Flibanserin: The FDA's Approval is Bad Science and Bad Precedent

By Christina Cherel, MPH

This year, the Food and Drug Administration (FDA) made history — for all the wrong reasons. After a five-year battle for approval, on August 18th, the agency succumbed to a relentless and clever public relations campaign and approved flibanserin, the first drug to treat hypoactive sexual desire disorder (HSDD) in women. That means that, as soon as October 17th, flibanserin will be available by prescription for premenopausal women with HSDD under the trade name Addyi. Despite proponents' claims, this approval is not a monumental event for women's sexual rights. The medicalization of sexual desire and sexual behavior should not be celebrated as revolutionary. We understand very little of what is "normal" for women when it comes to sexuality, so why is the FDA approving a drug to treat a disorder that may not be a disorder after all?

Viagra's approval and subsequent rocket sales in the 1990s prompted a race to create a "pink counterpart" for use by women. For more than 15 years, the pharmaceutical industry has been trying to produce a drug to treat women's sexual problems. But, sexual dysfunction drugs for women are critically different than drugs like Viagra for men. Whereas Viagra helps men who *already want* to have sex but are physiologically unable to do so, flibanserin changes brain chemistry to help women want to *want to* have sex. The FDA had good reason to reject these drugs in the past — because they *just don't work.* Very little is known about women's sexuality. We do know that many of women's sexual problems are shaped by interpersonal, psychological, and social factors, which cannot be easily regulated by taking a daily pill.

The FDA rejected flibanserin twice before — in 2010 and 2013 — because it was clear to Federal reviewers that *it simply didn't work.* The drug's sponsor, Sprout Pharmaceuticals, Inc., had to change its own definition of effectiveness to show even modest (at best) improvements in sexual desire outcomes. The FDA's own internal investigation of flibanserin indicated there were many unresolved questions about the seriousness, severity, duration, and frequency of the drug's side effects. Women reported experiencing sudden prolonged unconsciousness, and serious blood pressure declines with dystolic readings in the 40s. These serious adverse reactions were uncommon, but raised troubling questions about the safety of this drug. Also, flibanserin clinical trial data revealed higher dropout rates among women who were randomized to take flibanserin versus a placebo. The discrepancy in dropout rates between the case and control arms of the trial isn't trivial. For the FDA's Advisory Committee and staff, flibanserin's minimal effectiveness did not justify the drug's potentially devastating complications.

Then came a misleading campaign called "Even the Score," which enlisted women's health advocates, organizations, and even Members of Congress to call for "gender parity" in sex drug approval. The campaign claimed that men had 26 drugs to treat sexual dysfunction and women had 0, a gross exaggeration and manipulation of the actual numbers (tactics included counting all generic drugs separately to make the discrepancy look bigger than it is). The campaign implied the FDA's review of flibanserin's application was sexist, and that it held women's sex drugs to a higher approval standard than men's. Requiring sound clinical trials and proof of safety and efficacy isn't sexist — it's good science.

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The FDA was right to reject this drug twice before; unfortunately, the marketing campaign swayed the FDA the third time around. (Read more

CONTINUED ON PAGE 11

DIRECTOR'S MESSAGE
The Network: Inside & Out

FROM PAGE 2

Network members play a big role in determining who serves on the Board: you're eligible to submit nominations for Board candidates, and cast your ballot for the candidates you think are best for the organization. This issue includes information about Board nominations: if you're interested in serving on the Board, or know someone who would make a great board candidate, turn to page 3 for more information.

And finally, our dedicated staff. When staff members come or go, we often take a moment to tell you a little bit about them, or thank them for their years of service. But, we rarely talk about what we do internally to support these fantastic individuals. Laura Kaplan presents an interesting commentary about the ways non-profit organizations can support staff beyond paying good salaries. She mentions the Network's transit benefit as an example of a creative way to support staff.

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FROM PAGE 7

about the campaign in the *Women's Health Activist's* March/April 2015 issue.)

Despite the drug's approval, there are lingering concerns. The FDA expressed special concern about flibanserin's ability to drastically reduce blood pressure and the implications for women who consume alcohol while taking it. Based on these concerns, in 2013, the FDA recommended that Sprout provide further evidence of flibanserin's safety, specifically regarding its interaction with alcohol and its effect on driving ability. Flibanserin is taken on a daily basis indefinitely; hence, many women who take it are likely to have a drink at some point — and they absolutely need to know what the side effects will be.

Inexplicably, in its 25-person study, the sponsor was only able to recruit **two** women who consumed moderate amounts of alcohol to test its effect. So, the company conducted an alcohol study conducted primarily *in men* to assess flibanserin and alcohol's effect ***In women***. The FDA required Sprout to conduct post-approval trials testing the safety of using alcohol while taking flibanserin. This is a weak and inadequate measure to ensure the safety of women who use the drug, particularly since, historically, a substantial proportion of post-approval trials are never completed — despite being a condition of approval. There are many unanswered questions about how the drug will interact with hormonal contraception and many other common medications, as well.

Women experiencing distress as a result of unsatisfying sexual lives deserve to have their concerns taken seriously — but at what cost to their health? Some flibanserin proponents argue that fainting isn't a serious side effect and that women should be able to decide if the risks are worth the drug's minimal efficacy. Fainting while you are driving, however, could be fatal and is not simply a matter of inconvenience.

Women must be able to rely on the FDA to ensure that any drugs or devices marketed to, and used by, them are safe and effective. Flibanserin's approval set the dangerous precedent that clever marketing can sway the FDA's evidence-based, decision-making process even when the data reveal minimal efficacy and serious adverse events.

Despite the FDA's approval, women still do not have all the information they need to make informed decisions about flibanserin's safety and effectiveness. Women deserve better research that examines the causes of, and possible treatments for, sexual disorders. And, we need more research on sexuality in general, since we currently do not understand what is "normal" for women and men to experience throughout their sexual lifetimes. Sexual experiences can be a meaningful part of life, and help should be available for those who need it. In the future, it may be possible to develop a drug that's effective for some of women's sexual problems. We're not there yet, however.✥

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