

Little Pink Pill

By Reg P. Wydeven
August 30, 2015

I'm definitely excited that the NFL season is right around the corner. While watching preseason games, however, I'm getting a little concerned about the demographic I may belong to. In addition to typical beer, fast food and snack commercials, there are also many ads for Viagra and Cialis.

Well, about halfway through the season, I may be seeing some completely different ads.

Last week the U.S. Food and Drug Administration approved Flibanserin, the first drug designed to boost women's libido. According to Cindy Whitehead, CEO of Sprout Pharmaceuticals which makes the pill, the drug will be marketed under the brand name of Addyi and will hit pharmacies October 17. The drug has been dubbed "Viagra for Women," and is commonly called the "little pink pill," in contrast to Viagra's "little blue pill."

The journey leading to the approval of Flibanserin has been a fascinating tug-of-war between the demands of consumers and the FDA's legal obligation to carry out its function of protecting those same consumers from their own demands.

The agency had targeted low libido in women as an area of need in medicine, citing that it affects 10% of women. Flibanserin is specifically designed to treat premenopausal women suffering from Hypoactive Sexual Desire Disorder, or a lack of desire for sex that causes personal distress or difficulty in relationships.

Approval of the drug garnered lots of support from such groups as the National Organization for Women, the Society for Women's Health Research and the International Society for the Study of Women's Sexual Health. The advocacy group Even the Score also supported the drug, describing itself as "a voice for American women who believe that it's time to level the playing field when it comes to the treatment of women's sexual dysfunction."

Eleven members of Congress even sent a letter to the FDA that read, "We firmly believe that access to health care should be a fundamental right, regardless of whether you are a man or a woman."

While the FDA quickly rejected any claims of gender bias, critics of Flibanserin claim drugs for women should be held to a higher level of scrutiny because of the difference between men and women's sexual dysfunction. For men, it is almost universally a medical one – blood flow – which can successfully be treated with medication.

For women, however, experts claim it is almost more often caused by psychological, rather than physiological, issues. Things like body image, self-esteem, comfort in the relationship, stress, etc., can all contribute to dysfunction. Unlike Viagra, which is taken "when the mood strikes," Addyi is taken every night as it works on the central nervous system, which is why it's in the same category as an antidepressant.

Critics are wary of the side effects of the drug, which include dry mouth, dizziness, nausea, fatigue, and insomnia. They also include drowsiness, low blood pressure and fainting, which could be significantly increased if mixed with alcohol. Opponents of the pill point to the FDA's rejection of the drug twice in the past five years due to concerns over these side effects. Approval was granted this go-around on the condition that safety restrictions were added, such as prominent warnings on the box and training for doctors and pharmacists.

Of course, cynics add that there's too much money at stake to reject the drug, seeing as Pfizer earned \$1.6 billion last year from the sale of Viagra.

This fall, if I see ads for Addyi, I'll just know I'm not watching enough football.

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