Society for Women's Health Research

May 20, 2015

Kalyani Bhatt

Designated Federal Officer

Food and Drug Administration (FDA)

Center for Drug Evaluation and Research (CDER)

Office of Executive Programs (OEP)

Division of Advisory Committee and Consultant Management (DACCM)

RE: Docket Number: FDA-2015-N-0001

Dear Ms. Bhatt,

On behalf of the Society for Women's Health Research (SWHR®), I am writing to you regarding docket number: FDA-2015-N-0001 for a therapy to treat the most common form of sexual dysfunction, one that affects 1 in 10 women- -female sexual interest/arousal disorder (FSIAD). Overall, 43% of women in the US compared to 31% of men suffer from a sexual function complaint and it often goes overlooked by the medical community. Quality of life and relationships are both negatively impacted by painful sex for both men and women. There is an association between anxiety or depression, poor body image, and low self-esteem and both painful sex and low desire[i]. Thus, we are very appreciative of the fact that the Food and Drug Administration (FDA) has recognized FSIAD as an important women's health condition and held a public meeting and scientific workshop on the condition, October 2014. SWHR believes that FSIAD is an area of women's health that is of great importance to overall quality of health and life and should have greater recognition from the scientific and medical community at large. We are in support of FDA's continued review of the potential therapy under consideration and encourage that

if the scientific evidence demonstrates benefit that outweighs potential risk, we believe it should be an approved therapy for women.

SWHR, widely recognized as the thought leader in research on the biological differences in disease, is dedicated to transforming women's health and women's health research though science, advocacy, and education. We have collaborated with leaders in the scientific and medical communities to raise awareness about research into specific sexual health challenges that women face through their lifespan including sexual desire disorders, sexual arousal disorders, orgasmic disorders, and sexual pain disorders. SWHR has consistently advocated before the FDA on behalf of the scientific evidence, not only for FSIAD but for many therapies for women where the benefit outweighs the risk.

There has been much discussion on the fact that there are already 26 FDA-approved drugs on the market for male sexual dysfunction and many fewer options for women. While SWHR is hopeful that through research more will be understood about these disorders and more therapies will be available to health care practitioners, SWHR believes that female sexuality and sexual dysfunction are complex and multifaceted and that not every woman who suffers from these disorders can be treated with the same form of therapy. While we acknowledge and understand that FDA must make determinations on approvals for any potential treatments based on the scientific evidence presented and balance the benefit/risk for the patient, we believe quality of life issues are of equal importance to patients and urge the FDA to weigh those as part of its patient centered drug development and drug approval determination.

Low sexual desire is a common problem among pre- and post-menopausal women, and recent studies demonstrate that approximately 36% of women between the ages of 30-70 indicate that they have experienced low desire[ii]. Women who want to have a healthy sexual function should not have to suffer if there is a treatment that could work for them. Regardless of the comparisons made to the number of approved treatments for female sexual dysfunction versus the numbers of approved treatments for male sexual dysfunction, SWHR does believe the medical community has downplayed the role of female sexual function as an integral part of health and well-being.

SWHR understands that for purposes of the application before the FDA, a higher than average number of women were studied to prove that the data showed a benefit over placebo. Further, the safety profile most common side effects were dizziness, sleepiness, nausea. Such data is important to your deliberations. The scientific evidence demonstrated that a woman's sexually satisfying events increase two fold with treatment than placebo. In light of the alternative of no sexually satisfying events in a given month, the benefit outweighs the risk of sleepiness, headache, dizziness and nausea. We recognize that the female libido has psychological roots and is not as easy to measure as erectile dysfunction but that is not a sufficient reason to deny a treatment that would benefit women with sexual dysfunction. Female sexual dysfunction is real and should be treated with equal important to male sexual dysfunction. There are currently two

FDA-approved drugs for female sexual dysfunction (both for the treatment of postmenopausal painful intercourse due to vaginal dryness) compared to over 10 FDA-approved treatments available to men

SWHR would like to further emphasize the importance FDA gives to the nature of the side effects in relation to the dramatic impact a treatment option of this type would have on a women's life and her relationship with her partner. When considering how few women actually had side effects compared to those who did not, the nature of the side effects themselves, the vast majority of the patients wanted to still take the drug because of the benefit it provided to them. When the FDA approved Viagra in 1998 for erectile dysfunction, the risk of death did not outweigh the benefit of an erection for purposes of approval. Nor did the possibility of having an erection lasting over 4 hours requiring needle drainage of blood from the penis in the ER outweigh the benefit. It is hard to compare these potential side effects and consider that the FDA would not provide women with this treatment option.

For decades, women's sexual function and female sexual response were taboo topics. Even today, we know that women want to discuss their sexual health problems with physicians and healthcare providers, but often do not because of embarrassment[iii] or because physicians do not have time[iv]. Women also report that they believe that sexual health is not a medical issue and is not hormone or menopause related[v]. We also know that physicians are hesitant to discuss sexual health with their female patients, which we believe results from a lack of education and training regarding female sexual function and/or a lack of time[vi]. Women with FSIAD and their partners should not have to continue to suffer if appropriate therapies could be available. If the scientific information presented to the FDA indicates a true benefit to women who struggle with low sexual desire the FDA should stand by such evidence for such women who will benefit from this drug, even if FDA's considers it a "modest affect". The women who suffer with this disorder should have the right to determine if the benefit outweighs the risk from the potential side effects.

Continued investment in research into female sexual dysfunction is critical to ensuring that health care providers and women have the ability to determine all options for safe and effective treatments. SWHR strongly encourages the NIH and FDA to focus research resources into FSIAD and to design clinical trials that enable women to more easily participate and in a way that more accurately and fairly tests the outcomes desired the unique needs and daily burdens of women and not create greater burden and anxiety than already exists for the participants. Further, the measurement tools and time frames prescribed for FSD trials should follow standard measurements utilized for other comparable drug therapies and not impose undue and unnecessary burdens on women.

Many drugs and devices already on the market may impact both sexual desire and function, and in some incidences indicate such on the label. This is valuable information for both healthcare providers and patients, so that they can appropriately discuss the impact of potential

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treatments on the quality of the lives and relationships. Therefore, SWHR feels that the FDA should ensure that it appropriately captures in the drug labeling process the impact of any therapy on sexual desire and function, both during the approval process as well as in post market surveillance.

We appreciate that FDA is again considering the application for a treatment for women who are suffering from FSIAD and urge you to appropriately weigh the scientific evidence and the benefit to a women's quality of life in your review.

Thank you for your consideration of our comments.

Sincerely,

Phyllis Greenberger, MSW
President and CEO
Society for Women's Health Research (SWHR)

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[i] Lieblum SR, Koochaki PE, Rodenberge CA, Barton IP, Rosen RC. Hypoactive Sexual Desire Disorder in Postmenopausal Women: US results from the Women's International Study of Health and Sexuality. Menopause 2006;13,46-56.

[ii] West SL, D'Aloisio AA, Agans RP, Kalsbeek WD, Borisov NN, Thorp JM. Prevalence of Low Sexual Desire and Hypoactive Sexual Desire Disorder in a Nationally Representative Sample of US Women. *Arch Intern Med.* 2008;168(13):1441-1449. doi:10.1001/archinte.168.13.1441.

[iii]Korenman SG. *AM J MED*. 1998;105:135-144

[iv] Baum N, et al. Patient Care. Spring 1998 (suppl):17-21.

[v] Wyeth REVEAL: Revealing Vaginal Effects at Mid-Life: Surveys of Postmenopausal Women and Health Care Professionals who Treat Postmenopausal Women Madison, NJ: Wyeth; 2009. Available from: http://www.revealsurvey.com/pdf/reveal-survey-results.pdf.

[vi] Broekman CPM, et al. International Journal of Impotence Research. 1994;6:67-72.