Prepared for FDA Advisory Committee Hearing on Flibanserin
June 18, 2010
by the New View Campaign

http://newviewcampaign.org/flibanserin.asp

FACT SHEET

Distress

Problem #1: The focus on "distress" is driven by industry needs not women's experiences

Claims that women are distressed by low sexual desire are based on weak evidence

- Recent baseline measures of distress were only 0.8 on Item 13 from the Female Sexual Distress Scale-Revised (FSDS-R) demonstrating that women were only 'rarely' "bothered by low sexual desire" (B-I Press Release 2010).
- Independent epidemiological studies report that a significant portion of women with low desire are not distressed (e.g. Bancroft et al. 2003).
- The inclusion of distress needs to be re-evaluated (Balon & Clayton 2009).

The developers of the FSDS-R have financial affiliations to Boehringer-Ingelheim (B-I) (Derogatis et al. 2008).

- "Relationships between medicine and industry may create conflicts of interest, potentially resulting in undue influence on professional judgments… and thereby may jeopardize the integrity of scientific investigations" (IOM 2009).

Problem #2: Aspects of the validity and reliability of the FSDS-R are questionable

A number of issues with the FSDS-R validation are evident in Derogatis et al. (2008)

- A 15.4 percent rate of false positives at four weeks for the FSDS-R, and no sensitivity or specificity measures at all provided for Item 13, despite it being commonly used as a stand-alone measure of distress in HSDD studies.
- Construct validity only demonstrated in comparison to a scale also developed by a drug company developing a new product for FSD (Proctor & Gamble).
- Test samples were predominantly white, heterosexual, and married, and subject to stringent exclusion criteria, such that the measures may not be generalizable.
- No attention to social desirability, a likely source of bias given that the FSDS-R is self-report and that sexuality is highly influenced by cultural messages.
- Insufficient attention to recall bias, a likely problem for the FSDS-R given that it can have recall periods as high as three months.
- Low test-retest reliability coefficients for Item 13 (between 0.475 and 0.674).

Problem #3: "Distress" is more indicative of sexual context than of biochemistry

In order for distress to be a meaningful indicator of HSDD, it must be solely attributable to a woman's low sexual desire (Horowitz 2007). However, evidence suggests that a woman's distress may be from a number of other sources

- Baseline characteristics of women in the HSDD Registry indicate high rates of psychiatric diagnoses (17.7%) (Maserejian et al. 2009)
- The items in the FSDS-R cannot distinguish between distress coming from interpersonal expectations versus that from low sexual desire, yet many women say their distress comes from guilt and/or anxiety about their partner.

Women's assessments of their own sexual desire, and subsequent distress, are highly influenced by perceived cultural norms and expectations

- In U.S. culture female sexuality is constrained by limited sex education, and the sexualization of girls and women in the media, yet powerful and misleading "empowerment" messages deny these realities by telling women that they are sexually liberated. Thus women are bombarded with contradictions, creating dissonance that is subjectively distressing (APA 2007).

- Bancroft et al. (2003) argue that it is not clear what proportion of problems identified as sexual dysfunctions could be best identified as "adaptive or understandable reactions to current circumstances."

It is unpersuasive to regard women's distress as indicative of unbalanced biochemistry

- "Distress is a normal human emotion, not a disorder, when it both emerges and persists in proportion with external stressful situations" (Horowitz 2007).
- Women's distress needs to be recognized, and responded to, as a valid and meaningful response to a complex and contradictory sexual context.

Problem #4: Flibanserin is distressing

The marketing of HSDD by B-I contributes to women's distress about low sexual desire

- It gives the message that a woman who does not desire sex may be disordered.
- It encourages women and their partners to monitor their desire and therefore probably increases anxiety about their sexuality and sexual relationships.
- It worsens conflict in couples over desire discrepancies by arming one with a cloak of "normality" and the other with a cloak of "pathology."

Research on depression demonstrates that biochemical theories and their associated pharmaceutical interventions are highly disempowering for women by leading to feelings of a loss of autonomy, marginalization, delegitimization, and stigmatization (e.g. Lafrance 2007).

References

APA (2007) "Report of the APA Task Force on the sexualization of girls." http://www.apa.org/pi/women/programs/girls/report.aspx

Balon, R., & Clayton, A. (2007) "Sexual dysfunction, disorder, or variation along normal distribution: Toward rethinking DSM criteria of sexual dysfunctions." *American Journal of Psychiatry 164:* 198–200.

Bancroft, J., Loftus, J., & Long, J. (2003) "Distress about sex: A national survey of women in heterosexual relationships." *Archives of Sex Behavior 32:* 193–208.

B-I Press Release (2010, May 19th) "Women with hypoactive sexual desire disorder (HSDD) report that flibanserin increased their sexual desire and reduced associated distress." http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2010/19_may_2010.html

Connor, M., et al. (2009) "Measures of sexual desire and distress among premenopausal women in the HSDD Registry for Women at baseline." Poster presentation at *3rd International Consultation on Sexual Medicine,* 10th-13th July, Paris, France.

Derogatis L., et al. (2008) "Validation of the Female Sexual Distress Scale-Revised for assessing distress in women with Hypoactive Sexual Desire Disorder." *Journal of Sexual Medicine 5*(2): 357–64

Horowitz, A. (2007) "Distinguishing distress from disorder as psychological outcomes of stressful social arrangements." *Health (London) 11*: 273–89.

IOM (2009) "Conflict of interest in medical research, education, and practice." http://www.iom.edu/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx

LaFrance, M. (2007) "A bitter pill: A discursive analysis of women's medicalized accounts of depression." *Journal of Health Psychology 12*: 127–140.

Maserejian, N., et al. (2009) "Baseline characteristics of premenopausal women with Hypoactive Sexual Desire Disorder enrolled in the HSDD Registry for Women." Poster presentation at *3rd International Consultation on Sexual Medicine*, 10th-13th July, Paris, France.

Shifren, J., et al. (2008) "Sexual problems and distress in United States women." *Obstetrics & Gynecology 112*: 970–978.