FDA Tries to Limit Drug Suits in State Courts

Agency's 'Federal Preemption' Policy Included in Labeling Guidelines for Medications

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People who believe they were injured by drugs approved by the Food and Drug Administration should not be allowed to sue drug companies in state courts, the agency said yesterday in a formal policy statement.

The FDA's controversial assertion of "federal preemption" was included as a preamble to long-awaited guidelines designed to make drug labeling information more accessible and readable for doctors and consumers. Agency officials said that though the preemption policy does not have the weight of law or formal regulation, they hope state judges will accept their position.

"We think that if your company complies with the FDA processes, if you bring forward the benefits and risks of your drug, and let your information be judged through a process with highly trained scientists, you should not be second-guessed by state courts that don't have the same scientific knowledge," said Scott Gottlieb, the FDA's deputy commissioner for medical and scientific affairs.

The new labeling rules require drugmakers to highlight the most important advisory information in the "package insert" issued with every prescription and to cut back on the often-technical legal language that officials said is included more to protect drugmakers from lawsuits than to inform doctors and patients. Gottlieb said drug industry officials convinced the agency that they deserved more broadly stated FDA support because the new, more streamlined labeling would make them more vulnerable to lawsuits.

While the new labeling guidelines were widely applauded yesterday, the claim of federal preemption was quickly attacked by trial lawyers and members of Congress as another effort by the Bush administration to limit the public's ability to bring and win lawsuits.

Without state product liability laws, the critics said, drug companies could escape responsibility for injuries and deaths caused by drugs such as Merck & Co.'s Vioxx, which an FDA medical officer estimated had killed as many as 55,000 Americans.

"Eliminating the rights of individuals to hold negligent drug companies accountable puts patients in even more danger than they already are in from drug company executives that put profits before safety," said Ken Suggs, president of the Association of Trial Lawyers of America.

"The fact that the drug industry can get the FDA to rewrite the rules so that CEOs can escape accountability for putting dangerous and deadly drugs on the market is the scariest example yet of how much control these big corporations have over our political process," he said.

Anticipating that the FDA would make the preemption claim, the National Conference of State Legislatures, a bipartisan group that represents state legislators, said last week that the agency was seizing authority that it did not have. Yesterday, Sen. Edward M. Kennedy (D-Mass.) expanded on that criticism.

"It's a typical abuse by the Bush Administration -- take a regulation to improve the information that doctors and patients receive about prescription drugs and turn it into a protection against liability for the drug industry," he said in a statement.

The Bush administration has intervened in a number of state liability cases against drug and medical device manufacturers with friend-of-the-court briefs supporting the companies. Yesterday's policy statement was just a way to make the same points on a broad and general basis, Gottlieb said.

The drug labeling guidelines were first proposed as a new regulation in December 2000 and have been subject to years of debate and public hearings. The new guidelines -- which will go into effect on June 30 -- were announced yesterday by Surgeon General Richard H. Carmona and top FDA officials, who called them a major public health advance.

"Americans are overwhelmed with the complexity of health information. We have hit a point of information overload, and the public health message is being diluted," Carmona said. "This is of great concern when it comes to making sure a patient knows how to use prescription drugs safely and effectively. This problem is compounded by prescription medication information that reads more like legal disclaimers than useful or actionable health information."

The new labeling -- the first revision of its kind in 25 years -- is required for all new drugs that come on the market and those approved in the past five years. Officials said the new "highlights" section and a table of contents that organizes the information will help avoid some of the estimated 300,000 preventable drug-related complications reported in hospitals, many of which are the results of confusing medical information.

Although the new labeling will make it easier for doctors to digest information about the drugs they prescribe, consumers may not find it much more accessible. The patient information leaflets written in laymen's language that patients receive with their prescriptions are commercially produced and not approved or scrutinized by the FDA.

Sidney Wolfe, director of Public Citizen's Health Research Group, said patients should get the new, FDA-approved labeling information as well.

"It is time to end the double standard where doctors and other health professionals are informed by FDA-approved labeling, but patients are treated like second-class citizens, receiving whatever the out-of-control purveyors of patient information leaflets choose to dispense," he said.