

Congress of the United States
Washington, DC 20515

September 15, 2023

The Honorable Robert Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Janet Woodcock
Principal Deputy Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Kaveeta Vasisht
Associate Commissioner for Women's Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf, Principal Deputy Commissioner Woodcock, and Associate Commissioner Vasisht:

As members of Congress who are concerned about maternal and child health, we write to request that the Food and Drug Administration (FDA) take swift action to protect the lives of pregnant and lactating women and their infants by aligning federal policies related to inclusion of these populations in clinical research. We encourage the FDA to expeditiously harmonize regulations and guidance governing the inclusion of pregnant women in clinical research with the Federal Policy for the Protection of Human Subjects (the "Common Rule").¹ Given how critical the pregnant and postpartum periods are, a lack of a solid research and evidence base poses a direct risk to the lives and health of both mothers and infants.

Historically, pregnant and lactating women have been excluded from clinical trials, leading to large evidence gaps that are impacting the health outcomes of mothers and infants. The *21st Century CURES Act*, signed into law in 2016, included the bipartisan *Safe Medications for Moms and Babies Act*, which required the Department of Health and Human Services (HHS) to establish a Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). The Task Force provided released a report with 15 recommendations outlining key steps for federal agencies, industry, and stakeholders to carry out these recommendations.²

Additionally, the *21st Century CURES Act* mandated that HHS, to the extent possible, harmonize the differences between the Common Rule and FDA's own regulations governing research in

¹ 45 C.F.R. Part 46, Subpart A.

² U.S. Department of Health and Human Services. (2018, September). *List of recommendations from the Task Force on research specific to pregnant women and lactating women (PRGLAC)*. Eunice Kennedy Shriver National Institute of Child Health and Human Development. <https://www.nichd.nih.gov/about/advisory/PRGLAC/recommendations>

human subjects by December 13, 2019. However, four years later, the FDA has still not fulfilled the request of Congress, risking the lives of mothers and infants across the nation.

The United States has one of the highest maternal mortality rates in the developed world – a rate that has been rising since 2000 and that has increased by over 63% between 2019 and 2021.³ For women of color and people in living in rural communities, those numbers are much higher.⁴ The leading causes of maternal deaths include maternal mental health conditions, excessive bleeding, cardiac or coronary conditions, infection, thrombotic embolism, cardiomyopathy, and hypertensive disorders of pregnancy.⁵ Maternal Mortality Review Committees have determined that 80% of maternal deaths are preventable.⁶ Preventing these deaths will take a well-rounded approach, and research is a critical component to saving mothers' lives.

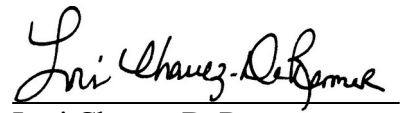
The inclusion of pregnant and lactating women in clinical trials has garnered bipartisan support within Congress and across Republican and Democratic Administrations. Past and current Administrations emphasized the need for increased participation of these populations to improve maternal health and reduce maternal mortality.^{7 8}

For these reasons, we urge the FDA to work expeditiously to harmonize with the Common Rule, helping address gaps in knowledge and research to advance the health of moms and babies. We also request a briefing within 90 days of receipt of this letter on the agency's plan to include these populations in clinical trials.

Sincerely,



Kathy Castor
Member of Congress



Lori Chavez-DeRemer
Member of Congress

³ Hoyert DL. Maternal mortality rates in the United States, 2021. NCHS Health E-Stats. 2023.

DOI: <https://dx.doi.org/10.15620/cdc:124678>.

⁴ Ibid.

⁵ Centers for Disease Control and Prevention. (2022, September 19). *Four in 5 pregnancy-related deaths in the U.S. are preventable*. Centers for Disease Control and Prevention. [https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html#:~:text=The%20leading%20underlying%20causes%20of,bleeding%20\(hemorrhage\)%20\(14%25\)](https://www.cdc.gov/media/releases/2022/p0919-pregnancy-related-deaths.html#:~:text=The%20leading%20underlying%20causes%20of,bleeding%20(hemorrhage)%20(14%25))

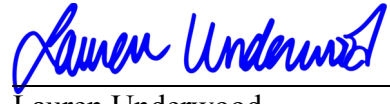
⁶ Ibid.

⁷ Office of the of the Surgeon General (OSG). The Surgeon General's Call to Action to Improve Maternal Health [Internet]. Washington (DC): US Department of Health and Human Services; 2020 Dec. PMID: 33661589.

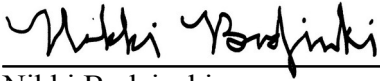
⁸ *White House blueprint for addressing the Maternal Health Crisis*. The White House. (2022, June). <https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf>



Maria Elvira Salazar
Member of Congress



Lauren Underwood
Member of Congress



Nikki Budzinski
Member of Congress



Mark Pocan
Member of Congress



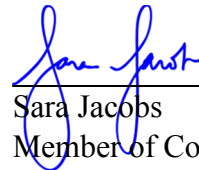
Young Kim
Member of Congress



Julia Letlow
Member of Congress



Colin Z. Allred
Member of Congress



Sara Jacobs
Member of Congress

CC: Commissioners Andi Lipstein Fristedt, James Sigg, Heidi Rebello, RAMD Richardae Araojo, Carol Cave