Rx

# Flibanserin and Female Sexual Desire

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***Editor's note:*** *The Rx column is intended to objectively inform and report on new developments in pharmacologic treatments and medical devices. Because in many cases the products being reported on have not been on the market for an extended period, the literature cited is likely to include trials sponsored by the pharmaceutical manufacturer(s).*

According to the World Health Organization, sexual health is a multifaceted state of physical, emotional, mental, and social well-being in relation to sexuality, and it includes not only the absence of dysfunction but also having pleasurable sexual experiences (2015). Sexual health

**Abstract** Female hypoactive sexual desire disorder (HSDD) is one type of sexual problem that can affect women. It is characterized by low or absent sexual desire that cannot be attributed to another cause and results in difficulty in interpersonal relationships. HSDD is not well understood, and women may not report symptoms of difficulties to their health care providers. In August 2015, the U.S. Food and Drug Administration approved flibanserin, a nonhormonal oral medication for the treatment of HSDD in premenopausal women. Flibanserin is the only currently available pharmacologic treatment for HSDD. This article will provide an overview of flibanserin, including potential adverse reactions, special considerations for use, and implications for nursing practice. http://dx.doi.org/10.1016/j.nwh.2016.03.002

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disorders, including disorders of low desire, have complex etiologies that have been difficult to accurately define and treat (Nappi, 2015). Researchers have estimated that approximately 12% of women will experience some type of self-reported sexual problem in their lifetime, including problems with sexual desire (Shifren, Monz, Russo, Segreti, & Johannes, 2008).

Hypoactive sexual desire disorder (HSDD) is one type of sexual problem reported by women, although the exact incidence is difficult to estimate because of lack of validated measurement tools, lack of clinical experts, and reluctance of women to discuss sexual concerns with their health care providers (DeRogatis et al., 2011). Female HSDD is characterized by low or absent interest in sex that results in personal distress and difficulty within intimate relationships (American Psychiatric Association, 2013; Kingsberg & Woodard, 2015). Until recently there have been no approved pharmacologic therapies to treat HSDD in women. In August 2015, the U.S. Food and Drug Administration (FDA) approved flibanserin (Addyi, Valeant Pharmaceuticals, Laval, Quebec, Canada) as the first medication to treat HSDD in premenopausal women (FDA, 2015). This column will review flibanserin's mechanism of action and adverse effects, special considerations for use, and implication for nurses who work with women experiencing HSDD. (Note: Recent revisions to the *Diagnostic and Statistical Manual of Mental Disorders* [American Psychiatric Association, 2013] changed the diagnosis of HSDD to *female sexual interest/arousal disorder* [Joffe et al., 2016], but for this column the term *HSDD* is used.)

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## Controversy Surrounding FDA Approval

The approval of the first pharmacologic treatment for HSDD in women has not been without controversy (Joffe et al., 2016). First, the prevalence of HSDD has been questioned. The prevalence of any female sexual problem has been reported at more than 40% by some researchers, although this figure is from a study that was published more than 16 years ago; the researchers did not specifically examine HSDD but instead included it among many other sexual complaints (Laumann, Paik, & Rosen, 1999). In addition to questions about the prevalence of HSDD, some health care providers have questioned whether this disorder has been created merely to sell a product and increase pharmaceutical profits (Meixel, Yanchar, & Fugh-Berman, 2015). Because there is no established norm for sexual desire, others have questioned whether HSDD is a condition that needs treatment or is a normal variant on a continuum of sexual expression and interest (Quigley, 2015). These views conflict with those of clinicians and researchers who believe that women's sexual health has been long overlooked and recognize HSDD as a prevalent condition that has not received enough attention (Kingsberg & Woodard, 2015; Nappi, 2015).

An additional concern that has been raised is the possibility of off-label use in populations of women with a broader range of health conditions than were initially included in clinical trials (Gellad, Flynn, & Alexander, 2015). Women who participated in the clinical trials were excluded if they were taking multiple different medications or had pre-existing medical conditions. Therefore, to meet the criteria for HSDD and treatment with flibanserin, a woman must be experiencing symptoms of HSDD that are not caused by a pre-existing medical or psychiatric condition, medication/substance use, or difficulty within her relationship (Sprout Pharmaceuticals, Inc., 2015). Because no postmenopausal women were included in clinical trials, the FDA has approved flibanserin for use in only premenopausal women (Sprout Pharmaceuticals, Inc., 2015), thus excluding a large population of women who may be experiencing low sexual desire. When all of these criteria are considered, the population of women who are considered appropriate candidates according to the FDA approval decision becomes narrower. This increases the chance that health care providers might choose to prescribe this medication for a broader population of women than was

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