CAMT

Coalition to Advance Maternal Therapeutics

March 24, 2021

President Joseph R. Biden, Jr.
United States of America
Washington, DC 20230

Vice President Kamala Harris
United States of America
Washington, DC 20230

Dear President Biden and Vice President Harris,

On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), we write to offer our perspective on important steps that your administration can take to improve the lives of pregnant and lactating Americans and align federal policies related to inclusion of this population in clinical trials.

The Coalition to Advance Maternal Therapeutics (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. CAMT and its member organizations are committed to raising awareness among policy makers and industry about the need to include pregnant and lactating people in clinical trials, where appropriate, to close our gaps in knowledge, and ultimately improve the health of women and their families.

Each year, nearly four million people in the U.S. give birth[i] and more than three million breastfeed their infants.[ii] Although more than 90 percent of pregnant people report taking a medication during pregnancy, only 1 percent of clinical trials mention the words pregnancy or pregnant and only 0.5 percent mention breastfeeding or lactation.[iii] Not enough is known about the effect of most drugs on a woman or a pregnancy, or the ways in which pregnancy may alter the uptake, metabolism, and efficacy of medication. For example, the rate at which certain drugs are excreted through the kidney may increase by 50% during pregnancy. People with chronic diseases, such as diabetes, hypertension, depression and asthma, are becoming pregnant, and they need safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond. In the context of COVID-19, pregnant and lactating people were largely excluded from clinical trials for treatments and vaccines, leaving them and their clinicians without clear evidence on safety and efficacy to guide clinical decision-making.

Without reliable data, people who are pregnant or nursing may decide to stop taking necessary medications, increasing risks for both mother and child. In other cases, people may choose not to initiate breastfeeding or may wean earlier than desired because they lack information about the extent of drug transfer into human milk, the potential impacts of the drug on milk production, and the impact of exposure to the infant. Even when drug safety data is available, such data is usually limited, and often does not address how the changes of pregnancy and breastfeeding will affect dosage.

We can and must do better for pregnant and lactating people.

To address this problem, CAMT advocated for the creation of the federal Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) which was established under the 21st Century Cures Act (P.L. 114-255) to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for

pregnant and lactating women. In 2018, PRGLAC released a Report to Congress that included 15 detailed recommendations to promote the inclusion of pregnant and lactating people in clinical trials.[iv] PRGLAC took these recommendations further in an implementation report to the Secretary of Health and Human Services (HHS) released in August 2020 (PRGLAC Implementation Plan).[v]

We write now to request that your administration act as quickly as possible to harmonize agency-wide policies to make clear that default research protocols should be inclusion, and not exclusion, of pregnant and lactating people in clinical trials as recommended and described in the PRGLAC Implementation Plan.

In January 2019, HHS and other agencies implemented changes to the so-called "Common Rule"[vi] regulations for the protection of human subjects in research, including the removal of pregnant women as an example of a "vulnerable population" that requires additional ethical scrutiny prior to participating in research. While this was an important first step, we write now to request that HHS Office for Human Research Protections (OHRP) issue additional guidance to signal that inclusion of pregnant women and lactating women in research, with appropriate protections, is expected. Such additional HHS guidance could serve as a valuable educational document for institutional review boards (IRBs) and clinical researchers across the country. We likewise request that the Food and Drug Administration (FDA) update its policies to reflect the 2019 change to the Common Rule.

We further ask that the National Institutes of Health and FDA require clinical trial sponsors to provide justification for exclusion of pregnant or lactating people from their study design in any applications to the government. Such guidance could shift expectations for research collaborations across federal agencies and/or with non-governmental research entities, including industry, from a culture of protecting pregnant and lactating people *from* research to protecting them *through* research. Requiring this justification may be implemented without any statutory changes and this policy change would be a clear signal that your administration is committed to tackling this issue.

We note for future conversations that even with the revisions to the Common Rule described herein, ethical concerns and the potential for liability remain for research conducted during pregnancy and lactation. While no single solution to these concerns may be apparent, we encourage your administration to continue conversations centered on liability issues as a mix of protections and incentives that may partly address these issues.

Finally, we encourage you to extend PRGLAC's charter or establish another advisory committee with a similar range of expertise to ensure that the steps recommended by PRGLAC are implemented and progress is monitored. As described herein, much work is left to do to improve treatment options for pregnant and lactating people, and PRGLAC's charter expired March 13, 2021. Oversight from a dedicated group of experts is needed to continue to make progress in establishing therapeutic options for pregnant and lactating people.

We thank you for your time and consideration and urge you to take steps to continue this important work. CAMT, and its member organizations, stand ready to assist you. If you have questions, please contact Elizabeth Karan at ekaran@artemispolicygroup.com.

Coalition to Advance Maternal Therapeutics
American Academy of Pediatrics
American Association of Colleges of Pharmacy
American College of Nurse-Midwives
American College of Obstetricians and Gynecologists
Association of Maternal & Child Health Programs
Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society
March of Dimes
Maternal Mental Health Leadership Alliance
National Association of Nurse Practitioners in Women's Health
Organization of Teratology Information Specialists
Preeclampsia Foundation
Society for Birth Defects Research and Prevention
Society for Maternal-Fetal Medicine
Society for Women's Health Research
Treatment Action Group (TAG)
WomenHeart: The National Coalition for Women with Heart Disease
2020 Mom

CC: Jerry Menikoff, Director, Office for Human Research Protections, Department of Health & Human Services
Francis Collins, Director, National Institutes of Health
Janet Woodcock, Acting Commissioner, Food & Drug Administration
Carrie D. Wolinetz, Chief of Staff, Office of the Director and Associate Director for Science Policy, National Institutes of Health
Jodi B. Black, Director, Office of Clinical Policy and Programs, Food & Drug Administration

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[i] https://www.cdc.gov/nchs/fastats/births.htm
[ii] https://www.cdc.gov/breastfeeding/data/facts.html
[iii] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf
[iv] https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf
[v] https://www.nichd.nih.gov/sites/default/files/inline-files/PRGLAC_Implement_Plan_083120.pdf
[vi] Codified at 45 CFR 46, Subpart A, and titled the “Federal Policy for the Protection of Human Subjects.”