International Partnership for Microbicides

New Science, New Hope – Giving Women Power Over AIDS

Women’s Policy, Inc. Briefing

Zeda Rosenberg, ScD, Chief Executive Officer

Washington, DC, December 1, 2010
People Living with HIV in 2009

Total: 33.3 million

North America
1.5 million
Caribbean
240 000
Latin America
1.4 million

Western & Central Europe
820 000

Middle East & North Africa
460 000

Sub-Saharan Africa
22.5 million

Eastern Europe & Central Asia
1.4 million

East Asia
770 000

South & South-East Asia
4.1 million

Oceania
57 000

UNAIDS/WHO 2010
Women’s Vulnerability to HIV

Biological, economic and socio-cultural factors:

• Male-to-female transmission higher
• Young women at even greater risk
• Financial dependence on male partners
• Inequality of women (exploitation and violence)
• Cultural practices such as early marriages, intergenerational sex and concurrent partnerships
The Face of HIV/AIDS in the US

- 27% of US AIDS cases women
- Nearly 90% of new HIV infections among girls ages 13-19 is due to high-risk heterosexual contact
- Rate of new HIV infections among African-American women higher than all other groups of women in US
  - One in 30 African-American women is HIV-positive
- Washington, D.C. highest AIDS prevalence in the US (~3%)
The Face of HIV/AIDS in Africa

- **Female**
  - 76% in sub-Saharan Africa

- **Young**
  - Risk of infection highest among women 20-24 years old

- **Married and monogamous**
  - Stable relationships not a haven

- **A mother**
  - Pregnancy complicated by HIV

World Bank Photo
HIV Prevention – The Global Response
From AIDS Treatment to HIV Prevention

1981
First AIDS case reported in the US

1983
HIV virus identified

1987
ARV “one drug” mono-therapy approved for use

1997
Three-drug therapy: HAART

2002
Drug combinations/reducing pill burden

2003
36 approved drugs for treatment: research continues

2006
Global Fund established

2010
PEPFAR launched

2010
ARVs in gel and pill effective for HIV prevention
# Current and Potential HIV/AIDS Interventions

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Treatment and Care</th>
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<tbody>
<tr>
<td><strong>Non ARV-based</strong></td>
<td><strong>ARV-based</strong></td>
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<tr>
<td>Behavior change</td>
<td>Prevention of mother to child transmission</td>
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<tr>
<td>Male and female condoms</td>
<td>Post-exposure prophylaxis (PEP)</td>
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<tr>
<td>STI treatment</td>
<td>Pre-exposure prophylaxis (PrEP)</td>
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<tr>
<td>Male circumcision</td>
<td>Microbicides</td>
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<tr>
<td>HIV vaccines</td>
<td></td>
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<td></td>
<td><strong>ARV treatment</strong></td>
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<td></td>
<td>Treatment for opportunistic infections</td>
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<td>Basic care</td>
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</table>
Promise of ARV-Based PrEP

- Proof-of-concept for Truvada®
- Potential to be used for men and women
- Uses approved ARV drugs
- Convenient oral dosing
- Potential for different dosing strategies
  - Intermittent
  - Monthly injection
- Can combine more than one ARV in a single product
Promise of ARV-based Microbicides

- **Antiretroviral (ARV)-based microbicides:**
  - Target HIV specifically
  - Based on the same types of drugs successfully used to treat HIV and prevent mother to child transmission
  - Can be delivered in a variety of user-friendly forms: vaginal gel, ring, film, others
  - Potential to be developed as combination products

- **Proof of concept: tenofovir gel**
Need for Multiple Products & Formulations

- Different women, different preferences
- More product choices, more options for protection
- Impact of adherence on efficacy – product won’t help if women don’t use it
- Male partners’ opinions and preferences important
Vaginal Rings: An Attractive Technology

- Long-acting
- Easy to use
  - Flexible ring, can be self-inserted
- Suitable for developing world
  - Heat-stable
- Used safely for other purposes
  - Contraceptive and hormone therapy rings
- Suitable for drug combinations
- Phase III dapivirine ring program planned 2011
Benefiting People, Communities, Countries

- Promote reproductive health and HIV awareness
- Empower women through education and counselling
- Involve men in HIV prevention
- Encourage HIV testing
- Strengthen delivery of and access to health services
- Engage communities, build community advisory boards
- Provide employment and professional development
- Building medical research capabilities in geographical areas of need
Path to Product Access

- Regulatory approval process defined by US Food and Drug Administration, other national regulatory bodies

- PEPFAR, other donors will assist partner countries in preparations for eventual microbicide introduction
Current Resource Environment
## Investments from Industry

<table>
<thead>
<tr>
<th>Compound</th>
<th>License</th>
<th>Year</th>
<th>Mechanism of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dapivirine</td>
<td>tibotec</td>
<td>2004</td>
<td>Reverse transcription: Stops virus from copying its genetic material inside human cells</td>
</tr>
<tr>
<td>DS001 (L-860,167)</td>
<td>Merck</td>
<td>2005</td>
<td>Cell Attachment: Prevents virus from attaching to human cells</td>
</tr>
<tr>
<td>DS004 (L-860,872)</td>
<td>Merck</td>
<td>2005</td>
<td>Cell Attachment</td>
</tr>
<tr>
<td>DS005 (L-860,882)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DS003 (BMS-599793)</td>
<td>Bristol-Myers Squibb</td>
<td>2005</td>
<td>Cell Attachment</td>
</tr>
<tr>
<td>Tenofovir (IPM &amp; CONRAD)</td>
<td>Gilead</td>
<td>2006</td>
<td>Reverse transcription</td>
</tr>
<tr>
<td>Maraviroc</td>
<td>Pfizer</td>
<td>2008</td>
<td>Cell Attachment</td>
</tr>
<tr>
<td>DS007 (L-000889644)</td>
<td>Merck</td>
<td>2008</td>
<td>Cell Fusion: Prevents virus from entering human cells</td>
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Non-exclusive, royalty-free licenses to develop, manufacture and distribute compounds as microbicides in developing countries
Past and Current Donors Supporting Microbicide Research

- Belgium
- Canada
- EC
- Denmark
- France
- Germany
- India
- Ireland
- Netherlands
- Norway
- South Africa
- Spain
- Sweden
- United Kingdom
- United States
- UNFPA
- World Bank
- Foundations
  - Bill & Melinda Gates
  - Wellcome Trust
  - Rockefeller
### US Government Funding for Microbicide Research

<table>
<thead>
<tr>
<th></th>
<th>FY05</th>
<th>FY06</th>
<th>FY07</th>
<th>FY08</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11 Pres. Budget</th>
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<tbody>
<tr>
<td>NIH</td>
<td>65,826</td>
<td>85,693</td>
<td>96,413</td>
<td>115,495</td>
<td>128,670</td>
<td>136,353</td>
<td>143,855</td>
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<tr>
<td>CDC</td>
<td>5,185</td>
<td>3,435</td>
<td>3,417</td>
<td>900</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>USAID</td>
<td>29,760</td>
<td>39,600</td>
<td>39,600</td>
<td>44,636</td>
<td>45,000</td>
<td>45,000</td>
<td>45,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100,771</td>
<td>128,728</td>
<td>139,430</td>
<td>161,031</td>
<td>173,670</td>
<td>181,353</td>
<td>188,855</td>
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Source: Data from NIH OAR Trans-NIH AIDS Research Budget FY 2011
FY 2011 approved for microbicides at USAID
  • $51M Senate
  • $45M House

USAID microbicide request FY 2012
  • Up to $65M to support robust pipeline of research

Funding, not science, is the primary obstacle to providing these lifesaving products to women
Microbicides: Cause for Optimism

- New generation of microbicides with highly potent ARVs
- Proof of concept! (tenofovir gel)
- Multiple mechanisms of action against HIV
- Single drugs or combinations
- Longer duration of protection
- Multiple formulations to give women more options
- Increased focus on adherence
- Support from governments, donors, pharma, scientific, advocacy and local communities
“Now we must build upon the CAPRISA trial results and optimize a highly effective and acceptable microbicide for women and others at high risk of HIV infection which could be deployed by PEPFAR and other programs”

Anthony S. Fauci, MD, Director NIH/NIAID
September 29, 2010