies that will accelerate the inclusion of pregnant and lactating populations in clinical trials. Specifically, we ask you to include three PRGLAC recommendations in the Next-Generation Cures bill:

- **Require the FDA to remove regulatory barriers to the participation of pregnant women in clinical trials**. With the *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. We urge you to include provisions in the Next-Generation Cures bill that would require FDA 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 HHS relating to the inclusion of pregnant women as subjects in clinical research.

- **Accelerate NIH research on the safety and efficacy of medications used during pregnancy and lactation**. National Institutes of Health (NIH) research investigating the safety and efficacy of medications commonly prescribed to pregnant women and those who are lactating is significantly underfunded. We recommend the creation of a new program at NIH that provides dedicated funding to conduct priority research projects on existing medications and therapeutics prescribed to pregnant and lactating women. The new program should 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.

- **Educate stakeholders on opportunities for pregnant and lactating women to participate in clinical research.** Enrolling sufficient pregnant or lactating women in trials and registries is a significant barrier to research in these populations. We encourage you to provide funding for a new education campaign that would seek to make it easier for clinicians, patients, and families to identify research opportunities that exist for these populations. The campaign should 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 campaign should be developed in consultation with outside organizations that have subject-matter expertise in pregnant women, lactating women, and infants, and all campaign information should be available via a public-facing website.

Key aims of the *21st Century Cures Act* were to improve patient health and to support biomedical research. Ensuring that pregnant and lactating populations are appropriately included in research—via the implementation of the PRGLAC recommendations—should be prioritized to ensure that we can achieve optimal outcomes for both mothers and their babies.

As you work to build upon the legacies of the *21st Century Cures Act* and *Cures 2.0*, we urge you to prioritize efforts aimed at improving the inclusion of pregnant and lactating populations in research to ensure optimal outcomes for women and their infants. Fulfilling the goals of the PRGLAC Task Force hold tremendous potential for improving maternal health outcomes in the United States.

Thank you for your time and consideration.

Sincerely,

The Steering Committee of the Coalition to Advance Maternal Therapeutics

Constituted of:

American College of Obstetricians and Gynecologists

Elizabeth Glaser Pediatric AIDS Foundation

Epilepsy Foundation

March of Dimes

Preeclampsia Foundation

Society for Maternal-Fetal Medicine

Society for Women's Health Research