January 25, 2023

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-2810.

Founded in 1988, HealthyWomen is the leading nonprofit women’s health information source with a mission of educating women ages 35 to 64 to make informed health choices. Throughout the years, we have informed healthcare consumers and healthcare providers (HCPs) about advances in women’s health, from the latest information on diseases and conditions to milestones pertaining to access to care. We ensure that women have accurate, balanced, evidence-based information so they can make educated decisions in partnership with their healthcare providers. We also educate our audience regarding innovations in research and science, as well as changes in policy that affect women’s access to treatment and care so that women are prepared to self-advocate for better health outcomes.

HealthyWomen believes that ensuring access to effective preventive treatment options for illness is a top wellness priority for women and one that has become even more critical in the last few years as a result of the pandemic.

We appreciate the diligent work by the FDA in conducting consistent and thorough assessments of the current protections available as this virus mutates. Open and transparent communication from the FDA around how the science is evolving to keep up with the virus will help all Americans to better understand their options and the best next steps to ensure their ongoing health.

We look forward to hearing more from the FDA at the upcoming VRBPAC meeting on how it is assessing the next phase of recommended vaccines for COVID-19, including the use of the new bivalent boosters. As we enter the fourth year of this pandemic, we are seeing the effects of continually spreading misinformation, vaccine fatigue and ongoing vaccine hesitancy. We believe the FDA plays an important role in helping organizations like ours to address these barriers head on within our communities and are eager to hear how the FDA is evolving its approach in light of these challenges.

Despite the progress made in providing broad access to effective vaccines against this virus, there is still more to be done to ensure equitable protection. While many in our society are pushing to move on and disregard many of the safety protocols that we know have been effective in protecting the most vulnerable, we must not allow pandemic fatigue to cloud the truth that millions of Americans are still very much at risk from this deadly virus.

An estimated 7 million immunocompromised individuals in the U.S., who have limited options for protection against COVID-19, remain isolated and frustrated, waiting on the sidelines as others
return to normal life. We know that current vaccines and treatments don’t work for everyone, and some are unable to take any of the options currently offered. This includes organ transplant patients, and those who rely on medications that suppress their immune systems do not feel protected. People living with conditions that compromise the strength of their immune systems, such as HIV, cancer and many autoimmune diseases, feel exposed. And many older Americans who manage their chronic conditions through multiple medications are now severely limited in their options for treatment given the fear of drug interactions.

In July 2022, Healthy Women was joined by 20 advocacy organizations on a letter to the FDA urging the agency to continue its extraordinary commitment to ensuring that we have a variety of COVID-19 treatment and prevention options in place to address new variants as they arise and that broaden protections for everyone, but particularly for the most vulnerable among us. Antibody treatments in particular show incredible promise for both prevention and treatment of COVID-19 for patients living with weakened immune systems. They also hold lower risk of drug interaction for individuals living with chronic diseases who rely on multiple medications.

Without a diverse array of treatment and prevention options, our society’s health and the health of our economy will be held hostage by the unpredictable nature of future variants. Moving forward, it is critical that the U.S. have a strong public health arsenal of multiple tools for both the prevention and treatment of COVID-19.

We look forward to hearing the FDA’s discussion at the January 26 meeting of VRBPAC and will continue to do our part to provide our communities with the most accurate and up-to-date information on the use of vaccines as the pandemic continues to evolve.

Thank you for the opportunity to comment.

Sincerely,

Martha Nolan
Senior Policy Advisor