

United States Senate

WASHINGTON, DC 20510

March 08, 2020

VIA ELECTRONIC DELIVERY

Dr. Rochelle Walensky, MD, MPH
Director, Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Director Walensky:

We write regarding the role that the Centers for Disease Control and Prevention (CDC) plays in providing public health guidance to the American people and ensuring that pregnant and lactating individuals have access to safe and effective COVID-19 vaccines. As the Nation's lead agency in providing public health guidance and expertise, we appreciate your ongoing efforts in helping Americans during this devastating pandemic, which has killed over 525,000 people in this country alone. We therefore respectfully request that you update Congress on the CDC's efforts to provide the American people with the latest guidance and recommendations regarding the COVID-19 vaccines' safety and efficacy for pregnant and lactating individuals.

While the overall situation with regards to COVID-19 cases and deaths is improving, providing us with hope for better days ahead, we understand that many hurdles remain and that safe and effective vaccines are our best way to get individuals, families and businesses back on their feet.

There are more than 3.7 million people who give birth in the United States each year, the majority of whom breastfeed their infants. In particular, individuals identifying as women make up the backbone of our healthcare workforce. For example, they hold over three-fourths of all full-time, year-round jobs in healthcare occupations, and an estimated 330,000 of these health workers were pregnant or breastfeeding during the early stages of the COVID-19 vaccine rollout. On top of that, millions of women work in frontline and essential jobs, such as in healthcare, restaurants, retail and housekeeping. Many such jobs are low-paying and are often filled by women of color. It is well-established that people of color, including Black, Hispanic/LatinX and American Indian /Alaska Native people, are more likely to become severely ill or die from COVID-19. Further, pregnant individuals in particular are at increased risk of becoming severely ill or dying from COVID-19 infection compared to non-pregnant individuals, and they are also at increased risk of adverse pregnancy outcomes, such as pre-term birth.

While experts agree there is no reason to think the current COVID-19 vaccines would react differently in pregnant people, data are needed to support evidence-based recommendations for use of these vaccines in pregnant people, similar to the available data informing recommendations in non-pregnant people. No COVID-19 vaccines authorized for emergency use by the Food and Drug Administration (FDA) included pregnant and lactating individuals in their clinical trials, despite calls for their inclusion by medical experts, professional organizations and the FDA. Thankfully, that is now changing. We appreciate the thoughtful and thorough process

of the CDC's Advisory Committee on Immunization Practices (ACIP) to review the available data of the authorized vaccines and recommend that the vaccines be made available to pregnant and lactating people who choose to be vaccinated. There are now more than 10,000 individuals enrolled in CDC's V-Safe smartphone app, who identify as pregnant and who have received a COVID-19 vaccine; there have been no serious concerns raised by the patient or provider community with regards to the safety and efficacy of either vaccine.

It is for these reasons that, with respect to pregnant individuals in particular, twenty-one maternal vaccination experts, including the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP) and the Society for Maternal-Fetal Medicine (SMFM) recently reinforced that the COVID-19 vaccines must be made available to pregnant individuals. This is consistent with the recommendation provided by the CDC, which states that pregnant individuals may be vaccinated if they choose. Further, ACIP has included individuals at high risk of developing severe COVID-19 illness, which includes pregnant individuals, in its recommended Phase 1c priority group.

Unfortunately, despite these recommendations, pregnant and lactating individuals who choose to get vaccinated are receiving conflicting information from a variety of resources, including vaccine administrators and healthcare providers, with some even being turned away from vaccination sites. Given the CDC's role in coordinating and leading the Nation's public health response to the COVID-19 pandemic, we respectfully request that the agency:

- Prioritize pregnant and lactating people when it comes to data analysis and reporting;
- Clarify that pregnant people are included in Phase 1c; and
- Encourage states to follow ACIP's recommended distribution phases.

We ask that you provide us with an update by March 26, 2021 on these items, as well as efforts to ensure pregnant and lactating individuals, their clinicians and vaccination sites have the latest recommendations and guidance regarding the safety and efficacy of COVID-19 vaccines in this population. We also urge you to work with Congress in ensuring that the CDC, as well as clinicians and state, local, territorial and Tribal public health departments, have the resources they need to continue to address this public health crisis.

Sincerely,



Tammy Duckworth
United States Senator



Jeffrey A. Merkley
United States Senator



Elizabeth Warren
United States Senator



Tammy Baldwin
United States Senator



Tim Kaine
United States Senator



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United States Senator



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