Infective Disease, Condom Reduce HIV Spread

San Francisco — When used intravaginally in combination with a condom, the investigational microbicide PRO 2000/5 gel appeared to reduce HIV transmission by 30% in a large, international, randomized study called HPTN 035.

The finding, which fell short of statistical significance, was seen in a study called HPTN 035 (Phase II/III Safety and Effectiveness Study of the Vaginal Microbicides Buffergel and 0.5% PRO 2000/5 Gel [P] for the Prevention of HIV Infection in Women). A reduction of 33% would have reached statistical significance, according to Dr. William Cates Jr., president of research at Fam- 

ily Health International, which designed and launched the trial. FHII is a non-profit foundation in Research Triangle Park, N.C.

The study followed 3,099 women at one U.S. site and at sites in five African countries. All women were given free condoms, HIV risk reduction counseling, and diagnosis and treatment of sexually transmitted diseases. The study participants were then randomized to one of 11 treatment groups. The women in the PRO 2000/5 gel, one-quarter were given an another microbicide called BufferGel, one-quarter were given a placebo gel, and the remaining women did not receive any gel. The gels were provided as single-use, prefilled applicators and the study participants were instructed to apply one dose of the contents intravagi-

nally up to 60 minutes before each vagi- nal intercourse. The women were not married and were of average age 20 years and were evaluated monthly; 94% of the women completed study visits through the follow-up period.

Participants in the three gel groups re-

ported using the gel during 81% of all sex acts, and nearly all women (99%) said they would use the products if approved for HIV prevention. Women in the three gel groups reported using condoms 72% of the time, and women in the no-gel group reported using condoms 81% of the time.

In all, 194 of the women acquired HIV; 36 women in the PRO 2000/5 group, 54 in the BufferGel group, 51 in the placebo gel group, and 53 among participants who used no gel. This corre-

sponds to an effectiveness rate of 30% for the 3 gel groups combined.

The study was designed to show that 46.3% would have been statistically significant. In a subanalysis based on reliability of con-

dom use, there was little difference in the infection rate among women who used condoms more than 85% of the time. However, the infection rate was 4.6 per 100 person-years among the low-con-
don-use women given the placebo gel compared with 1.0 per 100 person-years among the low-cond-
don-use women given PRO 2000/5 gel. The variation corre-

sponded to an effectiveness rate of 78% for the microbicide.

Dr. Cates acknowledged at a meeting on contraceptive technology sponsored by Contemporary Forums that the final data would not carry the statistical weight of a primary outcome. “It’s not our study, by any means, it’s the study of others,” he said.

The investigational microbicide PRO 2000/5 gel (0.5% dose) was developed by Indevus Pharmaceuticals Inc. of Lexington, Mass., and is an entry/fusion inhibitor designed to make it difficult for HIV to attach to and infect healthy cells. The investigational microbicide BufferGel was developed by ReproTech, Inc. of Baltimore, and is thought to work by boosting the natural acidity of the vagi-

nal pH, the prevention of where the microbe.

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Dr. Cates disclosed that he had no conflicts of interest. Contemporary Fo-
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