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**Action:** Special Controls

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**Comments Submitted by:** Hon. Mark E. Souder  
Chairman, Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, U.S. House of Representatives

The Food and Drug Administration’s recommendations for new condom labels finally acknowledge the fact that condoms do not provide effective protection against certain sexually transmitted diseases spread by contact with infected skin outside the area covered by a condom. Inasmuch as the new label recommendations make this acknowledgement, this is a step in the right direction.

Nonetheless, I am discouraged by the FDA’s misleading recommendation that condom use may lower a user’s risk of developing HPV-related diseases, such as genital warts and cancer. Such a statement is based upon inconclusive and conflicting scientific data, and addresses only the *effect* of an HPV infection, but not the underlying infection itself. This dangerous assurance overlooks the fact that condoms will not protect a user from contracting or spreading the sexual disease to others.

The FDA’s new recommendations, in the form of a “Special Controls Guidance” (which is non-binding on manufacturers), are the result of a law passed by Congress five years ago, signed by President Clinton, that directs the FDA to ensure that condom labels are medically accurate regarding their overall effectiveness or lack of effectiveness in preventing infection with sexually transmitted diseases (STDs), including human papillomavirus (HPV).

A Workshop on condom effectiveness conducted in 2001 by the FDA, CDC, NIH, and USAID<sup>1</sup> concluded that there was “no epidemiologic evidence that condom use reduced the risk of HPV infection.” This analysis is the largest ever conducted to review the available scientific data on condom effectiveness. While it did find that condoms reduce, but do not eliminate, the risk of HIV and gonorrhea (for men only), it also concluded that that “the published epidemiologic data were insufficient to draw meaningful conclusions about the effectiveness of the latex male condom to reduce the risk of transmission of genital ulcer diseases (genital herpes, syphilis and chancroid).”

Additionally, the National Cancer Institute (NCI) found that “condoms are ineffective against HPV.” In a statement to Congress, the NCI stated that “the conclusion that condoms are

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<sup>1</sup> National Institute of Allergy and Infectious Diseases, National Institutes of Health, “Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention,” July 20, 2001.

ineffective against HPV infection is based on the results of several long term studies that have failed to show that barrier contraceptives prevent cervical HPV infection, dysplasia, or cancer.”<sup>2</sup>

HPV infection is the primary cause of cervical cancer, and there is no cure for HPV infection, which may also cause genital warts, and may be transmitted to children during childbirth. Cervical cancer will kill an estimated 3,700 American women this year.

In the five years it has taken the FDA to comply with this simple law, an estimated 27 million Americans have become infected with HPV, over 50,000 women have been diagnosed with invasive cervical cancer, and nearly 20,000 women have died from the disease. Despite these tragic numbers, very few Americans are even aware of HPV or its link to cervical cancer.

To take five years to provide the condom industry with a non-binding special controls guidance that contains misleading information is not the quality work Americans should expect from the FDA.

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<sup>2</sup> Richard D. Klausner, Director of the National Cancer Institute, correspondence to U.S. House Commerce Committee, February 19, 1999.