

TO: Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

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RE: Docket No. 00D:1278  
Draft Guidance: Female Sexual Dysfunction:  
Clinical Development of Drug Products for Treatment

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I. Introduction

The development of drug products is presently commercial rather than patient centered. The FDA must rise above the drug industry's desire to make money at the expense of women's health (refer to the estrogen testing on *men* several decades ago whose results subsequently harmed women; it seems clear that womern's hormone trials should have been done on women, for obvious reasons). The growing distrust of FDA approved drugs, both recalled and unrecalled, reflects an apparent lack of knowledge and integrity on the part of the FDA. This, in turn, reflects commercialism instead of consumer safety values. You could include in your guidance document the questions: "How might the consumption of this drug--if it proves to be physically safe--adversely affect women personally, relationally, and socially? Will it promote sexual pleasure for women's partners without regard for women in toxic relationships? "

The current state of uncertainty as well as historically patronizing views about female sexuality and female sexual problems lends itself to biased and irrelevant classification, assessment, treatment, and outcome criteria. In the confusion and hurry to make a commercial product without adequate information, drugs with harmful side affects can once again be developed and marketed. Women's sexuality is associated with relationship, history, conditioning, and other social and cultural realities. It makes good sense to postpone drug development until multidisciplinary agreement (this would include professions without prescription privileges as well as the medical) on assessment, diagnosis, treatment, and outcome can be tied to the promotion of *womens health* and appropriate treatment of FSD equally with industry profits.

II. Definition of Female sexual dysfunction

"Associated subtypes" of desire and arousal problems, or even better, a different format and paradigm for FSD, should be included in the definition for the research to have validity. In the first two components, decreased desire and decreased arousal (can you define the difference?), inTERpersonal as well as inTRApersonal influences must be considered or research results lose clinical meaning. As a matter of fact, research to date can show no biological difference between desire and arousal for medical and treatment purposes; therefore, it is presumptuous to develop

00D-1278

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drugs based on lack of information instead of a firm foundation of knowledge about women's sexuality and its associated problems.

Your "Appropriate definition of the patient population" is not patient-centered. It seems another thinly veiled way to increase pharmaceutical profits, hopefully without the usual harmful long and short term side effects. Women (and men) deserve better. So, for that matter, does the pharmaceutical industry.

For example, drug treatment is inappropriate for increasing the arousal of a woman willing to have impersonal, dutiful, or obligatory sex (unless she is in the business of getting paid for it); a woman whose partner is slovenly, drunk, intimidating, abusive, withdrawn, depressed, unwilling to discuss conflict, claim his part in their sexual problem, or has no personal or positive emotional connection with his female partner. It is sexual exploitation to prescribe a drug that inspires such a woman to ignore her depressing situation and enjoy self-exploitation in a *relationship* that obviously needs repair. Thus, the definition should be expanded to include maturational, relational, cultural, and social assessment, treatment, and outcome.

Dyspareunia has at least two components: physical and relational. A drug may be able to erase the pain of intercourse caused by a yeast infection, pelvic inflammatory disease, adhesions, irritable bowel, hernias, appendicitis, endometriosis, interstitial cystitis, genital warts, etc etc. However, it is vital to include in the definition of pain, that caused by a woman's reluctance to refuse sex verbally, women who are afraid that, by speaking the truth, they will hurt or enrage a timid, disagreeable, disrespectful, or emotionally disconnected partner. Can you assess for this unconscious etiology?

"Achievement" is an unfortunate choice of words to associate with women's orgasm. Achieving orgasm is a male definition that should not be generalized to women. Women's bodily integrity often unconsciously disallows orgasm under emotionally intolerable circumstances that women (not men) have been conditioned for centuries to consciously tolerate. This is not a physical disorder to be alleviated by a drug, but a social, cultural, relational, and maturational problem. Not having an orgasm is very often a woman's attempt to communicate that she does not feel whole and respected in a relationship where both partners consciously or unconsciously discount her integrity. Learning self-respect is part of the message of anorgasmia. The current guideline to develop drugs without considering women's reality is an example of the discount.

### III. Appropriate Study Populations

The exclusion of relationship difficulties does not make any more sense than testing female hormones on male subjects whose bodies obviously respond in a nongeneralizable way. Women's problems occur in the context of living situations and historical issues, not in isolation. Context is the cause of much, if not most non-medical/surgical FSD, so why would excluding it even be a consideration? Present guidelines do not reflect reality.

### IV. Other Study Considerations

Women use elective drugs more than men do and can be exploited as well as helped by their availability. Social conditioning tells women the doctor knows best when the woman, with some emotional education, maturity, and integrity, might take better charge of her own health and sexuality. Women have different messages about sex than men do, and are socially and culturally taught to be sexually inhibited. What is learned can be restructured without drugs. The FDA needs to be aware of non-drug treatment, too. Your outcome criteria need to be of value to women based on women's, not marketing, issues.

"Recording the number of events" is quantitative and mostly irrelevant data for women who want loving sex instead of regular mechanical, monotonous intercourse even when it results in orgasm. Diary recording and counting orgasms or genital episodes encourages women to stretch the truth in both directions. Qualitative research is more useful here.

When alternative treatment questions (hypotheses) are omitted in clinical trials, (for example, do phytoestrogens and herbs work as well and have fewer side effects than do synthetic estrogens?) you do a biased, noninclusive disservice in the apparent interest of financial gains for producers of prescription and OTC drugs. This exclusion seems a commercial bias, as if the FDA were a subsidiary of the drug industry instead of a government agency dedicated to consumer safety.

#### V. Use of Scales, Questionnaires, and Other Instruments during Drug Development

Instruments are developed using current theory and knowledge. The current state of knowledge about FSD does not lend itself to the development of valid or reliable instruments, particularly if the industry wants to exclude women's real life situations in favor of a nonexistent population (i.e., women without relationship issues, medication, partner sexual dysfunction, etc.) as proposed. FSD is not often a medical disorder that can be treated with a pill. FSD is often a statement of a woman's level of individual maturity, relationship stagnance, social and cultural conditioning, among other influences. Instruments must reflect this or be thinly disguised drug promotions with disregard for women's reality and women's health.

#### VI. Clinical Trial Endpoints

When orgasm is the measure used to decide the results of sexual pleasure, we cheat the individual of an opportunity to mature. Why not sexual intercourse that results in increased arousal or desire? Increased feelings of tenderness, connectedness, and love? Feelings of fullness? Orgasm as an endpoint ignores feminine reality. Women like orgasms, but many women also want closeness, intimacy, and emotional/mental connection as an endpoint or outcome measure. These women are not willing to relinquish integrity. When men do not have orgasms with intercourse it causes a different physical, personal, and relational result than when women don't. It is a mistake to measure women's physiology against men's because they are decidedly different at least hormonally, biologically, and emotionally. The feminine aspect of intercourse is different from the masculine. Women and men are biologically different. Endpoints should be linked to clinically meaningful values of women, not pharmaceutical companies or unreal populations. This has not yet been demonstrated in your draft guidance. Thus, I suggest a postponement until enough knowledge can be amassed so that women's issues, problems, and development are not further ignored.



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