

October 19, 2016

The Honorable Lamar Alexander
Chairman
Committee on Health Education Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20515

The Honorable Patty Murray
Ranking Member
Committee on Health Education Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20515

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20510

The Honorable Frank Pallone
Ranking Member
House Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20510

Dear Chairman Alexander, Ranking Member Murray, Chairman Upton and Ranking Member Pallone:

On behalf of the signatories below, members of the Coalition to Advance Maternal Therapeutics, we are writing to urge you to retain section 8, "Task Force on Research Specific to Pregnant Women and Lactating Women," of S. 2745, the Advancing NIH Strategic Planning and Representation in Medical Research Act, in any final package reconciling the 21st Century Cures Act and the Senate's Innovations for Healthier Americans initiative.

This language is nearly identical to HR 5219, the Safe Medications for Moms & Babies Act, which enjoys bipartisan support in the House of Representatives. The language would create a much-needed interagency task force to advance research on medications taken by pregnant and breastfeeding women. Additionally, we encourage you to create a mechanism by which the U.S. Food & Drug Administration (FDA) will report information to Congress on the data it collects on this subject.

Each year, almost four million women in the United States give birth, and 75% of them breastfeed their infantsⁱⁱⁱ. There are 73.7 million women of childbearing age in the U.Sⁱⁱⁱ. Nearly all of these women will take a medication or receive a vaccine during pregnancy, but little is known about the effect of most drugs on a pregnant woman or her child, or the ways in which pregnancy may alter the uptake, metabolism and effect of medication. This gap in understanding has become increasingly problematic as more women with chronic disease become pregnant, requiring medications to manage chronic conditions throughout pregnancy. While the federal [LactMed](#) database collects and distributes the available information on drug levels in human milk, significant gaps still remain on the impact of drugs on breastfeeding women and their children.

The lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding is due in part to the fact that FDA does not require drugs to be tested among pregnant or lactating mothers^{iv}. In fact, the vast majority of drug trials explicitly exclude this population. 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 on the infant. Even when drug safety data is available, there is usually limited data about how the changes of pregnancy and breastfeeding affect the proper dosage.

In addition to the Task Force language, we urge you to include the second provision of HR 5219 in any final package, which requires an annual report from FDA on approved new drug applications with information on pregnancy and lactation. It is vital for Congress and stakeholders to understand what information is currently being collected by FDA in order to assess gaps, opportunities and needs.

Our organizations have come together to support progress toward the inclusion of pregnant and breastfeeding women in clinical trials, so that consumers and health care professionals have the most up-to-date and accurate information on the safety and efficacy of drugs that women are prescribed while pregnant or breastfeeding. We strongly urge you to include these two important provisions in any legislation that advances the goals of 21st Century Cures and Innovations, given their impact on such a large population. The better information and data we have on the effects of medications during pregnancy and breastfeeding, the healthier our mothers and babies will be. Please do not hesitate to contact Becca Nathanson with the American Congress of Obstetricians and Gynecologists at rnathanson@acog.org, Katie Schubert with the Society for Maternal-Fetal Medicine at kschubert@smfm.org or Jaimie Vickery with the March of Dimes at jvickery@marchofdimes.org should you have any questions.

Sincerely,

American Academy of Pediatrics
American College of Nurse Midwives
American Congress of Obstetricians and Gynecologists
Association of Maternal & Child Health Programs
Association of Women's Health, Obstetric and Neonatal Nurses
March of Dimes
National Association of Nurse Practitioners in Women's Health
North American Society for Psychosocial Obstetrics and Gynecology
Society for Maternal-Fetal Medicine
Society for Women's Health Research

ⁱ Martin JA, et al. "Births: Final data for 2013." *National vital statistics reports*; 64 .1. (2015).

ⁱⁱ McDowell, et al. "Breastfeeding in the United States: findings from the national health and nutrition examination surveys, 1999-2006". *US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics*, 2008.

ⁱⁱⁱ Annual Estimates of the Resident Population for Selected Age Groups by Sex for the United States, States, Counties, and Puerto Rico Commonwealth and Municipios: April 1, 2010 to July 1, 2013 Source: U.S. Census Bureau, Population Division. Release Date: June 2014

^{iv} 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