

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

Federal Register Docket No. 2004D-0555

To Whom It May Concern:

The National Coalition of STD Directors (NCSA) 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.

NCSA represents the 65 state, city, and territorial STD directors. As directors of public health sexually transmitted disease (STD) prevention efforts across the United States, our members serve on the front lines of the epidemic, representing clinics that distribute condoms and see people every day who use them.

As such, an important goal for our organization and others dedicated to reducing 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 STDs that condoms, used correctly and consistently, are a necessary and effective way to prevent infection. We are concerned that any new labeling not undermine the public's confidence in condoms.

We were particularly concerned that the Intended Use statement in the draft guidance is restricted to pregnancy and HIV prevention and does not mention the many other STDs that are prevented by correct and consistent condom use.

NCSA suggests the following revisions to the Intended Use statement proposed in the draft guidance:

*“When used correctly every time you have sex, latex condoms ~~greatly reduce, but do not eliminate,~~ the risk of pregnancy and ~~the risk of catching or spreading~~ **transmission of HIV, the virus that causes AIDS and other sexually transmitted diseases (STDs).**”*

The revised guidelines published in the *Federal Register* are consistent with the current published scientific evidence about condom effectiveness. However, 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* 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:

*“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). The FDA should use the best available science, using the most up-to-date information available.

Similarly, we believe it is critically important that a warning statement addressing vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission appears on the retail package. The warning against rectal use is appropriate and necessary. The warning on vaginal irritation, while also important, should clarify that research has shown increased vaginal irritation only with frequent use. The term “frequent” should be defined based on the best scientific data available. Moreover, the warnings for nonoxynol-9 (N-9) are sufficiently important to be included on the primary condom package (individual foil).

We fully support the FDA’s efforts to ensure that people receive medically accurate information about all available methods to reduce the risk of 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,

Don Clark
Executive Director
National Coalition of STD Directors