

June 1, 2015

Honorable Barbara Mikulski
U.S. Senate
Washington, DC 20515

RE: Pending FDA drug application of flibanserin

Dear Senator Mikulski,

As long-time supporters of women's health and safety, we the undersigned organizations and individuals are writing to thank you for your continuous support for the Food and Drug Administration's (FDA) stringent, evidence-based drug review process. You may have become aware that a company seeking approval for a new drug to treat female sexual desire disorder is claiming that the FDA has displayed gender bias in its evaluation of the drug. We would like you to understand the perspective of the undersigned organizations and individuals, all of which have long and extensive experience advocating for women's health. We are concerned about the safety and efficacy of this drug, flibanserin, and believe that women's health will be best served if the FDA is allowed to do its job of carefully weighing the evidence.

The impact and profitability of male-targeted erectile dysfunction drugs have prompted a rapidly accelerating race to create similar drug treatments for women. However, despite more than a decade of research and millions of dollars spent on development, industry has so far failed to find a product that is safe and effective for women dealing with female sexual arousal or desire problems. The FDA has asked companies to use rigorous effectiveness standards, and to fully explore possible serious safety concerns — and for good evidence based reasons.

The FDA is holding an advisory committee meeting this week, on June 4, 2015, to consider flibanserin's application. This will be the third time the FDA has been asked to approve flibanserin, which is sponsored by Sprout Pharmaceuticals. Sprout is a lead sponsor of a marketing campaign called *Even the Score*, which claims that the FDA is holding drugs for women to a different standard than those for men. We believe that this claim does not take into account the valid safety and efficacy concerns identified by the FDA.

The gender equity argument ignores the real safety difference between flibanserin and the drugs approved for men: a different indication for use, specifically the dosage and administration. All but one of the drugs approved for men are taken on an as-needed basis. Flibanserin, a central nervous system serotonergic agent with effects on adrenaline and dopamine in the brain, requires chronic – daily, long-term – administration. Given the difference between drugs administered daily and those administered on an as-needed basis, it is appropriate for the FDA to subject flibanserin to a higher level of safety scrutiny. A substantial number of adverse events reports and drop-out rates in the trials as well as the lack of long-term safety data, rightly require serious consideration.

No amount of slick marketing can obfuscate the fact that the pharmaceutical industry has yet to produce a female sexual dysfunction drug that actually works. There are many reasons why flibanserin and past female sexual disorder drug contenders have not effectively increased women's sexual arousal or desire. Chief among them is the heterogeneity of female sexuality and arousal, and the fact that sexual problems are most shaped by interpersonal, psychological, and social factors which cannot be treated by a drug. And, as we know, sexual desire differs over time and between people for a range of reasons largely related to relationships, life situations, past experiences, and individual and social expectations.

We recognize that a lack of sexual desire can be a real and distressing problem for many women. It is not only reasonable, but vitally important for women's health advocates to press on all fronts for women to have both the information and the resources needed to achieve fulfilling sexual lives. However, women also rely on the FDA to ensure that any drugs or devices used for this purpose are both safe and effective. The problem with flibanserin is not gender bias at the FDA but rather the drug itself.

The FDA rejected flibanserin in 2010 because it failed to meet basic effectiveness standards and because the initial sponsor, Boehringer-Ingelheim, had inappropriately changed clinical trial methods midstream. In 2013, Sprout Pharmaceuticals, the current sponsor, resubmitted flibanserin's application and the FDA again rejected it because the minimal benefits in increasing women's sexual satisfaction were offset by worrisome side effects and unknown long-term effects. The fact remains that the benefits of flibanserin do not outweigh the drug's inherent risks.

Because several drugs have been approved to treat male sexual dysfunction, questions have been raised about whether the FDA holds women's sexual satisfaction to a different standard. *Even the Score* claims that there are 26 drugs approved for men, and zero for women. This number, however, represents a miscalculation of the number of drugs available for men. It correctly identifies 8 drugs approved for treating erectile dysfunction, but lists 17 brand name forms of testosterone, none of which are approved to treat men's sexual dysfunction. It also includes one drug approved for Peyronie's disease, penile curvature that interferes with intercourse, which is not considered a sexual dysfunction. In reality, there are no drugs approved for treating low sexual desire in men. The repeated use of the number "26" is a flagrant disregard of the facts. The FDA should not approve a drug that is unsafe or ineffective simply because there are not yet safe and effective treatment options available.

As patients, consumer and women's health organizations and supporters, we support the FDA's concern for drug safety shown in its appropriate handling of the flibanserin applications. We also appreciate your longstanding support for women's health and safety. *Even the Score's* effort to make this a conversation about gender equality is misleading and dangerous. The FDA should continue to balance a serious and respectful incorporation of patient input while maintaining a rigorous, science-based review standard for the drugs and devices it approves.

Sincerely,

Jacobs Institute of Women's Health

Our Bodies Our Selves

National Women's Health Network

Radical Women

Reproductive Health Technologies Project

The New View Campaign

WoodyMatters

Women's Therapy Centre Institute

(All professional associations for individual signatories are for identification purposes only)

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