

April 5, 2022

HealthyWomen is submitting the following written comment to the FDA's Vaccines and Related Biological Products Advisory Committee (Vrbpac) for the meeting with docket number FDA-2022-N-0336 in support of the use of COVID-19 booster doses to protect Americans from COVID-19.

The COVID-19 pandemic has served to highlight the immense efficacy of vaccines in terms of protection from serious illness and death. Throughout the pandemic, there have been ongoing clinical studies to monitor the safety and efficacy of the authorized vaccines. The research has shown that all authorized COVID-19 vaccines remain highly effective against the virus. This includes the added protection which the booster dose provides against new variants of COVID-19.

A recent study from the Center for Disease Control and Prevention (CDC) showed that the third booster dose decreased COVID-19 hospitalizations considerably as compared to those who had not received the third dose.

COVID-19 still poses a serious threat and new variants continue to reach our borders such as we are currently seeing with the BA.2 strain that has become the new dominant strain in the United States. This will require us to remain diligent in our assessment of the current vaccine regimen's ability to protect our population and to provide guidance around the use, of and access to, additional protection options as needed.

HealthyWomen supports the FDA's recent authorization of the use of a second booster dose for older Americans and those living with immunocompromising conditions and encourages the continued analysis of the use of this protective option for a broader population as needed against new variants of this virus.

While we believe it is important for fully vaccinated adults to receive a booster shot in accordance with FDA approval and CDC recommendations, we also feel it is of critical importance to continue our efforts to encourage family and friends who have yet to receive a COVID-19 vaccine to do so as soon as possible. This is especially true for women who are often the primary caregivers for their family. Ensuring protection against the ongoing strains of this disease is vital to maintaining their ability to remain healthy and able to continue caring for their loved ones.

We thank this committee for your tireless work on this issue and for diligently remaining at the forefront of this evolving threat to our health and well-being. We will continue to share these critical updates within our community to encourage women, men and children who are eligible for the COVID-19 vaccine and boosters to take this important step toward prevention.