First-ever drug to treat female sexual dysfunction has been twice rejected; defenders say FDA biased

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With 31 percent of men reporting some form of sexual dysfunction, the field for treatments is crowded, from testosterone pills and penile pumps to more than two dozen drugs approved by the Federal Drug Administration, including the blockbuster Viagra.

But even though more women reportedly experience sexual dysfunction — 43 percent,according to research published in the Journal of the American Medical Association — the number of FDA-approved treatments for them is zero. “For women,” said Dr. Irwin Goldstein, director of sexual medicine at Alvarado Hospital in San Diego, “they tell you to have a glass of wine and go see a psychologist.”

At a public hearing on Thursday — on what could be the first-ever drug to be approved by the FDA for the treatment of women’s sexual dysfunction — the FDA may also have to answer charges that the relative lack of progress stems from bias in how women’s sexual health is treated.

The hearing has been called by an FDA advisory committee that will vote on recommending approval for the drug flibanserin, developed by the Raleigh, North Carolina-based company Sprout Pharmaceuticals. The FDA has already rejected flibanserin twice because of concerns that it causes low blood pressure and fainting, side effects that are

exacerbated when the drug is combined with alcohol. Sprout has presented additional clinical trial data requested by the FDA showing that the drug has a small but statistically significant effect on both women's sexual desire and the number of sexually satisfying events they experienced after they took it, as compared to a placebo.

The agency said it recognizes the distress experienced by women who have reduced sexual desire. "This condition is clearly an area of unmet medical need," it said in the supporting documents posted on its website ahead of Thursday's hearing (PDF). "However, for any product intended to treat an unmet medical need, the FDA is still required to base its regulatory decisions on an assessment of whether the benefits outweigh the risks."

In the statement, the FDA acknowledged that there are no approved drugs for the treatment of women's sexual dysfunction, but called accusations of gender bias "misleading and inaccurate." The statement was signed by Dr. Hilton Joffe, director of the agency's divison of bone, reproductive and neurological products.

"The FDA rejects claims of gender bias," the statement read.

Goldstein, who is on Sprout's advisory board, has helped the company conduct clinical research and has received honoraria from the company, noted that the FDA fast-tracked Viagra in six months based on data from a few thousand patients. Flibanserin has been tested on 11,000 patients, and side effects like dizziness are mitigated by the fact that the drug is taken at night, he said.

"From the perspective of the practitioner, there's only one conclusion that can be reached," Goldstein said. "For whatever reason, the FDA has given importance to men's sexual problems."

In addition to being the first drug aimed at women's sexual dysfunction, flibanserin is also the first drug to try to address sexual dysfunction though brain chemistry rather than sex hormones such as testosterone. Barry Komisaruk, a psychology professor at Rutgers University and author of the book "The Science of Orgasm," explains that erectile dysfunction drugs including Cialis and Levitra work to increase blood flow to the penis, and thus to enhance the ability to have erections. When such drugs are given to women, they work to engorge the clitoris, "but that's not critical to sexual response and sexual arousal," Komisaruk said.

Flibanserin was initially developed as an antidepressant in the same class as Paxil or Prozac. While it wasn't very effective in that role, it did appear to increase sexual desire. The drug is supposed to work by stimulating a serotonin receptor that heightens sexual response, and by blocking a serotonin receptor that inhibits it.

Still, Komisaruk said scientists don't fully understand sexual desire — as opposed to physical sexual function— or how the brain produces it. "That is a much more mysterious mechanism," he said.

Following Thursday's hearing, an external advisory panel will recommend whether the drug should be approved, after which the FDA will make a decision.

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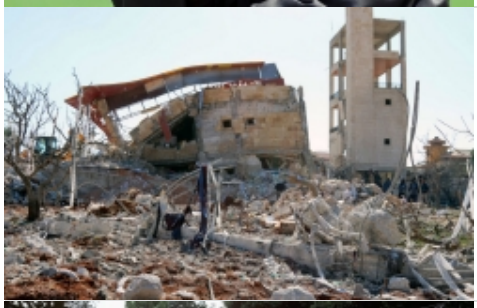

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