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A Blow To State Encroachment On Federal Turf

Law360, New York (April 16, 2014, 7:15 PM ET) -- For more than half a century, the U.S. Food and Drug Administration has been the exclusive regulator of the prescription medicine and medical device industry in the United States, whose innovations continue to lead the world. The FDA is responsible for enforcing complex federal regulations relating to, among other things, the content and format of labeling and promotional materials and compliance with prescription drug and medical device manufacturing practices. In fact, one reason why the U.S. continues to produce such innovative medicines and medical devices is that the FDA has provided a uniform and stable regulatory environment.

This regulatory uniformity and predictability has been imperiled in recent years by a surge in legal actions by state attorneys general against pharmaceutical and medical device manufacturers. State attorneys general have increasingly launched investigations and filed lawsuits 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 FDA. For example, in one recent, widely publicized matter, Arkansas Attorney General Dustin McDaniel brought suit against Ortho-McNeil-Janssen Pharmaceuticals Inc. and Johnson & Johnson, arguing to an Arkansas jury that FDA-approved drug product labeling for Risperdal violated state law and that an FDA warning letter was conclusive evidence of violations of federal law supporting consumer protection claims brought by the state.[1]

Matters such as the Arkansas Risperdal litigation have sparked an ongoing debate about the propriety of the states' efforts to encroach on the food and drug regulatory territory exclusively inhabited by the FDA; whether conflicts exist when, as often happens, private counsel is hired by states on a contingency-fee basis to handle litigation against pharmaceutical and medical device companies; and whether the collateral consequences of these state actions impede FDA's ability to regulate the industry through proven, traditional agency processes and procedures.

Much of the increase in the states' involvement in this area can be attributed to private counsel in the plaintiffs' bar, who have suggested to state attorneys general the use of consumer protection or other state statutes as a basis for bringing actions against pharmaceutical and medical device companies for what amount to alleged violations of federal food and drug laws.[2] Often, those private counsel are hired by state attorneys general on a contingency-fee basis to pursue litigation against pharmaceutical companies. Civil justice reform groups and even Congress have expressed concern about such arrangements. In fact, a congressional committee recently held a public hearing to investigate the potential for conflicts and other harms associated with this practice.[3]

Regardless of the impetus, many in the pharmaceutical and medical device industry believe that with

the increase in activity, the states are encroaching on the FDA's regulatory primacy and threaten the agency's ability to resolve matters quickly and collaboratively through traditional, proven agency processes. They cite examples such as the Arkansas Risperdal litigation, in which the state argued that FDA-approved labeling violated state law. As a further example, they point out that state attorneys general often support their state-law 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.

Such was the case in the Arkansas Risperdal matter, where McDaniel argued to an Arkansas jury that an FDA warning letter was definitive proof of violations of federal law that supported state consumer protection claims. This strategy creates a fundamental tension: The FDA has repeatedly stated that warning letters are advisory and not final agency action that can be challenged in court, while state attorneys general contradict the FDA's view by attempting to present such letters to courts and juries as "findings" of violations by the agency.

The Arkansas Supreme Court's Decision

In a significant decision handed down in late March, the Arkansas Supreme Court overturned a $1.2 billion judgment and $180 million attorney-fee award against Janssen in the Risperdal litigation brought by the Arkansas Attorney General Dustin McDaniel alleging thousands of violations of the Arkansas Medicaid Fraud False Claims Act ("MFFCA") and Arkansas Deceptive Trade Practices Act ("DTPA").[4] The litigation had been ongoing since late 2007, after McDaniel was "approached in early 2007 by outside law firms" about bringing the suit.[5]

In its decision, the Arkansas Supreme Court first addressed, reversed and then dismissed the state's MFFCA claims based on its interpretation of the relevant statutory provisions, finding that the provisions did not apply to Janssen.[6] This portion of the decision eliminated more than 99 percent of the $1.2 billion civil penalty at issue.[7] But, other portions of the decision reversing admission of an FDA warning letter were perhaps even more important for the broader trend of state attorneys general bringing cases based on alleged agency findings.

In its consumer protection case, Arkansas asserted that a 2003 Janssen dear doctor letter, sent to physicians in response to FDA-mandated label changes to include class warnings about diabetes for second-generation anti-psychotic drugs such as Risperdal, violated the Arkansas DTPA.[8] In 2004, the 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.[9] Although Janssen disagreed with the FDA's position, the company followed the agency's directive and sent a follow-up corrective letter to physicians.[10] Later in 2004, the FDA closed the matter without further action.[11]

At trial, Arkansas introduced, over Janssen's objection, the 2004 warning letter and, apparently unable to point to any independent evidence of fraud, relied on it heavily in support of its consumer protection allegations.[12] Indeed, "[t]he '[w]arning [l]etter' was referred to repeatedly throughout the trial; in closing arguments alone it was mentioned at least [15] times."[13] On appeal, Janssen argued, among other things, that the warning letter was inadmissible because: (1) 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 (2) the prejudice of admitting the warning letter outweighed any probative value as evidence.[14]

The Arkansas Supreme Court agreed with both arguments. The state high 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)[.]”[15] The court also found that the warning letter was “highly prejudicial[,]” and indeed “more prejudicial than probative.”[16] As such, the it held that the lower court abused its discretion by admitting the warning letter, and reversed and remanded the state’s consumer protection claims.[17]

Implications for Future State Actions and the Broader Discussion

The Arkansas Supreme Court's decision sends a strong message to state attorneys general 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 Supreme Court's decision, therefore, interprets evidentiary rules in a manner that is consistent with the FDA’s longstanding view on warning letters, and with federal case law that adheres to the agency's view.[18]

More broadly, the decision dealt a blow to state attorneys general seeking to pursue state action in regulatory matters within the primary jurisdiction of the FDA. It could signal that courts are growing uncomfortable with the states’ encroachment into federal regulatory matters, which in turn may give state attorneys general pause before initiating lawsuits and outsourcing them to private counsel with financial incentives to pursue enormous recoveries in court.

Many in the industry would argue this would help to strike a more appropriate balance and restore the FDA’s primacy in the regulation of pharmaceutical drugs and medical devices, thereby providing the stable regulatory environment that has led to so many medicinal breakthroughs in the U.S.

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[1] See generally Judgment, State v. Ortho-McNeil-Janssen Pharms., Inc., No. CV2007-15345 (Ark. Cir. Ct. May 9, 2012); Ortho-McNeil-Janssen Pharms., Inc. v. State, 2014 Ark. 124, No. CV-12-1058 (Mar. 20,

2014).

[2] See Peter Loftus, States Take Drug Makers to Court Over Marketing, THE WALL STREET JOURNAL, Apr. 23, 2013, at B3 ("Plaintiffs' law firms have been pitching new consumer-protection lawsuits to state attorneys general, according to Oregon's Mr. [David] Hart[, Assistant Attorney in Charge, Consumer Protection Section, Oregon Department of Justice]. Some states have outsourced such litigation to outside counsel after issuing requests for proposals.").

[3] See Contingent Fees and Conflicts of Interest in State AG Enforcement of Federal Law: Hearing Before the Subcomm. on the Const. of the H. Comm. on the Judiciary, 112th Cong. (2012).

[4] See Ortho-McNeil-Janssen Pharms., Inc. v. State, 2014 Ark. 124, No. CV-12-1058 (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).

[5] See Janssen 1, 2014 Ark. 124, No. CV-12-1058, slip op. at 7.

[6] See id. at 9-16.

[7] See id. at 8.

[8] See id. at 2, 7-8.

[9] Id. at 4.

[10] Id. at 4-5.

[11] Id. at 6.

[12] See id. at 18.

[13] Id. at 26.

[14] See id. at 16-17.

[15] Id. at 26.

[16] Id.

[17] Id.

[18] See, e.g., Holistic Candlers & Consumers Ass'n v. Food & Drug Admin., 664 F.3d 940, 944 (D.C. Cir. 2012) (holding that FDA warning letters compel no action by their recipient, do not constitute final agency action, "[n]or do the letters represent a decision determining rights or obligations, or one from which legal consequences flow").
