NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

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Dear Colleague:

On July 16, 2012, the U.S. Food and Drug Administration (FDA) approved the use of Truvada® (a fixed dose combination of emtricitabine/tenofovir disoproxil fumarate) as a pre-exposure prophylaxis (PrEP) for HIV-negative individuals who are at high risk of acquiring HIV. As part of PrEP, HIV-uninfected individuals who are at high risk will need to take Truvada daily to lower their chances of becoming infected with HIV should they be exposed to the virus.

In 2011, the New York State Department of Health (NYSDOH) AIDS Institute issued a Dear Colleague letter regarding the use of Truvada as PrEP. At that time, results of the published Global iPrEX study (N Engl J Med November 23, 2010 (10.1056/NEJMoa1011205) demonstrated that, in the controlled environment of a clinical trial, the daily use of a co-formulation of two antiretroviral medications, tenofovir and emtricitabine (brand name Truvada), could prevent the sexual acquisition of HIV in gay and bisexual men and transgender women, when combined with a comprehensive package of prevention services -- monthly HIV testing, condom provision, counseling, and management of other sexually transmitted diseases. Since then, additional studies have also demonstrated PrEP safety and efficacy among heterosexual men and women.

To assist prescribers and other health care professionals in advising uninfected people considering Truvada, the medicine is being approved by the FDA with a Risk Evaluation and Mitigation Strategy (REMS). The REMS for Truvada is aimed at educating health care professionals and uninfected individuals to ensure its safe use; it will include a training and education program which will not restrict the distribution of Truvada but will provide information regarding the important elements of a comprehensive HIV prevention strategy, the need for strict adherence, and the serious health consequences of taking Truvada for PrEP should the recipient be already infected with HIV or become infected with the virus while taking Truvada for the PrEP indication.

Truvada's manufacturer, Gilead Sciences, Inc., is required to collect viral isolates from individuals who acquire HIV while taking Truvada and evaluate these isolates for the presence of resistance. The company is required to collect data on pregnancy outcomes for women who become pregnant while taking Truvada for PrEP and to conduct a trial to evaluate levels of drug adherence and their relationship to adverse events, risk of seroconversion, and resistance development in seroconverters.

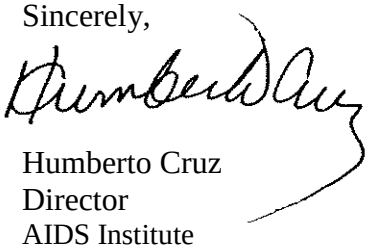
The use of Truvada for uninfected adults as a means of preventing acquisition of HIV is a milestone in the fight against the epidemic. The NYSDOH AIDS Institute is encouraged about the potential for adding pre-exposure prophylaxis to the menu of evidence-based HIV prevention

interventions. Truvada for PrEP is meant to be used as part of a comprehensive HIV prevention plan that includes behavioral, structural, and biomedical interventions such as risk reduction counseling, consistent and correct condom use, regular HIV testing and sexually transmitted infection screening and treatment. Individuals interested in this drug should seek advice from a qualified physician. Individuals are cautioned against accessing this or other medications via on-line sources or without the supervision of a physician.

The NYSDOH AIDS Institute is seeking additional information to formulate policy and guidance that address the key areas of this announcement and the future use of Truvada as a prevention intervention.

For additional information, please refer to the Centers for Disease Control and Prevention web site links:
http://www.cdc.gov/hiv/prep/pdf/PrEPfactsheet.pdf
http://www.cdc.gov/nchhstp/newsroom/docs/CDC-Interim-PrEP-Guidance-012811.pdf

Sincerely,



Humberto Cruz
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