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NJ Reglan Ruling Widens Generic Label Preemption Split

By **Emily Field**

Law360, New York (August 22, 2016, 11:12 PM ET) -- The New Jersey Supreme Court's ruling on Monday that state law claims alleging generic-drug manufacturers didn't adequately warn of neurological risks for Reglan aren't preempted by federal law widens an emerging split between appellate courts on the issue that may require the U.S. Supreme Court's resolution, attorneys say.

The New Jersey high court ruled that in order for generic-drug manufacturers to find a safe harbor from state law failure-to-warn claims in the Food Drug and Cosmetic Act's sameness requirement that a drug's labeling must match its brand-name counterpart, they must be reasonably diligent to monitor for updates to the brand-name maker's labeling.

In affirming a lower court's decision to let consumers continue with their claims that generic-drug makers tarried in changing their labels for metoclopramide products, the state high court took a different tack than the Fifth Circuit in a similar case three years ago.

In that 2013 decision, a Fifth Circuit panel decided not to revive failure-to-warn claims against generic makers, finding that they didn't have a duty to warn about the health risks of Reglan because brand-name manufacturers didn't take action. Similarly, the Sixth Circuit in the same year also ruled that such claims against generic-drug makers over Reglan labeling were preempted.

However, another state high court, this one in Pennsylvania, ruled in 2014 that state law claims over generic Reglan labels weren't necessarily preempted. And last year, the U.S. Supreme Court denied three petitions by drugmakers to review the ruling.

"This could mean that at some point, the U.S. Supreme Court is going to need to resolve the split," Peter Goss of Blackwell Burke said.

The New Jersey case centers on a label warning that the U.S. Food and Drug Administration approved for Reglan in July 2004 that advised therapy should not last beyond 12 weeks, as well as a related "black box warning" that treatment with metoclopramide can cause tardive dyskinesia, which the regulator approved in 2009.

Hundreds of consumers in the multicounty litigation have accused the generic Reglan makers of delaying label updates that would adequately warn of the risk of tardive dyskinesia, a neurological disorder characterized by involuntary, repetitive body movements.

The New Jersey high court's ruling put the onus on generic manufacturers to look out for the FDA's brand-name labeling updates, attorneys noted, whereas the circuit rulings stated that the generic company's duty to update labels is triggered once the brand-name manufacturer changes its label.

"The two different applications make it difficult for generics to act uniformly," said Daniel Eichhorn of Cullen and Dykman. "It would make sense for the Supreme Court to make a decision that uniformly unites the issue."

In its ruling, the New Jersey high court rejected an argument by the drug companies — which include Pliva Inc., Actavis Elizabeth LLC and Teva Pharmaceuticals USA Inc. — that the U.S. Supreme Court's landmark Pliva v. Mensing decision backed finding that the consumers' claims were preempted by the FDCA. The country's high court found that under federal law, generic-drug makers must provide the same warning labels as those provided by the brand-name manufacturer.

However, the New Jersey high court said that decision didn't directly address the instant issue, as the generic makers in this case didn't comply with the FDCA sameness requirement — whereas in the high court case, the manufacturers did — meaning the consumer claims are not preempted by the federal law.

"I think [the courts] are troubled by the fact that people who take generics have really no remedy if they experience these serious side effects after Mensing," said Steven Casey of Jones Walker.

While the opinion doesn't set a time limit for generics to update their labels, it does indicate that companies don't have a long period of time to act, attorneys noted. According to the ruling, the drug companies took from six months to a year and a half to change their labels after the FDA approved stronger warnings in 2004, implying that the generic makers in the instant case have about the same timeframe to update the labels.

"What this decision provides is a pretty short window — no more than a month or six weeks — to detect the label change and adopt it," Goss said.

Given the logistics and difficulties of changing product labels, this places a significant burden on companies, according to experts.

"[Changing labels] takes a while, and it can't just be done overnight," Casey said.

While the ruling is a blow to generic-drug manufacturers, the consumers also face hurdles in the litigation ahead.

The 2004 label update was relatively small as it changed from saying that using Reglan beyond 12 weeks hadn't been evaluated and therefore couldn't be recommended to warning that Reglan shouldn't be used after 12 weeks, according to Susan Burnett of Bowman and Brooke LLP.

The consumers will have to show that this minor change would have caused doctors to hold off from prescribing the drug for more than 12 weeks in order to show proximate cause, Burnett said.

And even before the 2004 change, the label on Reglan still warned against the risk of developing tardive dyskinesia "very, very well," Casey said.

Also, the consumers still have to see if they can win one of these cases in front of a jury.

“It’s not the end of the ball game — [the drugmakers have] lost battle but not lost the war,” Burnett said.

The generics manufacturers are represented by Kirkland & Ellis LLP, Ulmer & Berne LLP, Goldberg Segalla LLP, McElroy Deutsch Mulvaney & Carpenter LLP, Harris Beach PLLC, Goodwin Procter LLP and Archer & Greiner PC.

The consumers are represented by Louis M. Bograd of Motley Rice LLC and Theodore Oshman and Jason L. Pullman of Oshman & Mirisola LLP.

The case is In re: Reglan Litigation, case number 075269, in the Supreme Court of the State of New Jersey.

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Bowman and Brooke LLP