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January 23, 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:

Through its work as an independent, not-for-profit organization focusing on reproductive health research, policy analysis and public education in the United States and internationally, the Guttmacher Institute has developed and analyzed a great deal of information on unintended pregnancy and sexually transmitted infections (STIs) and their implications for the health of women and men. Thank you for the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance on latex condoms, both with and without nonoxynol-9 (N-9), entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex."

Our comment is limited to three aspects of the draft guidance:

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The draft guidance for latex condoms with N-9 states correctly that the extent of additional pregnancy protection provided by N-9 has not been measured, and that the N-9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 STIs. Moreover, 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 STIs during anal intercourse.

Because of this evidence, the Guttmacher Institute has lent its name to a campaign to caution the public about the appropriate use of N-9 and to encourage responsible behavior

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by industry. Led by the Global Campaign for Microbicides and endorsed by more than 80 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 contain is dangerous if used rectally and offers no demonstrated contraceptive benefit. While there has been progress on this front, we are disappointed that some companies continue to produce N-9 condoms.

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. You should never use condoms with N-9 for anal sex.*~~

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. You should never use condoms with N-9 for anal sex.

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

A. Labeling Recommendations for Latex Condoms

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

The draft package insert appropriately states that male latex condoms used consistently and correctly can greatly reduce, but do not eliminate, the risk of pregnancy and the risk of contracting or spreading HIV, and that condoms can also reduce the risk of other STIs, 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 STIs that also can be spread through skin-to-skin contact, however, is confusing. It is true that these STIs cannot be entirely prevented by condom use. The fundamental point, however, is that although condoms provide less protection against these STIs, they do afford some protection. We recommend deleting the second, fourth and fifth sentences of the paragraph on STIs spread through skin-to-skin contact to simplify the statement on condom effectiveness against these STIs:

*“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.~~”***

A. Labeling Recommendations for Latex Condoms

1. Pregnancy

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 significantly reduced from that which appears in the current labeling for combined oral contraceptives.

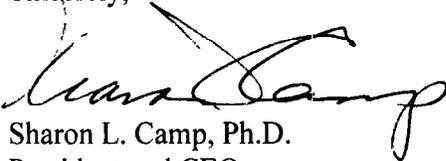
We recommend that the full scope of information on contraceptive options be included in the table on method effectiveness, not just information on other barrier methods. Choosing a contraceptive is a complex process. American women (and men), and the medical professionals they consult, depend on the FDA to develop labeling guidance that is complete and medically accurate in order to help them make informed decisions with respect to the different options available to them.

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.

Finally, the table should be based on the best available science, using the most up-to-date information available. For an updated version of the table of method effectiveness, see Trussell J, Contraceptive failure in the United States, *Contraception*, 2004, 70:89–96. See also Trussell J, Contraceptive efficacy, in: Hatcher RA, et al., eds., *Contraceptive Technology*, 18th revised edition, New York: Ardent Media, 2004, pp. 773–845.

We thank the FDA for the opportunity to provide these comments and would be happy to respond to any questions it may have.

Sincerely,

A handwritten signature in black ink, appearing to read "Sharon L. Camp". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Sharon L. Camp, Ph.D.
President and CEO