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February 18, 2014

Hand Delivered

The Honorable Daniel E. Shearouse
Clerk of Court
South Carolina Supreme Court
1231 Gervais Street
Columbia, SC 29201

RE: State of South Carolina ex. rel. Alan Wilson in his capacity as Attorney General of the State of South Carolina v. Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and Johnson & Johnson, Inc.
Civil Action No. 2007-CP-42-1438
Our File No. 03501/01534

Dear Mr. Shearouse:

Pursuant to Rule 208(b)(7), SCACR, the Appellant hereby files this supplemental citation letter. The decision of the Louisiana Supreme Court in *Caldwell ex rel. State of Louisiana v. Janssen Pharmaceutica, Inc.*, 2012-2447 consol. with 2012-2466 (La. Jan. 28, 2014), ___ So.3d __, 2014 La. LEXIS 203, 2014 WL 341038, *reh'g requested*, is hereby brought to the attention of the Court. This decision relates to argument on page 59 in Appellant's brief. The decision also relates to page 69 in Respondent's brief, as Respondent there cited to an intermediate appellate court decision in *Caldwell*. A copy of the Louisiana Supreme Court's decision is attached hereto for the Court's convenience.

With kind regards, I remain

Sincerely yours,

C. Mitchell Brown

CMB:lpw
Enclosure

cc: Alan Wilson, Attorney General
C. Havird Jones, Jr., Sr. Assistant Attorney General
John B. White, Jr., Esquire
Donald C. Coggins, Jr., Esquire
John S. Simmons, Esquire
Fletcher V. Trammell, Esquire
Elizabeth Dwyer, Esquire
Robert W. Cowan, Esquire
Steven J. Pugh, Esquire
Thomas F. Campion, Esquire
Edward M. Posner, Esquire
Kenneth A. Murphy, Esquire

Supreme Court of Louisiana

FOR IMMEDIATE NEWS RELEASE NEWS RELEASE #007

FROM: CLERK OF SUPREME COURT OF LOUISIANA

The Opinions handed down on the **28th day of January, 2014**, are as follows:

BY GUIDRY, J.:

2012-C -2447
C/W
2012-C -2466

"BUDDY" CALDWELL, ATTORNEY GENERAL EX REL. STATE OF LOUISIANA v. JANSSEN PHARMACEUTICAL, INC., ET AL. (Parish of St. Landry)

We hereby reverse the district court's judgment in favor of the Attorney General, and render judgment in favor of the defendants. REVERSED.

JOHNSON, C.J., dissents for reasons assigned by Justice Hughes.
KNOLL, J., dissents for the reasons assigned by Justice Hughes.
HUGHES, J., dissents with reasons.

SUPREME COURT OF LOUISIANA

No. 2012-C-2447

Consolidated with

No. 2012-C-2466

**JAMES D. "BUDDY" CALDWELL,
ATTORNEY GENERAL EX REL. STATE OF LOUISIANA**

VERSUS

JANSSEN PHARMACEUTICA, INC., ET AL.

**ON WRIT OF CERTIORARI TO THE COURT OF APPEAL
THIRD CIRCUIT, PARISH OF ST. LANDRY**

GUIDRY, Justice

The Attorney General for the State of Louisiana brought an action against the defendant pharmaceutical companies alleging *inter alia* certain violations of the Louisiana Medical Assistance Programs Integrity Law ("MAPIL"). Following trial in September 2010, the district court entered a judgment upon the jury's verdict in favor of the Attorney General finding the defendants' alleged misconduct in marketing certain drugs had violated provisions of MAPIL as it read in November 2003, and awarding civil penalties of $257,679,500.00, attorney fees of $70,000,000.00, and costs in the amount of $3,000,200.00. The court of appeal affirmed the district court's judgment. We granted the writ applications of both the Attorney General and the defendants to determine the correctness of the lower courts' rulings. For the reasons set forth below, we find the Attorney General failed to establish sufficient facts to prove a cause of action against the defendants under MAPIL because no evidence was presented that any defendant made or

attempted to make a fraudulent claim for payment against any Louisiana medical assistance program within the scope of MAPIL. Accordingly, we reverse the district court's judgment in favor of the Attorney General.

FACTS AND PROCEDURAL HISTORY

The Attorney General filed the instant suit in September 2004 against Janssen Pharmaceutica, Inc., and Johnson & Johnson (hereinafter, "defendants"), asserting various legal theories of recovery stemming from the allegedly improper marketing of a particular drug, Risperdal, manufactured by the defendants.[1] By the time of trial, however, the Attorney General had narrowed his cause of action to alleged violations of La. Rev. Stat. 46:438.3, a subsection of MAPIL, which prohibits health care providers and other persons from presenting, or causing to be presented, false or fraudulent claims or misrepresentations seeking payment from Louisiana medical assistance programs.

In its suit, the Attorney General alleged the defendants "knowingly misrepresent[ed]" that Risperdal was "safer and/or more effective" than other antipsychotics. Further, the Attorney General alleged: that the defendants' marketing misrepresentations affected the decisions of prescribing physicians, who relied upon the misleading information disseminated by the defendants; that the defendants knew that many of the prescriptions written for Risperdal would be paid for by Louisiana's Medicaid program; that the State would not have purchased, or reimbursed for, Risperdal had it known of the defendants' misrepresentations; and that the State had suffered actual damages "in excess of one thousand dollars" related to misrepresentations made by the defendants in the marketing of Risperdal.

[1] Over the course of the litigation, Janssen Pharmaceutica, Inc., was succeeded by Janssen, L.P., and then, at the time of trial, by Ortho-McNeil-Janssen Pharmaceuticals, Inc., the entity appearing before this court along with Johnson & Johnson.

Risperdal was introduced in 1994 as a second-generation or atypical anti-psychotic, and is considered to be highly beneficial in permitting schizophrenia patients consigned to institutional care to return to living more productive lives. The defendants do not dispute that Risperdal, like other atypical antipsychotics, has the potential for serious side effects, but such side effects, including new onset diabetes, are generally fewer and milder, and more treatable, than first generation antipsychotics. In May 2000, the Federal Food and Drug Administration ("FDA") asked all manufacturers of atypical antipsychotics to conduct a comprehensive data review for a possible association between such drugs and new onset diabetes. The defendants responded in August 2000 with fifteen volumes of data arising out of 66 clinical trials involving more than 11,000 Risperdal patients. The defendants maintained that the clinical trials, supported by epidemiologic review and patient monitoring, showed a low incidence of diabetes and related conditions in patients taking Risperdal. The FDA took no action on the defendants' submission until September 2003, some three years later.

The Attorney General's case begins with the FDA's action in September of 2003, when the FDA notified all manufacturers of atypical antipsychotics, not only the defendants, that new class warnings would be required to be included on the drug labeling to advise health care providers and the public of the increased risk of hyperglycemia and diabetes-related adverse events associated with this class of drugs. The defendants, believing a uniform class warning to be unjustified, thereafter corresponded with the FDA to attempt a negotiation of certain aspects of the warning to be required for Risperdal, succeeding only in part.[2] The warning ultimately required by the FDA and added to the Risperdal label was as follows:

[2] The defendants believed the warning did not adequately differentiate between Risperdal and its main competitor, Zyprexa, especially with regard to the risk of weight gain and diabetes. Consequently, the defendants asked the FDA to omit the following statements from the proposed

Hyperglycemia and Diabetes Mellitus

> Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics including RISPERDAL®. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiologic studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.
>
> Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Additionally, the FDA required all atypical antipsychotic drug manufacturers to send out a letter to all health care providers nationwide (a type of correspondence referred to in the drug manufacturing industry as a "Dear Health Care Provider" letter (hereinafter, "DHCP letter")) to advise of the label change.

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warning to be added to the product labeling: (1) that hyperglycemia was "in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death"; (2) that "epidemiological studies suggest an increased risk of treatment emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics studied;" (3) that "[p]recise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available"; (4) that "[t]he available data are insufficient to provide reliable estimates of differences in hyperglycemia related adverse event risk among the marketed atypical antipsychotics"; and (5) that patients who are "starting treatment" with atypical antipsychotics should "undergo blood glucose testing at baseline." The requests to omit the first three of these statements were denied, but the FDA agreed to omit the fourth statement and to change "baseline" in the fifth statement to "at the beginning of treatment."

On November 10, 2003, the defendants sent out a DHCP letter stating the FDA had requested all manufacturers of atypical antipsychotics, including Risperdal, to include a class warning label regarding hyperglycemia and diabetes mellitus in their product labeling and to enclose updated prescribing information for Risperdal (generically known as "risperidone"). The November 10, 2003 DHCP letter included the diabetes class warning label within the attached prescribing information, but the letter also included the following additional statements:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics. [Footnotes omitted.]

These additional statements arguably constituted off-label statements, and they are the subject of the Attorney General's contention that the defendants engaged in misrepresentation in an attempt to defraud Medicaid by failing to truthfully and fully disclose information required under MAPIL.

On April 19, 2004, after a review of the defendants' November 10, 2003 DHCP letter, the FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") sent a "warning" letter to the defendants, directing the defendants to deliver corrective information about Risperdal, relating to hyperglycemia and diabetes, to the recipients of its DHCP letter.[3] Although the defendants disagreed with the DDMAC's instruction, maintaining that the

[3] The defendants' November 10, 2003 DHCP letter was actually mailed out several weeks prior to the FDA's request for a DHCP; the defendants asked that the FDA consider this DHCP letter as having satisfied the FDA request. The defendants point out that they heard nothing from the FDA until April 19, 2004.

statements contained in the November 2003 letter were scientifically correct, the defendants complied and sent out a "correction" letter on July 21, 2004, to all health care providers nationwide. That letter bore the caption "**IMPORTANT CORRECTION OF DRUG INFORMATION**," and stated, in part, as follows:

> The Food and Drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen Pharmaceutica Products, L.P. recently received a Warning Letter concerning the promotion of Risperdal® (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and Diabetes Mellitus.
>
> The Warning Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider (DHCP) dated November 10, 2003 that omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act ["FDCA"].
>
> Specifically, the Warning Letter stated that the DHCP letter omitted important information regarding hyperglycemia and diabetes, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approved product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma and death; minimized the importance of blood glucose monitoring; suggested that Risperdal did not increase the risk of diabetes, contradicting the Warning in the revised product labeling; and made misleading claims suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical antipsychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal.

The July 21, 2004 correction letter further stated that hyperglycemia and diabetes warnings had been added to the product labeling in November 2003; the entire text of that FDA-required warning (set forth above) was also quoted in the correction letter. The FDA's DDMAC closed the matter in October 2004 without taking any further action.

The matter went to trial on the issue of whether the defendants had any liability, under MAPIL, arising out of their dissemination of the off-label statements contained in the November 10, 2003 DHCP letter to Louisiana health

care providers. The district court, interpreting MAPIL and its application to the Attorney General's allegations, found that "if [the Attorney General and the State] prove false, misleading, misrepresentative, deceitful, intent to defraud type statements, attempts to defraud type statements, that in and of itself is the causation [] needed" for the defendants to be liable for civil penalties. Following trial held in September and October of 2010, the jury via interrogatories found the following: the defendants "knowingly presented or caused to be presented a false or fraudulent claim in violation of [MAPIL];" the defendants "knowingly engaged in misrepresentation to obtain, or attempt to obtain, payment from the Medical Assistance Program Funds in violation of [MAPIL]"; the defendants "conspired to defraud, or attempted to defraud, the Medical Assistance [Program Funds] through misrepresentation or by obtaining or attempting to obtain, payment for a false or fraudulent claim in violation of [MAPIL]." Finding the State was entitled to recover civil penalties, the jury found 35,146 violations of MAPIL (this number consisted of the 7,604 copies of the November 10, 2003 DHCP letter mailed to Louisiana health care providers, and 27,542 sales calls made by sales representatives on Louisiana doctors during the ensuing nine-month period; the Attorney General had contended that each letter and sales call was a separate violation of MAPIL). Without finding any evidence of actual damages sustained by the State, the jury assessed a civil penalty of $7,250.00 per violation. The jury apportioned 90% liability to Janssen Pharmaceutica and 10% to Johnson & Johnson.

The district court on March 9, 2011 signed a judgment in favor of the Attorney General and against the defendants in the following amounts: $257,679,500.00, with legal interest from the date of the jury's October 14, 2010 verdict; $70,000,000.00 in attorney fees; $3,000,200.00 in costs and expenses; and

legal interest on the attorney fees and costs from the date of the district court's February 11, 2011 oral reasons and rendition of judgment on those issues.

Both the Attorney General and the defendants appealed the district court's judgment to the court of appeal, which affirmed the judgment in its entirety. *See Caldwell ex rel. State v. Janssen Pharmaceutical, Inc.*, 2011-1184 (La. App. 3 Cir. 8/31/12), 100 So.3d 865. Thereafter, on the application of both the Attorney General and the defendants, this court granted writs to determine the correctness of the lower courts' rulings. *See Caldwell ex rel. State v. Janssen Pharmaceutical, Inc.*, 2012-2447, 2012-2466 (La. 1/18/13), 107 So.3d 620.[4]

LAW and ANALYSIS

The defendants maintain the district court erred in entering judgment against them because the trial record is insufficient to establish a violation of MAPIL. Their argument, raised in a motion for summary judgment and at trial, centers on their position that Subsections A, B, and C of La. Rev. Stat. 46:438.3 do not apply to the improper marketing or labeling conduct challenged by the Attorney General, because there is no evidence the defendants presented or caused to be presented any false claim or misrepresentation for payment out of medical assistance program funds. The Attorney General contends this interpretation ignores the broad purpose of MAPIL, which is 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.

[4] Although the title of the Third Circuit opinion styled the name of one of the defendants as "Janssen Pharmaceutical, Inc.," we note that the Attorney General's petition in the district court, as well as the defendant's answer, the district court's title of the case, and the evidence submitted in the district court, all reflect the defendant's correct name was "Janssen Pharmaceutica, Inc." Though the discrepancy was carried forward in this court's actions, granting writ applications of the parties, the error has been corrected in the title of this opinion.

The Attorney General contends the defendants, based on their misrepresentations, fraudulently received payments, or attempted to seek payment for a claim.

Thus, the issue presented is twofold: the interpretation and applicability of MAPIL and La. Rev. Stat. 46:438.3. Accordingly, the interpretative aspect of this case presents us with a question of law, which is reviewed by this court under a *de novo* standard of review. *First Nat. Bank, USA v. DDS Const., LLC*, 11-1418, p. 11 (La. 1/24/12), 91 So.3d 944, 952; *Broussard v. Hilcorp Energy Co.*, 09-0449, p. 3 (La. 10/20/09), 24 So.3d 813, 815-816; *Louisiana Municipal Ass'n. v. State*, 04-0227, p. 35 (La. 1/19/05), 893 So.2d 809, 836. We need not give deference to the legal conclusions made by the courts below, because this court is the ultimate arbiter of the meaning of the laws of this state. *Id.*; *Broussard*, 09-0449, p. 3, 24 So.3d at 816; *Cleco Evangeline, LLC v. Louisiana Tax Com'n*, 01-2162, p. 3 (La. 4/3/02), 813 So.2d 351, 353.[5]

[5] Whether MAPIL applies to the conduct alleged was raised initially in the defendants' motion for summary judgment. In denying the motion, the district court relied on *State of West Virginia ex rel. Darrell V. McGraw, Jr., Attorney General v. Johnson & Johnson et al.*, Civil Action No. 04–C–156, Circuit Court of Brook County, West Virginia, in which that court, interpreting West Virginia's consumer protection law, found that, for the purposes of determining an appropriate civil penalty, as a matter of law, whenever false or misleading promotional materials that concern health are delivered to the public, or its healthcare providers, such promotional materials in and of themselves cause harm and injury. The district court here then reasoned that "proof of delivery to the public or to healthcare providers of false or misleading promotional materials concerning Risperdal may be used by the plaintiff in an attempt to establish a MAPIL claim." Not only did the district court's interpretation not comport with traditional civilian statutory analysis, but the West Virginia circuit court relied on by the district court was itself reversed by a superior court. *See State ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677 (W. Va. 2010).

The issue was raised again prior to trial. The district court believed the Attorney General's theory of the case "is to attempt to show that none of those prescriptions, or many of them, should not or may not have been written because the doctors weren't given full information. That's their theory. I don't know whether it's right or not." The district court, after reviewing the language of the statutes and its prior ruling on the motion for summary judgment, found that "if [the Attorney General and the State] prove false, misleading, misrepresentative, deceitful, intent to defraud type statements, attempts to defraud type statements, that in and of itself is the causation they need to get to their penalty statute." On appeal, rather than properly reviewing the question of law *de novo*, *see Red Stick Studio v. State ex rel. Dept. of Econ. Dev.*, 10-0193 (La. 1/19/11), 56 So.3d 181, 187, the court of appeal found the district court's interpretation reasonable and not an abuse of the district court's discretion.

The method for judicially interpreting statutory law, and determining whether it applies to a specific set of facts, is well-settled in our jurisprudence. The essential question in all cases of statutory interpretation is legislative intent and the ascertainment of the reason or reasons that prompted the legislature to enact the law. *Pumphrey v. City of New Orleans*, 05–979 (La. 4/4/06), 925 So.2d 1202, 1210; *In re Succession of Boyter*, 99–0761, p. 9 (La. 1/7/00), 756 So.2d 1122, 1128. The rules of statutory construction are designed to ascertain and enforce the intent of the legislature. *McLane Southern, Inc. v. Bridges*, 11-1141 (La. 1/24/12), 84 So.3d 479, 483; *Stogner v. Stogner*, 98–3044, p. 5 (La.7/7/99), 739 So.2d 762, 766. Legislation is the solemn expression of legislative will, and therefore, interpretation of a law involves primarily a search for the legislature's intent. La. Rev. Stat. § 1:4 (2004); La. Civ. Code art. 2 (2004); *Lockett v. State, Dept. of Transp. and Development*, 03–1767, p. 3 (La. 2/25/04), 869 So.2d 87, 90.

It is a fundamental principle of statutory interpretation that "[w]hen a law is clear and unambiguous and its application does not lead to absurd consequences, the law shall be applied as written, and no further interpretation may be made in search of the intent of the legislature." La. Civ. Code art. 9 (2004); *McLane Southern, Inc.*, pp. 5-6, 84 So.3d at 483; *Conerly v. State*, 97–0871, p. 3–4 (La. 7/8/98), 714 So.2d 709, 710–11. When the language of the law is susceptible of different meanings, it must be interpreted as having the meaning that best conforms to the purpose of the law, and the words of law must be given their generally prevailing meaning. La. Civ.Code arts. 10 and 11 (2004); *Lockett*, 03–1767 at p. 4, 869 So.2d at 91; *Ruiz v. Oniate*, 97–2412, p. 4 (La. 5/19/98), 713 So.2d 442, 444. When the words of a law are ambiguous, their meaning must be sought by examining the context in which they occur and the text of the law as a whole, and laws on the same subject matter must be interpreted in reference to each other. La.

Rev. Stat. § 1:3 (2004); La. Civ. Code. arts. 12 and 13; *Lockett*, 03–1767 at p. 4, 869 So.2d at 91.

The meaning and intent of a law is determined by considering the law in its entirety and all other laws on the same subject matter and placing a construction on the provision in question that is consistent with the express terms of the law and with the obvious intent of the legislature in enacting it. *Boyter*, 99–0761 at p. 9, 756 So.2d at 1129; *Stogner*, 98–3044 at p. 5, 739 So.2d at 766. The statute must, therefore, be applied and interpreted in a manner that is consistent with logic and the presumed fair purpose and intention of the legislature in passing it. *McLane Southern, Inc.*, pp. 5-6, 84 So.3d at 483; *Boyter*, 99–0761 at p. 9, 756 So.2d at 1129. This is because the rules of statutory construction require that the general intent and purpose of the legislature in enacting the law must, if possible, be given effect. *McLane Southern, Inc.*, pp. 5-6, 84 So.3d at 483; *Backhus v. Transit Cas. Co.*, 549 So.2d 283, 289 (La. 1989). Courts should give effect to all parts of a statute and should not give a statute an interpretation that makes any part superfluous or meaningless, if that result can be avoided. *McLane Southern, Inc.*, pp. 5-6, 84 So.3d at 483; *Boyter*, 99–0761 at p. 9, 756 So.2d at 1129. It is likewise presumed that the intention of the legislative branch is to achieve a consistent body of law. *Id.*; *Stogner*, 98–3044 at p. 5, 739 So.2d at 766.

In *Pumphrey*, we explained that "[i]t is a fundamental principle in the construction of statutes that the meaning of a word or phrase may be ascertained by the meaning of other words or phrases with which it is associated." 05-0979, p. 14, 925 So.2d at 1211. "[G]eneral words are not to be construed in their widest extent, but are to be held as applying only to such classes of things of the same general kind as those specifically mentioned." *Id.* (citing *Continental Group, Inc. v. Allison*, 404 So.2d 428, 431 n.4 (La. 1981)).

We necessarily start with the language of the statutes under review. *M.J. Farms, Ltd. v. Exxon Mobil Corp.*, 07-2371 (La. 7/1/08), 998 So.2d 16, 27. At all pertinent times, La. Rev. Stat. 46:438.3 provided as follows:[6]

> 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.

The purpose of these provisions and MAPIL, enacted in 1997 by Act No. 1373, § 1, could not be more clearly stated by the legislature in La. Rev. Stat. 46:437.2(A): "to combat and prevent fraud and abuse committed by some health care providers participating in the medical assistance programs and by other persons and to negate the adverse effects such activities have on fiscal and programmatic integrity." The legislature further stated its intention to designate the Department of Health and Hospitals, the attorney general, and private citizens as agents of the state "to pursue civil monetary penalties, liquidated damages, or other remedies 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, as set forth in this Part, to obtain payments to which these health care providers or persons are not entitled." The Attorney General does not argue that the defendants are health care providers within the meaning of the statutes, but instead focuses on the inclusion of "other

[6] La. Rev. Stat. 46:438.3 was amended in 2007, by Act No. 14, § 1, and again in 2009, by Act No. 426, § 1.

persons" who engage in fraud or misrepresentations against the medical assistance programs.[7]

A claim is defined as including "any request or demand...made against medical assistance programs for payment." La. Rev. Stat. 46:437.3(6). A payment is defined as "the payment to a health care provider from medical assistance funds pursuant to a claim, or the attempt to seek payment for a claim." La. Rev. Stat. 46:437.3(18). "Medical assistance programs" refers to Medicaid, Title XIX of the Social Security Act, "and other programs operated by and funded in the department which provide payment to health care providers." La. Rev. Stat. 46:437.3(14). The record does not establish that the defendants ever made any request or demand for payment to a health care provider from medical assistance funds. Accordingly, we turn to the specific language of each provision of La. Rev. Stat. 46:438.3 to determine whether the defendants' actions fall within the scope of the prohibited conduct.

La. Rev. Stat. 46:438.3(A)

La. Rev. Stat. 46:438.3(A) provides: "No person shall present or cause to be presented a false or fraudulent claim." As noted above, there is no evidence the defendants ever presented a claim for payment from medical assistance funds. Accordingly, the Attorney General focuses on the language "or cause[s] to be presented a false or fraudulent claim." The Attorney General contends the defendants' conduct, in which they misrepresented the potential for known side effects from the use of Risperdal, caused a false or fraudulent claim to be presented for payment. The legislature has defined a "false or fraudulent claim" as follows:

[7] La. Rev. Stat. 46:437.3(10) defines a "health care provider" as "any person furnishing or claiming to furnish a good, service or supply under the medical assistance programs, any other person defined as a health care provider by federal or state law or by rule, and a provider-in-fact." The record establishes the defendants did not furnish Risperdal directly to patients or to the medical assistance programs.

"A '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**." La. Rev. Stat. 46:437.3(8)(emphasis supplied). Thus, to be liable under this provision, the person liable under this provision must cause a health care provider or his billing agent to make a request or demand for payment from medical assistance program funds that the health care provider or his billing agent knows to be false, fictitious, untrue, or misleading. "Knowing" or "knowingly" means that "the person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information." La. Rev. Stat. 46:437.3(12). Even if the defendants misrepresented the efficacy or safety of their product to Louisiana doctors, there is simply no evidence in this record, and moreover no allegation, that this misrepresentation in fact 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.

The flawed interpretation of this provision advanced by the Attorney General is evidenced by examining the improper conduct that would have had to have been proven at trial. To be liable under this provision, the Attorney General would have had to show that a Louisiana doctor who prescribed Risperdal for his patient, or a health care provider who dispensed the drug to the patient, knew that the defendants had made misleading statements about their product, but nonetheless prescribed or dispensed the drug to the patient knowing that there may be drugs that are equally safe, and less expensive, or safer than Risperdal, and notwithstanding that knowledge, prescribed or dispensed Risperdal. Of course, the doctor or health care provider could have still medically determined that Risperdal is the more appropriate drug for a particular patient, despite the misleading

statements of the defendants, in which case there could be no legitimate basis for alleging the doctor knowingly presented a false claim for payment. The doctor or health care provider would have had to have knowingly committed malpractice, prescribing or dispensing Risperdal despite knowing there were better, cheaper, or safer, more efficacious drugs available, for the defendants to be liable under this provision. Certainly the record contains no evidence that any doctor or health care provider knowingly committed malpractice based on the defendants' improper marketing statements, and then submitted a claim for payment from medical assistance program funds.

The Attorney General places much emphasis on the second sentence in the definition of "false or fraudulent claim," in which the legislature adds that a "[f]alse 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 Attorney General argues the defendants' marketing statements constituted a pattern in violation of FDA rules. Again, even if this were so, and we assume for the sake of argument that the defendants' conduct did initially run afoul of FDA DDMAC instructions, the clear wording of the statute is that the "claim," i.e., the "request or demand . . . made against medical assistance program funds for payment," La. Rev. Stat. 437.3(6), must be shown to be part of a pattern of incorrect submissions in regard to material information or is part of a pattern of such claims in violation of federal law or rule. The Attorney General suggests the defendants' labeling misstatements were "a pattern in violation of federal or state law or rule," and that the claims for payment were "part" of that pattern. But such an interpretation is overly expansive, and loses sight of the original provision that requires that, to be liable under MAPIL, the 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. *See* La. Rev. Stats. 46:438.3(A) and 46:437.3(8). There is no evidence in this record that the defendants' improper marketing statements caused any health care provider or his 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. Accordingly, we find that La. Rev. Stat. 46:438.3(A) does not apply to the defendants' improper marketing statements.

La. Rev. Stat. 46:438.3(B)

La. Rev. Stat. 46:438.3(B) provides as follows: "No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs." "Payment" is defined as "the payment to a health care provider from medical assistance program funds pursuant to a claim, or the attempt to seek payment for a claim." La. Rev. Stat. 46:437.3(18). "Misrepresentation" is defined in MAPIL as "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." La. Rev. Stat. 46:437.3(15). "Obtain" is not defined in MAPIL, but its common definition is "to gain or attain usually by planned action or effort." *Merriam-Webster.com.* Merriam-Webster, n.d. Web. 14 Jan. 2014. <http://www.merriam-webster.com/dictionary/obtain>. Although the Attorney General asserts the defendants engaged in "misrepresentation" in an attempt to obtain payment, and that they eventually received Medicaid funds as a result of the purchases of their product Risperdal by pharmacies and health care providers, 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. As the trial court itself

found, there was no showing on the record that the defendants themselves at any time made or attempted to make a request or demand for payment from medical assistance program funds.

Further, we decline to read the definition of "misrepresentation" as proposed by the Attorney General. The Attorney General asserts that a "misrepresentation" may occur in four ways: (1) the knowing failure to truthfully or fully disclose any and all information required; (2) the concealment of any and all information required on a claim; (3) the concealment of any and all information required on a provider agreement; or (4) the making of a false or misleading statement to the department relative to the medical assistance programs. The Attorney General argues that the provision at issue is "the knowing failure to truthfully or fully disclose any and all information required," without regard to whether or not the person deals directly with the Department of Health and Hospitals. The Attorney General argues that under La. Rev. Stat. 46:438.3(B), only "non-disclosures" by a person who knowingly obtains or attempts to obtain payment from medical assistance program funds are prohibited.

Aside from the fact there is no showing the defendants knowingly attempted to obtain payment from the medical assistance programs pursuant to a claim, as discussed above, the Attorney General's proposed construction of the definition of "misrepresentation" is inconsistent with the purpose of MAPIL and could lead to absurd consequences. Although there is a disjunctive comma after "information required," divorcing the clause "the knowing failure to truthfully or fully disclose any and all information required" from "on a claim or a provider agreement" renders the "information required" vastly broad in scope. The Attorney General does not specify who would determine what information is required, or when that information is required, or by whom it should be disclosed, but instead suggests the

"information required" in this case was the proper labeling instructions requested of the drug manufacturers by the FDA DDMAC. However, if that were the case, then nothing in the statute as construed by the Attorney General would limit the "information required" to information necessarily related to a claim for payment from the medical assistance program funds as administered by the Department of Health and Hospitals. Such a result would lead to absurd consequences, in that potentially any information required by any federal or state agency or source, which is not fully disclosed by any person who ultimately receives Medicaid funds, directly or indirectly, could, if not truthfully or fully disclosed, subject that person to civil penalties under MAPIL.

The clear intent of the legislature in enacting MAPIL is set forth in La. Rev Stat. 46:437.2(B), that is, "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 or persons are not entitled." Reading the definition of "misrepresentation" *in pari materia* with this stated intent, as well as other portions of MAPIL, we determine that a "misrepresentation" under La. Rev. Stat. 46:437.3(15) is (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.[8] Disclose means to make something known. "Disclose." *Merriam-Webster.com*. Merriam-Webster, n.d. Web. 14 Jan. 2014. <http://www.merriam-webster.com/dictionary/disclose>. To conceal means to prevent disclosure or to place out of sight. "Conceal." *Merriam-*

[8] Provider agreements and the requirements therefore are set forth in La. Rev. Stats. 46:437.11 and 46:437.12.

Webster.com. Merriam-Webster, n.d. Web. 14 Jan. 2014. <http://www.merriam-webster.com/dictionary/conceal>. The failure to disclose information is not necessarily the same act as the concealment of information, such as the destruction thereof, nor need it envision the same actor. Accordingly, our reading of La. Rev Stat. 46:437.3(15) logically places the obligation of truthful and full disclosure on the health care provider or any person seeking to obtain payment through a claim made against medical assistance program funds or entering into a provider agreement. It similarly prohibits the concealment by any person or health care provider of any and all information that may be required on a claim for payment or on a provider agreement.

In this case, there was no showing the defendants either failed to disclose or concealed information required on a claim for payment made against the medical assistance program funds. *See* La. Rev. Stats. 46:437.3(15) and (6). Further, there was no showing that the off-label statements, even if misleading, were made 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. *See* La. Rev. Stats. 46:438.3(B) and 46:437.3(15). Accordingly, we find La. Rev. Stat. 46:438.3(B) also does not apply to the defendants' improper marketing statements.

La. Rev. Stat. 46:438.3(C)

Lastly we turn to La. Rev. Stat. 46:438.3(C), which provides as follows: "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." The defendants assert Paragraph (C) of La. Rev. Stat. 46:438.3 is a conspiracy statute, given that La. Rev. Stat. 46:438.3 itself was based on the federal False Claims Act, 31 U.S.C. §3729(a)(1)(1986)

("FCA").[9] The defendants contend MAPIL Paragraph (A), as part of an expanding circle of violators, is directed to persons who present or cause the presentment of a false or fraudulent claim; Paragraph (B) is directed to persons who use false statements to obtain payment pursuant to a claim; and Paragraph (C) is directed to persons who conspire with others to use false statements to obtain payment pursuant to a claim. The Attorney General counters that there is a disjunctive comma between "conspire to defraud" and "or attempt to defraud," such that there is no conspiracy element of the attempt to defraud medical assistance programs through misrepresentation. We need not decide whether there can be a conspiracy to attempt to defraud, as we find the evidence does not support a finding that the defendants violated Paragraph (C) by attempting to defraud the medical assistance programs through misrepresentation.

MAPIL was enacted with the express purpose of combatting fraud and abuse of the medical assistance programs through the use of punitive measures against any person or health care provider who seeks to obtain payment to which that person or health care provider is not entitled. La. Rev. Stat. 46:437.2(B). As outlined above, a "misrepresentation" under La. Rev. Stat. 46:437.3(15) is (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. Even if the defendants were attempting to gain a competitive edge over other manufacturers of atypical anti-psychotics through the use of misleading off-label statements minimizing the potential risks of side effects from the use of their product,

[9] "The civil False Claims Act imposes liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim for money to the government." *See* 31 U.S.C. § 3729; *United States v. Southland Mgmt. Corp. (Southland I)*, 288 F.3d 665, 674 (5th Cir.2002), *vacated on reh'g en banc on other grounds*, 326 F.3d 669 (5th Cir.2003).

Risperdal, there has been no showing the 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. Further even if the defendants' conduct was intended to influence the prescribing decisions of doctors treating schizophrenia patients, there has been no causal connection between this conduct and any false or fraudulent claim for payment to a health care provider or other person. The purpose of MAPIL is to prevent false or fraudulent claims from being presented to and paid by the medical assistance programs. Thus, 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. Accordingly, we find La. Rev. Stat. 46:438.3(C) also does not apply to the defendants' improper marketing statements.

CONCLUSION

For the reasons set forth above, we find the Attorney General failed to prove the defendant drug manufacturers, by misrepresenting through off-label statements the potential for the risk of side effects from the use of Risperdal, violated provisions of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:438.3. Having determined the legislature's intended scope of MAPIL, we find the Attorney General failed to establish sufficient facts to prove a cause of action against the defendants under MAPIL. 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. Because we find the Attorney General failed to prove a violation of MAPIL, we pretermit discussion of

the remaining evidentiary and penalty issues. We hereby reverse the district court's judgment in favor of the Attorney General, and render judgment in favor of the defendants.

DECREE

REVERSED.

SUPREME COURT OF LOUISIANA

NO. 2012-C-2447

CONSOLIDATED WITH

NO. 2012-C-2466

JAMES D. "BUDDY" CALDWELL, ATTORNEY GENERAL EX REL. STATE OF LOUISIANA

VERSUS

JANSSEN PHARMACEUTICA, INC., ET AL.

ON WRIT OF CERTIORARI TO THE COURT OF APPEAL, THIRD CIRCUIT, PARISH OF ST. LANDRY

HUGHES, J., dissenting.

With respect, the majority opinion conflates the subparts of the definition of "misrepresentation" to include the requirement of a "claim" *not provided* by the statute.

While acknowledging that LSA-R.S. 46:438.3(C) proscribes an attempt to defraud the medical assistance programs through misrepresentation, the majority cites LSA-R.S. 46:437.3(15) defining misrepresentation as three subparts: "(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." Opinion at page 20 (emphasis added).

However, the definition of misrepresentation actually 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. [Emphasis added.]

Thus the majority erroneously writes in the requirement of "a claim or provider agreement" to the "failure to truthfully or fully disclose" subpart of the definition. But the disjunctive "or" cannot be ignored;[1] the requirements of the second subpart cannot leap across the "or" to be grafted onto the first. When the majority states that "there has been no showing the defendants failed to truthfully or fully disclose or concealed any information required on a claim for payment made against medical assistance programs, or that these statements were made to the department relative to the medical assistance programs" (opinion at page 21), all three subparts of the definition are conflated to impose upon the plaintiff a burden the legislature did not.

The three subparts of the definition of misrepresentation separated by the conjunctive "or" each stand alone in accordance with the accepted legislative interpretation. To conflate the provisions of one subpart to reach a desired result with another subpart is unsupportable.

The majority further attempts to insert a non-existent "claim" requirement into LSA-R.S. 46:438.3(C) by reference to the "purpose" of the law. The majority writes: "The purpose of MAPIL is to prevent false or fraudulent *claims* from being presented to and paid by the medical assistance programs. Thus, 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." Opinion at page 21 (emphasis added).

[1] Louisiana Revised Statute 1:9 provides:

> Unless it is otherwise clearly indicated by the context, whenever the term "or" is used in the Revised Statutes, it is used in the disjunctive and does not mean "and/or".

This desired result of the majority is likewise unsupported by the actual words of the law.

Louisiana Revised Statute 46:437.2 provides:

> A. This Part is enacted to combat and prevent fraud and abuse committed by some health care providers participating in the medical assistance programs and by other persons and to negate the adverse effects such activities have on fiscal and programmatic integrity.
>
> B. The legislature intends the secretary of the Department of Health and Hospitals, the attorney general, and private citizens of Louisiana to be agents of this state with the ability, authority, and resources to pursue civil monetary penalties, liquidated damages, or other remedies 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, as set forth in this Part, to obtain payments to which these health care providers or persons are not entitled.

This broad statement of intent and purpose is much more consistent with the findings of the jury and the court of appeal that by violating federal labeling laws the defendants violated LSA-R.S. 46:438.3[2] than with the attempt by the majority to limit its application by writing into the law requirements the legislature did not.

In any event, "When a law is clear and unambiguous and its application does not lead to absurd consequences, the law shall be applied as written and no further interpretation may be made in search of the intent of the legislature." LSA-C.C. art. 9.

One cannot seriously argue that an anti fraud and abuse statute that penalizes one who violates federal drug labeling laws to the detriment of the citizens of Louisiana presents an absurd consequence.

It is the duty of the legislature, not judges, to make the law. Judges may not like the law, they may even consider it unwise, but they have a duty to apply the law as written. Judicial re-writing of the law to achieve a desired result and overturn a jury verdict is inimical to our system of separated powers.

[2] The jury determined that the defendants violated all three sections (Paragraphs (A), (B), and (C)) of LSA-R.S. 46:438.3.