



New Products, New Paradigms: Combination Products for Women

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FDA Disclaimer

The views in this presentation represent the author's opinion and not necessarily official policy of the Food and Drug Administration

Women and HIV Prevention

- **Recent exciting advances in the HIV prevention field**
 - Proof-of-concept for vaginal microbicide tenofovir gel in CAPRISA 004 trial (2010)
 - Antiretroviral treatment prevents HIV-1 transmission observed in HPTN 052 trial (2011)
 - Approval of oral Truvada as pre-exposure prophylaxis or PrEP for reducing the risk of sexual acquisition of HIV-1 infection (2012)

Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women

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The **NEW ENGLAND**
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Prevention of HIV-1 Infection with Early Antiretroviral Therapy

Myron S. Cohen, M.D., Ying Q. Chen, Ph.D., Marybeth McCauley, M.P.H., Theresa Gamble, Ph.D.,
M. C. Horowitz, M.D., Neelima K. Karim, M.P.H., James C. Habber, M.D.

FDA NEWS RELEASE

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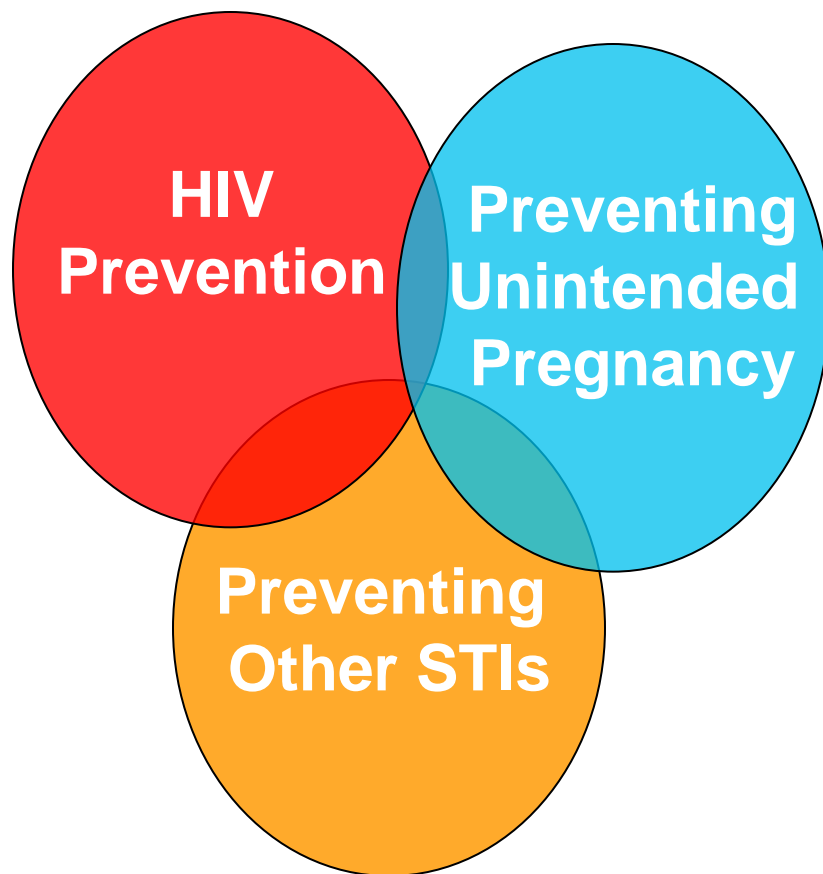
Consumer Inquiries: 888-INFO-FDA

FDA approves first drug for reducing the risk of sexually acquired HIV infection

Evidence-based approach enhances existing prevention strategies

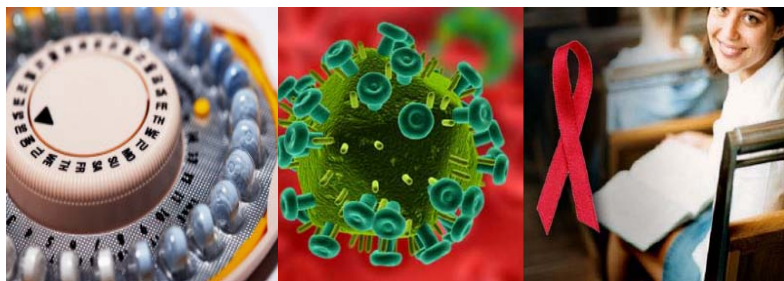
Today, the U.S. Food and Drug Administration approved Truvada (emtricitabine/tenofovir) for reducing the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and partners. Truvada, taken daily, is to be used for pre-exposure prophylaxis (PrEP) in combination with condoms to reduce the risk of sexually-acquired HIV infection in adults at high risk.

Addressing Multiple Reproductive Health Needs



- **At a prevention crossroads of multiple sexual and reproductive women's health issues**
 - Unintended pregnancy
 - HIV acquisition
 - Other sexually transmitted infections (STIs)

Combining Multiple Preventive Products



- **Integrating products to address multiple reproductive health needs of women**
- **Advantages**
 - Convenient to use
 - Improves adherence
 - Broadens range of available options

The Regulatory Pathway

- **Critical to demonstrate combination is safe and effective in preventing conditions or diseases**
 - Formulating an appropriate regulatory approach to obtain data necessary for approval
 - Essential to review the data supporting the efficacy and safety claims



Regulatory Collaboration

- **An effective MPT will be used by women worldwide**
 - Collaborative regulatory efforts are important so developers can meet the requirements of national regulatory authorities



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