

International Partnership for Microbicides



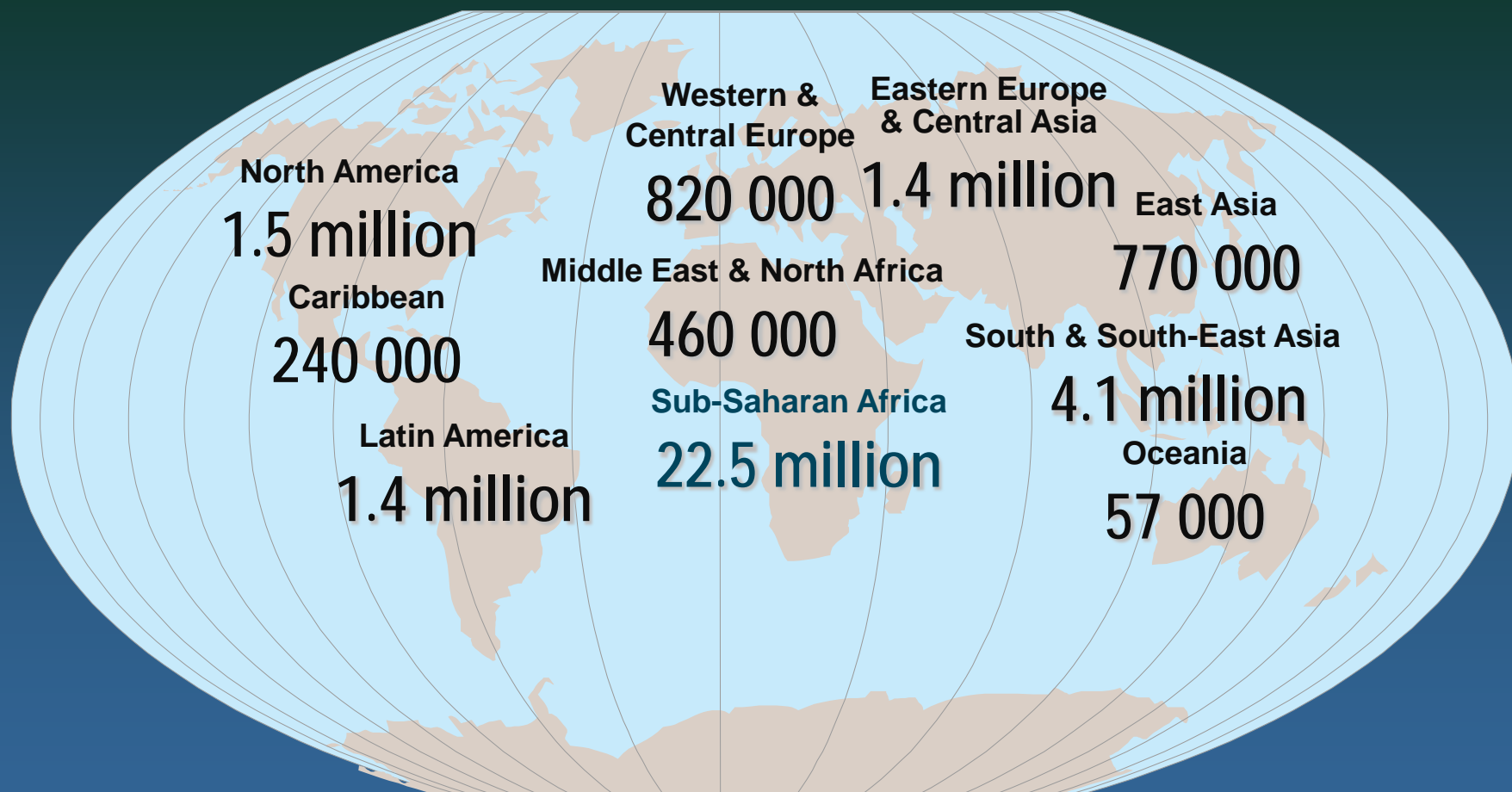
New Science, New Hope – Giving Women Power Over AIDS

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

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

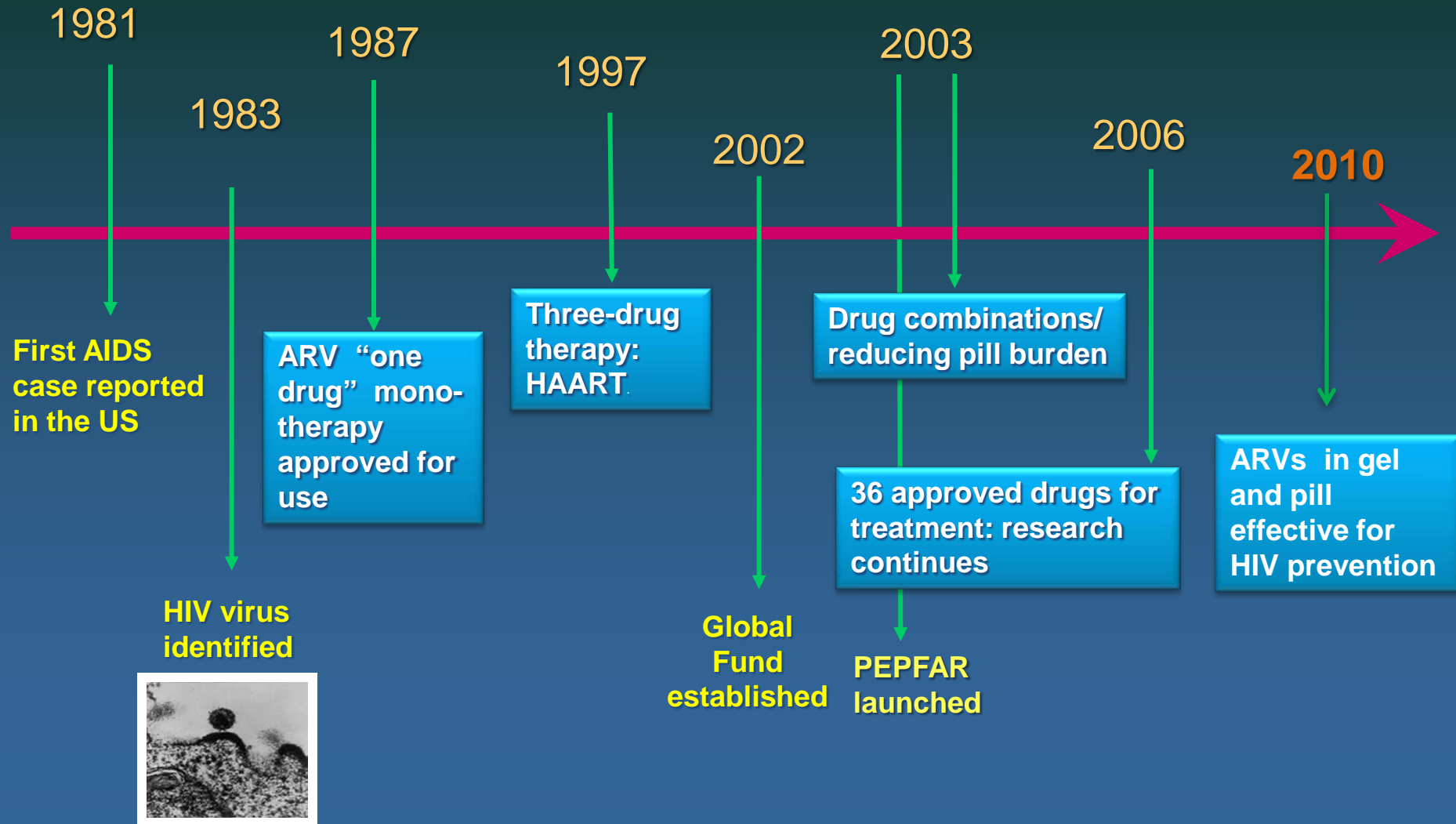
- Pregnancy complicated by HIV



World Bank Photo

HIV Prevention – The Global Response

From AIDS Treatment to HIV Prevention





Current and Potential HIV/AIDS Interventions

Prevention		Treatment and Care
Non ARV-based	ARV-based	
<ul style="list-style-type: none">▪ Behavior change▪ Male and female condoms▪ STI treatment▪ Male circumcision▪ HIV vaccines	<ul style="list-style-type: none">▪ Prevention of mother to child transmission▪ Post-exposure prophylaxis (PEP)▪ Pre-exposure prophylaxis (PrEP)▪ Microbicides	<ul style="list-style-type: none">▪ ARV treatment▪ Treatment for opportunistic infections▪ Basic care

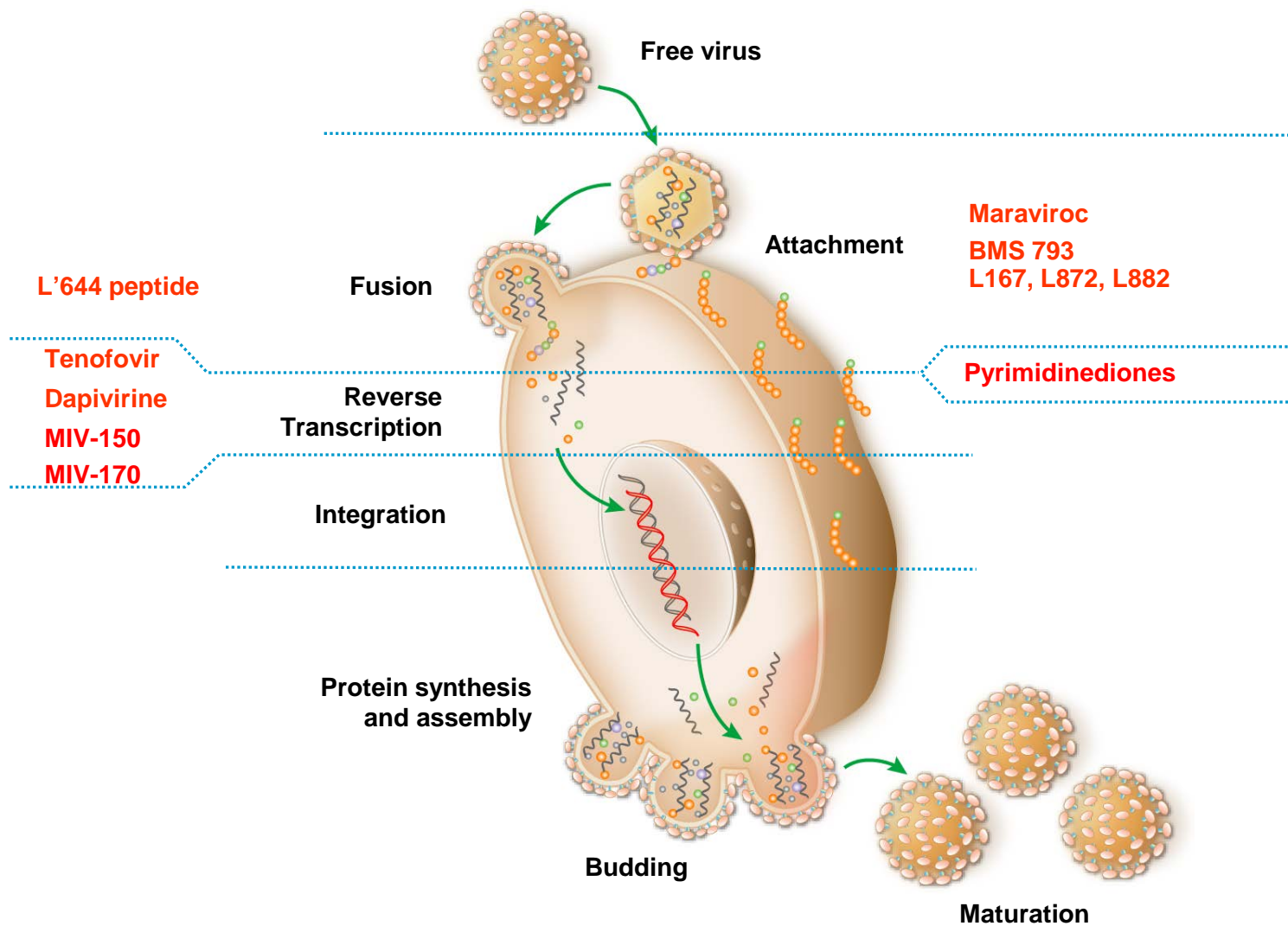
Promise of ARV-Based PrEP



- 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



Microbicides in Product Development



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

Scienceexpress

Research Article

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

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The Washington Post

Gel found to reduce AIDS risk in women

By David Brown
Washington Post Staff Writer
Tuesday, July 20, 2010; A01

A woman's risk of infection with the AIDS virus can be significantly cut by the use of a vaginal gel, a study has found. The research marks the first success in a 15-year search for a way women can independently protect themselves from contracting HIV infection through sex.

Short of a vaccine, an effective vaginal microbicide has been the most elusive goal in the epidemic.

The research, which was conducted in South Africa and will be presented Tuesday at the 18th International AIDS Conference in Vienna, tested a gel containing the antiretroviral drug tenofovir. While far from perfect, it was unambiguously helpful, reducing the risk of HIV infection by 39

with the AIDS virus, 16 million are women. In Africa, 60 percent of people with HIV infection are women, nearly all of whom acquired the virus through sex. For many, the proven methods of preventing infection, such as abstinence, being faithful and using condoms, are either not an option or out of their control. A vaginal microbicide that could be used with or without a man's knowledge is considered essential, missing until now.

News of the results of the Caprisa-004 study, which leaked out a day before they were to be presented, sent a wave of optimism through the AIDS research community.

"We have never had any kind of tool that has effectively allowed women to protect themselves," said Bruce Walker, an AIDS researcher at Harvard Medical School. "This is really a game-changer."

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

Compound	License	Year	Mechanism of Action
Dapivirine		2004	Reverse transcription: Stops virus from copying its genetic material inside human cells
DS001 (L-860,167) DS004 (L-860,872) DS005 (L-860,882)		2005	Cell Attachment: Prevents virus from attaching to human cells
DS003 (BMS-599793)		2005	Cell Attachment
Tenofovir (IPM & CONRAD)		2006	Reverse transcription
Maraviroc		2008	Cell Attachment
DS007 (L-000889644)		2008	Cell Fusion: Prevents virus from entering human cells

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

	FY05	FY06	FY07	FY08	FY09	FY10	FY11 Pres. Budget
NIH	65,826	85,693	96,413	115,495	128,670	136,353	143,855
CDC	5,185	3,435	3,417	900	0	-	-
USAID	29,760	39,600	39,600	44,636	45,000	45,000	45,000
Total	100,771	128,728	139,430	161,031	173,670	181,353	188,855

Source: Data from NIH OAR Trans-NIH AIDS Research Budget FY 2011



USAID: Current Status

- 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

Women Urgently Need Microbicides



“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