FDA withdraws approval of drug meant to prevent preterm births

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The U.S. Food and Drug Administration on Thursday formally withdrew

its approval of a drug that was meant to prevent preterm births.

Sold as Makena, the drug was first approved in 2011 under the FDA's accelerated approval program, but subsequent research questioned the medication's effectiveness and noted serious side effects that included blood clots and depression.

"It is tragic that the scientific research and medical communities have not yet found a treatment shown to be effective in preventing preterm birth and improving neonatal outcomes—particularly in light of the fact that this serious condition has a disparate impact on communities of color, especially Black women," FDA Commissioner Dr. Robert Califf said in an agency news release.

"Fundamentally, however, the touchstone of FDA drug approval is a favorable benefit-risk assessment; without that favorable assessment, the drug should not have the status of being FDA-approved," Califf added.

The decision follows a meeting of one of the agency's advisory committees last October where panel members voted 14-1 to recommend that Makena be pulled from the market. FDA officials have long said they want to withdraw the medication because of lack of evidence that it works and its side effects.

"It would be unfair to keep the drug on the market and expose especially vulnerable populations to an ineffective therapy," panel member Dr. Mark Hudak, a pediatrician at the University of Florida College of Medicine, said during the committee meeting, NBC News reported.

In withdrawing its approval of Makena, FDA officials noted the agency is keenly aware of the fact that preterm birth is a significant health risk that disproportionately affects Black women.

"We acknowledge at the outset the serious problems of preterm birth with respect to both maternal and neonatal health and the contribution of institutional forces that have led to health disparities, including preterm birth, among Black women," said FDA chief scientist Namandjé Bumpus. "Nothing in this opinion today is intended to minimize these concerns—to the contrary, our hope is that this decision will help galvanize further research."

In the past, some groups have defended the drug.

"The need for an effective treatment for preterm birth is great," the American College of Obstetricians and Gynecologists has said. "Makena and its associated generics represent the only treatment currently available to obstetrician-gynecologists to help prevent this condition."

But a 2019 international study of 1,700 women found the drug didn't reduce premature births but could cause side effects that included blood clots and depression.

Just last month, drugmaker Covis Pharma pulled Makena from the marketplace.

"While we stand by Makena's favorable benefit-risk profile, including its efficacy in women at highest risk of preterm birth, we are seeking to voluntarily withdraw the product and work with the FDA to effectuate an orderly wind-down," Covis chief innovation officer Raghav Chari said in a company statement at the time.

Preterm birth can lead to serious health conditions and even infant death. About 10% of U.S. births happen before 37 weeks, CDC data shows.

More information: The U.S. Centers for Disease Control and Prevention has more on preterm birth.