Tuesday, August 18th, 2015 marked a historic day for Female Sexual Health as the US Food and Drug Administration (FDA) approved Flibanserin, the first drug of its kind in the treatment of female sexual dysfunction.

Addyi, by trade name, is a non-hormonal drug to treat Hypoactive Sexual Desire Disorder (HSDD). HSDD is the persistent loss of desire for sexual activity that causes personal distress. Flibanserin was studied in over 11,000 women and demonstrated a 53% improvement in desire as measured by the Female Sexual Function Index, a doubling of satisfying sexual events and a one-third reduction in distress. Reported side effects include somnolence, dizziness and nausea.

The medication is targeted for women whose low desire is due to biological factors. It is not appropriate for women whose loss of sexual interest is due to relationship factors, depression, or stress.

Physicians prescribing Flibanserin and pharmacists dispensing the medication will require certification. The FDA was concerned about possible hypotension with the interaction of Flibanserin in combination alcohol and issued a "black box warning" to physicians and consumers. The consumption of alcohol will be contraindicated in patients taking Flibanserin.

The approval of a safe and effective medication for premenopausal women suffering from low sexual desire is long overdue. SMSNA would like to thank the FDA for recognizing the important unmet medical need in women's sexual health. In approving this landmark treatment, it will promote further research and drug development in this field.

For interviews of key opinion leaders or questions regarding the approval please contact:

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