

**Endocrine Society Testimony to the
Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and
Drug Safety and Risk Management Advisory Committee**
June 4, 2015

On behalf of the Endocrine Society, representing more than 19,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the Food and Drug Administration's June 4, 2015 meeting on the new drug application (NDA) 022526, flibanserin 100 milligram (mg) tablets, submitted by Sprout Pharmaceuticals Inc., proposed for the treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women. Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders, such as infertility, women's health, osteoporosis, diabetes, hypertension, obesity, and thyroid disease.

The Society is encouraged by the FDA's focus on drug development for FSD, but cautions that most existing medications should be limited in their use due to limited efficacy data from studies published to date. However, studies with flibanserin show an effect size similar or greater than studies for drugs for male sexual dysfunction. Thus, similar levels of evidence should be used to approve drugs for women as for men.

Concerning the use of androgens for FSD, the Society's recently published clinical practice guideline, *Androgen Therapy in Women*, specifically recommends against the use of testosterone therapy for female sexual dysfunction other than for treatment of hypoactive sexual desire disorder (HSDD), and recommends against the generalized use of DHEA for women due to lack of evidence of efficacy and long-term safety. We recommend against the use of pharmacologic levels of androgen for any symptoms.

In order to be able to more effectively treat patients with FSD, the Society's guideline calls for more research into the role of androgens. Specifically, trials of androgen therapy should assess the safety and risk of androgen administration using multiple end points, including sexual function, mood, and cognitive, bone, cardiovascular, dermatologic, breast, and endometrial health. The Society also calls for the development of sensitive and specific assays to accurately measure testosterone and free testosterone, and studies in women with low sexual interest/incentives and low arousal (and typically few orgasms) to reflect the prevalent clinical situation. Most clinical trials to date also have excluded women with clinical depression, those using antidepressant therapy, or those with problematic relationships, poor health, or partners with sexual dysfunction, yet these comorbidities are common. Research exploring these psychosocial factors, along with optimal hormonal evaluation, is needed.



The Society appreciates the opportunity to provide comments to FDA on drug development for FSD. Please do not hesitate to contact Stephanie Kutler, Director of Quality Improvement, at skutler@endocrine.org if we may provide any additional information or assistance as FDA moves forward in developing their strategy.