

Pass legislation to force disclosure of drug info

Many consumers are still reeling from the recent run of frightening news about the safety of prescription drugs in the U.S.

The parents of children taking the antidepressant Paxil were stunned last year to learn not only that the medication was not effective in children but also that it may increase the risk of suicide in children and teenagers. In September, millions of Americans taking the arthritis-pain drug Vioxx saw it pulled from the market after its link to heart-attack risk was firmly established. A few months later came the news that Celebrex, the most widely prescribed arthritis-pain medication, raised similar concerns.

How can drugs approved by the federal government and heavily advertised sometimes do more harm than good?

The answer lies primarily in gaps in our nation's drug-safety system. Before new drugs are allowed on the market, pharmaceutical companies must test them on individuals for safety and effectiveness, and the information is submitted to the Food and Drug Administration. But after a drug is approved, neither the drug company nor the FDA is required to make details of clinical-trial results public; how the drug was tested, its effectiveness, and

information on possible side effects can remain hidden from the public for years.

This can lead to situations such as the one involving Paxil. GlaxoSmithKline, the maker of Paxil, had a study of the drug published in a psychiatry journal, but it referred to the increased suicide risk as mere emotional instability. Two other studies showing that the drug was ineffective were never published. Those three studies circulated at the FDA for close to a year and a half before the agency required that the strongest warning be placed on Paxil.

Reports show that the drugmaker Merck and the FDA were aware of the heart-attack risk of Vioxx for years; Merck changed the package-insert information but did not publicize the change.

Critics inside and outside the FDA say that after drugs are approved, the agency does not adequately monitor or effectively address subsequent safety problems. The public needs an independent, effective, and vigorous office to follow and act on ongoing studies, one that is not stymied or influenced by the office of drug approval.

The results of all clinical drug trials should be available to the public in an easily understandable format. Ensuring

what you can do

For more information on this issue and on Consumers Union's other efforts to make prescription drugs safe, effective, and affordable, go to our public-policy Web site at www.ConsumersUnion.org.

that consumers, doctors, and researchers know about possible safety problems will help ensure that drugmakers and the FDA quickly address any negative finding raised in a study. These drug trials should be registered as they begin, in a central, public location, perhaps on the Internet.

Pharmaceutical industry trade groups have said that they will voluntarily register and release results of some of their trials. But without a legal requirement for disclosure, the incentive to hide or downplay safety information is too great.

Consumers Union supported legislation last year in Congress that would require registration of clinical trials and make their results public. This session, there has been a renewed bipartisan call for these reforms, and we will work to ensure their passage. Look for updates on legislation and other drug-approval and safety developments in a future issue.

then & now tilling tools



In the summer of 1952, we first tested the wheel hoe and praised its simplicity. Priced at less than \$10, the wheel hoe was easier to handle than a garden tractor, required little storage space, and was ready on a moment's notice.

Mini-tillers, which we recently tested (see report on page 45), accomplish what the wheel hoe did but are equipped with a motor or engine, making easier work of deep digging for garden preparation. As with the other gas-powered tillers we tested, the top-ranked Honda Harmony (at right) provides power and mobility, but the engine is noisy. Between the noise and the recommended ear protection, gone are the sounds of birds chirping while you work.

