FDA’s Brisdelle Override. Power Politics or Mere Desperation?

May 18, 2014 By Mike Barr

I realize it’s not the first time something like this has happened, but really??

The Reproductive Health Drugs Advisory Committee of FDA voted 10-4 AGAINST approval of the antidepressant paroxetine (basically low-dose Paxil) for menopausal hot flashes in women. But their superiors decided to approve it anyway.

Surely GSK and its shareholders welcome a new indication for a novel reformulation of a blockbuster drug that lost patent protection some 10 years ago.

The evidence of benefit? Median of 5.0 vs. 5.6 “moderate to severe” hot flashes per day (at Week 12), paroxetine vs. placebo.

Admittedly it will be an apples to oranges comparison, but I will look up the effect size from acupuncture and, if available, herbal medicine trials and post later today. (I finally got around to looking up the Norwegian (AcuFlash) study stats: number of hot flashes decreased by average (mean) of 5.8 per 24 period in the acupuncture group--vs. mean reduction of 3.7 in the control (“advice on self-care”) group. Hot flash intensity also decreased by roughly twice as much in the acupuncture group compared to control group: 3.2 vs. 1.8. All results were statistically significant: $p<0.001$.)

And the Black Box warning on the medication?: *Although the risk of suicidality associated with Brisdelle is uncertain, it is noteworthy that the concerns about suicidality associated with higher doses of paroxetine pertain to children and young adults, a population for whom Brisdelle clearly is not indicated. Nonetheless, the Brisdelle label recommends monitoring patients for suicidal thoughts and behaviors and discontinuing treatment if there is worsening depression or suicidality.*

Plus... as a potent inhibitor of cytochrome P450-CYP2D6 paroxetine, even at this relatively low dose, also has the potential for a wide array of drug-drug interactions: most notably, with tamoxifen, where it reduces plasma levels of the drug by 64%.

This decision is particularly surprising because the current FDA Commissioner, Peggy (aka Margaret, former NYC health chief) Hamburg has historically been very women’s health and “community” friendly--or at least she used to be before, maybe, she obtained so much power or

responsibility? Maybe she doesn't know about the AcuFlash studies or the bevvy of Chinese herbal formulas for managing menopausal symptoms: Er Xian Tang, Geng Nian An Pian, Da Bu Yin Tang and (Zhi Bai) Di Huang Tang aka "Rehmannia 6." (Personally, I prefer Health Concerns' tweaking of the classic formula, which they playfully call Three Immortals. They add Er Zhi to Er Xian--plus magnolia tree and lycium root bark (Mu Dan Pi, Di Gu Pi, respectively).) Should we write Dr. Hamburg--or the committee members--a letter?

A "Perspective" of the FDA's decision to override its own advisory committee appears in this week's New England Journal of Medicine. Read the full (free) text here. The NEJM editors conclude that: "Recognizing that no hormone-free drug product has been approved to treat vasomotor symptoms, and after careful review of the efficacy results, the FDA concluded that *Brisdelle* offers a clinically meaningful benefit for some menopausal women."

Clearly we have alot of work still to do.

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