

Ask Your Pharmacist

Proper Testing By Pharmaceutical Companies Is Essential

As a pharmacist, the recent rash of drug recalls and warnings in the news overwhelms me. I wonder if the pharmaceutical companies, prior to FDA approval, conducted proper testing. I understand that the adverse, and sometimes fatal, side effects related to some of these medications could not be detected during early testing phases. A much smaller segment of the population is studied during these phases, and many adverse effects are not apparent until a drug has been on the market for many years and dispensed to greater numbers of patients. However, when physicians and their patients fail to report side effects, the risks increase for everyone.

In a new study, Harvard Medical School researchers called on the FDA to "consider raising its threshold for approving new drugs when safe, effective therapies already exist." The Harvard group calculated that a new drug has a one in five chance of causing death or serious injury due to unforeseen side effects.

In the early 1990s, Congress passed legislation designed to accelerate the approval process of drugs used to treat "serious or life-threatening" conditions. According to an investigation by the *Los Angeles Times*, seven drugs approved in the 1990s, but later withdrawn, are suspected of having caused 1002 deaths. Experts told the paper that the number of deaths and serious injuries might be much higher, because doctors are not required to report adverse drug reactions to the FDA.

One of the drugs withdrawn during that time period was Redux, which

was used for weight control. It was implicated in 123 deaths due to heart valve damage. It is estimated that American Home Products, Inc., the Redux marketer, will pay more than \$10 billion in damages. Rezulin, a diabetes drug, approved in 1997 and withdrawn in 2000, has been implicated in more than sixty deaths from liver failure and may be responsible for many more unreported deaths.



Ira Friedberg

The recent withdrawal of Vioxx, a popular medication used to treat arthritis and pain, has caused an uproar in the industry. Celebrex, a related drug, is under scrutiny. These drugs have been found to cause a greater risk of heart attack or stroke. Warnings have also been issued for Bextra, a sister drug to Vioxx and Celebrex. Naproxen (over-the-counter Aleve and prescription Naprosyn) has also been linked to heart attacks and strokes in a recent trial, even though it has been on the market for many years.

The FDA should require the pharmaceutical companies to collect more extensive data for new drug applications, including more stringent reporting of adverse reactions.

Please feel free to call me for information on any concerns you may have for possible side effects of your medications.

Ira Friedberg is a registered pharmacist and owner of Ira's Discount Pharmacy. They specialize in Old Tyme, Courteous, Efficient Service at Discount Prices. They are located in the Boca Ray Plaza, 4900 Linton Blvd., #21/22, Delray Beach, Fl. (across from Poppies). Call 561-455-0090 for more information or to call in or fax 561-455-0091 your prescription. (Free delivery is limited to local area.)



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in the equities basket.

Howard M. Rosenfield is an attorney specializing in arbitration and mediation for investors who have a dispute with their broker and/or brokerage firm. He is a member of the Public Investors Arbitration Bar Association (PIABA) and can be contacted by calling 1-800-637-3243.

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