



Highlights of [GAO-05-399](#), a report to congressional requesters

## Why GAO Did This Study

Preventing the transmission of HIV, the virus that causes AIDS, is an important public health challenge. Researchers have sought to develop a microbicide—a substance to help users protect themselves against HIV. In the mid-1980s, researchers found that Nonoxynol-9 (N-9), a spermicide found in various contraceptive products, showed potential as a microbicide. However, more recent studies raised concerns that N-9 may increase certain users' risk of contracting HIV.

GAO was asked to describe federal agencies' and contraceptive product manufacturers' actions related to N-9 and HIV. In this report, GAO reviewed (1) the efforts by federal agencies and manufacturers of contraceptive products to assess the safety of N-9 and its effectiveness as a microbicide for preventing HIV transmission and (2) the information provided to the public about the safety of N-9 and its effectiveness as a microbicide.

GAO reviewed journal articles, *Federal Register* notices, product packaging, educational materials, and other documents. GAO also interviewed officials from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and selected manufacturers of N-9 contraceptive products.

[www.gao.gov/cgi-bin/getrpt?GAO-05-399](http://www.gao.gov/cgi-bin/getrpt?GAO-05-399).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marjorie Kanof at (202) 512-7114.

## HHS

# Efforts to Research and Inform the Public about Nonoxynol-9 and HIV

## What GAO Found

Federal agencies have undertaken a variety of efforts to research N-9 as a potential microbicide—including conducting, funding, or reviewing studies on the safety and effectiveness of N-9. In the 1990s, CDC and NIH conducted and funded research on the effectiveness and safety of N-9 as a microbicide to prevent HIV infection. For example, in 1996 CDC and others began a 4-year study on the effectiveness of an N-9 vaginal contraceptive product in preventing the transmission of sexually transmitted diseases, including HIV. The results of the research by the agencies during this period were inconsistent—some research indicated that N-9 reduced the incidence of HIV while other research suggested that frequent use of N-9 may increase the risk of contracting the virus. Then in 2000, the preliminary results of a major clinical study suggested more strongly that N-9 vaginal contraceptive products did not prevent HIV infection and may increase the risk of infection among frequent users. As a result of the study, CDC and NIH stopped conducting and funding research on N-9 as a microbicide out of concern for participants' safety. FDA continued to review available research on the safety of N-9 as part of its regulation of vaginal contraceptive products and, in 2003, proposed new warning labels for N-9 vaginal contraceptive products. As of March 2005, FDA was also in the process of developing a proposal for new warning labels for N-9 condoms. As of that date, FDA had not finalized the new warning labels for N-9 vaginal contraceptive products and had not proposed new warning labels for N-9 condoms. Representatives from two manufacturers of N-9 contraceptive products have reviewed research on N-9's safety for the purpose of commenting on FDA's proposed warning labels.

The information CDC and FDA have provided to the public about the use of N-9 as a microbicide has been, at times, inconsistent. In the early 1990s, CDC cautioned that there was insufficient information to conclude that N-9 may prevent HIV transmission. By 1998, in response to new research, the agency informed the public that N-9 vaginal contraceptive products did not prevent HIV. During the same period, FDA also cautioned that N-9 had not been proven to prevent HIV transmission, but in 1999, a brochure posted on its Web site stated that N-9, along with a condom, may be used to prevent HIV transmission. By 2000, CDC had responded to new research findings and had revised its educational publications to state that N-9 may actually increase the risk of contracting HIV when used frequently. In contrast, FDA did not revise the brochure on its Web site that stated that some experts believe N-9 may prevent HIV and suggested using N-9 along with a condom. FDA left this information on its Web site until these statements were deleted in September 2003 when FDA officials realized the information was inconsistent with proposed warning labels.

In commenting on a draft of this report, the Department of Health and Human Services (HHS) provided clarification that GAO incorporated where appropriate.