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DEPARTMENT OF STATE

[Public Notice: 10583]

**Notice of Public Meeting of the President's Emergency Plan for AIDS Relief
(PEPFAR) Scientific Advisory Board**

In accordance with the Federal Advisory Committee Act (FACA), the PEPFAR Scientific Advisory Board (hereinafter referred to as "the Board") will meet on Friday, October 12, 2018 at 1800 G St NW, Suite 10300, Washington, D.C. 20006. The meeting will last from 8:30 a.m. until approximately 5:00 p.m. and is open to the public.

The meeting will be hosted by the Office of the U.S. Global AIDS Coordinator and Health Diplomacy, and led by Ambassador Deborah Birx, who leads implementation of the President's Emergency Plan for AIDS Relief (PEPFAR), and the Board Chair, Dr. Carlos del Rio.

The Board serves solely in an advisory capacity concerning scientific developments, program implementation, and policy matters related to the global response to the HIV epidemic, which can influence the priorities and direction of PEPFAR evaluation and research, the content of national and international strategies, and the role of PEPFAR in international discourse regarding an appropriate and resourced response. Topics for the meeting will include the risks and benefits of fixed-dose Dolutegravir in light of a preliminary safety signal for women using it at the time of conception; approaches for monitoring progress as countries approach epidemic control; HPV vaccination to prevent

cervical cancer; and new data from the Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe (DREAMS) initiative.

The public may attend this meeting as seating capacity allows. Admittance to the meeting will be by means of a pre-arranged clearance list. In order to be placed on the list and, if applicable, to request reasonable accommodation, **please register online as soon as possible**

(https://docs.google.com/forms/d/e/1FAIpQLSccvU95o_2MsSn8jRwGI4r9kpxBSkOQ-nARjdwNaa3HIn8PMg/viewform?c=0&w=1). While the meeting is open to public attendance, the Board will determine procedures for public participation.

This announcement will appear in the *Federal Register* less than 15 days prior to the meeting. The Department of State finds that there is an exceptional circumstance in that this advisory committee meeting must be held on October 12th for the following reasons:

- On May 18, the World Health Organization (WHO) issued recommendations for Dolutegravir use by women of childbearing age living with HIV, following unscheduled, interim analysis of an ongoing observational study in Botswana that found an increased risk of neural tube defects in children born to women taking Dolutegravir at the time of conception.
- The final results of the study, which are needed to confirm or dispel these observations, are expected in early 2019.
- However, many countries have taken a very conservative interpretation of WHO's recommendations and are withholding a preferred first-line antiretroviral medication from women of child-bearing age, who constitute the majority of persons receiving HIV medical treatment in PEPFAR-supported programs.

- These policies deny women access to a regimen that offers superior time-to-viral suppression, side effect, and resistance profiles.
- Two independent modeling studies have shown that the clinical and public health benefits of Dolutegravir vastly outweigh the risk of possible and rare, birth defects. A consultation with African women living with HIV infection underscored that they be permitted to make informed decisions about their own medical care and to opt to take Dolutegravir rather than other, inferior regimens.

Given the above facts, the Department urgently needs the advice of the PEPFAR SAB to inform treatment considerations that the Department must release as part of its 2019 Country Operational Plan guidance that will be developed in November-December 2018, for release in January 2019. October 12th is the only date in the near future when both the members of the SAB and Ambassador Birx are available to meet on this issue.

For further information about the meeting, please contact Dr. Andrew Forsyth, Designated Federal Officer for the Board, Office of the U.S. Global AIDS Coordinator and Health Diplomacy (ForsythAD@state.gov).

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