FDA gives new form to inserts

The pharmaceutical safety sheets will be easier to understand. New rules also try to limit liability of drug firms.

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After five years of rewriting, regulators last week unveiled a new look for those feathery paper safety sheets accompanying prescription drugs.

Gone will be the turgid prose and arcane diagrams, replaced by easier-to-read information for patients and physicians on how to use a medicine safely. Clinical information will upstage legal disclaimers. There will be phone numbers and Web sites for getting more information.

But one change doesn't appear in the small print at all, with potential benefit for drugmakers, to the chagrin of consumer advocates and plaintiff lawyers.

In a preamble to its rule on the inserts, the U.S. Food and Drug Administration asserted that makers of FDA-approved drugs should enjoy immunity from certain product-liability and false-claims lawsuits in state courts. The statement codifies a principle that the FDA, until now, espoused only in friend-of-the-court briefs in individual cases.

Critics and supporters of the new rule agreed that the package inserts generally are read about as closely as VCR instructions.

They say the new format, overall, will make the information more readable. It even may help restore the inserts' original purpose: informing physicians and patients about safety and proper use of a medication.

"The package insert has become mostly a legal document, realistically, more than a medical document," said Brian Strom, chairman of biostatistics and epidemiology at the University of Pennsylvania Medical School. "If the rule corrects that and makes it more medically useful, it could be a very big contribution."

Regulators proposed the changes five years ago after realizing drug companies increasingly were using the package inserts as liability shields and marketing tools, rather than as medical information for physicians.

Susan Bro, an FDA spokeswoman, said company information about "speculative risks, theoretical risks" of drugs "had begun to take over the label" as companies sought ways to disclaim responsibility for possible legal action down the road.

The new package insert will not allow such unconfirmed information, the FDA said.

The FDA also created a "highlights" section at the top to summarize key items in the full insert.

Pharmaceutical lobbyists opposed the "highlights," fearing a patient who later sues a company may be able to claim he or she never saw a warning because it didn't appear in the highlights.

In response, the FDA inserted the strong preamble language asserting its expertise and authority "preempts" anything that a state legislature or court may come up with - essentially a form of immunity for drugmakers on certain claims in state courts.

Tort lawsuits, including product-liability and failure-to-warn cases, cost U.S. health-care companies an estimated $50 billion a year, said Jim Copland, director of the Center for Legal Policy at the nonprofit Manhattan Institute, a think tank. His estimate could not be verified.

"If you can wipe out half the claims, you can wipe out half the cost," Copland said.

Copland and former FDA chief counsel Dan Troy, now at the Washington law firm Sidley Austin L.L.P., predicted drug companies quickly will look for ways to incorporate the FDA language into their defenses.

At least one corporation, Merck & Co. Inc., which is fighting thousands of personal-injury lawsuits over the recalled pain-reliever Vioxx, welcomed the FDA statement but declined to elaborate on its strategy, said a spokesman for Hughes Hubbard & Reed L.L.P., one of Merck's law firms.

Some consumer advocates and plaintiff lawyers who handle pharmaceutical litigation called the FDA action a giveaway to corporations at consumers' expense.

Tom Kline, a plaintiff attorney from Philadelphia-based Kline & Specter P.C., blasted the FDA but predicted plaintiffs will succeed in "shooting down" the industry's new arguments before state judges.

In a separate change, the FDA also tweaked the type of clinical-trial information that drugmakers may include or exclude from the insert. Those changes, in turn, may affect things drug companies and their sales representatives say about a drug - both positive and negative - in sales pitches, medical conferences and advertisements.

For example, a drug insert now can include reliable clinical-trial data on "unapproved doses" of a drug, though the company cannot market the drug in that dosage. It also may include data on economic or"quality of life" effects of using the drug, as long as the data are grounded in test results.

Bro, the FDA spokeswoman, said the goal was to better inform physicians about all aspects of a drug.

Scott Lassman, assistant general counsel at the industry lobby group, Pharmaceutical Research and Manufacturers of America, called most of those changes minor and doubted they would lead to changes in conduct of sales representatives.