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August 2, 2005

The Honorable Lester Crawford
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

With the Food and Drug Administration (FDA) now reviewing the labeling of condoms, I am writing to bring to your attention an important new research study. The study found that consistent condom use reduced the risk of human papillomavirus (HPV) acquisition in women by 70%. The study may explain why condoms protect against cervical cancer, a potentially lethal illness caused by certain strains of HPV.

In recent months, several conservative organizations and members of Congress have called on FDA to change condom labeling to say that condoms do not protect against HPV. Such a move, however, would appear to contradict the best available scientific evidence and mislead consumers.

I urge FDA to review this new research carefully before proposing any changes to condom labeling involving HPV.

Background

For several years, scientific consensus has supported the effectiveness of condoms in protecting against cervical cancer. In 2001, a comprehensive review by the National Institutes of Health (NIH) found that of ten studies of condoms and precancerous or cancerous changes in the cervix, six found statistically significant reductions in risk, ranging from 39% to 80%.[1] In 2004, the Centers for Disease Control and Prevention (CDC) issued a report to Congress on the

[1] National Institutes of Health, *Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention* (June 12 – 13, 2000) (online at http://www.niaid.nih.gov/dmid/stds/condomreport.pdf).

prevention of HPV.[2] The CDC panel found that "[a]vailable studies suggest that condoms reduce the risk of the clinically important outcomes of genital warts and cervical cancer."[3]

An important scientific question underlying these findings is how condoms protect against cervical cancer. One potential explanation is that condoms reduce the risk of acquiring HPV in the first place. Until recently, evidence was not adequate to evaluate this possibility. In 2000, NIH found that "most of the reviewed studies did not obtain sufficient information on condom use to allow careful evaluation of the association between correct condom use without breakage and HPV infection or disease."[4] CDC concurred that "[p]ublished studies that have assessed the effectiveness of male condoms to prevent HPV infection or any STD other than HIV are limited by multiple methodologic issues."[5]

Both CDC and NIH called for better research to assess whether condoms prevent against HPV. According to CDC, "Studies with optimal designs would collect information on consistent and correct condom use and would be able to determine whether HPV infection preceded or followed condom use."[6]

Recent Research

The type of study called for by government experts was recently presented at a meeting of the International Society for Sexually Transmitted Diseases Research.[7] In the study, 200 female university students were followed for an average of 22 months. Every four months, women had medical exams at which they were tested for the presence of the virus.

The study found that condoms significantly reduced the risk of HPV acquisition among women. Compared to women who used condoms less than 5% of the time, those who used them

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[2] U.S. Centers for Disease Control and Prevention, *Report to Congress: Prevention of Genital Human Papillomavirus Infection* (Jan. 2004) (online at http://www.nccc-online.org/hpv_report_jan%202004.pdf).

[3] *Id.* at 15.

[4] National Institutes of Health, *supra* note 1 at 25.

[5] CDC, *supra* note 2 at 13.

[6] *Id.* at 13-14.

[7] Rachel L. Winer et al., *The Effect of Consistent Condom Use on the Risk of Genital HPV Infection Among Newly Sexually Active Young Women* (July 11, 2005) (presented at the 2005 meeting of the International Society for Sexually Transmitted Diseases Research).

consistently — that is, for 100% of acts over the past eight months — were 70% less likely to acquire HPV in the cervical or vulvovaginal area. The effect for cervical HPV only was even greater, with 80% risk reduction. Even women who used condoms for only 55% to 99% of acts experienced risk reduction of 50%. These data were adjusted for all other factors in the study.

This study has impressed experts in the field of sexually transmitted disease. One such expert is Dr. King Holmes, Director of the University of Washington's Center for AIDS and Sexually Transmitted Diseases. Citing this study, Dr. Holmes stated, "Recent evidence suggests that condom use reduces risk of HPV infection, and the risk of HPV-associated diseases."[8]

Political Pressure on FDA

The new study, combined with previous evidence, seriously undermines the call by some conservative organizations and lawmakers for labeling that warns consumers that condoms do not protect against HPV.

In February 2005, HHS Secretary Michael O. Leavitt received several letters urging prompt action on condom labeling. One letter was from Senators Tom Coburn and James Inhofe; one was from Congressmen Tom Davis and Mark Souder; and one was from the leaders of multiple organizations, including Focus on the Family, the National Abstinence Clearinghouse, the Traditional Values Coalition, and the Culture of Life Foundation.[9] The organizations urged Secretary Leavitt to direct the FDA to "immediately comply with the law by requiring condom labels to provide consumers with medically accurate information that condoms do not provide effective protection against HPV infection."[10] Senators Inhofe and Coburn similarly urged the agency to "require condom labels to be medically accurate regarding the lack

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[8] Letter from King K. Holmes, M.D., Ph.D. to Henry A. Waxman, Ranking Minority Member, Committee on Government Reform, U.S. House of Representatives (May 27, 2005) (online at http://www.democrats.reform.house.gov/Documents/20050713100607-40261.pdf).

[9] Letter from Sens. James A. Inhofe and Tom A. Coburn to Secretary Michael O. Leavitt (Feb. 9, 2005); Letter from Reps. Tom Davis and Mark Souder to Secretary Michael O. Leavitt (Feb. 11, 2005); Letter from Leslee Unruh, National Abstinence Clearinghouse, Beverly LaHaye, Concerned Women for America, Tony Perkins, Family Research Council, Paul M. Weyrich, Coalitions for America, Peter M. Brandt, Focus on the Family, Phyllis Schlafly, Eagle Forum, Gary Bauer, American Values, Andrea Lafferty, Traditional Values Coalition, Colin A. Hanna, Let Freedom Ring, William J. Murray, Religious Freedom Coalition, Barret Duke, the Ethics and Religious Liberty Commission, Larry Cirignano, CatholicVote.org, and Austin Ruse, Culture of Life Foundation, to Secretary Michael O. Leavitt (Feb. 11, 2005).

[10] Letter from Leslee Unruh et al., *supra* note 9.

of protection against HPV infection."[11] Reps. Davis and Souder asserted that the law requires that condom labels to be "medically accurate regarding the lack of effectiveness of condoms in preventing HPV infection."[12]

As I have previously written to Secretary Leavitt, these demands are based on a misreading of the law and an ideologically skewed interpretation of the scientific evidence.[13] There has long been ample evidence that condoms do protect against cervical cancer, which is the most serious health outcome of HPV infection. Any warning about HPV that does not emphasize the protection against cervical cancer would seriously mislead consumers.

This new study underscores the error of what these organizations and members of Congress are recommending. They are pressuring FDA to require labeling to state that condoms offer no protection against HPV. In fact, the exact opposite appears to be true.

Conclusion

As a science-based agency, FDA must make its decisions on condom labeling based on the best available scientific evidence. I urge you to consider this important new research before proceeding with any proposal involving condom labeling and HPV.

Sincerely,

Henry A. Waxman
Ranking Minority Member

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[11] Letter from Sens. James A. Inhofe and Tom A. Coburn, *supra* note 9.

[12] Letter from Reps. Davis and Souder, *supra* note 9.

[13] Letter from Rep. Henry A. Waxman to Secretary Michael O. Leavitt (Apr. 5, 2005) (online at http://www.democrats.reform.house.gov/Documents/20050405174528-92431.pdf).