

#DON'T NEED DRUGS TO SCORE

MYTH: *There is a gender disparity regarding FDA-approved treatments for sexual dysfunction.*

FACT: The FDA **has never approved any drug for “male sexual dysfunction.” No drug for men has been FDA-approved specifically for increasing libido.** The FDA has approved drugs to treat erectile dysfunction or hypogonadism in conditions such as Klinefelter’s, a genetic disorder in which men have an extra chromosome. **No drug for men has been approved specifically for any sexual dysfunction other than erectile dysfunction.**

MYTH: *There are 26 drugs that are FDA-approved for male sexual dysfunction and no drugs approved for women.*

FACT: This is false. Eight products have been FDA-approved for erectile dysfunction and some of these drugs are identical (see table). **The “26 drugs” have never been disclosed.**



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.org**

“Even the score” is not a grassroots feminist movement: it is an industry-funded social media campaign to promote flibanserin.

MYTH: *43% of women suffer from sexual dysfunction.*

FACT: A 15-year-old study reported that 43% of women have a sexual concern; however, concerns ranged from trivial and temporary to persistent and distressing. The lead author stated that the study **was never intended to represent the number of women with a treatable medical condition.**¹

MYTH: *Women’s groups support the concept that the FDA is sexist.*

FACT: Women’s groups that don’t take money from pharmaceutical companies **support the FDA’s decision on flibanserin.**²

MYTH: *The FDA is sexist for not approving drugs for female sexual dysfunction*

FACT: As a coalition of consumer advocacy groups puts it: **“The problem with flibanserin is not gender bias at the FDA but the drug itself...The FDA wisely rejected flibanserin in 2010 because it failed to meet effectiveness standards... In 2013, the FDA again did not approve flibanserin because the minimal benefits in increasing women’s sexual satisfaction were offset by a worrisome side effects profile and unknown long-term effects. The benefits did not outweigh the risks.”**²

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1. Moynihan R. The marketing of a disease: female sexual dysfunction. *BMJ*. 2005 (Jan 22); 330(7484): 192-194.

2. Letter to the FDA re: flibanserin by various women's groups. Available at: <http://freepdfhosting.com/24ddebcdf8.pdf>

Eight drugs approved for erectile dysfunction (several are also available as generics)

Five are administered orally

Cialis (tadalafil)
Levitra (vardenafil)
Staxyn (vardenafil)
Stendra (avanafil)
Viagra (sildenafil)

Three are administered via injection or insertion into the penis:

Caverject (alprostadil), injected
Muse (alprostadil), inserted
Edex (alprostadil), injected

OTHER RESOURCES

Thacker P. How to handle FDA rejection. *Slate*. 2014 (Apr 6). Available at: http://www.slate.com/articles/double_x/doublex/2014/04/female_viagra_and_the_fda_the_agency_s_rejection_of_flibanserin_has_nothing.html

Silverman E. Is the FDA sexist? Regulators pressed to OK drugs for female sex problems. *Wall Street Journal Pharmalot Blog*. 2014 (Jul 8). Available at: <http://blogs.wsj.com/pharmalot/2014/07/08/is-the-fda-sexist-regulators-pressed-to-ok->

Tiefer L. Female sexual dysfunction: A case study of disease mongering and activist resistance. *PLoS Med*. 2006 (Apr 11); 3(4): e178. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1434501/>

Moynihan R. The making of a disease: female sexual dysfunction. *BMJ*. 2003 (Jan 4); 326(45). Available at: <http://www.bmj.com/content/326/7379/45>

For more information, please visit
www.newviewcampaign.org/flibanserin.asp

PharmedOut is a Georgetown University Medical Center project that advances evidence-based prescribing and educates healthcare professionals about pharmaceutical marketing practices. Find more information at **pharmedout.org**