DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 19 2005

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6148

Dear Mr. Chairman:

This is in response to your letter of September 29, 2005, regarding condom labeling. As you know, the Food and Drug Administration's (FDA) Center for Devices and Radiological Health has developed a regulatory plan to provide condom users with more informative labeling about the extent of protection against sexually transmitted diseases (STDs), including human papillomavirus (HPV) infection that they should expect from condom use. FDA has drafted new guidance on condom labeling to address these issues. FDA also intends to propose to amend the classification regulations for condoms in order to establish the labeling guidance as a special control for manufacturers of condoms. These documents are currently under review at the Office of Management and Budget (OMB).

The questions you are asking about FDA's review and characterization of published literature examining the efficacy of condom use in preventing HPV transmission and studies about the efficacy of condom use in limiting certain clinical outcomes of HPV infection are addressed in the draft guidance and proposed rule currently at OMB, along with questions about condoms and the transmission of other STDs. We would be glad to arrange a time to discuss the contents of those documents with you after they have published in the *Federal Register* and you have had an opportunity to review them. As you know, however, FDA does not discuss the details of proposed regulatory initiatives while they are under development.

Responses to your other questions are below.

To what extent has the FDA relied on the unpublished Winer study in its evaluation of condom effectiveness in preventing HPV infection?

As mentioned above, a notice of proposed rulemaking and draft labeling guidance based upon FDA's evaluation of condom effectiveness completed Agency and department review earlier this year and was forwarded to OMB in the spring. Those documents discuss in detail FDA's evaluation of condom effectiveness and its scientific basis. The Winer study was not presented until this summer at an STD conference. Therefore, that study was not included in our evaluation. We will continue to monitor scientific evidence relating to the degree to

which male condoms provide protection from HPV, HPV-related disease, and other STDs, as it becomes available.

Has the FDA evaluated and peer-reviewed research that would justify a repudiation of the following statement from the CDC's 2004 Report to Congress: "The available scientific evidence is not sufficient to recommend condoms as a primary prevention strategy for the prevention of genital HPV infection?" Please characterize any such research.

FDA agrees with CDC's assessment that there is insufficient data to justify the significant effort and expense of a national public health program to recommend condoms as a primary prevention strategy to reduce HPV infection. However, as we explained in our letter of September 16, 2005, a number of scientific and public health Agencies, including CDC, have concluded that there may be some protective effect from HPV associated with the use of condoms. The same CDC 2004 report you have cited also states that "there is evidence that indicates that use of condoms may reduce the risk of cervical cancer."

We hope this information addresses your concerns. If you have further questions, please let us know.

Sincerely,

Patrick Ronan

Patrick Ronan
Associate Commissioner
for Legislation