**Who We Are**

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 advocated for the creation of a federal task force (the Task Force on Research Specific to Pregnant Women and Lactating Women, PRGLAC) to identify and address gaps in knowledge regarding safe and effective therapies and vaccines for pregnant and lactating women.

CAMT 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 our gaps in knowledge, and ultimately improve the health of women and their families.

**The Problem**

Each year, nearly four million women in the U.S. give birth and more than three million breastfeed their infants. Nearly all of these women will take a medication or receive a vaccine. Yet not enough is known about the effect of most drugs on a woman and her pregnancy, or the ways in which pregnancy may alter the uptake, metabolism, and effect of medication. For example, the rate at which certain drugs are excreted through the kidney may increase by 50% during pregnancy. As more women with chronic diseases, such as diabetes, hypertension, depression and asthma, are becoming pregnant, safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond are needed.

Without reliable data, women who are pregnant or nursing may decide to stop taking necessary medications, increasing risk for both mother and child. In other cases, women 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 are available, such data is usually limited, and often does not address how the changes of pregnancy and breastfeeding will affect dosage.

The lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding is, in part, due to the fact that the Food and Drug Administration (FDA) has not historically required or otherwise incentivized drugs to be tested among pregnant or breastfeeding women. In fact, the vast majority of trials have excluded this population. Efforts are
underway to revise and update how women are treated for the purposes of research, but we need special
and immediate attention to this issue in the context of COVID-19 to move us forward toward innovation
and cures.

**COVID-19**

As research related to COVID-19 moves forward at lightning speed, CAMT urges corporate and federally-
funded researchers to include pregnant and lactating women in the development of vaccines and
therapeutics.

There remain significant gaps in understanding the effects of COVID-19 on pregnant women and lactating
women and their infants, and there are few recommendations specific to these populations regarding the
virus. Based on available information, pregnant people seem to have the same risk of COVID-19 as adults
who are not pregnant. However, much remains unknown and research from previous coronaviruses, such
as SARS-coV and MERS-coV, identified pregnant women as particularly vulnerable relative to the general
population. Accordingly, we urge you to ensure that pregnant women and lactating women are included
in any clinical research related to vaccines and treatments for COVID-19. It is critical that they not be left
behind the general population as we search for a vaccine.

We are disappointed that pregnant women and breastfeeding women are explicitly excluded from the
Adaptive COVID-19 Treatment Trial currently underway at the National Institutes of Health. Failure to
gather clinical trial data on these populations forces pregnant and lactating women diagnosed with
COVID-19 and their health care providers to make care decisions based on incomplete evidence.

We are also concerned that new vaccine candidates will become available without sufficient data to
recommend them for use in pregnant and lactating women. This would prevent millions of expecting and
new mothers from participating in any future mass immunization campaigns, putting their health and the
health of their infants, and the public at risk.

Rather than excluding pregnant and lactating women from research, we urge industry and federal
agencies to ensure the development of vaccines and treatments suitable for this population by investing
in early non-clinical studies to provide for the eventual enrollment of these women in late-stage clinical
trials.

CAMT stands ready to work with you to remove any barriers and work with researchers to ensure that
pregnant women and lactating women are included in this critical research. To draw on our assistance,
please contact Kerri Wade at kwade@smfm.org.

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iii U.S. Food and Drug Administration, “Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling,” 2014.