

United States Senate

WASHINGTON, DC 20510-3604

November 2, 2006

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

Dear Secretary Leavitt,

The development of a vaccine to prevent infection with some strains of human papillomavirus (HPV), which is associated with nearly all cervical cancer, is one of the most significant breakthroughs in our efforts to eventually eliminate cancer. While this vaccine is not a panacea, it certainly holds the potential to greatly reduce the number of women who develop cervical cancer and other health problems associated with HPV infection.

As you know, the Food and Drug Administration (FDA) approved the vaccine in June for use in girls and women ages 9 to 26 and the Centers for Disease Control and Prevention (CDC) has included Gardasil in its Vaccines for Children (VFC) program, under which the government buys vaccines for uninsured and low income schoolchildren.

As a practicing physician who has treated countless women and girls for a variety of HPV related health abnormalities, I support widespread availability of this vaccine along with informed consent by patients.

I wrote a law-- Section 317P of the Public Health Service Act-- signed by President Clinton in December 2000 that requires all educational and prevention materials prepared and printed "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 Government Accountability Office recently reviewed this law and concluded that "it provides that materials *that are specifically designed to address sexually transmitted diseases* shall contain medically accurate information on condom effectiveness. The syntax of the sentence and Congress's choice of the mandatory 'shall' clearly indicate that materials specifically designed to address sexually transmitted

diseases are to contain medically accurate information as to the effectiveness of condom use in preventing transmission of such diseases. Therefore, the Secretary, grantees, and others to whom the statute applies are required to include information on condom effectiveness, and that information must be medically accurate, in materials otherwise meeting the statutory criteria.”

Any federal health program that addresses HPV, which is a sexually transmitted disease, therefore, is statutorily obligated to provide individuals with medically accurate information about the effectiveness of lack of effectiveness of condoms in preventing HPV. This would obviously now include VFC and other programs providing the HPV vaccine.

The science on HPV and condoms is quite conclusive.

In a February 1999 letter to the U.S. House Commerce Committee, Dr. Richard D. Klausner, then-Director of the National Cancer Institute, stated “Condoms are ineffective against HPV because the virus is prevalent not only in the mucosal tissue (genitalia) but also on dry skin of the surrounding abdomen and groin, and it can migrate from those areas into the vagina and the cervix. Additional research efforts by NCI on the effectiveness of condoms in preventing HPV transmission are not warranted.”

In 2001, the National Institute of Allergy and Infectious Diseases along with FDA, CDC and the U.S. Agency for International Development issued a consensus report regarding condom effectiveness that concluded “there was no epidemiologic evidence that condom use reduced the risk of HPV infection.”

In November 2002, a meta-analysis of “the best available data describing the relationship between condoms and HPV-related conditions” from the previous two decades was published in the journal *Sexually Transmitted Diseases*. The meta-analysis concluded: “There was no consistent evidence of a protective effect of condom use on HPV DNA detection, and in some studies, condom use was associated with a slightly increased risk for these lesions.”

In January 2004, the CDC issued a report that concluded “The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection.”

This information must be provided, as required by law, to each patient offered the HPV vaccine as part of any federal program.

I have been extremely disappointed with the implementation of this law by both CDC and FDA. Congress has, in essence, been forced to drag CDC kicking and screaming to comply with the law and FDA has yet to meet the statutory requirements of the agency six years after it was signed. I trust that the HHS will ensure that the law is applied to VFC without delay or excuse.

Please provide an update of the actions HHS and CDC are taking to ensure that Section 317P of the Public Health Service Act is applied to VCF and other federal health programs expected to provide coverage of HPV vaccines, including any guidance or printed materials prepared for health care providers, the public, contractors, grantees, subgrantees or other government partners.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in blue ink, appearing to read "Tom A. Coburn". The signature is fluid and cursive, with a long horizontal stroke at the end.

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