



## FDA Comment

Docket Number 2004N-0556

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February 13, 2006

Andrew von Eschenbach, MD  
Acting Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, Maryland 20852

Dear Dr. von Eschenbach:

On behalf of the Illinois Caucus for Adolescent Health (ICAH) and its statewide membership of individuals and organizations committed to the sexual health of Illinois young people, we are submitting public comment for docket number 2004N-0556, "Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex."

ICAH supports condom labels that not only provide accurate information the transmission of HIV and other sexually transmitted infections (STIs) including human papillomavirus (HPV), but also emphasize the importance of condoms in decreasing the likelihood of disease transmission. It is critical that labeling underscore the fact that latex condoms, when used correctly and consistently, are currently the single most effective form of protection against HIV and other STIs.

**In the draft warning label released by FDA, we are concerned with the following statement:**

*Condoms provide less protection for certain STDs, including 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. Using latex condoms every time you have sex may still give you some benefits 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.*

By placing undue emphasis on what condoms cannot do, and making an afterthought of what they can do, the comment undermines most prevention efforts that stress condom use and may deter individuals from using them at all. By first highlighting that condoms are the most effective form of protection available, the label would successfully reinforce the importance of using condoms consistently and correctly, and would then remind condom users that they are highly effective but not foolproof.

It is of paramount importance that we inform and educate people in a way that encourages healthy behavior and choices that mitigate some risk rather than dissuading people from taking precautions. A grave error has been made if the response to these labels is reluctance to use protection. To achieve this, the labels should be written to encourage, rather than discourage, condom use by underscoring their importance in greatly reducing the risk of transmission of STIs.

Sincerely,

Jobi Petersen  
Executive Director

Karen A. Reitan  
Public Policy Director