

FACT SHEET

Clinical Trials

Problem #1: Lack of transparency

- Prior to the FDA hearing, flibanserin clinical trial data have only been presented in press releases and conference abstracts.
 - This flouts Institute of Medicine (2009) recommendations. Its report, *Conflict of Interest in Medical Research, Education and Practice*, advises ways to staunch the erosion of public trust in medicine and preserve the integrity of science and medical education.
 - By failing to publish their results in the accepted scientific manner, Boehringer-Ingelheim (B-I) does not “provide information” to inform the public, but rather to promote product and company-enhancing images, guard against unfavorable information and protect “proprietary” information.
- B-I gives us “pooled” data, preventing close examination of methods, adverse effects, efficacy results, drop-outs, and individual treatment arm results.
- B-I gives us no information as to whether allocation concealment (if subjects guess correctly if they had pill or placebo) was successful. This is crucial because subjective satisfying sexual events (SSE) and questionnaire measures are subject to expectation bias.
- **It is impossible to prepare comments on trials that are secret**

Problem #2: Marginal and unpersuasive outcomes

- Press releases from 2009 indicate that pooled data from two of three trials show small beneficial effects. Relative to placebo, the drug increased the number of “satisfying sexual encounters” (SSE) by 0.7 per month. Women taking flibanserin also “improved” their scores on questionnaire measures of sexual desire and distress, although “very much improved” “much improved” and “minimally improved” scores were lumped together. “Minimal” improvement is unlikely to be worth the risk of daily taking a 100mg dose of a new brain drug for weeks, months or even longer.
- A third trial did not show significant benefit on SSE. We assume the company puts its best case in press releases, so that lack of significance in a reported trial strongly suggests a drug with little benefit.
- High placebo rates on most published study endpoints are repeatedly found in papers on “female sexual dysfunction” and “HSDD” with all pharmaceutical treatments, and appear caused by relationship improvement (despite noninvolvement of partners in trials) (Bradford & Meston 2007, 2009). This is consistent with our argument that desire problems are rarely medical.

Problem #3: Psychological as well as physiological risks of flibanserin

- Physiological Risks (see ADR fact sheet)
 - There are special risks related to the premenopausal age group, the unknown mechanism of action, and the required weeks of daily high dosage administration. Side effects of dizziness, nausea, fatigue and somnolence suggest a sedative effect.
- Psychological Risks (see Distress and Gender fact sheets)
 - have to do with escalating sexual standards and pressures on women, exacerbating the conflictual element of desire discrepancies within relationships, and the fact that lengthy pill-taking produces self-monitoring and feelings of disempowerment in many women.

Problem #4: Selection and preparation of participants

- In clinical practice, women’s complaints of low desire usually fall into one of two groups: chronic problems and recent or temporary problems. The psychoeducational treatments for these two groups of women are likely to be quite different because the etiologies of their concerns are likely to be quite different. Were the trial participants

complaining of chronic or acquired low desire?

- In psychoeducational treatments for women's sexual complaints, sex education is an essential element, and often the primary element. Were the trial participants assessed for sexuality and relationship knowledge, and what information were they given?
- Why is this application testing a new drug for pre-menopausal women when epidemiological studies repeatedly show that desire problems are substantially more common in older than younger women? (West et al. 2008; Shifren et al. 2008).

References

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