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December 8, 2005

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

*Federal Register* **Docket No. 2004D-0555**

Dear Dockets Management Administrator,

We write to provide the input of Public Health – Seattle & King County regarding the condom labeling being proposed by the Food and Drug Administration (FDA) in the Federal Register of November 14, 2005 in relation to issues requiring special controls. We understand that the need for additional labeling language was required by Congress, and that the proposed language was generated, after extensive reviews of the evidence, by the FDA in consultation with the National Institutes of Health and the US Centers for Disease Control and Prevention (CDC).

In short, we think that the proposed labeling guidelines, as published in the *Federal Register* Docket, are consistent with the current published and presented but not yet published scientific evidence about condom effectiveness, and that these guidelines should NOT be further modified, especially in any way that make condoms, correctly used, appear any less effective in the areas addressed (e.g., pregnancy, HIV prevention). We are pleased that the guidelines reflect some condom effectiveness against both herpes simplex virus, type 2, and human papilloma virus, since the evidence of their effectiveness against transmission of these diseases, with lesions often not covered by condoms, 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).

Although we understand this Congressionally-required need for Special Controls labeling, we are very concerned that the addition of extensive labels to condom packaging may constitute “red flags” to consumers intending to have sex, and that those flags may increase sex without the protection of condoms. Given that many persons prefer sex without condoms and the new

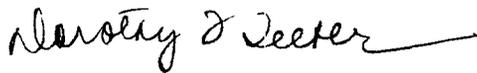
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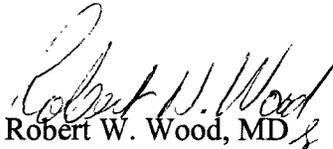
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labeling clarifying that condoms may not be as effective as desired or imagined, many people may chose to simply have sex, forego the condom, and take their risks. If such labeling increases the number of persons who have intercourse without condoms, one would logically expect an increase in unwanted pregnancies and of sexually transmitted diseases (STD). Thus, the introduction of extensive new labeling deserves careful study. Given the potentially huge national impacts of unwanted pregnancies and of STD, we urge FDA to work with NIH, CDC, and other research colleagues to monitor the impact of labeling and to learn how to better reduce the adverse consequences of unprotected sex.

Respectfully yours,



Dorothy F. Teeter, MHA  
Interim Director & Health Officer



Robert W. Wood, MD  
Director, HIV/AIDS Control Program