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April 24, 2012

Commissioner, Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Subject: Antiviral Drugs Advisory Committee; Notice of Meeting

(Document ID FDA-2012-N-0218-0001)

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To Whom It May Concern;

The FDA Antiviral Drugs Advisory Committee is currently reviewing an application by Gilead Sciences for a prevention indication for Truvada as Pre-Exposure Prophylaxis (PrEP) for HIV prevention. The American Academy of HIV Medicine (AAHIVM) would like to offer the following comments for the public advisory committee to consider regarding the application.

The American Academy of HIV Medicine is an independent organization of HIV Specialists, and other providers dedicated to promoting excellence in HIV/AIDS care and to ensuring better care for those living with AIDS and HIV disease. Our members and the providers we credential provide direct care to more than two thirds of the patients in active treatment for HIV disease. The Academy has a diverse membership composed of Infectious Disease, Internal Medicine, Family Practice and General Practice providers as well as Nurse Practitioners, Physician Assistants, Dentists, and Pharmacists. Member distribution among these provider groups is proportionate to the specialty distribution of frontline providers nationwide. A majority of our members work in health facilities that receive Ryan White funding. HIV care providers are on the front lines of the U.S. response to the disease, both domestically and internationally.

Over the past two years, the AAHIVM National Board, Public Policy Committee, and membership has taken a close interest in the subject of PrEP use for HIV prevention. The subject has been a focus of the last two meetings of our National Board, and AAHIVM formed a special committee on PrEP to consider the issue and monitor new developments. A representative from the Centers for Disease Control and Prevention (CDC), Dawn Smith, attended the most recent meeting of our Board in February to update the members on the most current science and policy developments.

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Several studies have indicated incredibly promising possibilities, particularly that the use of PrEP in MSM populations has the potential to substantially reduce transmission of the disease. Other studies have showed somewhat lesser or mixed results, and even indicated possible ineffectualness for some populations, such as women. The studies have also indicated certain medical side effects (such as bone density loss) that must be taken into account in any risk-evaluation.

As the news from these studies has emerged the level of debate and consideration has risen among the scientific and medical community, as well as among HIV policy experts and patients. There are strong emotions on all sides of this issue, as well as a significant amount of excitement over what many see as the positive potential of this proposed medical intervention. There are also concerns among some in the scientific and policy community over the possibility of unintended consequences, such as drug resistance.

Ultimately, the American Academy of HIV Medicine urges the FDA to adhere to a rigorous scientific and evidence-based standard for consideration of this application. It is critical that the Advisory Committee ensure that preconceived opinions and agendas do not influence the analysis of the available scientific data. The FDA is well-suited to apply rigorous standards for the evaluation of the available scientific literature, and evaluate the available data in an evenhanded manner based solely on those standards.

Thank you for consideration of the above comments. Like all in the HIV community, we eagerly await the decision of the FDA on this indication. For more information, please contact Holly Kilness, Director for Public Policy at the American Academy of HV Medicine at 202-659-0699 x20.

Sincerely,

Donna Sweet
National Board Chair
The American Academy of HIV Medicine