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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 American Social Health Association (ASHA) 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 remain unconvinced that this guidance was necessary; however, we believe the proposed language reflects the published scientific evidence about condom effectiveness.

ASHA is a 92-year-old nonprofit organization dedicated to providing factual, unbiased information about sexually transmitted diseases (STDs), including HIV, to improve the health of individuals, families, and communities. ASHA provides information to health care providers, policy makers, the press and to millions of people who have been diagnosed with an infection or are concerned about STD prevention.

We are deeply committed to increasing levels of consistent and correct condom use to stop the spread of infections among those who are sexually active.

The condom label should be easy to read and understand.

We are concerned that the addition of overly complex language to the condom label may confuse consumers about the risks and benefits of condoms. It is imperative that the condom label communicate clearly that condoms, used correctly and consistently, can reduce the risk of sexually transmitted infections, HIV and pregnancy.

The proposed language would benefit from simpler wording and a lower reading level. The draft guidance on STDs currently reads at a *twelfth-grade reading level* on the Flesch-Kincaid scale, although the reading comprehension of the average American adult is *below the ninth-grade* level. Improving the readability would permit greater comprehension among condom users in a range of literacy levels. The language should be short and simple.

The Intended Use statement should reflect the scientific finding that condoms reduce the risk of transmitting STDs.

We are particularly concerned by the omission of protection against STDs in the Intended Use statement. The draft guidance in section VI provides recommended labeling relative to the principal intended actions [“Intended Use”] of latex condoms, which informs a prospective user about the primary reasons for using a product.

The Intended Use statement should clearly communicate the *complete* intended actions of latex condoms. It should refrain from wordy sentences, laden with multiple clauses. It should not include any language that makes it difficult for consumers to understand the simple purpose of latex condoms.

ASHA is extremely concerned that the Intended Use statement in the draft guidance is misleading. The statement is restricted to pregnancy prevention and HIV prevention and does not mention the many other STDs that can be prevented by correct and consistent condom use.

In the preamble the FDA cites “strong support for the conclusion that condoms are effective in reducing the overall risk of STD transmission...” ASHA agrees with this conclusion. The Intended Use statement must convey to people who are purchasing condoms (and, therefore, likely to have sex and be at risk for STDs) that condoms, used correctly and consistently, are a necessary and effective way to prevent infection. Put simply, the Intended Use statement should communicate that condoms reduce the risk of pregnancy and transmitting HIV and STDs.

Limiting the proposed Intended Use statement to preventing pregnancy and the transmission of HIV without referencing efficacy against other STDs is incomplete. Yes, STDs are transmitted differently, and effectiveness varies; however, the overall message of STD transmission reduction for persons who are sexually active is medically accurate and must be included.

Therefore, ASHA 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 draft 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 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 appropriate follow-up care. These issues are clearly complex. The proposed guidance is unnecessarily confusing.

ASHA recommends editing the proposed paragraph for clarity as follows:

“Condoms provide less protection for certain STDs, such as genital herpes and human papillomavirus (HPV) infection, that can also be spread by contact with infected skin outside the area covered by the condom. ~~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). Dr. Winer’s article has been submitted to the *New England Journal for Medicine*. The FDA should use the best available science, utilizing the most up-to-date information available.

Condoms with N-9

ASHA recognizes the importance of having a warning statement on the retail package that addresses vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission. The warning against rectal use is appropriate and necessary. The warning on vaginal irritation, should clarify that research has shown increased vaginal irritation occurs 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.

Currently, condoms are the best available means to reduce the transmission of sexually transmitted infections, HIV and unintended pregnancy. Labels should be medically accurate without undermining public confidence in condoms.

We appreciate the opportunity to provide comments on condom labeling and look forward to the day when the FDA will be regulating the use of vaccines, microbicides and other products to expand options for the prevention of HIV and other sexually transmitted infections.

Respectfully,

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