



# The Microbicide Timeline

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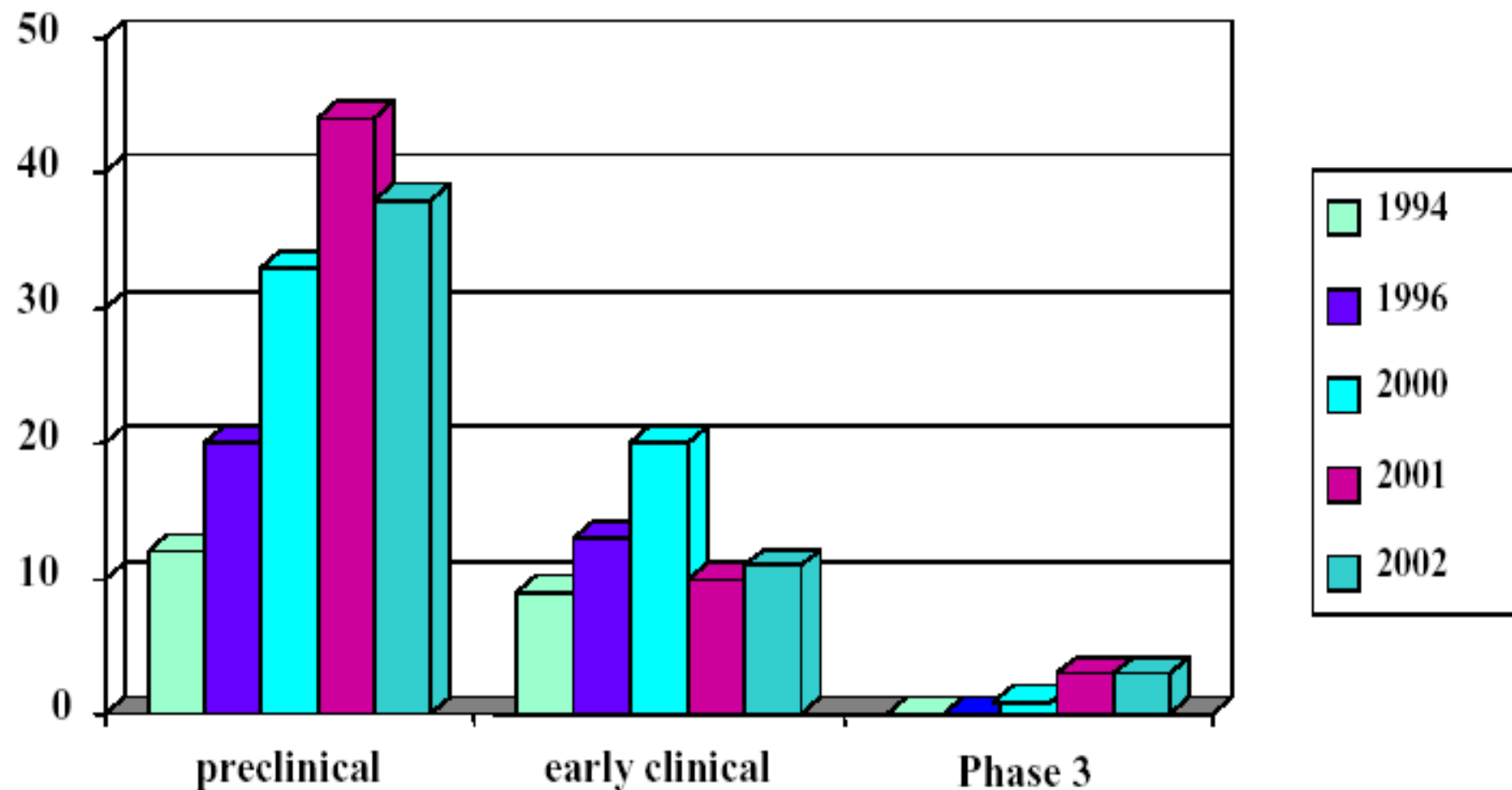
International Partnership for Microbicides

Diaphragm Renaissance Meeting

September 9, 2002



## *trends in microbicide development*



# Candidates for Phase II/III

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- BufferGel
- Carraguard (PC-515)
- Cellulose Sulfate
- Emmelle (Dextrin Sulfate)
- PRO 2000
- Savvy (C31G)

# Timelines

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- Most optimistic
  - If Phase III trials begin as scheduled in 2003, effectiveness >60%, “perfect” study stopped early, NDA submission “flawless”, product licensure in 2007
  - Product reasonably available in high-risk settings - 2009

# Timelines

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- Conservative scenario
  - Studies slow to enroll, data available by 2007, NDA submission delayed, product licensure in 2009
  - Product reasonably available in high-risk settings - 2011

# Timelines

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- Worst-case scenario
  - The products in phase III do not protect against HIV infection
- Next generation products
  - Phase II/III clinical trials could begin 2004/2005
  - Best case – product available 2010
  - Conservatively - 2012

# Next Generation for Phase III

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- Polystyrene sulfonate
- Topical PMPA
- Dendrimers
- Acidform
- Lactin Vaginal Capsules  
(Lactobacillus)

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Diaphragm or Microbicide

That is NOT the question!

# We Need Both

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- More options, more use, more infections averted
- If effective, diaphragm can be readily available sooner – best case 2007
- Combination diaphragm/microbicide
- Need for a non-contraceptive method
- This is not a competition – but it is a race (to save lives) – a tie for first place (3-5 ways) would be ideal!