

# The Usage of Flibanserin to Treat Women's Hypoactive Sexual Desire Disorder in the U.S.

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## Introduction

A key component of women's reproductive and sexual health that often gets overlooked in dominant discourse is women's libido. This topic has remained largely unstudied in the biomedical realm until relatively recently. Sex-positive feminist movements have brought women's sexual desire into the forefront, convincing scientists and healthcare practitioners alike that this issue is of legitimate concern to women's overall health and is a topic that merits comprehensive research within the medical community. Arising from the newfound attention to how women's sexual desire intersects with their sexual, mental, and physical health is the diagnosis for hypoactive sexual desire disorder (HSDD).

According to The Medical Letter on Drugs and Therapeutics (2015), HSDD is defined as "a deficiency or lack of sexual thoughts or desire that causes personal distress or interpersonal difficulty"<sup>5</sup> and can be characterized as "lifelong or acquired, situational . . . or generalized"<sup>5</sup>. HSDD is not diagnosed if the problems are believed to be caused by "another medical or psychiatric condition, the effects of another drug, or relationship difficulties"<sup>5</sup>. HSDD is believed to affect approximately 14% of premenopausal women<sup>5</sup>, a large enough segment of the population to justify demand for a medical treatment. Until 2015, all proposed treatments for HSDD were non-pharmacological, such as cognitive behavioral therapy and psychotherapy.<sup>5</sup> In 2015, the U. S. Food and Drug Administration (FDA) approved the first prescription drug on the market designed specifically to treat HSDD in premenopausal women.<sup>5</sup> The drug, produced by Sprout Pharmaceuticals, is called Addyi (a brand name for flibanserin).<sup>5</sup> While the approval of a drug touted to help women

achieve sexual satisfaction signifies a greater inclusion of women's sexual health needs within the medical establishment, the drug's efficacy, health risks, and potential implications on the pathologization of women's sexuality need to be critically assessed. If left ignored, the drug could inadvertently contribute to detrimental health consequences for individual women, disproportionately benefit some women while further excluding marginalized women, and encourage the over-medicalization and exertion of unnecessary control over women's sexual and reproductive health decisions.

## Literature Review

### *Efficacy*

The development of Addyi stemmed from a burgeoning demand for a medical treatment that would enhance sex drive for women suffering from HSDD. While the exact science behind flibanserin's mechanism of action is unknown,<sup>5</sup> it is believed to tweak neurotransmitters in the brain to optimize sexual desire by decreasing serotonin and increasing norepinephrine and dopamine in the prefrontal cortex.<sup>5</sup> The Medical Letter on Drugs and Therapeutics (2015) meta-analysis, which aggregated the results of three separate randomized clinical trials (DAISY, VIOLET, and BEGONIA), quantified Addyi's effectiveness by measuring changes in the women's reports of "[the] number of satisfying sexual events and the frequency and intensity of experiencing sexual desire" throughout the trial durations.<sup>5</sup> They found that, after controlling for a placebo effect, there was only around a 10-13% increase in desire and 8-9% increase in satisfying sexual events among the women studied.

The meta-analysis conducted by Deeks (2015) found similar results in the DAHLIA study, which showed no statistically significant changes in number of satisfying sexual events or desire scores,<sup>3</sup> as well as the ORCHID study, which showed no statistically significant improvements at 50mg dosages of flibanserin and only improvements in sexual desire (not sexual function) at the 100mg dosages.<sup>3</sup> Deeks did, however, note statistically significant improvements in both sexual desire and function compared to placebo groups in the ROSE and SUNFLOWER studies.<sup>3</sup> Interestingly, Deeks also noted that Addyi showed statistically significant results in the SNOWDROP study, which had the same setup as the other trials except all the women studied in this trial were postmenopausal.<sup>3</sup> Rao (2015) compiled various clinical studies and found that on average, women only reported 0.5-1.0 more sexually satisfying events per month than the control group, findings they considered “statistically significant . . . but clinically unimpressive”.<sup>12</sup> Overall, they concluded that “the benefits associated with treatment were considered meaningful in only 10% more women who received flibanserin than those who received placebo.”<sup>12</sup> The three meta-analyses compiled here point to similar conclusions and offer convincing data on the underwhelming efficacy of Addyi as a viable treatment option. For context, meta-analyses are typically considered the gold standard of high-quality research, and all of the studies analyzed within these individual meta-analyses were double-blind randomized control trials (which are also considered high quality research designs).<sup>15</sup>

#### *Confounding Variables and Study Recruitment Issues*

Before flibanserin was investigated as a possible treatment option for HSDD, it was initially studied for its potential as an antidepressant.<sup>7</sup> Because depressive symptoms like fatigue, stress, anxiety, and low self-esteem can consequently suppress a woman’s sexual desire and pleasure,<sup>2</sup> Kennedy (2010) aimed to confirm that any improvements in women’s sexual arousal after flibanserin treatment were actually due to effects on neurobiological sexual arousal pathways and not confounded by the alleviation of depression.<sup>7</sup> They analyzed various studies that all came to the conclusion that flibanserin was ineffective as an antidepressant, thus ruling out any potential confounding effects between depression alleviation and enhanced sexual arousal.<sup>7</sup>

It is always important to consider who was excluded from research trials in order to gain a clearer picture of possible confounding variables or misleading results. According to

Basson (2015), the reality that diagnostic criteria for HSDD is not well-defined or uniformly understood throughout the medical establishment means that there is likely an unusually high error rate in diagnoses, which could affect the accuracy of the randomized control trials that were conducted as ‘proof’ of Addyi’s efficacy.<sup>2</sup> It should also be noted that women with depression who experience “a muting of all phases of sexual response . . . were not the cohort recruited for the flibanserin trials”.<sup>2</sup> According to Rao (2015), “all women in these studies were generally healthy, so the findings of safety and efficacy cannot be generalized to women with medical and neuropsychiatric conditions, especially those receiving psychotropic drugs.”<sup>12</sup> Joffe (2015) notes that individuals on the FDA approval committee “questioned the generalizability of the . . . safety data to all premenopausal women likely to use flibanserin, given the trials’ extensive exclusion criteria.”<sup>6</sup>

#### *Safety, Side Effects, and Contraindications*

Beyond discovering if Addyi is indeed effective at providing the benefits it claims, it is imperative to determine that these benefits do not come at an unreasonable burden to other aspects of a woman’s health. Ideally, side effects from any FDA-approved drug should be rare and mild. Kingsberg (2015) collected data from multiple studies showing that the main side effects associated with Addyi were dizziness, central nervous system depression, nausea, fatigue, and insomnia.<sup>8</sup> Side effects were reported in women taking Addyi at double the rates of the placebo group.<sup>8</sup> According to the Medical Letter of Drugs and Therapeutics (2015), clinical trials have demonstrated that approximately 21% of premenopausal women with HSDD who were taking Addyi experienced symptoms of central nervous system depression, compared to only 8% on the placebo drug.<sup>5</sup> Joffe (2016) reported increased risks of side effects for individuals currently taking antiretrovirals, drugs to reduce blood pressure, or antibiotics, as well as people who took the drug during the day and people who consume alcohol.<sup>6</sup> However, the alcohol contraindication is unconvincing. The study population for the (singular) trial that investigated flibanserin interactions with alcohol upon which this guideline was based consisted of *23 men and only 2 women*,<sup>6</sup> despite the fact that the objective of the trial was to find out what effect alcohol consumption would have on women who were taking Addyi to treat HSDD.

In the New England Journal of Medicine, Joffe (2016) outlined the drug’s unusual pathway to FDA approval.<sup>6</sup> The

FDA rejected flibanserin as a treatment for HSDD on two separate occasions before its ultimate approval in 2015, citing lack of sufficient evidence of the drug's efficacy as well as safety concerns regarding somnolence and harmful drug interactions.<sup>6</sup> After their second rejection, a backlash ignited with various advocacy groups accusing the FDA of being biased against women and disregarding women's valid demands for the availability of treatment options to enhance their sexual pleasure.<sup>6</sup> This backlash campaign, called Even the Score, was partially funded by Sprout Pharmaceuticals.<sup>6</sup> It was not until after this backlash and accusations of sexism that the FDA agreed to approve the drug,<sup>6</sup> although this approval was contingent on several limitations. Addyi had to be issued with a 'black box warning', the most severe of the packaging warnings mandated by the FDA, and was mandated participation in a risk evaluation and mitigation strategy (REMS) protocol, which places strict limitations on who can prescribe and dispense the drug and stipulates additional informed consent guidelines that pharmacists must legally adhere to.<sup>6</sup> Addyi was not approved for distribution in Canada or the European Union due to safety concerns and a lack of convincing efficacy data.

## Discussion

### *Cost-Benefit Analysis*

Immediately following the market release of Addyi in 2015, some feminists have interpreted its approval as a long-awaited necessity that empowers women to improve their sexual lives and health, while others view Addyi as yet another marketing scheme that medicalizes women's sexuality and whose side effects put women at an unsafe and unacceptable level of risk. It is likely that neither of these polarized interpretations explain the full story. To more clearly delineate the true effects Addyi will have on women's sexual health, it is vital to firstly weigh the costs versus benefits that flibanserin can provide the women who choose to go on it. According to the various meta-analyses assessed in the literature review portion of this paper,<sup>3,5,12</sup> flibanserin *can* improve women's HSDD symptoms, but the proportion of women who actually experienced these benefits and the amount of symptom alleviation they experienced is utterly underwhelming.<sup>3,5,12</sup>

Women who are taking Addyi are recommended to wholly abstain from consuming alcohol in order to avoid harmful interactions.<sup>5</sup> They have to remember to take a pill before bedtime every night. There is a laundry list of potential risky

side effects. There is the added financial burden of paying for monthly supplies-- \$800 for a 30 day supply<sup>5</sup> if uninsured or if the drug is not covered by the woman's insurance (but even with insurance, the co-pay can still be cost-prohibitive to many women). Is a drug that only meaningfully helps 10% of the women who take it adequate enough to justify its approval and widespread use? Of course, for some women, even a small potential for improvement of their HSDD may be worth the associated drawbacks, but as a whole it should be considered unacceptable for FDA-approved drugs to have such marginal effectiveness while simultaneously putting other aspects of an individual woman's health at risk.

It is critical to study not only how effective Addyi is at alleviating symptoms, but also the potential side effects or contraindications associated with its use. As seen in the literature review, the risk that these side effects pose are far from trivial. The FDA rejected the drug from the market twice before, in 2010 and again in 2013, because of "marginal effectiveness and serious side effects".<sup>7</sup> However, according to the *New England Journal of Medicine* (2016), the individuals voting on whether or not to approve Addyi "acknowledged the small treatment effects and substantial safety concerns but considered the unmet medical need. All votes for approval were contingent on the inclusion of risk-mitigation strategies beyond labeling".<sup>6</sup> Though this risk management protocol is certainly an important safeguard to have in place, Sprout Pharmaceuticals and other drug manufacturers need to be actively striving to either increase the safety of the current formulation or develop alternative pharmacological options that will have a much more acceptable risk-benefit ratio for the women seeking relief from HSDD.

### *Research Flaws and a Controversial History*

Investigating the complicated history of Addyi's journey into the U.S. pharmaceutical market has revealed several problematic features of the research upon which its approval was based. Perhaps most concerning is the fact that in the first round of efficacy trials, where data was collected after each of the women's sexual encounters individually, the results were even less impressive and, notably, below the threshold of statistical significance.<sup>17</sup> In response, the researchers changed course and began collecting women's responses on a monthly rather than case-by-case basis.<sup>17</sup> This deliberate change in data collection technique allowed their outcomes to (just barely) cross the threshold into statistical significance.<sup>17</sup> The researchers subsequently used this second set of results as evidence to advocate for FDA approval

of Addyi.<sup>17</sup> In science, it is generally considered unethical for researchers to change their study methodologies in order to get results that conform to the outcomes they want or expect: “Falsification is the manipulation or misrepresentation of data or results that were obtained from experiments . . . the ‘trimming’ or ‘fudging’ of data to fit preconceived expectations . . . or statistical handling of the data by design to achieve certain ends”.<sup>14</sup> Relying on a singular study, particularly one which demonstrated less than ideal research practices, as the primary evidence used to convince the FDA to approve a pharmaceutical drug is unwise and leads to a skewed picture of Addyi’s actual effectiveness.

Another disconcerting research flaw that has emerged from the literature is the development of Addyi’s alcohol contraindication. When scientists began to investigate possible negative interactions between flibanserin and alcohol that could put women’s health at risk, they somehow decided that an appropriate study population to elucidate this relationship was a group of 23 men and only two women.<sup>6</sup> Not only is this an inappropriately small sample size to justify the study’s role as the sole basis for ‘proving’ a relationship between two variables, it is ultimately nonsensical to use an almost entirely inapplicable study demographic as the target to reach a scientific conclusion about a specific population. Beyond being simply illogical, this pattern embodies a problematic historical trend within the biomedical paradigm of assuming that women are solely deviants of male bodies, fostering the illusion that any results found in males can be extrapolated to ‘all women’ and still hold true. The alcohol contraindication study not only represents the systematic disregard for including women in research *even when it directly pertains to them*, it also contributes to policing women’s choices in the face of insufficient information. Instead of conducting additional trials to bolster the scientific knowledge regarding Addyi’s interactions with alcohol for women, it is easier to dictate that women just stop drinking altogether--even if such an overarching and restrictive recommendation is not rooted in scientific fact.

Overall, before health care practitioners begin to prescribe Addyi on a widespread scale, further rigorous double-blind randomized control trials need to be independently conducted in order to achieve a more conclusive representation of how effective Addyi actually is at improving women’s sexual desire and the possibilities of negative interactions between alcohol or other concurrent medications. Such a commitment by the medical community is the only way we can obtain an accurate perspective of the costs and benefits of using flibanserin as a treatment for HSDD. This knowl-

edge is vital for advancing agency and reproductive justice for women who are trying to make an informed decision whether or not this drug is an appropriate choice for them.

A further cause for concern in the Addyi debate that needs to be assessed is whether or not the FDA was unfairly pressured into approving a drug that in reality is not adequately safe or effective. The most prominent source of backlash that materialized in response to two previous FDA rejections of the drug came from a campaign called Even the Score. It brands itself as an advocate for women’s sexual health equity and has a wide range of reputable supporters like the National Organization for Women (NOW), the Society for Women’s Health Research, and the American Sexual Health Association.<sup>17</sup> It accused the FDA of gender bias, citing a large range of pharmaceutical options to treat male sexual dysfunction on the market while there remained zero viable options for women.<sup>6</sup> It suggested that perhaps the FDA was sexist, viewing male sexual dysfunction as a priority that warranted scientific research and development but not holding women’s sexual desire to that same standard.

However, it is important to note the unique contexts of this campaign-- Even the Score is funded by Sprout Pharmaceuticals, the developers of Addyi.<sup>17</sup> Sprout had obvious conflicts of interest here; another FDA rejection would result in the loss of a potentially significant revenue stream for their company. Leading a campaign that is framed as a way to demand increased attention to women’s sexual pleasure and ensure equitable treatment options for women’s sexual dysfunction allowed Even the Score to gain real traction with legitimate and credible feminist organizations.

But what are the true motives at play? Is pressuring a regulatory agency to approve a drug that is not proven to be sufficiently safe or effective for women really a noble crusade for reproductive justice--or just a thinly veiled attempt to profit from the development of a drug that, to date, has no competition in the pharmaceutical market? (Interestingly, Sprout Pharmaceuticals was sold to large pharmaceutical company Valeant Pharmaceuticals International for \$1 billion in cash *one day* after the FDA approved Addyi.)<sup>11</sup> It is not enough that women should have a medical option to treat sexual dysfunction disorders available to them--that drug must be *safe*. It is unjust to force women to choose between ill sexual health and the risk of ill physical health. This view is corroborated by Our Bodies Ourselves:<sup>17</sup>

We want the FDA to base approval decisions on scientific evidence . . . we believe that the FDA caved in to a marketing campaign in a way that sets a disturbing

precedent. Women deserve safe and effective medical treatment, but there is every reason to believe that Addyi is not safe or effective for many of the women who will be taking it. The drug maker developed a slick marketing campaign that underscored the importance of women's choices and paid nonprofit organizations and health experts to actively oppose the FDA decision . . . while many of those supporters clearly believe in Addyi, some lack the scientific expertise needed to make sound judgments about the drug's safety or effectiveness.<sup>17</sup>

In order to *truly* prioritize women's sexual health, we should not settle for such a mediocre drug simply to give women the appearance of an alternative option. We need to demand that the options provided can adequately protect and empower the women who need to pursue them.

#### *Who is Left Out?*

It is common within the biomedical sphere to inappropriately classify women as a monolithic, homogenous group.<sup>13</sup> There is a recurring pattern of extrapolating results from narrow study populations that are erroneously assumed to encompass 'all women'. Utilizing a feminist lens to question this assumption, it is clear that women's experiences and health concerns are subject to vast differences, even when other factors like race, age, socioeconomic status, sexual orientation, geographic location, etc. are taken into account.<sup>13</sup> Perhaps unsurprisingly, analysis of the literature regarding flibanserin as a treatment for HSDD revealed glaring omissions. This is troubling considering that the only stipulation noted by the FDA was that Addyi should be prescribed only to premenopausal women.

No studies have been conducted on the effects of Addyi in sexual minority women<sup>16</sup> or people who identify as non-binary or transgender.<sup>10</sup> There have been no studies conducted on the effects of Addyi on women who are pregnant or the possible implications of the drug on an unborn fetus or a woman's fertility.<sup>9</sup> There is not even sufficient evidence backing up the FDA's reason for excluding postmenopausal women. The Deeks (2015) meta-analysis shows that randomized control trials testing effects of Addyi in postmenopausal women had nearly imperceptible differences in efficacy compared to premenopausal women.<sup>3</sup> Women suffering from concurrent medical and mental health illnesses were also excluded. According to the Rao et. al (2015) meta-analysis,<sup>12</sup> the study populations of the DAISY, VI-

OLET, BEGONIA, and SNOWDROP randomized control trials were all deliberately comprised of women who were "generally healthy", and therefore "the findings of safety and efficacy cannot be generalized to women with medical and neuropsychiatric conditions, especially those receiving psychotropic drugs."<sup>12</sup> This sentiment is not adequately publicized in the FDA's approval of Addyi, which never mentions what specific medical and neuropsychiatric conditions were excluded from flibanserin study trials. Women who are afflicted with these conditions will remain uninformed that their illness was specifically excluded from efficacy trials, potentially putting them at greater risk for unknown health consequences or contraindications. This massive scientific neglect of individuals that comprise a significant portion of the monolith population of 'women' is a quintessential embodiment of reproductive injustice. It is unacceptable for drugs that have real capacity for harm (or real chances of being ineffective) to be prescribed to women on whom the effects have not been studied.

#### *Overmedicalization of Women, Social Construction of Women's Sexual Pleasure*

A significant concern that arises repeatedly in feminist analyses of women's sexual health is the overmedicalization and pathologization of women's bodies.<sup>13</sup> Historically, in many contexts, women have been subject to an extreme level of scrutiny and control within the biomedical paradigm. This phenomenon stems from deep-seated societal anxieties surrounding women's sexuality and agency, and the desire to uphold imbalanced power structures as a way to maintain control over women. Taking these oppressive contextual underpinnings into account, we can employ a feminist perspective to analyze whether or not 'hypoactive sexual desire disorder', and flibanserin as a treatment, serves as an example of pathologization and overmedicalization of women.<sup>13</sup> On one hand, the diagnosis of HSDD can be interpreted as a way of acknowledging (and thus normalizing) the reality that women do in fact want and deserve to experience feelings of sexual desire and arousal, and that a woman's sex drive is a critical component to her overall health. The mere existence of such a diagnosis can be seen as liberating.

On the other hand, we must also acknowledge the more adverse implications of HSDD as a diagnosis. In the medical community, diagnoses are strictly defined for the sake of consistency and research purposes. While the importance of having a standard definition in place is clear, the quantification of 'sexual dysfunction' can prove very harmful. Cate-

gorizing women's sexual functioning as 'normal' or 'disordered' using a standardized checklist of criteria is a severe oversimplification of a complex psychosocial process, and can cause women to feel inadequate or 'diseased' if they feel that they don't live up to this arbitrary standard. According to Basson (2015), "sexual and non-sexual distractions, fatigue, low self-image, depressive thoughts, anxiety and stress can lessen sensitivity to inhibit sexual arousal, pleasurable physical sexual sensations and orgasms".<sup>2</sup>

This complexity is further muddled by repeated changes in the diagnostic criteria for HSDD and even changes in the name of HSDD itself (other common names historically used to describe the same problem include female sexual dysfunction, vaginal engorgement insufficiency, clitoral erectile insufficiency, among others).<sup>17</sup> Besides the fact that HSDD is obviously very complex, is it even something that we should be aiming to fix with the quick pop of a pill? Why should a socially constructed standard of what is considered an 'appropriate' level of sexual desire impose a need for a pharmaceutical treatment? According to Tiefer (2006), this phenomenon is a case of deliberate disease-mongering:

Recently, the pharmaceutical industry has taken an aggressive interest in sex, using public relations, direct-to-consumer advertising . . . and other tactics to create a sense of widespread sexual inadequacy and interest in drug treatments. The public finds medicalization attractive because the notion of simple but scientific solutions fits in with a general cultural overinvestment in biological explanations and interventions, and promises to bypass sexual embarrassment, ignorance, and anxiety.<sup>17</sup>

Overall, women who are suffering from the frustrating effects of HSDD can certainly benefit from pharmaceutical treatments and having that option available to them is crucial in the advancement of reproductive justice. However, we must remain extremely careful that in the process of diagnosing aspects of a woman's sexuality, we do not inadvertently uphold socially constructed standards of what 'ideal' sex should look like. We must avoid neglecting to address the array of psychosocial and emotional factors that may be the true cause of an individual's HSDD in favor of a 'quick fix'. Ultimately, we must strive to ensure that women who decide that taking flibanserin is the appropriate choice for them do so from a place of agency, not inadequacy, and are provided with proper information about the variety of alternative treatment options as well.

## Summary and Conclusions: Future Directions

The introduction of a medical treatment designed specifically to enhance women's sexual satisfaction has resounding implications on many facets of women's health. Sexual desire and arousal are intricately linked to a woman's sexual, psychological, and physical health status.<sup>8</sup> The fact that research and funding have been devoted to addressing women's sexual pleasure is a much needed step forward in the prioritization of women's health in the biomedical paradigm. That being said, despite the obvious potential benefits Addyi provides, we must remain critical of the conditions upon which this drug was approved. As explored throughout this paper, it is clear that the flibanserin story is a microcosm of larger themes that transcend all aspects of women's health--ranging from the inappropriate homogenization of women into a singular entity, systematic exclusion from scientific research, and the overmedicalization and pathologization of women's bodies. As it stands, Addyi is not good enough. It has been shown that Addyi is not actually very effective and, worse, can cause debilitating side effects. Women should not have to choose between suffering from HSDD or paying for a drug that may not work and may even put their health at risk.

I can personally relate to the hopeless feeling of being trapped between two subpar choices. When first choosing a contraceptive method, I felt utterly defeated by the complex list of pros and cons of each option. There did not seem to be a single method that had everything I was looking for without being accompanied by some major drawback or downfall. To me, this is unacceptable. Women deserve to have better options and to be able to take full control over their reproductive health without being forced into make unfair compromises.

The flibanserin story does not have to end here--in its current state of mediocrity. The drug can continue to be improved and has enormous potential to become an option for women with HSDD. But to get to that point, more robust studies need to be conducted that include a wider range of women (like transgender individuals, lesbian women, pregnant women, and women with concurrent medical conditions) and that explore revamped formulations that optimize the drug's effectiveness and reduce the risk of side effects. Additionally, it is imperative that health care providers regularly ask patients about their sexual health and are equipped with sufficient knowledge and resources to offer the highest standard of care in this area. Current medical training often disregards sexual satisfaction as an important component

of one's overall health, leading to a gaping disconnect in patient-provider communication around sexual functioning. In the future, it needs to become the norm that healthcare providers are responsible for fostering open, nonjudgmental dialogues with their patients about sex. If these actions are carried out, not only will women suffering from HSDD benefit but women's sexual and reproductive health will be improved.

## References

1. Alcohol and Pregnancy: Why take the risk? (2016, February 2). Retrieved March 8, 2016, from <http://www.cdc.gov/vitalsigns/fasd/index.html>
2. Basson, R., Driscoll, M., & Correia, S. (2015). Flibanserin for Low Sexual Desire in Women: A Molecule From Bench to Bed? *EBioMedicine*, 2(8), 772–773. <http://doi.org/10.1016/j.ebiom.2015.08.009>
3. Deeks, E. D. (2015). Flibanserin: First Global Approval. *Drugs*, 75(15), 1815–22. <http://doi.org/10.1007/s40265-015-0474-y>
4. Do We Need a 'Female Viagra'? (2016). Retrieved April 10, 2016, from <http://www.besthealthmag.ca/best-you/relationships/do-we-need-a-female-viagra/>
5. Flibanserin (Addyi) for Hypoactive Sexual Desire Disorder. (2015). *The Medical Letter on Drugs and Therapeutics*, 57(1478), 133-135. Retrieved April 10, 2016, from <http://secure.medicalletter.org.proxy.lib.umich.edu/TML-article-1478a>
6. Joffe, H. V., Chang, C., Sewell, C., Easley, O., Nguyen, C., Dunn, S., . . . Beitz, J. (2016). FDA Approval of Flibanserin — Treating Hypoactive Sexual Desire Disorder. *The New England Journal of Medicine*, 374(2), 101-104. Retrieved April 10, 2016, from [nejm.org](http://nejm.org).
7. Kennedy, S. (2010). Flibanserin: Initial evidence of efficacy on sexual dysfunction, in patients with major depressive disorder. *Journal of Sexual Medicine*, 7(10), 3449–3459. <http://doi.org/10.1111/j.1743-6109.2010.01938.x>
8. Kingsberg, S. A., Clayton, A. H., & Pfaus, J. G. (2015). The Female Sexual Response: Current Models, Neurobiological Underpinnings and Agents Currently Approved or Under Investigation for the Treatment of Hypoactive Sexual Desire Disorder. *CNS Drugs*, 29(11), 915–33. <http://doi.org/10.1007/s40263-015-0288-1>
9. Marks, L. (2015, December 15). What Is Addyi (Flibanserin)? Retrieved April 10, 2016, from <http://www.everydayhealth.com/drugs/flibanserin>
10. Nowogrodzki, A. (2015, September 3). Sex, Drugs, and Women's Desire. Retrieved April 10, 2016, from <http://www.pbs.org/wgbh/nova/next/body/sexual-desire/>
11. Pollack, A., & Bray, C. (2015, August 20). Maker of Addyi, 'Female Viagra' Drug, Being Sold to Valeant for \$1 Billion. Retrieved April 10, 2016, from [http://www.nytimes.com/2015/08/21/business/dealbook/valeant-pharmaceuticals-to-buy-sprout-maker-of-addyi-female-viagra-drug.html?\\_r=2](http://www.nytimes.com/2015/08/21/business/dealbook/valeant-pharmaceuticals-to-buy-sprout-maker-of-addyi-female-viagra-drug.html?_r=2)
12. Rao, T. S. S., & Andrade, C. (2015). Flibanserin : Approval of a controversial drug for a controversial disorder. *Indian Journal of Psychiatry*, 57(3), 221–224. <http://doi.org/10.4103/0019-5545.166630>
13. Schuiling, Kerri D. "Women's Health from a Feminist Perspective." *Introduction to Women's Gynecologic Health*. By Lisa K. Low. N.p.: Jones and Bartlett, n.d. 3-19.
14. Souba, W. W., & Wilmore, D. W. (2001). *Surgical research*.
15. Strecher, V. (2016, January 12). *Death*. Lecture presented at Public Health 300 Lecture in School of Public Health, Ann Arbor.
16. Tiefer, L. (2006). Female sexual dysfunction: A case study of disease mongering and activist resistance. *PLoS Medicine*, 3(4), 436–440. <http://doi.org/10.1371/journal.pmed.0030178>
17. Zuckerman, D. (2015, September 8). The Facts About Addyi, its Side Effects and Women's Sex Drive. Retrieved April 10, 2016, from <http://www.ourbodiesourselves.org/2015/09/addyi-side-effects-and-womens-sex-drive/>