Comments delivered to the FDA's Antiviral Drugs Advisory Committee (AVDAC) Meeting
By Mitchell Warren, Executive Director, AVAC,
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Good afternoon and thank you for the opportunity to provide comments to the Advisory Committee and the FDA.

My name is Mitchell Warren, and I am the executive director of AVAC, a non-profit organization dedicated to accelerating the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic. We take no funding from any pharmaceutical companies, including Gilead.

AVAC was founded 17 years ago – and we have spent most of our time advocate for the ethical development of these options, so it is with particular pleasure that I stand before you all today as we discuss the possibility of delivering at least one new option. We have tracked PrEP research since the first trials were begun, and our advocacy has, I hope, been clear: follow the science. That science leads us here today, and we think the evidence is quite clear and compelling, and we urge the Committee and the FDA to follow the evidence!

I am struck by the timing – the last time the FDA considered a new option to help men and women reduce risk of sexually acquired HIV was May 1993. And that product was the female condom. Happily, the FDA approved that application, and I hope that 19 years later, we will finally be able to say that we have one more option to add in our collective fight.

Like the female condom, oral PrEP with TDF/FTC, or Truvada, is not perfect. No HIV prevention method is. Like the female condom, oral PrEP with Truvada can protect some people, some of the time, in some situations and prevent some new infections. And like the female condom – and the male condom and all other drugs and devices – oral PrEP with Truvada only works when it is used.

The data that has emerged over the past 18 months is as exciting as it is complex and challenging. Some argue the data is mixed; but we believe the data strongly supports a favorable risk-benefit assessment adequate to approve Truvada for a PrEP indication for sexually active men and women, and we urge this Committee to recommend, and the FDA to approve, the PrEP indication for all of these groups.

And please don't confuse the populations in which the studies were conducted with what the evidence actually says – we at AVAC think the data is increasingly clear:

If you are at risk of sexual transmission of HIV
If you perceive your risk
If you take your pill
If the pill is part of a full package of interventions, including testing
You can derive significant protection.

The "if"s and "how"s are huge and complex, but they are not the reasons not to approve this supplemental NDA. Rather they are exactly why we should, so that the FDA, Gilead, health providers, public health agencies, community groups and potential users can "focus, focus, focus" – on the label, on evidence-based educational materials and on the Risk Evaluation and Mitigation Strategy. This approval is actually the best way to put us on the road of designing and implementing interventions, post-marketing studies and demonstration projects to reduce the concerns of condom migration, resistance, adherence, etc.

While this application is about Truvada, PrEP is not just a pill; the PrEP intervention includes counseling, condoms and testing.

In recommending approval of the indication, we also strongly recommend the following key components to ensure that we translate efficacy into effectiveness, while minimizing the risks.

- Three to six monthly testing for monitoring of biological markers and HIV-1 infection.
- A variety of plain language medication guides and educational initiatives suitable for different populations.
- Post-marketing surveillance including data collection on adherence as well as safety tracking and reporting.
- Discussions with FDA, public representatives, clinical investigators and the manufacturer to determine the need for further manufacturer post marketing studies.

Given that behavioral, cultural and situational contexts around sexual risks may vary tremendously among PrEP users, the FDA should include knowledgeable and representative public participation in FDA-required wording, format and content of educational/informational materials and programs to support safe use and adherence as a feature of post-marketing requirements. Furthermore, we request that the Committee and FDA include community input representative of the men and women who have and are most likely to be prescribed PrEP in the processes designed to negotiate the content and breadth of educational materials, and not engage in such negotiations solely between the manufacturer and FDA.

No one thinks PrEP is a magic pill. It will help some people, some of the time. We still need more options – which leads us to the final question in front of you. Approving PrEP does not diminish the need for all the other things we still need in our method mix and research must continue. But PrEP will increasingly be part of the prevention package in other HIV prevention trials, and trial designs will need to grapple with the question of placebo-control. We don't think this approval is necessarily the end of placebo control. But trials may become larger, longer and more complex – but that is success in reducing incidence.

We also urge the Committee to consider the consequences should it vote *against* approval. TDF/FTC is available off-label today to anyone who is able to obtain a prescription for it.

Health providers and potential PrEP users need accurate information – and an FDA-approved label, REMS and evidence-based health education materials that should be required as part of FDA approval of this application, are the best ways to ensure safe and effective use of PrEP.

Moreover, a decision by FDA to approve the new HIV prevention indication for Truvada will have immediate and far reaching implications for HIV prevention in the USA and globally. It will accelerate licensure decisions in other countries, provide the opportunity to launch demonstration projects to address some of the open questions we all have, and ensure that the drug can be safely and sustainably delivered to populations in greatest need.

PrEP, together with other prevention strategies, could help to significantly reduce HIV infections and could be a life-saving intervention for some men and women. Multiple clinical trials have clearly shown that PrEP is safe and effective when used as prescribed.

We all must now act on the scientific evidence and translate it into practice and impact. We simply cannot afford to dismiss any new options in the quest to end AIDS.

For more information, visit www.prepwatch.org and www.avac.org/prep.

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