

June 7, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA-2018-D-1201-0001 “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials; Draft Guidance.”

To Whom It May Concern:

On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), we appreciate the opportunity to provide comment on the U.S. Food and Drug Administration’s (FDA) draft guidance for industry entitled, “Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials.”

CAMT is comprised of a dozen organizations whose members and supporters believe strongly that every woman and family should have the information necessary to make empowered, informed, science-based decisions about pregnancy and childbearing. We are dedicated to ensuring that our government facilitates the generation of data about the safety and effectiveness of medications taken by pregnant and nursing mothers. As such, CAMT appreciates FDA’s effort to issue guidance that provides clearer parameters for the inclusion of pregnant women in clinical trials. We would urge the agency, however, not simply to permit and facilitate the inclusion of pregnant women in trials, but also to actively encourage drug and device developers to pursue such studies. FDA should send a strong signal to drug and device developers that they should be moving steadily toward including pregnant and lactating women in clinical trials on a routine basis in all appropriate cases.

While we appreciate the focus in this guidance on pregnancy, we question the apparent exclusion of lactating women. CAMT respectfully requests that FDA either include information about lactating women in this guidance or issue a similar guidance specific to the inclusion of lactating women in trials. It is imperative that any studies done in pregnant women also examine the impact of medications on breastfeeding and the nursing infant.

Further, CAMT maintains that any research guidance should proceed with a presumption of inclusion, i.e., that pregnant and lactating women should be included in research unless otherwise determined inappropriate. Today it is no longer acceptable to exclude pregnant and lactating women from studies as a matter of course. This shift in perspective would go a long way toward encouraging all drug developers to include pregnant and lactating women in studies. We also note that the requirement that the father of the fetus provide consent for research with direct benefit solely to the fetus is inconsistent with consent requirements for pediatric studies which only require the consent of one parent.

We encourage FDA to further define “experts in obstetrics” to include the full breadth and depth of expertise – including physicians, researchers, breastfeeding experts and affiliated women’s health care providers with expertise in treating and researching pregnant and lactating women. It will be essential

to ensure that appropriate background and experience is brought to such studies to ensure they are designed, executed, and analyzed appropriately.

Once again, CAMT commends FDA for taking an important step toward ensuring that pregnant or lactating women who may require medication to treat either pregnancy-related conditions or underlying chronic or acute medical conditions and their health care providers have better and more complete information to inform treatment decisions. However, we encourage FDA to include lactating women explicitly in this guidance as well as to further encourage sponsors to utilize innovative study design, leverage existing data sources such as pregnancy exposure registries and multicenter clinical trials where appropriate, and engage in long-term. Should you have any questions or require any clarification, please do not hesitate to contact Katie Schubert, SMFM's chief advocacy officer, at (202) 517-6122 or kschubert@smfm.org.

Sincerely,

Coalition to Advance Maternal Therapeutics Steering Committee*

*Steering Committee Members: American Academy of Pediatrics | American College of Obstetricians & Gynecologists | March of Dimes | Society for Maternal-Fetal Medicine