Advocating for Rectal Microbicides
by Jim Pickett
Director of Public Policy, AIDS Foundation of Chicago

“Rectal Microbicides – A New Frontier in HIV Prevention”
Cape Town – April 24, 2006

IRMWG International Rectal Microbicide Working Group
Advocating for Rectal Microbicides

• **International Rectal Microbicide Working Group (IRMWG)**
  – Who we are
  – What we do
  – Focus/advocacy strategy
  – Collaborative process
    • Successes and challenges

• “Rectal Microbicides: Investments & Advocacy”
  – Summary
  – Investments 2000 – 2006
  – Recommendations
• **Who we are**
  – Microbicide advocates and researchers, sexual and reproductive health advocates, policy makers
  – 110 participants/members and growing
  – 5 continents, 8 countries currently represented

• **History, what we do**
  – Formed June 2005
  – Communicate via global listserv
  – Collaborative process
  – Teleconferences
    • Monthly (or so)
    • Presentations from researchers, slides shared online
    • Dialogue
IRMWG – Focus and Advocacy Strategy

- Positioning rectal microbicides (RMs) (collaborative process)
- Push for rectal safety data on vaginal microbicides (VMs)
- Promote lubricant safety studies, disseminate findings
- New prevention technologies (PrEP, vaccines, PEP)
- Sexual harm reduction
Two major projects

LifeLube

Rectal Microbicides: Investments & Advocacy

IRMWG International Rectal Microbicide Working Group
Released TODAY!

Rectal Microbicides: Investments & Advocacy

- Fiscal sponsors
  - AIDS Action Committee of MA
  - AIDS Foundation of Chicago
  - The AIDS Institute
  - AIDS Project Los Angeles
  - AIDS Vaccine Advocacy Coalition
  - Canadian AIDS Society
  - Community HIV/AIDS Mobilization Project
  - Fenway Institute at Fenway Community Health
  - Gay Men’s Health Crisis
  - Global Campaign for Microbicides
  - Institute for Gay Men’s Health
  - SafeGuards Project/Family Planning Council
  - San Francisco AIDS Foundation
  - Sister of Perpetual Indulgence
  - UK Campaign for Microbicides
"This important document describes the current landscape of rectal microbicide research and helps define what resources will be needed to develop a safe and effective rectal microbicide."

–Ian McGowan MD, PhD

UCLA AIDS Institute
“All people have the right to be able to protect themselves from HIV, and to do so requires prevention tools that are both practical and effective. Another world of HIV prevention is possible, and this report helps pave the way to a broader range of real-life options for people of all genders.”

– Julie Davids, CHAMP
"The information in this report will help us to complete our Canadian Microbicides Action Plan, bringing together communities, researchers, industry, governments and our global partners in the search for microbicides for women and men."

— Marc-Andre LeBlanc

Canadian Microbicides Advocacy Group Network
"At any given moment, more heterosexual women than gay men are engaging in anal intercourse. A receptive sex partner is a receptive sex partner. We need rectal microbicides, just as we need vaginal microbicides, to help receptive sex partners save their own lives."

— Anna Forbes
Global North Programs Coordinator
Global Campaign for Microbicides
Available online

www.LifeLube.org
Investments

• Methodology of data retrieval
  – Reference the HIV Vaccine and Microbicide Tracking Working Group’s (UNAIDS, AVAC, IAVI, AMD) annual report “Tracking Funding for Microbicide Research and Development” to gauge RM specific funding.
  – Data collated from public and private sectors, supplemented by interviews with experts.
Investments

• Methodology of data retrieval
  – Self-reporting by recipients and representatives of the funding sources
  • Survey inquiries include:
    – Confirmation of past, current, future funding for RM research.
    – Annual disbursements of research from 2000 onward.
    – Institutions receiving/disbursing – avoid double counting.
Investments

- **Methodology of data retrieval**
  - Report tracks research focused on rectal mucosal transmission, rectal acceptability and safety markers, rectal explant studies, and AI (anal intercourse) behaviors.
  - VM studies (preclinical and clinical), although useful as support for RM, not included in this analysis.
Investments

- Total 2000 – 2006 = $34M

2000 = $2M
2006 = $7.2M (estimated)
Investments

- Public Sector
  - U.S. = $33.1M, 00-06, 97.4%
    - NIH = $30.8M, 00-06
      - 06 = $6.6M
        » .023% of overall budget
      - 07 = $5.5M (projected)
    - CDC = $2.3m, 01-06
      - “The Evaluation of Topical Microbicides in Men Who Have Sex With Men”
      - CDC vaginal - $2.4M, 01-06
    - 12 cents per capita

- Europe?
  - Funds not apportioned specifically, VM $?, Britain’s Microbicide Development Programme - Phase 1 rectal safety study in 06 but investment totals could not be confirmed, other spending too elusive to track…
Investments

• Philanthropic Sector
  – $739,649 - 00-06
  – Approx. 2.2% total funds
  – Trend from 00-06
    • 00 = $337,455
    • 01 = $268,194
    • 02 = $99,000
    • 03 = $0
    • 04 = $10,000
    • 05 = $0
    • 06 = $25,000
  – *amfAR* primary investor
    • No dedicated RM stream, funding levels fluctuate.
    • Direct research support, meeting support.

• Commercial sector
  – $100,000 - 06
  – Most support in-kind
    • Time spent, pipeline compounds, infrastructure.
    • Likely waiting for proof of concept before fiscal risk.
  – Biosyn 06 – $100,000 – in kind
  – Gilead – no figure given
Projection estimate

• For the purpose of the following analysis, the following assumptions are made:
  – Product is small molecule, stable at room temp and can be made at 1kg scale economically.
  – Commercial sponsor provides active ingredient.
  – Chemistry, stability, prelim. pharmokinetics profiles completed.
  – Investigator brochure avail. with some preclinical toxicology.
# Projection estimate

<table>
<thead>
<tr>
<th>Phase of Development</th>
<th>Specific Study</th>
<th>Participants</th>
<th>Approx. Duration</th>
<th>Approx. Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation development</td>
<td>Development of one rectal formulation</td>
<td>20</td>
<td>1.5 years</td>
<td>$2.5 million</td>
</tr>
<tr>
<td>Preclinical animal toxicology</td>
<td>Species 1 toxicology</td>
<td>N/A</td>
<td>6 months</td>
<td>$150,000</td>
</tr>
<tr>
<td></td>
<td>Species 2 toxicology</td>
<td>N/A</td>
<td>6 months</td>
<td>$150,000</td>
</tr>
<tr>
<td>Phase 1 safety studies (N=3)</td>
<td>Sexually abstinent population (HIV-neg.)</td>
<td>40</td>
<td>1.5 years</td>
<td>$750,000</td>
</tr>
<tr>
<td></td>
<td>Sexually active population (HIV-neg.)</td>
<td>40</td>
<td>1.5 years</td>
<td>$750,000</td>
</tr>
<tr>
<td></td>
<td>Sexually abstinent population (HIV-pos.)</td>
<td>40</td>
<td>2 years</td>
<td>$1 million</td>
</tr>
<tr>
<td></td>
<td>Penile acceptability</td>
<td>10</td>
<td>6 months</td>
<td>$150,000</td>
</tr>
<tr>
<td>Phase 2 safety</td>
<td>Extended exposure</td>
<td>200</td>
<td>2 years</td>
<td>$4 million</td>
</tr>
<tr>
<td>Phase 2B/3 efficacy</td>
<td>Efficacy study</td>
<td>4000</td>
<td>4 years</td>
<td>$60 million</td>
</tr>
<tr>
<td><strong>Total Time / Cost</strong></td>
<td></td>
<td></td>
<td>10–15 years</td>
<td>$69,450,000</td>
</tr>
</tbody>
</table>
Projection estimate

• Conservatively, field probably needs 5 candidates over 10 – 15 year period.
• Will require minimum $350M, or at least $35M/year for 10 years.
• Annual spending needs to increase 5-fold.
“Greater strides in the development of rectal microbicides can be achieved by targeted grant funding. At present, this area is just a side project of vaginal microbicides.”

-Osmond D’Cruz, Parker Hughes Institute
Recommendations

Whatever the strategy, the securing of public funding for every stage of rectal microbicide R&D must be a priority.

IRMWG International Rectal Microbicide Working Group
Recommendations

• Donors must:
  – Provide a minimum of $350 million for targeted RM research funding over the next 10 to 15 years, or an average of at least $35 million per year to build a comprehensive RM research program.
  – Provide transparency and an increase in institutional commitment to explicitly fund RM development.
  – Commit to supporting phase 1 rectal safety studies for all vaginal microbicide candidates being evaluated in phase 2B/3 efficacy trials.
Recommendations

• Intl nongovernmental orgs must:
  – Form a body to specifically track RM development, to ensure funding, and to coordinate research, regulatory approval, and advocacy.

• Researchers must:
  – Recruit new scientists to the field and promote RM research within the scientific community.
  – Initiate ideas for grant proposals to create demand for funding.

IRMWG  International Rectal Microbicide Working Group
Recommendations

- Advocates must:
  - Reach out to affected communities to educate and to promote RM trial preparedness.
  - Promote global, national, and regional surveillance efforts to determine percentage of HIV infections attributed to AI in order to better assess the need for RM development.
  - Raise awareness, educate, and mobilize communities to foment a stronger, more visible demand for RM and to elevate the profile of microbicides among policymakers.
  - Ensure linkages to the broader microbicide movement and to advocates working on other prevention technologies.

IRMWG  International Rectal Microbicide Working Group
Recommendations

- Regulatory agencies like the U.S. FDA, the EMEA, and others must:
  - Develop support and development guidelines to accelerate the study and licensure of RM.
  - Request that all New Drug Applications for vaginal microbicides include at least one rectal safety study as part of the submission package.
Recommendations

• The U.S. Congress must:
  – Pass the Microbicide Development Act, and other countries should consider similar legislation.
Thank You

Jim Pickett
AIDS Foundation of Chicago
411 South Wells Ste 300
Chicago, IL USA 60607
+1-312-334-0920
LifeLube.org
JPickett@aidschicago.org

IRMWG International Rectal Microbicide Working Group