

Congress of the United States
House of Representatives
Washington, DC 20515

April 5, 2005

Honorable Michael O. Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Dear Mr. Secretary:

We are aware that you have received three letters about human papillomavirus from two Senators, two House members, and thirteen organizations. These letters distort medical facts, ignore critical lifesaving information related to cervical cancer, and lead to conclusions that are contrary to public health.

The best way to fight HPV infection and all other sexually transmitted infections is with the best available science, not ideology. We urge you to block any political interference with the public health experts in your Department working on these issues.

Human Papillomavirus

Human papillomavirus, or HPV, comprises several strains, some of which are sexually transmitted.¹ In the vast majority of instances, HPV causes no symptoms and the body clears the virus on its own.² In some cases, however, HPV can lead to tissue changes which, if undetected and untreated, can develop into cervical cancer.³

Fortunately, there have been major advances in the detection and prevention of cervical cancer. The most important are Pap smears, which can detect early tissue changes in the cervix.⁴

¹ U.S. Centers for Disease Control and Prevention, *Human Papillomavirus (HPV) Infection* (online at <http://www.cdc.gov/std/hpv/default.htm>).

² 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>).

³ U.S. Centers for Disease Control and Prevention, *Human Papillomavirus (HPV) Infection*, *supra* note 1.

⁴ U.S. Centers for Disease Control and Prevention, *Cervical Cancer and Pap Test Information* (online at <http://www.cdc.gov/cancer/nbccedp/info-cc.htm>).

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Because cervical cancer typically has a long pre-invasive state and treatment at this stage is effective, screening programs can greatly reduce the occurrence of invasive cervical cancer.⁵ According to the National Institutes of Health (NIH):

If all women had pelvic exams and Pap tests regularly, most precancerous conditions would be detected and treated before cancer develops. That way, most invasive cancers could be prevented. Any invasive cancer that does occur would likely be found at an early, curable stage.⁶

For this reason, the American Cancer Society, the U.S. Preventive Services Task Force, and the American College of Obstetricians and Gynecologists recommend that women begin cervical cancer screening within three years after the onset of sexual intercourse, but no later than age 21.⁷ Unfortunately, according to the U.S. Preventive Services Task Force, "Most cases of cervical cancer occur in women who are not screened adequately."⁸ Therefore, increased screening could reduce U.S. cervical cancer mortality rates.

Two other ways to reduce the risk of cervical cancer are condoms and vaccination. Condoms cannot block all HPV transmission, because HPV can be transmitted via exposed skin. According to the Centers for Disease Control and Prevention (CDC), however, evidence indicates that condoms do reduce the risk of cervical cancer itself, possibly by reducing the quantity of virus transmitted.⁹ In addition, CDC found that condom use is associated with

⁵ U.S. Centers for Disease Control and Prevention, *Basic Facts on Screening and the Pap Test* (online at http://www.cdc.gov/cancer/nbccedp/cc_basic.htm).

⁶ National Institutes of Health, *What You Need to Know about Cancers of the Cervix* (updated Sept. 16, 2002) (online at <http://www.cancer.gov/cancertopics/wyntk/cervix/page5>).

⁷ See D. Saslow, et al., *American Cancer Society Guideline for the Early Detection of Cervical Neoplasia and Cancer*, CA: A Cancer Journal for Clinicians, 342–362 (Nov.–Dec. 2002); see also U.S. Preventative Services Task Force, *Screening for Cervical Cancer* (Jan. 2003) (online at <http://www.ahcpr.gov/clinic/uspstf/uspstfcerv.htm>); see also American College of Obstetrics and Gynecology, *Cervical Cytology Screening*, ACOG Practice Bulletin No. 45 (2003) (online at http://www.acog.org/from_home/publications/press_releases/nr07-31-03-1.cfm).

⁸ U.S. Preventive Services Task Force, *Screening for Cervical Cancer* (Jan. 2003) (Publication Number APPIP03-0004) (online at <http://www.ahrq.gov/clinic/3rduspstf/cervcan/cervcanwh.pdf>).

⁹ U.S. Centers for Disease Control and Prevention, *Report to Congress: Prevention of Genital Human Papillomavirus Infection*, 4, 15 (Jan. 2004) (online at

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“significantly higher rates” of clearance of genital HPV infection in women and of regression of HPV-related lesions on the cervix and penis.¹⁰ The National Institutes of Health also reported that six of ten studies on condoms and cervical cancer found risk reductions ranging from 39% to 80%.¹¹

Another promising prevention strategy relates to vaccination. In the first large-scale clinical trial of a vaccine for a strain of HPV involved in half of all cervical cancers, there were zero cases among women who received the vaccine, compared to 41 cases among women in the placebo group.¹²

The Letters

Last month, you received several letters drawing attention to the issue of HPV and cervical cancer. 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.¹³ Overlapping in content, and in some sections nearly identical, the letters address the implementation of provisions in Public

online.org/hpv_report_jan%202004.pdf) (“[A]vailable studies suggest that condoms reduce the risk of the clinically important outcomes of genital warts and cervical cancer”).

¹⁰ *Id.* See also K. Holmes et al., *Effectiveness of Condoms in Preventing Sexually Transmitted Infections*, Bulletin of the World Health Organization, 454 (June 2004) (online at <http://www.who.int/bulletin/volumes/82/6/en/454.pdf>).

¹¹ National Institutes of Health, *supra* note 2, at 3.

¹² L.A. Koutsky, K.A. Ault, C.M. Wheeler et al., *A Controlled Trial of a Human Papillomavirus Type 16 Vaccine*, New England Journal of Medicine, 1645 (Nov. 21, 2002).

¹³ 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; Austin Ruse, Culture of Life Foundation; to Secretary Michael O. Leavitt (Feb. 11, 2005).

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Law 106-554. This law directs the Secretary of Health and Human Services, through the Food and Drug Administration (FDA) and CDC, to take action on HPV.

The letters propose specific measures that are unsupported by medical evidence and inconsistent with the recommendations of public health authorities.

All three letters discuss the topic of a public education campaign on HPV. Public Law 106-554 required the Secretary, along with CDC, to develop educational materials that address:

- a) modes of transmission;
- b) consequences of infection, including the link between HPV and cervical cancer;
- c) the available scientific evidence on the effectiveness or lack of effectiveness of condoms in preventing infections with HPV; and
- d) the importance of regular Pap smears, and other diagnostics for early intervention and prevention of cervical cancer

According to the outside organizations, you should implement this provision by instructing the CDC to launch “a large scale effort to educate the public that only abstinence and a mutually faithful relationship with an uninfected spouse can prevent an HPV infection.”¹⁴ Senators Inhofe and Coburn similarly urge an effort teaching that “only abstinence and mutual faithfulness can prevent HPV infection and condoms do not provide effective prevention against HPV.”

None of the letters contains evidence that an abstinence-only campaign would have the desired effect on behavior. Moreover, these recommendations and the letter from Reps. Davis and Souder omit any mention of Pap smears, despite the consensus among all major medical organizations and the CDC that women should have them annually to prevent the development of cervical cancer.

The letters also propose specific wording for condom labels to be imposed by the FDA, which regulates condom labeling. Public Law 106-554 required the Secretary to “examine existing condom labels that are authorized pursuant to the Federal Food, Drug, and Cosmetic Act to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases.” According to the outside organizations, you should 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.”¹⁵ Sens. Inhofe and Coburn similarly

¹⁴ Letter from Leslee Unruh et al., *supra* note 13.

¹⁵ *Id.*

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urge you to direct the agency to “require condom labels to be medically accurate regarding the lack of protection against HPV infection.” Reps. Davis and Souder assert that by not having changed condom labels to be “medically accurate,” FDA is out of compliance with the law.¹⁶

But the authors have selected the scientific evidence that supports their position and dismissed the evidence that does not. Both CDC and NIH have found that evidence shows that while condoms have not been shown to reduce the transmission of the HPV virus itself, they can reduce the risk of cervical cancer — the most feared potential outcome of HPV infection.¹⁷ The CDC also found that condom use is associated with faster clearance of genital HPV infection in women and faster regression of HPV-related lesions on the cervix and penis.¹⁸

What the writers urge is that FDA provide only partial information on condoms and HPV, not the medically accurate information that the law, and public health, require. According to the American College of Obstetricians and Gynecologists:

To cast doubt on condom effectiveness ... is misleading and potentially dangerous. The condom if used properly not only reduces the risk of STIs — as well as the risk of unintended pregnancy — it is ... the *only* device currently available to reduce the risk of HIV infections and STIs. Misinformation about condom effectiveness will simply increase the likelihood that people will fail to use condoms, and put men and women at unnecessary risk.¹⁹

Conclusion

Over the past several years, there has been rising concern among scientists and clinicians about the influence of ideology on reproductive health policy. Recently, for example, political officials interfered with the FDA’s decision of whether to switch the emergency contraceptive Plan B to over-the-counter status. Political officials also directed a change in policy on HIV prevention materials at CDC, adding an extra layer of political review of these materials.

¹⁶ Letter from Reps. Davis and Souder, *supra* note 13.

¹⁷ U.S. Centers for Disease Control and Prevention, *supra* notes 2, 9.

¹⁸ *Id.* See also K. Holmes et al., *supra* note 10.

¹⁹ American College of Obstetricians and Gynecologists, *Statement of the American College of Obstetricians and Gynecologists on a Report on Condom Effectiveness* (July 25, 2001) (online at http://www.acog.org/from_home/publications/press_releases/nr07-25-01.cfm).

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It is clear that some would have HHS base HPV policy on ideology as well. We urge you not to interfere with the scientists and public health experts who are trying to use the best scientific and medical evidence to promote the health of all Americans.

Sincerely,



Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



Barbara Lee
Member of Congress

Enclosures (3)

February 11, 2005

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Leavitt:

The Centers for Disease Control and Prevention (CDC) estimates 20 million Americans are currently infected with human papillomavirus (HPV) and 5.5 million Americans become infected with HPV every year. Medical experts agree that infection with certain strains of HPV is the primary cause of nearly all cervical cancer. According to the American Cancer Society, nearly 13,000 women develop invasive cervical cancer annually in the United States and over 4,000 women die of the disease every year. HPV infection is also associated with other cancers and more than one million pre-cancerous lesions that impact both women and men.

Studies have repeatedly demonstrated over the past decade that condoms do not provide effective protection against HPV infection. With that knowledge, Public Law 106-554 was signed by President Clinton more than four years ago. The law directs the Food and Drug Administration (FDA) to reexamine condom labeling to ensure that they are medically accurate regarding the limitations of condoms in preventing HPV transmission. This law also requires the CDC to educate the public and health care providers about HPV infection and how HPV can be prevented.

This law became necessary because the FDA and the CDC have failed to educate the public about HPV. Over the four years since this law was signed, both agencies have continued to abdicate their responsibilities to protect the public from HPV by repeatedly delaying and avoiding compliance with the law. This continued delay undermines the scientific integrity of the Health and Human Services (HHS), as a whole, and further jeopardizes the confidence of the public and many in Congress in the HHS's ability to fulfill its mission.

We urge you to take action against the FDA and the CDC. 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. Likewise, instruct the CDC to comply with the law by launching a large scale effort to educate the public that only abstinence and a mutually faithful relationship with an uninfected spouse can prevent an HPV infection.

We are also very concerned about a \$10 million NIH funded HPV study conducted by the H. Lee Moffitt Cancer Center & Research Institute. This study will test minority men for

HPV, but will not disclose test results to those who are infected. Withholding this information will deny study participants the ability to protect current and future partners from HPV infection. The study abstract also states, "we hypothesize that current condom use and circumcision confers reduced risk of incident HPV infection." While studies indicate that circumcision may reduce HPV risk, studies-- including NIH studies-- have concluded that condoms do not provide effective protection against HPV infection. This study is based upon an unscientifically sound premise and raises serious ethical questions. Therefore, we encourage you to challenge the researchers in this study to disclose HPV status to those infected and to counsel them on prevention; only abstinence until marriage to an uninfected spouse offers 100 percent protection against sexually transmitted diseases.

Thank you for your consideration regarding these important matters. The lives of so many rest in your hands. We are confident that you will provide the strong leadership necessary to protect the health of all Americans.

Leslee Unruh, President and Founder
Abstinence Clearinghouse

Beverly LaHaye, President and Founder
Concerned Women for America

Tony Perkins, President
Family Research Council

Paul M. Weyrich, Chairman
Coalitions for America

Peter Brandt, Sr. Director Government and Public Policy
Focus on the Family

Phyllis Schlafly, President
Eagle Forum

Gary Bauer, President
American Values

Andrea Lafferty, Executive Director
Traditional Values Coalition

Colin A. Hanna, President
Let Freedom Ring, Inc.

William J. Murray, Chairman
Religious Freedom Coalition

Barret Duke, Ph.D, Vice President for Public Policy and Research
The Ethics and Religious Liberty Commission

Larry Cirignano, Executive Director
CatholicVote.org

Austin Ruse, President
Culture of Life Foundation

February 9, 2005

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Congratulations on your appointment and confirmation as Secretary of Health and Human Services.

Cervical cancer is a largely preventable disease. Yet according to the American Cancer Society, an estimated 13,000 new cases of invasive cervical cancer are diagnosed annually and over 4,000 women die of the disease every year. Tens of thousands of others will be treated for related pre-cancerous conditions.

Nearly all cases of cervical cancer are directly associated with human papillomavirus (HPV). The Centers for Disease Control and Prevention (CDC) estimates 20 million Americans are currently infected with HPV and 5.5 million Americans become infected with HPV every year. HPV infection is also associated with other cancers and more than one million pre-cancerous lesions that impact both women and men.

Studies have repeatedly demonstrated over the past decade that condoms do not provide effective protection against HPV infection and the risk of pervasive HPV infection and cancer increase with the number of sexual partners and the younger the age of initiation of sexual activity.

Public Law 106-554, signed by President Clinton more than four years ago, directs the Food and Drug Administration (FDA) to reexamine condom labeling to ensure that such labels are medically accurate regarding the lack of effectiveness of condoms in preventing HPV infection. This law also requires the CDC to educate the public and health care providers about HPV infection and how HPV can be prevented. This law became necessary because FDA and CDC had failed to educate the public about HPV.

Over the four years since this law was signed, both agencies have continued to abdicate their responsibilities to protect the public from HPV by repeatedly delaying and avoiding compliance with the law. This continued delay undermines the scientific integrity of both agencies and further jeopardizes the confidence of the public and Congress in the agencies' ability to fulfill their mission.

We are also concerned about a \$10 million study financed by the National Institutes of Health and conducted by the H. Lee Moffitt Cancer Center & Research Institute. This study will test minority men for HPV, but will not disclose test results to those who are infected. Withholding this information will deny study participants the ability to protect current or future partners from HPV infection. The study abstract also states, "we hypothesize that current condom use and circumcision confers reduced risk of incident HPV infection." The truth is studies-- including NIH studies-- have concluded that condoms do not provide effective protection against

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HPV infection. This study, therefore, is based upon an unscientifically sound premise and raises serious ethical questions.

We urge you to immediately direct:

- (1) The FDA to immediately comply with the law by requiring condom labels to be medically accurate regarding the lack of protection against HPV infection;
- (2) The CDC to comply with the law by launching a large scale effort to educate the public that only abstinence and mutual faithfulness can prevent HPV infection and condoms do not provide effective protection against HPV; and
- (3) The NIH to disclose to those test subjects diagnosed with HPV that they are infected with HPV and counseling on how to protect their own health and protect current or future partners from HPV infection.

We would also request:

- (1) An explanation for the continued delay by the FDA in complying with this four year old law;
- (2) A complete listing of all participants in all the CDC consultation meetings related to Public Law 106-554 including dates and locations of these meetings;
- (3) Copies of all hand outs, documents and papers reviewed in the CDC consultation meetings; and
- (4) An explanation from NIH on the ethics of withholding diagnosis from infected test subjects, including any ethical reviews that were conducted.

Thank you for your attention to this matter. We look forward to working with you in protecting the health of all Americans.

Sincerely,

James M. Inhofe
U.S. Senator

Tom A. Coburn, M.D.
U.S. Senator

2/15/2005

TOM DAVIS, VIRGINIA
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED NINTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM
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WASHINGTON, DC 20515-6143

Majority (202) 225-6074
Minority (202) 225-6061

February 11, 2005

Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

The Centers for Disease Control and Prevention (CDC) estimates 20 million Americans are currently infected with human papillomavirus (HPV) and 5.5 million Americans become infected with HPV every year. Medical experts agree that infection with certain strains of HPV is the primary cause of nearly all cervical cancer. According to the American Cancer Society, nearly 13,000 women develop invasive cervical cancer annually in the United States and over 4,000 women die of the disease every year. HPV infection is also associated with other cancers and more than one million pre-cancerous lesions. By way of comparison, nearly the same number of women die annually as a result of cervical cancer as do women who die of HIV/AIDS in the United States.

On January 31st of this year, the National Institute of Environmental Health Sciences and the National Toxicology Program finally added HPV to the official list of known cancer-causing agents. While the Subcommittee applauds this decision, the lack of action by other federal agencies remains of great concern.

Public Law 106-554, signed by President Clinton more than four years ago, directs the Food and Drug Administration (FDA) to reexamine condom labeling to ensure that such labels are medically accurate regarding the lack of effectiveness of condoms in preventing HPV infection.

The Subcommittee first wrote to the FDA requesting a status update on the enactment of this law on August 23, 2001. "FDA is currently developing an implementation plan for carrying out Public Law 106-554," was the response from Melinda K. Plaisier, FDA Associate Commissioner for Legislation, dated November 20, 2001.

On February 12, 2004, the Subcommittee wrote to Dr. Mark B. McClellan, FDA Commissioner, requesting "the agency's timetable for relabeling condoms in compliance with Public Law 106-554." In a response to the Subcommittee dated March 10, 2004, Amit K. Sachdev, FDA Associate Commissioner for Legislation, stated, "the Agency is working on developing a proposed rule to be accompanied by draft labeling guidance for public comment later this year."

In a hearing before the Subcommittee on March 11, 2004, Dr. Daniel G. Schultz, FDA Director of Device Evaluation, stated "FDA is working to present a balanced view of the risks and benefits in condom

labeling ... FDA is preparing new guidance on condom labeling to address these issues, with the target of publishing that guidance as a draft for public comment later this year."

This same timeframe for enactment of the four-year-old law— by the end of 2004— was repeated in staff level discussions throughout the year.

On November 19, 2004, the Subcommittee sent a letter to Acting FDA Commissioner Lester Crawford requesting an update on whether or not the oft repeated deadline previously provided would be met. The agency failed to meet the deadline and, more than two months later, the Subcommittee still has received no response or explanation from FDA.

Over the four years since this law was signed, the FDA has repeatedly delayed and found excuses to avoid complying with the simple requirement of the law to ensure condom labels are medically accurate. This continued delay undermines the scientific integrity of agency and further jeopardizes the confidence of the public and many in Congress in the agency's ability to fulfill its mission.

Likewise, the CDC has also delayed enacting provisions of the same law that require the agency to educate the public about HPV. The Subcommittee understands that the CDC is sponsoring a consulting group and that group has done 20 focus group meetings and will do more. The Subcommittee is very interested in learning more about these consultations.

I request that the Department provide the following information to the Subcommittee within 30 days:

- (1) A date certain as to when the FDA will finally be in compliance with Public Law 106-554 by requiring condom labeling to be medically accurate;
- (2) An explanation for the continued delay by the FDA in complying with this four year old law;
- (3) A complete listing of all participants in all the CDC consultation meetings related to Public Law 106-554 including dates and locations of these meetings;
- (4) All handouts, documents and papers reviewed in the CDC consultation meetings;
- (5) An explanation as to how the information from the CDC consultation meetings will be utilized.

Thank you for your attention to this request. I look forward to a timely response.

Sincerely,



Tom Davis
Chairman
Committee on Government Reform



Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources