



Testimony

Before the Subcommittee on Criminal  
Justice,

Drug Policy, and Human Resources

Committee on Government Reform

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## **FDA's Implementation of Public Law 106-554**

*Statement of*

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### **INTRODUCTION**

Good morning, Mr. Chairman and Members of the Subcommittee. I am Dr. Daniel Schultz, Director of the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am pleased to speak today about FDA's implementation of Public Law (P.L.) 106-554 with respect to the labeling of condoms. Specifically, FDA has complied with P.L. 106-554, by reexamining existing condom labeling to determine whether the labels are medically accurate, regarding the overall effectiveness or lack of effectiveness of condoms in preventing sexually transmitted diseases (STDs), including human papilloma virus (HPV). FDA has conducted an extensive literature and labeling review. Based on these reviews, we are developing a draft guidance document on condom labeling and correlating proposed rule, which would make the guidance a special control for condoms.

## **REGULATORY BACKGROUND**

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, food, cosmetics, medical devices, and products that emit radiation. We do this by keeping abreast of public health issues, writing regulations that further protect the American people, and enforcing those regulations and the statutes that govern us. This hearing specifically touches on our medical device regulatory authorities. As defined by Federal law, the term "device" covers several thousand health products, ranging from simple articles such as tongue depressors and heating pads, to cutting-edge and complex devices such as pacemakers, lasers, and imaging technologies. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act gave FDA specific authority to regulate the safety and effectiveness of medical devices.

Using a risk-based classification framework, FDA places every medical device into one of three "classes" depending on the degree of regulatory control needed to provide reasonable assurance of safety and effectiveness. Devices posing the lowest risk, such as elastic bandages, are placed in Class I (General Controls). These general controls include the classification process itself, establishment registration and premarket notification, Quality System Requirements for manufacturing, provisions regarding adulteration and misbranding, recordkeeping, and reporting of adverse events. If general controls alone do not reasonably ensure the safety and effectiveness of a device, but FDA can identify an additional measure or measures that would provide that assurance -- "special controls" - FDA places that type of device into Class II (Special Controls), e.g., laparoscopes. Such Class II devices generally pose higher risks than Class I devices. They are then subject to the general controls that also apply to Class I devices, plus one or more of a wide range of special controls that the Agency may designate. These special controls may include performance standards, postmarket surveillance, patient registries, guidance documents, labeling, and/or clinical studies which, taken together with the general controls, are sufficient to provide a reasonable assurance of safety and effectiveness of the device. When FDA cannot be assured that the combination of general controls and special controls is sufficient to reasonably ensure safety and effectiveness of a medical device - generally higher risk devices - such devices are placed into Class III (Premarket Approval), e.g., the newer generation of global endometrial ablation systems. Premarket Approval (PMA) requires manufacturers to submit an

application to FDA, which is then subject to careful scientific review to provide reasonable assurance of the safety and effectiveness of the device. FDA approval of a PMA application is necessary before a Class III device may be marketed. Once approved for marketing, Class III devices also remain subject to the general controls already described.

## **REGULATION OF CONDOMS**

**Condoms are Class II medical devices.** <sup>(1)</sup> Presently, FDA addresses condom labeling with general device labeling regulations (21 CFR part 801), as well as two specific labeling regulations, one on condom expiration dating (21 CFR 801.435) and another on user warnings about allergic reactions to natural rubber latex (21 CFR 801.437). In addition, dating back to 1987, FDA has issued a series of guidance documents that address specific elements of condom labeling related to protection against STDs.

It is important to recognize that latex condoms for men are a well-made medical device that laboratory studies have shown to provide an essentially impermeable barrier to particles the size of STD pathogens. FDA has oversight responsibility to ensure that condoms are manufactured properly, and manufacturers - in turn - follow quality system regulations, including design controls, to ensure that their products do what they are intended to do: protect against pregnancy and sexually transmitted diseases. Condoms manufactured today meet performance standards for strength and freedom from holes (leakage). These standards ensure a minimum level of performance with respect to condom strength and barrier properties, characteristics that we believe are tied to what a condom is intended to do. To encourage conformance with these standards, FDA has officially recognized these standards and integrated them into both its premarket and postmarket device programs.

The typical condom package contains a front panel on the external box that is referred to as the "principal display panel." The "principal intended action" of any device must be stated on this display panel. In addition, every condom box includes more detailed information: directions for use and other important information on an insert or printed on the inside of the box.

Current FDA guidance recommends that the principal display panel of the primary retail package for condoms include a "principal intended action" statement regarding contraception and a second statement on STD risk reduction such as the one below:

Protection against sexually transmitted diseases (STDs):

*If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases.*

In addition, our current guidance recommends that the package insert for condoms contain the following expanded statement:

*If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many other sexually transmitted diseases, including chlamydia infections, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.*

#### **AGENCY ACTIVITIES RELATED TO CONDOM LABELING**

In 2001, FDA began a systematic and comprehensive review of the medical literature and key studies underlying the 2001 workshop [\(2\)](#) summary report and related conclusions, as well as many other clinical studies on the subject that have been published since the workshop. In short, our analysis of available studies and related reports on this topic have led us to a number of findings, which are consistent with both the 2001 workshop summary and the recent Centers for Disease Control and Prevention (CDC) Report to Congress on Genital HPV Infection. Our basic conclusions are as follows:

- Depending on the transmission vector(s) of a particular STD, the specific infectivity of the virus or bacteria, and the biological mechanisms of progression from infection to disease, the protection a condom may provide against different STDs will vary. P.L. 106-554 asks particularly about HPV infection, which can manifest as lesions - symptomatic or asymptomatic - on a man's penis or scrotum, a woman's vulva or cervix, or either's perianal areas. Because condoms do not cover all of these areas, they may not provide the same protection as they do against STDs transmitted through bodily fluids, like HIV or Gonorrhea. These same factors noted above, namely transmission vectors, infectivity, and biological mechanisms, also limit the ability to properly conduct well-controlled clinical studies that are necessary to more clearly determine condom effectiveness.
- Correct and consistent use of condoms can reduce the risk of sexual transmission of HIV (the virus that causes AIDS). We also believe that condoms, when used consistently and correctly, can reduce the risk of other STDs that are transmitted by genital secretions (such as semen or vaginal fluids), and these include gonorrhea, chlamydia, and trichomoniasis.]

- Scientific studies on STDs characterized by genital ulcers, e.g., genital herpes and syphilis, are inconclusive as to whether the risk of these diseases is lowered for condom users. However, based on what we do know about the transmission vector for these diseases, we believe that the condom will provide some measure of protection when it covers the ulcer.
  
- Clinical studies evaluating the relationship between condoms and HPV-related disease have not been consistent. However, even though the biological mechanism has not been conclusively demonstrated, women whose partners use condoms seem to be at reduced risk for genital warts, as well as at reduced risk for cervical cancer - compared to women whose partners do not use condoms. Therefore, there does appear to be a benefit from condom use for prevention of HPV-related disease.

#### **AGENCY ACTIVITIES RELATED TO IMPLEMENTATION OF P.L. 106-554**

P.L. 106-554, enacted in December 2000, directs the Secretary of Health and Human Services to do the following review:

*The Secretary of Health and Human Services, shall reexamine 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, including HPV.*

FDA has carefully reexamined existing condom labeling to determine whether the labels are medically accurate regarding the overall effectiveness of condoms in preventing STDs, including HPV. Although the interest of this hearing targets HPV, we complied with the law by exploring the labeling regarding other STDs as well. To fully accomplish this task, Agency staff have conducted a comprehensive systematic review of the published medical literature on condoms and STDs. Given the enormous scope of this effort, we have just completed this literature review and are now looking at how the results from this review might impact condom labeling.

Based on the review of the current condom literature, CDRH has developed a regulatory plan to provide condom users with a consistent labeling message about STDs and the protection they should expect from condom use. 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. FDA also anticipates proposing to amend the classification regulations for condoms, to make such labeling guidance a special control for condoms.

### **NEW TECHNOLOGIES TO HELP DETECT AND PREVENT HPV INFECTION**

In 2004, the American Cancer Society estimates that 10,520 women will be diagnosed with cervical cancer and 3,900 women will die from it. However, with proper screening, cervical cancer is avoidable and, if caught early, curable. Regular cervical cancer screening for all sexually active women and treatment of precancerous lesions remains the key strategy to prevent cervical cancer. [\(3\)](#)

FDA is committed to help bring safe and effective technologies to the market quickly. As noted in the testimony of CDC and NIH, there are many strains of HPV. In 1995, FDA approved the first DNA test for detection of HPV. In 1999, we approved an improved version of the test, the HC2 High-Risk HPV DNA Test, which can identify 13 of the most frequently occurring high-risk types of HPV associated with the development of cervical cancer. On March 31, 2003, the Agency approved expanded use of this test, so it now can now be used, in conjunction with a Pap test, for screening women over the age of 30. In addition, since the mid-1990s, FDA has reviewed and approved several automated and computerized systems to allow for better slide preparation and more rapid screening of Pap tests. These devices are now widely used in clinical laboratories to aid in Pap test screening.

In addition, FDA's Center for Biologics Evaluation and Research (CBER) is currently working with manufacturers to bring preventive HPV vaccines to market. CBER convened an FDA Vaccines and Related Biological Products Advisory Committee meeting, in November 2001, to address endpoints for HPV vaccine efficacy trials. CBER staff have also presented at WHO meetings on HPV vaccine development, where the focus was also cervical cancer-related indications. Currently, CBER has a number of investigational new drug applications (INDs) for vaccines for the prevention of HPV infection, several of which are in advanced clinical development.

In addition to efforts directed at HPV infection, treatment of cervical cancer is a very active field for clinical research and several novel technologies are currently being applied for the treatment of this disease. CBER has more than a dozen INDs under review, for treatment of cervical cancer.

### **CONCLUSION**

P.L. 106-554 directs FDA to look at condom labeling, not only with respect to their "overall effectiveness" in preventing STDs, but also with respect to their "lack of effectiveness." Since we have completed our literature review, we are exploring new opportunities to best inform condom users about important limitations of the device. FDA is working to present a balanced view of the risks and benefits in condom labeling, being careful to neither encourage device use in circumstances where it may not be medically appropriate, nor to discourage device use in circumstances where it is.

Mr. Chairman, I want to reiterate that FDA is committed to monitoring closely the body of scientific evidence relating to the degree to which male condoms provide protection from HPV, HPV-related disease, and other STDs. We will continue to exercise our regulatory responsibilities appropriately in accordance with the best available science. I am happy to answer any questions you might have.

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<sup>1</sup> FDA has not to date specified any measures as special controls for condoms. Condoms were devices marketed before the passage of the Medical Device Amendments of 1976, and as such, were classified into Class II as part of the initial classification of all existing devices. At that time, the statute anticipated that mandatory performance standards would be established to govern each Class II device type. This proved to be an overwhelming task for FDA, and in 1990, as part of the Safe Medical Devices Act of 1990 (P.L. 101-629), Congress changed the definition for Class II devices to make them subject to special controls--a wider range of measures than mandatory performance standards. FDA is working to specifically identify special controls for devices that were classified into Class II prior to the 1990 statutory change. While not presently designated as special controls, however, there are several existing requirements and recommendations for condom labeling that address specific safety and effectiveness issues that condoms pose.

2. The June 2000 workshop was led by the National Institute of Allergy and Infectious Disease, in partnership with the National Cancer Institute, National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention, the U. S. Agency for International Development, FDA, and other Federal agencies.

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<sup>3</sup> January 2004 "Report to Congress: Prevention of Genital Human Papillomavirus Infection," prepared by the Centers for Disease Control and Prevention.