



February 10, 2006

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

RE: **Comments on FDA Condom Labeling Guidance**  
*Federal Register* Docket No. 2004D-0555 (November 14, 2005)

To the Center for Devices and Radiological Health, OB/GYN Gastroenterology and Urology Devices Branch:

Please accept the following comments on the condom labeling guidance proposed by the Food and Drug Administration (FDA). These comments are submitted on behalf of SMART, Inc. (Sisterhood Mobilized for AIDS/HIV Research and Treatment), a community prevention and education program created and operated by women with HIV; the AIDS Law Project of Pennsylvania, a state-wide legal advocacy organization assisting thousands of individuals with basic health and survival issues; Hyacinth Foundation, New Jersey's oldest and largest HIV/AIDS client service organization; and the Center for HIV Law and Policy, a national HIV resource and support center for HIV advocates. Each of these organizations strongly believe that access to complete, accurate, unbiased information about sexual health and disease prevention options – the benefits as well as the risk – is central to slowing the spread of HIV in this country.

Together we are, and/or we serve, many women living with HIV who likely would be uninfected today if their sexual partners consistently used condoms, and if they were encouraged to insist on their use as the best current protection available against HIV and other sexually transmitted diseases. A woman's marital status or faithfulness, in our experience, often is irrelevant – most of the women we know were infected through sex with a spouse or a partner they thought was monogamous and heterosexual. In fact, faithful married women tend to take fewer precautions and consequently are often, in this country and around the world, more likely to get infected. For most women, condoms are the best, most affordable, and usually the only available protection against pregnancy, HIV infection and other diseases. A suggestion, through unnecessarily complex, ambivalent or vague labeling, that the protection against disease that condoms offer is not offset by their failure rate or the inconvenience of using them could have deadly consequences.

Of course, condoms are not perfect – no currently available protection against sexually transmitted disease, including recommending abstinence from intercourse, is perfect. But just as we would not want condom labeling to overstate effectiveness, we believe it

is important that any labeling convey clearly that condoms, used correctly and consistently, are a necessary and effective way to prevent pregnancy and HIV infection.

We think that the revised condom labeling guidelines on effectiveness are largely consistent with the current scientific evidence. However, the addition of unnecessarily complicated (and ultimately incomplete) language concerning the risk of transmission of STDs by skin-to-skin contact could sufficiently confuse consumers and discourage condom use by suggesting that condoms don't provide sufficient protection to justify their use. Promoting condom use to prevent HIV, for example, has been quite effective in slowing disease transmission yet presents ongoing challenges, as most people would prefer not to use condoms at all. In addition, current cultural realities among some populations require constant, ongoing reinforcement and encouragement to empower women and younger people to insist on consistent condom use. The clear, accurate and simple message is that although condoms provide less protection against STDs such as genital herpes and human papillomavirus (HPV), they *do* provide a level of protection.<sup>1</sup>

In particular, the guidance on STDs that can be spread by skin-to-skin contact should be simplified. The current labeling proposal could confuse consumers into believing that condoms are of little value in preventing infection, and that HPV is a frequent cause of cervical cancer, when in fact most of the millions of people who contract HPV in this country suffer no ill effects and cervical cancer is relatively rare in the United States. The facts, including the importance of regular Pap smears for early detection of cervical cancer and other disease, are simply too complex to attempt inclusion on condom packaging without causing confusion. Therefore, we recommend editing the relevant 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.~~

Further, it is critically important that a warning statement addressing vaginal irritation, damage to the rectal epithelium and HIV/AIDS transmission appears on the retail package, and that the warnings for nonoxynol-9 (N-9) be included on the individual condom foil packaging.

Finally, we also believe that the full scope of information on contraceptive options be included in the table on method effectiveness, along with the perfect-use and typical-use effectiveness rates for every method, and that it be revised to reflect the best science and the most up-to-date information available.

The single most realistic, accessible and affordable tool in the public health fight to prevent HIV is informed, correct, consistent condom use. We believe in the importance of FDA leadership and its central, critical role in ensuring that people receive medically

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<sup>1</sup> E.g., Wald A. et al., 143 ANN INTERN MED. 707-713 (2005).

accurate information about all available methods to reduce the risk of HIV, unsafe or unplanned pregnancies, and sexually transmitted disease.

Respectfully submitted,

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