FDA Lacks Desire for Flibanserin—But Does Hypoactive Sexual Desire Disorder Even Exist?

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By Ronald W. Pies, MD [7]

Consider the predicament of Mrs M, a 38-year-old premenopausal mother of two. Mrs M tells her primary care physician, “I just don’t have a strong desire for sex. It’s been about 10 years now, and I hardly ever have sexual thoughts or fantasies. In the past 10 years, I’ve had an orgasm maybe 2 or 3 times. My husband is kind and gentle with me, and I don’t have any pain when we have sex, but I really could care less about having intercourse. If my husband didn’t lobby for it so often, I’d be fine with-out sex—but that would cause big problems in my marriage.”

Does Mrs M have a psychiatric or a sexual disorder? Should her family physician “treat” this condition—and if so, how? These questions are especially pertinent in light of the recent FDA advisory panel’s decision to reject Boehringer Ingelheim’s drug flibanserin as a treatment for hypoactive sexual desire disorder (HSDD). Sometimes called “the female Viagra,” flibanserin works quite differently than sildenafil (Viagra), acting via the serotonergic and dopaminergic systems. The FDA panel was unimpressed by the 2 clinical trials of flibanserin, and panel chair Julia Johnson, MD, commented that “the efficacy was not sufficiently robust to justify the risks.”

To be clear: the FDA advisory panel did not deny the reality of HSDD, defining it as “the persistent or recurrent deficiency or absence of sexual thoughts, fantasies, and/or desire for sexual activity, which causes marked distress or interpersonal difficulty.” Indeed, some specialists regard HSDD as a pathological condition with a high prevalence and high degree of associated dysfunction. J. A. Simon, a specialist in reproductive endocrinology and infertility, said that HSDD “is relatively common among women and causes considerable distress as well as interpersonal difficulties. Nevertheless, many women with HSDD remain untreated because they are reluctant to discuss sexual issues with their physicians and have low expectations concerning the prospects for help.”

In contrast, Annemarie Jutel, RN, PhD, a medical sociologist, writes that “in a society which portrays female hypersexuality as desirable, and where women’s tumultuous lives don’t usually result in perfectly timed and balanced sexual urges, it hasn’t been hard to describe low libido as abnormal in order to sell an expensive cure. . . . The problem is the hidden commercial interests behind the science. . . . Sexuality is a complex expression of social, cultural, psychological, and physiological
factors and many of us struggle with it, without being ‘sick.’ Don’t let the pharmaceutical industry tell you otherwise.”

Similarly, Ingrid Nygaard, MD, editorialized that “one obvious question was raised by a patient recently, who, not bothered herself by her lack of interest but very bothered by her husband’s distress at her lack of interest, asked, ‘Why am I the abnormal one?’ What’s to be gained by overinflating rates and turning symptoms into diseases? Lots—market shares, provider income, grant support, and so forth. . . . What’s lost is less tangible: an increasing sense held by Americans that no one is actually normal, or entirely healthy.”

In contrast, Dr Sue W. Goldstein, who oversees clinical trials at the San Diego Sexual Medicine Center, writes, “We are the forgotten gender. . . . We’ve been told to accept this dysfunction. Do we accept cancer or heart disease? Do we or do we not have the right to choose whether we want treatment?”

Comparing reduced sexual desire to heart disease or cancer seems quite a stretch to me. But in weighing this spectrum of divergent views, it’s clear that much turns on our philosophical understanding of terms such as “disease,” “disorder,” “dysfunction,” and “medical condition.” For example, a major study showed that whereas about 44% of women report some kind of sexual problem, a much smaller proportion (12%) reported “sexually related personal distress.”

Lead author Jan Shifren, MD, opined: “For a sexual concern to be considered a medical problem, it must be associated with distress, so it’s important to assess this in both research studies and patient care [italics added].”

No argument there—but what if the woman’s “distress” is related solely or primarily to the expectations of her sexual partner, as in the case of Mrs M? If Mrs M were suddenly marooned on a desert island, without her demanding husband (now there’s a fantasy), would she experience any sexually related “distress”? I have argued in several contexts that true disease generally ought to meet 2 criteria: the presence of intrinsic suffering and substantial incapacity. I have used the “desert island test” to distinguish between conditions such as major depression and schizophrenia and, on the other hand, antisocial personality disorder (APD). The first two usually meet the desert island test, whereas the third (APD) usually does not (although there are undoubtedly exceptions).

For example, the person with severe, melancholic major depressive disorder is likely to experience both intrinsic suffering and incapacity, even on a desert island—despite the absence of interpersonal contact and responsibilities. He or she is still likely to feel guilty, worthless, and suicidal, and to have difficulty in concentrating (for example, on building a raft), eating, sleeping, and so forth. All other things being equal, the stranded person with APD is likely to feel just fine, thanks—except perhaps for missing those exhilarating Ponzi schemes. (I acknowledge that these hypotheses require confirmation through actual research, which I suspect would not pass muster with most institutional review boards.) By these lights, APD is not usually an instantiation of disease (dls-ease), but I am aware that some “sociopaths” are subjectively distressed and certainly provoke distress in others. This same logic suggests that most otherwise healthy women with reduced sexual desire, but no intrinsic suffering or incapacity, should not be considered diseased. However, this doesn’t mean that such women should be denied counseling, psychotherapy, or even medical/pharmacological treatment should they experience significant distress at some point. After all, mental health professionals treat all kinds of “V code” conditions (such as V62.89, “Phase of Life Problem”) that do not meet criteria for a mental disorder or disease. But in such instances, we should be extremely careful regarding the nature of our treatment. For example, the substantial adverse-effect profile of flibanserin—dizziness, nausea, fatigue, somnolence, and sedation—probably justifies the FDA advisory panel’s decision, pending more research. In my view, pharmacological therapies generally ought to be second-line treatment options for HSDD. Indeed, although 4 years have passed since psychiatrist Rosemary Basson’s review, I see little reason to alter her recommendations: “For women with desire and arousal disorders . . . the evaluation involves taking a detailed history of sexual difficulties from both partners, preferably seen individually as well as together. Also included are an assessment of the woman’s mental health (including self-image), feelings about the relationship, medical history, and her thoughts and emotions during sexual activity. On the basis of clinical experience and limited data on outcomes, I would recommend a combination of cognitive-behavioral therapy and sex therapy (typically 3 to 6 sessions). . . . Any apparent interpersonal problems should be addressed before further sexual therapy is pursued. . . . I would not recommend any pharmacological therapy, pending the availability of more (and longer-term) data in support of such treatment.”
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