



Testimony of Terry O'Neill, President National Organization for Women (NOW)

Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee Concerning New Drug Application 022526 for flibanserin 100 mg tablets

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Equality for women should be a fundamental principle: in our legal system, in education, in economic opportunity and in access to health care. The World Health Organization has adopted a working definition about a fundamental human right to sexual health that recognizes the "need for gender equality" ... and a "need for recognition of the value of sexual pleasure enjoyed throughout life in safe and responsible manners within a values framework that is respectful of the rights of others."

Women, no less than men, deserve the full range of health care services and medications found safe and effective. That is the motivation for the National Organization for Women's involvement with the HSDD (or, FSAD) drug and with other drugs and devices that have come before the FDA for evaluation. To be absolutely clear: NOW does *not* endorse flibanserin or any other drug aimed helping women with sexual dysfunction disorder and this organization does not receive compensation from the drug's sponsor for this or other drugs and devices.

NOW's objective in advocating for an effective treatment for pre-menopausal hypoactive sexual desire disorder (HSDD) or female sexual arousal disorder (FSAD) falls in line with our mission in advocating for equality: with several dozen treatments for men's sexual dysfunction – the first available nearly two decades ago – it is way beyond the time when effective treatments should have been made available for women. Unless this first drug is allowed to go forward, we fear, it is unlikely that sponsors of other women's sexual desire disorder drugs will want to commit the substantial sums of money necessary to get their drug to market. We have heard from one other company hoping to submit their drug to the FDA soon, perhaps others will follow.

If the Food and Drug Administration approves of flibanserin women at last will have a treatment for a health condition that many of them find very troubling. Hypoactive Sexual Desire Disorder or Female Sexual Arousal Disorder – as it has been described here – is a *real* health condition and has been recognized by medical professionals for 30 years. Some 43 percent of women report having some type of sexual dysfunction, with the most common complaint being low sexual desire not connected with menopause, or any other health problem and to report HSDD that is combined with a level of distress is necessary for a clinical diagnosis.

About one in ten women have low sexual desire, according to a 2008 survey of 50,000 households. For women in a relationship where sexual activity is or could be an important component, it must be very distressful to not feel sexual interest in your partner. We must believe what women report about their sex lives. Believing what women say about the important elements of their lives is a necessary practice. Women must be respected and believed – that is a fundamental principle for NOW.

Flibanserin has been tested in more than 11,000 women -- 15 times the usual number of trial subjects and substantially more women receiving flibanserin found their HSDD improved than those receiving the placebo in the Violet, Daisy and Begonia trials. As reported, flibanserin showed a highly statistically significant difference over placebo on three key endpoints, including increase in sexual desire, decrease in distress from the loss of sexual desire and an increasing in the frequency of satisfying sex, with sustained effects. Side effects as reported by a small group of subjects were mild, including fatigue, dry mouth, sleepiness or difficulty sleeping, dizziness and nausea. The FDA-required follow-up safety trial found that women treated with up to 200 mg of flibanserin at bedtime had no next-day impairment of driving ability.

Brain imaging studies provide graphic evidence that women suffering from HSDD have different prefrontal brain circuitry response to sexual stimuli than women who do not report hypoactive sexual desire disorder. These images attest to what should be obvious: that there is variation in the level of women's sexual desire. We know that female sexual desire is produced by a complicated interplay of brain chemistry and hormones. Like many other human capacities, there is a range of ability and performance.

Some organizations that work on women's health issues have suggested that this medication and others which are reported to be in the pipeline are simply engaging in "medicalizing" – that is, attempting to manufacture a health problem when there is none existing only to make millions selling a treatment. We know that has been case with some so-called disorders, but when 10 percent of the surveyed female population reporting low or no sexual desire and turning to unproven – and perhaps – risky medications sold over the internet, it's time to start believing – and respecting -- what women say about their sex lives.

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Sprout Pharmaceuticals Presents Phase 1 Clinical Trial Data Showing Treatment with Flibanserin Results in No Next-Day Driving Impairment, <http://sproutpharma.com/sprout-pharmaceuticals-presents-phase-1-clinical-trial-data-showing-treatment-with-flibanserin-results-in-no-next-day-driving-impairment/>