

February 10, 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:

We greatly appreciate the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance on latex condoms, both with and without nonoxynol-9 (N-9), entitled "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural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." As America's oldest, largest, and most trusted provider of family planning services, education, and reproductive health care, Planned Parenthood Federation of America (PPFA), believes in the right of every individual to have access to the information, services, and products people need to stay healthy, plan their families, and make responsible choices about sex and reproduction that best suit their health needs. This philosophy is what we practice in our 120 affiliates that serve five million women, men and adolescents each year in over 850 health centers in communities across the nation.

After careful review of the Draft Guidance we find that the FDA has made a good faith effort to respond to a Congressional mandate requiring that condom labels be reexamined, "to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases, including HPV." We believe that the FDA is headed in the right direction in attempting to inform consumers that condoms are not perfect in protecting against sexually transmitted infections (STIs) and pregnancy and that N-9 does not provide any protection against STIs. However, PPFA does have some concerns and suggestions that are detailed below: 1) the labeling recommendations regarding STIs transmissible by contact outside the area of the condom, 2) the labeling recommendations regarding pregnancy and 3) the labeling recommendations for condoms that contain N-9.

Our primary concern with the draft guidance is that it lacks a balanced approach regarding the benefits of condoms for STI prevention and protection against pregnancy. The overemphasis on condom imperfection without the balance of condom benefits could dissuade sexually-active individuals from using condoms. Any confusion regarding risks and benefits that might scare sexually-active individuals away from condom use poses a serious threat to public health. The very act of seeking condom use is a hallmark of responsible sexual behavior. Most individuals who purchase, or otherwise acquire condoms, intend to engage in sexual activity and are seeking the protection that condoms accord. With the goal of reducing unintended pregnancy and STIs in mind, we believe that consumers reading a condom label should get a clear message that condoms, even though imperfect, do greatly

reduce risks for pregnancy and STIs and that correct and consistent use increases their effectiveness. Most importantly, condoms provide the best protection against STIs for a sexually-active individual.

These messages need to be prominently and explicitly conveyed within every "Important Information" section of the primary condom package (individual foil), retail package, and package insert so that consumers can balance condom protection against condom imperfection with respect to STIs and pregnancy prevention. However, with warning labels taking up such a large amount of space on the condom packaging, we worry that consumers will find the information cumbersome and that condoms will appear undesirable. Due to the fact that such an extensive amount of information is being conveyed, we suggest that the most important messages be in boldface type and that the language be simplified to the extent possible. Again, it is essential that the information provided assist the individual in making an informed decision about condom use; and should be described in a way that does not dissuade condom use.

VI.(A.) Labeling Recommendations for Latex Condoms

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

An example of overly complex language that may confuse consumers about risks and benefits that could lead to decreased condom use is found in the FDA's suggested statement on condom effectiveness against STIs transmissible by contact outside the area covered by the condom. While it is true that condoms provide less protection against STIs such as genital herpes and human papillomavirus (HPV), the key message is that they do provide *some* protection.

This message is especially important, given recent evidence that finds that consistent use is associated with lower infection rates of herpes simplex virus-2 (Anna Wald et al. 2005. The Relationship between Condom Use and Herpes Simplex Virus Acquisition. *Annals of Internal Medicine*, 143, 707–713), that condoms significantly reduce the risk of HPV transmission among women (Winer R.L. 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) and that regression of HPV lesions in women and men is accelerated by condom use (C.G. Maaike et al. 2003. Condom Use Promotes Regression of Cervical Intraepithelial Neoplasia and Clearance of human Papillomavirus: A Randomized Clinical Trial. Condom Use Promotes Regression of Human Papillomavirus-Associated Penile Lesions in Male Sexual Partners of Women with Cervical Intraepithelial Neoplasia. *International Journal of Cancer*, 107, 811–816 & 804–810).

Additionally, we are concerned that the guidance may confuse condom users about the risk of contracting cervical cancer. The reality is that the vast majority of sexually-active individuals will become infected with HPV at some point in their lives, but in most cases the virus will clear with no ill effects. It is only in rare instances that persistent infection with certain strains of HPV leads to cervical cancer. Without the inclusion of this other important

information about HPV, the guidance could confuse condom users about the risks of contracting cervical cancer.

Given these concerns we recommend simplifying the suggested statement with the following changes:

“Condoms provide less protection for certain STDs, such as genital herpes and human papillomavirus (HPV), 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.~~ Condoms only protect skin that is covered; STD’s located on skin outside the condom could be spread to an uninfected partner. 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.~~”

VI.(A.) Labeling Recommendations for Latex Condoms

1. Pregnancy

Another example of overly complex language that is featured several times in a number of different contexts throughout the draft guidance, including in the recommendations with respect to pregnancy, that might lead to confusion is the phrase “*but do not eliminate*”. For instance, the example of an acceptable statement on page 10 says, “*When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy*”. The line “*latex condoms greatly reduce*”, implies the same thing as “*but do not eliminate.*” The “*but do not eliminate*” line is repetitive, unnecessary, and could dissuade condom use. Nowhere do the guidelines suggest that latex condoms always prevent the risk of pregnancy or infection, so the guidelines should simply state that condoms reduce the risks. We, therefore, recommend that the “*but do not eliminate*” line be removed from the recommendations.

On a separate note, the table of method effectiveness rates is an important resource that should allow consumers to be able to compare contraceptive methods. The table should be up-to-date and include all barrier methods (e.g., Lea’s Shield[®] and FemCap[®]). Additionally, we recommend including in the table not just barrier contraceptive methods but the full range of methods, just as they are included in the current labeling for combined oral contraceptives. Choosing a contraceptive method is an often overwhelming and complex experience, and the labeling should present a full picture of the different options available.

We also recommend that “perfect-use” data be incorporated in addition to the “typical-use” data for each method. The consumer should be informed about “perfect-use” data as well as “typical use” data — because the “typical-use” data only accounts for couples who don’t use a condom correctly and for every act of intercourse. A consumer may fall into either or both of these categories, depending upon pattern of use and should be informed about what can be achieved with “perfect use” so that they can determine how “typical” or “atypical” they may

be in the use of a particular option. Including perfect-use data would be helpful to reinforce the importance of using a condom correctly and consistently with every act of intercourse in order to approach the highest level of effectiveness. And it is important to further encourage consumers to read the directions carefully. This emphasis can be achieved through boldface type.

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

The draft guidance correctly states that Nonoxynol-9 (N-9) kills sperm but that the extent of additional pregnancy protection provided by N-9 has not been measured and that N-9 does not protect against HIV/AIDS or other STIs. We agree that a warning advising against anal use and about damage to rectal epithelium and increased risk for HIV/AIDS transmission should appear on the retail package of condoms containing N-9. We also agree that the warning should address vaginal irritation, however, the warning about vaginal irritation should clarify that research has shown increased vaginal irritation only with frequent use. The term "frequent" should be defined based on the best scientific evidence available.

We also believe it is important for the N-9 information to be clearly separated from the general information about condoms, so that the consumer clearly understands the information is only about N-9 and, if concerned, she/he should choose a condom without N-9. This can be done by prefacing the N-9 information with a heading such as "About Nonoxynol-9 (N-9), the Lubricant found on this Condom". Additionally, consumers should be warned that the information about N-9 also applies when a condom without N-9 is used in conjunction with a vaginal spermicide, since all U.S. spermicides contain N-9.

In closing, PPFPA would like to reiterate that the FDA is headed in the right direction in its attempts to improve accuracy and truth in labeling. With the addition of more balanced information individuals will be able to make informed choices that best suit their health needs. We hope that this move toward more accurate labeling is not limited to condoms. While all products should have similar labeling requirements, we are unaware of any other over-the-counter product that has been singled out in this manner. We support the efforts to ensure that consumers receive medically accurate and easily understood information that helps them make responsible choices about reducing the risk of unintended pregnancy and STIs. Again, thank you for the opportunity to provide comments on this important public health matter.

Sincerely,



Karen Pearl
Interim President
Planned Parenthood Federation of America

