

San Francisco AIDS Foundation Letter to the Food and Drug Administration on Labeling for Male Latex Condoms

February 7, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0555

To Whom It May Concern:

The San Francisco AIDS Foundation appreciates the opportunity to provide comments on the condom labeling guidance proposed by the Food and Drug Administration (FDA) in the *Federal Register* of November 14, 2005. We understand that Congress required a review of the label, and that the proposed language was developed after extensive review of available scientific evidence.

An important goal for public health providers and organizations dedicated to reducing HIV and other sexually transmitted diseases (STDs) is to increase levels of consistent and correct condom use in all sexually active populations. Given that most people purchasing condoms are intending to have sex, it is important that the label convey to people who are at risk for HIV and other STDs that condoms, used correctly and consistently, are an effective way to prevent such infections. The San Francisco AIDS Foundation is concerned that new labeling not undermine the public's confidence in condoms.

We are pleased that, overall, the revised guidelines published in the *Federal Register* are consistent with the current published scientific evidence about condom effectiveness. We do, however, have some concerns about the draft guidelines and appreciate your consideration of our recommendations. Our comments are limited to two aspects of the draft guidance:

A. Labeling Recommendations for Latex Condoms

2d. STDs transmissible by contact outside the area covered by the condom.

We are concerned that the addition of overly complex language to the condom label may confuse consumers about the risks and benefits and could inadvertently lead to decreased use of condoms. In particular, the guidance on STDs that can be spread by skin-to-skin contact is confusing. The key message is that although condoms provide less protection against STDs such as genital herpes and human papillomavirus, they do provide *some*

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protection. The reality is that the vast majority of sexually active Americans will at some point be infected with HPV, but in most cases the virus will clear with no ill effects. The greatest risk factor for cervical cancer is the failure to receive timely screening and follow-up care if indicated. These issues are clearly complex.

Therefore, we recommend editing the proposed paragraph for clarity as follows: (proposed new language appears in **bold** and language to be deleted is ~~crossed-out~~.)

*“Condoms provide less protection for certain STDs that can also be spread by contact with infected skin outside the area covered by the condom, **such as genital herpes and human papillomavirus (HPV) infection.** ~~Condoms cannot protect against these STDs when they are spread in this way.~~ **Still, using latex condoms every time you have sex may still gives you some benefits protection** against these STDs. ~~For example, using a condom may lower your risk of catching or spreading genital herpes. Using a condom also may lower your risk of developing HPV-related diseases, such as genital warts and cervical cancer.~~”*

Such a clarification is particularly important given that the evidence of condom effectiveness against transmission of these diseases has been strengthened by recent published data (Wald A et al. *Ann Intern Med.* 2005;143:707-713) and by presented data (Winer RL et al. *The effect of consistent condom use on the risk of genital HPV infection among new sexually active young women.* Poster presented at the 16th meeting of the International Society for Sexually Transmitted Diseases Research, Amsterdam, the Netherlands, July 2005).

B. Labeling Recommendations Related to the Use of N-9 in Condoms with Spermicidal Lubricant

The draft guidance for latex condoms with Nonoxynol-9 (N9) states correctly that the extent of additional pregnancy protection provided by N-9 has not been measured, and that the N-9 lubricant does not protect against HIV/AIDS or other STDs. Recent studies by the Joint United Nations Programme on AIDS (UNAIDS), the World Health Organization (WHO), and the Centers for Disease Control and Prevention (CDC) have concluded that N-9 not only does not help prevent STIs, it actually increases the risk of contracting HIV, the virus that causes AIDS

As a result of this research, the CDC and WHO have recommended that couples be informed that N-9, when used vaginally multiple times per day, can cause genital lesions—a condition that may increase a woman’s risk of acquiring HIV. Finally, and of extreme importance, these studies have found that, even at low doses, N-9 can cause massive, short-term damage to the rectal epithelium (lining), thereby increasing an individual’s risk of contracting HIV and other STDs during anal intercourse.

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Because of this evidence, the San Francisco AIDS Foundation has joined with a broad coalition of women's health groups, HIV/AIDS organizations, state and local public health officials, and research scientists calling on manufacturers to remove N-9 from condoms and lubricants, because the small amount of N-9 they contain is dangerous if used rectally and offers no documented contraceptive benefit. While there has been progress on this front, we are disappointed that some companies continue to produce N-9 condoms. **The San Francisco AIDS Foundation strongly encourages the FDA to take immediate steps to end the manufacturing or sale of condoms containing N-9.**

In light of FDA's decision to proceed with the labeling of condoms with N-9, we agree that a warning statement addressing vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission **must** appear on the retail package. The warning on vaginal irritation, however, should clarify that *frequent use* can increase vaginal irritation, and it should define that term. Adding "(more than once a day)" would make the guidance consistent with the proposed warning statement for over-the-counter vaginal spermicides containing N-9, proposed by the FDA on January 16, 2003 (Docket No. 80N-0280).

We further suggest that all of the information on the retail package about N-9 be grouped together and that the second bullet point under the N-9 warning in the draft guidance, which is repetitive, be deleted in order to sharpen the critical messages for consumers.

In summary, we recommend that the **retail package** include the following statements on N-9, and that these statements be grouped together; (proposed new language appears in **bold** and language to be deleted is ~~crossed out~~.)

*"The lubricant on this condom contains ~~the spermicide~~ nonoxynol-9 (N-9), which kills sperm; however, the amount of additional pregnancy protection provided by the N-9 **on this condom** has not been measured, **and N-9 does not protect against HIV/AIDS or other sexually transmitted diseases.***

Nonoxynol-9 Warning:

- ***Frequent use (more than once a day) of the spermicide nonoxynol-9 (N-9) can irritate the vagina, which may increase the risk of getting HIV/AIDS from an infected partner.***
- ~~*If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected, you should choose a latex condom without N-9.*~~
- ~~*You should not use condoms with N-9 for anal sex. N-9 can damage the rectum and may increase the risk of getting HIV/AIDS from an infected partner. Condoms with N-9 should not be used for anal sex; however, if*~~

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a condom containing N-9 is the only method available, using this condom is significantly safer than using no condom at all.

Finally, the warnings for N-9 are sufficiently important to be included, by themselves, on the **primary condom package** (individual foil). The following is suggested language for the back of an individual foil packet of male latex condoms with N-9:

“N-9 Warning: The lubricant on this condom contains nonoxynol-9 (N-9), which kills sperm. Frequent use (more than once a day) of N-9 can irritate the vagina, which may increase the risk of getting HIV/AIDS from an infected partner. N-9 also can damage the rectum and may increase the risk of getting HIV/AIDS from an infected partner. Condoms with N-9 should not be used for anal sex; however, if a condom containing N-9 is the only method available, using this condom is significantly safer than using no condom at all.

For more important information on N-9, please read the box or package insert.”

We fully support the FDA’s efforts to ensure that people receive medically accurate information about all available methods to reduce the risk of unplanned pregnancy and sexually transmitted infection. Clearly, the FDA has a public health responsibility to ensure that medical device labels are easily understood, and reflect the best science available. We appreciate the opportunity to provide comments on condom labeling.

Respectfully,

Fred Dillon
Public Policy and Communications Director