

Tom A. Coburn, M.D.
FAMILY PRACTICE
P.O. Box 1760
Muskogee, Oklahoma 74402
(918) 687-8950

August 12, 2003

Ms. Dara Corrigan
Acting Principal Deputy Inspector General
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Corrigan,

Cervical cancer is a largely preventable disease, yet according to the American Cancer Society, an estimated 13,000 new cases of invasive cervical cancer were diagnosed in 2002 and over 4,000 women die of the disease every year. Tens of thousands of others will be treated for related pre-cancerous conditions.

Experts agree that infection with certain strains of the human papillomavirus (HPV) is one of the strongest risk factors for cervical cancer. HPV infection, in fact, is associated with nearly all cervical cancer. HPV has also been linked to other forms of cancer and to genital warts.

HPV is the most common sexually transmitted disease and scientific studies have repeatedly concluded that condoms do not provide effective protection against HPV infection. In 2001, the National Institutes of Health along with the U.S. Agency for International Development, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) released a report entitled "Scientific Evidence on Condom Effectiveness for STD Prevention." This report provided the single most comprehensive review of the published scientific data on the effectiveness of condoms in preventing sexually transmitted diseases (STDs). The document states "for HPV, the Panel concluded that there was **no** epidemiological evidence that condom use reduced the risk of HPV infection."

Because of the widespread prevalence of HPV, a general lack of knowledge about the disease and how to prevent its transmission, the significant numbers of Americans harmed or killed as a result of HPV infection every year, and the failure of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to address the epidemic, Congress passed and President Clinton signed Public Law 106-554 in 2000.

This law requires CDC to educate the public about HPV and the lack of effectiveness of condoms in preventing HPV infection. All educational materials produced by CDC and other federal agencies and federal grantees are also required to provide similar medically accurate information about HPV and condoms. The law directs the FDA to "reexamine existing condoms labels... to determine whether the labels are medically accurate regarding the overall effectiveness or lack of effectiveness in preventing sexually transmitted diseases, including HPV." The law also required CDC to conduct HPV research and provide recommendations regarding "the best strategies to prevent future [HPV] infections."

As the author of this law and a practicing physician who has cared for countless patients affected by HPV, I am deeply troubled by the federal bureaucracy's continued failure to address the HPV and to adhere to and abide by the legal requirements of P.L. 106-554.

I sent a letter to the Department of Health and Human Services July 18, 2001 regarding my concerns and requested that the Department take "appropriate actions to properly enact the law." I did not receive a response and it is obvious that actions to properly enact the law have still not been undertaken.

Expressing similar concerns, Congressmen Billy Tauzin, Chairman of the House Energy and Commerce Committee, and Joe Pitts sent a letter to the Department of Health and Human Services in May 2002 requesting an update on the status of the implementation of the law but 15 months later have still not received a response.

An independent review by another Congressional Subcommittee has found that two and a half years after the effective date of the federal HPV prevention and education law, CDC and FDA have largely ignored the law and maintain the indifferent attitude towards the HPV epidemic that prompted the need for this law.

In addition to ignoring much of the law, the areas of the law that CDC has implemented have been done so in a manner that appears to deliberately undermine its intent.

The law is clear that the CDC and other government agencies and partners must provide "medically accurate information regarding the effectiveness or lack of effectiveness of condoms" in preventing HPV and other sexually transmitted diseases (STDs). Yet in a July 2001 "Dear Colleague" letter to its partners, the CDC issued inaccurate information regarding the effectiveness of condoms. The CDC states "epidemiological studies have generally not demonstrated an association between condom use and the risk of HPV infection, but these studies are inconclusive because of limitations in how they were designed. Again, these limitations would generally lead to an underestimation of the protective effect." The inaccurate claim that studies are "inconclusive" is repeated several times in the CDC letter. The CDC letter also provides what is labeled "Theoretical Basis for Protection" that claims "consistent and correct use

of latex condoms would be expected to protect against transmission of genital ulcer diseases and HPV in some, but not all, instances.” This is medically inaccurate and does not reflect the available clinical science.

The law also states that the “educational material” on HPV required to be printed by this law “and all other relevant educational and prevention materials prepared and printed from this date forward for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address STDs including HPV shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address.” The law provides a clear mandate for all federal agencies and private partners. Yet the CDC’s July 2001 letter states that the requirement is limited to only materials “funded by CDC.” To the contrary, the law does not apply to only CDC funded materials. It is, rather, a requirement that all organizations receiving federal funding must abide by as a condition of eligibility for federal funding.

The CDC was directed to conduct a number of research activities on HPV. These included investigating the impact of HPV-related diagnosis on individuals, the development of educational messages and information for the public, patients and their partners and determine the public and the medical community’s knowledge and awareness about HPV. The CDC has provided a \$940,000 grant to Planned Parenthood of Southwest and Central Florida to conduct this study. Planned Parenthood opposed the enactment of this law and has consistently downplayed the impact of HPV infection on women’s health and distorted the facts about the lack of effectiveness of condoms in preventing HPV. The selection of such a biased organization is just another indication that CDC is intentionally undermining this law.

The actions and lack of actions taken by the CDC and FDA to undermine this law are both illegal and threaten the health of millions of Americans.

The following chart outlines the provisions of Public Law 106-554 and the status of the each:

Public Law 106-554 Provision	Status
Conduct HPV prevalence and prevention research	CDC has selected Planned Parenthood, which opposed the enactment of the HPV law, to conduct this research.
Progress reports on HPV research to be submitted to Congress before January 2001	Incomplete -- Over one and a half years overdue.
Develop and disseminate educational materials on HPV and its prevention	Incomplete.
Report providing recommendations of the best strategies to prevent HPV infection	Due December 2003.

All educational materials on STDs, HPV and condoms prepared by federal agencies and their partners must provide medically accurate information including the lack of effectiveness of condoms in preventing infection	CDC has issued inaccurate claims based upon a “theoretical” and unproven hypothesis, inconsistent with both the law and scientific data.
Condom labels to be rewritten to be medically accurate to reflect the effectiveness or lack of effectiveness in preventing HPV and other STDs	Incomplete.

I would request that the Office of the Inspector General conduct a thorough investigation to determine why Public Law 106-554 has been both misinterpreted and largely ignored by CDC and FDA and to make recommendations to ensure that these agencies immediately comply with the directives and intent of this law. Please also determine if federal agencies and organizations receiving federal funds are providing medically accurate information about HPV, reflecting the findings of the 2001 scientific report issued by NIH/CDC/FDA/USAID.

Thank you for your assistance with this request. Please do not hesitate to contact me if you have any questions or if I can be of any assistance with this investigation.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress (retired)

cc: Honorable Judd Gregg, U.S. Senate
Honorable Billy Tauzin, Member of Congress
Honorable Joe Pitts, Member of Congress
Honorable David Weldon, MD, Member of Congress
Honorable Mark Souder, Member of Congress
Honorable Sue Myrick, Member of Congress