Concerns remain for 'Viagra for women' twice rejected by FDA

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In this Friday, Sept. 27, 2013, file photo, a tablet of flibanserin sits on a brochure for Sprout Pharmaceuticals in the company's Raleigh, N.C., headquarters. Sprout Pharmaceuticals, the makers of the twice-rejected pill intended to boost libido in women, will make a third attempt this week at convincing regulators to approve the drug as the first prescription treatment for low sexual desire in women. A panel of FDA experts will discuss the drug at a public meeting Thursday, June 4, 2015 before voting on whether to recommend its approval.(AP Photo/Allen G. Breed, File)

The makers of a pill intended to boost sexual desire in women will try again this week to persuade regulators that the drug warrants approval after two rejections.

But a new review released by the Food and Drug Administration shows government scientists still have concerns about whether the drug's benefits outweigh its risks. The FDA review highlights several safety issues with flibanserin, including low blood pressure and fainting spells. Those problems increased when patients combined the drug with alcohol and some other medications, according to the document.

A panel of FDA experts will discuss the drug at a public meeting Thursday, before voting on whether to recommend its approval.

The ongoing saga of Sprout Pharmaceutical's much-debated drug illustrates the complex politics and science surrounding women's sexuality.

For decades, drugmakers have tried unsuccessfully to develop a female equivalent to Viagra, the blockbuster drug that treats men's erectile dysfunction by increasing blood flow. But disorders of women's sexual desire have proven resistant to drugs that act on blood flow, hormones and other simple biological functions.

Supporters of Sprout's drug say women's sexual disorders have been long overlooked by the FDA. But critics argue that drug development efforts like Sprout's medicalize women's sexual problems, which are often related to stress, relationship issues and other life circumstances.

"There are certainly women who have low libido and are distressed by it," says Dr. Adriane Fugh-Berman, an associate professor at Georgetown University. "But for those women therapy is the best solution, because this is not a medical disease."

Other critics say they would support a safe and effective drug for treating women's libido problems, but none has yet emerged.

"If a company could show that a drug is effective based on clinically significant outcome measurements, then we'd be for it," says Cindy Pearson, executive director of the National Women's Health Network.

Flibanserin is the first drug to approach the issue through brain chemistry. Originally studied as an antidepressant, the pill was repurposed as a libido treatment after women in company studies reported higher levels of sexual satisfaction. But the FDA has twice rejected the drug because of lackluster effectiveness and side effects including fatigue, dizziness and nausea.

Clinicians who helped study flibanserin point out that they already prescribe other antidepressants without FDA approval to treat sexual desire disorders. They argue that those drugs, including Wellbutrin and Viibryd, carry worse side effects than flibanserin, such as agitation and seizures.

"We use them all the time for female sexual dysfunction," says Dr. James Simon, a gynecologist who helped conduct several key studies of flibanserin. "The problem is that the side effect profile for doses that are effective for increasing desire and orgasm can be very high."

Simon says the lack of an FDA-approved option for female sexual dysfunction means doctors must balance issues of safety and lack of insurance coverage while trying to help patients.

"We're out there in the trenches every day trying to find a happy medium."

It's not entirely clear how flibanserin increases desire, but researchers

point to its ability to boost dopamine—a brain chemical associated with appetite—while lowering serotonin, which is linked to feelings of satiation.

The FDA first rejected flibanserin in 2010 after a panel of expert advisers unanimously voted against the drug, saying its benefits did not outweigh its risks. Company studies showed women taking flibanserin reported roughly one more sexually satisfying experience per month than women taking placebo.

The drug's initial developer, Boehringer Ingelheim, abandoned work on the drug in 2011 and sold it to Sprout, a startup company from Raleigh, North Carolina. Sprout resubmitted the drug with additional effectiveness and safety data, but the FDA again rejected the drug in October 2013. Sprout submitted the drug yet again earlier this year after filing a formal dispute over the FDA's second rejection.

FDA's review posted Tuesday underscores the ongoing rift between regulators and the company. The FDA acknowledges that flibanserin resulted in statistically significant increases in sexual events and desire, while decreasing distress. But the review concludes: "The fundamental question is whether these observed placebo-corrected treatment effects outweigh the risks associated with treatment."

The FDA will ask its expert panel whether extra safety measures—including certification for doctors who wish to prescribe the drug—should be required if the drug is approved.

The FDA is not required to follow the advice of its panelists. The agency is expected to make a decision on whether to approve the drug in August..