



*microbicide research & development:
overview and update*

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**Harnessing Medical Technology to Fight Global Diseases
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a “topical microbicide” is ...

... a substance that can significantly reduce sexual transmission of HIV and/or other viral, bacterial, or protozoan pathogens, when applied to genital mucosal surfaces



what might a microbicide look like?

- **gel or cream**
- **film**
- **suppository**
- **pre-loaded diaphragm or cervical cap**
- **sponge or vaginal ring slowly releasing active ingredient**
- **a new formulation ???**



why are microbicides needed?

for individuals...

- **consistent condom use difficult in stable relationships**
- **individuals willing to use condoms with “outside” partners unwilling or unable to use with primary partner**
- **childbearing tied to self-worth, position**



why are microbicides needed?

for global public health...

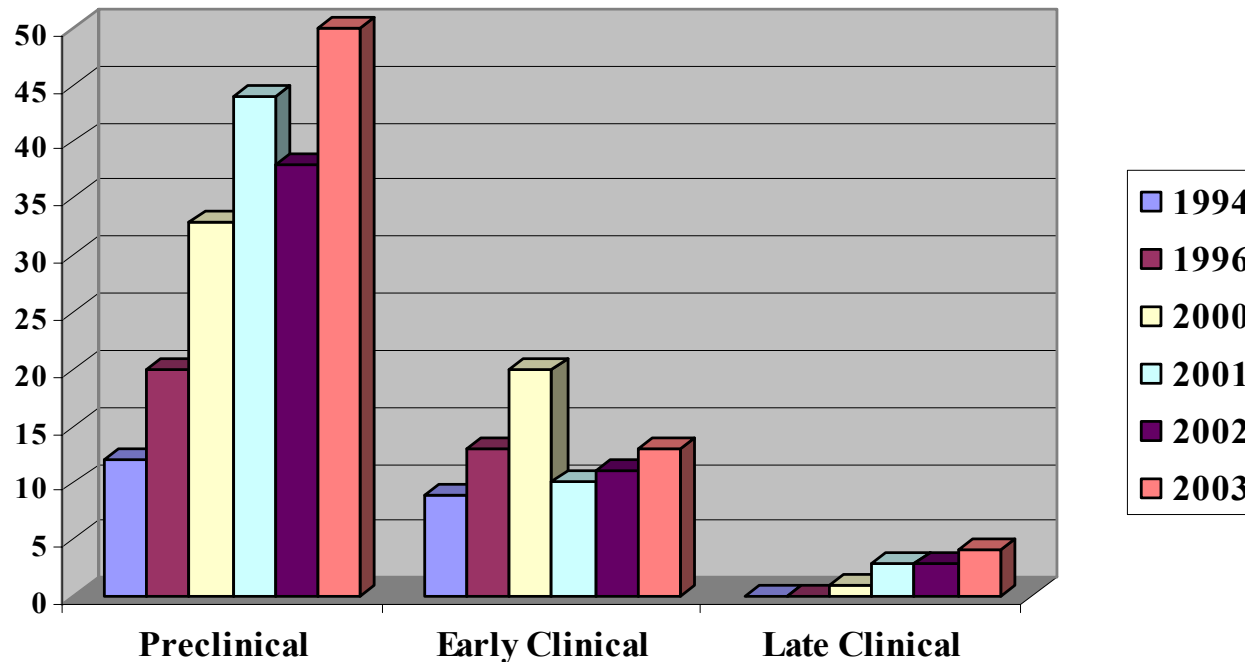
- **60% efficacious microbicide would avert 2.5 million HIV infections over 3 years**
(Watts, et al. 2002 [LSHTM])

NOTE:

- **newly infected with HIV in 2002 = 5 million**
- **adult AIDS deaths in 2002 = 2.49 million**



microbicides in development, 1994-2003



who is doing the work?

- **biopharmaceutical companies (~25)**
- **non-profit research entities (~38)**
- **public-sector entities worldwide (~5)**
- **institutions conducting supportive research (~36)**

working on:

- **at least 67 product leads**
- **5+ devices and special formulations**



where are we?

Phase 3	1
Phase 2/3	3
Phase 2	3
Phase 1/2	1
Phase 1	9

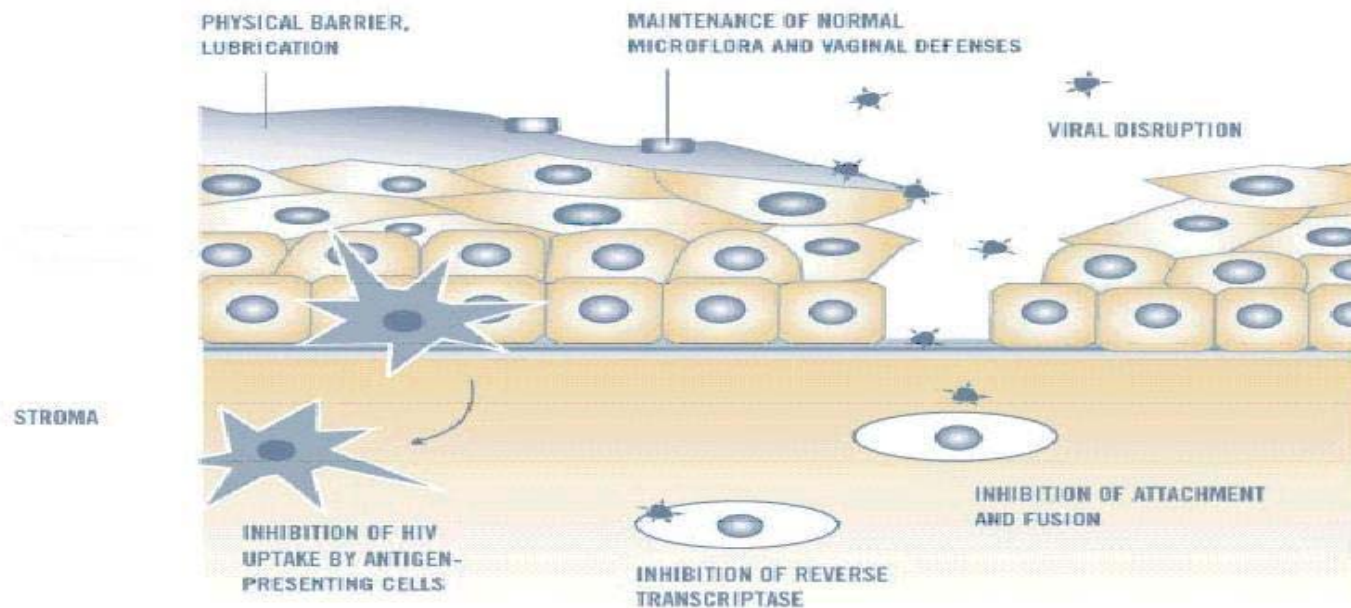
total in clinical stages: 17

total in preclinical stage: 50

total products in development: 67



potential mechanisms of action for HIV microbicides

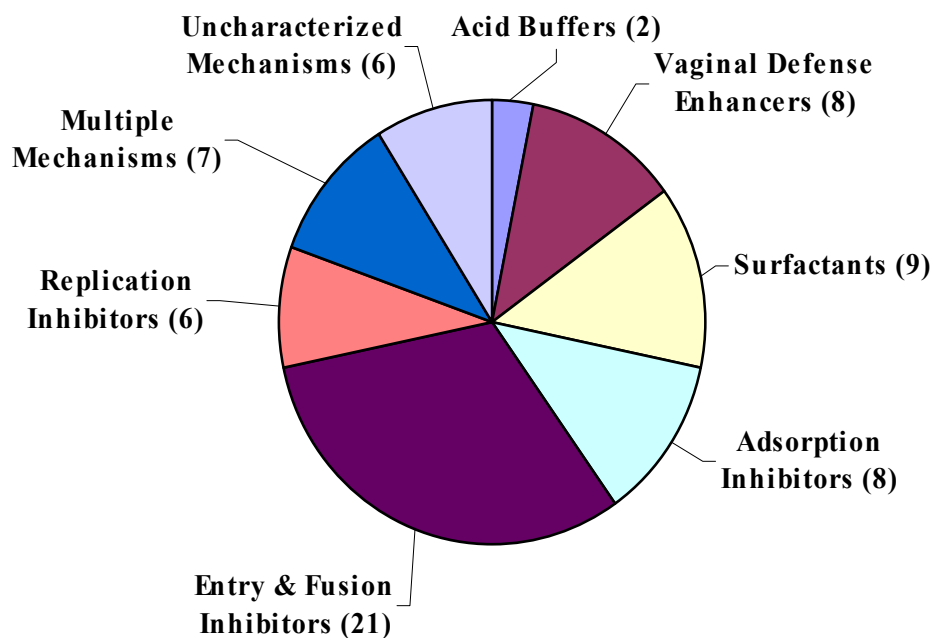


mechanisms of action for HIV microbicides

- acid buffers [2]
- vaginal defense enhancers [8]
- surface-active agents (“surfactants”) [9]
- adsorption inhibitors [8]
- entry and fusion inhibitors [21]
- replication inhibitors [6]
- multiple mechanisms [7]
- uncharacterized mechanisms [6]
- devices [5]
- formulations [5]



microbicide pipeline by primary mechanism of action, 2003



products in clinical trial phase 1

(N=10)

- **Acidform™ (GMP)**
- **benzalkonium chloride (Biofem)**
- **calanolide A (Advanced Lifesciences, Sarawak)**
- **cellulose acetate phthalate (NY Blood Ctr.)**
- **cellulose sulphate/Ushercell™ (GMP, Polydex)**
- **dendrimer nanostructure/VivaGel™ (Starpharma)**
- **human monoclonal antibodies (Polymun Scientific)**
- **polystyrene sulfonate (GMP)**
- **praneem polyherbal formulations (IRR, India)**
- **tenofovir™ (Gilead, HPTN)**



*products in clinical trial
phase 1/2, phase 2*

phase 1/2 [total = 1 product]

- Invisible Condom™ (Laval U)

phase 2 [total = 2 products]

- dextran-2-sulphate/Emmelle™ (ITM, ML Labs, MRC)
- Lactin V Capsule (Osel Inc.)



products in clinical trial phase 2/3, phase 3

phase 2/3 [total= 3 products]

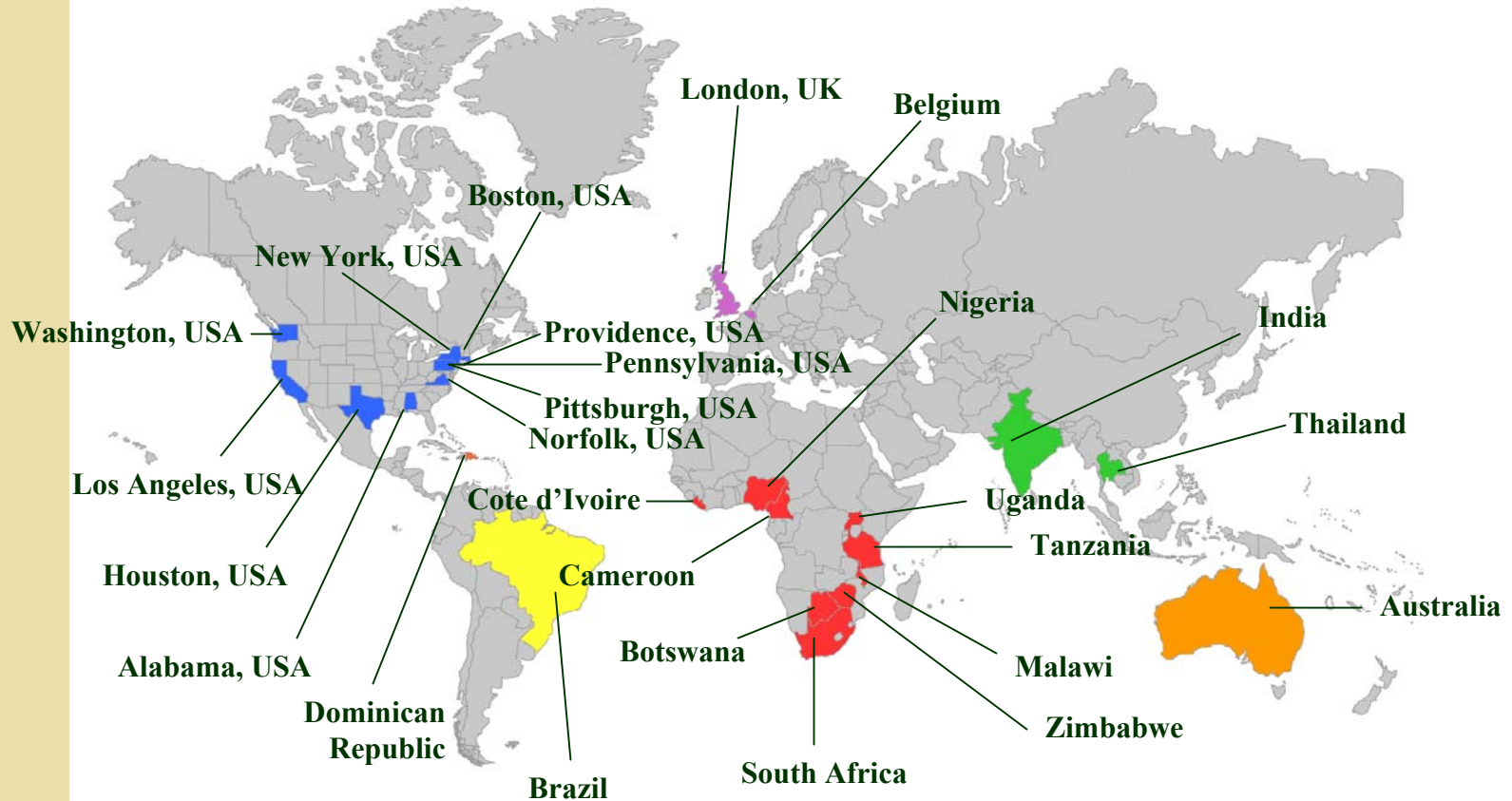
- **BufferGel™ (HPTN, ReProtect)**
- **C31G/Savvy™ (NICHD, Biosyn)**
- **PRO 2000/5™ (HPTN, Indevus)**

phase 3 [total= 1 product]

- **Carraguard™ (Population Council, CDC)**



clinical trial sites (N=26+)



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