

FDA could approve first female libido pill soon

August 17 2015, by Dennis Thompson, Healthday Reporter



But flibanserin's safety and effectiveness still being debated.

(HealthDay)—The U.S. Food and Drug Administration could soon approve a controversial drug aimed at boosting libido in women.

If it gets the agency's nod, flibanserin would become the first such FDA-approved medicine.

Proponents say the drug would provide an important option for millions of American [women](#) who suffer from hypoactive [sexual desire](#) disorder, which causes a persistent or recurring lack of desire or an absence of sexual fantasies.

"This would bring another option to the table that doesn't currently exist," said Fred Wyand, spokesman for the American Sexual Health Association, a group that testified at an FDA hearing in favor of flibanserin. "There really are not any medical options available for

women who have [low sexual desire](#). There just aren't a lot of choices out there."

But opponents note a host of concerns regarding the drug, which has already twice been turned down by the FDA, once in 2010 and again in 2013.

An FDA advisory panel voted 18 to 6 in June to recommend the drug's approval, but the endorsement was somewhat muted. The committee called the drug's benefits "moderate" or "marginal," and the panel members who voted yes said full FDA approval should come with conditions.

The FDA typically follows the recommendations of its advisory panels, but is not bound to do so.

Flibanserin hasn't been shown to be very effective, said psychotherapist Keesha Ewers, founder and chief medical officer of the Functional Sexology Institute.

Women in [clinical trials](#) for the drug reported, at best, an increase of one additional satisfying sexual event per month, according to FDA documents. Plus, clinical trials have also shown that the drug doesn't appear to directly boost a woman's libido, Ewers added.

"Not one person in the studies that have been done has actually reported an increase in sexual desire," she said. "What has been reported is a decrease in the distress that is felt about lack of sexual desire."

That distress is one of the clinical parameters used to diagnose a person with [hypoactive sexual desire](#) disorder. And, that is what has allowed the drug's proponents to contend that it can be useful in treating some women who have sexual dysfunction.

There are also some safety concerns about flibanserin. One in five people in clinical trials reported that the drug caused feelings of extreme fatigue and sedation. Accidental injuries associated with this fatigue occurred twice as often in women taking flibanserin compared with those taking a placebo, FDA documents showed.

Flibanserin's opponents contend that the FDA is being muscled into approving the drug through a slick marketing campaign called "Even the Score," which uses a gender-rights argument to advocate for the [drug's](#) approval. The campaign receives funding from Sprout Pharmaceuticals, Palatin Technologies and Trimel Pharmaceuticals, all of which are working on drugs to treat female sexual disorders.

A number of high-profile groups such as the National Organization of Women have signed onto the campaign, which argues that women deserve a medication that helps sexual function since men already have Viagra and Cialis.

"We live in a culture that has historically discounted the importance of sexual pleasure and sexual desire for women," NOW President Terry O'Neill said in an NPR interview earlier this year. "And, I fear that it's that cultural attitude that men's sexual health is extremely important, but women's [sexual health](#) is not so important. That's the cultural attitude that I want to be sure the FDA has not, maybe unconsciously, imported into its deliberative process."

Other groups in support of Even the Score include the American Sexual Health Association, the Association of Reproductive Health Professionals, the National Association of Clinical Nurse Specialists, the Society for Women's Health Research, and the Institute for Sexual Medicine.

"What makes me sad, worried, and to be honest, annoyed, is that there

are no medical options available for women for whom biological factors are at play. Not one," said Lynn Barclay, the American Sexual Health Association's president and CEO, who testified before the FDA advisory committee in June.

Ewers said it's a false argument to compare flibanserin for women to Viagra or Cialis for men. "To say that we're going to give equal rights to women by giving them the pink version of Viagra is ridiculous and unintelligent," she said.

Viagra works on a man's body, stimulating blood flow to create easy erections. "That's an actual physiological function—erection," Ewers said. "It's not affecting their desire. It's affecting their plumbing."

Flibanserin, on the other hand, works by affecting a woman's brain chemistry, which can have a host of unintended consequences, she contended.

"The problem is that these two things are not the same," Ewers said. "It's being presented with this very black-and-white argument, as equal time for women, and that's just not the case."

More information: Learn more about sexual dysfunction in women from the [National Women's Health Information Resource Center](https://www.nwhc.org/).

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Citation: FDA could approve first female libido pill soon (2015, August 17) retrieved 10 May 2024 from <https://medicalxpress.com/news/2015-08-fda-female-libido-pill.html>

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