SEX PROTECTION: BALANCING THE EQUATION

FDA ponders the first female condom

By KATHY A. FACKELMANN

AIDS has ushered in a new era, one in which the most intimate of acts can prove fatal.

In the past, contraceptive researchers focused on birth control methods. While pregnancy prevention remains important, today's epidemics of AIDS, genital herpes and other sexually transmitted diseases have forced many of these investigators to search for ways to protect against a host of disease-causing microbes.

The condom, once hidden behind the drugstore counter, has enjoyed a surge in popularity and is now openly displayed, in a variety of colors and textures, on supermarket shelves. The reason for the boom: Recent data show that condoms provide some protection against HIV, the AIDS-causing virus, as well as other sexually transmitted microbes, including the virus that causes genital herpes (SN: 2/1/92, p.68).

Some men, however, refuse to use condoms. That leaves many women without a safeguard.

A drug company in Jackson, Wis., wants to balance the sex-protection equation. Wisconsin Pharmacal Co. is poised to market the first condom-like contraceptive designed for women. On Jan. 31, the so-called female condom passed its first regulatory hurdle by gaining a conditional okay from a panel of experts appointed by the U.S. Food and Drug Administration. This group, the Obstetrics and Gynecology Devices Panel, studied preliminary data on the female condom's safety and efficacy. Some panelists raised concerns about the incomplete nature of the data. However, the panel finally recommended FDA approval, pending the completion of additional studies verifying the device's efficacy as a contraceptive.

Wisconsin Pharmacal's senior vice president, Mary Ann Leeper, says the firm can get the requested data to FDA by June. If the new information passes muster with FDA, the firm will begin marketing the female condom under the brand name Reality. The one-size-fits-all device will be available without a prescription for about $2.25 apiece, Leeper says. Wisconsin Pharmacal is licensed to market it in the United States and Canada. Chartex International, a British firm, owns worldwide rights to the device, which is already available in Switzerland and is expected to reach the marketplace in Britain and France later this year.

The female condom is made of a strong polyurethane, a clear plastic that looks like that used to make food storage bags. Most male condoms are made of latex, a material derived from rubber that is likely to lose strength during storage.

The design of the female condom relies on two flexible rings that are connected by a polyurethane sheath. One ring lies inside the sheath and is inserted in much the same way as a diaphragm, fitting over the cervix, the opening from the vagina to the uterus. The other ring remains outside the vagina and covers the external female genitalia, a safety feature designed to cut down on exposure to microbes found in semen or shed from the skin. The device is designed to be discarded after one act of intercourse.

On Jan. 31, the FDA panel and spectators gathered in Rockville, Md., to hear the evidence on the female condom. The day-long hearing began with impassioned pleas by consumer groups to approve the device. Next, Wisconsin Pharmacal scientists and outside consultants presented safety and efficacy data. The FDA scientists reviewed the information, and the panel debated the merits and flaws of the culled data.

Preliminary data from an ongoing Phase II study proved crucial in the panel's deliberations.

Investigators at six U.S. medical centers recruited 236 women who agreed to use the new device and discontinue all other forms of birth control. Most of the women had some college education and were either married or in a stable relationship.

Based on a statistical method that takes into account when a pregnancy occurs and other factors, interim data revealed that the device had a six-month failure rate of 12.2 percent, testified Gaston Farr, project manager of the trial and associate director of clinical trials at Family Health International in Research Triangle Park, N.C. This means that about 12 women out of 100 could expect to get pregnant during a six-month period while using the device, Farr told SCIENCE NEWS.

The trial, which was funded by the Agency for International Development, also included 110 women recruited from medical centers in Mexico and the Dominican Republic. The failure rate among these women was 20.6 percent, raising the study's overall failure rate to 15.1 percent. Although the women in Latin America had less education than the women in the United States, the researchers say they cannot pinpoint the reasons for the different pregnancy rates. In most cases, pregnancies occurred because recruits used the device improperly or didn't use it every time they had intercourse, Farr says.

How does the female condom's pregnancy-prevention prowess compare with that of birth control methods already available in the United States?

James Trussell at Princeton University's Office of Population Research offered the panel some comparative statistics. Trussell told the panel that the U.S. failure rate for the diaphragm, a plastic or rubber cup that covers the cervix, ranges from 7.6 to 8.7 percent per six months. The contraceptive sponge, a throwaway diaphragm-like device, has an 11.7 percent six-month failure rate. As for the latex male condom, Trussell told the panel that one-year failure rates for this time-honored method of birth control range from 7.2 to 14.8 percent.

"Reality's failure rate is similar to [that of] other barrier contraceptives," Leeper said at the hearing.

Wisconsin Pharmacal maintains that these preliminary data provide sufficient evidence for approval of the female condom. However, FDA scientists who reviewed the findings want to see final data confirming the female condom's ability to guard against pregnancy. FDA's Eugene

Williams noted, for example, that a six-month overall failure rate of 15.1 percent could reach as high as 25 percent by the end of a year.

Of course, pregnancy protection isn't the only issue. FDA's expert panel also had to consider the female condom's potential for shielding women from sexually transmitted microbes such as HIV.

For ethical reasons, Wisconsin Pharmacal cannot ask women to expose themselves to HIV simply to test the device. However, a study by David E. Soper of the Medical College of Virginia in Richmond offers a clue to the device's power to stop the spread of at least one sexually transmitted bug.

> ***"It would be a tragedy to lose this opportunity," testified San Francisco physician Mervyn F. Silverman.***

Soper studied 104 women with trichomoniasis, a relatively harmless infection caused by a protozoan that is transmitted sexually. All 104 women had had their fallopian tubes tied or were taking birth control pills. The volunteers received a drug called metronidazole to treat the trichomoniasis, which causes itching and a vaginal discharge. To see whether the female condom could protect women from being reinfected by their partners, 54 of the 104 recruits agreed to use it. The remaining 50 women served as controls.

Six weeks after treatment, the women returned to the clinic. Soper discovered that seven of the 50 controls had trichomoniasis infection again. Among the 20 women who said they had used the female condom properly each time they had intercourse, Soper found no cases of reinfection. But among the 34 women who failed to use the device properly or forgot to use it, five showed up with another case of trichomoniasis and three others had a sexually transmitted infection known as chlamydia, which can lead to pelvic inflammatory disease and sterility.

"Nothing's going to be 100 percent [effective against sexually transmitted microbes]," Soper notes. However, the preliminary findings from this study suggest the female condom may prove about as effective as the male condom in blocking the spread of disease-causing microorganisms. Nonetheless, further study is needed to assess the female condom's value as a disease preventive, Soper told SCIENCE NEWS.

Wisconsin Pharmacal

The female condom relies on two flexible rings connected by a plastic sheath.

Several other studies detailed at the FDA hearing raise concerns about the risk of exposure to disease-causing microbes. In one study, investigators discovered that the condom's cervical ring slipped away from the cervix as much as 24.5 percent of the time. Leeper says the slipping female condom "rides the penis" and thus does not result in any spill of semen into the vagina.

Other studies revealed that in as many as 17.7 percent of cases, intercourse pushes the outer ring into the vagina, a "risk event" that leads to skin-to-skin contact and perhaps exposure to semen, FDA's Gary Kamer said at the hearing. In fact, no one really knows exactly how effective the female condom is at disease protection. That uncertainty may lead to a guessing game for those trying to figure out the risk of sex.

"If Reality is less effective than the male condom in preventing [disease] transmission, those using Reality instead of no device may benefit," Kamer told the panel, "but those using Reality as an alternative to the latex male condom or to abstinence may be at increased risk."

Despite the preliminary nature of the data and the concerns of FDA scientists, a number of public health experts have urged the agency to approve the female condom.

"It would be a tragedy to lose this opportunity," testified San Francisco physician Mervyn F. Silverman, president of the American Foundation for AIDS Research. He acknowledged the female condom's flaws but went on to stress the dire need for a safeguard against HIV.

The male condom was designed 400 years ago, he added. "This is the first time in 400 years that we have a female equivalent."

Others agreed with the urgency of the situation.

"The incidence of sexually transmitted diseases has become epidemic," testified Cynthia A. Pearson, director of the National Women's Health Network in Washington, D.C. Pearson noted that a woman's risk of acquiring HIV from an infected male partner is much higher than a man's risk of getting HIV from an infected woman (SN: 10/5/91, p.219).

And HIV is just one threat. Syphilis, gonorrhea, genital herpes, chlamydia and the human papillomavirus all contribute to the risky new sexual climate, she added.

"Ironically, a heterosexual woman's best protection against AIDS and other [sexually transmitted diseases] depends entirely on the cooperation of her partner," Pearson told the panel. "Women cannot always count on their male partners to use condoms."

Pearson and many others who specialize in women's health issues believe that the data on disease prevention, although incomplete, offer enough evidence to warrant speedy government approval. "Reality appears to be as effective as other barrier methods currently in use," Pearson argued. "We believe these data are enough for a woman to make an informed choice."

In the end, the FDA panel seemed to agree with that assessment. The group voted unanimously to advise FDA to approve the device, contingent on favorable results from the Phase II pregnancy study. And to make sure the female condom doesn't break or tear excessively, the panel instructed the company to complete a "rip-and-tear" study. If the new data satisfy FDA, the female condom seems likely to join the rows of male condoms on drugstore and supermarket shelves sometime later this year. □