New Products, New Paradigms: Combination Products for Women

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Multipurpose Prevention Technologies Satellite
AIDS 2012, Washington D.C.
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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)
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