## IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania,

Appellant

•

v. : No. 802 C.D. 2011

Argued: May 16, 2012

**FILED: July 26, 2012** 

Ortho-McNeil-Janssen

Pharmaceuticals, Inc., f/k/a

"Janssen Pharmaceutica, Inc."

and/or "Janssen, LP"

BEFORE: HONORABLE DAN PELLEGRINI, President Judge

HONORABLE BERNARD L. McGINLEY, Judge HONORABLE RENÉE COHN JUBELIRER, Judge

HONORABLE ROBERT SIMPSON, Judge

HONORABLE MARY HANNAH LEAVITT, Judge HONORABLE PATRICIA A. McCULLOUGH, Judge

HONORABLE ANNE E. COVEY, Judge

OPINION BY JUDGE SIMPSON

## I. Introduction

This appeal involves a civil suit by the Commonwealth of Pennsylvania against the manufacturer of a drug, Risperdal, the cost of which is reimbursed through several Commonwealth agencies. The Commonwealth's theory of recovery at trial was that the drug manufacturer, Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Janssen), fraudulently withheld information regarding the safety and efficacy of the drug, thereby misleading those paying for the drug into believing it had a high intrinsic value that justified its price premium over generic alternative drugs. The Commonwealth sought to recover the difference in price between the amount it reimbursed for Risperdal and the drug's true value, which it asserts was about the price of a generic alternative drug.

The Court of Common Pleas of Philadelphia County (trial court) entered orders that dismissed the Commonwealth's suit and denied post-trial relief. The Commonwealth challenges these orders on appeal, raising numerous issues. Upon review, we affirm.

## II. Factual and Procedural History

In 2007, the Commonwealth filed suit against three pharmaceutical companies, Janssen, Eli Lilly & Company, Inc., and AstraZeneca Pharmaceuticals, L.P. The Commonwealth claimed it was seeking to recover, among other things, expenses incurred for reimbursing pharmacies for the purchase of Risperdal and other antipsychotic drugs manufactured by these defendants. At that time, the Commonwealth alleged the defendant pharmaceutical companies promoted their respective antipsychotic drugs for non-medically accepted and non-medically necessary (off-label) uses. The Commonwealth also asserted the defendant pharmaceutical companies misrepresented the risks associated with these medicines.

The defendant pharmaceutical companies filed preliminary objections seeking to, among other things, sever the actions. In December, 2007, the trial court severed the claims and directed the Commonwealth to file separate complaints against each of the defendant pharmaceutical companies.

Relevant here, in early-2008, the Commonwealth filed a six-count complaint against Janssen, alleging in Count I—Submission of False & Fraudulent Claims Under Medicaid Program; Count II—Submission of False & Fraudulent

Claims Under Pharmaceutical Assistance Contract for the Elderly (PACE) Program; Count III—Negligence; Count IV—Fraud and Misrepresentation; Count V—Misrepresentation Under Restatement (Second) of Torts §402B; and, Count VI—Unjust Enrichment.

In January 2010, the Honorable Howland W. Abramson granted, in part, Janssen's motion for judgment on the pleadings, thereby dismissing the Commonwealth's civil action seeking double damages under the Medicaid fraud statute.

In April 2010, Janssen filed a motion for summary judgment seeking dismissal of the Commonwealth's common law fraud and misrepresentation and unjust enrichment claims. The next day, the Commonwealth filed a motion for leave to file an amended complaint, which the trial court granted. The Commonwealth filed its first amended complaint on May 17, 2010, alleging claims for fraud and misrepresentation and unjust enrichment against Janssen. Janssen filed preliminary objections.

Ultimately, the case proceeded to trial in late May 2010. After jury selection, the trial court held oral argument on Janssen's motion for summary judgment on the Commonwealth's initial complaint, Janssen's preliminary objections to the first amended complaint, and multiple motions *in limine* filed by the parties.

After opening statements on June 3, 2010, the Commonwealth presented its evidence over the course of one week of jury trial. The Commonwealth rested on June 10, 2010. Shortly thereafter, Janssen made an oral motion for compulsory nonsuit, and the parties submitted written memoranda.

On June 14, 2010, the trial court heard oral argument on Janssen's motion for compulsory nonsuit. Shortly thereafter, the trial court, through the Honorable Frederica A. Massiah-Jackson, granted Janssen's motion for nonsuit. About 10 days later, Judge Massiah-Jackson issued a written decision explaining her ruling in more detail.

Several months later, Judge Massiah-Jackson issued a written decision denying the Commonwealth's request to remove the compulsory nonsuit and denying the Commonwealth's motion for post-trial relief. The Commonwealth filed a notice of appeal to this Court, and the trial court directed the Commonwealth to file a statement of matters complained of on appeal pursuant to Pa. R.A.P. 1925(b), which it did. Judges Abramson and Massiah-Jackson subsequently filed opinions pursuant to Pa. R.A.P. 1925(a), further explaining the bases for their respective decisions.

With regard to his dismissal of the Commonwealth's statutory Medicaid fraud claims, Judge Abramson explained that, because Janssen was not a "provider" as defined by the pertinent statutory provision, it could not be the subject of a civil suit under the statute.

As to the Commonwealth's common law fraud and misrepresentation claims, in its opinion denying the Commonwealth's motion for post-trial relief, the trial court initially explained the Commonwealth waived issues that it briefed, but did not state in its motion for post-trial relief.

As to the merits of the Commonwealth's fraud and misrepresentation claims, the trial court determined the Commonwealth did not carry its burden of proving justifiable reliance and causation by clear and convincing evidence.<sup>1</sup>

Specifically, as to justifiable reliance, the trial court rejected the Commonwealth's claim that because a confidential relationship existed between the parties, it did not need to prove reliance. The trial court determined the Commonwealth and Janssen were sophisticated business entities, and it distinguished the cases upon which the Commonwealth relied. The trial court also rejected the Commonwealth's alternate theory of "fraud on the market" as inapplicable to the current situation.<sup>2</sup> Having concluded the Commonwealth was

The parties here agree that because the Commonwealth's claims for fraud and misrepresentation were in the nature of fraud claims, its burden was to prove the elements of the torts by "clear and convincing evidence," a different and higher burden of proof than "preponderance of the evidence." <u>Carlson v. Sherwood</u>, 416 Pa. 286, 206 A.2d 19 (1965); Pa. SSJI (Civ.) §5.10 (4<sup>th</sup> ed.).

<sup>&</sup>lt;sup>2</sup> This theory of recovery was recently discussed in <u>Clark v. Pfizer, Inc.</u>, 990 A.2d 17 (Pa. Super. 2010), in the context of a class action for securities fraud. The trial court here observed the theory has not been applied beyond that factual context and, in any event, the theory is dependent upon special proof that was not present here.

This Court recently declined to apply the "fraud on the market" theory to a suit under our consumer protection statute based on deceptive drug pricing, including the pricing of Risperdal, because proof consistent with the theory was not offered at trial. <u>Com. v. TAP Pharm. Prods.</u>, 36 A.3d 1112 (Pa. Cmwlth. 2011) (Johnson & Johnson Trial).

not excused from proving reliance, it determined that it did not prove that essential element.

Regarding causation, the trial court held the Commonwealth did not present evidence that in the absence of Janssen's conduct any physicians in Pennsylvania would have altered their prescription habits. The trial court discussed the Learned Intermediary Doctrine.<sup>3</sup>

Additionally, the trial court discussed the Commonwealth's claim for damages. More particularly, at trial, the Commonwealth proceeded without a damage expert, although it claimed losses greatly in excess of \$100 million. The trial court determined the magnitude and complexity of the case was beyond the experience and understanding of an average juror; therefore, expert testimony was needed to calculate damages. The trial court also determined the magnitude and complexity of the case required that Janssen be provided with an accurate written expert report covering damages, and that Janssen was prejudiced by this lapse. The trial court discussed the fluctuating amounts of damage estimates mentioned during trial.

Further, the trial court explained its decision to grant nonsuit as to the Commonwealth's claim for unjust enrichment. It briefly reasoned that because the

<sup>&</sup>lt;sup>3</sup> The trial court cited <u>Demmler v. SmithKline Beecham Corporation</u>, 671 A.2d 1151 (Pa. Super. 1996) (where drug is available only by prescription, adequacy of warning is not to the patient or the public but to the prescribing physician), and other cases. The trial court rejected the Commonwealth's argument that the Learned Intermediary Doctrine was inapplicable because its theory of recovery was not based on warnings but on pricing of Risperdal.

relationship between the parties was based on a written agreement, an equitable unjust enrichment claim could not lie.

#### III. Issues

On appeal, the Commonwealth raises several issues. It first asserts the trial court erred in granting judgment on the pleadings and dismissing its statutory Medicaid fraud claims. The Commonwealth next argues the trial court erred in determining it waived all challenges to the trial court's rulings based on its purportedly insufficient post-trial motion. Additionally, the Commonwealth contends the trial court erred in denying its motion for post-trial relief to the extent it found the Commonwealth did not prove by clear and convincing evidence all the elements of its fraudulent misrepresentation and nondisclosure claim. The Commonwealth also maintains the trial court erred in denying its motion for post-trial relief to the extent it found the Commonwealth could not recover on its unjust enrichment claim.

### IV. Discussion

# A. Standard and Scope of Review

The scope of review for an appellate court concerning a trial court's denial of a motion to remove a nonsuit and grant a new trial is limited to determining whether the trial court abused its discretion or committed an error of law. Thomas v. City of Phila., 804 A.2d 97 (Pa. Cmwlth. 2002). The standard for reviewing a decision to grant a nonsuit is that a nonsuit may not be granted unless, viewing all the evidence and all reasonable inferences arising from it in the light

most favorable to the plaintiff, the jury could not reasonably conclude the elements of the cause of action have been established. <u>Id.</u>

It is also well settled that a jury cannot be permitted to reach its verdict on the basis of speculation or conjecture, and that a judgment of nonsuit is properly entered if a plaintiff does not introduce sufficient evidence to establish the elements necessary to maintain an action. Morena v. S. Hills Health Sys., 501 Pa. 634, 462 A.2d 680 (1983). It is the duty of the trial judge to determine, prior to sending the case to the jury, whether or not the plaintiff met this burden. <u>Id.</u>

In addition, as to our review of the trial court's dismissal of the Commonwealth's statutory claim, we are mindful that a motion for judgment on the pleadings is in the nature of a demurrer. Trib Total Media, Inc. v. Highlands Sch. Dist., 3 A.3d 695 (Pa. Cmwlth. 2010), appeal denied, \_\_\_\_ Pa. \_\_\_\_, 24 A.3d 865 (2011). As such, all of the opposing party's allegations are viewed as true and only those facts specifically admitted by him may be considered against him. Id. In reviewing a motion for judgment on the pleadings, a trial court may only consider the pleadings and any documents properly attached to the pleadings. Id. A motion for judgment on the pleadings should be granted only when the pleadings show there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Id.

Our review of an order granting a motion for judgment on the pleadings is limited to determining whether the trial court committed an error of law or whether questions of material fact remain outstanding. <u>Id.</u>

#### B. Commonwealth's Statute-Based Medicaid Fraud Claims

The Commonwealth first argues the trial court erred in dismissing its statute-based Medicaid fraud claims on the pleadings. The Commonwealth does not dispute that Section 1407(c)(1) of the act known as the Medicaid Fraud Control Act (Fraud Act), 62 P.S. §1407(c)(1)<sup>4</sup> allows the institution of a civil suit against a "provider" who committed an act made unlawful. Also, the Commonwealth does not dispute that "provider" is a defined term.

Rather, the Commonwealth argues that whether Janssen qualifies as a provider does not limit its ability to prosecute the statute-based Medicaid fraud claims. This is because Janssen qualifies as a "person," and a different subsection makes unlawful described acts by any "person." Applying rules of construction favoring the public interest over private interests, any ambiguity should be resolved in its favor.

In the alternative, the Commonwealth argues Janssen is a "provider," not as a result of the statutory definition of that term, but based on an unrelated, 2001 trial court decision at the preliminary objection stage.

Janssen responds that by the plain terms of the statute, the Commonwealth may only seek civil penalties (double damages) against a "provider," but it may seek criminal penalties against any "person." Janssen distinguishes the 2001 trial court case on which the Commonwealth relies, because

<sup>&</sup>lt;sup>4</sup> Act of June 13, 1967, P.L. 31, <u>added by</u> the Act of July 10, 1980, P.L. 493, <u>as amended</u>, 62 P.S. §1407(c)(1).

the drug manufacturer's status as a "provider" was assumed for purposes of disposing of the preliminary objections.

The object of all statutory interpretation is to ascertain and effectuate the intention of the General Assembly and, if possible, give effect to all of a statute's provisions. 1 Pa. C.S. §1921(a). When the words of a statute are clear and free from all ambiguity, its letter is not to be disregarded under the pretext of pursuing its spirit. 1 Pa. C.S. §1921(b). Only "[w]hen the words of the statute are not explicit" may this Court resort to statutory construction. 1 Pa. C.S. §1921(c).

"The clearest indication of legislative intent is generally the plain language of a statute." Walker v. Eleby, 577 Pa. 104, 123, 842 A.2d 389, 400 (2004). It is presumed "[t]hat the General Assembly intends the entire statute to be effective and certain." 1 Pa. C.S. §1922(2). Thus, no provision of a statute shall be "reduced to mere surplusage." Walker, 577 Pa. at 123, 842 A.2d at 400.

In addition, although we must "listen attentively to what a statute says[;][o]ne must also listen attentively to what it does not say." Kmonk-Sullivan v. State Farm Mut. Auto. Ins. Co, 567 Pa. 514, 525, 788 A.2d 955, 962 (2001) (citation omitted). "[I]t is a canon of statutory construction that a court has no power to insert a word into a statute if the legislature has failed to supply it." Vlasic Farms, Inc. v. Pa. Labor Rels. Bd., 734 A.2d 487, 491 (Pa. Cmwlth. 1999), aff'd, 565 Pa. 555, 777 A.2d 80 (2001); see also Girgis v. Bd. of Physical Therapy, 859 A.2d 852 (Pa. Cmwlth. 2004) (we may not insert a word the legislature failed to supply into a statute).

Section 1407 of the Fraud Act contains provisions relating to both criminal penalties and civil remedies. As to criminal penalties, Subsection (b) states (with emphasis added):

- (b)(1) A <u>person</u> who violates any provision of subsection (a), excepting subsection (a)(11), is guilty of a felony of the third degree for each such violation with a maximum penalty of fifteen thousand dollars (\$15,000) and seven years imprisonment. ...
- (2) In addition to the penalties provided under subsection (b), the trial court shall order any <u>person</u> convicted under subsection (a):
- (i) to repay the amount of the excess benefits or payments plus interest on that amount at the maximum legal rate from the date payment was made by the Commonwealth to the date repayment is made to the Commonwealth;
- (ii) to pay an amount not to exceed threefold the amount of excess benefits or payments.

\* \* \* \*

(4) The Attorney General and the district attorneys of the several counties shall have concurrent authority to institute <u>criminal proceedings</u> under the provisions of this section.

62 P.S. §1407(b)(1), (2), (4).

As to the Fraud Act's civil remedies, Subsection (c)(1) states, as pertinent (with emphasis added):

(c)(1) If the department determines that a <u>provider</u> has committed any prohibited act or has failed to satisfy any requirement under section 1407(a) it shall have the authority to immediately terminate, upon notice to the <u>provider</u>, the provider agreement and to <u>institute a civil suit against such</u>

provider in the court of common pleas for twice the amount of excess benefits or payments plus legal interest from the date the violation or violations occurred.

62 P.S. §1407(c)(1). Thus, by its plain language, the Fraud Act limits civil remedies to suits against "providers." <u>Id.</u>

In turn, Section 1401 of the Fraud Act<sup>5</sup> defines "provider" (with emphasis added):

"Provider" means 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.

62 P.S. §1401.

We are bound by the statutory definition of "provider." Contrary to the Commonwealth's assertions, a drug manufacturer does not qualify. To that end, Janssen is not an "individual," see 1 Pa. C.S. §1991 (defining "Individual" as "A natural person."), or a "medical facility." See 62 P.S. §1401 ("a licensed or approved hospital, skilled nursing facility, intermediate care facility, clinic, shared health facility, pharmacy, laboratory or other medical institution.") Nor is Janssen a medical purveyor as defined by the Fraud Act. See 62 P.S. §1401 (defining "Purveyor" as "any person other than a practitioner, who, directly or indirectly, engages in the business of supplying to patients any medical supplies, equipment or services for which reimbursement under the program is received including, but

<sup>&</sup>lt;sup>5</sup> Section 1401 was added by the Act of July 10, 1980, P.L. 493, <u>as amended</u>.

not limited to, clinical laboratory services or supplies, x-ray laboratory services or supplies, inhalation therapy services or equipment, ambulance services, sick room supplies, physical therapy services or equipment and orthopedic or surgical appliances or supplies.") In contrast to drug manufacturers, who do not sell drugs directly to Medicaid recipients or receive reimbursements directly from Commonwealth agencies, pharmacies and practitioners supply drugs to recipients and receive reimbursements from the Commonwealth; therefore, they qualify as "providers."

Further, the term "person" is a broader term than "provider." It addresses not just entities subject to civil remedies but also entities subject to criminal sanctions. The General Assembly specifically chose to use the term "provider" in the Fraud Act's civil remedies provision. We cannot broaden that statutory provision by inserting the more expansive term "person." <u>Vlasic Farms</u>.

Moreover, <u>Commonwealth v. BASF Corp.</u>, No. 3127, CONTROL NO. 120186, 2001 WL 1807788 (C.P. Phila., filed Mar. 15, 2001), the trial court decision relied on by the Commonwealth, does not compel a different result. There, in a footnote to an opinion disposing of preliminary objections, the trial court stated:

Since neither party presents any argument for excluding Defendants from the [Fraud] Act, this court will assume that they may be included [within the definition of the term "provider."] Knoll [Pharmaceutical Company], especially, may be construed as a "provider" since it is a party to the Rebate Agreement and Addendum, which is a requisite agreement for getting reimbursed from PACE and the General Assistance Program. Am.Compl., Exhibit A, at 1.

<u>Id.</u> at \*15, n.7. Because the trial court in <u>BASF</u> assumed, without analysis, that the defendants were "providers" <u>where the defendants presented no argument in opposition to such a conclusion</u>, the trial court's opinion in <u>BASF</u> is not determinative of the issue now directly before us. As set forth more fully above, our analysis of the express language of the relevant provisions compels a conclusion that Janssen is not a "provider" subject to civil remedies (double damages) under the Fraud Act. Thus, we reject the Commonwealth's reliance on BASF.

For these reasons, we discern no error in the trial court's dismissal of the Commonwealth's Fraud Act claim against Janssen.

## C. Waiver Based on Post-Trial Motions

The Commonwealth next argues the trial court erred in determining that issues the Commonwealth briefed, but did not state in its motion for post-trial relief, were waived. The Commonwealth maintains that issues discussed in its brief or in its post-trial motion were preserved. It seeks to distinguish the cases upon which the trial court relied.

Janssen counters that the Commonwealth waived all issues related to removing the nonsuit because the language in its post-trial motions was too broad and conclusory and because discussions in the brief do not preserve the issues.

As mentioned above, in its opinion denying post-trial relief the trial court initially explained that issues that were briefed but not stated in the

Commonwealth's motion for post-trial relief were waived, and the court cited several cases.<sup>6</sup> The trial court did not specify which issues it considered waived, and it did not state all issues were waived. Instead, it discussed the merits of its ruling on the nonsuit.

A careful review of the Commonwealth's motion for post-trial relief, see Reproduced Record (R.R.), Vol. II, at 535a-38a, reveals that, with the exception of the Commonwealth's "fraud on the market" argument (discussed briefly below), all other arguments are stated in the motion. As such, there is no basis for concluding the Commonwealth waived all issues relating to the nonsuit.

## D. Nonsuit on Misrepresentation and Nondisclosure Claims

The Commonwealth further asserts the trial court erred in denying its motion for post-trial relief to the extent the trial court held it did not prove by clear and convincing evidence all elements of its fraudulent misrepresentation and nondisclosure claim. The Commonwealth argues the trial court did not grant nonsuit on that basis, and, at trial, the Commonwealth presented clear and convincing evidence of all elements of that claim.

Initially, the Commonwealth contends Janssen waived its arguments as to sufficiency of proof of the other elements of the fraud claims because it did not file a cross-motion for post-trial relief.

<sup>&</sup>lt;sup>6</sup> E.g., Weir ex rel. Gaspar v. Estate of Ciao, 521 Pa. 491, 556 A.2d 819 (1989) (issues briefed but not specified in post-trial motion, except for broad "boilerplate" statements, were waived).

The Commonwealth next discusses its proof of all the elements of fraud, contending it met its burden.

As to reliance, the Commonwealth contends it was entitled to a presumption of reliance because it is in a special or confidential relationship with Janssen. The relationship arises from an agreement required by the federal Medicaid statute involving rebates paid by drug manufacturers to those entities who reimburse for the drugs. The calculation of the amount of rebates is based on confidential information from the drug companies. Appellant's Br. at 46. The Commonwealth offers additional commentary that does not further explain the alleged confidential relationship, but purports to show how Janssen exploited the Medicaid program.

In the alternative, the Commonwealth asserts it proved that it relied on Janssen's nondisclosures when making its decision to place Risperdal on the Preferred Drug List (thereby enhancing the drug's availability for reimbursement). Appellant's Br. at 49-50; Appellant's Reply Br. at 7 (citing testimony of Dr. Mary Diamond, Notes of Testimony (N.T.), 6/9/10 am at 17-19, 31-33; testimony of Dr. Terri Cathers, N.T. 6/10/10 pm at 23-24).

Regarding causation, the Commonwealth argues it proved that had its actors known the true safety and efficacy situation with Risperdal, they would have undertaken measures to curb Janssen's fraud and considered appropriate restrictions or limitations on Risperdal coverage. Appellant's Br. at 53. Citing testimony by Dr. Mary Diamond, a member of the Department of Public Welfare

Pharmacy and Therapeutics Committee which reviewed drug utilization after 2005, about a different drug classified as "non-preferred" because it was a very expensive medication, the Commonwealth argues that "[t]he jury was entitled to make the direct inference that had similar information come to light about Risperdal, the [committee which reviewed drug utilization] would have acted in a similar manner relative to that drug." Appellant's Reply Br. at 8. The Commonwealth also argues the Learned Intermediary Doctrine does not apply outside a failure-to-warn suit for personal injuries.

In response, Janssen contends the Commonwealth did not prove any elements of the torts. More to the point, Janssen asserts a failure of proof by clear and convincing evidence of justifiable reliance on a misrepresentation, the Commonwealth is not entitled to a presumption of reliance, the Commonwealth did not prove that any misconduct by Janssen caused it to take or refrain from taking any action, and the involvement of a learned intermediary prescribing Risperdal breaks the chain of causation.

The elements of intentional misrepresentation are: 1) a representation; 2) which is material to the transaction at hand; 3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; 4) with the intent of misleading another into relying on it; 5) justifiable reliance on the misrepresentation; and, 6) resulting injury proximately caused by the reliance. Bortz v. Noon, 556 Pa. 489, 499, 729 A.2d 555, 560 (1999). Additionally, "[t]he tort of intentional non-disclosure has the same elements as intentional misrepresentation except in the case of intentional non-disclosure, the party

intentionally conceals a material fact rather than making an affirmative misrepresentation." <u>Id.</u> at 499, 729 A.2d at 560.

Although the parties discuss <u>all</u> liability elements of fraudulent misrepresentation or nondisclosure, our primary inquiry is whether the trial court erred in its conclusions regarding proof of reliance and causation. We reject the Commonwealth's waiver argument because this Court may affirm on other grounds, regardless of whether there is a cross-appeal. <u>See Mun. Auth. of Borough of West View v. Pub. Util. Comm'n</u>, 41 A.3d 929 (Pa. Cmwlth. 2012) (this Court may affirm for any reason and is not limited to grounds raised by the parties).

The Commonwealth's efforts to dispense with proof of reliance based on a confidential relationship lack merit. The relationship between the Commonwealth and Janssen is neither special nor confidential based on rebate agreements. Rather, the underlying drug pricing information upon which rebates are calculated is not provided to state Medicaid agencies. See Com. v. TAP Pharm. Prods., 36 A.3d 1112, 1138 (Pa. Cmwlth. 2011) (Johnson & Johnson Trial) (discussing rebate program, explaining that rebate information may not be used for reimbursement methodology; Risperdal among drugs at issue). Moreover, the rebate agreement has nothing to do with information regarding a given drug's safety or efficacy. Id. at 1142-43.7

<sup>&</sup>lt;sup>7</sup> Additionally, the cases cited by the Commonwealth to support its position that a special or confidential relationship existed between the parties here so as to permit a presumption of reliance, are readily distinguishable. See Young v. Kaye, 443 Pa. 335, 338-39, 279 A.2d 759, 761 (1971) (affirmative proof of fraud not required where confidential relationship existed between plaintiff, an elderly individual, and defendant, a tax consultant, who plaintiff considered a "friend and trustworthy advisor in tax and accounting matters."); New York Life Ins. Co. v. (Footnote continued on next page...)

Similarly, the Commonwealth's "fraud on the market" theory for dispensing with proof of reliance does not support post-trial relief. This is because the issue was not preserved for appellate review, for two reasons. First, it was not raised in the Commonwealth's post-trial motion. See Pa. R.C.P. No. 227.1(b)(2). Second, the issue was not preserved at trial because the Commonwealth did not offer the technical proof upon which the theory of recovery is based. See Clark v. Pfizer, Inc., 990 A.2d 17 (Pa. Super. 2010); Johnson & Johnson Trial ("fraud on the market" theory not applied in suit based on deceptive pricing of drugs, including Risperdal, because proof consistent with the theory was not offered at trial).

On the common law element of reliance, Section 17.240 of the Pennsylvania Suggested Standard Jury Instructions (Civil) provides: "Reliance' means a person would not have acted (or would not have failed to act) as he or she did unless he or she considered the misrepresentation to be true." Pa. SSJI (Civ) §17.240 (4<sup>th</sup> ed.). Comment 5 further explains as follows: "The appropriate test of reliance is whether the misrepresentation induced or influenced the plaintiff's course of conduct." <u>Id.</u> at Subcommittee Note (5). <u>See Johnson & Johnson Trial</u>, 36 A.3d at 1144 (discussing test and holding Commonwealth failed to prove

# (continued...)

<u>Brandwene</u>, 316 Pa. 218, 172 A. 669 (1934) (reliance presumed where insured made material misrepresentations regarding his medical history on life insurance application); <u>Zwiercan v. General Motors Corp.</u>, 58 Pa. D.&C.4th 251 (C.P. Phila. 2002) (reliance presumed where plaintiff, an ordinary consumer, relied on an active concealment concerning a defect by defendant, a sophisticated automobile manufacturer); <u>Katlin v. Tremoglie</u>, 43 Pa. D.&C. 4th 373 (C.P. Phila. 1999) (reliance presumed based on therapist-patient relationship in case where therapist allegedly misrepresented that he was licensed to practice medicine).

reliance in its common law negligent misrepresentation claim against drug manufacturers based on deceptive pricing, including pricing of Risperdal).

During a week of trial, the Commonwealth offered very little proof of reliance. After careful review of all the record citations offered by the Commonwealth, only the noted exchange is relevant.<sup>8</sup> The vague exchange shows that certain information would have been "useful," or "helpful." Supplemental

## A. No, they did not.

<sup>&</sup>lt;sup>8</sup> The following testimony is by Dr. Mary Diamond, a member of the committee that reviews drug utilization since 2005, Supplemental Reproduced Record (S.R.R.), Vol. III, at 935b-36b (with emphasis added):

Q. What is - - I believe you said it's a memo from Dr. Leber to Dr. Temple; is that right?

A. Yes, and Dr. Leber agrees with Dr. Laughren's conclusions and further states that there was - - there's no evidence to support the conclusion that Janssen would like to have approval for it that states that Risperdal is superior to Haldol and, as such, is superior to other antipsychotic medications.

Q. Dr. Diamond, <u>would you have found this information in the Leber and Laughren memos useful</u> to you in evaluating Risperdal in the P & T Committee?

A. Yes. We would find it very helpful, because in many ways I think that we are hoping that medications, particularly atypicals, will meet the needs of the people we serve with less side effects and much more safety and efficacious medicines and to find that the FDA states that, although it's a medication that has benefit, it shows no superiority, so that it would be equivalent to what we already have available.

Q. Did anyone from Janssen ever convey the information in these memos to you?

Reproduced Record (S.R.R.), Vol. III, at 935b-36b. The exchange does not clearly establish reliance.

Nevertheless, although not raised by the parties or discussed by the trial court, there is authority for the position that reliance may be presumed in this case. Our courts hold that reliance may be presumed from the materiality of the misrepresentation. <u>LaCourse v. Kiesel</u>, 366 Pa. 385, 77 A.2d 877 (1951) (citing RESTATEMENT (FIRST) OF CONTRACTS §479 (1932)); <u>Beeman v. Calvert Fire Ins.</u> <u>Co.</u>, 94 A.2d 90 (Pa. Super. 1953); Pa. SSJI (Civ) §17.240, Subcommittee Note (5). Because the noted testimony could establish that the information at issue was material given that it would have been "useful" or "helpful," S.R.R. at 935b-36b, this may be a sufficient basis for reliance to be presumed.

However, on the common law element of causation, the Commonwealth did not offer proof that it would have acted differently with knowledge of the "true" facts. After a week of trial, none of the Commonwealth witnesses stated that they would have acted differently regarding Risperdal. The Commonwealth argues that this could be inferred by the way the drug utilization committee treated a different drug, but that is not a reasonable inference, and it is not clear and convincing proof. See, e.g., Carlson v. Sherwood, 416 Pa. 286, 287, 206 A.2d 19, 20 (1965) (party alleging fraud must prove the facts upon which the alleged fraud is based "by evidence that is clear, direct, precise and convincing ....") The Commonwealth invites speculation by the jury, which is impermissible, especially in fraud cases. Cf. Johnson & Johnson Trial (extensive expert evidence supported finding of causation in suit by Commonwealth against drug

manufacturer for deceptive pricing). As a result, no error is apparent in the trial court's determination that the Commonwealth did not present clear and convincing proof on the essential element of causation. Therefore, the trial court properly granted nonsuit on Commonwealth's claims for fraudulent misrepresentation and nondisclosure.

In light of the foregoing, it is unnecessary to discuss application of the Learned Intermediary Doctrine.<sup>9</sup>

## E. Nonsuit on Unjust Enrichment Claim

As a final issue, the Commonwealth contends the trial court erred in denying its motion for post-trial relief to the extent it found the Commonwealth could not recover on its unjust enrichment claim.

In granting nonsuit on the Commonwealth's unjust enrichment claim, the trial court explained that, because the relationship between the parties is based on a written agreement, an equitable claim for unjust enrichment will not lie.

<sup>&</sup>lt;sup>9</sup> The Commonwealth also asserts the trial court erred in denying its motion for post-trial relief to the extent it found Janssen was prejudiced or surprised by the Commonwealth's pricing theory and damages evidence. Based on our determination that the Commonwealth did not prove causation by clear and convincing evidence, we need not address this issue.

However, given the complexity of this type of case, expert damage testimony is usually needed. Cf. In re Pharm. Indus. Average Wholesale Price Litig., 491 F.Supp.2d 20, 33 (D. Mass. 2007), aff'd, 582 F.3d 156 (1st Cir. 2009), cert. dismissed sub. nom., AstraZeneca Pharm. LP v. Blue Cross Blue Shield of Massachusetts, \_\_\_ U.S. \_\_\_, 131 S.Ct. 60 (2010) (extensive expert damage testimony quantifying overpayments caused by deceptive drug pricing); Johnson & Johnson Trial (extensive expert damage testimony quantifying overpayments by Commonwealth agencies caused by deceptive drug pricing, including pricing of Risperdal); Com. v. TAP Pharm. Prods., 36 A.3d 1197 (Pa. Cmwlth. 2011) (BMS Trial) (extensive expert damage testimony quantifying overpayments by Commonwealth agencies caused by deceptive drug pricing).

Although the trial court did not specify the agreement to which it referred, the parties' arguments discuss the rebate agreement under which drug manufacturers pay rebates to entities reimbursing for their drugs under the federal Medicaid program.

Rebate agreements are part of the same set of agreements that formed the basis for the Commonwealth's assertion that a special or confidential relationship exists between it and Janssen. Yet, the Commonwealth now argues that there was no proof during trial of an agreement between it and Janssen; therefore, the trial court erred in relying on it. The Commonwealth also correctly argues that the federal rebate agreement does not pertain to the pricing of Medicaid drugs for reimbursement.

Finally, the Commonwealth points out that proof for unjust enrichment need not be by clear and convincing evidence. It also argues it need not prove reliance, fraudulent intent, or any other element necessary in its fraud claims. The Commonwealth asserts it offered sufficient evidence to meet its burden.

Janssen counters that the Commonwealth's unjust enrichment claim is nothing more than a recasting of its fraud claim. The Commonwealth's claim must fail because it did not prove any benefit conferred on Janssen was unjust. It also specifies the trial record references to the rebate agreement, the existence of which bars recovery under an unjust enrichment theory.

The trial court's rationale on this issue is not supportable. As discussed above, the rebate agreement, while part of the overall Medicaid statutory framework, is different from the reimbursement part of the program. <u>Johnson & Johnson Trial</u>. Thus, the rebate program would not control the relationship of the parties regarding drug pricing for reimbursement. Nevertheless, for the following reasons, we affirm the trial court on alternate grounds on this issue.<sup>10</sup>

"Unjust [e]nrichment is an equitable doctrine." Com. v. TAP Pharm. Prods., 885 A.2d 1127, 1137 (Pa. Cmwlth. 2005) (TAP II). "Under the doctrine, the law implies that a contract exists when a party is found to have been unjustly enriched; the doctrine requires the offending party to pay the plaintiff the value of the benefit he has conferred on the defendant." Id. "A party alleging that a defendant has been unjustly enriched must establish the following: (1) plaintiff conferred a benefit on the defendant; (2) the defendant appreciated the benefit; and (3) acceptance and retention by the defendant of the benefits, under the circumstances, would make it inequitable for the defendant to retain the benefit without paying for the value of the benefit." Id.

"Further, a defendant need not have accepted and appreciated the benefit intentionally; instead, the focus remains on the question of whether the defendant has been unjustly enriched." <u>Id.</u> (citation omitted). "Additionally, the plaintiff bears the burden of establishing either that the defendant wrongfully

<sup>&</sup>lt;sup>10</sup> We may affirm a trial court's order based on a different rationale if the basis for our decision is clear on the record. <u>Guy M. Cooper, Inc. v. E. Penn Sch. Dist.</u>, 903 A.2d 608 (Pa. Cmwlth. 2006).

secured the benefit or passively received a benefit that it would be unconscionable to retain." Id.

In BMS Trial, a nonsuit was granted against the Commonwealth on its unjust enrichment claim based on deceptive pricing of drugs reimbursed by Commonwealth agencies. As here, the Commonwealth proved how much it paid to reimburse for various drugs, but its payments were not made to the drug Rather, its reimbursements were made to providers (mostly manufacturer. pharmacies)<sup>11</sup> that sold the drugs to Medicaid and Medicare recipients. As here, <sup>12</sup> the Commonwealth did not prove how much of that money made its way back to the drug manufacturer. In short, even with the benefit of expert testimony on damages, the Commonwealth in BMS Trial failed to quantify the benefit conferred on the drug manufacturer. BMS Trial, 36 A.3d. at 1217, 1264-65; see Johnson & Johnson Trial (non-jury verdict in favor of drug manufacturer on unjust enrichment claim based on deceptive pricing of drugs, including Risperdal). Thus, like the current case, the Commonwealth did not identify any fund retained by the drug manufacturer to which a common law equitable remedy would apply. Because of these similarities, the result for this claim here should be the same as the result in BMS Trial.

<sup>&</sup>lt;sup>11</sup> <u>BMS Trial</u>, 36 A.3d at 1215-16; <u>see Johnson & Johnson Trial</u>, 36 A.3d at 1123-25 (including Risperdal).

<sup>&</sup>lt;sup>12</sup> <u>See</u> S.R.R., Vol. III at 1010b-1020b, 1067b-68b, 1089b (testimony of Dr. Cathers), cited by the Commonwealth. Appellant's Br. at 58-59, n.12.

Moreover, because the Commonwealth did not prove causation, that is, failed to prove any Commonwealth actor would have acted differently with knowledge of the "true" facts about Risperdal, the Commonwealth did not prove any retention was unjust.

#### V. Conclusion

Based on the foregoing, we reach several conclusions. First, because a drug manufacturer is not a "provider" of medical goods and services to Medicaid recipients, its conduct does not support civil remedies pursuant to the Fraud Act. Therefore, the trial court properly granted Janssen's motion for judgment on the pleadings on the Commonwealth's claim under the Fraud Act.

In addition, contrary to the trial court's generalized statement of waiver, the Commonwealth preserved most of its arguments regarding the nonsuit by stating them in its motion for post-trial relief. However, as to its claims for misrepresentation and nondisclosure, the Commonwealth did not offer clear and convincing proof of the necessary element of causation. Also, as to its unjust enrichment claim, the Commonwealth did not quantify the benefit allegedly conferred on Janssen, and it did not prove any enrichment was unjust. Thus, no error is apparent in the trial court's grant of Janssen's motion for compulsory nonsuit on these claims.

For all the above reasons, we affirm the trial court's orders.

ROBERT SIMPSON, Judge

## IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Commonwealth of Pennsylvania, :

Appellant

v. : No. 802 C.D. 2011

Ortho-McNeil-Janssen : Pharmaceuticals, Inc., f/k/a :

"Janssen Pharmaceutica, Inc."

and/or "Janssen, LP"

# ORDER

**AND NOW**, this 26<sup>th</sup> day of July, 2012, the orders of the Court of Common Pleas of Philadelphia County are **AFFIRMED**.

ROBERT SIMPSON, Judge