



December 15, 2023

The Honorable Carolyn Mazure, PhD  
Chair of the White House Initiative on Women's Health Research  
Washington, D.C. 20500

Dear Dr. Carolyn Mazure,

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, we would like to applaud the White House for the creation of the first-ever White House Initiative on Women's Health Research. We are writing to express our interest in the initiative and request that the White House prioritize the inclusion of pregnant and lactating populations in clinical trials and research as part of the recommendations presented to the Biden-Harris Administration.

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. Of the 4 million women in the United States who give birth each year, 89% take at least one prescription medication during their pregnancy.<sup>1</sup> 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.<sup>2</sup> For women who live with chronic conditions like type 2 diabetes, narcolepsy, epilepsy, lupus, or hypertension, the lack of data creates challenges for management of their condition(s) during pregnancy, putting both moms and infants at risk.

In 2016, Congress took bipartisan, bicameral action within the *21<sup>st</sup> 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).<sup>3</sup> In 2018, under Secretary Azar, the Task Force identified 15 recommendations for the federal government to support the safe and ethical inclusion of pregnant and

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<sup>1</sup> 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>

<sup>2</sup> Ibid.

<sup>3</sup> 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](https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Implement_Plan_083120.pdf)

lactating women in clinical trials and research, which is a critical component of women's health across the lifespan.<sup>4</sup> Still, many of these recommendations have yet to be put into practice.

For example, one of the requirements in the *21<sup>st</sup> Century Cures Act* was harmonization of FDA human subjects protections with the Federal Policy for the Protection of Human Subjects, or the "Common Rule," which would remove pregnant women as a vulnerable population in research. This was to be completed by 2019. However, four years later, the FDA has still not harmonized with the Common Rule, thus creating increased barriers for the inclusion of pregnant women in research.

We appreciate the steps that the Biden-Harris Administration has already taken in this space and the value it places on research. Specifically, we commend the Administration's Blueprint for Addressing the Maternal Health Crisis,<sup>5</sup> which acknowledges the critical role that clinical trials play for overall maternal health and lifelong women's health. Understanding the safety and efficacy of medications and therapeutics on pregnant and lactating populations is an important part of that conversation.

Still, as the Administration endeavors to close longstanding research gaps and drive innovation, we hope that the Administration will consider prioritizing this critical population of women. The Coalition stands ready to provide our expertise and knowledge as the initiative develops its recommendations and action plan.

On behalf of the 4 million moms who give birth each year and their babies, we thank you for your attention to this critical matter. Please contact Rebecca Abbott at [rabbott@smfm.org](mailto:rabbott@smfm.org), (202) 644-9296 should you have any questions.

Sincerely,

The Steering Committee of the Coalition to Advance Maternal Therapeutics

Constituted of:

*American College of Obstetricians and Gynecologists*

*March of Dimes*

*Society for Maternal-Fetal Medicine*

*Society for Women's Health Research*

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<sup>4</sup> Ibid.

<sup>5</sup> The United States Government. (June 2022). White House Blueprint for Addressing the Maternal Health Crisis. The White House. p. 12.