

## Black Women's Orgs: FDA Should Set Up Equity-Focused Advisory Panel

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More than 30 Black women's organizations say FDA should set up an advisory committee focused on racial and gender equity in clinical trials and revise its Institutional Review Board policies to ensure Black women, femmes, girls and gender-expansive people are represented in clinical trials and equitably compensated for their participation.

The recommendations [are part of a broad Black Reproductive Justice Policy Agenda](#) released Tuesday (June 15) by In Our Own Voice: National Black Women's Reproductive Justice Agenda, Interfaith Voices for Reproductive Justice and SisterLove Inc. The groups say they worked on the agenda with more than 30 Black women's organizations and Reproductive Justice activists.

Clinical trials have long failed to include women, including women of color, in sufficient numbers to be able to make informed assessments about their health outcomes, the groups say. Black women especially are recruited for clinical trials significantly less than white men, they add.

[The organizations point to FDA's 2015 approval of Addyi](#), a drug to treat female sexual dysfunction. One of the studies that assessed whether the drug was safe to use with alcohol reportedly recruited 23 men and only two women, making the study population 92% male. The National Women's Health Network has also pointed out that in four of the initial clinical trials for Addyi, an overwhelming majority of participants, 89%, identified as white.

In October 2019, FDA approved Gilead's Descovy for pre-exposure prophylaxis. However, because Gilead did not include cisgender women in its clinical trials -- [a point of contention for advocates and FDA's own advisory panel](#) -- FDA did not approve the drug for use by cisgender women, despite the fact that heterosexual contact drives 85% of women's HIV infections, the Black Reproductive Justice Policy Agenda says.

Black women are disproportionately affected by those kinds of approval decisions because Black women account for 57% of the nation's HIV diagnoses, and Black women are more likely to be diagnosed with HIV in their lifetime compared to Hispanic and white women, the Black women's organizations say.

**To ensure equitable participation and compensation for participation in clinical trials, the organizations call for FDA to establish an advisory committee that is diverse and inclusive of Black researchers and focuses on racial and gender equity in trials.**

FDA also should improve its guidance for Institutional Review Boards and clinical investigators on ethical protocols for compensation of research participants, the policy agenda says.

Another key part of the effort to include more diverse populations in clinical trials is to recognize and respond to communities of color's mistrust in the medical enterprise. Black women have a long history of medical mistrust, which is compounded by the fact that few providers are Black themselves -- 5% of practicing physicians are Black and only 2% are Black women. There's also a reluctance to participate in research, including clinical trials, which creates subpar and ill-informed research, treatment and care for Black individuals, the policy paper says.

"Reproductive Justice can only be achieved when Black women, femmes, girls, and gender-expansive individuals are represented fairly and equitably in scientific research that has the potential to improve their health. Achieving

this goal is hampered by Black and Brown individuals' understandable suspicion of the medical system--and medical research in particular," the organizations say.

**The organizations' policy agenda calls for the medical and research communities to engage trusted community-based organizations and cultural brokers who can help educate people on the risks and benefits of clinical trials and recruit participants from specific populations.**

"They can help ensure that research protocols are culturally sensitive and inclusive, and help cultivate trust and good-faith with community members. Studies show that, when CBOs lead or contribute to research in their own communities, community members are more likely to be comfortable and participate in research," the organizations say. -- *Beth Wang* ([bwang@iwppnews.com](mailto:bwang@iwppnews.com))

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