ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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Pennsylvania Supreme Court Allows Negligent Design and Marketing Claims Against Drug Manufacturer to Proceed

In *Lance v. Wyeth*, --- A.3d ---, 2014 WL 260309 (Pa. Jan. 21, 2014), the Pennsylvania Supreme Court ruled that pharmaceutical companies can be held liable for negligence in the design and marketing of drugs.

In *Lance*, plaintiff alleged that her daughter's use of Wyeth's now-withdrawn diet drug Redux caused her death from primary pulmonary hypertension. *Id*. at *1. Plaintiff's central claim was that it was unreasonable for Wyeth to market Redux or fail to remove it from the market sooner given the product's risk profile. *Id*. at *2. The trial court granted Wyeth's motion for summary judgment, holding that plaintiff could not bring negligent design defect claims over a drug that had been properly tested, labeled and approved by the Food and Drug Administration (FDA). *Id*. at *3. On appeal, a three-judge panel of the Superior Court affirmed dismissal of plaintiff's claims that the manufacturer was negligent in marketing the drug and in its failure to take the drug off the market, but concluded that she could bring a claim of negligent design defect. *Id*. at *3-4.

On appeal to the Pennsylvania Supreme Court, Wyeth argued that Pennsylvania law did not recognize negligent design claims. *Id*. at *5-7. Wyeth also maintained that the Superior Court should have deferred to FDA's regulatory authority, noting that FDA had determined that the drug's benefits outweighed its risks when it approved the drug. *Id*. at *8. The Supreme Court upheld the Superior Court's ruling that plaintiff's negligent design claims could move forward, and reversed the trial court's findings on the subject of negligent marketing claims. The Court held that drug manufacturers can face liability for "a lack of due care result[ing] in the dissemination of a product which is not apparently useful or desirable, but rather, is effectively useless and dangerous." *Id*. at *13. Further, the Court stated that "a manufacturer or supplier has a duty to cease further distribution of a product at such point as it may know, or may reasonably be charged with knowledge that the commodity is too dangerous to be used by anyone." *Id*. at *19.

The *Lance* decision is more limited than it might seem from some of the broad language used. The Court acknowledged that the ability to assert a negligent design claim would be more difficult where a drug "maintained its FDA approval, it remained on the market, and U.S. doctors continued to prescribe it," *id*. at *18 n.33, and declined to address that situation. The Court may have been referring to the additional preemption hurdles in such cases and to the United States Supreme Court's rejection in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013) of "duty not to sell" theories of liability.

Louisiana Supreme Court Strikes Medicaid Fraud Risperdal Verdict: A Narrowing of State AG's Expansive Interpretation

On January 28, 2014, the Louisiana Supreme Court in *Caldwell ex rel. State v. Janssen Pharmaceutical, Inc.*, -

-- So.3d ---, 2014 WL 341038 (La. Jan. 28, 2014), reversed a trial court judgment of US$257,679,000 in civil penalties, US$70,000,000 in attorney fees and US$3,000,200 in costs and expenses, and granted judgment in favor of Defendants Janssen Pharmaceutical, Inc. and its parent company Johnson & Johnson, Inc.

In *Janssen*, Louisiana alleged that statements contained in a letter sent by defendants to doctors regarding a class-wide FDA warning failed to adequately characterize the risks associated with Risperdal® and violated certain provisions of Louisiana's Medical Assistance Programs Integrity Law (MAPIL), La. Rev. Stat. §§ 46:437.1, *et seq*. The trial court and intermediate appellate court ruled that to prove a claim under MAPIL, Louisiana need not prove that a false or fraudulent claim was actually submitted to Louisiana's Medicaid program, and that proof of false, misleading, misrepresentative or deceitful statements in general was sufficient to justify an award of civil penalties. *Caldwell ex rel. State v. Janssen Pharm., Inc.*, 100 So 3d 865, 876 (La. App. 2012). The trial court verdict thus represented an award of penalties for each letter sent to Louisiana doctors, despite plaintiff never introducing evidence that the State had overpaid for any Risperdal® prescription as a result of the letter.

The Louisiana Supreme Court reversed the trial court's and intermediate appellate court's sweeping interpretation of MAPIL, and held that evidence of actual false claims are required. The Court further held that the trial record was insufficient to find liability under MAPIL because the State provided no evidence that defendants presented any actual false claim for payment to the Louisiana Medicaid program. *Janssen*, 2014 WL 341038, at *12. Key to the Supreme Court's ruling was the statutory definition of a "false or fraudulent claim," which the Court observed required that a person must have "knowingly caused a health care provider or its billing agent to present a claim for payment the health care provider or its billing agent knew to be false or misleading." *Id*. at *8. In other words, the Court held, a false claim requires that the physician submitting the request to Medicaid for reimbursement *know* that the claim was untruthful or misleading. Plaintiff had failed to show that any doctor knowingly submitted such a claim.

In addition to announcing a narrower reading of MAPIL than the Louisiana attorney general had urged, this decision could potentially persuade other state courts to interpret their Medicaid fraud statutes in a similar fashion. We note that plaintiff has sought reconsideration of the decision, and that motion remains pending.

An in-depth advisory on *Janssen* published by Arnold & Porter attorneys is available here.

Putative Class Action Against Manufacturer For Allegedly Overcharging For Product By Packaging More Product Than Required Barred by Preemption

In *Thompson v. Allergan USA, Inc.*, --- F. Supp. 2d ---, 2014 WL 308794 (E.D. Mo. Jan. 28, 2014), the United States District Court for the Eastern District of Missouri held that federal law preempted claims against a drug manufacturer for allegedly "overfilling" vials of eye drop prescription medication.

In *Thompson*, plaintiff brought a putative class action for violations of the Missouri Merchandising Practices Act (MMPA) and for unjust enrichment against the manufacturers of eye drops alleging that that defendants "excessively overfill[ed]" single-use eye drop vials with more liquid than the recommended dosage. *Id*. at *1. Plaintiff claimed that by overfilling the vials, defendants made the eye drops more expensive and forced consumers to purchase more eye drops than a consumer could use under the dosage instructions. *Id*.

Applying the reasoning in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), and *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 133 S. Ct. 2466 (2013), the court found plaintiff's state law claims were preempted under federal law because defendants were unable to independently lower the volume of eye drops in each vial under an FDA regulation forbidding "qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Thompson*, 2014 WL 308794, at *5-6 (citing 21 C.F.R. § 314.70(b)(2)(i)). Because reducing the amount of medicine in each vial of eye drops would constitute a major change requiring FDA approval, the court concluded that it was impossible for defendants to independently comply with the state law duties alleged in plaintiff's complaint. *Id*. at *6.

Thompson demonstrates that federal preemption may turn on individualized facts, and litigants should be vigilant for preemption arguments that fit the unusual facts of the claim or product at issue. And while the claim in this case was atypical, the decision may be useful more broadly in combating design or manufacturing defect claims aimed at the manner in which products are formulated or packaged.

In-depth advisories regarding the Supreme Court's opinions in *Mensing* and *Bartlett* are available here and here, respectively.

Generic Pharmaceutical Association Criticizes Proposed FDA Rule and Proposes Alternative

On January 29, 2014, the Generic Pharmaceutical Association (GPhA) published a white paper, criticizing FDA's proposed rule which would allow generic drug manufacturers to independently submit changes to their drug labeling that differ from the reference listed drug (RLD) labeling to reflect new safety information.

In the white paper, GPhA attacked the proposed rule on multiple fronts. From a legal perspective, GPhA asserted that "such a regulatory change is contrary to the clear language of the statute governing [generic drugs] that requires 'sameness of labeling.'" GPhA also argued that permitting generic manufacturers to independently change labeling is "something the Supreme Court already stated the statute does not allow" in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The white paper also sharply criticizes the proposed rule from a public policy and public health standpoint. GPhA asserted that the proposed rule would lead to confusion and uncertainty for prescribers and patients alike – by allowing the same drug to have multiple, different labels conveying different safety information – and will harm rather than enhance patient safety. Moreover, it argues that the rule could have a "staggering impact on the future availability of low-cost generic drugs [and] increas[e] the number of instances during which life-saving drugs either are in short supply or are not available" and would likely result in high costs for generic drugs to counteract litigation risks and increased regulatory compliance costs.

While GPhA stated its support for modifications that would explicitly allow generic firms to actively assist FDA in its determination that a change to labeling based on new safety information is warranted and for an efficient and prompt review of such proposed changes by FDA, it denounced any process which would require submission of independent labeling changes by generic drug manufacturers. FDA has extended the comment period on the proposed rule to March 13, 2014.

The GPhA's white paper is available here.

For questions or comments on this newsletter, please contact the Product Liability group at product@aporter.com.

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