April 8, 2014

Janet Woodcock, MD  
Director  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: Flibanserin

Dear Dr. Woodcock,

As members of the Patient, Consumer, and Public Health Coalition, we are writing to support the agency’s evidence-based evaluation and decision regarding flibanserin. We agree with the FDA that there is no evidence that the very modest benefit would outweigh the risks.

Concerns that have been raised about gender equity and the variety of prescription drugs approved for male sexual dysfunction compared to zero for women’s sexual satisfaction are not relevant to the overriding issue: benefits should outweigh the risks. For example, the drugs approved for men are all taken on an as-needed basis, whereas flibanserin, a central nervous system serotonergic agent with effects on adrenaline and dopamine in the brain, requires daily, long-term use, which is much more dangerous.

However, the concerns that have been expressed about the FDA’s rejection of flibanserin, to some extent reflect the public’s concern and confusion about recent FDA approval decisions that seem to hold other prescription drugs, for women and men, to a lower standard. For example:
• Brisdelle (a low dose version of the antidepressant Paxil) was approved for hot flashes even though the women taking it in randomized clinical trials had similar numbers and severity of hot flashes to women taking placebo. But, Brisdelle increased the risk of suicide dramatically compared to placebo among women who were not depressed prior to taking the drug.1,2

• Farxiga was approved for diabetes, although the patients taking it in randomized clinical trials were 5 times as likely to be diagnosed with bladder cancer, twice as likely to be diagnosed with breast cancer, and had increased risk of renal failure.3 It lowered blood sugar, comparable to other diabetes drugs, but actual health benefits were questionable. In clinical trials for Farxiga, less than 4% of patients were African-Americans, a group with the highest diabetes rate in the country.3

• Sirturo (bedaquiline) was approved for multidrug-resistant tuberculosis even though patients taking it with the standard drug regimen were 5 times more likely to die than patients who only took the standard drug regimen.4

Too often, the FDA has decided in favor of approving a new drug even when there are many existing alternatives that are safer and equally or more effective. This inconsistency is opening the FDA to criticism when the FDA makes appropriate decisions to deny approval for unsafe or ineffective drugs.

As patient, consumer and public health organizations long engaged with the FDA, we support the agency’s concern for drug safety shown in its handling of the flibanserin applications. We ask that the very reasonable standards that you used in this decision be applied to other drugs that have similarly modest or unproven benefits with potentially serious risks.

Sincerely,

American Medical Student Association
American Medical Women’s Association
Annie Appleseed Project
Breast Cancer Action
National Research Center for Women & Families
Our Bodies Ourselves
The TMJ Association
WoodyMatters

For more information, contact Paul Brown at (202) 223-4000 or pb@center4research.org


Food and Drug Administration (December 12, 2013). Advisory Committee Materials for Endocrinologic and Metabolic Drugs. http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/ucm331504.htm