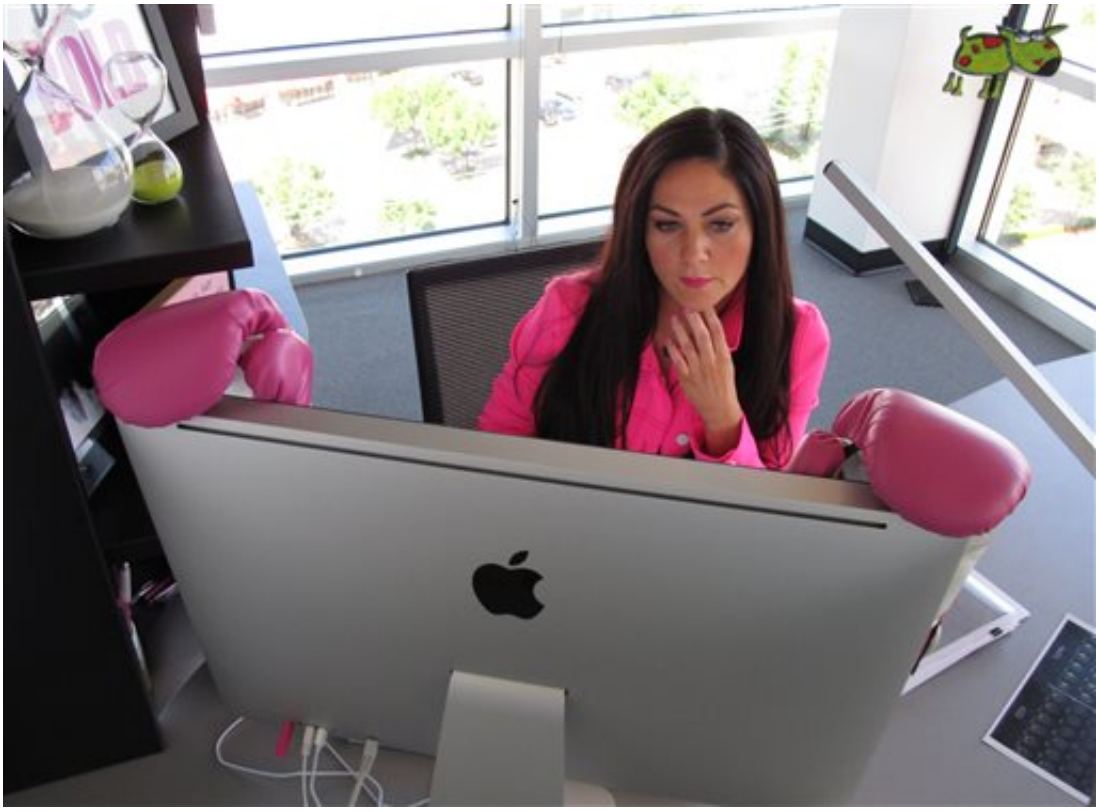
Drug execs behind female libido pill have run afoul of FDA

August 14 2015, byMatthew Perrone



In this June 22, 2015, photo, Sprout Pharmaceuticals CEO Cindy Whitehead works in her office in Raleigh, N.C. Sprout soon may succeed where many of the world's largest pharmaceutical companies have failed: in winning Food and Drug Administration approval for the first drug to boost women's sexual desire. (AP Photo/Allen G. Breed)

A small drugmaker from North Carolina may succeed next week where

many of the world's largest pharmaceutical companies have failed: in winning approval for the first drug to boost women's sexual desire.

The husband-and-wife team that founded Sprout Pharmaceuticals is not new to the pharmaceutical business or even to marketing drugs to people frustrated with their sex lives. The couple's previous company, Slate Pharmaceuticals, sold an implantable testosterone pellet to men with low levels of the hormone.

But Slate's marketing push ran afoul of federal rules, making misleading, unsupported statements about the benefits of testosterone therapy while downplaying risks. In fact, when the Food and Drug Administration held a meeting examining the overprescribing of testosterone last year, it played Slate's commercial as an example of inappropriate marketing.

That record worries Sprout's critics, who see a troubling pattern in the aggressive tactics it has used to urge the FDA to approve the women's desire drug, which was previously rejected twice because of lackluster effectiveness and side effects such as nausea, dizziness and fainting.

The search for a pill to increase women's libido has been something of a holy grail for the pharmaceutical industry since the blockbuster success of Viagra for men in the late 1990s. Pfizer, Bayer and Procter & Gamble all studied—then abandoned—potential treatments for female sexual desire disorder.

"This company already has a history of unethical marketing," said Dr. Adriane Fugh-Berman of Georgetown University. "If approved, I think this drug will be widely prescribed, and we would see an epidemic of adverse effects."

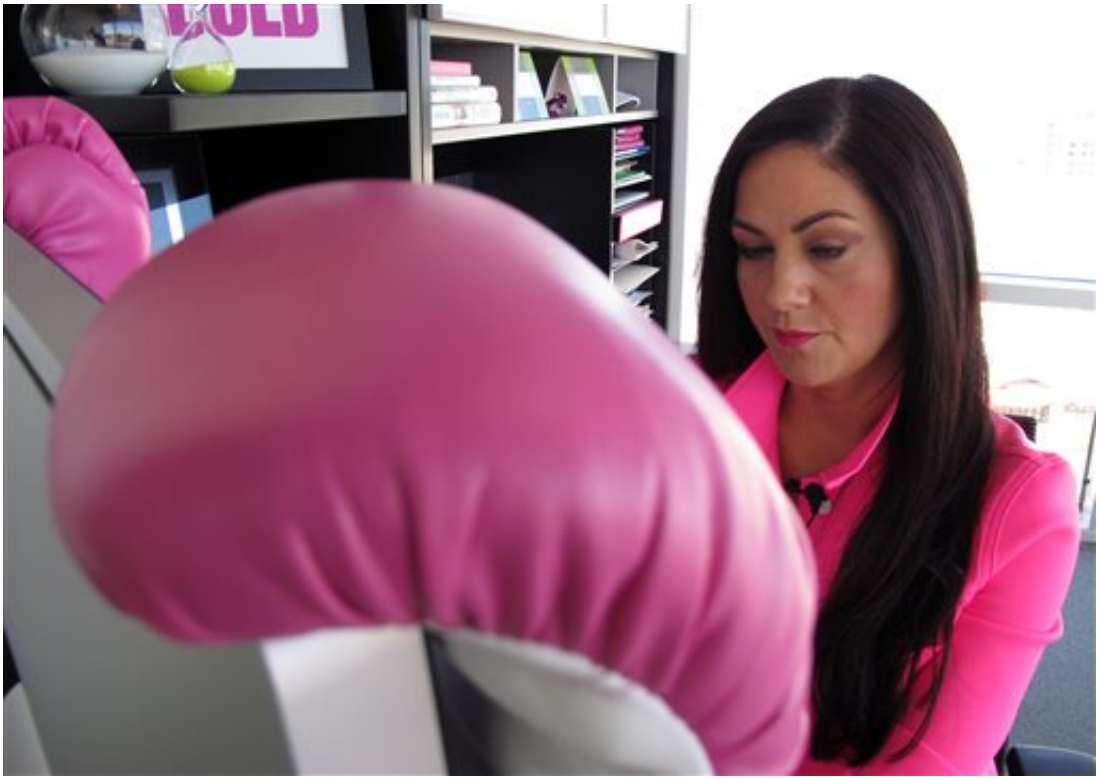
After a year of lobbying by Sprout-backed supporters, the drug won a surprising 18-6 recommendation from a panel of FDA advisers in June.

The FDA is scheduled to make its decision on the drug by Tuesday.

Sprout's drug was actually acquired from Boehringer Ingelheim in 2011. The German drugmaker shelved the pill after a unanimous vote against its approval by FDA advisers in June 2010.

CEO Cindy Whitehead and her husband, Bob Whitehead, who preceded her as CEO, paid for the drug, dubbed Addyi, by selling off their testosterone business, which had grown to nearly 100 employees.

These days, the executives like to emphasize their company's small size. In interviews, CEO Cindy Whitehead jokes that Sprout's entire staff of 25 could fit in an elevator.



In this Monday, June 22, 2015, photo, a pair of pink boxing gloves hang on the computer screen in the office of Sprout Pharmaceuticals CEO Cindy Whitehead, in Raleigh, N.C. Whitehead has been fighting for five years to win government

approval for a drug to boost women's sexual desire. (AP Photo/Allen G. Breed)

There is little financial information available about Slate or Sprout because they have both been privately held. The Whiteheads say their hormonal implant, Testopel, grew into the second most-prescribed testosterone treatment among urologists, ahead of competing gels and injections.

But the company's promotional efforts went too far.

In March 2010, the FDA sent Slate an 11-page warning letter, highlighting a host of misleading, unsupported and inaccurate statements in its brochures, websites and a video. In a rare step, the FDA held a teleconference with the company to outline its "serious concerns."

Among the many problems, the company's website suggested Testopel could benefit patients with depression, diabetes and HIV.

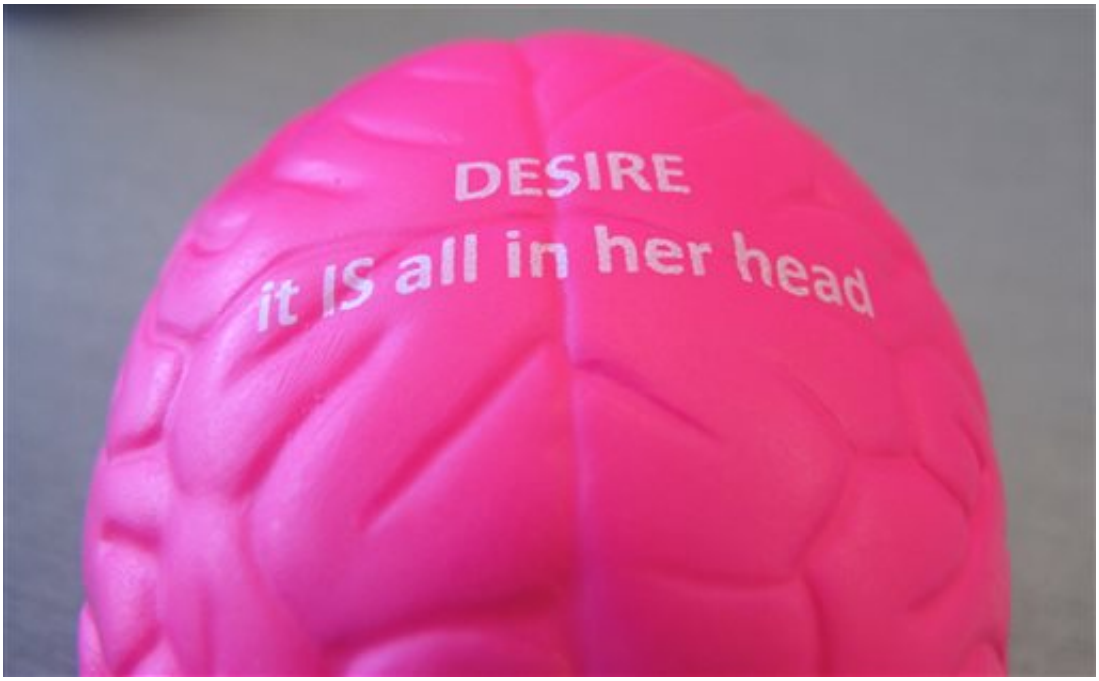
"The FDA is unaware of any data to support these claims," the letter said.

In a video, Slate featured Harvard Medical School professor Abraham Morgentaler, claiming that testosterone could boost men's energy and libido.

"Their strength may improve. Their workouts at the gym may get better. They start chasing their wives around the room a little bit. They just feel like guys again," Morgentaler said. The FDA said his claims were unproven.

This past May, the FDA directed all testosterone drugmakers to clarify

that their drugs are intended only for men with low testosterone due to disease or injury—not normal aging. And new warning labels also stress the risk of heart attack and stroke with the hormone.



In this June 22, 2015, photo, a brain-shaped stress ball sits on a worker's desk at Sprout Pharmaceuticals' Raleigh, N.C., headquarters. Sprout soon may succeed where many of the world's largest pharmaceutical companies have failed: in winning Food and Drug Administration approval for the first drug to boost women's sexual desire. (AP Photo/Allen G. Breed)

When Slate marketed Testopel, that information was not yet required. But the company's materials failed to disclose a laundry list of other known risks, including prostate cancer, swelling, nausea, vomiting, acne, liver problems and headaches.

"I can't remember seeing a warning letter with so many examples of misbranding in it," said Fugh-Berman, who recently signed a petition

urging the FDA to reject Addyi, citing minimal benefits and dangerous side effects.

Cindy Whitehead said Slate immediately discontinued the materials cited by the FDA. And she insists the company will promote Addyi carefully, focusing on educating doctors about who is likely to benefit from the drug.

"We would never want a patient who's not going to see a benefit to take it and tell everyone it doesn't work," she said. At the FDA meeting in June, Sprout offered to hold off on television advertising for up to 18 months after the drug's initial approval.

For now, the company has raised $50 million in venture capital to fund its efforts, according to a recent disclosure form.

Analysts said Sprout could easily recoup that money and eventually be purchased by a larger drugmaker.

"I think they'll sell a lot of it, and the company will probably get acquired by somebody who wants to acquire all of that cash flow," said Erik Gordon, a business professor at the University of Michigan.