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Justices Lay Out Failure To Warn 'Clear Evidence' Standard

By **Emily Field**

Law360 (May 21, 2019, 4:13 PM EDT) -- The U.S. Supreme Court's decision this week that it's up to a judge — not a jury — to decide if consumers' claims are barred by federal regulations when the U.S. Food and Drug Administration rejects a proposed labeling change has also provided some clarity for the "clear evidence" standard it set out for failure-to-warn cases a decade ago.

In a case over the fracture risks in Merck's osteoporosis drug Fosamax, the court unanimously found that "clear evidence" means there's evidence showing a drugmaker fully informed the FDA of the reasons for the label change and the FDA in turn rejected the change. The justices also said that a judge is "better equipped" to decide the question of whether failure to warn claims are preempted when a federal agency doesn't approve a warning.

Monday's ruling fleshes out the standard the high court set out in its 2009 decision in Wyeth v. Levine, which held that a state law failure to warn claim is barred by federal law if there's clear evidence that the FDA wouldn't have approved a labeling change.

What the high court meant by "clear evidence" has been a source of conflict in the decade since the Supreme Court's ruling as courts have tried to figure out what it meant, according to Max Kennerly of Kennerly Loutey LLC.

Now the high court has defined it narrowly to circumstances where the FDA has been fully informed and still said no.

This means that drug companies can't argue that they've had informal communications with the FDA and that the agency implied they wouldn't approve a labeling change, according to Kennerly.

"A drug company can't speculate about circumstances that might create preemption or trying to guess the FDA's intent," Kennerly said.

The decision was "a signal that Levine was unclear," said Michelle Bufano of Patterson Belknap Webb & Tyler LLP.

The high court in the ruling instructed the Third Circuit to decide if the claims brought by more than 500 patients who took Fosamax before a warning of atypical femoral fractures was added in 2011 are preempted.

The Third Circuit had revived the claims that Merck failed to warn of painful leg fractures associated with the drug in 2017 when it found that a jury must decide if the FDA would have blocked the warning.

A reasonable jury could conclude that a revised warning with different wording would have been accepted by the FDA, the Third Circuit said at the time.

But Monday's ruling sends a message that the Third Circuit was "wildly off base" in holding that a jury could decide the issue, Mayer Brown LLP partner Andrew Tauber said, noting that the opinion was unanimous and that even the justices less sympathetic to manufacturers found no merit in the panel's view.

"The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute," the high court said. "Moreover, judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination."

In adopting a rule that judges will decide this issue, cases will be resolved more quickly and without costly jury trials, Tauber said. And how preemption defenses are resolved will also become more predictable.

"Juries are notoriously unpredictable in how they reach a result and the results they ultimately reach," Tauber said.

The decision is in line with the high court's ruling in Daubert v. Merrell Dow Pharmaceuticals, which tasked courts with the role of "gatekeeper" of science, Bufano noted.

"If a jury is not equipped to distinguish legitimate science from junk science, it is hard to understand how it could or should supplant the scientific expertise of the FDA," Bufano said.

While the high court clarified the "clear evidence" standard, attorneys also noted that it didn't require companies to show more evidence in defending failure to warn claims.

"After Wyeth, plaintiffs certainly tried to take that language and suggest that it imposed a heightened burden on manufacturer defendants attempting to establish the preemption defense," Tauber said.

"The decision makes clear that it is not a heightened evidentiary burden, and that they merely need to persuade, under the normal rules, to a judge that in fact that the FDA would have rejected the warning that the plaintiff's claim is required by state law."

--Editing by Rebecca Flanagan and Kelly Duncan.