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# THE WALL STREET JOURNAL.



VOL. CCXLVII NO. 11 $1.50 - ★★★★ WEEKEND EDITION SATURDAY/SUNDAY, JANUARY 14 - 15, 2006 WSJ.com

# FDA Plan Would Aid Drug Makers In Liability Suits

*Agency's Approved Labels Would Pre-empt State Law; Plaintiffs' Lawyers Object*

By Anna Wilde Mathews

The Food and Drug Administration is preparing to declare that federally approved medication labels pre-empt state law, a move that could strengthen pharmaceutical makers' defenses against lawsuits claiming injury by the companies' products.

The policy could help companies argue they weren't required to warn consumers about a potential risk when the FDA had determined that the safety issue didn't warrant inclusion on a medicine's label. The new policy, which would address state liability statutes, has been written into a broad new drug-labeling rule that is likely to be issued shortly, according to people with knowledge of the matter, though the rule has been repeatedly delayed.

Product-liability suits have become a huge problem for drug makers. In one of the more high-profile cases lately, Merck & Co. faces dozens of lawsuits across the country over its withdrawn painkiller Vioxx. Merck pulled that hugely popular drug from the market in 2004 following a study that linked the drug to an increased risk of heart attacks and strokes in patients taking it for 18 months or longer. Merck and other companies have often struggled to explain the scientific nuances of their drug-safety defenses to juries. As yet, it isn't clear whether the new FDA policy would affect the Merck cases.

Kent Jarrell, a spokesperson for Merck, said, "We really can't get into discussing language of a proposed rule that we have not seen." A spokesman for

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drug maker Pfizer Inc. declined to comment.

Plaintiffs' lawyers, however, oppose the policy. "If the proposed changes were to be enacted, drug-product safety in the U.S. would suffer a major setback at a time when the conduct of pharmaceutical companies and the FDA have been called into question," said Thomas R. Kline, a plaintiffs' attorney with Kline & Specter and a key player in Vioxx litigation.

The controversial policy has been written into the preamble of an important FDA rule that is supposed to reform how drugs are labeled, according to people with knowledge of the matter. It could still be toned down or even removed before the rule becomes public, though it has already survived years of internal debate. The FDA has asserted similar arguments in briefs filed in legal cases, but the federal rule would be broader and likely have more impact on individual judges' decisions. Courts may still choose to reject the reasoning, however.

The policy would mesh with the White House's focus on tort reform. Indeed, other federal agencies have made similar moves toward helping to shield businesses from certain forms of legal action. The National Highway Traffic Safety Administration last August proposed a new rule on car-roof strength that would grant legal protection to car makers that adhere to the safety standard. The U.S. Office of the Comptroller of the Currency issued a sweeping regulation in early 2004 that said federal banking laws take precedence over a number of state consumer-protection statutes when applied to national banks. The agency challenged an investigation of potentially discriminatory lending practices by New York Attorney General Elliot Spitzer, arguing that his probe impinged on federal enforcement turf.

Inclusion of the new FDA policy in the long-awaited drug-labeling rule has sparked disagreements between FDA career officials and Bush administration appointees, according to people with knowledge of the matter. Some FDA career staffers have argued internally that it isn't relevant to the rule's focus on drug-labeling reform, and may draw controversy to an important regulatory improvement that isn't itself politically divisive. In addition, career officials believe debate over the matter has helped delay the labeling change from taking effect.

The new rule is expected to specify circumstances under which the legal shield would apply, though it may not limit the protections solely to those situations, according to people with knowledge of the matter. The drug company must have provided all its data to the FDA, these people said.

The drug-labeling rule's language pertaining to the new policy is likely to contribute to the growing clash over the proper bounds of state and federal regulatory authority. Big companies have long fought patchworks of laws that differ from state to state, and federal efforts to assert authority in various regulatory areas have drawn testy responses from state officials.

In the case of the new FDA rule, states argue that they weren't adequately informed that it was coming. Yesterday, the National Conference of State Legislatures protested the move in a letter to Health and Human Services Secretary Michael Leavitt, calling it a "thinly-veiled attempt on the part of FDA to confer upon itself authority it does not have by statute" and an "abuse of agency process."

Past FDA briefs arguing that agency guidelines pre-empt state law haven't always been accepted by courts. Last July, a federal judge in Minnesota turned down a Pfizer request to bar a suit over the antidepressant Zoloft, writing that "federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability. ... state-law protections reinforce and enhance" federal efforts to protect the public.

Defenders of the FDA's pre-emption briefs have argued that they simply articulate a stance that is implicit in federal law. If state lawmakers and courts can second-guess the FDA, some drug-industry officials say, it could lead to a morass of conflicting rules and undermine the decisions of the government's most qualified experts. "You want the FDA to have the last word if you believe in the FDA's expertise," said Daniel Troy, the former FDA chief counsel who filed several of the briefs and who represents industry clients in private practice.

The new drug-labeling rule, a major regulation that has been in development for years, will update the format of the FDA-approved documents that provide the definitive account of each medicine's uses and risks. They can stretch for dozens of pages, and even doctors often find them difficult to navigate. The new layout is expected to clarify the most important information at the top of the label in a standardized "facts box" format. It is the centerpiece of a broader FDA initiative to make drug information more accessible.

*—Heather Won Tesoriero and Barbara Martinez contributed to this article.*