



About the Preterm Birth Prevention Alliance



WHY WAS THE PRETERM BIRTH PREVENTION ALLIANCE FORMED?

The Preterm Birth Prevention Alliance (PBPA) formed as a coalition of organizations concerned about the state of preterm birth in the United States and its disproportionate impact on women of color. PBPA's mission is to improve preterm birth outcomes in the United States by preserving access to safe, Food and Drug Administration (FDA) approved treatment options and advocating for more diverse medical research that adequately represents the experiences of women and newborns of color.

Despite the high physical, emotional, and financial toll that preterm birth continues to take on our country—and disproportionately on women and families of color—not enough therapeutic tools currently exist to prevent it. Yet in 2020, the FDA proposed that the only therapy approved by the agency to reduce the risk of recurrent preterm birth, hydroxyprogesterone caproate or “17P”, be withdrawn from the market in all its forms—including the branded product and five generic versions.

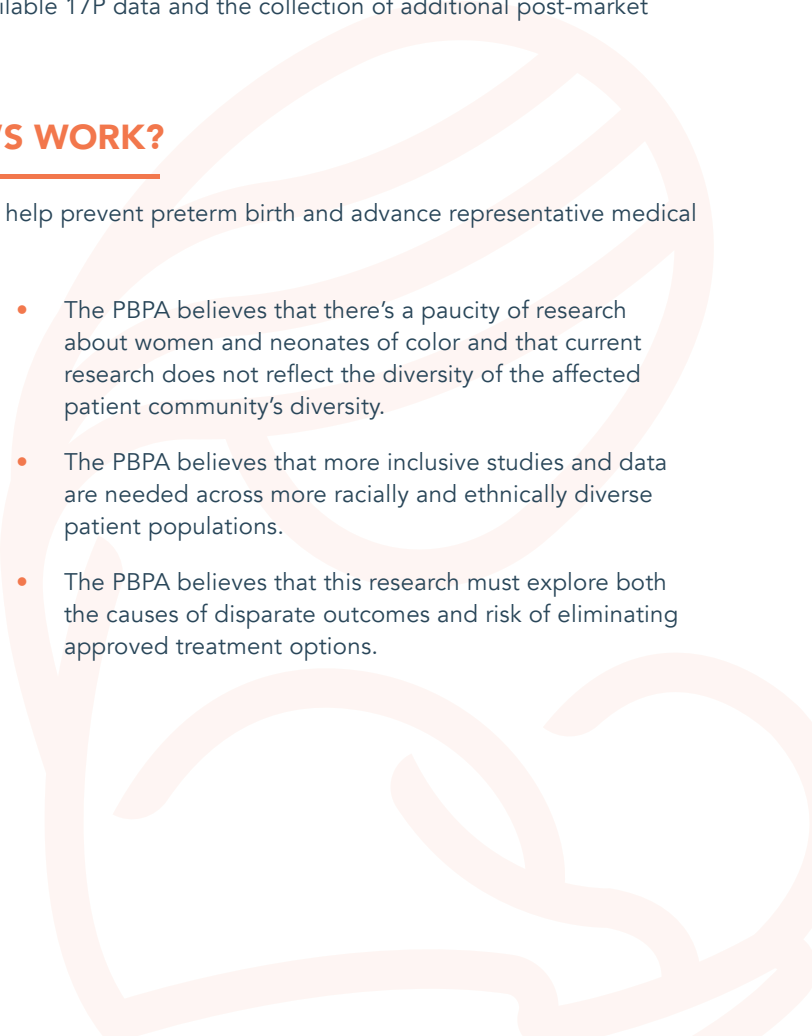
The Alliance is urging the FDA to ensure continued access to FDA-approved treatment options to reduce the risk of recurrent preterm birth and to hold a public hearing to fully consider all available 17P data and the collection of additional post-market data to determine for which populations 17P is most effective.



WHAT PRINCIPLES GUIDE THE PBPA'S WORK?

The Alliance's work to protect access to FDA-approved therapy to help prevent preterm birth and advance representative medical research is guided by the following principles:

- The PBPA believes 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.
- The PBPA believes 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.
- The PBPA believes 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 PBPA believes that leaving at-risk, pregnant women without a standard of care for spontaneous, recurrent preterm birth may further exacerbate systemic inequities in maternal and infant health.
- The PBPA believes that there's a paucity of research about women and neonates of color and that current research does not reflect the diversity of the affected patient community's diversity.
- The PBPA believes that more inclusive studies and data are needed across more racially and ethnically diverse patient populations.
- The PBPA believes that this research must explore both the causes of disparate outcomes and risk of eliminating approved treatment options.





WHAT ARE THE SPECIFIC OBJECTIVES OF THE PBPA?

The Alliance requests that:

1. 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.
2. 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.
3. 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.



WHY IS THE PBPA ADVOCATING FOR THE FDA TO GRANT A PUBLIC HEARING?

The PBPA believes that regulators need to hear directly from affected communities when making decisions about 17P in the absence of no other approved alternatives. A broad array of stakeholder voices will help ensure that regulators fully understand how a potential removal could leave patients and providers significantly disadvantaged in the fight against prematurity and underscore the need to collect additional post-market data to determine for which populations 17P is most effective.



WHO ARE THE ORGANIZATIONS INVOLVED?

Formed in 2021 by the National Consumers League, the Alliance includes leading maternal and women's health advocates collaborating to drive the strategic direction and activities of the Alliance. Current PBPA member organizations include:



HOW IS THE PROJECT FUNDED?

Initial support for the Preterm Birth Prevention Alliance is provided by Covis Pharma. We welcome the support of others to bolster the Alliance's work related to the state of preterm birth in the United States and its disproportionate impact on women of color.



HOW CAN I JOIN THE PRETERM BIRTH PREVENTION ALLIANCE?

Organizations interested in joining the Alliance or supporting its efforts should visit pretermbirthalliance.org to learn more.

