After lobbying push, drugmaker resubmits women's sex pill

17 February 2015, byMatthew Perrone

In this Friday, Sept. 27, 2013, file photo, a tablet of flibanserin sits on a brochure for Sprout Pharmaceuticals in the company's Raleigh, N.C., headquarters. The pill has been twice rejected, but Sprout Pharmaceuticals said Tuesday, Feb. 17, 2015, it is refiling its application for flibanserin, adding new information requested by the Food and Drug Administration about how the pill affects driving ability. (AP Photo/Allen G. Breed, File)

The makers of a twice-rejected pill designed to boost sexual desire in women are hoping a yearlong lobbying push by politicians, women's groups and consumer advocates will move their much-debated drug onto the market.

The ongoing saga of Sprout Pharmaceutical's female libido drug illustrates the complicated politics and unresolved science surrounding women's sexuality.

For decades, drugmakers have tried unsuccessfully to develop a female equivalent to Viagra, the blockbuster drug that treats men's erectile dysfunction drug by increasing blood flow. But disorders of women's sexual desire have proven resistant to drugs that act on blood flow, hormones and other simple biological functions.

Supporters of Sprout's drug say women's sexual disorders have been overlooked for too long by regulators at the Food and Drug Administration. But critics argue that women's sexuality is too complex to be addressed by a single pill.

Sprout's drug flibanserin is the first attempt to increase libido by acting on brain chemicals linked to appetite and mood. But the Food and Drug Administration has already twice rejected the drug because of lackluster effectiveness and side effects including fatigue, dizziness and nausea.

In an effort to break the regulatory logjam, groups sponsored by Sprout and other drugmakers have begun publicizing the lack of a "female Viagra" as a women's rights issue.

"Women deserve equal treatment when it comes to sex," states an online petition to the FDA organized by one such group, Even the Score, which garnered almost 25,000 supporters. The group's corporate backers include Sprout Pharmaceuticals, Palatin Technologies and Trimel Pharmaceuticals—all companies developing drugs to treat female sexual disorders. A spokeswoman for Blue Engine Media, the public relations group for Even the Score, declined to disclose how much of the group's funding comes from companies. The group's nonprofit supporters include the Women's Health Foundation, the Institute for Sexual Medicine and other organizations.

Drugmakers frequently cite a 1999 survey in the Journal of the American Medical Association that found 43 percent of U.S. women had some type of sexual dysfunction.

Sprout said Tuesday it is refiling its application for flibanserin, adding new information requested by the FDA about how the pill affects driving ability. FDA scientists requested that data after their most

recent rejection of the drug, in part, due to results showing nearly 10 percent of women in company trials reported sleepiness as a side effect.

The FDA first rejected flibanserin in 2010 after a panel of expert advisers unanimously voted against the drug, saying its benefits did not outweigh its risks. The drug's initial developer, Boehringer Ingelheim, abandoned work on the drug in 2011 and sold it to Sprout, a startup headed by a husband-and-wife team from Raleigh, North Carolina.

Sprout resubmitted the drug with additional effectiveness and safety data, but the FDA again rejected the drug in October 2013. After Sprout filed a formal dispute over the decision, FDA regulators requested the driving study and other details on the drug's interactions with other medications.

As Sprout gathered that data, the company also enlisted support from influential allies in Washington and beyond. Last January four members of Congress, including Rep. Debbie Wasserman Schultz, D-Florida, sent a letter to the FDA, urging a careful reassessment of the drug and lamenting the lack of drug options for low female libido.

"There are 24 approved medical treatments for male sexual dysfunction and not one single treatment yet approved for the most common form of female sexual dysfunction," states the letter, which was also signed by Rep. Louise Slaughter, D-New York, and two other Democratic congresswomen.

The talking point about the imbalance of drugs for men versus women was picked up by a coalition of seven women's and consumer health groups who met with the FDA early last year.

"We see this not only as an important unmet women's health issue, but an inflection point for the agency to ensure that similar standards are applied for drug approvals in conditions uniquely affecting women," states a follow-up letter to the agency from leaders of the National Organization for Women, the National Consumers League and four other groups.

Then last October the FDA held a two-day meeting at its headquarters to get public input on the problem of female sexual dysfunction and the challenge of developing treatments.

If approved, flibanserin would be labeled for premenopausal women with hypoactive sexual desire disorder, described as a lack of sexual appetite that causes emotional distress. Because so many factors affect female sexual appetite, there are a number of other possible causes doctors must rule out before diagnosing the condition, including relationship problems, hormone disorders, depression and mood issues caused by other drugs like sleeping aids and pain medications.

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