August 18, 2003

Tara P. Turner, Pharm.D.
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Turner:

The undersigned are AIDS activists working to end the AIDS epidemic by advancing research on HIV/AIDS. We are interested in vaginal microbicide research because of its obvious potential in the prevention of HIV transmission through a woman-controlled mechanism.

Our concerns regarding microbicide research extend to rectal safety and efficacy. Although many people associate anal intercourse exclusively with male homosexual activity, it is clear that anal intercourse is a frequent practice among heterosexuals as well. Approximately 6% - 8% of heterosexual survey respondents reported anal intercourse within the past 12 months. (Source: National Health and Social Life Survey, National Opinion Research Center, University of Chicago, 1992). Nearly 80% of these heterosexual respondents did not use condoms.

Given the unfortunate history of the marketing and use of nonoxynol-9, it is clear that any vaginal microbicide will be used by a wide range of people in conjunction with anal intercourse, notwithstanding any instructions for use. Again, given the history of nonoxynol-9, vaginal products must be shown to be safe for rectal use in order to avoid inadvertently increasing the transmission of HIV. Differences in the physiology and immunology of the anorectal and vaginal mucosa require separate and specific study of safety in the anorectal environment.

Participants in trials of vaginal safety and efficacy must be informed that the products have not been tested for safety rectally, should not be used rectally and that, absent safety data, use of the product when engaging in anal intercourse may increase the risk of HIV transmission. Any microbicides approved for vaginal use should also carry explicit warning labels warning against rectal use until such time as rectal safety and efficacy studies on these products have been completed.

We favor a more aggressive research program within the National Institutes of Health on the rectal mucosa, including development of safe and effective microbicides that could be used by anyone who engages in anal intercourse. Such a research program would also provide valuable data to guide the development of safe and effective vaginal microbicides.

These are urgent research agendas to advance our ability to prevent new HIV infections.

Very truly yours,

Lynda Dee, Baltimore, MD
Carlton Hogan, Minneapolis, MN
Robert Munk, PhD, Arroyo Seco, NM
Gerry Spillman, Redwood City, CA