

April 5, 2016

Dear Senate HELP Committee Members:

On behalf of the Coalition to Advance Maternal Therapeutics (CAMT), the undersigned organizations are writing in strong support of the section titled "Task Force on Research Specific to Pregnant Women and Lactating Women" included in the legislation pertaining to the NIH Strategic Plan and Inclusion in Clinical Research being marked up on April 6, 2016 in the Senate Health Education Labor and Pensions (HELP) Committee.

Research in pregnant and breastfeeding women is decades behind that for other populations, despite the increasing number of women already taking medications when they become pregnant or beginning to do so during pregnancy or lactation. The lightning-speed innovation seen in other areas of health care has not been reflected in research and development involving pregnant and breastfeeding women. We believe that this task force would accelerate the pace of cures and streamline discovery and development of medications for pregnant and breastfeeding women by improving federal interagency communication and coordination.

Currently, federal agencies are engaged in separate efforts to advance research and data on therapeutics in pregnancy and lactation. With the establishment of this task force, agencies will be encouraged to continue this valuable work, but with better communication, coordination and collaboration to ensure that research is complementary and not duplicative. In addition, there is a need for synchronization to ensure that existing variations, such as the appropriate research endpoints, are resolved. In other areas within HHS, coordinating committees have been effective in establishing consensus and fostering innovation.

Given the new FDA labeling guidance related to pregnancy and lactation, we also believe that an annual report from FDA to Congress on the implementation of this new guidance would be beneficial to determining potential next steps for the inclusion of pregnant and lactating women in clinical trials. Such a report would establish baseline metrics to track drug applications that include pregnant and breastfeeding women. Without that inclusion, the new information provided on drug labels will be of little use and may cause greater confusion when it is based on limited or no data. As more drug manufacturers submit label changes or new drug applications that comply with the final rule, we should take the opportunity to begin tracking that data and encourage greater inclusion. FDA is tracking this information; Congress should demonstrate support by directing the agency to report on it.

Again, we urge you to support this critical section establishing the Task Force on Research Specific to Pregnant Women and Lactating Women in this legislation on April 6, 2016. We appreciate the initial steps of creating this important task force, and look forward to seeing it implemented once it becomes law. Should you have any questions, please do not hesitate to contact Katie Schubert with the Society for Maternal-Fetal Medicine at kschubert@dc-crd.com or (202) 484-1100.

Sincerely,

American Academy of Pediatrics
American College of Nurse-Midwives
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
Society for Maternal-Fetal Medicine
Society for Women's Health Research