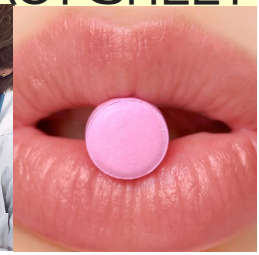
The National Women's Health Network

Female Sexual Dysfunction & "Pink Viagra"

Fact Sheet





The cultural impact and multi-billion dollar profitability of male impotence drugs has accelerated the race to develop and market a parallel drug treatment for women. The overnight success of Viagra, which was developed quite incidentally in an English lab in 1998 when clinical trial volunteers testing a high blood pressure medication reported a suspicious number of erections, prompted drug manufacturers to wonder if Viagra would have a similar effect on women.[1] It didn't. However, drug companies immediately attempted to create and market an expectation for a "pink Viagra." Soon thereafter, a new disease category called "Female Sexual Dysfunction" was created. Despite over a decade of research and millions of dollars spent on drug development, the U.S. Food and Drug Agency (FDA) has yet to approve a single drug treatment for women dealing with sexual problems.

This reality has promoted the pharmaceutical industry to launch a campaign headlined by many prominent women's health advocates in an effort to persuade the FDA to approve of a female sexual dysfunction drug for women. Members of the campaign called "Even the Score" are challenging the FDA on what they claim is a perpetuation of a gender bias by virtue of the claim that the FDA is holding drugs that treat women's sexual problem to a higher standard than those for erectile dysfunction. Even the Score has engaged prominent women's rights organizations, health care providers, the media and members of Congress in a public relations misinformation campaign to criticize the FDA. There are Female Sexual Dysfunction drugs currently under FDA review, and Even the Score is attempting to move the discussion away from the safety and effectiveness of these drugs and towards controversy about gender bias.[2]

The reality is that no amount of public relations or slick marketing can get around the fact that the drugs currently being proposed for Female Sexual Dysfunction simply don't work and may be quite dangerous. Poor efficacy, a strong placebo effect, and valid safety concerns have plagued all of the drugs that have been tested so far.[3] There are many reasons why the proposed drugs may not have been effective in increasing women's sexual enjoyment; chief among them is the heterogeneity of female sexuality and, of course, research demonstrating that sexual problems are mostly shaped by interpersonal, psychological, and social factors. Nevertheless, pharmaceutical executives will continue to drum up hype over the possibility of a "pink Viagra" because the profit market for this type of drug is estimated to be over $2 billion a year.[4]

Even the Score's petition and attempts to make this a conversation about gender equal-

ity is misleading and dangerous; while the FDA should be held accountable for gender equality, it should not compromise the safety of women's health by approving a drug that is not effective and not safe. The FDA should continue to balance a serious and respectful incorporation of patient input while maintaining a rigorous, uncompromised science-based review standard for drugs and devices they approve for women.

Below are some myths and facts to know about Female Sexual Dysfunction (FSD) and the Even the Score Campaign

Myth: There is a norm of female sexual function

Fact: The implied parallel between female sexual dysfunction and male impotence is actually very deceptive. The word "dysfunction" — medical jargon for anything that doesn't work the way it should — suggests that there is an acknowledged norm for female sexual function. That norm has never been established. Unlike erection, which is a quantifiable physical event, a woman's sexual response is qualitative. It reflects desire, arousal, and gratification — which are utterly subjective and rather difficult to quantify in objective clinical terms. As we all already know, sexual desire differs over time and between people for a range of reasons largely related to relationships, life situations, past experiences and personal and social expectations.

Myth: FSD is a defined disease category

Fact: Without an empirical standard by which to assess female sexual function, it is extremely difficult, if not impossible, to come up with criteria for female sexual dysfunction. But that hasn't stopped drug manufacturers from trying. Insidiously, every time a new drug sponsor touts a solution for women's sexual concerns, the purported cause of female sexual dysfunction changes. For example, when drugs affecting blood flow were being tested, the notion that women had an "insufficiency of vaginal engorgement" had scientific currency. When testosterone was proposed, claims were made that a vast number of women were suffering of a hormone deficiency. Most recently, as drugs that affect the neurotransmitters are being tested for female sexual dysfunction--we are being told that low libido is due to a chemical problem inside a woman's brain.

Myth: Drug developers are searching for a solution for women's sexual concerns

Fact: The pharmaceutical industry is driven by profit, and as such, if a solution is not found at the bottom of a pill bottle, they are simply not interested. If product-development-driven research was happening in a balanced context with proportionate attention being paid to the myriad of causes of women's sexual concerns, the focus on biomedical causes might not be so damaging. The focus on pharmaceutical rather than emotional solutions has serious limitations. The way the industry has shaped the FSD discussion threatens to make women's sexual experience, no less than men's, a performance issue. Also, without downplaying the significance of any woman's pain or distress, there can be real danger in defining difference as "dysfunction." There are many provocative research questions that don't attract pharmaceutical industry funding but yet would hold very important answers for women facing problems with sex, some of these include: What are the effective strategies for couples who are dealing with the impact of a major life crisis and how that affects sexual desire. What's the effect of exercise on sexual desire and does it differ by gender? How does a history of physical and sexual and gender based trauma impact women's sexual satisfaction through the course of their lives.

Myth: 43% of women suffer from FSD.

Fact: There is a perception that Even the Score is trying to advance which suggests that up to 43 percent of women suffer from FSD. The disorder is so widespread that American women are breaking down drug manufacturers' doors desperately pleading for solutions for their sexual problems. The making and marketing of FSD as a distinct

disease category was amplified by a 1999 Journal of American Medical Association piece which claimed that 43 percent of American women suffer from a sexual dysfunction. As should come as no surprise, the authors of the paper had financial ties to pharmaceutical companies. The 43 percent figure emerged from an analysis of responses by 1,749 women to a set of questions. Women who reported any of the following "symptoms" within the last two months — lack of sexual desire, difficulty in becoming aroused, inability to achieve orgasm, anxiety about sexual performance etc. — were considered to have sexual dysfunction. The study also found that women were more likely to suffer from sexual dysfunction if they were single, had less education, had physical or mental health problems, had undergone recent social or economic setbacks, or were dissatisfied with their relationship with a sexual partner.[5] In the years since the report's publication, researchers have revisited it and rightly challenged its conclusions.

Myth: The standard for FDA review of male impotence drugs should be the same for FSD drugs

Fact: Even the Score's gender equity argument ignores the real safety difference between FSD drugs that are currently being tested and the drugs approved for men: a different indication for use, specifically the dosage and administration. All but one of the drugs approved for men are taken on an as-needed basis, whereas the most recent drug being tested for women is a central nervous system serotonergic agent with effects on adrenaline and dopamine in the brain; it requires chronic -- daily, long-term -- administration. This raises toxicological concerns that make it appropriate for the FDA to subject that type of drug to an elevated safety scrutiny. Substantial adverse events reports and drop-out rates in the latest FSD trials also rightly require serious consideration.

Myth: There are 24 drugs approved for men, and none approved for women

Fact: Because several drugs have been approved for male sexual dysfunction, groups have asked whether the FDA is holding women's sexual satisfaction to a different standard. A recent blog titled "The FDA, Sexual Dysfunction and Gender Inequality" inaccurately claimed that there are 24 drugs approved for men, and zero for women.[6] This claim perpetuates a miscalculation. It counts each brand name drug and its identical generic counterparts or different formulations as unique treatment options, which artificially inflates the number of drugs available for men. In fact, there are only six different FDA-approved drugs available for male sexual dysfunction, including erectile dysfunction.[7] Nevertheless, the inflammatory claim of gender bias produced press and political attention.

Contact Us

The National Women's Health Network is committed to ensuring that women have access to accurate, balanced information. For more information, email us at healthquestions@nwhn.org or call the Women's Health Voice at (202) 682-2646. Stay informed, connect with us on Facebook and Twitter.

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