CARLTON FIELDS

A Double Play for Prescription Drug Manufacturers in the Eleventh Circuit

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Consistent with the U.S. Supreme Court's opinion in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Eleventh Circuit recently held that generic prescription drug manufacturers cannot be held liable under state-law failure to warn claims because those claims are preempted by federal law. *Guarino v. Wyeth, LLC, et al.*, No. 12-13263, slip op. at 6 (11th Cir. June 25, 2013). The plaintiff in *Guarino* was prescribed metoclopramide, a drug sold under the brand name Reglan, to treat her abdominal pain and digestive problems. *Id.* at 2. For four months she took a generic form of the drug, manufactured by Teva Pharmaceuticals, which she claims caused her to develop tardive dyskinesia.*Id.* at 3. The FDA had previously changed the label to explicitly provide that "[t]herapy should not exceed 12 weeks in duration" and two years after she took the drug the FDA ordered a black box warning cautioning against taking the medication for more than 12 weeks. *Id.* She sued Teva, as well as brand-name manufacturers Wyeth and Schwarz Pharma, under various liability theories, the basis for which was an alleged failure by the defendants to adequately warn medical providers of the risks associated with long-term use. *Guarino* at 6. The trial court dismissed her claims shortly after the Supreme Court held in *Mensing* that state-law failure to warn claims against generic manufacturers are preempted because the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399f, mandates that generic manufacturers label their drugs the same as brand-drug manufacturers. On appeal, the *Guarino* plaintiff argued that her negligence claim was "not preempted insofar as it alleges a 'failure to communicate' the label change to medical providers." *Id.* at 4. The Eleventh Circuit affirmed and held (in sum): Guarino's attempt

to elude *Mensing* by clothing her allegations as 'failure-to-communicate' claims rather than failure-to-warn claims does not alter our analysis. No matter the garb in which she attempts to present them, Guarino's claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing*'s grasp . . . . Were we to accept the failure-to-communicate theory, generic manufacturers such as Teva would need to take affirmative action to notify consumers, doctors, or pharmacists of FDA-approved changes to the drug label in order to avoid liability . . . . If generic-drug manufacturers, but not the brand-name manufacturer, sent additional communications such as "Dear Doctor" letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading. That fact is determinative here. *Id.* at 7-8. The brand-name manufacturers prevailed as well, as the Eleventh Circuit also affirmed the trial court's summary judgment in their favor and, consistent with existing Florida law, held that brand-name prescription drug manufacturers cannot be held liable for injuries suffered by consumers who ingested only the generic form of their drug. *Id.* at 15. *Originally published by the ABA Section of Litigation.*

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