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Flibanserin (Addyi), the Alleged "Libido Pill For Women"

What Women Need to Know Before Asking for it

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On August 18, 2015, the FDA proudly announced that they had approved (after 2 previous rejections) a new drug whose generic name is flibanserin (Addyi will be the brand name when it comes to your local drug store in mid-October). The only drug that Sprout Pharmaceuticals has ever marketed, flibanserin is purported to treat a "disease" called hypoactive sexual desire disorder (HSDD).

The drug has been approved only for premenopausal women. The company will offer the drug in a 100 mg dose, to be swallowed once per night, no matter if sexual encounter is anticipated or not. This pill is not a female Viagra!

In a related story, two days after the FDA's formal approval to market their only drug, Sprout announced that it had sold itself to a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc. for $1 billion dollars cash plus a portion of future earnings.

Below is some essential background information about the drug that hasn't been well covered in the mass media. Every interested patient (and their prescribing practitioners) should know about this information before they ask for a prescription from their psychiatrist, OB-GYN, internist, family physician or nurse practitioner.

Some of the downsides of this new, soon-to-be blockbuster drug

For one thing, the drug will be expensive, indeed, it will unaffordable unless health insurance companies can be hood-winked to pay for it. If they do, look for premiums to rise! Cindy Whitehead, the CEO of Sprout has stated that it will be charging pharmacies $400 for a 30 pill supply [which equates to over $13 per pill!]. Nobody knows what the mark-up will be at the pharmacy.

Secondly, the drug will very likely be destructive of serotonin nerves long-term just judging from the molecular structure, which contains a highly neurotoxic tri-fluoridated methyl group attached to an amphetamine-like benzene ring (= phenyl group). That particular moiety resulted in the banning (in 1997) of the methamphetamine-like, psycho-stimulating, appetite-suppressing, weight-loss drug fenfluramine (of Fen-Phen infamy) after it was discovered to have caused a number of cardiac deaths and serious disability, including heart valve damage, primary pulmonary hypertension, and the near total destruction of serotonin nerves in the frontal lobes of experimental monkeys who had been given only 4 doses of fenfluramine 17 months prior to their being sacrificed and their brains examined.

The dramatic brain biopsies that proved this serious outcome were published in 1975, twenty years before the drug was widely prescribed to unsuspecting over-weight patients by equally unsuspecting weight-loss physicians!

Here is the molecular structure of flibanserin:

It is important to note that the portion of the molecule at the end opposite of the tri-fluoridated phenyl group has a structure that resembles an indole ring, which is the base structure of the serotonin molecule. The drug company marketing this drug states that in the flibanserin rat studies, serotonin was found to be "decreased" in the brains of the treated rats while dopamine and norepinephrine were found to be "elevated". Those findings are consistent with what could be predicted to occur just from looking at the molecule. The serotonin, dopamine and norepinephrine receptor sites and reuptake pumps, just like all antidepressants, antipsychotics and psychostimulants, WILL be "messed with", even poisoned, but not in brain-healthy ways.

Flibanserin has not yet been tested – even in the animal labs – for long-term safety or efficacy. That will be done in the Phase IV (post-marketing) studies, which are typically done in a haphazard fashion. Judging from the Phase III clinical trials, the drug appears, at best, to be only marginally effective at raising female libido for only some patients. The study that was submitted to the FDA claimed that the patients taking the drug experienced only approximately one additional favorable sexual experience per month, compared to the placebo group.

Pharmaceutical companies typically exaggerate, by a sneaky statistical trick, a drug's effectiveness – the RRR (relative risk reduction). One can therefore expect flibanserin's marketers (aiming at both to physicians and the public) to claim a 30% or 40% relative risk improvement rate (which will be the deceptive "relative risk" improvement figure and not the "actual risk" improvement figure of one incident per month). Such statistical manipulations regularly fool both doctors and prospective patients to expect dramatic results – until reality hits much later.

Significant numbers of patients may be harmed and many will be disappointed with the mediocrity of the promised results, but in the meantime, some Big Pharma corporation will be raking in $400 per patient per month and some health insurance companies will be reluctantly paying out $400 per month until the duped patients sicken or drop out because of the drug's ineffectiveness and angrily quit the drug. Same old very profitable strategy that drug companies have used for generations, even with dangerous or ineffective drugs.

One of the published rat lab studies that I found online "suggested" that the sexually immature female rats used in the trial, after being on flibanserin for weeks, "appeared" to observers to be sexually interested in male rats, but that "suggested response" only happened after the rats had been given injections of synthetic estrogen and progesterone drugs! Reading the study made me shake my head, because the authors of the study (paid by the company) had not seen the obvious clinical inapplicability of those findings, which they regarded as good enough reasons to proceed to human studies.

It is important to realize that years earlier, this drug was thought by its original developer to be marketable as an antidepressant drug (it failed), probably because its molecular structure had some similarity to fluoxetine (Eli Lilly's Prozac), fluvoxamine (Solvay

Pharmaceutical's Luvox) and fenfluramine (Wyeth's Pondimin and Redux). Wyeth, incidentally, was acquired by Pfizer in 2009 for $68 billion after Wyeth settled the fenfluramine liability claims for an estimated $14 billion. Fenfluramine, it needs to be noted, is a now banned, long-acting psychostimulant (but very neurotoxic) drug because of the three highly electronegative fluorine atoms attached to its phenyl group.

When its use as an antidepressant drug failed, the original drug company gave up on it and sold its rights to Sprout.

What to do Before Taking Flibanserin

My advice to prospective patients, before submitting to an expensive, essentially untested and potentially dangerous brain-altering drug, is to first find out if your diminished libido was caused by current or previous psychiatric drug usage, since such usage (virtually epidemic in the US, especially for women) is a major root cause of sexual dysfunction in both men and women. That information is vitally important, because flibanserin WILL NOT WORK in (and the drug is not intended for) patients whose brains have been altered by prior or current psych drug usage.

Flibanserin is not indicated for use in cases of drug-induced diminished libido. Sprout Pharmaceuticals actually says, in its product information brochure, that the use of flibanserin is contraindicated in patients that are taking any of the following (CYP3A4 hepatic enzyme inhibitor)medications, which include many SSRI antidepressants. Note this partial list of commonly prescribed drugs that are CYPDA4 hepatic enzyme inhibitors):

Aminodarone, Azithromzcin, Cannabinoids, Cimetidine, Clarithromycin, Clotrimazole, Cyclosporine, Dexamethasone, Diltiazem, Disulfiram, Erythromycin, Ethinyl estradiol, Fluconazole, Fluoxetine (Prozac), Fluvoxamine (Luvox), Grapefruit juice, Isoniazid, Ketoconazole, Metronidazole, Miconazole, Nefazodone (Serzone), Paroxetine (Paxil), Propoxyphene (Darvon), Quinidine, Quinine, Ranitidine, Sertraline (Zoloft), Troglitazone, Valproic acid.

At the end of this article is another list of prescription drugs that can lower a person's libido. Flibanserin is not intended to be used in the treatment of such drug-induced sexual dysfunction.

SSRI-induced Sexual Dysfunction can be Permanent

The amphetamine molecule-based, halogenated/fluoridated SSRI drugs like Prozac, Zoloft, Paxil and Luvox, are notorious for causing high rates of sexual dysfunction in both females and males, and SSRI-induced sexual dysfunction can become permanent!

See http://www.australianprescriber.com/magazine/36/2/42/5 for a good introduction to the problem.

(Also watch this YouTube video taped by one of the victims of Post-SSRI Sexual Dysfunction (PSSD):

https://www.youtube.com/watch?v=I3db98NVDMw.) There is a 3,700 member support group serving victims of PSSD. Info about that group is available at https://groups.yahoo.com/neo/groups/SSRIsex/info.

Sexual dysfunction symptoms can be caused by many psychiatric drugs. Symptoms include diminished libido, anorgasmia, erectile dysfunction, delayed ejaculation and inability to ejaculate – not to mention worsening depression, suicidality, homicidality, akathisia, memory loss, insomnia, anhedonia and an "I don't give a damn attitude" (all of which are libido killers).

Except for gradually and carefully stopping the offending drug, there is no effective treatment for the most severe forms of SSRI-induced sexual dysfunction. Logic tells us that drug-induced sexual dysfunction can't be expected to resolve by adding another serotonergic or dopaminergic drug, all of whom cause brain problems that aren't understood. And, just like the withdrawal symptoms that always arise after discontinuing addictive medications, such drugs must be cautiously discontinued. In the case of patients who have already become permanently sexually disabled because of SSRIs, even stopping the drug may not cure the problem.

Knowing what I do about the molecular structure of such psychoactive drugs as flibanserin, I would predict that an unknowable percentage of patients trying this medication on a long term basis will be made worse in any number of ways.

Please study the list of offending drugs immediately below and inform your healthcare provider, who may not be fully aware of these issues. The list below is excerpted from the website of the International Society for Sexual Medicine.

Flibanserin has not been approved for use in drug-induced sexual dysfunction.

(http://www.issm.info/education-for-all/sexual-health-qa/what-medications-might-lower-a-persons-libido/)

Libido-lowering Medications

- *Antidepressants.*
- *Antipsychotics*
- *Benzodiazepines*
- *Beta-blockers*
- *Estrogen-containing drugs (may lower libido in men)*
- *Finasteride* (Proscar is prescribed for treating prostate enlargement. Propecia is prescribed for male-pattern baldness.)
- *Opioids (like morphine and oxycodone)*
- *Oral contraceptives*

"This is not an exhaustive list.

"Patients who think their medications are affecting their libido should talk to their doctor. Some drugs cannot be stopped abruptly and need a weaning period.

"Note: Testosterone contributes to sex drive in both men and women, but some drugs lower

libido without affecting testosterone levels. Scientists are not exactly sure how this happens, but it likely involves specific brain centers that manipulate dopamine."

Dr Kohls is a retired physician who practiced holistic, non-drug, mental health care for the last decade of his family practice career. He now writes a weekly column for the Reader Weekly, an alternative newsweekly published in Duluth, Minnesota, USA. Many of Dr Kohls' columns are archived at http://duluthreader.com/articles/categories/200_Duty_to_Warn.

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