Bloomberg BNA

BNA's
Health Care Fraud Report™

Evidence of a Knowing False Claim Required: Supreme Court of Louisiana Strikes $330 Million Off-Label Risperdal Verdict




BY KIRK OGROSKY, DREW HARKER, JOEL ROHLF AND DAVID FAUVRE

On Jan. 28, the Louisiana Supreme Court on a 4-3 vote granted judgment in favor of Defendants Janssen Pharmaceutica, Inc.[1] and its parent company Johnson & Johnson, Inc. and reversed a trial court award of $257.7 million in civil penalties, $70 million in attorneys' fees and about $3 million in costs and expenses. *See Caldwell ex rel. State v. Janssen Pharmaceutica, Inc.*, 2012-C-2447, 2012-C-2466,—So.3d—(La. 1/28/14).

The Louisiana Supreme Court held that Louisiana's Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1, *et. seq.*, (MAPIL) required demonstration that misrepresentations in pharmaceutical marketing "caused any health care provider or his billing agent to knowingly present a claim for payment that is false" or were made in an attempt to receive payment "directly from medical assistance program funds pursuant to a claim."[2]

Key Takeaways

The Attorney General of Louisiana has been particularly aggressive in bringing Medicaid fraud claims against pharmaceutical companies for promotional and marketing activities. The *Janssen* decision requires the State to prove a causal connection between marketing or promotional statements to doctors and the submission of a claim that the health care provider knew was false.

The Supreme Court's interpretation of MAPIL will have a significant impact on the numerous cases containing MAPIL claims that are currently pending against pharmaceutical manufacturers in Louisiana.[3]

[1] Janssen Pharmaceutica, Inc. has changed names multiple times since the litigation in Louisiana commenced. For simplicity, this article refers to the company as Janssen.

Ogrosky (Kirk.Ogrosky@aporter.com) is a partner at Arnold & Porter, LLP where he defends companies and individuals in civil and criminal health-care fraud trials, investigations, and qui tam litigation. Harker (Drew.Harker@aporter.com) is a senior partner at Arnold & Porter and concentrates his practice on health care, government contracts, white collar, and other federal and state enforcement matters. Rohlf (Joel.Rohlf@aporter.com) is an associate in the firm's litigation group, where he represents clients in complex civil litigation, including government enforcement actions, and white collar criminal defense and compliance. Fauvre (David.Fauvre@aporter.com) is a litigator and counselor at the law firm with a varied practice that includes complex commercial litigation, white-collar criminal defense matters, and business, political law, and communications counseling.

[2] *Janssen*, 2012-C-2447, 2012-C-2466 at 14, 16.

[3] Arnold & Porter LLP attorneys, including some of the authors of this article, represent defendants in some of the pending enforcement actions brought by the Louisiana Attorney

In addition, the increased difficulty of succeeding on MAPIL claims may impact the ability of the Louisiana Attorney General to engage private counsel in other enforcement actions against pharmaceutical companies.

Under Louisiana law, the Attorney General cannot retain private counsel pursuant to a contingency fee agreement without legislative authorization.[4] As a result, private counsel retained by the Attorney General in pharmaceutical marketing cases have primarily relied upon attorney fee awards provided under MAPIL, La. Rev. Stat. § 46:438.6(D).[5] The Louisiana Unfair Trade Practices and Consumer Protection Law, La. Rev. Stat. § 51:1401 *et seq.*, another statutory cause of action commonly asserted in pharmaceutical marketing cases, does not authorize the recovery of attorneys fees in actions brought by the Attorney General.[6] Thus, the lack of a viable cause of action that permits attorney fee recoveries may impact the ability of the State to rely on private counsel to prosecute these kinds of cases.

Summary of Key Takeaways:

- Requires Louisiana to prove a causal connection between marketing or promotional statements and the submission of a knowingly false claim by a health care provider;
- May limit the Louisiana Attorney General's ability to hire private counsel to bring enforcement actions under MAPIL;
- May influence the interpretation of similar Medicaid fraud statutes in other states.

Finally, as discussed below, *Janssen* requires a showing of a knowing false claim in interpreting a state Medicaid fraud statute which is similar to the laws of other states. The Louisiana Supreme Court's decision and reasoning may be persuasive to other courts interpreting similar state Medicaid fraud statutes.

Procedural History of *Caldwell ex rel. State v. Janssen*

In *Janssen*, Louisiana alleged that statements made by sales representatives and contained in a letter sent by defendants to doctors regarding a class-wide Food & Drug Administration (''FDA'') warning failed to adequately characterize the risks associated with Risperdal® and violated the provisions of MAPIL, relying largely on a 2004 ''warning letter'' from the FDA.

Specifically, Louisiana alleged that the defendants violated subsections (A), (B) and (C) of La Rev. Stat. § 46:438.3 (2006), which provide:

> A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
>
> B. No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.
>
> C. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.[7]

The trial court ruled that ''the AG only need prove false, misleading, misrepresentative, deceitful, intent to defraud type statements, attempts to defraud type statements, that in and of itself is the causation [] needed'' and allowed the case to proceed without any evidence a false or fraudulent claim was ever submitted. Ultimately, a jury verdict awarded $257.7 million in civil penalties and the trial judge accessed $70 million in attorney's fees and about $3 million in costs and expenses after a separate hearing.

On appeal, defendants argued, among other things, that the trial record was insufficient to find liability under MAPIL because Louisiana provided no evidence that defendants presented or caused to be presented a false claim for payment to the Louisiana Medicaid program.

The Attorney General argued that MAPIL should be more broadly construed to apply to persons who make misrepresentations to healthcare providers and indirectly receive payments from Medicaid because of MAPIL's broad purpose ''to protect the fiscal and programmatic integrity of the medical assistance programs from health care providers and other persons who engage in fraud, misrepresentation, abuse or other ill practices to obtain payments to which these health care providers and other persons are not entitled.''[8]

The Louisiana Third Circuit Court of Appeal held ''that the trial court did not abuse its discretion in interpreting the MAPIL statute'' and the trial court's interpretation of the statute was correct.[9]

However, the Supreme Court rejected the trial court's and intermediate appellate court's sweeping interpretation of MAPIL, holding that ''there was insufficient evidence adduced that any defendant engaged in fraud, misrepresentation, abuse or other ill practices seeking to obtain, pursuant to a claim made against the medical assistance program funds, payments to health care providers or other persons to which the health care providers or other persons were not entitled.''[10]

General under MAPIL. Attorneys Jeffrey Handwerker, Rob Weiner and Stanton Jones wrote an amicus brief supporting Janssen and Johnson & Johnson's appeal.

[4] *Meredith v. Ieyoub*, 96-1110 (La. 9/9/97), 700 So. 2d 478, 481.

[5] *See .e.g.*, *Janssen Pharm.*, 100 So. 3d at 884 (affirming a 70 million dollar attorney fee award under La. Rev. Stat. § 46:438.6(D)).

[6] *See* La. Rev. Stat. §§ 51:1407-1408. In contrast, the private right of action under this statute explicitly authorizes recovery of fees and costs. *See id.* § 51:1409.

[7] *Janssen* involved a version of MAPIL effective from July 15, 1997 to June 17, 2007. The statute, including section 46:438.3(B), was subsequently amended on June 18, 2007, August 14, 2009 and August 15, 2011. *See* La. Acts 2007, No. 14, § 1, eff. June 18, 2007; La. Acts 2009, No. 426, § 1; La. Acts 2011, No. 185, § 1. These amendments do not appear to alter the requirement that a misrepresentation cause or be material to a false claim that was central to the Louisiana Supreme Court's decision.

[8] *Janssen*, 2012-C-2447, 2012-C-2466 at 8

[9] *Caldwell ex rel. State v. Janssen Pharm., Inc.*, 2011-1184 (La. App. 3 Cir. 8/31/12), 100 So. 3d 865, 876.

[10] *Janssen*, 2012-C-2447, 2012-C-2466 at 21.

  HFRA ISSN 1092-1079

The Louisiana Supreme Court's Decision

The Court addressed each of the three provisions of MAPIL at issue during the relevant time period. First, the Court analyzed Louisiana's claim under La. Rev. Stat. § 46:438.3(A), which provides ''[n]o person shall present or cause to be presented a false or fraudulent claim.'' The Court held that there is no evidence that defendants ''ever presented a claim for payment from the medical assistance funds.''[11] Thus, the Court assessed whether defendants ''caused'' a false or fraudulent claim to be submitted. Relying on the statutory definition of a ''false or fraudulent claim,'' La. Rev. Stat. § 46:437.3(8),[12] the Court held that Louisiana had not adduced evidence that the alleged misrepresentations ''caused any health care provider or his billing agent to knowingly present a claim for payment that is false, fictitious, untrue, or misleading in regard to any material information.''[13]

Rejecting Louisiana's argument that a pattern or practice of violating FDA rules, without more, constitutes a false claim, the Court held 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,'' even under the portion of the statute making a claim false if it was ''part of a pattern in violation of applicable federal or state law or rule.''[14]

The Court held that no evidence supported a finding that defendants' improper marketing statements caused any provider or billing agent to ''submit a claim for payment the provider or his agent knew was false or misleading or that violated a federal or state law or rule.''[15]

Second, the Court rejected Louisiana's claim under La. Rev. Stat. § 46:438.3(B), which provides ''[n]o person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs.''

The Court held that section 46.438.3(B) required a person to attempt to receive payment ''directly from medical assistance program funds pursuant to a claim.''[16] Because there was ''no showing that the defendants attempted to obtain payment to a health care provider directly from medical assistance program funds pursuant to a claim,'' this provision did not apply.[17]

The Court also rejected the Attorney General's broad interpretation of the definition of ''misrepresentation'' in La. Rev. Stat. § 46:437.3(15)[18] to include within its scope the failure to disclose information required by any state or federal requirement regardless of whether the defendants were required to disclose similar information to Louisiana.

Rather, because MAPIL was intended to ''protect the fiscal and programmatic integrity of the medical assistance programs,'' the Court limited the definition of ''misrepresentation'' to ''(1) the knowing failure to truthfully or fully disclose any information required on a claim or provider agreement; (2) the concealment of any and all information required on a claim or provider agreement; or (3) the making of a false or misleading statement to the department relative to the medical assistance programs.''[19]

The Court found that there was no showing that defendants failed to disclose or concealed information on a claim or made any of the allegedly false statements to the Department of Health and Hospitals ''relative to the medical assistance programs in an attempt to obtain payment on a claim made against the medical assistance programs.''[20]

Finally, the Court held defendants did not violate La. Rev. Stat. § 46:438.3(C), which provides ''[n]o person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.''

Relying on its earlier construction of ''misrepresentation,'' the Court held that subsection (C) was not violated because there was no evidence defendants ''failed to truthfully or fully disclose or concealed any information required on a claim for payment made against the medical assistance programs, or that these statements were made to the department relative to the medical assistance programs.''[21]

Additionally, the Court held that ''there must be a causal link between the misleading marketing statement and a false or fraudulent claim for payment to a health care provider or other person to establish liability under MAPIL.''[22]

On February 11, 2014, Louisiana filed an application for rehearing before the Louisiana Supreme Court, arguing for interpretations of the statute that were previously rejected by the Court. Notably, Louisiana stated that the existing decision will ''have the effect of totally eviscerating MAPIL and the ability of the State to impose civil penalties on companies who engage in misrepresentations with the intent to defraud the medical assistance program.''

The State points out that under the decision, ''the only manner in which the State may recover penalties against a pharmaceutical company who attempts to defraud the Louisiana Medicaid system through a cam-

---

[11] *Id.* at 13.

[12] Section 46:437.3(8) provided:

''False or fraudulent claim'' means a claim which the health care provider or his billing agent submits knowing the claim to be false, fictitious, untrue, or misleading in regard to any material information. ''False or fraudulent claim'' shall include a claim which is part of a pattern of incorrect submissions in regard to material information or which is otherwise part of a pattern in violation of applicable federal or state law or rule.

The current definition is identical but numbered subsection (7).

[13] *Janssen*, 2012-C-2447, 2012-C-2466 at 14 (emphasis removed).

[14] *Id.* at 15-16.

[15] *Id.* at 16.

[16] *Id.* at 16.

[17] *Id.* at 16-17.

[18] La. Rev. Stat. § 46:437.3(15) provides:

''Misrepresentation'' means the knowing failure to truthfully or fully disclose any and all information required, or the concealment of any and all information required on a claim or a provider agreement or the making of a false or misleading statement to the department relative to the medical assistance programs.

Subsequent amendments to the statute have not changed the definition of misrepresentation.

[19] *Janssen*, 2012-C-2447, 2012-C-2466 at *18.

[20] *Id.*

[21] *Id.* at 19-20.

[22] *Id.* at 20.

paign of misrepresentations is to show that the '**health care provider knowingly committed malpractice,' ''** by writing a prescription for the drug in question, a burden the State is not likely to be able to meet.

On February 21, 2014, Janssen and Johnson & Johnson opposed Louisiana's application for a rehearing, arguing that the State did ''nothing more than repackage'' interpretative arguments that the Court considered and rejected in its decision. Janssen and Johnson & Johnson argued that the Court correctly limited recovery under MAPIL to practices the Legislature expressly made unlawful and intended to penalize under the statute—''kickback and bribes'' and ''billing fraud.''

State Attorney General Suits Against Pharmaceutical Manufacturers

In recent years, state Attorneys General, including the Attorney General for the State of Louisiana, have brought claims against pharmaceutical manufacturers for marketing activities with increased frequency. Attorneys General are increasingly relying on private counsel retained on a contingency fee basis.

A key issue in recent cases, and one addressed squarely in the *Janssen* matter, is whether Medicaid fraud and state false claims statutes apply to marketing activity of drug manufacturers in instances where those manufacturers do not themselves submit claims or receive payments from Medicaid.

For example, in *Hood ex rel. Mississippi v. Eli Lilly & Company*, 671 F. Supp.2d 397, 455-456 (E.D.N.Y. 2009), Judge Jack Weinstein, dismissed claims brought by the Mississippi Attorney General alleging that Lilly violated the Mississippi Medicaid Fraud Control Act (''MFCA'') by failing to adequately warn doctors of weight and diabetes risks associated with Zyprexa® and promoting Zyprexa® for uses that were ''off-label or ''not medically necessary.''

The relevant sections of the MFCA provided that ''[a] person shall not make, present or cause to be made or presented a claim for medicaid benefits, knowing the claim to be false, fictitious or fraudulent'' or ''knowingly make or cause to be made a false representation of a material fact in an application for a medicaid benefit'' or ''for use in determining right to a medicaid benefit.''[23] Regarding Mississippi's allegations that ''Zyprexa prescriptions that resulted from Lilly's affirmative and consistent failure to warn that Zyprexa causes weight gain and diabetes were fraudulent claims,'' Judge Weinstein held that Mississippi failed to produce individualized evidence that ''the fraudulent claims resulted from, presumably, the reliance of prescribing physicians' [sic] on the absence of proper warnings.''[24]

In contrast, a few months earlier, a trial court in South Carolina held that the South Carolina Medicaid False Claim Act (''SCMFCA'') could apply to similar allegations regarding the marketing of Zyprexa® despite the fact that the relevant portions of the statute only applied to providers.[25]

The SCMFCA makes it ''unlawful for a provider of medical assistance, goods, or services to knowingly and willfully make or cause to be made a false claim, statement, or representation of a material fact . . . in an application . . . for a benefit, payment or reimbursement from'' Medicaid or ''on a report, certification, or similar document . . . submitted to'' Medicaid and ''unlawful for a provider of medical assistance, goods, or services knowingly and willfully to conceal or fail to disclose any material fact, event, or transaction which affects the'' provider's ''entitlement to payment, reimbursement, or benefits'' or ''amount of payment, reimbursement or benefit to which the provider may be entitled.''[26]

Provider is defined under SCMFCA ''to include persons who provides goods, services, or assistance and who is entitled or claims to be entitled to receive reimbursement, payment, or benefits under the state's Medicaid program.''[27] The South Carolina trial court held that Lilly was a provider and subject to the statute because it ''ultimately, although indirectly, received benefits through the Medicaid program.''[28] The South Carolina trial court ignored the subparts of section 43-7-60(B) that required the false statement to be in an application or report, certification or similar document submitted to Medicaid.[29]

On May 16, 2012, the Commonwealth Court of Pennsylvania upheld the dismissal of claims for double damages against Janssen and Johnson & Johnson under the Pennsylvania Medicaid Fraud Control Act, 62 P.S. § 1407 in connection with marketing Risperdal.[30]

Section 1407(a) makes it unlawful for ''any person'' to ''present for allowance or payment any false or fraudulent claims,'' among other acts. However, Pennsylvania is only authorized to bring a civil suit for double damages against a ''provider who committed any prohibited act.''[31]

The statute defines provider to mean ''any individual or medical facility which signs an agreement with the department to participate in the medical assistance program, including, but not limited to, licensed practitioners, pharmacies, hospitals, nursing homes, clinics, home health agencies and medical purveyors.''[32] Relying on the plain meaning of the definition of provider, the court held that a pharmaceutical manufacturer was not a ''provider.''[33]

Janssen May Be Persuasive to Other Courts Interpreting Similar Medicaid Fraud Statutes

Given the importance of the issues addressed in *Janssen* in other state Medicaid fraud cases, it is likely the

[23] Miss. Code Ann. §§ 43-13-211, 43–13–213.

[24] *Lilly*, 671 F. Supp.2d at 156 (internal quotations omitted).

[25] *State ex rel. McMaster v. Eli Lilly & Co.*, No. 2007 CP-42-1855, 2009 WL 6058384 (S.C.Com.Pl. Sept. 22, 2009).

[26] S.C. Code Ann. 43-7-60(B)-(C).

[27] *Id.* § 43-7-60(A)(1).

[28] *Lilly*, No. 2007 CP-42-1855, 2009 WL 6058384.

[29] *Id.*

[30] *Commonwealth ex rel. Ortho-McNeil-Janssen Pharm.*, 52 A.3d 498, 506-07 (Pa. Commw. Ct. 2012)

[31] 62 P.S. § 1407(c). In contrast, the state can criminally prosecute ''[a] person who violates any provision of subsection (a).'' *Id.* § 1407(b)(1); *see alsoOrtho-McNeil-Janssen Pharm.*, 52 A.3d at 506 (discussing the difference between the criminal and civil remedies).

[32] 62 P.S. § 1401.

[33] *Ortho-McNeil-Janssen Pharm.*, 52 A.3d at 507.

  HFRA ISSN 1092-1079

Janssen decision will bear on court decisions interpreting state Medicaid fraud statutes similar to MAPIL.[34]

Unlike the Commonwealth Court of Pennsylvania in *Ortho-McNeil-Janssen*, the Louisiana Supreme Court did not rely on a unique provision of state law limiting civil actions under a Medicaid fraud statute to providers,[35] but interpreted substantive language, borrowed from the Federal False Claims Act (''FCA''), 31 U.S.C. § 3729, and commonly used in state Medicaid fraud statutes, to hold that a pharmaceutical company's promotion to prescribers does not violate the statute unless there is a demonstration that such marketing activity caused a prescriber to submit a false claim.[36]

The Louisiana Supreme Court went further to narrow the application of the state false claims act statute than Judge Weinstein did in the Mississippi Zyprexa® action by holding that a pharmaceutical manufacturer's promotion is actionable only when it causes ''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''[37]

It is possible that other courts addressing state false claims acts with similar provisions to the Louisiana law will take a similarly narrow view of the actionable conduct covered by those statutes.

---

[34] *See, e.g.*, Ark. Code Ann. § 20-77-902; Miss. Code Ann. § 43-13-213; Or. Rev. Stat. Ann. § 180.755; Tex. Hum Res. Code § 36.002; W. Va. Code § 9-7-6.

[35] A handful of other states similarly limit the civil enforcement provisions of their Medicaid fraud statutes to providers. *See, e.g.*, Md. Code Ann., Crim. Law § 8-517.

[36] *CompareOrtho-McNeil-Janssen Pharm.*, 52 A.3d at 507 *with Janssen*, 2012-C-2447, 2012-C-2466 at 21.

[37] *Janssen*, 2012-C-2447, 2012-C-2466 at 14 (emphasis added)