

## **Women's Sexual Desire**

### **Challenging Narratives of "Dysfunction"**

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*European Psychologist* (2017), 22, pp. 27-38.

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**DOI: <http://dx.doi.org/10.1027/1016-9040/a000282>**

## **Abstract**

The recent changes in the classification of female sexual dysfunction in the 5<sup>th</sup> edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the U.S. Food and Drug Administration's (FDA) approval of the first drug to treat low sexual desire in women (Flibanserin) have both sparked significant debate among clinicians and researchers. We first discuss the rationale for the DSM changes and outline the DSM-5 criteria for Female Sexual Interest/Arousal Disorder. We provide an overview of some of the key events leading up to the approval of Flibanserin for the treatment of hypoactive sexual desire disorder in women and highlight the role of the "Even the Score" advocacy campaign, that accused the FDA of gender bias in not giving women with sexual desire problems access to treatment options. Incorporating narratives from testimonials of female patients attending the 2014 FDA Patient-Focused Drug Development Public Meeting, we examine some of these women's prevalent beliefs around sexual "normalcy" and the immutability of sexual desire. We critique how the media and pharmaceutical companies depict sexual norms and female sexual desire and how pharmaceutical trials often narrowly defines and assesses sexual desire and "sex." We end with some recommendations for how researchers, clinicians, and journalists can better acknowledge that sex and desire have multiple meanings and interpretations with a view to women being offered a truly informed choice concerning their sexual health.

Key words: sexuality; women; sexual desire; dysfunction; pharmacological treatment

## **Historical aspects of the classification of female sexual dysfunction**

The concept of “psychosexual dysfunction” first appeared in the third edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) (American Psychiatric Association (APA), 1980). The first two versions of the DSM did not include sexual disorders, although “frigidity” and vaginismus were listed in a section on “supplementary terms of the urogenital system” in DSM-I (APA, 1952). DSM-II included dyspareunia as an example of a “psychophysiological genitourinary disorder in which emotional factors play a causative role.” (APA, 1968, p. 47). Based on the Human Sexual Response Cycle (HSRC) developed by Masters and Johnson (1966), and later expanded to include the desire phase (Kaplan, 1974), a number of psychosexual dysfunctions were introduced in DSM-III (1980), including “inhibited sexual desire” (APA, 1980). In DSM-IV the terminology related to “inhibition” disappeared but psychosexual disorders were still organised around the HSRC model and defined as “disturbances in sexual desire and in the physiological changes that characterize the sexual response cycle” (APA, 1994, p. 493). An inherent feature of the HSRC is that it proposes a universal, linear series of ‘phases’ of sexual response – excitement, arousal, orgasm, and resolution – that are essentially the same in women and men. In DSM-IV-TR the essential criterion for Hypoactive Sexual Desire Disorder (HSDD) was identical for women and men: “persistently or recurrently deficient (or absent) sexual fantasies and desire for sexual activity” that causes “marked distress or interpersonal difficulty” (APA, 2000, p. 498).

In the last two decades many critiques of both the HSRC and the DSM-IV classification have been put forward (Boyle, 1994; Tiefer, 1991, 2001). Criticisms of DSM-IV included an over-emphasis on genital response, inadequate acknowledgment of relationship and partner factors, and the lack of any defined severity or duration criteria (Graham, 2010; Mitchell & Graham, 2008; Tiefer, 1991). The latter criticism is

supported by the fact that many epidemiological surveys have reported extremely high prevalence rates for sexual “dysfunction” e.g., the highly cited figure that 43% of American women have a “sexual dysfunction” (Laumann, Paik, & Rosen, 1999). Surveys that included more stringent severity criteria and assessed individuals’ distress about a sexual problem have consistently produced much lower prevalence rates (Hayes, Dennerstein, Bennett, & Fairley, 2008; Mitchell et al., 2013, 2015; Oberg, Fugl-Meyer, & Fugl-Meyer, 2004; Witting et al., 2008). For example, in the recent U.K. NATSAL-3 survey, among sexually active women aged 16-74, the one year population prevalence estimate of “lack of interest and arousal” was 6.5%, but after applying severity, (6 months or more), duration, (always/very often symptomatic) and distress criteria (fairly/very distressing), the estimate dropped to 0.6% (Mitchell et al., 2015).

After the publication of DSM-IV-TR (2000), a number of consultation groups and consensus panels proposed revisions to the DSM classification system (e.g., Basson et al., 2000, 2003; Lue et al., 2004). With the exception of the New View classification system (Kaschak & Tiefer, 2001), however, most of the revisions recommended were minor and maintained the HSRC structure of the DSM (Bancroft, Graham, & McCord, 2001).

The 5th. edition of DSM (APA, 2013) comprised major changes in the classification of sexual disorders, particularly for female sexual disorders (Graham, 2016). Firstly, the diagnostic categories no longer map onto Masters and Johnson’s HSRC phases. The revised definition of sexual dysfunction in DSM-5 reflects this: “a group of disorders that are typically characterized by a clinically significant disturbance in a person’s ability to respond sexually or to experience sexual pleasure.” (APA, 2013, p. 423). Secondly, specific duration and severity criteria were added to all of the sexual dysfunctions: a requirement that the symptoms must have persisted for a minimum

duration of approximately six months and have been experienced on all or almost all (approximately 75-100%) of sexual encounters. As in DSM-IV, there is also a requirement that the symptoms cause “clinically significant distress in the individual.” The introduction of more stringent severity and duration criteria was an attempt to distinguish between transient difficulties and more persistent, distressing problems and to “raise the bar” for diagnosis (Graham, Brotto, & Zucker, 2014).

Regarding desire and arousal-related disorders, both the Female Sexual Arousal Disorder and the HSDD diagnoses were deleted and one new disorder – Female Sexual Interest/Arousal Disorder (FSIAD) – was added in DSM-5. Qualitative, experimental and clinical studies, including research on the incentive motivation model (Laan & Janssen, 2007) had demonstrated no empirical basis for any distinction between subjective arousal and desire (Laan & Both, 2008; Meana, 2010) (for more a detailed justification for the DSM-5 changes, see Brotto, 2010; Graham, 2010, 2016). The criteria for low sexual desire/arousal were expanded in FSIAD to include subjective, behavioral, and physical aspects of desire/arousal. A polythetic approach was adopted: to meet criteria, a woman needs to meet three of six possible criteria: (1) absent/reduced interest in sexual activity; (2) absent/reduced sexual/erotic thoughts or fantasies; (3) no/reduced initiation of sexual activity and typically unresponsive to a partner’s attempts to initiate; (4) absent/reduced sexual excitement/pleasure during sexual activity on all or almost all...sexual encounters; (5) absent/reduced sexual interest in response to any internal or external sexual/erotic cues (e.g., written, verbal, visual); (6) absent or reduced genital or nongenital sensations during sexual activity on all or almost all...sexual encounters (APA, 2013, p. 433). A polythetic approach was chosen to recognize the fact that women do not experience desire/arousal problems in a uniform way (Brotto, Graham, Paterson, Yule, & Zucker, 2015). Many studies have demonstrated both

women's (Giles & McCabe, 2009; Sand & Fisher, 2007) and men's (Connaughton, McCabe, & Karantzas, 2016; Giraldi, Kristensen, & Sand, 2015) sexual experiences do not fit any "one size fits all" model of sexual response.

Some authors have asserted that the FSIAD diagnosis (Giraldi et al., 2015; Spurgas, 2016) replaces the HSRC model as a framework for DSM categories with Basson's (2000) circular model of sexual response, which emphasizes the role of "responsive" sexual desire rather than so-called "spontaneous" desire. However, as discussed above, in developing the polythetic new criteria for FSAID no one model of sexual response was privileged and, unlike DSM-IV, the criteria allow for the fact that there is variability in how sexual interest/arousal problems may be expressed. Other critics have expressed concern that the new criteria will mean that some women who would have met criteria for a DSM-IV diagnosis would no longer do so and would be excluded from treatment (Derogatis, Clayton, Rosen, & Pyke, 2011). It seems that this concern is largely about the impact that revised diagnostic criteria would have on the development and approval of pharmaceutical treatment for women with low desire (Brotto, Graham, Binik, & Segraves, 2011).

### **Pharmaceutical Treatments for Women's Low Sexual Desire**

In parallel with the criticisms of the DSM classification of sexual dysfunction, there has also been a longstanding critique about the growing medicalization of sexuality (Bancroft, 2001; Moynihan, 2003; Tiefer, 2001) that "prescribes and demarcates sexual interests and activity, defining normality and deviance in the language of sexual health and illness" (Tiefer, 2001, p. 65). After the approval in 1998 of Sildenafil (Viagra®) for men, there were sustained efforts by pharmaceutical companies to find a "female Viagra" (see Table 1 for a timeline of these developments). Creating a market for sexual pharmaceuticals for women included promoting the idea that Female

Sexual Dysfunction (“FSD”) was a serious public health concern and an unmet treatment need; CME workshops, professional meetings and media all contributed to this process (Cacchioni, 2015).

Initial trials of the use of Sildenafil for Female Sexual Arousal Disorder proved disappointing and in 2004 Pfizer discontinued their clinical trials of Viagra® for women with arousal disorders (Mayor, 2004), citing the fact that “men and women have a fundamentally different relationship between arousal and desire” (Harris, 2004). Attention turned to treatment of low sexual desire, with attempts to gain FDA approval for Intrinsa®, a testosterone patch for treatment in surgically menopausal women, and Libigel®, a transdermal testosterone gel, for postmenopausal women with HSDD. In the case of Intrinsa®, concerns over whether efficacy outweighed the safety risks led the FDA to reject the drug (although it was approved in 2005 by the European Medicines Agency, the European counterpart of the FDA). Libigel® was not approved by the FDA because of poor clinical efficacy data. Other drugs to treat women’s desire problems are also in development; for example, subcutaneously administered Bremelanotide, a melanocortin agonist, a treatment for FSAD and HSDD, is now in Phase III trials (<http://www.palatin.com/products/bremelanotide.asp>). Lybrido, containing testosterone and Sildenafil, and Lybridos, containing testosterone and buspirone, are other drugs intended to treat HSDD in women which are still at the stage of Phase III trials.

### **Flibanserin and the Even the Score Campaign**

The first medication to receive FDA approval for the treatment of HSDD in premenopausal women was Flibanserin (Addyi®) in 2015 (see Table 1 for timeline). Flibanserin is a drug with mixed effects on serotonergic and dopaminergic transmitter systems that was originally tested as an antidepressant but was ineffective (Basson,

Driscoll, & Correia, 2015). In 2010 the FDA rejected Boehringer Ingelheim's application for approval because of lack of clinical efficacy in two phase 2 trials. Sprout Pharmaceuticals then acquired the drug and re-applied for FDA approval in 2013 with data from a third trial, but again the FDA did not grant approval, citing safety concerns, which included somnolence, hypotension, and syncope, and limited efficacy.

The final, and successful, FDA application for the drug was submitted in 2015. Interestingly, this application contained no additional efficacy data and only limited additional safety data (Woloshin & Schwartz, 2016). For example, concerns about possible interactions of Flibanserin with alcohol were addressed with a study of 23 men and 2 women. The drug received approval for the treatment of HSDD in premenopausal women in August 2015, but with a "black box warning", the most serious FDA safety alert and the inclusion of risk evaluations and mitigation strategies (REMS), requiring prescriber and pharmacy certification to prescribe the medication. Although Flibanserin was only approved for pre-menopausal women, many have argued that it will almost certainly be used "off-label" e.g., among women who are post-menopausal, women with health conditions who were excluded from the trials (Gellad, Flynn, & Alexander, 2015).

Since approval of the drug, the first systematic review and meta-analysis on the impact of Flibanserin in women with HSDD was published (Jaspers et al., 2016). The findings suggested that the benefits of Flibanserin treatment are "marginal," particularly when taking into account the significant occurrence of adverse events. The authors concluded that treatment with the drug resulted, on average, in one-half additional "sexually satisfying event" per month and clinically increased the risk of dizziness, somnolence, nausea, and fatigue.

One notable difference from the earlier unsuccessful applications was that in the year leading up to FDA approval there was a concerted advocacy campaign ("Even the



Score”), including some women’s health organizations, health professionals and patients, and backed by Sprout Pharmaceuticals. The group’s purpose was to increase awareness of HSDD and to address what it considered a “persistent gender inequality” within the FDA regarding treatments for sexual dysfunction. Over the course of the campaign, the petition garnered more than 60,000 signatures. Even the Score argued that the FDA had approved 26 drugs marketed for male sexual dysfunction, compared to zero for women. This claim was misleading; there are no approved medications for low sexual desire for men and most of the 26 drugs are different formulations of testosterone. The Even the Score online campaign gathered momentum in the months leading up to the first Patient Focused Drug Development meeting held at the FDA in October, 2014, with letters of support from congresswomen and some women’s organizations (Tiefer, Laan, & Basson, 2015). Even the Score supporters were present and testified at both FDA Advisory Committee meetings prior to approval of the drug, wearing #WomenDeserve badges (see Table 1). Below we present some of the narratives from the patients who presented at the FDA-organized October 2014 Patient-Focused Drug Development meeting.

### **Women’s Narratives and the FDA-Sponsored Patient-Focused Drug Development Public Meeting**

On October 27<sup>th</sup> 2014, the Food and Drug Administration (FDA) held a public meeting to hear testimonials from women with FSD. Of the eight women on the patient panels, five had their travel to the meeting arranged and paid for by Veritas Pharmaceuticals. One panel member stated her travel expenses had been paid for by Veritas Pharmaceuticals through grants from Sprout Pharmaceuticals, Even the Score, and the Institute for Sexual Medicine. A further seven out of the twelve non-panel members who gave testimonials received the same. This information is not highlighted

to suggest that the women were blindly driven by pharmaceutical company motives, but the source of funding has to be taken into account when assessing the extent to which the group of women who gave testimonials are representative of women with sexual problems. It is also worth noting that all but one of the women who gave testimonials – both those who had paid for their own travel and those who received funding from Veritas Pharmaceuticals – had requested pharmaceutical treatment for FSD. All had sought pharmaceutical treatment (predominantly testosterone treatment), some were still taking it, and others had stopped due to side effects and lack of efficacy. Two women had participated in the Flibanserin clinical trials, describing themselves as “devastated” when the trials ended. During the trials, both described dramatic effects on their sexual desire:

“Going from no thoughts during the day and really no desire, no initiation to suddenly...I'd text him in the middle of the day and get a flutter and I did not mean in my heart...I began initiating where I had not in a long time.”<sup>1</sup>

“Within a couple of weeks [of being on the trial] my feelings had changed dramatically. I had sexual feelings which I had not felt in many, many years. I was the one initiating sex, much to the surprise of my husband and the experiences were very pleasurable.”

Other women as ones described similar feelings. Women talked of wanting to be “the woman my husband married not too long ago” and feeling guilty that their desire for their partners was no longer the same as it was when their relationship began. One woman described this guilt as feeling like “I pulled a bait and switch with my poor husband who is undoubtedly wondering where the old me has run off to.”

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<sup>1</sup> The transcript of the FDA Patient-Focused Meeting can be found at <http://www.fda.gov/downloads/drugs/newsevents/ucm423113.pdf>

Wanting to return to the level of sexual desire they experienced earlier in their relationships is a wish that runs through all of the women's testimonials, whether or not they had explored and/or received treatment. During their testimonials, the women spoke of wanting "the closeness, the feeling of well-being that comes with the passionate, satisfying sexual relationship," and "to want to want it all the time; I want to always desire my husband and I don't want it to be situational...and for it to not cause distress."

As one woman described it: "Sex is not just about orgasm. I mean a successful or satisfying event for me is more about feeling connected [to my husband] and being close and feeling arousal...it is not an issue of being able to have sex because I can perform any time. The difference in desire is that comes from within and that makes me feel alive and like a woman and desirable and feminine".

Lacking such desire, women spoke of feeling "dead inside" and "less of a woman", as though "my body was like a shell with nothing inside". For some this lack affected every aspect of their lives, forcing them to structure their lives around it. Some spoke of effects on familial relationships and friendships; others told of its impact on their work lives; one woman, in particular, recounted effects on her ability to concentrate and deal with colleagues. Inevitably, many women reported that their loss of desire had impacted their relationships with their partners. Many felt guilty for rebuffing attempts by their partners to initiate sex, some avoiding any situations with the potential for these attempts by, for example, going to bed after their partners and getting up before they woke. This guilt led others to report engaging in what they referred to as "duty sex," an activity they defined as having sex with their partners out of obligation rather than for pleasure.

Ageing, childbirth, hysterectomy, breast cancer, mastectomy, the stresses of raising children, working full time, fatigue, and side effects from medication, both for FSD and other conditions, though included in the women's testimonials, seemed to be dismissed by the women themselves as possible causes or contributors to their lack of desire. There is a sense that the women felt that desire should remain unaffected by anything outside of the bedroom, from the stresses of everyday life to the trauma of cancer. This isolates desire and raises the question of what part the women expect/want it to play in their lives. All of the women described their lack of desire in physiological terms and in the context of sexual interactions with their partners: they referred to their partners being understanding, knowing when their testosterone pellets needed to be replaced because their desire level would drop, discussing their low libido, and having intercourse to please their partner despite it giving them no pleasure. The women frequently referred to their previous sex lives (when they had sexual desire) as "normal." Without speaking to the women to clarify their definition of "normal," it is not possible to ascertain whether they meant normal for them or what they considered normal based on cultural cues.

The subject of sexual normalcy on a cultural level was raised by the one woman who was not seeking a pharmaceutical treatment. Her concern over her loss of libido had taken her away from "the pathological" to an exploration of her relationship with her husband and her own feelings about desire. As she explained it:

"I really thought I had lost something. I was resigned to the idea that sex was going to be a drag for the rest of my life. As I began my process I went down some of the common paths of pathology...Once I decided I didn't want to live a sexually repressed life I started finding information that would be helpful to me...What I would look for in an ideal treatment for my lack of desire is a broader definition of normal sexuality for both

sexes. I would appreciate a movement away from a culturally driven definition of normal that creates distress and anxiety in people when they don't think they are living up to an ideal. I think there are all kinds of reasons people don't relax sexually in their relationships and it is much more complex than physical diagnosis and physical treatments. It is my personal opinion that treatments that allow for sexual difference account for the human waxing and waning of physical and sexual desire and arousal and focus on relationship work in general would be most helpful. Where to go from there is more a question for each person than it is finding an answer for all.”

The women attended the meeting to discuss their sexual difficulties, their hopes for treatment choices, their attempts to obtain treatment, and their belief that they have a right to sexual health. However, their dismissal of potential contributors other than the physiological echoes a medicalised approach to sex encouraged by physicians to whom a number of the women said they had received treatment. The women spoke of wanting choices of treatment and their hope that the approval of a drug to treat FSD would provide them with that. However, that choice would be restricted by the efficacy of the drug and potential side effects (as witnessed by Flibanserin).

### **The meaning of 'sex' in research on women's sexual desire**

Within research and clinical work it is standard practice to operationalize definitions and clearly understand the meanings of terminologies to be certain all involved– participants, researchers and wider audiences – will follow and agree upon descriptors used to gather research data and latterly interpret findings. Thus, it would be expected for terms like “sex” to be specifically defined, not least because the term has multiple meanings and understandings across cultures, genders, sexualities and history (Carpenter, 2001; Jutel, 2010; Pitts & Rahman 2001; Sanders & Reinisch, 1999; Sanders et al., 2010). If this does not happen it is difficult to draw reliable conclusions from

studies. While this remains a problem across sexological research and is mirrored in much mainstream media coverage and the self-help market (Attwood, Barker, Boynton, & Hancock, 2015), it is particularly a problem in pharmaceutical trials of treatments for low sexual desire in women (Angel, 2012; Moynihan & Mintzes, 2010).

Where terminologies are not defined, it is unclear when participants are asked about “sex” and “desire,” what they are recalling or recording when they respond to open or closed research questions. “Sex” for participants in research (and society more generally) might include giving/getting masturbation, oral or anal sex; or other activities including fantasy and role-play, BDSM, or other pleasurable touch. By not measuring all possible means of enjoying “sex” (or letting participants clearly self define) there is limited scope for noting exactly where “problems” with desire/orgasm may exist, while still perpetuating the idea that the only valid means of having sex and orgasm is through PIV intercourse (Angel, 2010; Moynihan & Mintzes, 2010; Wood, Mansfield, & Koch, 2006). This is problematic as it limits both what might be deemed as sex for participants and creates hierarchies where “proper” sex is penetrative and goal-focused with the end aim of it being the “achievement” of orgasm. Participants who may well experience desire, pleasure or orgasm through non-PIV activities do not have scope to record those activities and may well be categorized as dysfunctional as a consequence. Moreover, in setting up “normal” sex as a quantitative, PIV penetrative activity, options for exploring pleasure as reported via the media, sex education or research are limited so people who may well benefit from having additional means to enjoy sexual pleasure are not informed of their choices (see Attwood et al., 2015; Frith, 2015). In turn this creates both a means of problematizing desire, defining ‘normality’ and offering solutions to fix those who do not fit the following representations of sex and relationships.

Looking at the publicity materials for Even the Score, press releases (and coverage) for Flibanserin/Addyi®, subsequent media coverage, the testimonies given at the FDA hearings (see above), and the content of pharmaceutically funded Continued Medical Education courses and materials, the following themes emerge around how sex is represented (see also Frith, 2015; Fishman & Mamo, 2002; Meana, 2010; Moynihan & Mintzes, 2015):

- “Desire” is strong and spontaneous rather than reactive and responsive.
- Orgasms are goals to be achieved.
- “Sex” is taken to mean penis in vagina intercourse. And “good” or “healthy” sex requires frequent and novel sexual experiences.
- While other sexual activities [including but not limited to kissing, cuddles, massage; sharing fantasies; talking about, reading or watching erotica/porn; mutual or solo masturbation; giving or receiving oral sex (including oral or analingus); using sex toys; BDSM; role play; anal intercourse] may be mentioned these are not commonly included in research on female sexual desire problems. They are presented as precursors or inferior alternatives to penis in vagina intercourse.
- Life events should not intrude into the regular schedule of having sex.
- (Frequent) Sex is the “glue” that holds relationships together.
- Sex is a vital, healthy/healthful and central part of any relationship.
- Male desire and orgasm is uncomplicated and ever-present, women’s desire and orgasm are complex, elusive and difficult/time consuming to “achieve.”

Publicity around developing drugs for women has rehearsed themes that at times are ahistorical and inaccurate. These include reclaiming feminist narratives with arguments like “my turn now” or “my right” to medication (Goldstein, 2009), usually

paired with the erroneous , discussed above, that there are 26 drugs for men but none for women. Alongside this are easily disprovable claims that women have historically been neglected from or understudied in sex research (Hall, 2003). These of accompanied by “choice” based arguments: women ought to have the right to choose drugs that might overcome sexual problems, if such drugs are available and where drugs are available, women would be able to weigh up any possible risks associated with any medication. This argument is problematic given how women are not offered informed choices and information about drugs nor alerted to the limitations and biases of existing studies, side effects, and alternatives that could be attempted to boost desire or enjoy sex more are not also explained.

Rather than seeing “sex” as varied and diverse – and desire in a similar way – and noting the varied, legitimate, reasons women may not desire sex (Brotto, 2010) pharmaceutically funded trials and associated press coverage report women who do not desire “sex” as having a clinical problem requiring a medical solution (Angel, 2010, 2012; Moynihan & Mintzes, 2015).

#### *Additional problems with media*

While the combination of sex and science proves consistently inviting to the press, the treatment of stories around FSD has included setting up false debates (e.g., should women be allowed drugs for desire? – yes/no) or framing complex discussions as two sided accounts. Whether it is due to time pressures, a lack of scientific understanding or a lack of awareness about the history of drugs in this area, press coverage has tended to be uncritical around key terms, identifying conflict of interest, or addressing core issues of trial design or safety/efficacy of drugs (Attwood et al., 2015; Moynihan & Mintzes, 2015).

#### *Limits of research – women not like us*



Alongside difficulties of defining key terminologies, the drug trials for FSD pharmaceuticals have been limited by who participated in the research. Studies (e.g. Katz et al., 2013; Goldfischer et al., 2011; Simon et al., 2014) have centred around heterosexual, Western (commonly American) middle aged, and women in monogamous, long-term relationships (cohabitation or marriage). Single women, younger and older women (under 30 and over 60), black and other ethnic minority women, and lesbian, bi and Trans women are either unrepresented or excluded from trials. It is unwise to draw conclusions about the sexual lives and desires of all women globally from these studies (Moynihan & Mintzes, 2015). In some cases, however, trials that are primarily about drugs to boost desire in women have not included women at all. For example, as discussed above, the additional safety trials required for Addyi on the interaction between alcohol use and the drug included a sample of only 25 participants, 23 of whom were men.

#### *Limitations of trials*

While it is common for drug trials to be tested against placebo, it would be useful in an area where there are multiple factors that might influence desire to test drugs against other kinds of intervention. For example, desire-enhancing drugs could be tested against sex education, using sex toys and/or lubricant, relationship therapy, or confidence/assertiveness courses.

#### **Recommendations**

We have several recommendations for researchers, clinicians, and journalists. Regarding research and clinical work, there is a pressing need for better definitions and assessments that acknowledge that sex and desire have multiple meanings and interpretations. Although qualitative research on women's sexual experience has increased in the last decade, we still understand little about what terms such as "desire"

or “distress” about lack of desire mean to women themselves. There also needs to be a better acknowledgment by researchers of the variability of women’s sexual experiences. More research is required on the experiences of women from different cultures and of different ages, ethnicities, and sexual orientation, all of whom have been under-represented, particularly in pharmaceutical trials.

Regarding the media, more comprehensive and critical coverage is needed, where the history, conduct, and outcomes of trials (including limitations and side effects) are noted. Media articles should also acknowledge where previously “hyped” trials were discontinued or where treatments were not approved. Any potential conflicts of interest of researchers involved in trials should be declared (as they are in scientific journal articles). This is challenging in the fast-paced media environment where journalists are often not trained or supported to find, critique, and explore research, especially in the area of “sex science,” where correspondents covering stories are not trained science reporters. As an addition to writing this paper we are creating guidance for journalists in how to cover sex research and further training for the media.

In conclusion, while the “Even the Score” campaign used the slogan that women have the right to make their own “informed choices” concerning their sexual health, we believe that to offer women a truly informed choice means more than making safe and effective drug treatments for low desire available. Women should also be reassured that transient (and often adaptive) reductions in sexual desire are not evidence of “dysfunction” and informed of the many non-pharmacological approaches to enhancing their sexual desire that are available.

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**Table 1. Timeline.**

DATE	EVENT(S)	CITED IN/BY
1999	<p>Journal of the American Medical Association publishes research claiming 43% US women and 31% men have a sexual dysfunction.</p> <p>Invitation-only pharmaceutical conference 'New Perspectives in the management of sexual dysfunction,' Boston.</p>	<p>Laumann, Paik, &amp; Rosen (1999) Sexual dysfunction in the United States: prevalence and predictors.</p> <p>Tiefer (2006) Female Sexual Dysfunction: a case study of disease mongering and activist resistance.</p> <p>Moynihan (2005). The marketing of a disease: Female sexual dysfunction.</p>
2000	<p>FDA Approves Eros Clitoral Therapy Device</p> <p>Proctor and Gamble begin trials of Intrinsa (testosterone patch)</p> <p>Second Boston Conference 'New perspectives in the management of sexual dysfunction'</p> <p>FDA issue draft guidelines for</p>	Tiefer (2006) <i>ibid.</i>

	<p>research protocols on drug development for Female Sexual Dysfunction (FSD). As yet these guidelines have not been formalised.</p> <p>New View Campaign launched</p>	
2001	<p>Pfizer begins sponsoring Continued Medical Education (CME) courses on Female Sexual Dysfunction.</p> <p>International Society for the Study of Women's Sexual Health (ISSWSH) launched, followed by regular local meetings and annual conferences.</p>	Tiefer (2006) <i>ibid.</i>
2002		
2003	<p>Non drug company funded research from the UK finds far lower levels of reported FSD and desire. Problems clearly linked to mental or physical health problems or relationship/cultural factors.</p>	<p>Nazareth, Boynton, &amp; King (2003) Problems with sexual function with people attending London general practitioners: cross sectional study.</p> <p>Mercer et al. (2003) Sexual function problems and help seeking behaviour in Britain: national probability sample survey.</p>
2004	Drug trials by Pfizer on Viagra for	

	<p>women are discontinued.</p> <p>Proctor and Gamble file drug application for Intrinsa (see above) for surgically menopausal women who have Hypoactive Sexual Desire Disorder. Application withdrawn when FDA raise concerns over risks of breast cancer and coronary heart disease outweighing benefits of drugs. Proctor and Gamble begin funding CME courses on FSD.</p> <p>New View CME course launched on Medscape</p>	
2005	<p>Journalist Ray Moynihan claims pharmaceutical industry has created a financial market by redefining normal variations in sexual desire as diseases.</p>	<p>Moynihan (2005) The marketing of a disease: female sexual dysfunction.</p>
2006	<p>Intrinsa approved by the European Medicines Agency for surgically post-menopausal women with Hypoactive Desire Disorder.</p> <p>Virus Inc. develop Alista testosterone to treat low desire in</p>	

	women but drug fails during trials. Boehringer Ingelheim discover during trials of an antidepressant (Flibanserin) that it potentially enhances libido for women.	
2007		
2008	A number of papers are published noting the prevalence of Hypoactive Sexual Desire Disorders	Nappi et al. (2008) Management of hypoactive sexual desire disorder in women: current and emerging therapies.  Shifren et al. (2008) Sexual problems and distress in United States women: Prevalence and correlates.
2009	Boehringer Ingelheim files drug application for Flibanserin (aka Giosa) with FDA.  Off label prescriptions for testosterone for women with Hypoactive Sexual Desire Disorder are recorded despite no standard guidance on appropriate testosterone therapy for women.	Snabes & Simes (2009).  Commentary: Approved hormonal treatments for HSDD: An unmet medical need.

2010	<p>Flibanserin is rejected in June by FDA advisory panel after trials show drug performs no better than placebo. Following this, in October Boehringer Ingelheim discontinues its development of the drug.</p>	
2011	<p>Sprout Pharmaceuticals acquires Flibanserin.</p> <p>Female Sexual Dysfunction (including Hypoactive Sexual Desire Disorder) is described by the FDA as one of 20 core “unmet medical needs” that have no safe/proven treatments.</p> <p>Libigel – trials on a testosterone gel for surgically menopausal women developed by BioSante.</p> <p>Pharmaceuticals are discontinued when it performs no better than placebo in trials.</p>	
2012	<p>Transparency Market Research estimates the global erectile dysfunction market (including Viagra, Cialis, Stendra/Spedra,</p>	



	<p>Levitra, Staxyn, MUSE, Zydena, Mvix and Helleva) is worth \$4.3 billion.</p> <p>European drug marketer for Intrinsic withdraws the drug citing 'commercial reasons'.</p>	
2013	<p>Hypoactive Sexual Desire Disorder is deleted from the DSM-5 and a new disorder-Female Sexual Interest/Arousal Disorder- added.</p> <p>FSAD requires that 3 of 6 possible symptoms be present for at least 6 months and cause clinically significant distress. Stresses need to assess relationship problems, medical, cultural, religious factors, partner difficulties, body image and existing physical or mental health problems.</p> <p>Sprout pharmaceuticals reapply to the FDA following additional data collected on Flibanserin. FDA rejects application requesting further studies due to risks of side effects (somnolence, fainting, dizziness,</p>	<p>IsHak &amp; Tobia (2013) DSM-5 changes in diagnostic criteria of sexual dysfunctions.</p>

	<p>exhaustion and nausea) plus unknown long-term effects.</p> <p>Concerns outweigh the modest benefit over unknown long-term effects. Sprout later appeal this and apply for a formal Dispute Resolution with the FDA. ISSWSH sends a petition signed by 4000 people to the FDA. The FDA's recommendation for more research stands.</p>	
2014	<p>In April a collective of health organisations, including the New View Campaign, Our Bodies Ourselves, the National Women's Health Network and the American Medical Women's Association, write to the FDA's Director requesting the FDA reject Flibanserin on the grounds that risks outweigh any minimal benefits.</p> <p>Two months later, on June 24, health and women's groups, backed by Sprout Pharmaceuticals</p>	

	<p>introduce 'Even The Score' campaign and accuse the FDA of 'persistent gender inequality' regarding treatment of sexual problems in women.</p> <p><b>October 2014:</b> FDA holds a two-day hearing on 27-28<sup>th</sup> Oct. on the 'unmet medical need' for treatment of FSD, with the first day a 'patient focused' event. There were some activists in the public comments section at the end of the meeting when anyone wishing to contribute was given two minutes. The people who spoke in this section were:</p> <p>Leonore Tiefer; Alessandra Hirsch from PharmedOut; Thea Cacchioni; Sidney Wolfe from the Health Researchers Group; Rebecca Holliman from PharmedOut; Judy Segal who was funded by the Social Sciences Humanities Research Counsel; Coco Jervis from the National Women's Health Network,</p>	
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	<p>speaking on behalf of Ashland; Kimberley, a member of the public who “viewed myself as a potential patient”; Sally Greenburg, Executive Director of the National Consumers League; Deborah Arrindell from the American Sexual Health Association; Susan Scanlan, Chair Emeritus of the National Council of Women’s Organizations; Beth Battaglino, CEO of healthywomen.org; Sue Goldstein; Amanda and her husband Ben who wanted a pharmaceutical treatment (Ben was the only male member of the audience who spoke); and Michelle King Robson of EmpowHER.com.</p>	
2015	<p><b>February:</b> Sprout resubmits Flibanserin, including the additional safety studies requested. They cited three trials that show that between 46 and 60 percent of the women involved responded to the drug, and that levels of desire and the number</p>	

	<p>of satisfying sexual events increased, and distress levels decreased, at rates modestly higher than placebo.</p> <p><b>March:</b> Even the Score announces 11 members of Congress have written FDA Commissioner Margaret Hamburg to urge the approval of Flibanserin, in addition to earlier pleas from five other lawmakers. All are Democrats.</p> <p><b>June 1:</b> An Even the Score online petition appears on change.org to change "#HERstory," urging the FDA approve flibanserin, garners more than 60,000 signatures. A New View online petition on change.org urging the FDA to reject flibanserin garners 652 supporters.</p> <p><b>June 4:</b> An FDA advisory committee votes 18-6 to recommend the FDA approve flibanserin for premenopausal women with conditions – a risk evaluation and</p>	
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	<p>mitigation strategy, including warnings not to take the drug with anti-fungal medications or alcohol.</p> <p><b>June 5:</b> The stock price of Palatin Technologies, manufacturers of another female desire medication seeking FDA approval, soars 46 percent, Business Insider reports.</p> <p><b>August 18:</b> FDA approves Flibanserin (Addyi). The following day Valeant Pharmaceuticals acquired Sprout Pharmaceuticals for \$500 million in cash initially and another \$500 million in the first quarter of 2016.</p> <p><b>August 20:</b> Sale of Sprout Pharmaceuticals to Valeant Pharmaceuticals announced. Valeant stock price drops 6%, New York Times reports.</p> <p>Valeant states it will make back investment if sales are \$200 million, but potential sales could be greater.</p> <p><b>October 16:</b> Addyi becomes</p>	
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	available on prescription. There are a reported 227 prescriptions issued in the first month following its release.	
2016	JAMA publish research overviewing the efficacy of Addyi, find it ineffective compared to placebo while an editorial notes problems with the FDA hearings.	Jaspers et al. (2016) Efficacy and safety of Flibanserin for the treatment of hypoactive sexual desire disorder in women: A systematic review and meta-analysis.  Woloshin & Schwartz (2016) US Food and Drug Administration approval of Flibanserin: Even the Score does not add up.

Adapted from 1952-2015: The path to 'female Viagra' has been a rocky one. Washington

Post. 18.08.15

<https://www.washingtonpost.com/news/to-your-health/wp/2015/08/17/female-viagra-could-get-fda-approval-this-week/>