

'Pink pill' to boost female libido eludes pharma

June 18 2010, By MATTHEW PERRONE , AP Business Writer

(AP) -- A "pink pill" to boost women's sex drive remains elusive after a decade of searching by some of the world's biggest drugmakers.

A panel of health experts on Friday rejected the latest offering submitted for federal approval: an antidepressant drug that failed to increase [sexual desire](#) in two studies.

The Food and Drug Administration's panel of reproductive advisers voted unanimously that the benefits of the pill from Boehringer Ingelheim did not outweigh side effects, including fatigue, depression and fainting spells.

"I am convinced that women's sexual health is important and that many women suffer from sexual dysfunction, but I'm not convinced of a clinically meaningful benefit for this drug," said panelist Paula Hillard, a gynecologist from Stanford University School of Medicine.

The FDA will make its own decision on the drug in coming months, though it usually follows the advice of its panelists.

The drug flibanerin, which acts on serotonin and other [brain chemicals](#), was originally studied as a depression therapy, but then repurposed as a libido pill after women reported unusually high levels of [sexual satisfaction](#).

Despite a modest uptick in sexually satisfying events reported in the

studies, panelists said the drug's benefits were not strong enough to warrant approval as a daily pill for women.

The attempt to trigger sexual interest through [brain chemistry](#) is the drug industry's latest approach to find a female equivalent to the blockbuster success of Pfizer's [erectile dysfunction](#) drug, Viagra.

Since that drug's 1998 launch, more than two dozen experimental therapies have been studied for so-called "female sexual dysfunction," a market worth an estimated \$2 billion.

Initially, Pfizer tested Viagra on women, hoping that the drug's ability to increase blood flow to the genitals would increase libido. When that didn't work, drugmakers turned to hormones, including testosterone.

In 2004, an FDA panel rejected Procter & Gamble's testosterone patch, Intrinsa, due to unknown risks from long-term use. Two years earlier a massive government study found that hormone replacement therapy in postmenopausal women increased heart disease and breast cancer, raising concerns about the safety of all hormones.

Decision Resources analyst Alasdair Milton says that after years of disappointing results, the search for "female Viagra" may be winding down.

"In this day and age, are you really going to spend a significant amount of money developing these compounds if you're not going to get a return on your investment?" Milton asked.

But experts who have watched the drug industry's dogged pursuit of a female dysfunction drug are not convinced the end is in sight.

Dr. Leonore Tiefer, a psychiatry professor at New York University who

runs a private sex therapy practice, said drug companies may target narrower groups of women to find an effective therapy, but won't give up the search anytime soon.

"I don't see that there's any incentive for the companies to stop, the market is just too big," said Tiefer.

Drug companies 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, though more rigorous, in-depth surveys have put the figure closer to 10 percent.

The field of potential competitors in the market has narrowed considerably over the years. Currently the only company with a drug in late-stage development is BioSante Pharmaceuticals Inc., a small specialty drugmaker developing a testosterone gel called LibiGel.

According to company executives, more than 1.8 million women received prescriptions for men's testosterone gel last year, suggesting a significant market. While currently marketed testosterone gels are designed to treat low hormone levels in men, doctors are free to prescribe them for alternate uses.

"That shows you doctors are willing to write prescriptions for testosterone off-label and women are willing to take it," said BioSante Chief Financial Officer Phil Donenberg.

But FDA approval of the company's LibiGel is far from certain. After lengthy discussions with the agency, the company has agreed to track over 3,000 women for more than a year to detect potential side effects.

Even if the gel turns out to be safe, Emory University Professor Kim Wallen said it's unlikely to prove effective.

"There have probably now been 50 studies on different kinds of testosterone regimens, and they all produce minimal or no effect" on sexual desire, according to Wallen. "This is a case where the pharmaceutical industry is looking in the wrong place."

Wallen still believes there could be pharmaceutical solutions to low sexual desire, possibly with other hormones like estrogen.

But he says the industry's search for a magic pill oversimplifies the problem. Sexuality is influenced by so many factors - including physical health, quality of relationships and lifestyle - that it's unrealistic to assume a drug could address millions of different cases of low libido.

"There are lots of reasons that people, both men and women, experience low sexual desire," Wallen said. "And to lump every individual into this group as potentially being amenable to drug therapy seems ill-advised."

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