The FDA may soon give women more options for boosting their libidos

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More than two decades after Viagra revolutionized the treatment of men's sexual health, women looking for a pharmaceutical boost in the bedroom are having another kind of Me Too moment.

In the coming days, the Food and Drug Administration is expected to decide whether to approve a new medication for pre-menopausal women whose flagging libidos are causing them personal distress.

If permitted to be sold in the U.S., the injectable drug Vyleesi would become just the second FDA-approved treatment for "female hypoactive sexual desire disorder," or HSDD. The condition, which was recognized in its gender-specific form only in 2012, is thought to affect as many as 1-in-10 women before the onset of menopause, and many more after that.

The approval of Vyleesi (also known by its generic name bremelanotide) would leave the number of pharmaceutical options for women's sexual health far short of the more than two-dozen drugs approved for men. But several more offerings for women experiencing sexual troubles are waiting in the wings. And in marketing materials, backers are not shy about suggesting these drugs have "blockbuster potential."

It's a "huge market with unmet medical need," said Eric Claassen, chief business officer of the Dutch firm Emotional Brain, which expects to bring a pair of female HSDD drugs to the FDA by 2023. Potential sales for his firm's "personalized medicine" drugs, Lybrido and Lybridos, could peak at $2 billion, he said. Both are still in clinical trials and expected to be approved for marketing in Europe first.

Vyleesi is the first investigational drug to be evaluated on measures that view women's sexual function—and dysfunction—as sharply different than men's.

Based on a compound first explored as a tanning product, bremelanotide is thought to amp up a woman's desire by changing the mix of neurochemicals involved in female sexual arousal.

But "thought to" is the key phrase here. As the FDA discovered in 2015, when it approved a pill called Addyi (fibanserin) as the first drug for female HSDD, controversy and questions abound when female sexual desire becomes the object of measurement, medicalization and pharmaceutical modification.

Vyleesi's sponsor, AMAG Pharmaceuticals of Waltham, Mass., hopes their product will put an end to those debates. Not only is their medication superior to the one on the market now, AMAG says, women's sexual concerns are better understood and the FDA's deliberations better reflect women's needs.

The times have changed, too. Thanks to the Me Too movement, women are claiming more control over their bodies and their sexuality, said Dr. Julie

Krop, the company's vice president and chief scientific officer. When that part of their lives falls short, they want to discuss it with their doctors and fix it, she said.

"It's shocking that this has been such a buried topic, taken for granted and not really valued," Krop said.

By making common cause with women's sexual health specialists, company officials helped shape the new measures by which the FDA would judge female sexuality drugs coming to market. And they have primed the public with a campaign of mass persuasion.

Long before the FDA's decision was scheduled, AMAG sponsored billboards, online forums and social media campaigns to spread the word about female hyposexual desire disorder through its unblush campaign. Radiological scans suggest it can be caused by an imbalance of certain hormones and neurotransmitters in the brain.

"It's not 'down there.' It's 'up here,' between your ears," the campaign materials explain without making reference to Vyleesi.

Drug-companies' yearly spending on such "disease awareness" campaigns has risen sharply in recent years, reaching $430 million in 2016. They're credited with lowering the stigma attached to many conditions, including depression and erectile dysfunction.

But by the measures FDA uses to determine the effectiveness of HSDD drugs, bremelanotide appears promising: in a final round of clinical trials, 60% of subjects taking bremelanotide reported improvement in the distress levels they felt over their low libido—a significant increase over the roughly one-third of women taking placebo medication.

AMAG is counting on Vyleesi to gain more traction with women and doctors than has Addyi, a medication that was shown in clinical trials to modestly increase women's sexual desire and the number of "sexually satisfying events" they reported in a month.

Since its 2015 approval, Addyi's commercial appeal has been limited not only by those modest claims of effectiveness, but by lingering safety concerns and cost as well. Women must take the medication daily, at a cost of as much as $426 a month. And while the FDA recently loosened warnings against any alcohol consumption by women taking Addyi, it has warned that the drug should not be used within two hours of alcohol consumption.

As an "on demand" drug—one designed to be taken only when women want to want sex—Vyleesi is likely to be less expensive than flibanserin, and to have fewer interactions with other drugs women take. While an earlier intranasal formulation of Vyleesi appeared to raise some women's blood pressure, the company has told the FDA that in its new injectable form, no such side effects have been found.

Dr. Sharon J. Parish, former president of the International Society for the Study of Women's Sexual Health, has prescribed Addyi and found it effective for some of her patients. But the ways in which women's sex lives can get off track are many, and women and their doctors need more options that work differently, she said.

"Bremelanotide's availability will offer a new approach," Parish said. "There's a select group of patients for whom enhancing certain neurotransmitters is just what they need to kick-start a complex process. I think it's a good time to be in the field of sexual medicine."