Statement of Coco Jervis, Program Director
Food and Drug Administration
Patient-Focused Drug Development Public Meeting on Female Sexual Dysfunction.
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I am speaking on behalf of the National Women's Health Network, a non-profit advocacy organization that works to improve the health of all women. We are supported by our members, and do not take financial contributions from drug companies, medical device manufacturers, insurance companies or any other entity with a financial stake in women's health decision-making.

Since the Network's founding almost 40 years ago, we have brought the voices of women to the FDA, advocating for medical products that meet women's real life needs and a drug development process that reflects women's lived experience.

We are pleased to have the opportunity today to comment on the patient-focused drug development initiative for female sexual dysfunction. My comments reflect the questions, input, concerns and perspectives from the women that the Network regularly communicates with via our Women's health voice information line.

As we all know, the cultural impact and huge profitability of male impotence drugs have contributed to an equally large interest in developing a parallel drug treatment for women. However we must be wary of the continued trend to frame women's sexual experience, no less than men's, as only a performance issue. We recognize that many of our members are struggling with sexual problems and are dissatisfied with their sex lives, but we caution that there is a real danger in labeling all sexual problems or frustrations as "dysfunctions." Many factors can contribute to a woman's sexual dissatisfaction including relationship issues, work burnout, economic anxieties, illness, past and present experiences with sexual and physical violence and daily life stressors- just to name a few. If the product development driven research was happening in a balanced context, proportionate attention would also be paid to the myriad of causes of women's sexual concerns.

Despite over 15 years of concerted attention on Female Sexual Dysfunction research and development we are still unable to identify a population of women for whom the drugs work consistently better than a placebo, perhaps in part because measures of physiological response do not adequately reflect the outcomes that matter most to women. There are many reasons that these drugs may have not been effective in increasing women's sexual enjoyment, chief among them the heterogeneity of female sexuality and, of course, research demonstrating that sexual problems are mostly shaped by interpersonal, psychological, and social factors.

The Network has serious questions about whether drug development itself is the best way to go about addressing women's problems with sexual satisfaction. If safe and effective drugs are going to be developed in this area, the development of patient reported outcomes is essential. A more open and multidisciplinary exploration of what is driving women's interest in female sexual dysfunction products and their definition of success would benefit everyone.

Finally, a recent public relations campaign has called for gender equality to be the FDA standard in access to sexual dysfunction treatments. This appeal is misleading and dangerous - the FDA must continue to balance a serious and respectful incorporation of patient input while maintaining a stringent, uncompromised science-based review standard. Women have answers to the age-old question "what do women want?" - just ask us. We want and demand products that are rigorously evaluated, safe, effective and meet our real needs.