



February 13, 2006

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:

I am writing on behalf of the National Family Planning and Reproductive Health Association (NFPRHA), to submit comments on the condom labeling guidance proposed by the Food and Drug Administration (FDA) in the *Federal Register* of November 14, 2005. A national non-profit membership organization, NFPRHA represents clinicians, administrators, researchers, educators, advocates and consumers in the family planning field. Our member organizations provide reproductive health care at more than 4,000 clinics nationwide, to nearly five million low-income women each year. We appreciate this opportunity to provide comments, and we understand that Congress required a review of the label and that the proposed language was developed after extensive review of available scientific evidence.

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 pregnancy and sexually transmitted diseases (STDs) that condoms, used correctly and consistently, are a necessary and effective way to prevent unintended pregnancy and infection. We are therefore concerned that new labeling not undermine the public's confidence in condoms.

Overall, we are pleased that the revised guidelines published in the *Federal Register* are consistent with the current published scientific evidence about condom effectiveness. We are concerned, however, 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 give 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).

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.

NFPRHA is extremely concerned that the Intended Use statement in the draft guidance is incomplete. The statement mentions pregnancy prevention and HIV prevention but does not mention that other STDs can be reduced by correct and consistent condom use. 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.

Therefore, we suggest 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).”

It is important that a warning statement addressing vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission related to nonoxynol-9 (N-9) appears on the retail package. The warning against rectal use is appropriate and necessary. The warning on vaginal irritation, while also important, should however clarify that research has shown increased vaginal irritation only with frequent use, and the term “frequent” should be defined based on the best scientific data available. Moreover, the warnings for N-9 are sufficiently important to be included on the primary condom package (individual foil). It is critical, however, that in the absence of additional evidence, these warnings not be extrapolated in ways that would discourage women from using N-9-containing

spermicides with products such as the diaphragm and cervical cap or in the contraceptive sponge, which remain important contraceptive options for women attempting to reduce their risk of pregnancy.

Finally, 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. 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. The table in the draft guidance is out of date. The FDA should use the best available science, using the most up-to-date information available.

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,

A handwritten signature in cursive script that reads "Judith M. DeSarno".

Judith M. DeSarno
President and CEO
National Family Planning and Reproductive Health Association