

# FDA: 'Female Viagra' falls short

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In this Oct. 30, 2007 file photo, employees are silhouetted at the Boehringer Ingelheim pharmaceutical factory in Ingelheim, central Germany. Boehringer Ingelheim has asked the Food and Drug Administration to approve its drug flibanserin for women who report a lack of sexual desire, a market that drugmakers have been targeting for more than a decade since the success of Viagra in men. Federal health regulators said Wednesday, June 16, 2010, the first pill designed to boost the female sex drive failed to make a significant impact on libido in two studies.(AP Photo/Michael Pobst, file)

(AP) -- The first pill designed to boost the female sex drive failed to make a significant impact on libido in two studies, federal health regulators said, though some women did report slightly more sexually satisfying experiences.

The Food and Drug Administration is considering Boehringer Ingelheim's drug flibanserin for premenopausal women who report a lack of sexual desire, a market that drugmakers have been targeting for

more than a decade since the blockbuster success of Viagra in men.

The search for so-called "female Viagra," has proved elusive though, with many drugs abandoned after showing lackluster results.

On Friday the FDA will ask a panel of experts to weigh in on the safety and effectiveness of Boehringer's drug. The agency is not required to follow the group's advice, though it often does.

In its review posted online Wednesday, FDA said two Boehringer studies failed to show a significant increase in sexual desire, as recorded by women in a daily journal. Women taking the drug reported slightly more sexually satisfying experiences, but FDA said that was not the primary measure of the study.

"The division wanted to see that an effect of treatment is an overall increase in sexual desire regardless of whether a sexual event occurred or not," states the FDA review.

The FDA also noted increased side effects like depression, fainting and dizziness seen among women taking the pink pill.

The drug, which is related to the antidepressant family, affects serotonin and several other brain chemicals, though it's not clear how that increases sex drive.

"We don't know specifically what the exact mechanism of action is but we believe it acts on brain chemicals that have a role in human sexual response," said Dr. Peter Piliero, executive director for Boehringer's U.S. medical affairs.

Since the launch of Viagra in 1998, more than two dozen experimental therapies have been studied for so-called "female sexual dysfunction," a

market which some analysts estimate at \$2 billion.

Dr. Elizabeth Kavaler, a urologist at Lenox Hill Hospital in New York, says arousal in women is so complicated that it may be unrealistic to expect a pill to completely address sexual problems.

"It's a fairly complicated area, unlike in men's sexual dysfunction where there's a major mechanical concern," said Kavaler. "In women there's no mechanical concern, so if she's not having a successful sex life, where is the problem?"

Pharmaceutical approaches to boosting female sexual libido have evolved over time. Initially, most treatments aimed to increase blood flow to the genitals, similar to Viagra. A second wave of would-be blockbusters focused on boosting hormones, including testosterone, which is linked to sexual interest. Flibanserin is the first drug to approach the problem through brain chemistry.

The FDA has approved an unusual handheld vacuum device that increases blood flow to the clitoris to increase sexual arousal. But all drug therapies have fallen short so far.

In 2004, Pfizer halted its study of Viagra in women due to inconclusive results. Later that year an FDA panel rejected Procter & Gamble's testosterone patch Intrinsa, due to risks of heart disease and cancer. Smaller companies are currently developing creams and nasal sprays to increase female libido.

BioSante Pharmaceuticals Inc. expects to submit its testosterone gel LibiGel for FDA approval next year.

Medical surveys have estimated more than 40 percent of women suffer from some form of sexual dysfunction; Boehringer estimates as many as

one in 10 women could be helped by its drug.

Boehringer tried to zero in on the chemical aspect of sexual dysfunction by only testing its drug on premenopausal women who were in stable relationships and not taking other medications. Despite wanting to have a sexual relationship, the women enrolled in company studies reported a persistent lack of desire that caused them "distress or interpersonal difficulty."

Leonore Tiefer, a psychiatry professor at New York University who runs a private sex therapy practice, believes drugmakers have oversimplified female sexuality. She says in most cases lack of sex drive has more to do with the quality of one's relationship and lifestyle than brain chemicals.

During the public comment period at Friday's meeting, Tiefer will ask the FDA to reject flibanserin, arguing it offers meager benefits for women with unknown long-term risks.

The modest results reported by Boehringer have also cooled Wall Street's expectations for the drug.

Decision Resources analyst Alasdair Milton said he expects flibanserin sales to peak at \$300 million after six or more years on the market. By comparison, male sexual dysfunction drugs including Viagra, Cialis and others posted combined sales of \$4.4 billion last year, according to health care data firm IMS Health.

Privately-held Boehringer Ingelheim posted sales of \$12 billion last year. The Ingelheim, Germany -based company makes a range of prescription drugs for heart disease, HIV and other diseases.

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