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# E-ALERT | Litigation

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## ARKANSAS SUPREME COURT OVERTURNS $1.2 BILLION JUDGMENT IN RISPERDAL® LITIGATION, CITING INADMISSIBILITY OF U.S. FDA WARNING LETTER TO PROVE CONSUMER PROTECTION VIOLATIONS

In recent years, state Attorneys General ("AGs") increasingly have launched investigations or brought civil actions against pharmaceutical companies under broad state statutes for alleged violations relating to the promotion of pharmaceutical products and pharmaceutical manufacturing issues that are the subject of extensive regulation by the U.S. Food and Drug Administration ("FDA"). The AGs often support their claims with little more than alleged findings of regulatory violations contained in FDA communications sent in connection with the agency's review of promotional activities or inspection of manufacturing facilities. This strategy creates a fundamental tension: FDA has repeatedly stated that warning letters are advisory and are not final agency action that can be challenged in court, while state AGs contradict FDA's view by attempting to present such letters to courts and juries as "findings" of violations by FDA.

In a significant decision handed down yesterday, the Supreme Court of Arkansas overturned a $1.2 billion judgment and $180 million attorney-fee award against Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (collectively, "Janssen") in a case brought by the Arkansas AG alleging thousands of violations of the Arkansas Medicaid Fraud False Claims Act ("MFFCA") and Arkansas Deceptive Trade Practices Act ("DTPA" or the "consumer protection" statute). *See Ortho-McNeil-Janssen Pharms., Inc. v. State*, 2014 Ark. 124, No. CV-12-1058 (Mar. 20, 2014) (reversing $1.2 billion civil penalty) (hereinafter "*Janssen 1*"); *Ortho-McNeil-Janssen Pharms., Inc. v. State*, 2014 Ark. 126, No. CV-13-468 (Mar. 20, 2014) (reversing $180 million attorney-fee award).

In its decision, the Court first addressed, reversed, and dismissed the State's MFFCA claims based on its interpretation of the relevant statutory provisions and finding that the provisions did not apply to Janssen. *See Janssen 1*, No. CV-12-1058, slip op. at 9-16. This portion of the decision eliminated more than 99 percent of the $1.2 billion civil penalty at issue, *see id.* at 8, but other portions of the decision reversing admission of an FDA Warning Letter were just as important for the broader trend of state AGs bringing cases based on alleged FDA findings.

In its consumer protection case, the State asserted that a 2003 Janssen Dear Doctor Letter (the "DDL"), sent to physicians in response to FDA-mandated label changes to include class warnings about diabetes for second-generation antipsychotic drugs such as Risperdal®, violated the Arkansas DTPA. *See id.* at 2, 7-8. In 2004, FDA sent a Warning Letter to Janssen outlining the agency's position that the DDL was "false and misleading" and directing the company to send a corrective letter to physicians. *Id.* at 4. Although Janssen disagreed with FDA's position, the company followed FDA's directive and sent a follow-up corrective letter to physicians. *Id.* at 4-5. Later in 2004, FDA closed the matter without further action. *Id.* at 6.

At trial, the State introduced (over Janssen's objection) the Warning Letter and relied on it heavily in support of its consumer protection allegations. *Id.* at 18. Indeed, "[t]he 'Warning Letter' was referred to repeatedly throughout the trial; in closing arguments alone it was mentioned at least fifteen times." *Id.* at 26. On appeal, Janssen argued, among other things, that the Warning Letter was inadmissible because: (i) it is hearsay under Rule 801 of the Arkansas Rules of Evidence and did not fall within any exception to the hearsay prohibition, including the exception for public records in Rule 803(8), and (ii) the prejudice of admitting the Warning Letter outweighed any probative value as evidence. *See id.* at 16-17.

The Court agreed with both arguments. The Court found that the Warning letter was "part of a special investigation of a particular complaint, case, or incident and falls directly within the parameters of the prohibited hearsay from [Rule] 803(8)(iv)[.]" *Id.* at 26. The Court also found that the Warning Letter was "highly prejudicial[,]" and indeed "more prejudicial than probative." *Id.* As such, the Court held that the lower court abused its discretion by admitting the Warning Letter, and reversed and remanded the State's consumer protection claims. *Id.*

The Arkansas Court's decision sends a strong message to state AGs seeking to use informal and advisory FDA communications as evidence of alleged consumer protection violations. The policies underlying the rules against admission of hearsay and disproportionately prejudicial evidence properly acknowledge the fairness issues that accompany such a practice: companies have no opportunity to cross-examine regulators on the purpose, context, and meaning of the communications, and may not be able to mount a challenge in court to the substance of the findings; state juries are then (improperly) asked to accept these unchallengeable federal regulatory observations as conclusive agency findings of liability. The Arkansas Court's decision therefore interprets evidentiary rules in a manner that is consistent with FDA's longstanding views on warning letters.

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Covington & Burling has extensive experience handling state consumer protection investigations and litigation, including matters relating to the promotion and manufacturing of pharmaceutical products and medical devices. If you have any questions concerning the material discussed in this client alert, please contact the following members of our pharmaceutical litigation and investigations practice group:


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