

The Honorable Diana DeGette  
United States House of Representatives  
2111 Rayburn House Office Building  
Washington, DC 20515

The Honorable Fred Upton  
United States House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

December 27, 2021

Dear Representatives DeGette and Upton:

The 15 undersigned organizations, representing professional associations, patient advocacy organizations, research and medical institutions, and women's health stakeholders, greatly appreciate your continued leadership in support of innovative biomedical research and patient access through your work on the Cures 2.0 Act (H.R. 6000). This legislation presents an important opportunity not only to stimulate greatly needed medical and public health progress, but to also continue the original legislation's legacy of furthering women's health.

As you work with your colleagues to advance this bill, we urge you to amend the legislation to include provisions encouraging the harmonization of agency-wide policies to ensure that research protocols for clinical trials include pregnant and lactating people, where appropriate, and providing adequate authority and resources for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) to implement the [recommendations of the Task Force on Research Specific to Pregnant Women and Lactating Women \(PRGLAC\)](#). By including new provisions in the Cures 2.0 Act specifically targeting pregnant and lactating populations, this bill could help close critical gaps in knowledge to improve the health of women and their families.

PRGLAC was established as part of the original 21<sup>st</sup> Century Cures Act (P.L. 114-255) to provide a path forward on the inclusion of pregnant and lactating people in research—and while progress has been made, much remains to be done.

Despite the fact that each year nearly 4 million people in the United States give birth<sup>1</sup> and more than 3 million breastfeed their infants,<sup>2</sup> not enough is known about the effect of most drugs on a woman or a pregnancy, or the ways in which pregnancy may alter one's response to medication. We saw this reality firsthand during the COVID-19 pandemic, when there was a significant delay in getting pregnant people included in the COVID-19 vaccine trials. Due in part to poorly justified concerns about the safety of medications and vaccines during pregnancy, these families missed an important health prevention opportunity, and many have suffered as a result.

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<sup>1</sup> <https://www.cdc.gov/nchs/fastats/births.htm>

<sup>2</sup> <https://www.cdc.gov/breastfeeding/data/facts.html>

The Cures 2.0 legislation provides an optimal opportunity to signal that you are committed to prioritizing the protection of pregnant and lactating people *through* research—shifting the narrative of protecting pregnant and lactating people from research—and to serving as a leader for those who will undoubtedly look to this legislation for guidance. When determining study design, pregnant and lactating populations must be included at the outset, as described and recommended in the PRGLAC Implementation Plan. Doing so will equip us with critical data on the safety of drugs taken by pregnant and nursing mothers, advance our scientific knowledge, and further the health and well-being of women and their children.

We thank you for your time and consideration and urge you to improve the Cures 2.0 Act by ensuring that it will continue to advance our shared goal of including pregnant and lactating people in research. We stand ready to assist in any way and to answer any questions. If you would like to discuss this letter, please contact Lindsey Horan at [lindsey@swhr.org](mailto:lindsey@swhr.org).

Sincerely,

2020 Mom

American Academy of Allergy, Asthma & Immunology, with and on behalf of  
the Vaccines and Medications in Pregnancy Surveillance System

American College of Obstetricians and Gynecologists

Association of Maternal & Child Health Programs

Coalition to Advance Maternal Therapeutics

Elizabeth Glaser Pediatric AIDS Foundation

Endocrine Society

March of Dimes

Maternal Mental Health Leadership Alliance

National Association of Nurse Practitioners in Women's Health

Organization of Teratology Information Specialists

Society for Birth Defects Research and Prevention

Society for Maternal-Fetal Medicine

Society for Women's Health Research

WomenHeart: The National Coalition for Women with Heart Disease