Atlanta Black Women Leaders On PrEP Respond To The FDA’s Decision To Approve Descovy

The Atlanta Black Women Leaders on PrEP met to discuss the FDA’s decision NOT to include vaginas (I know what I said) as an approved body part for Descovy, which is a drug now approved for use as PrEP to provide protection against HIV. Worldwide women make up the majority (52%) of the HIV cases. Nearly 40 years in this epidemic, women have consistently been in the background, as an “after-thought” and that has to stop!!! We don’t get to the end of the HIV epidemic without including strategies and resources to prevent new diagnoses among women. Decisions that are made to include some groups and not others send a message that our lives as women don’t matter.   
Yes, the group is frustrated and concern about Gilead’s decision to move forward with this drug without women in clinical trials to produce the efficacy results needed. But we are equally frustrated with the FDA’s decision to move forward with the approval of this drug for PrEP being fully aware that women would be excluded and we are also frustrated with advocates and leaders of our workforce who see this decision as a victory when all those impacted by HIV will not benefit the same.   
According to CDC, lifetime risk of HIV based on race and gender is 1 in 20 Black men, 1 in 48 Black women, 1 in 48 Latino men, 1 in 132 White men, 1 in 132 Latino women, and 1 in 880 White women. Lifetime risk of HIV for gay men 1 in 2 Black gay men, 1 in 4 Latino gay men, and 1 in 11 White gay men. Black women are disproportionately impacted at a greater rate than some of the subpopulations included for use of this drug for HIV prevention.   
We also recognize that the sample size needed to determine efficacy for women (500,000 women need to be included in the study) is unrealistic compared to the sample size used for men which was only 5,000 and 80% of the men were white and transgender women who had fewer than 100 participants.   
The Atlanta Black Women Leaders on PrEP have identified several areas where we will work with CDC, Gilead, and our local HIV workforce to ensure that Black women are prioritized in HIV prevention  
1. Submit a formal request to Gilead to conduct the research with Black women who have higher lifetime risk than any group based on race and gender except Black men. Since the FDA committee approved this drug for all men based on a sample size that was overwhelmingly white men, we ask that you make the same provisions by determining what the sample size needs to be if we focus on Black women.  
2. The group will develop a risk assessment tool that includes Black women who are perceived to be at risk and those who are not. We will share this tool with CDC, other federal, national, and local partners.   
3. We will work with our local PrEP champion Dr. Tosha Rogers to educate first, other Black OB-GYNs on PrEP in Atlanta so that their clients will at least be informed of their prevention options during their annual exams. We do know that non-Black OB-GYNs need to be informed as well, but this approach will ensure that we are contributing to the knowledge and education of Black clinicians serving Black women in our own community.   
4. Black women of trans experience were not adequately represented in the clinical trial either. We will follow the lead of our local Black trans women leaders on how to proceed in terms of advocacy. The group hopes that other advocates will model this example and stop speaking on behalf of groups you don’t represent, but support and uplift those who do.   
5. Advocate for Gilead to develop a media campaign that is specific for Black women in all our diversity. The campaign must address medical mistrust, real and anticipated side effects, competing priorities in the lives of Black women, and the need for family and friends to support us in our decision to use PrEP as a prevention strategy

**Who are we?**  
A group of Black women from the Atlanta HIV workforce. We do not represent any organization, we represent our community