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BUSINESS DAY

F.D.A. Panel Backs a Drug to Increase Women's Sex Drive

By ANDREW POLLACK JUNE 4, 2015

Government advisers Thursday recommended approval of what would be the first drug to treat lack of sexual desire in women.

The advisory committee to the Food and Drug Administration voted 18 to 6 that the drug, flibanserin, be approved. All of those who voted yes said approval should come only if certain measures are taken to reduce the risks of side effects.

Flibanserin, a pink pill that would be taken every day at bedtime, would be approved to treat lack of sexual desire in premenopausal women that cannot be attributed to disease or other known causes. Sprout Pharmaceuticals, which owns flibanserin, said that 7 percent of premenopausal women had this condition, known as hypoactive sexual desire disorder.

Flibanserin has been rejected twice already by the F.D.A., which said the drug's minimal benefits did not outweigh its risks. The first rejection in 2010 came after an advisory committee similar to the one that met Thursday voted unanimously that the drug should not be approved.

After the second rejection, in 2013, some women's groups, brought together by a consultant to Sprout, organized a campaign to press the F.D.A. into approving the drug. The campaign, called Even the Score, accused the agency of gender bias because it had approved Viagra and other drugs to help men have sex while leaving women without options.

Some other women's groups and individuals countered that Sprout and its allies were using women's rights as a cover to force approval of an undeserving drug.

In his introductory remarks at the start of Thursday's meeting, Dr. Hylton V.

Joffe, director of the division of bone, reproductive and urologic products at the F.D.A., said the agency "firmly rejects" the accusations of gender bias. He said that no drugs had been approved for either men or women to treat loss of sexual desire and that the agency recognized that there were people who would benefit from such treatments.

The F.D.A. however, questioned whether the benefits of flibanserin, which it called "numerically small but statistically significant," were meaningful enough, given side effects that include low blood pressure, fainting, sleepiness, nausea and dizziness.

Three clinical trials testing flibanserin were consistent in their results. The women who took part were having an average of two to three of what they defined as "sexually satisfying events" per month when the studies began. Once they started taking the drug, the number of such events increased, but by no more than one event per month more than for women in the trial who got a placebo.

Women getting flibanserin also reported on monthly questionnaires that they felt more desire, though the difference with a placebo was about 0.3 points on a scale ranging from 1.2 to 6.0.

The side effects of most concern to the F.D.A. were low blood pressure and fainting. While these were rare in the clinical trials, they seemed to raise the risk of accidental injury, with one woman having a concussion when she fell.

Moreover, the risk of such side effects increased when the women drank alcohol or took certain other medications, like fluconazole, which is used to treat fungal infections including vaginal yeast infections, and birth control pills. Much of the discussion in the meeting dealt with whether it was possible to reduce those risks, such as by requiring that women taking the drug refrain from drinking alcohol.

The meeting, at the F.D.A. campus in Silver Spring, Md., included nearly two hours of testimony from the public, an unusually large amount, with most speakers urging approval. Many were from organizations in the Even the Score coalition or doctors who treat sexual dysfunction. Their remarks were loudly applauded.

Some women with low sexual desire told of how the condition affected their lives and threatened their marriages, and said they resented being told that their problems were not medical but were caused by relationship problems or their busy schedules.

"Today is my son's first birthday and I'm missing it because I am here

desperately looking for help to recover what I have lost — a vital and beautiful part of my marriage," said Katherine Campbell, whose travel expenses from Indiana were paid for by Sprout.

"Critics say the improvement might only be modest, but oh what I would give for even a modest improvement," said Ms. Campbell, who has not tried flibanserin.

Supporters of the drug said that failure to approve it would discourage the pharmaceutical industry from pursuing treatments for female sexual disorder and that lack of an approved medicine would only cause women to use other drugs off label or seek help from dubious supplements hawked on the Internet.

Several speakers opposed approval. Dr. Adriane J. Fugh-Berman, director of the PharmedOut project at Georgetown University, called flibanserin "a mediocre aphrodisiac with scary side effects." She said that the clinical trials were restricted to healthy women, but that if approved the drug would be used by a wider range of women, resulting in "an epidemic of adverse events."

She also said the F.D.A. should resist the Even the Score campaign. "To approve this drug will set the worst kind of precedent — that companies that spend enough money can force the F.D.A. to approve useless or dangerous drugs."
