

Thank you for the important opportunity to speak today to the FDA's Center for Drug Evaluation and Research, Advisory Committee hearing with respect to its proposed market withdrawal of Makena and its five generic forms, the only class of treatments to help prevent spontaneous, recurrent preterm birth.

My name is Martha Nolan, and I am the Senior Policy Advisor for HealthyWomen.

HealthyWomen is the nation's leading nonprofit women's health information source dedicated to educating and empowering women ages 35-64 to make informed decisions about their healthcare. We educate healthcare consumers and providers about advances in women's health, from the latest information on diseases and conditions to various milestones pertaining to access to care. We ensure that women have accurate, balanced, evidence-based information on innovations in research and science, and changes in policy that affect their access to treatment and care so they are prepared to self-advocate for better health outcomes.

HealthyWomen urges the FDA to maintain patient access to Makena or 17P, an important therapy that healthcare providers say can help protect mothers and babies from preterm birth.

We believe that removing access will have a detrimental impact on the health of women and birthing people at risk of recurrent preterm birth and will not impact all women equally.

Preterm birth is an urgent public health crisis in our country with approximately [one in 10 babies](#) born prematurely each year. According to the CDC, each year 20,000 babies die in the U.S. and the prematurity rate has, after declining a fraction from 2019 through 2020, increased by 4% in 2021 to 10.48%, the highest level since 2007.

It is well documented that complications related to premature birth are the largest contributors to infant death in the U.S. and globally, and that a history of preterm birth is a significant risk factor for recurrent preterm birth. Further, a woman's quality of life and overall well-being can be profoundly impacted by early delivery.

While prematurity can be traumatic for any woman and child, it is an issue that affects women of color and their babies much more frequently. The preterm birth rate among U.S. Black women remains nearly [50% higher](#) than the rate among all other women.

Currently, Makena and its five generic equivalents are the only FDA-approved treatments available for pregnant women at risk for recurrent preterm birth. We

are concerned that removing this option for healthcare providers will only worsen the crisis for those at risk for preterm birth.

The health and well-being of a newborn begins with the health of the mother. 17P in all of its forms has played a significant role in protecting the health of mothers and their babies for nearly a decade. Proposing to withdraw 17P from the market would leave the women's reproductive healthcare community without an ACOG guidance-recommended standard of care and an uncertainty on treatment options.

We feel that 17p and its generic equivalents need to continue to be available to healthcare providers to prescribe, as they need, for their patients at risk of this complex and multifactorial condition while additional studies are conducted with adequate representation from the populations most affected by preterm birth.

As a women's health advocacy organization, we believe women should have access to necessary therapies and this is one of them. During a global pandemic, when pregnant women and the healthcare providers who serve them continue to face a unique set of challenges, Makena and all its generic forms should not be withdrawn, and pregnant women should continue to have access to treatment options that have potential to better their health and the health of their babies.

Thank you for the opportunity to speak today.