

United States Senate

WASHINGTON, DC 20510-3604

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January 25, 2007

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

Dear Secretary Leavitt:

On January 12, President Bush signed 'Johanna's Law,' the Gynecologic Cancer Education and Awareness Act, which is now Public Law 109-475.

Among the components of this law is a requirement for the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to comply with Public Law 106-554, which was signed by President Clinton on December 21, 2000. The new law specifically states: "Not later than March 1, 2008, the Secretary shall ensure that all provisions of this section, including activities directed to be carried out by the Centers for Disease Control and Prevention and the Food and Drug Administration, are fully implemented and being complied with. Not later than April 30, 2008, the Secretary shall submit to Congress a report that certifies compliance with the preceding sentence and that contains a description of all activities undertaken to achieve such compliance."

As you know, in the six years since P.L. 106-554 was signed by President Clinton, the FDA and CDC have failed to comply with this law requiring medically accurate information be provided to the public about human papillomavirus (HPV). The law, in fact, was passed by Congress precisely because of the reluctance of these federal agencies to provide such information. The statutory deadline established by P.L. 109-475 would mean that FDA and CDC would have been provided over seven years to fulfill the requirements of P.L. 106-554.

It is unfortunate that Congress had to pass the original law to compel federal health agencies to perform their responsibilities and alarming that another law had to be passed to force the same agencies to comply 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. It is impossible to determine how many women have been denied potentially lifesaving information about HPV and cervical cancer as a result of this continued abdication of responsibility.

Could you please provide an itemized blue print outlining how both CDC and FDA will take steps to ensure full compliance with P.L. 106-554 by April 30, 2008, as required by P.L. 109-475?

Thank you for your attention to this matter. As a member of the Senate Health, Education, Labor and Pensions Committee, I look forward to working with you on reauthorization of the Prescription Drug User Fee program this year and other important health issues in the future.

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