

A National Consumer Registry of Pharmaceutical Products

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I recommend the establishment of a national consumer registry of all pharmaceutical products where any interested person can be notified of and receive updated information on pharmaceutical products. In June, The American Medical Association recommended a mandatory, comprehensive centralized clinical trials registry. In addition to improving clinical trial disclosures, pharmaceutical users need a better way to receive direct information on the pharmaceutical products they use.

The recent alarming news on health risks associated with Vioxx and antidepressant use in children dredge up the ghosts of too many other pharmaceutical blunders. Into this Hall of Shame, I invoke the early birth control pill, DES, thalidomide, the Dalkon Shield IUD, silicone breast implants and Fen-Phen, to name a few.

It's unconscionable for a drug company NOT to do serious long-term patient follow up and NOT to notify all users when risks and dangers become clear. It's also an egregious breach of the public trust for a company to suppress *any* knowledge of negative effects. In fact, it's a criminal matter and a reason to revoke a company's public charter to do business, in my opinion.

If you don't hear about or see some announcement of a drug's harm in the media, how do you find out that a drug you take is dangerous? The burden falls on consumers to know how to take the initiative for following up on their pharmaceutical usage. Manufacturers of toaster ovens and curling irons ask their customers to mail in a simple warranty postcard that they include in the products' packaging. What we put into our bodies to keep healthy or fight disease merits that, at a bare minimum.

In the 1970s, I was persuaded by slick advertising that the Dalkon Shield IUD was 100% safe and effective as a contraceptive. After grievous injury, I campaigned nationally against its manufacturer for its scandalous misconduct in suppressing, for many years, vital information to physicians and women on that product's danger. Hundreds of thousands of women sustained terrible injuries, including infertility and even death.

Ten years ago, in my book on the Dalkon Shield matter, I recommended the establishment of a comprehensive, national registry database system for all

pharmaceutical products. We urgently need a program of notification and corrective action for every pharmaceutical drug and device. This registry (and its Internet address) could be announced on the patient information sheets included with every prescription. Let persons who want to be notified register with the database. If we really want to, we can devise a system that balances privacy rights with protecting the public's health.

We can and must do better in preventing medical drugs and devices from causing unnecessary harm. The Food and Drug Administration (FDA) is the government agency responsible for approving drugs and protecting all consumers of medical drugs and devices. Yet, the FDA has a pathetic history of failing to take decisive action on dangerous drugs and devices. This week, two editorials in the New England Journal of Medicine heap blame on the FDA for failing to act sooner in the Vioxx matter. To make matters worse, Charles Grassley, a leading U.S. Senate Republican, disclosed in the press last week that FDA officials pressured an FDA safety official to keep quiet or to water down his findings that Vioxx could be dangerous to the heart.

This registry system must be developed and supervised by an agency that is independent of pharmaceutical and other corporate interests. I recommend the creation of a federal commission composed of distinguished medical consumer advocates, Consumers Union experts who have a long history with consumer goods recalls and testing, government health and safety officials and reputable medical personnel. This commission will work out the logistics of this registry system. And the pharmaceutical industry, with a tiny fraction of its enormous profits, must underwrite the costs of implementing and maintaining the registry in restoring some integrity to its responsibility to do no harm.

Karen Hicks, Ph.D., is the founder of the Dalkon Shield Information Network and author of Surviving the Dalkon Shield IUD: Women vs. the Pharmaceutical Industry. She has been teaching and lecturing on women's health issues at the college level in the Lehigh Valley for over 20 years. Her email is: karenhicks12@hotmail.com.