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On the Issues

Striking a Balance: Drug Labeling and the FDA

By John E. Calfee

Today's pharmaceutical warning labels contain little useful information for consumers; rather, they attempt to over-warn of every potential side effect so as to protect manufacturers from getting sued. A new Food and Drug Administration labeling rule could provide better information to consumers and prevent hyperactive litigation.

With the fourth Vioxx lawsuit currently under way, a fourth jury is in the thick of trying to determine whether Merck is indeed liable for any injuries that may or may not have arisen from the use of its blockbuster arthritis drug. The trials have highlighted bad tort bar science in all its dubious glory—from questionable pathology reports to seriously exaggerated claims about the dangers of Vioxx—but they also raise a deeper issue. Every drug presents patients and doctors with a trade-off between benefits and risks. But how can physicians and drug companies strike a balance in the age of a hyperactive litigation?

Last week, the Food and Drug Administration (FDA) weighed in on that question when it published a long-awaited rule to simplify drug labels. Up to now, extensive, cringe-inducing lists of every imaginable side effect of a medicine were a drug company's best hope of immunizing itself from lawsuits down the road. The FDA wants to simplify those impenetrable reams of fine print by preempting state-court lawsuits claiming that an FDA-approved label failed to warn patients of a potential danger.

The FDA's New Labeling System

To achieve that, the FDA's new label rule includes a preamble essentially asking the courts to assume that FDA-approved labels preempt state laws when patients sue drug manufacturers for "failure to warn." If the courts accede to the FDA (which they can still choose not to do), plaintiffs would not be able to claim that manufacturers should have included a warning that the FDA had decided not to require.

The new label regulations have been through years of rulemaking, and rumors of a preemption clause have been a fixture among FDA watchers and litigators. The FDA's legal staff has already argued several times in court proceedings that federal law preempts failure-to-warn suits against manufacturers of pharmaceuticals and medical devices, especially when the plaintiff tries to win damages for failing to include a warning that the FDA had reviewed and rejected or even outright prohibited. And yes, there have been such suits. Manufacturers of over-the-counter nicotine patches and gum were indicted for failing to warn about birth defects even though the FDA had specifically prohibited such a warning on the labels after it found no supporting evidence. Manufacturers of the antidepressant Paxil were charged with failing to warn about it being addictive, again despite an FDA finding to the contrary. As the FDA has explained over and over again, these extra warnings would ward off the very users who stand to benefit the most from using the products.

Plaintiff attorneys and their allies have already protested the new rule, and Democrats are ready

John E. Calfee (jcalfee@aei.org) is a resident scholar at AEI. A version of this article appeared in the *New York Sun* on January 30, 2006.

to introduce legislation to overturn it. Let's hope they lose. What the FDA wants to do would be very good for consumers.

Fixing Failure-to-Warn Shortcomings

The failure-to-warn standard is extraordinarily plastic. Forget the most important information, such as an established risk of serious side effects; that kind of information is practically always clear to physicians from FDA-approved labels. But almost all drugs, especially the most powerful and useful ones, involve a multitude of both beneficial and harmful effects, far more than can be definitively measured by the clinical trials that manufacturers and the FDA rely upon in developing and approving drugs. No matter how much a label says, there is always something else that could have been said, a side effect that could have been emphasized a bit more, a benefit that could have been downplayed, and so on more or less ad infinitum. When one patient suffers a particular adverse effect out of all the things that could have happened, a smart lawyer can easily conjure up a different and better label or a different communication to a physician that could have made a difference.

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This means that the potential number of failure-to-warn cases is well-nigh infinite. The only constraints are the attitudes that jurors carry into the courtroom and the artfulness of the lawyers. Now that the industry is under assault on counts ranging from pricing and profits to marketing and safety, jurors are a lot more likely to support a failure-to-warn claim than they were five or ten years ago, quite aside from any changes in drug safety itself. Until failure-to-warn abuse is reined in, we can expect a steady escalation in pharmaceutical litigation.

That means higher costs and fewer useful drugs. Worse, the drugs that get hit the hardest will be the ones we need the most: the risk-reducing innovations that attack otherwise intractable conditions. With all the news about Vioxx litigation, it is easy to forget that rheumatologists around the world welcomed this drug because some 20,000 people die annually in America alone from the side effects of older pain relievers that cause ulcers.

That is not all. Failure-to-warn litigation actually makes it harder, not easier, for patients to get good information. Try reading the ten or twenty or forty inches or so of fine print accompanying the typical drug ad in a newspaper or magazine. Why is there so much information, and why is it so obscure? It is there mainly to fend off failure-to-warn suits. The idea is to include a technical statement on just about every item someone could sue about, even to the extent of warning about things that happen just as often to patients taking a placebo as they do to patients taking the pill.

A recent ad in a medical journal for the antidepressant Effexor contains half a page touting Effexor as a way to "break the cycle of unresolved depression," accompanied by two pages of text comprising mainly three dense columns, each containing more than 100 lines of fine print. The ad ends with a mind-numbing list of perhaps 500 different adverse effects involving pulse rates, chills, fever, neck rigidity, neck pain, leukocytosis, cyanosis, edema, dehydration, hostility, euphoria, "feeling drunk," conjunctivitis, and on and on and on. If you are not depressed when you start reading the ad, you sure are by the time you finish reading.

This warn-about-everything strategy does not always work, of course. Lawyers can always argue that one paragraph got too much emphasis and another, too little. But industry lawyers think these elaborate over-warnings provide better protection against litigation than more concise and readable warnings. It is no coincidence that the same rule that simplifies labels also asks the courts to defer to FDA warnings. The new liability environment that the FDA is trying to create will make it easier for pharmaceutical firms to implement new and better labels, bringing better informed physicians, smarter patients, and ultimately, better treatments.