

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

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Federal Register Docket No. 2004D-0555

To Whom It May Concern:

The undersigned organizations appreciate the opportunity to provide comments on the condom labeling guidance proposed by the Food and Drug Administration (FDA) in the *Federal Register* of November 14, 2005. We understand that Congress required a review of the label, and that the proposed language was developed after extensive review of available scientific evidence.

An important goal for public health providers and organizations dedicated to reducing unintended pregnancy and the transmission of sexually transmitted diseases (STDs) is to increase levels of consistent and correct condom use in all sexually active populations. 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 STDs that condoms, used correctly and consistently, are a necessary and effective way to prevent pregnancy and infection. We are concerned that new labeling not undermine the public's confidence in condoms.

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

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~~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 believe 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. 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. The term "frequent" should be defined based on the best scientific data available. Moreover, the warnings for nonoxynol-9 (N-9) are sufficiently important to be included on the primary condom package (individual foil).

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,

AIDS Action

AIDS Action Committee of Massachusetts, Inc.

AIDS Foundation of Chicago

The AIDS Institute

AIDS National Network, The Title II Community

AIDS Project Los Angeles

American Academy of HIV Medicine

American Academy of Pediatrics

American Association of Sexuality Educators, Counselors, & Therapists

American College of Obstetricians and Gynecologists

American Medical Student Association

American Public Health Association
American Social Health Association
Association of Reproductive Health Professionals
Catholics for a Free Choice
Center for Health and Gender Equity
Center for Women Policy Studies
Gay Men's Health Crisis
Guttmacher Institute
Healthy Teen Network
NARAL Pro-Choice America
National Abortion Federation
National AIDS Fund
National Alliance of State and Territorial AIDS Directors
National Coalition of STD Directors
National Association of Nurse Practitioners in Women's Health
National Family Planning and Reproductive Health Association
National Partnership for Women & Families
National Women's Health Network
Northwest AIDS Education and Training Center, Center for Health Education and
Research, University of Washington
Parents, Families and Friends of Lesbians and Gays
Pathfinder International
Planned Parenthood Federation of America
Planned Parenthood of South Central New York, Inc.
Reproductive Health Technologies Project
San Francisco AIDS Foundation
Society for Adolescent Medicine
The Society for the Scientific Study of Sexuality
Unitarian Universalist Association of Congregations
The Woodhull Freedom Foundation



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February 9, 2006

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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Please substitute the enclosed letter regarding docket number 2004D-0555 for the version that I suspect you received yesterday.

Thank you.

Sincerely,

Marilyn J. Keefe
Vice President of Public Policy