

Statement of Karen M. Hicks, Ph.D.

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I am Dr. Karen Hicks, a sexual health educator and founder of the Dalkon Shield Information Network. I ask the FDA to delay approval of the Intrinsa patch until relevant safety issues have been fully reviewed and documented.

Drug safety issues and scrutiny of the FDA have dominated the news lately due to the Vioxx scandal and risks of antidepressants for children. Today, as you deliberate the dawn of a whole new class of sexual medicines for women, it is timely to consider some new precedents for considering the safety issues relevant to a drug like Intrinsa.

I raise four questions:

1. What is the safe dosage for individual variations among women who may be very different from women in the clinical trials, particularly with regard to ages, differing weight profiles, general health status and possibly ethnic backgrounds?
2. What is or isn't known about the long term use of this drug? In the clinical trials, subjects used Intrinsa for time ranges between 14 and 24 weeks, yet it is intended to be used continuously, over the long term and possibly for years.
3. What potential adverse reactions have been anticipated and what might likely unexpected outcomes be? Experience with testosterone in pill or injectable form and other reproductive hormones prescribed to women demonstrates cancers of the breast and other tissues, liver ailments, masculinization, excessive hair growth, skin inflammation and acne, to name a few side effects.
4. How will problems in prescribing and dispensing be prevented or minimized? Based on the excitement being generated in the press for this drug already, I predict that off-label use will soon follow.

This week's *Journal of the American Medical Association* has two relevant editorials. The first speaks to the weaknesses of the current postmarketing surveillance process. The second explores the potential for conflict of interest in the evaluation of suspected adverse drug reactions. The journal editors recommend that an independent entity located outside the FDA be given primary authority for this task. The Vioxx and the Dalkon Shield IUD scandals hinged on the long suppression of information on dangers they posed to their users.

I offer 5 recommendations for setting new precedents:

1. Admit full disclosure of the clinical trials to the public;
2. Initiate a user registry under the purview of the FDA to all users who volunteer to be kept informed;
3. Upload all documentation on efficacy and safety to the FDA website and announce the URL and telephone numbers on pharmacy patient package inserts and information sheets;
4. If warranted, contact all users early through pharmacy databases about discoveries of dangers relative to this drug's use;
5. Include label warnings about duration of use beyond the length of the clinical trials.

The public perception, reflected by substantial press coverage, already suggests that Intrinsic is "Viagra for women." I find this notion distorted and disturbing. This treatment is not equivalent in manner or duration of use. It acts on different body systems and has different effects.

Please consider these recommendations as you deliberate later today.