

FDA approves first pill aimed at boosting female libido

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In this June 22, 2015, photo, a tablet of flibanserin sits on a brochure for Sprout Pharmaceuticals in the company's Raleigh, N.C., headquarters. The Food and Drug Administration on Tuesday, Aug. 18, 2015, approved the first prescription drug designed to boost sexual desire in women, a milestone long sought by a pharmaceutical industry eager to replicate the blockbuster success of impotence drugs for men. (AP Photo/Allen G. Breed)

The Food and Drug Administration has approved the first prescription drug designed to boost sexual desire in women, a milestone long sought

by a pharmaceutical industry eager to replicate the blockbuster success of impotence drugs for men.

But stringent safety measures on the daily pill called Addyi mean it will probably never achieve the sales of Viagra, which has generated billions of dollars since the late 1990s.

The drug's label will bear a boxed warning—the most serious type—alerting doctors and patients to the risks of dangerously low blood pressure and fainting, especially when the pill is combined with alcohol. The same problems can occur when taking the drug with other commonly prescribed medications, including antifungals used to treat yeast infections.

"Patients and prescribers should fully understand the risks associated with the use of Addyi before considering treatment," said Dr. Janet Woodcock, director of the FDA's drug center, in a statement announcing the approval Tuesday.

Under an FDA-imposed safety plan, doctors will only be able to prescribe Addyi after completing an online certification process that requires counseling patients about Addyi's risks. Pharmacists will also need certification and will be required to remind patients not to drink alcohol while taking the drug.

Opponents of the drug say it's not worth the side effects, which also include nausea, drowsiness and dizziness. They point out that the FDA rejected the drug twice, in 2010 and 2013, due to these risks.

"This is not a drug you take an hour before you have sex. You have to take it for weeks and months in order to see any benefit at all," said Leonore Tiefer, a psychologist and sex therapist who organized a petition last month calling on the FDA to reject the drug.

Patients should stop taking the drug after eight weeks if they do not see any improvement, notes the FDA release.

Sprout Pharmaceutical's drug is intended to treat women who report emotional stress due to a lack of libido. Its approval marks a turnaround for the FDA, which previously rejected the drug twice due to lackluster effectiveness and side effects. The decision represents a compromise of sorts between two camps that have publicly feuded over the drug for years.

On one side, Sprout and its supporters have argued that women desperately need FDA-approved medicines to treat sexual problems. On the other side, safety advocates and pharmaceutical critics warn that Addyi is a problem-prone drug for a questionable medical condition.

Beginning with the drug's launch in mid-October, doctors who see patients complaining about a loss of sexual appetite will have a new option.



In this June 22, 2015, photo, Sprout Pharmaceuticals CEO Cindy Whitehead works in her office in Raleigh, N.C. The Food and Drug Administration on Tuesday, Aug. 18, 2015, approved Sprout Pharmaceutical's first prescription drug designed to boost sexual desire in women, a milestone long sought by a pharmaceutical industry eager to replicate the blockbuster success of impotence drugs for men. (AP Photo/Allen G. Breed)

"Women are grasping, and I feel like we need to offer them something that acknowledges that, and that we can feel safe and comfortable with," said Dr. Cheryl Iglesia, a surgeon and official with the American Congress of Obstetricians and Gynecologists. Iglesia said she has occasionally resorted to prescribing testosterone creams to boost women's libido, a use not approved by the FDA.

The search for a pill to treat women's sexual difficulties has been

something of a holy grail for the pharmaceutical industry. It was pursued and later abandoned by Pfizer, Bayer and Procter & Gamble, among others. But drugs that act on blood flow, hormones and other biological functions all proved ineffective.

Addyi, known generically as flibanserin, is the first drug that acts on brain chemicals that affect mood and appetite.

Women and their doctors will have to decide whether the drug's modest benefits warrant taking a psychiatric pill on a daily basis.

Company trials showed women taking the drug generally reported one extra "sexually satisfying event" per month, and scored higher on questionnaires measuring desire.

Tiefer and other critics said the FDA was pressured into approving the drug by a feminist-themed lobbying campaign funded by Sprout and other drugmakers.

"It's just a mishmash of politics and science and sex and money," Tiefer said.

The lobbying group, dubbed Even the Score, began publicizing the lack of drugs for female sexual dysfunction as a women's rights issue last year.

"Women deserve equal treatment when it comes to sex," the group states in an online petition to the FDA, which attracted more than 60,000 supporters. Women's groups, including the National Organization for Women, signed on to the effort, though it was funded by Sprout and other companies working on female sex drugs.

At an FDA meeting in June, more than 30 members of the public called

for the drug's approval, frequently citing the Even the Score campaign. They vastly outnumbered speakers who spoke in opposition to the drug. At the meeting's conclusion, the panel of FDA advisers voted 18-6 to recommend approving the drug, with safety restrictions.

Read: [Q&A: First pill approved to boost sex drive in women](#)

Sprout declined to comment on how much it spent on the campaign.

For now, executives with the Raleigh, North Carolina-based company are setting modest expectations for Addyi, their first and only product. The company will focus its 200 sales representatives on promoting the drug to medical specialists.

"We will be small," CEO Cindy Whitehead said. "We will be specialty focused among the physicians who already have a familiarity with female sexual dysfunction."

Women with insurance can expect to pay between \$30 and \$75 per month for Addyi, depending on the terms of their coverage.

The FDA specifically approved the drug for premenopausal women with hypoactive sexual desire disorder, a lack of sexual appetite that causes distress.

Surveys estimate that 8 to 14 percent of women ages 20 to 49 have the condition, or about 5.5 to 8.6 million U.S. women. Because so many factors affect sexual appetite, there are a number of alternate causes doctors must rule out before diagnosing the condition, including relationship issues, medical problems, depression and mood disorders.

The diagnosis is not universally accepted, and some psychologists argue that low sex drive should not be considered a medical problem.

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