NATIONAL WOMEN'S HEALTH NETWORK

Statement of Amy Allina, Program Director at the June 18, 2010 meeting of the Food and Drug Administration's (FDA) Reproductive Health Drugs Advisory Committee

The National Women's Health Network (NWHN) is a nonprofit advocacy organization that works to improve the health of all women. We are supported by our members and do not accept financial support from drug companies or medical device manufacturers. We bring the voices, concerns and needs of women consumers to the policy and regulatory tables

Lack of sexual desire can be a real problem for women and for some, a drug may be an effective treatment. But this drug isn't it.

Boehringer Ingelheim, the sponsor seeking approval of flibanserin for treatment of hypoactive sexual desire disorder in women, was unable to demonstrate effectiveness by the prespecified measures for its trials. In the face of that failure, the company tried to move the goalposts. The analysis put forward in this application would get an F in any reasonable clinical trials design class.

But the questions we're asking aren't academic challenges based on research design alone – we're concerned about whether this drug would help women who are facing problems with sex that detract from their happiness and well-being. We recognize that even a numerically small improvement in this part of a woman's life can make a positive difference for her, but women don't just care about a drug's effectiveness. We also care about the drug's safety and about the side effects we might experience.

In the pivotal trials of flibanserin, women taking the drug were much more likely to drop out than women taking the placebo, and more than 14 percent of women taking the recommended dose of flibanserin discontinued because of an adverse event compared to less than 7 percent of those in the placebo arm. Common adverse events included drowsiness, fatigue, dizziness, nausea and anxiety. The FDA review also identified a number of worrisome safety signals including an increased frequency of accidental injury and depression in women taking the drug. No surprise that women taking a drug because they want to feel more interest in having sex voted with their feet when faced with these problems.

And there are also safety concerns about how flibanserin interacts with alcohol and with a long list of prescription drugs, including commonly prescribed antibiotics, hormonal contraception, migraine medications and antifungals used to treat yeast infections. Once you consider all the restrictions that would be necessary to try to ensure safe and well-tolerated use of this drug, it becomes clear that it would offer very little benefit to real women in the real world. The FDA review noted that drug labeling may not be sufficient to make women aware of the numerous drug interactions with flibanserin.

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We also want to make a larger point about the weak efficacy data and the problems with that aspect of the clinical trial design. The failure to show that this drug increases desire highlights the trouble with the push to put a label of disorder, dysfunction or disease on women's problems with sex. There is no empirical evidence to establish a single, normal level of sexual desire for women. To find real solutions to the problems with sex that women face we have to be able to acknowledge that there are normal ebbs and flows of desire in the course of a week, a month, a year, and even more obviously a lifetime. Any medical or research framework that doesn't allow room for that reality, will prevent us from confronting the complex causes of women's sexual dissatisfaction with the honesty required to find solutions.

Another concern we have with this application relates to drug company promotion campaigns. Anyone who has ever turned on a television knows that drug companies routinely overpromote products, targeting broad swaths of the population with advertisements for drugs that were tested in and intended for a much narrower patient group. Boehringer Ingelheim has already shown its intentions on this front, even before receiving FDA approval for the drug, by launching a substantial marketing campaign complete with promotion to clinicians, websites aimed at women and high visibility for a celebrity spokewoman famous for playing sexy characters on daytime and primetime soap operas. While this early phase of the campaign stays on the right side of the law by avoiding specific discussion of flibanserin, it clearly is intended to prepare the ground for promoting the drug. And it does this by presenting a distorted picture of the state of knowledge in the field including overgeneralizing about women's sexual difficulties and overstating evidence on the role of neurotransmitters in women's sexual desire.

Finally, committee members heard public comment to the effect that men have Viagra and women deserve to have something too. This analysis fails to recognize important differences between the two drugs. First of all, effectiveness – the clinical trials of Viagra found a higher level of effectiveness than the .8 increase in sexually satisfying events per month over placebo that flibanserin demonstrated. And secondly safety -- men take Viagra episodically as needed, but a woman would have to take flibanserin every day. That kind of chronic, daily use of a drug raises both short-term and long-term safety questions that the FDA and women who might consider taking a drug like this must weigh carefully.

Women do deserve to have our problems with sex taken seriously, and the NWHN strongly supports and advocates for sexual health research to find solutions to these problems. But this drug offers too little at too high a cost. We urge the committee to recommend against approval.