

Dr. Francis S. Collins
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dr. Stephen Hahn
Commissioner U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

June 15, 2020

Dear Dr. Collins and Dr. Hahn:

We, the undersigned organizations, write regarding the work that the National Institutes of Health and the Food and Drug Administration are doing to prioritize the rapid development of treatments and vaccines for the 2019 Novel Coronavirus (COVID-19). As your agencies work to combat this historic pandemic, **we urge you to consider including specific groups of women -- pregnant and lactating women, as well as women of color and women who live in poverty -- in COVID-19 research.**

This letter reinforces several points that were set forth in three previous letters sent to you about this topic from Senators Patty Murray (WA) and Elizabeth Warren (MA) dated March 10, 2020; the Coalition to Advance Maternal Therapeutics dated March 18, 2020; and 62 Members of Congress, led by Representatives Lauren Underwood (IL) and John Lewis (GA), dated June 5, 2020.

First, knowledge about the impact of COVID-19 during pregnancy and postpartum is limited, with significant gaps in understanding the impact of COVID-19 specifically on pregnant and lactating women and their infants. This knowledge gap will only be exacerbated if pregnant and breastfeeding women – who are often excluded from research and clinical trials due to the complexity of ensuring their safety and that of their children – are not included in ongoing research.

Second, stress and anxiety have reached unprecedented rates during the pandemic, and childbearing women are caught in a swirl of unanswered questions about how the coronavirus will impact them, their pregnancies, and their newborn infants. These stressors, coupled with social isolation, are increasing the rates of anxiety and depression for pregnant women and new mothers, which in turn can increase the risk of poor birth outcomes and poor health outcomes for both mother and baby.

Third, women of color and women who live in poverty are disproportionately affected by both mental health issues and the current pandemic. These groups of women are also often excluded from research.

Thus we urge you to take the following actions to ensure these vulnerable individuals have access to preventive measures in the face of the COVID-19 pandemic:

1. Incentivize and ensure the development of vaccine and treatment candidates suitable for use in pregnancy and lactation by investing in early non-clinical studies to provide for the eventual enrollment of these women in late-stage clinical trials.
2. Proactively remove barriers and work with sponsors and researchers to ensure that women who are pregnant and/or lactating, as well as women of color and women who live in poverty, are included in this critical research.
3. Consult with the Task Force on Research Specific to Pregnant and Lactating Women (PRGLAC) whose experts are charged with providing critical guidance to the Secretary of Health and Human Services on how to address the unique needs of pregnant and lactating women.

We thank you for all that your agencies are doing to protect American citizens during this pandemic, and we seek to ensure that women in high-risk populations – namely those who are pregnant or lactating,

women of color, and women who live in poverty -- are likewise protected *through* research and not *from* research.

Sincerely,

2020Mom

American College of Obstetricians and Gynecologists

Association of Maternal and Child Health Programs

Black Women's Health Imperative

California Black Women's Health Project

Every Mother Counts

Fairfax County (Virginia) Health Department

Johns Hopkins Women's Mood Disorders Center

Lifeline4Moms Center at the University of Massachusetts Medical Center

March of Dimes

Maternal Mental Health NOW

Maternal Mental Health Leadership Alliance

Mental Health America of Ohio

MomCongress

Mother Nurture Midwifery

National Association for Children's Behavioral Health

National Association of Nurse Practitioners in Women's Health

North American Society for Psychosocial Obstetrics and Gynecology

Perinatal Health Equity Foundation

Postpartum Resource Center of New York

Postpartum Support International

Postpartum Support Virginia

Serenity Solutions

Society for Women's Health Research

Speaking for Moms and Babies, Inc.

University of Illinois at Urbana-Champaign School of Social Work