

July 5, 2016

Dear Representative:

We, the undersigned organizations, as members of the Coalition to Advance Maternal Therapeutics (CAMT), a coalition of organizations dedicated to advancing the health and well-being of women and children, are writing in strong support of H.R. 5219, the Safe Medications for Mothers and Babies Act, and urge you to cosponsor this important piece of bipartisan legislation.

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 effects of most drugs on a woman and her pregnancy, or the ways in which pregnancy may alter the uptake, metabolism, and effect of medication. As more women with chronic diseases such as diabetes, hypertension, depression, and asthma become pregnant, the need for safe and effective medications to manage these ongoing conditions throughout their pregnancy and beyond is 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.

**H. R. 5219 is an important first step toward ensuring that pregnant and breastfeeding women have better information about the effects of medications on them and their babies.** This bipartisan legislation will advance research and information sharing on medication use during pregnancy and breastfeeding, and detail ways to promote safer medication use by establishing a public-private taskforce comprised of key federal agencies, medical experts, patient advocates, and others.

The task force will report to Congress regarding:

- A plan to identify and address gaps in knowledge and research regarding safe and effective medications for pregnant women and lactating women;
- Ethical issues around the inclusion of pregnant women and lactating women in clinical research; and,
- The state of federal research involving pregnant and lactating women, as well as recommendations for coordination and collaboration on related research.

The bill also requires an annual report from the Food and Drug Administration (FDA) on the number of new drug applications that contain data about the use of the drugs in pregnancy and breastfeeding, and the number of approvals with post-market study requirements in pregnant or breastfeeding women.

We fully endorse this important legislation and hope that it can be passed or included in a broader package of legislation later this year. With your cosponsorship of this legislation, we will be one step

closer to better and more accurate information about the effects of medications during pregnancy and breastfeeding.

Please contact Jessica Wixson in Congresswoman Herrera Beutler's office at [Jessica.Wixson@mail.house.gov](mailto:Jessica.Wixson@mail.house.gov) or Elizabeth Brown in Congresswoman Castor's office at [Elizabeth.Brown@mail.house.gov](mailto:Elizabeth.Brown@mail.house.gov) with any questions, or to cosponsor the Safe Medications for Moms and Babies Act. Should you have any questions for the Coalition to Advance Maternal Therapeutics, please contact Katie Schubert, Washington Representative for the Society for Maternal-Fetal Medicine, at [kschubert@dc-crd.com](mailto:kschubert@dc-crd.com) or (202) 484-1100.

Sincerely,

Academy of Breastfeeding Medicine  
American Academy of Pediatrics  
American College of Nurse Midwives  
American Congress of Obstetricians & Gynecologists  
Association of Maternal & Child Health Programs  
Association of Women's Health Obstetric and Neonatal Nurses  
March of Dimes  
Society for Maternal-Fetal Medicine  
Society for Women's Health Research