ARNOLD & PORTER LLP

Product Liability Litigation Update

Recent Developments in the Law

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Arkansas Supreme Court Reverses US$1.2 Billion Risperdal Verdict

In *Ortho-McNeil-Janssen Pharm., Inc. v. State*, ---S.W.3d---, 2014 Ark. 124 (2014), the Arkansas Supreme Court reversed a US$1.2 billion jury verdict against Janssen based on the companies' alleged improper promotion of its antipsychotic drug Risperdal.

The Court first reversed the circuit court's denial of Janssen's motion for a directed verdict on the Arkansas Medicaid Fraud False Claims Act (MFFCA) claim. In reaching this result, the Court considered both the statutory language and legislative history, holding that the MFFCA only applied to statements by healthcare facilities in applying for certification or recertification as described in the statute. *Id.* at *10-16. The Court determined that the MFFCA did not cover Janssen's alleged wrongdoing—alleged false statements made in Risperdal's FDA-approved labeling—and accordingly dismissed the MFFCA claim. *Id*. at *16.

The Court also reversed the circuit court's decision on the Arkansas Deceptive Trade Practices Act (DTPA) claim, holding that the key FDA Warning Letter used by the State to prove its DTPA claim was inadmissible hearsay. The Court held that the letter did not fit within the hearsay exception for "Public Records and Reports" under Arkansas Rule of Evidence 803 because that Rule does not permit the admission of factual findings "resulting from special investigation of a particular complaint, case or incident." The Court accordingly reversed the circuit court's decision and remanded the DTPA claim back to the circuit court for further proceedings. *Id*.

The Arkansas Supreme Court's decision comes on the heels of the Louisiana Supreme Court's reversal of a US$257 million dollar verdict against Janssen under Louisiana's Medicaid fraud statute. *See* Arnold & Porter Advisory *Louisiana Supreme Court Strikes Medicaid Fraud Risperdal Verdict: A Narrowing of State AG's Expansive Interpretation*. Both decisions have the potential to persuade other state courts to interpret their Medicaid fraud statutes in a similar fashion.

Fourth Circuit Upholds Dismissal of FCA Claims Against Pharmaceutical Services Provider

In *United States ex rel. Rostholder v. Omnicare, Inc.*, --- F.3d ---, No. 12-2431, 2014 WL 661351 (4th Cir. Feb. 21, 2014), the United States Court of Appeals for the Fourth Circuit affirmed the dismissal of a *qui tam* complaint against a pharmaceutical services provider under Federal Rule of Civil Procedure 12(b)(6) on the ground that Relator's allegations failed to plead a false statement and scienter.

Relator alleged that Omnicare, Inc. and a subsidiary (Defendants) failed to comply with the FDA's Current Good Manufacturing Practice regulations (CGMPs) by repackaging penicillin in the same facility as non-penicillin drugs, which caused the non-penicillin drugs to be "adulterated." Relator brought claims under the federal False Claims Act (FCA) and various state analogous statutes. Defendants moved to dismiss arguing that Relator had failed to state a claim under Rule 12(b)(6). The district court granted Defendants' motion.

United States ex rel. Rostholder v. Omnicare, Inc., No. 07-1283, 2012 WL 3399789 (D. Md. Aug. 14, 2012).

The Fourth Circuit affirmed the district court's dismissal. The Court first rejected Relator's argument that Defendants violated the Medicare and Medicaid statutes, holding that "once a new drug has been approved by the FDA and thus qualifies for reimbursement under the Medicare and Medicaid statutes, the submission of a reimbursement request for that drug cannot constitute a 'false' claim under the FCA on the sole basis that the drug has been adulterated as a result of having been processed in violation of FDA safety regulations." 2014 WL 661351, at *5. Second, the Court rejected Relator's assertion that a false claim had been stated because compliance with the CGMPs is material to the government's reimbursement for regulated drugs. *Id*. The Court explained that "because compliance with the CGMPs is not required for payment by Medicare and Medicaid, [Defendants have] not falsely stated such compliance to the government, as contemplated by the FCA." *Id*. (footnote omitted). Finally, the Court held that "[b]ecause the Medicare and Medicaid statutes do not prohibit reimbursement for drugs packaged in violation of the CGMPs, [Defendants] could not have *knowingly* submitted a false claim for such drugs." *Id*. at *6 (footnote omitted). Thus, the Court concluded that Relator "cannot plausibly allege that [Defendants] acted with the requisite scienter when submitting claims to the government for drugs not in compliance with the CGMPs." *Id*.

Relators in FCA actions often assert claims based on alleged violations of various FDA regulations. The *Omnicare* decision demonstrates that failure to comply with FDA regulations is insufficient to create liability under the FCA when reimbursement was not conditioned upon compliance with those regulations. The case should be useful precedent for challenging FCA actions based on such alleged violations.

Proposition 65 Actions Dismissed for Failure to Comply With Pre-Suit Notice Requirements

In *Physicians Committee for Responsible Medicine v. McDonald's Corporation*, 224 Cal. App 4th 166 (Feb. 27, 2014) (*PCRM*), the California Court of Appeal affirmed a trial court victory by several major restaurant companies in a California Proposition 65 action.

The case was brought by an organization called the Physicians Committee for Responsible Medicine (PCRM), which promotes a vegan diet. PCRM claimed that the companies had violated Proposition 65 for failing to warn of alleged exposures to a chemical called "PhIP," which may be formed as a byproduct of grilling chicken (whether prepared at home or in a restaurant). *Id*. at 170. In particular, PCRM sought warning signs specifically discussing the risks of cancer from consuming chicken -- warning language that departed significantly from Proposition 65 "safe harbor" warning language for restaurants. *Id*. In a first phase of the case, the restaurants won a ruling that PCRM was not entitled to seek specific warning language that differed from the regulatory safe harbor warning, which does not require mention of specific chemicals or specific products. *Id*. at 172.

In a second phase of the case, PCRM claimed that the restaurant companies had failed to post the regulatory safe harbor warning in California restaurants. *Id*. at 173-74. In the course of pre-trial proceedings, PCRM admitted that it had not conducted an investigation of warnings prior to issuing its Proposition 65 pre-suit notice letter. *Id*. at 176-77.

Under Proposition 65, a private enforcer must issue a 60-day notice letter before filing a lawsuit, and it must include a "certificate of merit" with the 60-day notice letter. Cal. Health & Safety Code § 25249.7(d)(1). The certificate of merit requires a plaintiff to have factual evidence showing a "reasonable and meritorious" case for the private action. *Id*. The restaurant companies moved to dismiss the lawsuit on the grounds that PCRM's 60-day notice and certificate of merit were invalid due to PCRM's failure to conduct an investigation. *PCRM*, 224 Cal. App 4th at 176-77.

The trial court granted judgment in favor of the restaurant companies. In a case of first impression on the question of whether Proposition 65 plaintiffs must investigate warning signage before issuing a pre-suit notice letter and certificate of merit, the Court of Appeal affirmed in its entirety the judgment of the trial court. *Id*. at 183. In addition to holding that the pre-suit notice and certificate of merit were defective, the Court of Appeal agreed that PCRM could not cure those defects by conducting an investigation after the lawsuit was filed. *Id*. at 179-82.

The *PCRM* decision establishes important constraints on private Proposition 65 plaintiffs. The decision makes clear that plaintiffs must have an adequate factual basis for all elements of their *prima facie* case before they file a lawsuit. This pre-suit requirement is a critical check on the powers of private plaintiffs, who are authorized under Proposition 65 to sue as "private attorneys general" without having to prove any injury or harm.

Arnold & Porter LLP represented McDonald's Corp., Applebee's International, Inc., Chick-fil-A, Inc., OSI Restaurant Partners, Inc., Brinker International, Inc., Carlson Restaurants Worldwide, Inc. and TGI Friday's, Inc.

More information on Arnold & Porter's Proposition 65 Practice can be found here.

Fifth Circuit Affirms Preemption Of Claims Against Generic Manufacturers and Rejects Innovator Liability

In *Lashley v. Pfizer, Inc.*, 2014 WL 661058 (5th Cir. Feb. 21, 2014), the United States Court of Appeals for the Fifth Circuit held that federal law preempts "parallel" state-law claims against generic drug manufacturers and affirmed a grant of summary judgment for brand-name manufacturers on grounds that they do not owe a duty to consumers of generic versions of the drug.

The Fifth Circuit's decision arose out of two separate actions by Plaintiffs, whose cases were consolidated on appeal, against generic and brand manufacturers for injuries allegedly related to their use of metoclopramide—the generic version of Reglan. On appeal, the Fifth Circuit affirmed the district courts' dismissals of the claims against the generic manufacturers as preempted under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharm., Co. v. Bartlett*, 133 S. Ct. 2466 (2013). The Court determined that all of Plaintiffs' claims against the generic manufacturers turned on the adequacy of labeling and related information, and could thus be construed as failure-to-warn claims, which are preempted by *Mensing*. *Lashley*, 2014 WL 661058, at *2. Significantly, the Court also rejected arguments that some of Plaintiffs' state law claims against generic manufacturers are parallel to federal law claims, and thus not preempted. Plaintiffs had pointed to two rulings allowing parallel state law claims against medical device manufacturers to proceed—*Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996) and *Hughes v. Boston Scientific*, 631 F.3d 762 (5th Cir. 2011). The Court, however, distinguished between express preemption in the medical device context and implied preemption, and stated that "the inquiry [here] is not whether there is a 'parallel' claim where one looks for absence of conflict with the statute; the inquiry is whether the state-law claim is impliedly preempted." *Id*. The Court accordingly held that even the supposedly "parallel" state law claims were impliedly preempted. *Id*. at *4. This ruling accentuates a circuit split on the question of whether plaintiffs suing generic companies can state a claim for parallel violations of federal law, such as "failure to update" the generic label to match the branded one. Compare *Lashley*, with *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013).

The Fifth Circuit also affirmed summary judgment in favor of the brand manufacturers because, under state law in Mississippi and Texas, the brand manufacturers owed Plaintiffs no duty because the Plaintiffs "did not ingest the . . . brand defendants' products." *Id*. at *4. The Fifth Circuit's refusal to hold brand-name manufacturers liable for injuries caused by the generic version of their drug is a reaffirmation of the overwhelming majority of precedent rejecting so-called "innovator liability."

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