Q&A: First pill approved to boost sex drive in women

August 19 2015, byMatthew Perrone

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)

Federal health officials on Tuesday approved the first-ever prescription drug intended to treat women suffering from a lack of sexual desire,

ending a vigorous debate over the drug's fate.

The daily pill, called Addyi, comes with warnings about risks of fainting if it is combined with certain other drugs or alcohol. Additionally, doctors won't be able to prescribe it unless they complete an online certification test.

Here's a look at the new drug from Sprout Pharmaceuticals:

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HOW DOES IT WORK?

Addyi, known generically as flibanserin, acts on brain chemicals associated with mood and appetite, similar to antidepressant drugs. In fact, it was originally studied as a treatment for depression before being repurposed into a libido drug. It's not entirely clear why the drug increases sexual desire but researchers point to its ability to increase dopamine—a brain chemical associated with appetite—while lowering serotonin—another chemical linked with feelings of satiation.

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WHO WILL TAKE THIS DRUG?

The FDA approved Addyi for premenopausal women with hypoactive sexual desire disorder, described as a lack of sexual appetite that causes emotional distress.

Surveys estimate that between 5.5 million to 8.6 million U.S. women have the condition, or roughly 8 to 14 percent of women ages 20 to 49. Because so many other factors affect sexual appetite, there are a number of alternate causes doctors must rule out before diagnosing the

condition, including relationship problems, medical conditions and mood issues caused by other medications like sleeping aids and painkillers.

The diagnosis is not universally accepted and many psychologists argue that low sex drive should not be considered a medical condition.

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I'VE HEARD THIS DECISION WAS CONTROVERSIAL, WHY?

The drug followed a long, contentious path to approval, including two previous rejections by the FDA. For years, two opposing sides have argued over the fate of the drug.

On one hand, drugmakers and some medical experts argue that women need FDA-approved medications to treat sexual disorders, which they consider serious medical problems. On the other side, consumer-safety advocates have said the drug's side effects are too risky, and there are those who question whether low libido is a medical condition.

On top of this debate, Sprout Pharmaceuticals enlisted outside politicians and women's groups to lobby the FDA to approve the drug.

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DOES THE DRUG WORK?

Experts usually describe Addyi's effect as "modest." In company studies, women taking flibanserin reported a slight increase in sexually satisfying events each month. Their answers to separate questionnaires indicated they experienced a slight increase in desire and a slight decrease in stress.

While FDA scientists describe these effects as "small," they were significant enough to meet FDA effectiveness standards.

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WHAT ARE THE SIDE EFFECTS?

About 10 percent of patients in Sprout's studies experienced the most common problems: dizziness, fatigue and nausea. The drug will also bear a boxed warning that women should not drink or take certain types of other medications, including antifungal drugs, because of an interaction that can cause low blood pressure and fainting.

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HOW MUCH WILL IT COST?

Sprout says women who have health insurance will pay between $30 and $75 for a month's supply of Addyi, depending on their coverage terms.

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WHY DID THE FDA APPROVE ADDYI THIS TIME AROUND?

When FDA regulators first rejected Addyi in 2010 they noted that the drug failed to achieve a key study goal—increasing desire based on patients' daily journal entries. Because of that lack of effectiveness, they said, the drug's negative side effects outweighed its benefits.

Since then, Sprout conducted another study of sexual desire using a different method that achieved statistical significance. The company also conducted several safety studies to more clearly define the drug's risks, which are outlined in its warning label.

While the FDA is required to make all decisions based on science, critics say that the concerted lobbying effort by Sprout-funded supporters also played a role in Addyi's approval.

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WHEN WILL THE DRUG BE AVAILABLE?

Sprout plans to launch the drug in mid-October.