

Congress of the United States

Washington, DC 20510

February 25, 2022

VIA ELECTRONIC DELIVERY

Dr. Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dr. Robert M. Califf, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Walensky and Dr. Califf:

We write regarding access to the COVID-19 vaccine booster (“fourth shot”) for moderately or severely immunocompromised people, who have received three primary doses or two primary doses and a booster shot. While we commend the efforts of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to quickly adjust guidance during this ever-changing pandemic, we have heard from constituents who are immunocompromised—or have loved ones who are immunocompromised—that they are being wrongfully turned away from pharmacies when they try to get their fourth shot. Others remain unaware that they should be seeking a fourth shot. As many States and municipalities move towards loosening pandemic-related restrictions, it is paramount that people who are at high risk of severe disease and death from COVID-19 get the protection they need through vaccination, and that the administration provide clear guidance that ensures the health and well-being of this population.

Millions of Americans could be considered at high risk for becoming severely ill, or even dying, from COVID-19—including the elderly, pregnant people, people with rare diseases or multiple comorbidities or those living in congregate settings. However, for the purposes of this letter, we are particularly concerned about moderately or severely immunocompromised people (“immunocompromised”). According to CDC’s current guidelines, people are considered moderately or severely immunocompromised if they meet a variety of criteria, including if they are receiving active cancer treatment; are organ or stem cell transplant recipients; are living with moderate or severe primary immunodeficiency; are taking immunosuppressants, including corticosteroids or are living with advanced or untreated HIV infection. For such patients, a fourth COVID-19 shot could be lifesaving.

Vaccination remains the leading public health prevention strategy to end the COVID-19 pandemic, and the CDC guidelines regarding a booster shot on top of a third dose of a primary series for immunocompromised people underscore the importance of getting vaccinated. This population is especially vulnerable to hospitalization or death from COVID-19, and research shows that many immunocompromised patients “produce few to no antibodies in response to the vaccine or an infection,” resulting in an insufficient immune response to the SARS-CoV-2 virus after the standard vaccine regimen. That is why it is vitally important that the guidance and

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policies provided by the administration are crystal clear and communicated effectively and efficiently.

The FDA recently updated its immunocompromised population guidance in the COVID-19 vaccine Emergency Use Authorizations (EUAs) for the Pfizer/BioNTech and Moderna vaccines. Currently, for the Pfizer/BioNTech vaccine, immunocompromised people ages 12 and up are eligible to receive a third primary dose of the vaccine, as well as a booster (a fourth shot), while immunocompromised people ages 5 to 11 are eligible for a third primary dose only. For immunocompromised adults 18 years of age and older, the Moderna vaccine is an additional option for the third primary dose plus booster vaccine regimen. The CDC also updated its website to include this information, and the administration has provided factsheets to healthcare providers, vaccine recipients and caregivers. Unfortunately, many people, including doctors, pharmacists and other essential personnel—as well as patients—find it difficult to stay abreast of the most current recommendations. Further, immunocompromised individuals who received the Johnson & Johnson (J&J) vaccine as their initial series currently lack any guidance on further doses, other than the blanket recommendation that all people who received the J&J vaccine receive an mRNA dose.

The American people rely on the administration, and especially the FDA and CDC, to provide clear, easy-to-understand public health advice, guidance and messaging. As such, it is important that your agencies continue to engage with relevant stakeholders, such as State and local governments, health departments, pharmacy workers, patients and healthcare and public health professionals, who work on the ground with affected groups. While we appreciate the administration's recently updated booster shot recommendations, more clarity is necessary to keep the American people safe from severe illness and death from COVID-19. We therefore respectfully request that you respond to the following questions:

1. What educational and awareness campaigns have your agencies implemented to ensure that providers, particularly in the fields of oncology, transplantation, neurology, infectious disease, rheumatology and any other disciplines that are routine prescribers of immunosuppressants, understand clearly that certain immunocompromised patients are eligible—and could benefit from—a fourth shot?
2. What educational or awareness campaigns have your agencies implemented to ensure that immunocompromised people are aware of the recommendation to obtain a fourth shot?
3. What guidance has been provided to immunocompromised people who initially received the J&J vaccine? What is being done to ensure pharmacies and pharmacy workers have the most up-to-date information regarding changes in vaccine schedules, since the timing of the guidelines frequently changes, so that employers can ensure appropriate staffing and training?
4. Have your agencies heard from patients, providers, healthcare workers or caregivers regarding patients being denied a fourth shot that they might be eligible for? If so, what follow-up actions have you taken to ensure providers, patients, advocacy groups and other relevant stakeholders understand the latest guidance and recommendations? and

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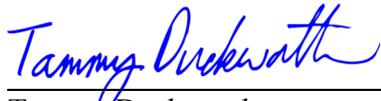
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5. Given the recommendation of receiving a third primary dose was announced after some of the immunocompromised population received their boosters (at the time “third” dose), are there plans to publish an alternative vaccine schedule to account for all dosing recommendations? This question is particularly important for the Moderna vaccine because the booster dose is half the full dose.

Finally, the constantly changing landscape of the COVID-19 pandemic may require that the definition of “immunocompromised” changes as more data become available. Until then, we urge you to engage soon, and frequently, with people who may be immunocompromised but who do not currently fall under the CDC’s specifically outlined categories with regards to getting a fourth shot.

It is crucial that the CDC communicate effectively with the American public and healthcare professionals on the availability of the fourth shot for the moderately or severely immunocompromised population. Thank you for your attention to this important matter. Please reach out to Stephanie DeLuca (stephanie_deluca@duckworth.senate.gov) and Zakiya Chambers (Zakiya_chambers@duckworth.senate.gov) on my staff if you have any questions.

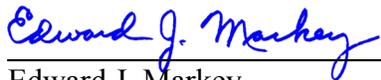
Sincerely,



Tammy Duckworth
United States Senator



Tina Smith
United States Senator



Edward J. Markey
United States Senator

Cc: Jeffrey Zients, White House COVID-19 Response Coordinator