



PACIFIC INSTITUTE FOR WOMEN'S HEALTH

April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

To Whom It May Concern:

We represent the California Microbicides Initiative, a statewide coalition of biotech companies, non-profit organizations and researchers working to bring microbicides to market. We are writing to comment on the proposed regulations concerning nonoxynol-9 in vaginal contraceptives released by the FDA on January 16, 2003.

We applaud the FDA for their proposed rule to add clarifying information on package inserts and labels regarding the lack of efficacy of such products against HIV and STIs. However, the proposed regulations do not go far enough in two specific ways. Although contraceptive products containing N-9 are designed exclusively for vaginal use, some individuals nonetheless use these products during anal intercourse. Given recent data demonstrating that even small amounts of N-9 can cause sloughing of the rectal epithelium, we suggest that an explicit warning be added that these products should not be used rectally because they may increase the risk of HIV and STIs.

In addition, the presence of nonoxynol-9 in condoms and personal lubricants also poses a substantial public health risk when used rectally. The risk of transmission of HIV is much greater during incidents of anal sex than vaginal intercourse, yet the FDA is not proposing similar warnings for non-contraceptive products containing N-9 used during anal sex. Therefore, we urge the FDA to include similar warnings on condom packages and vaginal lubricants containing nonoxynol-9.

Finally, we urge the FDA to review expeditiously alternative methods to prevent disease. Microbicides hold the best potential as a non-condom alternative for the prevention of sexually transmitted diseases. These products, like spermicides, would be used vaginally or rectally by individuals to protect themselves and their partners from infection. But their successful development depends on the support of U.S. health agencies, including the FDA.

Again, the California Microbicides Initiative applauds the FDA's efforts to address this issue, but we urge you to take further action to protect Americans' lives from this deadly epidemic.

Sincerely,

Alison Regan

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