

Public Comments submitted to the Task Force on Research Specific to Pregnant Women and Lactating Women by the Coalition to Advance Maternal Therapeutics
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July 1, 2020

On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), I am pleased to submit public comments to the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC or “the Task Force”).

CAMT was launched in 2014 with the goal of better understanding the safety and efficacy of prescription drugs, therapeutics, and vaccines used during pregnancy and breastfeeding. The coalition and its member organizations are committed to raising awareness among policy makers and industry about the need to include pregnant and lactating women in clinical trials, where appropriate, to close gaps in knowledge, and ultimately improve the health of women and their families. To help achieve that goal, CAMT led the charge to enact the legislation that created PRGLAC, and we have been closely following the Task Force’s efforts.

We want to thank members of the Task Force and its working groups for lending their time and expertise to develop a comprehensive plan to implement recommendations from the September 2018 PRGLAC Report to the Secretary of Health and Human Services (HHS) and the US Congress. The forthcoming implementation plan is critical to transitioning to a new status quo of greater inclusion of pregnant women and lactating women in clinical trials. We are pleased that a final plan will be delivered to the HHS Secretary this fall, and we are prepared to work with federal agencies and lawmakers to implement the plan’s steps.

In response to discussion at the June 24 Task Force meeting, members of CAMT would like to underscore the importance of the Task Force’s recommendation to “implement a proactive approach to protocol development and study design to include pregnant women and lactating women in clinical research” (Recommendation 10). The forthcoming plan must include concrete steps to implement Recommendation 10 and its subparts. Recommendation 10 is critical to moving toward a presumption of inclusion of pregnant and lactating women in clinical trials, rather than exclusion. The current practice of excluding pregnant women and lactating women from clinical trials perpetuates gaps in treatment options for this population. For instance, while research related to COVID-19 moves forward at lightning speed, clinical trials for COVID-19 treatments and vaccines have not included pregnant women and lactating women. This is despite the fact almost 3,000 pregnant women with COVID-19 have been hospitalized, and these women are at increased risk for intensive care unit admission and receipt of mechanical ventilation than nonpregnant women.¹ The failure of researchers to collect data on this population forces expecting and new mothers with COVID-19 to make treatment decisions without sufficient evidence. Further, if new vaccines become available without data to recommend them for use in pregnant women and lactating women, millions of expecting and new mothers will be excluded from future mass immunization campaigns, putting their health and the health of their infants and the public at risk. PRGLAC must incorporate strong steps for Recommendation 10 to ensure pregnant women and lactating women are included in clinical trials, when appropriate, going forward.

Members of CAMT would also like to express our support for including actionable steps to address liability concerns in the final implementation plan (Recommendation 7). While we appreciate that Task Force and working group members felt they lacked the expertise to fully develop a liability-mitigation strategy for research in pregnant women and lactating women as called for in the PRGLAC’s 2018

recommendations, we would urge the Task Force to include steps to incentivize research in this population.

Thank you for the opportunity to provide comments. We thank members of PRGLAC and its working groups for their efforts to advance research in pregnant women and lactating women and look forward to working with this esteemed group to advance our shared goals.

¹ Centers for Disease Control and Prevention. Data on COVID-19 during Pregnancy. Accessed June 30, 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/special-populations/pregnancy-data-on-covid-19.html>.