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High Court Snub To Teva Labeling Case Puts Focus On FDA

By **Sindhu Sundar**

Law360, New York (January 20, 2015, 9:45 PM ET) -- The U.S. Supreme Court's decision Tuesday not to review a challenge by generics makers including Teva Pharmaceuticals USA Inc. to failure-to-update labeling claims effectively puts the future of such suits in the hands of the U.S. Food and Drug Administration, which is considering a plan to allow generics makers to update labels, attorneys say.

The high court **denied a certiorari petition** by Teva, which had urged it to review an **interlocutory decision** by the California Court of Appeal that plaintiff Olga Pickerie's state law failure-to-update claims were not preempted by federal regulation. The denial followed an amicus brief **filed in the case last month** by U.S. Solicitor General Donald B. Verrilli, who encouraged the court not to weigh in this time, in part pointing to FDA regulations expected this fall that could help address the issue.

The agency is expected to finalize a proposal to require generic-drug makers to update their warning labels according to the latest available safety information, independently of branded-drug makers. The rule would represent a profound shift for generics makers, which have enjoyed federal preemption of a range of consumer injury claims against them because their products are required to hew to the formulation and labeling of their branded counterparts.

If finalized, the rule could make the companies liable for injuries if they fail to warn of their drugs' risks.

"I would not read too much into the denial — the government essentially said 'Wait and see. This is not the right time,'" said Mark Cheffo, the global co-head of Quinn Emanuel Urquhart & Sullivan LLP's product liability and mass tort practice. "The solicitor general, representing the FDA's view, is saying for one that there is current regulatory action to address the issue of generics makers' ability to update labels."

The question of whether generics makers can be held liable for failing to update warnings to match changes on brand-name versions has been a divisive one in pharmaceutical injury litigation, reflected by a split in federal and state appellate courts.

Plaintiffs argue that the Supreme Court's landmark Pliva v. Mensing decision does not foreclose claims involving a generics company's failure to update its labels to match changes on their branded counterparts.

The U.S. Supreme Court's 2011 decision in Mensing held that federal law preempts state-law tort claims against generic-drug manufacturers that have to use the same warning labels as brand-name companies. But some courts, notably the Iowa Supreme Court, hold that Mensing **does not necessarily shut out** all claims against generics makers.

The Iowa high court instead ruled that a generic-drug maker could still be held liable to the extent that it failed to adopt an updated warning that the FDA had approved.

Defendants argue that federal requirements to follow branded-drug makers tie the hands of generics makers and that the Food Drug and Cosmetic Act precludes such injury claims.

But plaintiffs attorneys counter that the solicitor general's own brief last month discredits this view, saying that it indicates that the FDA does not necessarily find failure-to-update claims to be in conflict with the FDCA.

In the brief, the solicitor general pointed to the FDA's limited resources to oversee the 11,000 drugs on the market and argued that such failure-to-warn suits "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug-labeling at all times."

"The Supreme Court's denial gives greater credence to what the solicitor general said," said plaintiffs attorney Bill Curtis of the Curtis Law Group. "Generics companies would like the world to believe that they don't have any duty to update the label, and that even if they do, they can't send the updated information to anyone, and that's not true. And in many cases, the generics companies are the only ones still making the drug, which makes it even more critical that their labels are accurate."

The FDA proposed the controversial rule in 2012. The agency was expected to finalize it in December 2014 but then changed its projected date to September 2015. Amid a lack of consensus among courts about whether Mensing forecloses such failure-to-warn claims, attorneys say that the FDA regulation could offer more clarity.

Lou Bograd, senior litigation counsel at the Center for Constitutional Litigation, referenced the high court's landmark 2009 ruling in Wyeth v. Levine, in which it found that the FDA's approval of a drug label did not preempt state failure-to-warn claims.

"Obviously, this is an issue that could be rendered moot when the FDA gets to finalizing its generic-drug regulations," he said, "moving it to the same world that branded drugs are in after Wyeth v. Levine."

--Editing by Jeremy Barker and Brian Baresch.