

Panel to Review Drug for Low Female Sex Drive

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Men have Viagra and other pills to fight sexual impotence. Now women might soon have something roughly equivalent.

Procter & Gamble will try today to persuade a federal advisory panel to recommend approval of the first drug to increase a woman's sex drive.

The company plans to tell the committee, which advises the Food and Drug Administration, that the drug Intrinsa increases the sexual desire of women and the frequency with which they have "satisfying" sex. Some experts say approval of Intrinsa would bring a new era in the handling of women's sexual problems.

"It's a big breakthrough in acknowledging there are medical aspects to sexual dysfunction in women," said Jennifer R. Berman, director of the Female Sexual Medicine Center at the University of California, Los Angeles, and a consultant to Procter & Gamble. "It's not all in our heads."

But Intrinsa might not sail smoothly toward a positive recommendation from the advisory committee, which will meet in Gaithersburg, Md. The F.D.A.'s own staff, in its review of the data, questioned whether the benefits of Intrinsa were "clinically meaningful" because the drug increased the number of times women had satisfying sex by only once a month compared with a placebo.

In documents posted on the F.D.A. Web site yesterday along with the company's data from clinical trials, the agency's reviewers also said they had concerns about the long-term safety of the treatment, which consists of the hormone testosterone.

Other hormone therapies, involving estrogen and progestin, were widely used in the past by women after menopause, but were later found to raise the risk of heart attacks, strokes and breast cancer, they wrote. Intrinsa has been studied for longer than a year only in a small number of women.

The F.D.A. staff often tends to be more critical of drugs than the advisory panels, which are made up mostly of practicing physicians.

Elaine Plummer, a spokeswoman for Procter & Gamble, said the company was "prepared to address those questions" at the meeting.

The shares of Procter & Gamble gained \$1.18 yesterday, to close at \$54.66. Part of that run-up could be a result of positive economic news about consumer spending that spurred strong gains in the overall stock market.

Intrinsa, which Procter & Gamble developed with Watson Pharmaceuticals, involves a patch, worn on the abdomen, that delivers a steady stream of testosterone. While that hormone is usually associated with men, women also make lesser amounts of it and it helps stimulate sexual desire. Some women already use testosterone products

approved for men, but those products contain far too much testosterone for women, experts said.

Women produce about half their testosterone in their ovaries, so Procter & Gamble is initially seeking F.D.A. approval for Intrinsa as a treatment for women who have had their ovaries removed. It said that 17 to 30 percent of the 10 million women who have undergone such surgery have "hypoactive sexual desire disorder," meaning low sex drive that they find distressing.

But the company is also testing the drug in women who undergo natural menopause.

In clinical trials, women who used Intrinsa had an increase in the number of "satisfying episodes" of sex to five a month, from three. But women who received the placebo also had an increase - to four a month, from three. The definition of satisfying sex was left to the women, who kept log books during the clinical trials.

Some experts say they worry that Intrinsa will be used as a means of enhancing sex by women who are not post-menopausal or do not suffer from hypoactive sexual desire disorder.

"The off-label uses of this is obviously where they are heading," said Leonore Tiefer, a psychologist and sex therapist at New York University. While Viagra is also misused, she said, it is taken occasionally while the Intrinsa patch would be worn continuously, posing more possible risk from side effects.

Dr. Tiefer said she did not believe that "hypoactive sexual desire disorder" was even a condition that could be treated with drugs. "There's an endless number of reasons that people can lose their sexual desire" she said. Intrinsa, she added, is a "not-well-understood drug for a not-well-understood condition."

But Sheryl A. Kingsberg, a psychologist at Case Western Reserve Medical School, disagreed.

"This is not a manmade disorder to create a market," said Dr. Kingsberg, who was an investigator in the Intrinsa clinical trials and is paid by Procter & Gamble to educate physicians about sexual dysfunction. "Women come into my office every day complaining they've lost sexual desire and they want it back."

While Intrinsa is sometimes popularly called the "female Viagra" it is not really equivalent. Viagra deals with a physiologic problem involved in arousal while Intrinsa is meant to restore desire.

"Desire was not the problem for men - erections were," said Dr. Kingsberg. "For women, desire really is the problem." Indeed, Pfizer, which makes Viagra, gave up trying to broaden the drug's use to women this year, saying it did not work.

But Intrinsa and other drugs for women are like Viagra in that manufacturers hope they will attain big sales. Viagra had sales of \$1.9 billion worldwide last year and analysts estimate sales of Intrinsa will be several hundred million dollars a year.

About 10 companies now developing drugs for female sexual dysfunction, whether other forms of testosterone like gels and sprays, or other drugs. They include small companies like BioSante, Cellegy, and Vivus. But Procter & Gamble appears to have at least an 18-month lead.

Procter & Gamble has said it wants to expand more into prescription drugs, which carry higher profit margins than products like Tide detergent, Crest toothpaste and Pampers diapers.

Prescription drugs last year accounted for \$1.67 billion of the company's \$51.4 billion in revenue, a spokesman said. The company currently sells seven prescription drugs, according to its Web site, with the biggest seller being Actonel, for osteoporosis. It also sells over-the-counter medicines, including Prilosec for heartburn.