

'Female Viagra' gets green light from US expert panel (Update)

June 4 2015

A US advisory panel on Thursday urged regulators to approve a drug nicknamed the "female Viagra" because it could help increase women's sex drive.

If the US Food and Drug Administration gives flibanserin the go-ahead, it would be the first drug on the market to boost female libido.

The FDA is not required to follow the advice of the panel, but it often does.

The experts voted 18-6 in favor of allowing the drug on the market, but with some additional risk-control measures to make sure doctors prescribe it only to patients who need it and that women are aware of the risks.

Flibanserin, which is aimed at pre-menopausal women, can have significant side effects including nausea, dizziness and sleepiness.

"The treatment effects are numerically small," said doctor Christina Chang, speaking to the panelists on behalf of the FDA, asking the committee to weigh in on the evidence of benefits and risks in women studied.

Safety concerns include sleepiness, fainting, low blood pressure and the potential for hormonal contraceptives and alcohol use to make side effects worse, Chang said.

Experts at the hearing also raised questions about the possibility for the treatment to be used as a "date-rape drug" and the increased risk of breast cancer seen in one of two studies on lab animals.

But during the public comment period, women who had taken the drug said the benefits were considerable.

"I am one of the lucky 11,000 women that was a patient on the flibanserin clinical trial," said Amanda Parrish, who said she lost desire for sex with her husband, and their marriage had suffered.

"What a relationship-saving eight months that was. As if the light switch had been turned on, so was I."

Rejected before

Two attempts at bringing the drug to market have already failed in 2010 and 2013, given what experts described as inconclusive advantages when compared to a placebo.

After it was initially rejected by the FDA, flibanserin was sold by its developer, the German laboratory Boehringer Ingelheim, to a US firm called Sprout Pharmaceuticals.

According to documents on the FDA website, women taking flibanserin reported on average 4.4 sexually satisfying encounters per month, compared to 3.7 in a placebo group and 2.7 before beginning the study.

The difference between flibanserin and a sugar pill was deemed statistically insignificant in 2010 after a debate among the committee members which included seven women and four men.

"What I know is that flibanserin, taken each night worked for me, and

worked for my marriage," said Parrish.

"For me the effects were not modest, but significant."

Among the six who voted against the approval, concerns included negative interactions with alcohol, risks such as fainting and low blood pressure, the drug's minimal effectiveness and the lack of long-term data on safety.

But the majority of the experts said the approval should provide an option for women who suffer from loss of interest in sex for the first time, as long as "certain risk management options beyond labeling" are instituted, such as doctor training and post-marketing studies.

The aphrodisiac properties of flibanserin were discovered accidentally when it was tested as an anti-depressant, the drug-maker said.

Viagra's ability to cause an erection was discovered after it was tested as a heart medication. Other big drug companies have already thrown in the towel when it comes to developing a female version, including Pfizer and Procter and Gamble.

© 2015 AFP

Citation: 'Female Viagra' gets green light from US expert panel (Update) (2015, June 4) retrieved 6 May 2024 from https://medicalxpress.com/news/2015-06-discuss-female-viagra_1.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.