



February 10, 2005

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 Sexuality Information and Education Council of the U.S. (SIECUS), a 41-year-old national, not-for-profit organization that supports sexual and reproductive health and rights is pleased to submit comments regarding the Food and Drug Administration's (FDA's) draft guidance on latex condoms entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex."

We would like to commend the FDA for holding true to scientific integrity in its careful consideration of the issues related to the efficacy of male latex condoms and the prevention of unintended pregnancy and sexually transmitted diseases (STDs), including HIV/AIDS. We applaud the FDA for its handling of the issues set forth in the guidance document as was required by Congress in the legislation of 2000 (*Public Law 106-554*), and are pleased that, overall, the revised guidelines are consistent with the current published scientific evidence about condoms effectiveness.

We do, however, wish to offer comments on the draft guidance for the labeling of male latex condoms with a focus on our concern that the addition of overly complex language may confuse consumers about the risks and benefits of condoms and may inadvertently lead to decreased condom use. Our comments are limited to three key areas of the labeling recommendations: male latex condoms containing N-9, STDs transmissible by skin-to-skin contact, and the table of method effectiveness rates.

VI. Labeling Recommendations

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

The draft guidance for latex condoms with N-9 states correctly that the extent of additional pregnancy protection provided by N-9 has not been measured, and that the N-9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. Moreover, additional research shows that in 2002 the Centers for Disease Control and Prevention and the World Health Organization 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, studies show 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.

Because of this evidence, SIECUS has lent its name to a campaign to caution the public about the appropriate use of N-9 and to encourage responsible behavior by industry. Led by the Global Campaign for Microbicides and endorsed by more than 85 scientists and public health organizations, the campaign calls on manufacturers to remove N-9 from condoms and lubricants, because the small amount of N-9

they offer no demonstrated benefit contain and may be dangerous if used rectally. While there has been progress on this front, we are disappointed that some companies continue to produce N-9 condoms.

We agree that a warning statement addressing vaginal irritation, damage to the rectal lining, and HIV/AIDS transmission must appear on the retail package; however, we feel that the guidance language stating the risk posed by N-9 is too definitive and may dissuade potential users from utilizing condoms altogether, even if no other barrier method of contraception is available.

For example, the suggested labeling regarding anal sex is definitive in its conclusion that condoms containing N-9 should not be used. While we in no way dispute that scientific evidence leads to this conclusion, SIECUS fears that such a strongly worded warning may lead potential users (and readers of the product labeling) to reject condom use altogether. Perhaps, the best way to remedy this situation is to include language that explains that use of an N-9 containing condom is significantly safer than not using a condom at all.

In addition, the warning on vaginal irritation should clarify that *frequent use* can increase vaginal irritation, and 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 the second bullet point under the N-9 warning in the draft guidance be deleted. This bullet, which begins “*If you or your partner has HIV/AIDS, or if you do not know if you or your partner is infected...*” as the suggested language for labeling concerns us because the majority of people in the United States do not know their HIV status. The suggested labeling language is such that we fear condom use may be rejected entirely in such a situation where an N-9 condom is that only barrier method available.

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 alone** 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 an N-9 containing condom is the only method available, using this condom is significantly safer than not using a condom at all.***

A. Labeling Recommendations for Latex Condoms

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

The draft guidance for the package insert is appropriately consistent with the current published scientific evidence about condom effectiveness in stating that male latex condoms used consistently and correctly can greatly reduce, but not eliminate, the risk of pregnancy and the risk of contracting or spreading HIV, and that condoms can also reduce the risk of other STDs, such as Chlamydia and gonorrhea, that are spread to or from the penis by direct contact with the vagina and genital fluids.

The FDA's suggested statement on condom effectiveness against those STDs that can be spread through skin-to-skin contact, however, is confusing. It is true that these STDs cannot be entirely prevented by condom use. The fundamental point, however, is that although condoms provide less protection against these STDs, they do afford *some* protection. Therefore, we recommend editing the proposed paragraph on STDs spread through skin-to-skin contact to simplify the statement on condom effectiveness against these STDs and clarify as follows:

*“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 infection by human papillomavirus (HPV)**—a virus that is linked to cervical cancer and genital warts. ~~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.~~”*

1. Pregnancy

Finally, we agree with the FDA that the table of method effectiveness rates is an important tool for couples, and no doubt many health professionals as well, in comparing various contraceptive methods. In that light, it is disappointing that the draft guidance includes a table that is out-of-date and contains significantly scaled back content from that which appears in the current labeling for combined oral contraceptives.

We recommend that the full scope of information on contraceptive options be included in the table on method effectiveness, not just information on other barrier methods. Moreover, we believe that both the perfect-use and typical-use effectiveness rates should be presented for every method. Couples need to be informed about what can be achieved with perfect use so that they can determine for themselves how “typical” or “atypical” they may be in terms of their ability to comply with a particular contraceptive regimen.

Choosing a contraceptive is a complex process. American women and men, and the medical professionals they consult, depend on the FDA to develop labeling guidance using the best available science and most up-to-date information available.

We thank the FDA for this opportunity to offer our comments on the important issue of condom labeling.

Sincerely,



William Smith
Vice President for Public Policy, SIECUS