

New View Campaign statement following the
FDA Reproductive Health Advisory Committee meeting
on "flibanserin" held on June 18, 2010

The New View Campaign, founded in 2000 to challenge the medicalization of women's sexuality, is extremely pleased that the FDA Reproductive Drugs Advisory Committee voted UNANIMOUSLY (11-0) to recommend AGAINST approval of "flibanserin" at the end of their hearing in Gaithersburg, MD, USA on June 18, 2010.

This unanimous decision accurately reflected the doubts and concerns expressed by the FDA staff, members of the Advisory Committee and the public with regards to the drug's:

- Short and long-term safety, especially for young women
- Effectiveness as compared with placebo pills
- Commercialized and biased pre-launch marketing campaigns

Flibanserin, a central nervous system drug that affects neurotransmitters in the brain, had originally been developed by German manufacturer Boehringer-Ingelheim as an anti-depressant around 1999, but it was not effective and drug development was stopped. Clinical trials for the drug as a treatment for pre-menopausal women distressed about libido loss of unknown origin began five or so years later, and were conducted in 15 countries over a period of several years. Positive results were meager and the FDA Advisory Committee felt the health risks were not worth the small benefits. Side effects of nausea, fatigue and dizziness caused many women to drop out of the trials, and although those who stayed showed improvement on some questionnaire measures, there were conflicting findings even there. The FDA scientists were worried about potentially dangerous interactions with alcohol and other drugs, about the impact on pregnant and nursing women, and about the possible depressing effects of the drug.

All six speakers against flibanserin during the public section of the hearing (sociologist, filmmaker, physician, sex educator, clinical psychologist, and health care advocate) are member/supporters of The New View Campaign (Thea Cacchioni, Liz Canner, Adriane Fugh-Berman, Karen Hicks, Leonore Tiefer, and Amy Allina). Our remarks focused on drug safety, legitimacy of the "hypoactive sexual desire disorder" diagnosis, the pre-launch marketing and medical education circus, and the need to situate women's sexual desire in a broad psycho-sociocultural context respecting lifestage and cultural diversity. We brought a petition signed by 650 people from 22 countries and 47 U.S. states, and Rachel Liebert twittered live from the hearing on the New View twitter page.

Boehringer-Ingelheim, in its rush to market, brought the public a flawed product, and in a hearing open to the press and the public, the limited benefits and potential dangers of its neurotransmitter-altering drug were clear for all to see.

New View testimonies and our 6 impressively documented Fact Sheets will all be posted on our webpage, <http://newviewcampaign.org/flibanserin.asp>, along with references and resources, photos, the petition, and other materials. We invite scholars, journalists, students and the public to use these resources to better understand the full scope of this chapter in the pharmaceutical industry's ill-starred "hunt for the pink Viagra."