

Pink Viagra Race Renews Call for Rx Registry System

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Happy 10th Birthday, Viagra. You, Cialis and Levitra are a boon to many, but certainly not all men. Move over, boys! The race is on for female equivalents. The bucks are flowing in Big Pharma R&D departments to win FDA approval for assorted pills, patches and gels that will “cure” women’s sexual problems. Pharmaceutical PR money is also being spent prematurely to position newspaper and internet stories about these drugs before they’re even approved! It is not reassuring to read quotes from the doctors directing this research already boasting about the \$3 billion profit potential. Big Pharma critics, which include many authoritative physicians as well as consumer advocates, charge the industry with “disease mongering”—the fabrication of dubious medical diagnoses for many “quality of life” health concerns. Filling a prescription for real diseases and pathologies is a whole different decision-making process.

It is timely and prudent to set up a national registry for monitoring this new class of medicines for women. It is imperative to prevent the mistakes of the past that have resulted from quality of life medicines which caused grave adverse drug reactions (ADRs). We are all witnessing a litany of blockbuster drugs now linked to ADRs in men, women and children -- Vytorin, Vioxx, antidepressants, hormone replacement drugs, to name a few. Presently, we have an impotent post-surveillance marketing system at the FDA which fails consumers miserably. Additionally, Consumers Union just published the results of a survey which found that only 35 percent of survey participants were even aware that they could report negative side effects to the FDA. That organization is now calling for inclusion of the FDA’s Medwatch website in all pharmaceutical marketing.

I call for the bold and exemplary creation of a drug registry system for the entire class of new sexual medicines for women, to be set into motion before the first one gains FDA approval. Any woman being prescribed these sexual drugs should have full and detailed disclosure about their claimed benefits and all potential risks. An Internet-based registry system would allow users to register themselves (voluntarily, of course). The homepage of the system’s website would post regular public updates on the products and send news alerts to registry users. This registry’s website and toll-free telephone number would be printed in all of the company’s marketing materials, on every Rx label and in the pharmacy patient information pamphlets. Users could sign up voluntarily to complete questionnaires periodically that would ask them follow-up questions on effectiveness and safety of the products they use.

In 2004, Proctor & Gamble sought FDA approval for Intrinsa, the testosterone patch for boosting women’s sexual desire. In a surprising twist not seen often enough in the FDA

approval process, the FDA's advisory panel of experts rejected Intrinsa on the grounds that there was not sufficient safety data. Subjects in clinical trials for drugs like Intrinsa actually take the drug for less than one year. The next kid on the blockbuster trail is LibiGel, a testosterone gel that gets rubbed into the skin. It's now in clinical trials and is predicted to come before the FDA for approval within the next 2 years. Many other products are racing close behind.

Finally, this sexual medicine registry must be adequately funded and be operated independently of either the pharmaceutical industry or the FDA. A student of mine who now works for Genentech has just advised me about a socially responsible, ethically-motivated registry system that Genentech and some other biotech and pharmaceutical companies have adopted for tracking patients trying certain drugs for serious diseases. Registry models like Genentech's exist. If Big Pharma wants to regain some confidence from the public, they can hardly object to this consumer protection innovation. We have seen women in the past blindly following doctors' orders to take DES, Fen-Phen, the high-dose birth control, the Dalkon Shield, hormone replacement, etc., with little or no safety data to inform their decisions. We can learn from these mistakes. A consumer registry would be a step in the right direction.

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