Hydroxyprogesterone caproate—or “17P”—has been approved since 2011 and is the only FDA-approved class of treatments to help prevent spontaneous, recurrent preterm birth in the United States. However, in 2020, the FDA proposed withdrawing 17P in all its forms, including the branded product and its five generic versions, based on conflicting efficacy data from two studies composed of vastly different populations, one inclusive of women in the U.S. most vulnerable to preterm birth and one not. The FDA further stated that if 17P is withdrawn from the market, compounding it for the specific indication “to reduce the risk of recurrent preterm birth” would not be allowed.

The original approval trial demonstrated that 17P substantially reduced the rate of recurrent preterm delivery among women who were at particularly high risk for preterm birth. A majority of the participants in this trial were African American (59 percent) and other women of color in the United States.

A subsequent confirmatory trial conducted primarily outside of the U.S. after 17P was FDA-approved included a predominantly white population. While this trial reaffirmed the safety of 17P, it did not confirm the same benefit for a very different population of women compared to those in the United States at the highest risk for preterm birth.

The removal of 17P would leave providers and their patients without FDA-approved treatment options to prevent a second, or subsequent, spontaneous preterm birth. Despite multiple formal requests to consider additional data and alternate ways to study this class of drug’s efficacy before depriving women of access, FDA made its recommendation without engaging the most important stakeholders—patients at highest risk. Even after a meta-analysis that pooled data from 31 trials concluded that both 17P injections and vaginal progesterone reduced the risk of preterm birth before 34 weeks in high-risk women with singleton pregnancies, FDA persisted in this recommendation.

The Preterm Birth Prevention Alliance (PBPA) is a newly formed coalition of organizations concerned about the state of preterm birth in the United States and its disproportionate impact on women of color, and is guided by the following principles:

• We believe in standing up for the needs of moms and babies of every race and ethnicity, and fighting for a more inclusive healthcare system that gives everyone an equal chance of having the best possible outcomes.

• We believe that regulators need to hear directly from women facing prematurity, and the providers who treat them, about their real-world experiences before withdrawing the only FDA-approved treatment option.

• We believe that evidence of efficacy for women of color in the U.S.—who are at highest risk of adverse outcomes—should be more determinative than a lack of demonstrated treatment efficacy on primarily white women from other countries.
The Preterm Birth Prevention Alliance is a coalition of maternal and women’s health advocates who share a common concern about the state of preterm birth in the United States and the proposed market withdrawal of 17P, the only FDA-approved class of treatments to help prevent spontaneous, recurrent preterm birth. Formed in 2021 by the National Consumers League, we seek to improve preterm birth outcomes in the United States by maintaining access to safe, FDA-approved treatment options and advocating for more diverse medical research that adequately represents the experiences of women and newborns of color. Women of color need a seat at the table.*

The Preterm Birth Prevention Alliance is working together to advocate for at-risk pregnant women and infants’ health interests and demand the immediate suspension of any FDA actions to limit access to 17P.

We also request that:

- The FDA hold a public hearing to fully consider all available 17P data, review additional research methods to further study 17P while maintaining patient access, and hear stakeholder perspectives.
- Additional studies be conducted to collect and make publicly available other post-market data to better understand potential variations in the efficacy of 17P across different populations.
- Public and private actors invest in research to improve understanding of the causes of disparate outcomes across diverse populations and the impact that a lack of approved treatment options could have on affected moms and babies.

**ABOUT US**

The Preterm Birth Prevention Alliance is a coalition of maternal and women’s health advocates who share a common concern about the state of preterm birth in the United States and the proposed market withdrawal of 17P, the only FDA-approved class of treatments to help prevent spontaneous, recurrent preterm birth. Formed in 2021 by the National Consumers League, we seek to improve preterm birth outcomes in the United States by maintaining access to safe, FDA-approved treatment options and advocating for more diverse medical research that adequately represents the experiences of women and newborns of color. Women of color need a seat at the table.*

**ALLIANCE PARTNERS**


*Initial support for the Preterm Birth Prevention Alliance has been provided by Covis Pharma