

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

COMMONWEALTH OF PENNSYLVANIA	:	
c/o OFFICE OF GENERAL COUNSEL,	:	January Term, 2008
Plaintiff	:	
	:	No. 2181
vs.	:	
	:	
ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., f/k/a	:	
JANSSEN PHARMACEUTICA, INC.	:	
and/or JANSSEN, L.P.,	:	
Defendant	:	

Appeal of	:	
COMMONWEALTH OF PENNSYLVANIA:	:	COMMONWEALTH COURT
Appellant	:	802 CD 2011
	:	

PRESENTED FOR REVIEW
JUN 21 11 12 AM '11
PRO FROTHY

OPINION TO THE HONORABLE
COMMONWEALTH COURT

MASSIAH-JACKSON, J.

June 21, 2011 *SE*

Commonwealth Of Pa Vs Janssen Pharmaceutica -OPFLD



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On April 19, 2011, the Commonwealth of Pennsylvania filed a Notice of Appeal. First, the Commonwealth appeals the Order entered by Honorable Howland W. Abramson on January 5, 2010, which granted in part Defendant-Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion for Judgment on the Pleadings. Second, the Commonwealth appeals the Order entered by Honorable Frederica A. Massiah-Jackson on March 22, 2011, which denied the Commonwealth's Motion for Post-Trial Relief Seeking Removal of Nonsuit and New Trial.

On May 18, 2011, the Commonwealth submitted a Concise Statement of Matters Complained of on Appeal Pursuant to Rule 1925(b) of the Pennsylvania Rules of Appellate Procedure. See, Court Exhibit "A", attached hereto. In accordance with Rule 1925(a) of the Pennsylvania Rules of Appellate Procedure, Judge Abramson will file an Opinion to explain the reasons for his ruling.

By way of background: Following the entry of the January 5, 2010 Order, the plaintiff was permitted to file its First Amended Complaint. The new pleading significantly narrowed and changed the focus of the issues to be litigated. Jury selection for trial commenced on May 28, 2010.

On June 14, 2010, at the conclusion of the Plaintiff-Commonwealth of Pennsylvania's case-in-chief, and after written and oral submissions to the Trial Court, this Court granted the Defendant-Ortho-McNeil-Janssen Pharmaceuticals, Inc. Motion for Nonsuit with a ruling from the bench. On June 24, 2010, this Court filed a Memorandum in Support of Order Granting the Defendant's Motion for Nonsuit, Per Rule 230.1.

After receipt of the transcripts, all counsel and the Court coordinated a briefing schedule. The parties agreed to waive oral argument.

On March 22, 2011, this Court filed an Order which denied the Commonwealth of Pennsylvania's Motion for Post-Trial Relief Seeking Removal of Nonsuit and New Trial. See Court Exhibit "B", attached hereto. Judgment was docketed on March 30, 2011.

The underlying action for fraudulent misrepresentation requires five elements of proof. In Delahanty v. First Pennsylvania Bank, N.A., 464 A.2d 1243 (Pa. Superior Ct. 1983), the elements were reviewed at 1252:

"The elements of fraud are as follows: 'there must be (1) a misrepresentation, (2) a fraudulent utterance thereof, (3) an intention by the maker that the recipient will thereby be induced to act, (4) justifiable reliance by the recipient upon the misrepresentation, and (5) damage to the recipient as the proximate result.' *Scaife Co. v. Rockwell-Standard Corp.*, 446 Pa. 280, 285, 285 A.2d 451, 454 (1971), cert. denied, 407 U.S. 920, 92 S.Ct. 2459, 32 L.Ed.2d 806, quoting *Neuman*, 356 Pa. at 442, 51 A.2d at 763; See e.g. *Edelson v. Bernstein*, 382 Pa. 392, 115 A.2d 382 (1955); *Gerfin v. Colonial Smelting & Refining co.*, 374 Pa. 66, 97 A.2d 71 (1953); *Shane v. Hoffman*, 227 Pa.Super. 176, 324 A.2d 532 (1974); *Laughlin v. McConnel*, 201 Pa.Super. 180, 191 A.2d 921 (1963)."

The plaintiff failed to meet the legal standards of the burden of proof for either its claim for fraud or its claim for unjust enrichment.

The plaintiff had the burden to prove all of the elements of all of its claims. The defendant must have adequate notice of all of the elements. Conjecture and speculation prejudices the defendant, confuses the jury, and undermines the work of the courts.

In accordance with Rule 1925(a) of the Pennsylvania Rules of Appellate Procedure, this Court respectfully submits to the Honorable Commonwealth Court, the **Memorandum in Support of Order Denying the Commonwealth of Pennsylvania's Motion for Post-Trial Relief Seeking Removal of Nonsuit and New Trial**, dated March 22, 2011, Court Exhibit "C", attached hereto, as the reasons for the rulings.

Finally, there is a question which must be fully answered by Appellant: Is the entity which has filed an appeal "Commonwealth of Pennsylvania", the same party which was the party-plaintiff in all of the proceedings in the Court of Common Pleas, First Judicial District, and formerly known as "Commonwealth of Pennsylvania c/o Office of General Counsel." This Court is unaware of any request or agreement to amend the caption, or change the name of the party, or substitute a new party.

BY THE COURT:

Date: June 21st, 2011


FREDERICA A. MASSIAH-JACKSON, J.

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ATTORNEY FOR PLAINTIFF

COMMONWEALTH OF PENNSYLVANIA

COURT OF COMMON PLEAS OF
PHILADELPHIA COUNTY

v.

JANUARY TERM, 2008

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.
(f/k/a JANSSEN PHARMACEUTICA, INC.)

No. 002181

**CONCISE STATEMENT OF MATTERS COMPLAINED OF ON APPEAL
PURSUANT TO Pa. R.A.P. 1925(b)**

COMES NOW, Plaintiff the Commonwealth of Pennsylvania (the “Commonwealth”), by and through the undersigned counsel, and pursuant to Pennsylvania Rule of Appellate Procedure 1925(b) and the Order of April 25, 2011 by the Court of Common Pleas of Philadelphia County, submits this Concise Statement of Matters Complained of on Appeal:

1. The issue to be raised by the Commonwealth on appeal from the Common Pleas Court’s Order of January 5, 2010 granting in part Defendant’s Motion for Judgment on the Pleadings (“Judgment on the Pleadings Order”) follows below. The Commonwealth has generally stated this issue pertaining to the Judgment on the Pleadings Order, pursuant to Pa. R.A.P. 1925(b)(4)(vi), because the Commonwealth cannot readily discern the basis for the Common Pleas Court’s decision:

a. *The Trial Court erred by granting judgment on the pleadings in Defendant's favor under the Medicaid Fraud Control Act ("MFCA"), 62 P.S. §§ 1401, 1407(a), (c), et al. (Judgment on the Pleadings Order at 1.)*

To the extent that the Court's ruling was based on Defendant's status (or purported lack thereof) as a "provider," which had the purported effect of immunizing Defendant from liability under the MFCA, that ruling was in error because the interpretation of the statute is incorrect and contrary to the General Assembly's intent. Further, while the MFCA may prescribe the actions the Department of Public Welfare alone may take against "providers," the MFCA does not limit the Commonwealth's enforcement powers and right to recover damages against "persons" who violate the MFCA. 62 P.S. § 1407(a).

2. The issues to be raised by the Commonwealth on appeal from the Common Pleas Court's Order of March 22, 2011 denying the Commonwealth's Motion for Post-Trial Relief ("Post-Trial Order"), which challenged the Trial Court's entry of nonsuit, are as follows:

a. *The Trial Court erred in determining that the Commonwealth had "waived any and all challenges to the pre-trial and trial rulings made by the Trial Court" because the Motion for Post-Trial Relief purportedly contained "broad and non-specific paragraphs" requesting said relief. (Post-Trial Order at 2.)*

The Commonwealth was permitted under Pa. R. Civ. P. 227.1(b) and interpretive case law to preserve and present its arguments against the Common Pleas Court's entry of nonsuit *both* in its Motion for Post-Trial Relief and accompanying Memorandum of Law in Support of the Motion, thus fully complying with the purpose of Rule 227.1(b), which is to afford the Trial Court the opportunity to correct an error at the time it was

made. The Commonwealth apprised the Trial Court and Defendant of the issues necessitating correction. In addition, the Commonwealth's Motion for Post-Trial Relief did not contain "broad and non-specific paragraphs," but instead fully apprised the Court and Defendant of the exact issues to be challenged following entry of nonsuit. Cases relied upon by the Common Pleas Court in its finding of waiver address issues that were entirely "left unstated" in those post trial motions. All issues that were briefed in the Commonwealth's Memorandum of Law in Support of the Motion were initially raised in the Motion itself.

b. *The Trial Court erred in finding that the Commonwealth failed to prove all the elements of its fraud claim by clear and convincing evidence.*

The Commonwealth has generally stated this issue pursuant to Pa. R.A.P. 1925(b)(4)(vi) because the Commonwealth cannot readily discern the basis for the Common Pleas Court's decision. The Trial Court initially did not grant nonsuit on the basis of the Commonwealth's failure to adduce sufficient evidence of Defendant's fraudulent misrepresentations or omissions or that Defendant intended to induce reliance. Instead, the Trial Court specifically determined that the Commonwealth had failed to meet its burden as to the *justifiable reliance* and *causation* elements of its fraud claim.

The Post-Trial Order is broader than the express grounds underlying the Trial Court's grant of nonsuit. The Commonwealth contends that it adduced sufficient, clear and convincing evidence to reach the jury on all elements of its fraud claim.

c. *The Trial Court erred in finding that the Commonwealth failed to prove the element of an actionable misrepresentation in support of its fraud claim by clear and convincing evidence, thereby also failing to give the Commonwealth the benefit of all the*

evidence favorable to it together with all reasonable inferences, and failing to resolve all conflicts of evidence in its favor.

The Commonwealth's evidence of Defendant's marketing materials, business plans, sales representative training guides, and similar evidence, together with testimony that such plans, materials, and guides were used throughout the United States (including in Pennsylvania), revealed a systematic and calculated effort by Defendant to misrepresent its drug Risperdal's safety and efficacy to Pennsylvania prescribers and to Medicaid officials. Such evidence constituted not only *reasonable inferences* and/or *circumstantial evidence* of misrepresentation (under, e.g., the so-called *Hillmon* doctrine) (Post-Trial Order at 5), but was indeed direct evidence of actionable misrepresentation. The Commonwealth's arguments relative to the *Hillmon* doctrine were merely an adjunct to the Commonwealth's direct evidence—not the Commonwealth's only evidence. In any event, the *Hillmon* doctrine, long a part of Pennsylvania law, is clearly applicable here and if properly applied by the Court should have led the Court to deny Defendant's nonsuit motion and let the jury determine the issue.

d. *The Trial Court erred in finding that the Commonwealth was not entitled to a presumption of justifiable reliance, thereby also failing to give the Commonwealth the benefit of all the evidence favorable to it together with all reasonable inferences, and failing to resolve all conflicts of evidence in its favor.*

The Commonwealth maintained before and at trial that it was entitled to a presumption of reliance under various theories. The Trial Court's conclusion that the Commonwealth raised this argument "for the first time and in the midst of trial" is incorrect. (Post-Trial Order at 5.) On a more substantive level, because the theory of the

case tried is, at its core, a “pricing” case, the Commonwealth was entitled to rely on the Commonwealth Court’s ruling in *Commonwealth v. TAP Pharmaceuticals*, in which parallel fraud and unjust enrichment claims based on false prices were allowed to proceed. The Commonwealth was also entitled to a finding that a confidential, special, or fiduciary relationship existed between it and Defendant, thus supporting a finding of justifiable reliance under Pennsylvania law. Furthermore, the Trial Court’s ruling ignores the Commonwealth’s argument that Defendant committed fraud directly upon the Commonwealth and its representatives by failing to inform the Commonwealth’s Medicaid and PACE officials of Risperdal’s true safety and efficacy profile, along with the fact that the FDA had determined that Defendant’s marketing statements about Risperdal’s alleged superiority was false and misleading. Thus, at a bare minimum, there is evidence in the record that, since 2005, Defendant made direct misrepresentations and fraudulent omissions to the Commonwealth Medicaid Pharmacy and Therapy Committee responsible for determining Risperdal’s reimbursement status, on which the Commonwealth Department of Welfare justifiably relied, and the jury was entitled to consider that evidence. Lastly, the Trial Court erred in finding that Pennsylvania courts have foreclosed the fraud on the market theory of reliance in pharmaceutical cases, as well as erred in determining that the Commonwealth abandoned such a theory prior to trial. (Post-Trial Order at 5-6.)

e. *The Trial Court erred in finding that the Commonwealth failed to prove the element of causation in support of its fraud claim by clear and convincing evidence, thereby also failing to give the Commonwealth the benefit of all the evidence favorable to*

it together with all reasonable inferences, and failing to resolve all conflicts of evidence in its favor.

The Trial Court misconstrued the Commonwealth's "pricing claim" as a garden variety failure-to-warn claim to which the learned intermediary doctrine applies. (Post-Trial Order at 6.) It is not such a claim. As the Commonwealth argued at summary judgment oral argument before trial, "[t]here was fraud underlying the price in [the *TAP Pharmaceuticals* case], as here; there were misrepresentations that allowed the company to sustain that false price, as here. And the basis and facts underlying the actual fraud don't really matter because the result was the same: The Commonwealth paid more than it had to pay [for Risperdal]." (Trial Tr. (06/02/10 a.m.) at 59:21-60:3.) Doctors' individual decisions to prescribe or not prescribe Risperdal (considered by the Trial Court under the inapposite "learned intermediary doctrine") do not enter into the jury's decision because the Commonwealth's claim is not based on whether too much Risperdal was prescribed, but rather, that the price Janssen set for Risperdal was premised on false "superiority" claims about the drug's safety and effectiveness. The causation question to be presented to the jury was not "did Defendant's misrepresentations cause Pennsylvania doctors to prescribe more Risperdal (or to prescribe Risperdal at all)." Instead, the correct causation question for the jury to answer was, for the quantity of Risperdal that actually was prescribed in Pennsylvania during the relevant time period (specific evidence of which was presented at trial), "did the Commonwealth pay too much for Risperdal *because of* an inflated price that was established and sustained through Defendant's fraudulent misrepresentations about Risperdal's alleged superiority over other drugs." Lastly, the Court also erred in granting Janssen's motion *in limine* that

precluded the Commonwealth from presenting evidence of how Janssen's misrepresentations and nondisclosures affected Pennsylvania physicians who prescribed Risperdal to Medicaid and PACE participants. By granting that motion *in limine*, the Court prevented the Commonwealth from presenting evidence that the Court contends was required to be presented by the Commonwealth.

f. *The Trial Court erred in finding that Defendant was prejudiced, surprised, and/or "ambushed" by the Commonwealth's pricing theory and/or damages evidence. (Post-Trial Order at 6-9.)*

There is no rule of law that requires an expert to present damages evidence to the jury where the damages can be calculated by simple mathematics. Furthermore, Defendant was not prejudiced by not having been presented with the Commonwealth's written damages calculation prior to trial and, likewise, did not move for nonsuit or otherwise make a timely objection on that basis. Defendant also sought no continuance prior to trial based on alleged prejudice as to damages. Indeed, the Trial Court overruled Defendant's motion *in limine* to preclude the Commonwealth's damages evidence on the basis of alleged prejudice. Additionally, Defendant had the opportunity to cross-examine the Medicaid official presenting the damages evidence, as well as the Commonwealth's expert witnesses at trial. The Trial Court acknowledged the same during pretrial oral argument on Defendant's own motion to preclude the Commonwealth's damages evidence, denying Defendant's motion and *cautioning against* Janssen's counsel's eleventh-hour attempt to demonstrate prejudice. Further, the fact that the Commonwealth's damages model had alternate damages figures does not in and of itself indicate that it was speculative. In fact, of the relevant variations in the Commonwealth's

damages model, more than one was a product of the Trial Court's rulings made immediately prior to trial relative to the applicable damages period and requisite comparator drug. Specifically, there were at least two pretrial rulings by the Trial Court that significantly altered the damages model that the Commonwealth was to present during trial: the damages period was narrowed; and, the Commonwealth was required to use haloperidol as the comparator to Risperdal in support of its damages model, even though the Commonwealth had already prepared to use risperidone (generic Risperdal) as the comparator. As a result of the Court's pretrial rulings, Defendant was no more prejudiced than the Commonwealth by its altered damages model just prior to trial.

g. *The Trial Court erred in finding that the Commonwealth failed to prove its unjust enrichment claim, thereby also failing to give the Commonwealth the benefit of all the evidence favorable to it together with all reasonable inferences, and failing to resolve all conflicts of evidence in its favor.*

The Post-Trial Order simply states in a sentence that the Plaintiff-Commonwealth's unjust enrichment claim is based on the same circumstances as the fraud claim. (Post-Trial Order at 6.) That is not a proper basis for denying post-trial relief nor for entering nonsuit. Unjust enrichment is an equitable claim that does not incorporate or necessitate the same type or quantum of proof as a fraud claim. Furthermore, the Trial Court erred by limiting its order granting nonsuit on the unjust enrichment claim to the alleged existence of a contract (rebate agreement) between the Commonwealth Medicaid program and Defendant, because no such contract exists. Rather, such a contract exists only between Defendant and the federal government, as trial testimony by the Commonwealth's Department of Public Welfare representative

made clear. The Trial Court did not grant nonsuit as to the unjust enrichment claim on any other basis. In granting nonsuit on that lone, mistaken premise, the Trial Court committed reversible error.

Respectfully submitted,

COHEN, PLACITELLA & ROTH, P.C.

By: s/Michael Coren
STEWART L. COHEN
MICHAEL COREN

Counsel for Plaintiffs

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DATED: May 18, 2011

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Plaintiff's Concise Statement of Matters Complained of on Appeal Pursuant to Pa. R.A.P. 1925(b) was served this date on the judges whose orders are being appealed via hand delivery, and on counsel for all parties by first-class mail, addressed as follows:

Honorable Frederica A. Massiah-Jackson
First Judicial District of Pennsylvania
Court of Common Pleas
Room 344, City Hall
Philadelphia, PA 19107

Honorable Howland W. Abramson
Philadelphia Court of Common Pleas
Room 485, City Hall
Philadelphia, PA 19107

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Attorney for Defendant ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., f/k/a
"JANSSEN PHARMACEUTICA, INC." and/or "JANSSEN, LP"

Dated: May 18, 2011

/s/Michael Coren
MICHAEL COREN

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

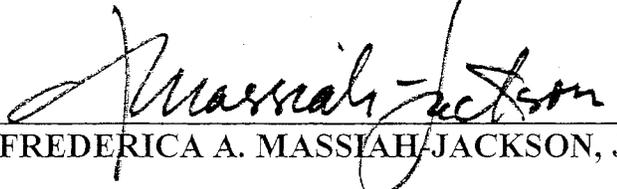
COMMONWEALTH OF PENNSYLVANIA	:	
c/o Office of General Counsel,	:	January Term, 2008
Plaintiff	:	
	:	No. 2181
vs.	:	
	:	
ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., f/k/a	:	
JANSSEN PHARMACEUTICA, INC.	:	
and/or JANSSEN, L.P.,	:	
Defendant	:	

ORDER

And Now, this 22nd day of March, 2011, upon consideration of the Plaintiff's Motion for Post-Trial Relief, and the response thereto, it is hereby ORDERED that:

Exhibits B and C of Plaintiff's Brief in Support of its Motion for Post-Trial Relief, and Exhibits S and V of the Reply Brief in Support of its Motion for Post-Trial Relief are Withdrawn by the Plaintiff, and, Exhibit BB refers to Trial Exhibit 2138, as per correspondence dated December 7, 2010.

BY THE COURT:


FREDERICA A. MASSIAH JACKSON, J.

DOCKETED
MAR 22 2011
R. POSTELL
DAY FOF

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

COMMONWEALTH OF PENNSYLVANIA	:	
c/o Office of General Counsel,	:	January Term, 2008
Plaintiff	:	
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vs.	:	
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ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., f/k/a	:	
JANSSEN PHARMACEUTICA, INC.	:	
and/or JANSSEN, L.P.,	:	
Defendant	:	

MEMORANDUM IN SUPPORT OF ORDER DENYING
PLAINTIFF'S MOTION TO REMOVE THE NONSUIT

MASSIAH-JACKSON, J.

DOCKETED
MAR 22 2011
R. POSTELL
DAY FORWARD

March 22nd, 2011

I. PROCEDURAL HISTORY

Following a week of trial testimony in June, 2010, the Plaintiff-Commonwealth of Pennsylvania rested its case-in-chief. Defendant-Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Janssen”), presented an oral Motion for Compulsory Nonsuit on June 10, 2010.

On June 14, 2010, after consideration of written memoranda and oral argument, this Court issued a bench ruling and filed an Order granting the Motion for Nonsuit. See Hearing Transcript, dated June 14, 2010, incorporated herein and attached hereto as Exhibits “A” and “B”.

On June 25, 2010, this Court filed a Memorandum in Support of Order Granting The Defendant’s Motion for Nonsuit, per Rule 230.1, incorporated herein and attached hereto as Exhibit “C”.

Plaintiff-Commonwealth filed its Motion for Post-Trial Relief seeking removal of the nonsuit and a new trial, which is opposed by Defendant-Janssen. The parties submitted extensive memoranda and agreed to waive post-trial argument. After considering the post-trial motion and memoranda, the Plaintiff’s Motion for Post-Trial Relief is **DENIED**.

II. LEGAL DISCUSSION

A. The Issues Relied On in The Commonwealth's Post-Trial Brief Were Not Stated in its Motion for Post-Trial Relief, dated June 24, 2010

In the Reply Brief, dated September 20, 2010, the Commonwealth contends that the guidelines of Rule 227.1 of the Pennsylvania Rules of Civil Procedure are “nonsense.” This Court is constrained to comment that the concepts of waiver are well-established in Pennsylvania. Dilliplane v. Lehigh Valley Trust Co., 322 A.2d 114 (Pa. 1974). A reading of the broad and non-specific paragraphs of the Commonwealth's Motion for Post-Trial Relief, dated June 24, 2010, supports Janssen's argument that this plaintiff has waived any and all challenges to the pre-trial and trial rulings made by the Trial Court. e.g. Weir v. Estate of Ciao, 556 A.2d 819, 825 (Pa. 1989), holding that when the issues relied on in a post-trial brief were “left unstated” in the motions themselves, they were waived; Carnicelli v. Bartram, 433 A.2d 878, 881 (Pa. Superior Ct. 1981), for an issue to be properly before the Court, it must have been “specifically assigned” in post-trial motions, citing Tagnani v. Lew, 426 A.2d 595 (Pa. 1981).

B. The Entry of Nonsuit Was The Proper Disposition of This Action

A party must prove each element of a claim in order to establish that the law entitles it to the relief requested. The plaintiff is not entitled to recover unless it proves all material allegations essential to the cause of action. A jury cannot be permitted to reach a decision on the basis of speculation or conjecture.

The Pennsylvania Appellate Courts have explained the circumstances by which a nonsuit may be entered. In Cruet v. Certain-Teed Corporation, 639 A.2d 478 (Pa. Superior Ct. 1994), the Superior Court referred to well-settled case law and quoted Morena v. South Hills Health System, 462 A.2d 680, 682-683, (Pa. 1983), at 639 A.2d 479:

“A judgment of nonsuit can be entered only in clear cases, and a plaintiff must be given the benefit of all evidence favorable to him, together [with] all reasonable inferences of fact arising therefrom, and any conflict in the evidence must be resolved in his favor. Thus an order granting a nonsuit is proper only if the jury, viewing the evidence and all reasonable inferences arising from it, in the light most favorable to the plaintiff, could not reasonably conclude that the elements of the cause of action have been established.

However, it is also well settled that a jury can not 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 has not introduced sufficient evidence to establish the elements necessary to maintain an action. In addition, it is the duty of the trial judge to determine, prior to sending the case to the jury, whether or not the plaintiff has met this burden.”

See also: *McDonald v. Aliquippa Hospital*, 414 Pa.Super. 317, 319-320, 606 A.2d 1218, 1219-1220 (1992); *Thomas v. Duquesne Light Co.*, 376 Pa.Super. 1, 8-9, 545 A.2d 289, 292-293 (1988), *aff'd*, 528 Pa. 113, 595 A.2d 56 (1991).”

In the case at bar, the Plaintiff-Commonwealth was expected to meet the burden of proof for fraudulent misrepresentation by clear and convincing evidence. See, Trial Court’s Memorandum in Support of Order Granting Nonsuit, dated June 25, 2010. In

order to satisfy the “clear and convincing” standard, which is a high burden of proof, the Pennsylvania Supreme Court explained the test in Rohm and Haas Company v. Continental Casualty Co., 781 A.2d 1172, 1179 (Pa. 2001), noting that the party alleging fraud must present evidence:

“ . . . so clear, direct, weighty, and convincing as to enable the jury to come to a clear conviction, without hesitancy, of the truth of the precise facts of the issue.”

See also, In re: Cicchetti, 743 A.2d 431, 443 (Pa. 2000); Lessner v. Rubinson, 592 A.2d 678, 681 (Pa. 1991); Scaife v. Rockwell-Standard Corporation, 285 A.2d 451, 454 (Pa. 1971).

C. The Plaintiff Failed To Prove All of The Elements of Either Its Claim for Fraud or Its Claim for Unjust Enrichment

In Delahanty v. First Pennsylvania Bank, N.A., 464 A.2d 1243 (Pa. Superior Ct. 1983), the elements of fraudulent misrepresentation were explained, at 1252:

“The elements of fraud are as follows: ‘there must be (1) a misrepresentation, (2) a fraudulent utterance thereof, (3) an intention by the maker that the recipient will thereby be induced to act, (4) justifiable reliance by the recipient upon the misrepresentation, and (5) damage to the recipient as the proximate result.’ *Scaife Co. v. Rockwell-Standard Corp.*, 446 Pa. 280, 285, 285 A.2d 451, 454 (1971), cert. denied, 407 U.S. 920, 92 S.Ct. 2459, 32 L.Ed.2d 806, quoting *Neuman*, 356 Pa. at 442, 51 A.2d at 763; See e.g. *Edelson v. Bernstein*, 382 Pa. 392, 115 A.2d 382 (1955); *Gerfin v. Colonial Smelting & Refining co.*, 374 Pa. 66, 97 A.2d 71 (1953); *Shane v. Hoffman*, 227 Pa.Super. 176, 324 A.2d 532 (1974); *Laughlin v. McConnel*, 201 Pa.Super. 180, 191 A.2d 921 (1963).”

This Trial Court is unable to conclude that the Order for entry of nonsuit should be removed. The presentations by the plaintiff prior to trial and during trial prejudiced the defendant, confused the jury and failed to meet the legal standards of the burden of proof for this cause of action.

- In the absence of direct evidence, the Plaintiff-Commonwealth argued that circumstantial evidence, “the Hillmon Doctrine”, supported inferences that marketing programs were carried out for the time period from January, 1994 through November, 2004. June 14, 2010, N.T. 42-43, citing Mutual Life Insurance Co. v. Hillmon, 145 U.S. 285 (1892); Commonwealth v. Begley, 780 A.2d 605 (Pa. 2001).

- The Plaintiff-Commonwealth sought to be relieved of its obligations to prove inducement or justifiable reliance. For the first time and in the midst of trial, it invoked a presumption of reliance by unilaterally asserting a purported “confidential” relationship with Janssen. June 14, 2010, N.T. 37; Basile v. H & R Block, Inc. 11 A.3d 992, 996 (Pa. Superior Ct. 2010); Silverman v. Bell Savings & Loans, 533 A.2d 110, 114-116 (Pa. Superior Ct. 1987).

- In an alternative position, abandoned by this plaintiff shortly before Opening Statements, but argued in post-trial briefs, the Plaintiff-Commonwealth claimed that it was entitled to a presumption of reliance and causation based on a fraud on the

market theory. But see, UFCW Local 1776 and Participating Employers Health and Welfare Fund v. Eli Lilly and Co., 2010 WL 3516183 (2d Cir. Sept. 10, 2010); Clark v. Pfizer, Inc., 990 A.2d 17 (Pa. Superior Ct. 2010).

- In its post-trial briefing, the Plaintiff-Commonwealth continued to reject its obligation to establish causation. It denied that Pennsylvania’s Learned Intermediary Doctrine is applicable. It declined to address the “Internal Causal Nexus Quandry”.

- The Plaintiff-Commonwealth’s unjust enrichment claim, based on the same circumstances as the fraud claim, must fail.

D. The Commonwealth of Pennsylvania Was Not Ready for Trial

In pre-trial proceedings and during trial, Janssen presented oral and written objections to the plaintiff’s evidence of damages. At the Hearing on June 2, 2010, the parties considered Defendant’s Motion in Limine To Preclude Any Evidence of Damages Based on The Difference in Price Between Risperdal and Other Medicines (Control No. 10051393). Janssen argued at N.T. 5-6:

“Again, this is the motion that challenges the basis for . . . about our challenge to the legal basis for recovering price differential damages and the context in the preliminary objections. This motion addresses the same damages but rests on the failure to disclose any damages data or damages calculation in discovery. We asked for information about the damages. We asked specifically for the amount of funds that would have been saved had a first-generation antipsychotic been prescribed in place of Risperdal and the Commonwealth simply didn’t respond. What it said was the request was premature and then it said the request is properly the subject

of expert testimony. We still don't have a substantive response. What we have is a pretrial memo that says we spent \$260 million on Risperdal. That's it, two sentences.

We also have a paper filed this morning at 11 o'clock in opposition to the preliminary objections or served then which says we spent 550 million. We have a slide for the opening tomorrow which says 550 million. It says it twice. First time we heard the number. It's now two-hours old. We were entitled to information about damages. They didn't provide it. Damages proved to be precluded."

At that time on the day before Opening Statements to the jury, the plaintiff was uncertain as to the time period of its damage claims. June 2, 2010, N.T. 10-12. Defendant-Janssen repeatedly argued that it was prejudiced by the plaintiff's inability to articulate the basis for its calculations. See, N.T. 19-21, where the Court ordered that the information be transmitted to the defendant.

On June 3, 2010, during Opening Statements and as part of the PowerPoint slide presentation, the Commonwealth told and showed the jury, Janssen and this Court its new damage calculations at N.T. 58:

"Again, we spent \$568 million on Risperdal. The evidence will show that the Commonwealth was overcharged a total of \$289 million. So by the end of the trial, you'll understand why the evidence will force me to ask you for a verdict of \$289 million."

On June 4, 2010, Janssen again sought clarification and challenged the Plaintiff-Commonwealth's "damage figures", at N.T. 101:

"On Wednesday, the plaintiff supplied us with new damages figures. As you saw in the openings, the number went down as they promised from 550 million to 568 million. I've tried -- we've had some very smart people and good consultations trying to replicate that number since and we can't do it. We don't know how it was derived and we would like to really make a simple request. We don't want to revisit everything about preclusion and discovery, but we would like maybe two paragraphs in the next day which explain how they get to \$568 million total spend and how they get to the 289 million overcharge so that we have some inkling before we go into this next week."

Again, the Plaintiff-Commonwealth did not have any answer, but, offered this explanation at N.T. 103:

"This issue is it's not written down and it's going to take -- in order to have it be clear, because of the nuances of the Medicaid law, it is going to take -- to be clear so that they will be able to make use of it, it will take longer than one day to supply that. We were aware that this request was coming. I heard Mr. Posner make it the other day. We've begun working in that regard, but it simply is going to take a little bit more time than to do it in the next 24 hours."

Three years after the Complaint was filed and even after trial testimony had started, the Plaintiff-Commonwealth did not know and could not prove to the jury or demonstrate to the defendant all of the elements of its cause of action. See June 4, 2010 at N.T. 105:

"There's one person that has been -- has devoted his time on our team that has been working with the state on that number. This information is in his head and on his Excel spreadsheet. In order to digest that and explain it to someone else is going

to require writing it all out, and that's all we're asking, for some time to do is to write it all out. The process has been determined.”

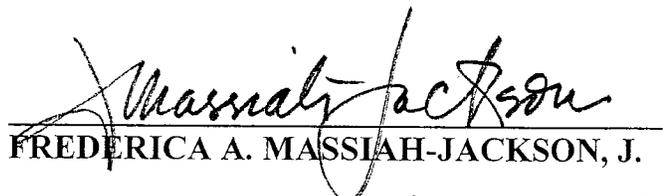
In the second week of trial, on June 8, 2010, Janssen once again objected to more “new” damage calculations which were, “. . . a surprise . . . prejudicial . . . and . . . improper.” A.M., N.T. 104-106. This Trial Court noted at N.T. 110-111, “It shifts . . . it evolves . . . transforms . . . morphs. . . it prejudices the Commonwealth . . . it also prejudices the defendants.”

By the end of the plaintiff's case, this Court concluded that trial by ambush was not sustainable. It was the duty of the Court to determine, prior to sending the case to the jury, whether the plaintiff had met its burden. The inability of Plaintiff-Commonwealth to articulate or prove a coherent and consistent damage calculation for the defendant, even after commencement of the trial, caused irreparable prejudice to Janssen. Moreover, the jury was being asked to speculate due to inconsistent presentations. When viewing the evidence in a light most favorable to this plaintiff, the jury would have been confused. The jury could not reasonably conclude that the elements of this cause of action had been established. See, June 2, 2010, P.M., N.T. 5, 6, 10-21; June 3, 2010, P.M., N.T. 31, 58; June 4, 2010, P.M., N.T. 101-105, 109-110; June 8, 2010, A.M., N.T. 104-113; P.M., N.T. 156-157; June 10, 2010, A.M., N.T. 61 (compare, June 3, 2010, P.M., N.T. 51-58); June 10, 2010, P.M. N.T. 4-13. Janssen's Motion for Nonsuit was granted on June 14, 2010.

III. CONCLUSION

For all of the reasons set forth above, and for the reasons set forth in this Court Memorandum in Support of Order Granting The Defendant's Motion for Nonsuit, per Rule 230.1, dated June 25, 2010, the Plaintiff's Motion for Post-Trial Relief is **DENIED**.

BY THE COURT:


FREDERICA A. MASSIAH-JACKSON, J.
3-22-2011

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

COMMONWEALTH OF PENNSYLVANIA	:	
c/o Office of General Counsel,	:	January Term, 2008
Plaintiff	:	
	:	No. 2181
vs.	:	
	:	
ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., f/k/a	:	
JANSSEN PHARMACEUTICA, INC.	:	
and/or JANSSEN, L.P.,	:	
Defendant	:	

ORDER

And Now, this ^{14th} day of June, 2010, after consideration of the Motion of Defendant for Compulsory Nonsuit, pursuant to Rule 230.1, and the Plaintiff's response thereto, and after oral argument held June 14, 2010, it is hereby ORDERED that the Motion of Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica, Inc. and/or Janssen, L.P., is **GRANTED**, and Count I and Count II of Plaintiff's First Amended Complaint is **DISMISSED** (Memorandum will follow).

DOCKETED

JUN 14 2010

R. POSTELL
DAY FORWARD

BY THE COURT:


FREDERICA A. MASSIAH-JACKSON, J.

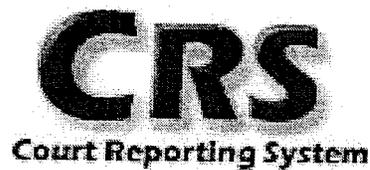


First Judicial District of Pennsylvania

08012181

Janssen Pharmaceutica, Inc. Trading As Janssen, L.P.

*Trial (Jury) Volume 1
June 14, 2010*



*First Judicial District of Pennsylvania
100 South Broad Street, Second Floor
Philadelphia, PA 19110
(215) 683-8000 FAX:(215) 683-8005*

Original File 061410am.txt, 71 Pages
CRS Catalog ID: 10091126

— **Exhibit "B"** —

[1] June 10th, lines 12 to 16.
[2] "And you've already told me you have no
[3] proof whatsoever that any representation was
[4] made to a physician in the Commonwealth that
[5] was inconsistent with what the FDA said in
[6] 1993, correct?
[7] "Correct."

[8] And, again, at page 125, line 15. 15
[9] to 18. "Right. And just so we're clear --
[10] just so that we're clear, Janssen as far as you
[11] know, has never told anybody that it,
[12] indeed" -- it meaning Risperdal -- "it indeed
[13] is better than haloperidol, correct?"

[14] **Answer from Dr. Cathers:** "I don't have
[15] proof of that."

[16] Dr. Diamond also had no proof that
[17] Janssen made a superiority representation. She
[18] testified on June 9 in the morning at page 104,
[19] **lines 11 to 25:** "Are you aware of any
[20] representation made by Janssen to the
[21] Commonwealth, to Commonwealth physicians
[22] regarding superiority?"

[23] There was an objection. Mr. Murphy
[24] repeated the question.

[25] "Answer: No.
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[1] "In your capacity as a state entity
[2] representative, are you aware of such?

[3] "Answer: The fact that the information
[4] was not --

[5] "Question: Are you aware of such --

[6] "Answer: I don't have individual
[7] people that provide that -- can testify to
[8] that."

[9] Now, the Commonwealth did introduce
[10] evidence of business plans and other internal
[11] marketing materials and I think it introduced
[12] one sales aid. We may talk later, if we have
[13] time, about what they say and why they are not
[14] false or misleading, but the bottom line, the
[15] most important point for these purposes is that
[16] there is no clear, precise and convincing
[17] evidence that Janssen distributed those
[18] materials to any physician treating
[19] Pennsylvania Medicaid participants. There's no
[20] clear, precise and convincing evidence that
[21] Janssen told any Pennsylvania prescriber or for
[22] that matter anyone else outside of Janssen that
[23] Risperdal was superior to Haldol. To the
[24] extent that this is a case about
[25] misrepresentations to prescribers, then it

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[1] fails for lack of proof of misrepresentation.

[2] In addition, the Commonwealth has not
[3] proved that any Pennsylvania physician, any
[4] doctor treating a Medicaid participant relied
[5] on a misrepresentation that anything that was
[6] said by Janssen actually made a difference to
[7] the doctors' prescribing decisions. The
[8] Commonwealth simply hasn't found a way around
[9] the learned intermediary bar to causation
[10] proof. It hasn't shown that any Janssen
[11] misrepresentation to a Pennsylvania prescriber
[12] led the doctor to prescribe a medicine which
[13] she would not otherwise prescribe it. If no
[14] prescriber relied, if no prescriber would have
[15] done anything differently had she been told the
[16] truth, the Commonwealth cannot recover. The
[17] alleged misrepresentations cannot have caused
[18] its loss.

[19] Doctors do not, as the Court knows,
[20] simply follow the recommendations of
[21] pharmaceutical representatives when deciding
[22] what medicines to prescribe. They are not, as
[23] the Pennsylvania Supreme Court has said, dupes,
[24] although perhaps there's an exception to that,
[25] a single one. When prescribing for an

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[1] individual patient, the doctor looks for the
[2] medicine that will work best for the patient.
[3] She considers the patient's medical history,
[4] she considers the nature of the patient's
[5] illness, its manifestations in the individual
[6] patient. She takes into account the various
[7] treatments that might work and the possible
[8] benefits and the risks of each and she makes a
[9] choice that's specific to that patient. She
[10] exercises her informed medical judgment as to
[11] the best treatment for that individual patient.

[12] Doctors have information about risks
[13] and benefits of a medicine from many sources.
[14] They read the labels. They have information
[15] from academic journals, from continuing medical
[16] education courses, from the state, itself,
[17] which engages in academic detail. They have
[18] information from conferences and from
[19] presentations and they typically have their own
[20] experience with the medicine. It may have
[21] worked in the past for their patients who have
[22] certain kinds of illnesses or maybe it didn't
[23] and, of course, they have information from
[24] pharmaceutical manufacturers. But before a
[25] pharmaceutical manufacturer can be held liable

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[1] for a misstatement or an omission to a
[2] prescriber, the plaintiff must show that what
[3] the manufacturer said or did not say made a
[4] difference; that but for the misstatement the
[5] doctor would not have made the same judgment
[6] and would not have prescribed the
[7] manufacturer's medicine. That is the learned
[8] intermediary doctrine. That's what must be
[9] proved to show causation when a prescriber's
[10] decision is at issue. And in this case, the
[11] Commonwealth has no evidence that any
[12] prescriber would have done anything differently
[13] had there been no representation of
[14] superiority. If a prescriber would have
[15] prescribed Risperdal, representation or no
[16] representation, the Commonwealth cannot
[17] recover.

[18] Because the Commonwealth cannot prove
[19] that prescribers would have acted differently
[20] if there had been no misrepresentations, it
[21] cannot recover on the claims that Janssen
[22] defrauded prescribers, that Janssen used
[23] misleading marketing materials and so forth,
[24] and it cannot recover on claims, any claims,
[25] that misrepresentations somehow allowed Janssen

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[1] to, their words, sustain an inflated price.
[2] What plaintiff must mean by sustaining an
[3] inflated price is that doctors kept prescribing
[4] Risperdal at the price that Janssen said
[5] because Janssen misled them about the safety
[6] and efficacy of the medicine.

[7] But remember Mr. Cowan told the Court
[8] on June 2nd that Janssen could set the price of
[9] Risperdal wherever it chose. His words were it
[10] certainly could set a very high price, market
[11] the drug truthfully and sell none of it or very
[12] little of it. Instead, he said Janssen chose
[13] to create this aura about the drug that simply
[14] was not true and the crux of our claim, he went
[15] on, is his words, that they were -- they were
[16] able to sustain a false price by this aura of
[17] misrepresentation about the safety and efficacy
[18] of the medicine. That's in the transcript at
[19] page 61. Well, if that's the crux of the
[20] claim, the claim fails in its entirety for the
[21] Commonwealth has not shown that doctors would
[22] not have prescribed Risperdal in the same
[23] circumstances in the same amounts if there had
[24] been no misrepresentations.

[25] Your Honor, all of the claims fail
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[1] because there's no proof of reliance by
[2] prescribers and no proof of causation.

[3] Let me turn to the claim which is not
[4] in the complaint which wasn't in the precise
[5] statement of claim which wasn't even in the
[6] openings that Janssen said something directly
[7] to the Commonwealth or, rather, did not say
[8] something directly to the Commonwealth that was
[9] fraudulent that caused the Commonwealth to
[10] suffer a loss. The Commonwealth has not shown
[11] that Janssen ever told the Commonwealth, this
[12] is the affirmative misrepresentation part, it's
[13] not shown that Janssen ever told the
[14] Commonwealth that Risperdal was better than
[15] Haldol. Dr. Cathers admitted she has no proof
[16] that Janssen told Risperdal is better than
[17] Haldol and neither did Dr. Diamond, because
[18] there's no proof of an affirmative
[19] misrepresentation. The Commonwealth switched
[20] its theories.

[21] Now the complaint is, as I understand
[22] it, that Janssen did not stop by Dr. Cathers's
[23] office in August of 2005 and tell her that
[24] Janssen had been advised 12 years earlier not
[25] to make superiority claims in promotional

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[1] materials until and unless there was sufficient
[2] evidence to support them, that is, the
[3] Commonwealth is now taking the position that
[4] Janssen should have told the Commonwealth that
[5] it was not supposed to make claims in its sales
[6] materials, even though there is no evidence
[7] that Janssen ever did make such superiority
[8] claims to the Commonwealth or to any
[9] Pennsylvania physician.

[10] Well, there's sometimes a duty to
[11] disclose material information. This is not
[12] material information. There's a duty like
[13] that, for example, when the parties are in a
[14] fiduciary or confidential relationship. And if
[15] I understood the arguments ten days ago, the
[16] argument was, well, that's what we have here, a
[17] confidential relationship. But this isn't a
[18] confidential relationship of the sort that
[19] could give rise to a duty to disclose, to make
[20] disclosures. There's a case known as eToll,
[21] E-T-O-L-L at 811 A.2d 10, and in that case, in
[22] that opinion, the Superior Court said, "A
[23] confidential relationship is marked by such a
[24] disparity and position that the inferior party
[25] places complete trust in the superior party's

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[1] advice and seeks no other counsel so as to give
[2] rise to a potential abuse of power."

[3] That's not the situation here. This
[4] was an arms-length commercial relationship in
[5] which the Commonwealth and Janssen negotiated
[6] rebates and negotiated price. The argument
[7] that the rebate agreement -- and this is the
[8] argument that I understood was being made --
[9] the argument that the rebate agreement is
[10] indicative of a confidential relationship
[11] because it has a clause that says confidential
[12] information is simply frivolous. That's a
[13] nondisclosure clause. It has nothing to do
[14] with the confidential information or
[15] confidential relationship that would give rise
[16] to a duty of the sort that fiduciary has to
[17] make disclosures.

[18] But let's assume for a moment that
[19] Janssen did have an obligation to knock on Dr.
[20] Cathers's door back in 2005. What difference
[21] would it have made? What is the Commonwealth's
[22] evidence of reliance and causation? Dr.
[23] Diamond, who also wanted a knock on the door,
[24] was not clear as to what she might have done.
[25] She said that she would have shared memorandum,

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[1] the letter with the Pharmacy and Therapeutics
[2] Committee. Now, as I understand the testimony,
[3] all that the Pharmacy and Therapeutics
[4] Committee might do, all that it could do if it
[5] thought that Risperdal was overpriced is to
[6] impose a prior authorization requirement. It
[7] might require doctors who choose to prescribe
[8] Risperdal first to pick up the telephone, to
[9] call the Department of Welfare's phone call
[10] center and to get approval when they put a
[11] patient on Risperdal for the first time. But
[12] there's no evidence whatsoever that the
[13] committee would have imposed a prior
[14] authorization requirement. Dr. Diamond said
[15] that her office was adamantly opposed, her
[16] words, to fail first requirements. And,
[17] secondly, there's -- we have the fact that the
[18] Commonwealth did not impose a prior
[19] authorization requirement in 1997 when it filed
[20] this lawsuit or at any time since. And there's
[21] no evidence that imposition of a prior
[22] authorization requirement would have made, and
[23] this is the most important part, would have
[24] made the slightest difference in the number of
[25] prescriptions written or in the amount paid by

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[1] the Commonwealth because, again, we don't have
[2] any evidence from Pennsylvania prescribers.

[3] Dr. Cathers said she would have asked
[4] Provider Synergies to review both first and
[5] second-generation antipsychotics if she had
[6] known. Indeed, she testified she had made such
[7] a request the night before her testimony or
[8] maybe the day of her testimony there's a
[9] statement in the brief that refers to her
[10] deposition, which is not consistent with the
[11] record, she said she learned about it the day
[12] before. As best I can tell, that's exactly
[13] what Provider Synergies has been doing for the
[14] last five years. In any event, there's no
[15] testimony and no evidence that that kind of
[16] review would lead to prior authorization and,
[17] again, there's no reason to believe that prior
[18] authorization would lead to fewer prescriptions
[19] or less money spent. How would the
[20] Commonwealth prove that without presenting
[21] evidence from prescribers? There simply is no
[22] clear, precise and convincing evidence of
[23] reliance or causation. Indeed, there's no
[24] proof at all of reliance and causation. Simply
[25] speculation.

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[1] Let me turn to the Commonwealth's
[2] damages model, and we've briefed this and I'm
[3] not going to repeat what's in the brief. I'm
[4] simply going to highlight some points. We rely
[5] on our brief for the arguments that we're not
[6] discussing today. The Commonwealth's damages
[7] model uses the price of haloperidol, the
[8] generic form of Haldol, as a benchmark price.
[9] It assumes that Risperdal was worth no more and
[10] should have cost no more than haloperidol and
[11] it applies the difference between Risperdal's
[12] price and benchmark price to the actual number
[13] of Risperdal tablets that were prescribed. So
[14] what I'd like to focus on today is the use of
[15] generic haloperidol as a benchmark for pricing
[16] for setting the value of Risperdal, if you
[17] will.

[18] For the benchmark to make any sense,
[19] the Commonwealth must establish that Haldol
[20] (haloperidol) is a safe and effective
[21] substitute for Risperdal, but we know from the
[22] testimony already that for several significant
[23] categories of patients that is not the case.
[24] We know that Risperdal has been approved by the
[25] FDA for the treatment of certain conditions for

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[1] which haloperidol is not approved. We know
[2] that some patients do not respond or do not
[3] react well to first-generation antipsychotics
[4] and they are switched to Risperdal and other
[5] second-generation antipsychotics. We know that
[6] some group of patients have, in Dr. Wirshing's
[7] words, better subjective experiences using
[8] Risperdal than Haldol. They like it better.
[9] And as Dr. Wirshing has also acknowledged, some
[10] doctors have concluded based on their own
[11] experience and exercising their own independent
[12] judgment that Risperdal works better.

[13] So Dr. Cathers, when she testified last
[14] week, posed a rhetorical question. She said,
[15] why shouldn't Risperdal be priced the same as
[16] generic haloperidol? When one considers all of
[17] these categories of patients for whom
[18] haloperidol is not a better treatment, not even
[19] a substitute treatment, the question becomes
[20] not why shouldn't, but why should Risperdal be
[21] priced the same as generic haloperidol?

[22] Let's look for, if we can, at
[23] plaintiff's damages numbers. I'm looking right
[24] now at Plaintiff's Exhibit 2140 at -- it
[25] doesn't have a page number, it has the page
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[1] that has 2005 on it. Do you have it? Got it?
[2] If you could highlight the line for four
[3] milligram tablets, 2005. Okay.

[4] According to this spreadsheet, this is
[5] Exhibit 2140, as an example, there were 244,230
[6] four milligram tablets of Risperdal prescribed
[7] within the Medicaid Fee For Service Program in
[8] 2005. It's the last number. Now, these
[9] prescriptions represent, of course, actual
[10] treatments for people suffering from a variety
[11] of mental health conditions. We don't know
[12] anything more about these people. We don't
[13] know how many of the people taking these
[14] 244,000 tablets could have been prescribed
[15] haloperidol instead. We don't know how many
[16] tried first-generation antipsychotic and had it
[17] fail. We don't know how many were suffering
[18] from a condition that fell outside of
[19] haloperidol's list of approved indications. We
[20] don't know how many went to see a Pennsylvania
[21] doctor who thinks that haloperidol may be
[22] unsafe or ineffective. The answer is we just
[23] don't know. There's nothing in the record even
[24] to make an estimate of that number. And if the
[25] jury were asked how many of these 244,230

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[1] tablets of Risperdal could have been safely and
[2] effectively switched in 2005 to haloperidol or
[3] some other first generation, they'd be guessing
[4] as much as we are today.

[5] Now, what about the remainder of the
[6] population? We talked about certain groups,
[7] but the unknown number who do not fall into one
[8] of the categories we've talked about. Is it
[9] possible that if we went back to Pennsylvania
[10] doctors and we asked them to look at the
[11] patient's medical records, some of the doctors
[12] would say that certain of their patients could
[13] have been prescribed haloperidol instead of
[14] Risperdal? Sure. That's possible. But
[15] plaintiff didn't do that survey. It didn't
[16] even present that sort of proof on an anecdotal
[17] basis. Plaintiff did not ask a single
[18] Pennsylvania doctor why he or she prescribed
[19] Risperdal and whether haloperidol could have
[20] been prescribed instead. So even as to the
[21] balance of the mental health patients in the
[22] Medicaid program where haloperidol might
[23] conceivably be an option, we simply don't know
[24] how many would have been safely and effectively
[25] switched to the cheaper first-generation

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[1] antipsychotic. Without that information, Your
[2] Honor, plaintiff cannot possibly make the case
[3] that haloperidol is an appropriate benchmark
[4] for its damages proof, even if it had a
[5] fraud-on-the-market theory.

[6] Finally, unjust enrichment. We argued
[7] earlier that the unjust enrichment claim is
[8] duplicative of a fraud claim and now the
[9] Commonwealth has effectively admitted that it
[10] is. Page 6 of its brief on unjust enrichment,
[11] it says, both claims are based on same conduct.
[12] Well, the Commonwealth has put in all its proof
[13] about that conduct and it's not sufficient.
[14] For that reason, Your Honor, the Court should
[15] enter an nonsuit on unjust enrichment claim.
[16] All the predicate fraud proof is in. There's no
[17] reason not to rule on its sufficiency, but
[18] there's a second reason as well, which we
[19] raised in our brief. Janssen and the
[20] Commonwealth entered into supplemental rebate
[21] agreements for the Medicaid program. As the
[22] Commonwealth has acknowledged, these agreements
[23] governed the price that Janssen could charge
[24] the Commonwealth for Risperdal. The
[25] Commonwealth's unjust enrichment claim

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[1] asserting that the price for Risperdal is
[2] inflated necessarily seeks to avoid payment of
[3] the contract price, which the Commonwealth now
[4] says was too high, it was unfair. Under
[5] Pennsylvania law, as we say in our brief, the
[6] existence of these written contractual
[7] agreements that govern price precludes the
[8] Commonwealth's unjust enrichment claim. That's
[9] the Lackner case. Lackner explains by its
[10] nature the doctrine of quasi contract. Unjust
[11] enrichment is a quasi contract theory, is
[12] inapplicable where a written or expressed
[13] contract exists.

[14] So, Your Honor, for all of these
[15] reasons and for all the other reasons set forth
[16] in our briefs, Janssen respectfully respects
[17] the entry of a compulsory nonsuit on all of the
[18] Commonwealth's claims.

[19] THE COURT: Thank you, Mr. Posner.

[20] MR. COWAN: Good morning, Your Honor.

[21] THE COURT: Good morning, Mr. Cowan.

[22] MR. COWAN: If it's all right, I'm
[23] going to come back to my place where I was last
[24] time. That's where I feel most comfortable.

[25] THE COURT: That's fine.
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[1] MR. COWAN: Good morning, Your Honor,
[2] Robert Cowan for the Commonwealth. May it
[3] please the Court, first and very briefly, the
[4] Commonwealth desires to address kind of a
[5] lingering issue that has been resurfacing and
[6] resurfaced again in Janssen's brief, and that
[7] is this notion that its nondisclosure claim is,
[8] as Janssen has written in its brief, a
[9] belatedly maintained or the latest iteration of
[10] an evolving claim when it had wrote at pages 20
[11] and 5 of its brief, respectfully, and I'd like
[12] the Court to consider these allegations,
[13] "Defendant deceived physicians, consumers, the
[14] Commonwealth and others regarding the
[15] comparative efficacy of Risperdal to other
[16] atypicals and traditional antipsychotics.
[17] Defendant failed to warn and affirmatively
[18] misled physicians, consumers, the Commonwealth
[19] and others in the medical community regarding
[20] Risperdal's association with diabetes,
[21] diabetes-related conditions, movement
[22] disorders, EMS and other side effects.
[23] Anecdotal evidence of Risperdal's usefulness
[24] for a given condition could not be presented as
[25] the equivalent of the findings of a

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[1] well-designed clinical trial. Failure to
[2] comply with these standards violated the
[3] defendant's legal duty to provide accurate and
[4] non-misleading information."

[5] These are excerpts not from the live
[6] complaint, but from the original complaint in
[7] this lawsuit that was served on Janssen in
[8] January of 2008, and I can promise you the very
[9] same allegations were in the original complaint
[10] before the cases were severed. And so this
[11] idea that the nondisclosure claim is something
[12] that's a new -- generated a new or a recent
[13] conception of the Commonwealth simply is just
[14] not the case. It has become an increased focus
[15] of the Commonwealth as our case has developed
[16] but, you know, the narrowing of the claims and
[17] the fine-tuning of the claims is certainly to
[18] be expected. I, in fact, I think it's demanded
[19] at trial very often times and so I simply
[20] wanted to raise that issue as a very
[21] preliminary matter.

[22] In short, the Commonwealth has from day
[23] one asserted that Janssen failed to inform and
[24] falsely misled Pennsylvania doctors and
[25] Medicaid program, itself, regarding the true

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[1] safety and efficacy of Risperdal, and that is
[2] what the evidence has proven here and our brief
[3] shows and I'll discuss.

[4] I'd like to address the two concerns
[5] that Your Honor raised with counsel last
[6] Friday, and those specifically are the learned
[7] intermediary doctrine and the reliance and
[8] causation issues. As far as learned
[9] intermediary is concerned, it's the
[10] Commonwealth's view that instead of addressing
[11] the Commonwealth's claims directly, Janssen has
[12] premised most of its defense on attempting to
[13] confuse the jury over hypothetical Pennsylvania
[14] doctors' testimony that is not part of the
[15] record. The issue from Janssen's point of view
[16] seems to be whether or not the Commonwealth can
[17] show that the misrepresentations made to
[18] Pennsylvania doctors by Janssen's sales
[19] representatives either caused themselves to
[20] write Risperdal prescriptions when they
[21] otherwise would have written Haldol
[22] prescriptions, or more generally caused those
[23] doctors to write more Risperdal's prescriptions
[24] than they otherwise would have. But both are
[25] red herrings and have been disclaimed by the

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[1] Commonwealth, and I'll explain why.
 [2] At the risk of sounding like a broken
 [3] record, the Commonwealth does not allege that
 [4] Janssen's conduct caused Pennsylvania doctors
 [5] to write more Risperdal prescriptions than they
 [6] otherwise would have, nor is it our contention
 [7] that Risperdal prescriptions should not have
 [8] been written for those patients who need it.
 [9] Again, Janssen's familiar learned intermediary
 [10] refrain goes something like this: The
 [11] fraudulent misrepresentations and omissions the
 [12] Commonwealth has alleged cannot be the cause of
 [13] its damages because the learned intermediary
 [14] doctrine breaks the causal chain, that is,
 [15] doctors' independent decisions to prescribe
 [16] medicine and to prescribe Risperdal, or not to
 [17] prescribe Risperdal, trumps any influence,
 [18] misleading information, failure to deprive
 [19] complete information, etcetera, concerning
 [20] Risperdal.

[21] In effect, Janssen is trying to turn
 [22] this case, and it's not, but they are trying to
 [23] turn this case into a personal injury
 [24] failure-to-warn claim in which we would be
 [25] required to show that the doctor would have
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[1] done something different. But the reason
 [2] Janssen's contingent is misguided is it
 [3] addresses the quantity of Risperdal
 [4] prescriptions written, which is irrelevant to
 [5] the Commonwealth's case and the Commonwealth's
 [6] damages calculation, and the reasons for which
 [7] the prescriptions were written which, again,
 [8] does not matter. The Commonwealth's claims do
 [9] not involve whether Janssen did or did not
 [10] cause a particular patient to take Risperdal or
 [11] a particular doctor to prescribe it versus
 [12] another drug. The Commonwealth's actual
 [13] claims, as pled directly, undermine Janssen's
 [14] contention, pursuant to the learned
 [15] intermediary doctrine, that, quote, plaintiff
 [16] must provide evidence that had purported,
 [17] accurate and complete information had been
 [18] provided prescribing physicians would not have
 [19] prescribed, end quote, Risperdal to their
 [20] patient's, and that's paragraph 21 of their
 [21] brief.

[22] The question, as I said, is not whether
 [23] any Commonwealth physician would have done
 [24] anything different had they been fully informed
 [25] about the truth about Risperdal, which is the
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[1] foundation of the learned intermediary
 [2] doctrine. So let me tell you what the
 [3] Commonwealth's claim is.
 [4] Again, the Commonwealth believed and
 [5] relied on the representations about Risperdal
 [6] in, for example, reimbursing for the drug at
 [7] the price set by Janssen, which was based on
 [8] fraudulent misrepresentations about the drug;
 [9] calculating and receiving rebates from Janssen,
 [10] which were based on that fraudulent price;
 [11] reimbursing for the drug without prior
 [12] authorization or other coverage limits in
 [13] place, and adding the drug to its preferred
 [14] drug list without comparative analysis against
 [15] first-generation drugs.

[16] The Commonwealth is not a learned
 [17] intermediary. It doesn't write prescriptions.
 [18] It does pay for them however. The focus is on
 [19] Janssen's misrepresentations and nondisclosures
 [20] about Risperdal to Pennsylvania physicians in
 [21] the Commonwealth itself and the fact that
 [22] Commonwealth Medicaid was entirely unaware of
 [23] the way that Janssen was portraying and
 [24] marketing the drug in direct contravention of
 [25] explicit instruction from the FDA not to do so,
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[1] which was material to the Commonwealth. The
 [2] evidence shows that Janssen set out to
 [3] establish a, quote, premium price for Risperdal
 [4] and to maintain it by distinguishing it from a
 [5] crowded field of first-generation
 [6] antipsychotics that had been on the market for
 [7] decades. They primarily determined to do that
 [8] by claiming Risperdal to be a new and improved
 [9] safer version of their older drug Haldol. Then
 [10] the FDA threw a wrench in that plan by saying
 [11] you can't compare yourself to Haldol because
 [12] the test you designed don't show that you're
 [13] better or safer than Risperdal and they never
 [14] did a test that did show it, and the FDA never
 [15] changed its position over the next 14 years.
 [16] Janssen reacted to that by proceeding anyway
 [17] for the next 14 years to market the drug in
 [18] contravention of what the FDA had told them to
 [19] do, and it worked. And no one was the wiser
 [20] until this lawsuit and others like it were
 [21] filed.

[22] The FDA never changed its position on
 [23] the issue of Risperdal's comparative claims
 [24] during the entire relevant time at issue.
 [25] Janssen never informed the Commonwealth, who
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[1] had to pay for the drug, of the truth about
[2] Risperdal and the false and misleading manner
[3] in which it was marketing the drug. It's true
[4] that Janssen never ever informed the
[5] Commonwealth of those misrepresentations when
[6] it was afforded a platform for doing so on an
[7] annual or semiannual basis beginning in 2005
[8] with Medicaid's chief pharmacist and chief
[9] psychiatrist in attendance.

[10] Thus, as Judge Weinstein finds in the
[11] parallel Mississippi vs. Eli Lilly litigation
[12] rejecting the identical argument that the
[13] learned intermediary doctrine cuts off in this
[14] instance. He said the total fraud resulted in
[15] an increased price. So the fact that some
[16] doctors, patients or others were aware of the
[17] fraud is irrelevant. Without the fraud, the
[18] price would have been lower to all payers.
[19] I'll add for the record that Judge Abramson
[20] denied Janssen's learned intermediary defense
[21] when it was raised in Janssen's motion for the
[22] judgment on the pleadings.

[23] **THE COURT:** You agree nonsuit is a
[24] different stage of the proceeding?

[25] **MR. COWAN:** I understand. Janssen is
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[1] free --

[2] **THE COURT:** Do you understand that to
[3] reject that at summary judgment stage, you
[4] understand that's where we are now?

[5] **MR. COWAN:** Yes, I understand.

[6] **THE COURT:** Fair enough.

[7] **MR. COWAN:** I simply wanted to remind
[8] the Court.

[9] **THE COURT:** I apologize. All right.

[10] **MR. COWAN:** In terms of the reliance
[11] and causation issues, which I know the Court is
[12] interested in, I've touched on aspects of the
[13] Commonwealth's reliance just now and I'll
[14] expand further on that. The Commonwealth has
[15] demonstrated evidence of reliance regardless of
[16] whether the Court adopts a presumption of
[17] reliance and instructs the jury on the same, as
[18] it should.

[19] First, Dr. Cathers testified that the
[20] Medicaid program necessarily relies on drug
[21] manufacturers to provide fair pricing
[22] information for the determination of the
[23] Commonwealth's rebate that is not based on
[24] fraud, and that was Cathers's testimony at page
[25] 27, 28 and 57.

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[1] The net price paid by the Commonwealth
[2] takes into account the price set by Janssen
[3] less the rebate amount provided under federal
[4] law. Therefore, this case, like the case in
[5] Commonwealth vs. Tap Pharmaceuticals, the
[6] Commonwealth necessarily here relies on the
[7] price published by the manufacturer to be a
[8] true and accurate price that is not based on
[9] fraud, misrepresentations or nondisclosure. In
[10] both this case and that one, the inflated price
[11] was not based on any real superior performance
[12] of the drugs at issue, but instead on a
[13] misrepresentation about the drug by the company
[14] that sold it.

[15] So the misrepresentation in the Tap
[16] case was that the price did not reflect
[17] kickbacks and other financial incentives that
[18] were provided -- actually provided by the
[19] company. And here the misrepresentation is
[20] based on the drug safety and performance which
[21] did not reflect the true clinical data about
[22] Risperdal which Janssen misrepresented, despite
[23] FDA admonitions not to do so and besides a
[24] legal duty to only provide fair and balanced
[25] information under the very regulations that

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[1] govern Janssen's conduct. Thus, the
[2] Commonwealth relied on Janssen's disclosures
[3] about Risperdal in absence of information to
[4] the contrary which only Janssen possessed in
[5] reimbursing for the drug at price set by
[6] Janssen, which was based on the fraudulent
[7] misrepresentations about the drug and in
[8] calculating and receiving rebates from Janssen,
[9] which were based on the fraudulent price.

[10] Dr. Cathers further testified that
[11] based on the disclosure of the comparative
[12] studies discussed in the FDA memos and letters,
[13] Medicaid was undertaking a comparative
[14] re-review of all the antipsychotics in one
[15] class, first generation -- first and
[16] second-generation antipsychotics, so there will
[17] be a full comparison between the drugs in the
[18] future. That was at page 98 and 99 of
[19] Cathers's testimony.

[20] Dr. Diamond testified that she believed
[21] the FDA memos and letters she was shown at
[22] trial would have been integral to determining
[23] whether the benefits of Risperdal warranted the
[24] cost to the Commonwealth as well as other
[25] considerations, and the other considerations

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[1] are whether the drug is included or excluded
[2] from the PDL or whether it's referred to the
[3] DUR Board for prior authorization or
[4] consideration of safety and efficacy. Dr.
[5] Diamond testified to that at pages 15 through
[6] 18. Medicaid was able to do none of that by
[7] virtue of Janssen's failures to disclose all
[8] material information about Risperdal.

[9] Second, the Commonwealth's reliance is
[10] also grounded in Dr. Cathers's testimony that
[11] the information shared with Medicaid concerning
[12] the unit rebate amount is confidential and may
[13] not be disclosed to anyone. As noted, that
[14] unit rebate amount factored with the price of
[15] the drug set by the manufacturer, the
[16] fraudulent price, is integral to the
[17] calculation that determines the net price that
[18] the Commonwealth has to pay for Risperdal and
[19] other drugs. Therefore, even aside from actual
[20] reliance, the Commonwealth is entitled to a
[21] presumption of reliance based on the
[22] confidential or fiduciary relationship that
[23] exists between the state and Janssen and we
[24] cite the relevant cases in our brief for that
[25] proposition.

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[1] Excuse me, Your Honor, I'm going to
[2] take a drink of water. (Pause.)

[3] THE COURT: Off the record.
[4] (Discussion off the record.)

[5] MR. COWAN: Third, as we have again
[6] argued in our brief, Pennsylvania law supports
[7] a presumption of reliance based on the fact of
[8] misrepresentations -- the occurrence of
[9] misrepresentations themselves, and that's the
[10] argument we made at summary judgment and that
[11] relevant case law is also cited in our brief.
[12] Therefore, Janssen's argument at page 25 of its
[13] brief that Pennsylvania law does not recognize
[14] a presumption of reliance is plainly mistaken.

[15] Importantly, the Clark vs. Pfizer case,
[16] in which Janssen relies, is entirely inapposite
[17] here. In that case, individual class members
[18] were attempting to show through aggregate
[19] evidence that each class and specific doctor
[20] relied upon the defendant's off-label promotion
[21] of the drug at issue causing -- they wanted to
[22] rely on aggregate evidence to show that the
[23] doctor relied on off-label promotion by the
[24] manufacturer in prescribing the drug. The
[25] Superior Court decertified the class holding

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[1] that the typicality and commonality aspects of
[2] the class action, the certification
[3] requirements could not be met, unsurprisingly.
[4] Basically, that the doctor's individual
[5] reliance could not be shown through statistics.
[6] But far from rejecting the concept of a
[7] presumption of reliance, the Superior Court
[8] actually observed in part that because the
[9] case, quote, does not involve price inflation,
[10] reliance could not be shown in the aggregate.

[11] Further here as explained, this is not
[12] a class action. Individual doctor's testimony
[13] is not relevant and the misrepresentations made
[14] affected and were material only to one claimant
[15] in the lawsuit and that is Pennsylvania
[16] Medicaid.

[17] Finally, there can be no serious
[18] contention that the Commonwealth has adduced
[19] insufficient evidence of proximate causation as
[20] Janssen --

[21] THE COURT: Say that sentence again.

[22] MR. COWAN: Sure.

[23] THE COURT: Finally what?

[24] MR. COWAN: There can be no serious
[25] contention that the Commonwealth has adduced

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[1] insufficient evidence of proximate causation as
[2] Janssen alleges.

[3] THE COURT: Okay.

[4] MR. COWAN: As Janssen observes in its
[5] own brief, and I'm quoting, "To the extent
[6] there was any concern about the cost of
[7] therapeutic benefit or value of Risperdal,
[8] Medicaid could address that concern by
[9] restricting use of the medicine." And as I've
[10] already stated, Drs. Cathers and Diamond
[11] concurred with that assessment, but the point
[12] is that Medicaid was not given the opportunity
[13] to make those decisions based on complete
[14] information, full disclosures about the drug
[15] because of the information that Janssen failed
[16] to disclose and the information that an
[17] independent body determined about what Janssen
[18] was permitted to say and not say about the
[19] safety and efficacy of its drug.

[20] I want to address very briefly some
[21] other mischaracterizations or misapprehensions
[22] that Janssen has about the state's evidence,
[23] just some general loose ends. First, Janssen
[24] consents that Risperdal, the Risperdal-Haldol
[25] comparison claims and other affirmative

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[1] misrepresentations, were never made to
[2] Pennsylvania prescribers or anyone at the
[3] Commonwealth, and that in any case
[4] Commonwealth's witnesses had no proof that they
[5] were made. But that is simply false. As an
[6] initial matter, Janssen's defense counsel is
[7] engaging in a sleight of hand by asking the
[8] Commonwealth's witnesses to testify about
[9] evidence that both parties know exists on the
[10] record, but that particular witness has not
[11] been privy to, although it's been presented to
[12] the jury.

[13] An example of this is cited in
[14] Janssen's brief at page 9 and 10 where the
[15] excerpt shows Mr. Murphy questioning Dr.
[16] Plunkett where she personally has evidence or
[17] knowledge of whether misrepresentations were
[18] made by Janssen to Pennsylvania doctors. Of
[19] course Dr. Plunkett is not offered as a fact
[20] witness and was not engaged to give an opinion
[21] as to whether Janssen's marketing plans and
[22] materials actually reached Pennsylvania
[23] doctors. In fact, she was expressly precluded
[24] from giving testimony of the nature Mr. Murphy
[25] questioned her about. The same line of

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[1] questioning was deployed on Dr. Cathers and
[2] Diamond, and when they were unable to identify,
[3] based on their own personal knowledge,
[4] affirmative representations made directly to
[5] the Commonwealth or prescribers, Mr. Murphy
[6] repeatedly declared for the jury that there was
[7] no evidence of any fraud, but there is valuable
[8] evidence of nondisclosure to the Commonwealth
[9] itself, which I discussed a few minutes ago, in
[10] the context of learned intermediary and
[11] reliance and which is set forth in our brief.
[12] There is also direct and unequivocal testimony
[13] by Janssen's employees regarding the
[14] comprehensive national scope of Janssen's
[15] marketing and promotional plans and materials.

[16] But all that aside, the Janssen sales
[17] aids and business and marketing plans
[18] themselves that the Commonwealth's witnesses
[19] testified about constitute jury evidence that
[20] Janssen subsequently acted in accordance
[21] therewith in accordance with the sales aids and
[22] business plans. And applicable legal doctrine
[23] is called the Hillmon doctrine from Mutual Life
[24] Insurance Company vs. Hillmon, 145 U.S. 285,
[25] and it's been cited repeatedly in the

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[1] Commonwealth cases, for example, by the
[2] Pennsylvania Supreme Court at Commonwealth vs.
[3] Begley, 566 Pa. 239 with a pinpoint of 270 to
[4] 271. Those cases stand for the proposition
[5] that not only are such out-of-court statements
[6] admissible, and Janssen doesn't challenge the
[7] admissibility here, they are circumstantial
[8] evidence that an intended plan was actually
[9] carried out. I've also cited -- I will also
[10] cite for the Court Commonwealth vs. Lowenberg,
[11] 481 Pa. 244, 254 to 255. Hillmon is, of
[12] course, the seminal law school book case where
[13] one person, Walters, had written that he was
[14] leaving Wichita on a trip with a man named
[15] Hillmon, and that writing was admitted as
[16] principal proof that Hillmon had actually
[17] traveled with Walters.

[18] Under Pennsylvania law, the jury is
[19] perfectly entitled to consider this evidence
[20] as, at a minimum, circumstantial proof that
[21] Janssen's marketing plans were, in fact,
[22] carried out.

[23] Janssen next argues that the -- that
[24] Commonwealth has neither pled nor proven
[25] materiality, but as the Commonwealth notes in

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[1] its brief at paragraph ten, a fact is material
[2] if it is one that would be of importance to a
[3] reasonable person in determining a choice of
[4] action. The amended complaint is replete with
[5] that, allegations that Janssen's deceptive and
[6] false allegations including Risperdal safety
[7] and efficacy profile, quote, impacted and
[8] falsely inflated the cost of Risperdal
[9] prescriptions. That's at paragraph 77. And
[10] that, quote, the price the Commonwealth paid
[11] for Risperdal was falsely inflated and
[12] sustained through defendant's false
[13] misrepresentations as compared to the value
[14] that would have attached to Risperdal had its
[15] true safety and efficacy profile been
[16] disclosed. That's paragraph 75.

[17] Plainly, those are pleadings setting
[18] forth material facts that would have been
[19] important to a reasonable person in determining
[20] a choice of action. The case on which Janssen
[21] relies did not involve the frequency with which
[22] claimants invoked the word "material" in their
[23] complaint. Instead, the McShay case involved
[24] an attempt by the plaintiff to shoehorn a
[25] breach of contract claim into what was clearly

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[1] a gross negligence claim. And the Court saw
[2] through that measure, that attempt. That is
[3] not what we have here.

[4] Moreover, the Commonwealth has adduced
[5] evidence of materiality. I've already
[6] described in our response of paragraph 3
[7] incorporates the response -- the importance or
[8] significant upon which Dr. Cathers or Diamond
[9] placed the nondisclosed information they
[10] testified about at trial, but for the record,
[11] I'll additionally identify Dr. Cathers's
[12] testimony discussed at paragraph 5 of our
[13] response as well as the evidence and testimony
[14] I have argued earlier this morning relative to
[15] reliance.

[16] A very brief word on unjust enrichment.
[17] The primary complaint about this claim, it's
[18] the same claim as the Commonwealth's fraud
[19] case. While it's certainly true that the two
[20] claims are based on the same conduct, the
[21] Commonwealth has satisfied the very different
[22] elements of both claims. For unjust
[23] enrichment, the Commonwealth has shown it has
[24] confirmed a benefit on Janssen, that Janssen
[25] appreciated those benefits through increased

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[1] sales and market share and that retention of
[2] those benefits would be unjust because the
[3] Commonwealth did not receive what it paid for.
[4] The proof of those elements is set forth in our
[5] brief.

[6] Janssen also argues that the conduct
[7] that the parties is governed by a written
[8] contract and, therefore, the claim in equity
[9] for unjust enrichment cannot be had, but there
[10] is no agreement between the Commonwealth and
[11] Janssen concerning Pennsylvania Medicaid.
[12] Instead, that agreement is with the federal
[13] government as Janssen's brief acknowledges at
[14] page 8.

[15] Indeed, Janssen should be judicially
[16] estopped from arguing that it had a written
[17] agreement with the Commonwealth as it has
[18] already successfully argued to the Court that
[19] it is not a provider under the Medicaid laws
[20] and a provider agreement is the only type of
[21] agreement that the applicable law contemplates
[22] that Janssen could have had with the
[23] Commonwealth.

[24] In summary, the evidence demonstrates
[25] that Janssen was actively marketing Risperdal

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[1] in Pennsylvania in a false and misleading
[2] manner about which the Commonwealth and its
[3] Medicaid department were unaware, and when
[4] Janssen had the opportunity to tell the truth
[5] about what it knew about Risperdal's lack of
[6] comparative efficacy and safety to either
[7] doctors or to the Commonwealth itself, it chose
[8] not to do so, but instead opted to keep the
[9] Commonwealth uninformed about the drug's
[10] equivalency to much cheaper antipsychotic drugs
[11] like Haldol.

[12] Given the extremely high standard for
[13] establishing a compulsory nonsuit in a clear
[14] case where the facts and evidence may lead only
[15] to the conclusion that there is a lack of
[16] evidence, the Court should deny Janssen's
[17] motion. Commonwealth is entitled to every
[18] inference and advantage that may be drawn from
[19] the evidence. It is not enough that there is
[20] discrepant evidence, but it must be
[21] inconceivable on any reasonable hypothesis that
[22] the collective mind of the jury could find in
[23] favor of the Commonwealth in order to grant
[24] Janssen's nonsuit. Janssen has simply not
[25] carried that burden.

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[1] The Commonwealth incorporates by
[2] reference to its arguments and the evidence set
[3] forth in its brief submitted to the Court last
[4] Friday morning.

[5] Thank you.

[6] **THE COURT:** Okay. Before we go
[7] forward, does anyone know the control number of
[8] the nonsuit motions? Were they E-filed last
[9] week?

[10] **MR. POSNER:** They were, Your Honor.

[11] **THE COURT:** Okay. Then I'll find them.

[12] Do you want to make a response?

[13] **MR. POSNER:** I do.

[14] **THE COURT:** All right. And if either
[15] side needs a break before we go forward, let me
[16] know.

[17] 15 minutes.

[18] **MR. POSNER:** Yes, Your Honor. The
[19] first point in the response is that I started
[20] my presentation by pointing out to Your Honor
[21] that there was no proof from the Commonwealth
[22] of anything that was done or any reliance
[23] before November of 2004. There was no response
[24] to that.

[25] Secondly, a minor point, perhaps, but
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[1] maybe not, Mr. Cowan's statement that there is
[2] no supplemental rebate agreement with the
[3] Commonwealth, literally true. Since Risperdal
[4] became a generic in 2008, it does not pay
[5] supplemental rebates to the Commonwealth. It
[6] has not been a preferred drug since 2009.
[7] That's the tie between being a preferred drug,
[8] paying supplemental rebates.

[9] During the period in question, there
[10] was a supplemental rebate agreement, and when
[11] Mr. Cowan stood here before you on the 2nd of
[12] June, he told you that. He said there's
[13] actually a rebate agreement that is entered
[14] into between the Commonwealth and the company
[15] that sets forth these provisions as applicable
[16] to an individual drug company. There were
[17] supplemental rebate agreements.

[18] Third point, Your Honor precluded
[19] evidence of misrepresentations to Pennsylvania
[20] physicians. You entered an Order saying no
[21] proof of such representations and no proof that
[22] such representations caused any loss to the
[23] Commonwealth. There is no such proof, and to
[24] stand here today and say, well, first of all,
[25] that doesn't matter is just inconsistent with,

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[1] for example, how the damages are computed.
[2] Damages are computed by multiplying the
[3] difference in price times the number of tablets
[4] of Risperdal that were actually prescribed. If
[5] the argument is that prescribers were defrauded
[6] and they, therefore, prescribed Risperdal when
[7] Haldol was just as good, then the question of
[8] why they prescribed Risperdal is at issue.
[9] That is where the learned intermediary doctrine
[10] fits in and it fits in in the unjust enrichment
[11] claim.

[12] I just heard Mr. Cowan say to you that
[13] they got increased market share. Well, how do
[14] you get increased market share unless
[15] prescribers are relying on these supposed
[16] misrepresentations, unless prescribers are
[17] making decisions because they have
[18] misinformation from Janssen. That is the
[19] learned intermediary issue.

[20] Third point, circumstantial evidence.
[21] Well, we could go through the documents, the
[22] marketing plans and so forth and we could see
[23] what they say really, but I don't think we need
[24] to do that. I think the bottom line on this
[25] issue of circumstantial evidence is, of course,

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[1] you can prove things by circumstantial
[2] evidence, but you still have to prove them by
[3] circumstantial evidence and that circumstantial
[4] evidence and that proof, just like direct
[5] evidence, must be clear, precise and
[6] convincing.

[7] So there is no clear, precise and
[8] convincing proof in this case that a
[9] positioning statement in a marketing plan
[10] translated into an improper statement to a
[11] physician anywhere in the United States much
[12] less in Pennsylvania. Dr. Cathers's testimony
[13] about fair pricing information, and she was
[14] relying on the fact that the pricing
[15] information given to the Commonwealth wasn't,
[16] quote, based on fraud. Mr. Murphy
[17] cross-examined her on that. He asked her
[18] whether what we were talking about was whether
[19] Janssen provided accurate information to the
[20] Commonwealth. She agreed that Janssen provided
[21] accurate pricing information to the
[22] Commonwealth. The Tap case involved
[23] allegations of something quite different. The
[24] Tap case involved allegations that
[25] pharmaceutical manufacturers reported to state

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[1] entities or governmental entities prices that
[2] they weren't actually charging.

[3] As for the reliance of Dr. Cathers and
[4] Dr. Diamond back at 2005 on Dr. Cathers said
[5] she'd do a full review, okay? Dr. Diamond
[6] said -- I can't remember what the argument was
[7] that Dr. Diamond was going to do. I think she
[8] was going to go to the DUR Committee. Here's
[9] what Dr. Diamond said on -- I'm not sure what
[10] -- she testified at page 53. She said if she
[11] had known that the FDA had said something
[12] shouldn't be included in promotional materials,
[13] quote, then I certainly might have made the
[14] same decision, but I would have wanted to know
[15] that. That's not reliance. That's not
[16] materiality. That is maybe I would have done
[17] something different.

[18] Finally, Clark against Pfizer. Now
[19] that I'm confused by, because Clark vs. Pfizer
[20] wasn't initially cited by us, it was cited by
[21] them in the precise statement of claim, and
[22] they referred to note 4, and note 4 is dictum
[23] and it characterizes the Zyprexa case and
[24] references to the Zyprexa case in the Neurontin
[25] decision. The Zyprexa case, the Mississippi

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[1] case, is a case that was decided by Judge
[2] Weinstein in the Eastern District in the
[3] multi-district litigation, and we've talked
[4] about it in our brief. It's an interesting
[5] decision. It's a very long decision. It's an
[6] interesting decision because Judge Weinstein
[7] says, I think I'm likely to be reversed on
[8] this. There's another Second Circuit decision
[9] that goes the other way where they reversed me
[10] before, and written a brief for the Second
[11] Circuit and maybe he'll have some luck this
[12] time, but maybe not. In any event, he stayed
[13] the case to see what would happen.

[14] But more important, the case involved
[15] statistical proof, economic proof. The
[16] plaintiffs brought in an economist of sorts
[17] from Harvard who did a study and purported to
[18] show by this elaborate econometric analysis
[19] that, in fact, there was this connection. And
[20] he said, okay, I looked at that proof, I see
[21] that proof and I see some evidence that
[22] confirms that that proof might apply in a
[23] particular case of Zyprexa. There's a drop in
[24] demand and, therefore, I'm going to allow the
[25] proof. That's what he said. We don't have

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[1] proof like that in this case, none at all.
[2] That case has absolutely no application. You
[3] don't have to read the 117 pages, they don't
[4] bear on what we're facing here.
[5] So, Your Honor, we stand on our
[6] arguments. There is no proof of a
[7] representation to anyone. There is no proof of
[8] reliance by any prescriber anywhere and they
[9] need that sort of proof to prevail.

[10] THE COURT: Thank you.

[11] Mr. Cowan?

[12] MR. COWAN: I really have just two
[13] brief points, Your Honor.

[14] I did respond to Janssen's timeline
[15] argument relative to reliance, and I explained
[16] to the Court the different ways that the Court
[17] can find reliance. And I pointed to the Court
[18] that there is evidence of direct reliance in
[19] the testimony by Dr. Cathers and Dr. Diamond.
[20] And while it's true that those doctors were not
[21] at Medicaid, at Pennsylvania Medicaid before
[22] 2004-2005, that time frame, there are other --
[23] there is other means, other legal doctrine by
[24] which the Court may determine that there was
[25] reliance. And I'll specifically point to the

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[1] confidential fiduciary special relationship
[2] that exists between the state, the Commonwealth
[3] Medicaid system and the drug companies as proof
[4] of reliance under Pennsylvania law as one
[5] example.

[6] There was also a comment about
[7] supplemental rebates, just to clear this up,
[8] and my intention certainly is not to mislead
[9] the Court in any way. My understanding is that
[10] the supplemental rebate agreement that was
[11] entered into with respect to the Commonwealth
[12] and Janssen had to do with the PACE program.
[13] There was, and those are directly controlled by
[14] Pennsylvania law, but my understanding from
[15] information that I've been given from Medicaid
[16] personnel, including Dr. Cathers and Dr.
[17] Diamond, is that there is not or was not a
[18] direct supplemental rebate agreement between
[19] Janssen and the Commonwealth. The rebate
[20] agreement that was entered into was entered
[21] into with the federal government and the
[22] Commonwealth is a beneficiary of that agreement
[23] as a part of the federal state Medicaid
[24] program.

[25] And unless Your Honor has any further
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[1] questions...

[2] THE COURT: No. Thank you very much.

[3] MR. COWAN: Thank you, Your Honor.

[4] THE COURT: We can take a short break,
[5] stand up and stretch, and then I'll come back,
[6] okay?

[7] (Whereupon, a short recess was taken.)

[8] THE COURT: Have a seat, everyone.
[9] Thank you. All right.

[10] Well, as you know, this is, I believe,
[11] the first opportunity for me to make a ruling
[12] in a dispositive way on this case. When we
[13] were back on our day of hearings pretrial,
[14] although Janssen felt those were dispositive, I
[15] didn't agree because of the summary judgment
[16] related to the first complaint, and the
[17] preliminary objections I don't consider
[18] dispositive, and I think that's why I'm not
[19] really as focused on that Commonwealth vs. Tap
[20] case as I've been hearing throughout the trial
[21] because that's preliminary objections also. I
[22] just don't think that that's as dispositive as
[23] where we are today. So I do want to thank both
[24] teams, the plaintiff's team and the defense
[25] team, for your memos, your copies of cases and

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[1] your cooperation.
 [2] The Janssen motion for nonsuit is
 [3] granted. I'm going to file an Order today, but
 [4] I ask if you'd give me a little time to get my
 [5] memo typed up. My secretary has got her son
 [6] who's graduating the end of the week, Larry is
 [7] gone; I just won't have anybody to type this.
 [8] So if you could give me, at least, until the
 [9] end of the month, but as far as your date for
 [10] calculating any post-trial matters, today is
 [11] the day. I'll file the Order today. I'll
 [12] probably call one person from each side. Mr.
 [13] Coren, I'll get you next time. I'll call one
 [14] person from each side and let you know when I'm
 [15] going to actually file the memo, but I wanted
 [16] to give you some comments from the bench so
 [17] that both sides would have an opportunity to
 [18] have an idea where I'm thinking and what my
 [19] thoughts are, so bear with me, please.
 [20] The procedural history of this case, I
 [21] think, we know, but I'll state it, is that in
 [22] February 2007, the Commonwealth of Pennsylvania
 [23] commenced litigation against three
 [24] pharmaceutical companies, Eli Lilly, Janssen
 [25] and AstraZeneca. The Commonwealth claimed at
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[1] that time that it was seeking to recover inter
 [2] alia expenses incurred and reimbursing
 [3] pharmacies for the purchase of Risperdal and
 [4] other antipsychotic drugs manufactured by those
 [5] three defendants. At that time, the plaintiff
 [6] alleged that the defendant pharmaceutical
 [7] companies promoted their respective
 [8] antipsychotic drugs for non-medically-accepted
 [9] and non-medically-necessary uses. The
 [10] Commonwealth also asserted at that time that
 [11] defendants misrepresented the risks associated
 [12] with those medicines. The defendants filed
 [13] preliminary objections seeking to sever the
 [14] actions and to drop mis-joined parties.
 [15] In December 2007, the Court severed the
 [16] claims filed by the Commonwealth and directed
 [17] the plaintiff to file separate complaints
 [18] against each of those defendants. This action
 [19] was filed against Janssen in January, 2008, and
 [20] there were six causes of action, six counts.
 [21] On January 5th, 2010, Judge Abramson
 [22] granted in part Janssen's motion for judgment
 [23] on the pleadings pursuant to Rule 1034 point
 [24] something or other and dismissed counts 1, 2
 [25] and 3 and count 5 of the complaint. That was
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[1] January 17th of '08. But on January 8th -- I'm
 [2] sorry, January 17th of '08, right.
 [3] January 5th of 2010 was the judgment on
 [4] the pleadings. January 8th of 2010, the
 [5] Commonwealth advised Janssen that it was
 [6] abandoning certain theories and would proceed
 [7] on more narrow theories, and that's this letter
 [8] that we all know that the Commonwealth still
 [9] seeks to recover the difference between the
 [10] price of Risperdal's prescriptions and the cost
 [11] of a cheaper, safer, generic alternative.
 [12] Then on April 12th, 2010, Janssen filed
 [13] their motion for summary judgment urging
 [14] dismissal of the newly -- well, at least, of
 [15] the first complaint of counts 4 and counts 6.
 [16] The next day, the Commonwealth filed a motion
 [17] for leave to file an amended complaint April
 [18] 13th, 2010. That leave was granted by the
 [19] Court and the first amended complaint was filed
 [20] on May 17th, 2010 asserting count 1, the fraud
 [21] and misrepresentation and, count 2, the unjust
 [22] enrichment. Janssen filed the preliminary
 [23] objections to the first amended complaint on
 [24] May 24th, and in anticipation of our jury
 [25] selection on May 28th and after reviewing what
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[1] I call the evolution of the litigation, this
 [2] Court requested each party to submit a precise
 [3] statement of claims and defenses.
 [4] On May 27th, 2010, counsel and the
 [5] Court participated in a pretrial telephone
 [6] conference to discuss trial logistics. Jury
 [7] selection took place May 28th, June 1st and
 [8] June 3rd. On June 2nd, 2010, this Court
 [9] convened a full day of hearings for oral
 [10] argument to consider the defendant's motion for
 [11] summary judgment on the initial complaint and
 [12] preliminary objections to the first amended
 [13] complaint and multiple motions in limine filed
 [14] by both parties.
 [15] After opening statements on June 3rd,
 [16] 2010, and for the next week we've heard from
 [17] the Commonwealth witnesses. The Commonwealth
 [18] rested on June 10th, and on June 10th, 2010, we
 [19] saw a revised claim from the plaintiff that had
 [20] been further narrowed and was based on
 [21] allegations solely involving Medicaid damages.
 [22] The PACE had been withdrawn.
 [23] So we're here today to consider the
 [24] motions for nonsuit. I'm just going to address
 [25] bullet points. I'm not going to mention too
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[1] many case names. I think all of you can fill
 [2] in the case names at this juncture. I'll put
 [3] it all in a memo.
 [4] First of all, my conclusion is that the
 [5] absence of expert testimony on the damage issue
 [6] was extraordinary and possibly, in fact, fatal
 [7] to this litigation. As attorneys, we all know
 [8] that all of the federal entitlement legislation
 [9] is complex, Social Security, Medicare,
 [10] Medicaid, and now we have this new health care
 [11] plan. And then in our case we have the second
 [12] layer of the state entitlement legislation, the
 [13] PACE, the PACENET that we heard about. The
 [14] jury heard about discounts, rebates, take-backs
 [15] and an assortment of formulas overlapping the
 [16] state and federal requirements. The
 [17] Commonwealth requires vendors to sort through
 [18] some of the numbers and the state employees who
 [19] testified did not the basis of all the computer
 [20] printouts, they were not familiar with certain
 [21] extraction specifications, the fields used or
 [22] whether there were certain take-backs,
 [23] something called a TPL, and other things. So I
 [24] conclude that it was too simplistic, T-O-O
 [25] simplistic, and not reasonable for the
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[1] Commonwealth to suggest that simply adding or
 [2] subtracting computer tallies is sufficient to
 [3] avoid jury confusion and speculation.
 [4] In the memoranda, simply writing the
 [5] word, quote, "simply" as the introductory word
 [6] to set forth damage theories does not render
 [7] the damage calculation simple. For example,
 [8] simply put, the damage theory is X, Y or Z or
 [9] the measure of damages is simply X, Y or Z.
 [10] Well, it's not simple. It's very complex.
 [11] Equally important to and a concern to
 [12] the jury confusion and speculation is the
 [13] necessity that the defendant have an
 [14] opportunity to see a report, written report,
 [15] written understanding prior to trial which sets
 [16] forth the facts and the data which form the
 [17] basis of a plaintiff's claims. So the damage
 [18] calculations in this case are such a magnitude
 [19] and complexity, are beyond the realm of a
 [20] juror's ordinary understanding and expertise
 [21] and experience, and the damage calculations in
 [22] a case of this magnitude and complexity should
 [23] have been presented to the defendants prior to
 [24] trial to enable any defendant to analyze the
 [25] damage theories because the damage theories
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[1] here evolved just as the liability theories.
 [2] Now, the liability focusing, of course,
 [3] on reliance and causation, the linchpin of a
 [4] fraudulent misrepresentation and/or
 [5] nondisclosure case involves reliance,
 [6] justifiable reliance and/or detrimental
 [7] reliance. At one point, the Commonwealth
 [8] appeared to be basing its reliance claim on a
 [9] fraud in the market theory. And if you look at
 [10] the complaint, if you look at pages 4 of 7 and
 [11] 5 of 7 of that letter of May 28th, there
 [12] appears to be an assertion that the
 [13] Commonwealth was injured directly and causing
 [14] economic loss, and reliance was presumed. And
 [15] if you look at the text, you'll see that the
 [16] text of that letter is at odds, I'll put it
 [17] that way, with the response to the motion for
 [18] compulsory nonsuit. The problem, of course,
 [19] with the fraud on the market theory is that
 [20] it's been permitted only in limited
 [21] circumstances, usually in the securities fraud
 [22] actions, to establish that reliance needed.
 [23] Fraud in the market has been rejected in common
 [24] law cases and specifically rejected by Clark
 [25] vs. Pfizer. Today I hear that Clark vs. Pfizer
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[1] is not applicable, but if we go back to May
 [2] 28th, Commonwealth thought it was applicable.
 [3] Certainly no one can claim that in our
 [4] litigation we had any expert testimony about
 [5] statistical proof or analysis about anything.
 [6] Now, when I, over the weekend, of
 [7] course, when I read the memo in opposition to
 [8] the nonsuit, we have a different theory which
 [9] was mentioned briefly during trial that the
 [10] reliance should be presumed because there was a
 [11] special or confidential or fiduciary
 [12] relationship between Janssen and the
 [13] Commonwealth. The few cases which permit this
 [14] newest theory are distinguishable. The Basile
 [15] vs. H & R Block involve the statute
 [16] Pennsylvania Consumers Protection Law, and
 [17] there was a clear fiduciary relationship, the
 [18] nature of the parties were not equal. In
 [19] Catalan vs. Trimagli, it was a doctor/patient
 [20] relationship, although the doctor was a false
 [21] doctor, and but there was certainly a
 [22] difference in relationship there. A couple of
 [23] footnotes that we saw in the Clark case, Weiner
 [24] vs. Dannon Yogurt permitted an inference of
 [25] reliance for a class action which, again,
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[1] involved the statutory interpretation of unfair
 [2] competition law in California. Kelly vs.
 [3] Microsoft, which was another footnote in the
 [4] Clark, did not permit a presumption of reliance
 [5] in that case and that was also a statutory
 [6] Consumer Protection Act case. That Court noted
 [7] that when plaintiffs complain of both
 [8] misrepresentations and omissions, Courts will
 [9] decline to permit a presumption of reliance.
 [10] Then the Commonwealth cited Affiliated UTE,
 [11] U-T-E, Citizens vs. United States in the
 [12] weekend memorandum, but that's not on point.
 [13] It's a securities action filed pursuant to Rule
 [14] 10(b)(5) and there the Supreme Court commented
 [15] that where the legislative and statutory
 [16] fundamental purpose is to substitute a
 [17] philosophy of full disclosure for a philosophy
 [18] of caveat emptor in the securities industry,
 [19] reliance may be presumed in certain
 [20] circumstances. Well, that's certainly not the
 [21] case that we have here.

[22] In our case, simply -- and I use the
 [23] word respectfully -- simply prepping a witness
 [24] to use the word "confidential" repeatedly does
 [25] not create a special relationship or a

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[1] fiduciary relationship or a confidential
 [2] relationship. Those special relationships
 [3] generally are not applicable to business
 [4] entities where both parties are sophisticated,
 [5] and there's no question under the circumstances
 [6] of this litigation both sides are
 [7] sophisticated.

[8] The only reason that the Commonwealth
 [9] has been forced to go through these exercises
 [10] of shifting theories and evolving concepts is
 [11] an attempt to avoid the unavoidable, that is,
 [12] the learned intermediary rule which has been
 [13] the law in Pennsylvania since, at least, the
 [14] early 1970's. That rule says that a plaintiff
 [15] in an action against a drug manufacturer for
 [16] prescription drugs must establish causation by
 [17] showing that if the defendant manufacturer had
 [18] issued the proper warning or a different
 [19] warning then the prescribing physician would
 [20] change his or her prescription habits. We
 [21] heard every Commonwealth witness agree that the
 [22] ultimate decision as to whether or not to
 [23] prescribe Risperdal or another SGA or FGA was
 [24] ultimately up to the physician. That medical
 [25] professional would assess the risks and the

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[1] benefits and the tolerance of particular
 [2] patients.
 [3] And then finally just a comment about
 [4] causation, which I had another concern about
 [5] the causal nexus, and as a surprise -- I guess
 [6] I shouldn't be surprised -- but Mr. Posner sort
 [7] of mentioned this, but there was no showing
 [8] that if either the 1993 letter or any of the
 [9] internal Janssen marketing materials had been
 [10] provided to the Drug Utilization Committee or
 [11] the Pharmacy and Therapeutic Committee or any
 [12] other Medicaid or PACE committees that there
 [13] would have been any actions taken that were
 [14] different. There was no record of whether any
 [15] recommendations which those committees might
 [16] have made or could have made or would have made
 [17] would have been accepted or rejected. There
 [18] was no evidence of what would have caused a
 [19] different course of conduct by either DPW,
 [20] Department of Aging or Medicaid or the PACE
 [21] departments, so that's an internal causal nexus
 [22] concern that I have about this whole causation
 [23] business.

[24] So for those reasons, that would be
 [25] count 1 where nonsuit is granted. As to unjust
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[1] enrichment, which is at count 2, I would simply
 [2] say that the Commonwealth failed to present a
 [3] claim for which equitable relief can be
 [4] granted, and I'll just leave it at that because
 [5] we didn't go through a lot of unjust
 [6] enrichment. But the Commonwealth did
 [7] acknowledge in the memo that it's the same
 [8] evidence which would have been presented for
 [9] both the fraud as well as the unjust
 [10] enrichment.

[11] For so for all of those reasons, and
 [12] whatever I can write and get typed up in the
 [13] next few days or so, the motion for nonsuit is
 [14] granted.

[15] All right. Now, at this point, I'd
 [16] like to just talk to two lawyers, whoever the
 [17] two are, to talk about our jury issues for
 [18] tomorrow over here on this side. Thank you.

[19] (Discussion at sidebar off the record.)

[20] **THE COURT:** As you know, tomorrow,
 [21] Tuesday, I believe we have 12 jurors who are
 [22] due to be here in City Hall. And what we'll do
 [23] is once they gather in the jury room, Larry and
 [24] I will thank them for their service. Larry
 [25] will get the paperwork together to escort them
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[1] across the street. They can pick up their
 [2] checks for their time of service. Some of
 [3] them, most of them, started that first week,
 [4] but some of them started different days along
 [5] those three days of jury selection. And then I
 [6] do send all jurors a thank you note from the
 [7] Courts, and like the last line says something
 [8] to the effect if you have any comments, feel
 [9] free to write back. If they write back
 [10] something about the case, I share it with
 [11] counsel. Usually it's just to say thank you to
 [12] Larry, if I ever hear from them, you know, but
 [13] most of them don't write anything.
 [14] I have a standard rule in my courtroom
 [15] that I ask both sides, the lawyers, and any of
 [16] your team members and consultants or whatever,
 [17] do not have any contact with the jurors after
 [18] they are excused tomorrow. They will be
 [19] excused tomorrow morning. Because from the
 [20] Court's perspective we need these ladies and
 [21] gentlemen when they get subpoenaed in another
 [22] two or three years. We need them to come back,
 [23] hopefully, with an open mind, and if any of you
 [24] are lawyers in this room, you want clear,
 [25] unbiased jurors to be part of your panel, so I

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[1] find it's helpful for the Courts as well as
 [2] helpful for counsel.
 [3] But I, again, want to thank both sides
 [4] for all of the work that you've put into this
 [5] case. I really do appreciate it. Thank you.
 [6] (Whereupon, case concluded.)
 [7] ---
 [8]

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CERTIFICATION

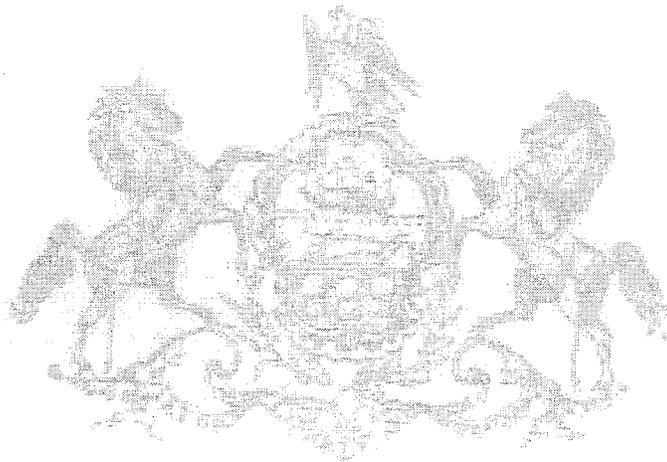
[1] I hereby certify that the proceedings and
 [2] evidence are contained fully and accurately in the
 [3] notes taken by me on the trial of the above cause,
 [4] and that this copy is a correct transcript of the
 [5] same.
 [6]

Robin G. Bobbie, RMR, CRR
Official Court Reporter

June 14, 2010

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 [3] NO. 5000.7. UNAUTHORIZED PHOTOCOPYING OR OTHER
 [4] DUPLICATION WITHOUT EXPRESS APPROVAL BY THE COURT
 [5] REPORTER SHALL BE SUBJECT TO ALL APPROPRIATE LEGAL
 [6] PROCEEDINGS, INCLUDING BUT NOT LIMITED TO A CIVIL
 [7] ACTION AGAINST SAID PERSON AND NOTIFICATION TO THE
 [8] PENNSYLVANIA DISCIPLINARY BOARD.
 [9]

ROBIN G. BOBBIE, RMR, CRR
OFFICIAL COURT REPORTER



IN THE COURT OF COMMON PLEAS OF PHILADELPHIA
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

COMMONWEALTH OF PENNSYLVANIA	:	
c/o Office of General Counsel,	:	January Term, 2008
Plaintiff	:	
	:	No. 2181
vs.	:	
	:	
ORTHO-MCNEIL-JANSSEN	:	
PHARMACEUTICALS, INC., f/k/a	:	
JANSSEN PHARMACEUTICA, INC.	:	
and/or JANSSEN, L.P.,	:	
Defendant	:	

MEMORANDUM IN SUPPORT OF ORDER GRANTING THE
DEFENDANT'S MOTION FOR NONSUIT, PER RULE 230.1

MASSIAH-JACKSON, J.

BOOKETED

JUN 25 2010

R. POSTELL
DAY FORWARD

June 25th, 2010

I. PROCEDURAL HISTORY

In February, 2007, the Commonwealth of Pennsylvania commenced litigation against three pharmaceutical companies: Eli Lilly & Company, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Janssen”), and AstraZeneca Pharmaceuticals, L.P. The Commonwealth claimed it was seeking to recover, *inter alia*, expenses incurred for reimbursing pharmacies for the purchase of Risperdal and other antipsychotic drugs manufactured by these defendants. At that time, the plaintiff alleged that the defendant pharmaceutical companies promoted their respective antipsychotic drugs for non-medically accepted and non-medically necessary uses. The Commonwealth also asserted that the defendants misrepresented the risks associated with these medicines.

The defendants filed Preliminary Objections seeking to sever the actions and to drop misjoined parties. In December, 2007, the Court severed the claims filed by the Commonwealth, and directed the plaintiff to file separate Complaints against each of the defendants.

This action was filed against Janssen on January 17, 2008, alleging in Count I – False and Fraudulent Claims Under Medicaid Program; Count II – False and Fraudulent Claims Under PACE Program; Count III – Negligence; Count IV – Fraud and Misrepresentation; Count V – Misrepresentation Under Restatement (Second) of Torts

§402B; and, Count VI – Unjust Enrichment. On January 5, 2010, Honorable Howland W. Abramson Granted in Part Janssen’s Motion for Judgment on the Pleadings, per Rule 1034, and dismissed Counts I – III and V of the Complaint.

On April 12, 2010, Janssen filed a Motion for Summary Judgment urging dismissal of Counts IV and Count VI of the Complaint.

On April 13, 2010, the Commonwealth filed a Motion for Leave to file an Amended Complaint, which was granted by the Court. The Commonwealth’s First Amended Complaint was filed on May 17, 2010, asserting Count I – Fraud and Misrepresentation, and, Count II – Unjust Enrichment. Janssen filed Preliminary Objections to the First Amended Complaint on May 24, 2010.

In anticipation of jury selection on May 28, 2010, and after reviewing the evolution of the litigation, this Court, on May 25, 2010, requested each party to submit a precise statement of claims and defenses. On May 27, 2010, counsel and the Court participated in a pre-trial telephone conference to discuss trial logistics. Jury selection took place on May 28, June 1, and June 3rd.

On June 2, 2010, this Court convened a day of hearings for oral argument to consider the Defendant’s Motion for Summary Judgment on the initial Complaint, Preliminary Objections to the First Amended Complaint, and multiple Motions in Limine filed by both parties.

After Opening Statements on June 3, 2010, and for the next week, we heard from the Commonwealth witnesses. The Commonwealth rested on June 10, 2010. By June 10, 2010, the revised claim from plaintiff was further narrowed, and was limited to Medicaid damages only, in the amount of \$148.8 million.

Following Janssen's oral Motion for Compulsory Non Suit on June 10, 2010, written memoranda were submitted by the parties on June 11th.

On June 14, 2010, a Hearing was convened by the Court to consider the Nonsuit Motions. The transcript of that Hearing is incorporated in this Memorandum as if fully set forth herein. Following oral argument, this Court provided a preliminary outline to the parties and explained the basis for the Order, dated June 14, 2010, which granted the Motion for Nonsuit.

For the reasons which follow, the Motion of Ortho-McNeil-Janssen Pharmaceuticals, Inc. for Compulsory Nonsuit, pursuant to Rule 230.1 of the Pennsylvania Rules of Civil Procedure, to Count I and Count II of the First Amended Complaint, was GRANTED on June 14, 2010.

II. LEGAL DISCUSSION

The entry of nonsuit is proper when a plaintiff has failed to introduce sufficient evidence to establish the necessary elements to sustain the action. It is the duty of the Trial Court to make a determination prior to submission of the case to a jury. In making this determination, the plaintiff must be given the benefit of all facts and all reasonable

inferences arising from the evidence. The lack of evidence must be clear and all conflicts in evidence must be resolved in plaintiff's favor. See generally, American States Insurance Co. v. Maryland Casualty Co., 628 A.2d 880 (Pa. Superior Ct. 1993); Remier v. Tien, 514 A.2d 566 (Pa. Superior Ct. 1986).

The Pennsylvania Supreme Court affirmed the judgment of nonsuit in Flagiello v. Crilly, 187 A.2d 289 (Pa. 1963), and held that a party who bears the burden of proof may not rest on guess or speculation. The Supreme Court wrote at 187 A.2d 290:

“In *Smith v. Bell Telephone Co.*, 397 Pa., *supra*, the Court said (pages 138, 139): ‘We have said many times that the jury may not be permitted to reach its verdict merely on the basis of speculation or conjecture, but that there must be evidence upon which logically its conclusion may be based.’ *Schofield v. King*, 388 Pa. 132, 136, 130 A.2d 93 (1957); *Connor v. Hawk*, 387 Pa. 480, 482, 128 A.2d 566 (1957); *Ebersole v. Beistline*, 368 Pa. 12, 16, 82 A.2d 11 (1951).

‘. . . when a party who has the burden of proof relies upon circumstantial evidence and inferences reasonably deducible therefrom, such evidence, in order to prevail, must be adequate to establish the conclusion sought and must so preponderate in favor of that conclusion as to outweigh in the mind of the fact-finder any other evidence and reasonable inferences therefrom which are inconsistent therewith.’”

In the case at bar, this plaintiff-Commonwealth asserts that it has met its burden of proof for fraudulent misrepresentation by claiming it is entitled to a presumption of reliance and causation, and, that circumstantial evidence supports an inference that the

defendant's marketing programs were carried out, and, that it is exempt from Pennsylvania's Learned Intermediary Doctrine. This Trial Court concluded that the jury should not be asked to speculate in order to reach its verdict.

The Commonwealth claimed that Janssen made false representations about its prescription antipsychotic drug, Risperdal. According to the plaintiff, Janssen fraudulently represented that Risperdal was superior (safer and more effective) than both conventional antipsychotic drugs (first generation, "FGA"), as well as newer antipsychotic drugs (second generation, "SGA" or "atypical"). Further, the plaintiff asserted that from 2005-2007, "Janssen never shared any information with the Commonwealth", about the FDA's determination relating to Risperdal, even though Janssen representatives testified at the annual Pharmacy and Therapeutic Committee (P&T) meetings for Pennsylvania Medicaid. Plaintiff's Memorandum in Opposition to Nonsuit, June 11, 2010, p. 5. (The Commonwealth did not present the transcripts of those public hearings).

In Scaife Company v. Rockwell-Standard Corporation, 285 A.2d 451 (Pa. 1971), the Supreme Court summarized the elements of fraudulent misrepresentation at 454:

"Summarizing the essential elements of this cause of action, Mr. Justice (later Chief Justice) Jones in *Neuman v. Corn Exchange Nat. Bank and Trust Co.*, 356 Pa. 442, 450, 51 A.2d 759, 763 (1947), stated, 'there must be (1) a misrepresentation, (2) a fraudulent utterance thereof, (3) an intention by the maker that the recipient will thereby be induced to act, (4) justifiable reliance by the recipient upon the misrepresentation and (5) damage to the recipient as the

proximate result.’ *Accord, Eden Roc Country Club v. Mullhauser*, 416 Pa. 61, 204 A.2d 465 (1964); *Savitz v. Weinstein*, 395 Pa. 173, 149 A.2d 110 (1959). Concerning the proof of fraud, our cases have consistently enunciated a very high standard. *E.g., Yoo Hoo Bottling Co., Inc. v. Leibowitz*, 432 Pa. 117, 247 A.2d 469 (1968) (‘clear, precise and convincing’); *Gerfin v. Colonial Smelting and Refining Co., Inc.*, 374 Pa. 66, 97 A.2d 71 (1953) (‘clear, precise and indubitable’); *New York Life Ins. Co. v. Brandwene*, 316 Pa. 218, 172 Atl. 669 (1934) (‘clear and satisfactory’).”

See also, Restatement (Second) of Torts, §525, 551. The plaintiff-Commonwealth asserts that it has presented clear, precise and convincing evidence to establish a legal basis for proof of fraud. This Court does not agree.

The plaintiff-Commonwealth alleged that as a result of Janssen’s fraudulent misrepresentations or nondisclosures, it suffered a monetary loss . . . “calculated as the difference between what the Commonwealth paid for Risperdal and the actual, real or intrinsic value of the therapeutically equivalent Haloperidol”. Plaintiff’s Memorandum in Opposition to Nonsuit, June 11, 2010, pages 7-8. According to plaintiff, it has presented clear, precise and convincing evidence to establish losses through the Medicaid program in the amount of One Hundred Forty Eight Million, Eight Hundred Thirty Three Thousand, Six Hundred Seventy-Five Dollars (\$148,833,675.00) for the period of 1994 through the first half of 2008. This Court does not agree.

A. The Linchpin of Common Law Fraud is Proof of Plaintiff's Justifiable Reliance on a Defendant's Misrepresentation or Nondisclosure

One of the essential elements for fraud is reliance. It is a fundamental principle of the law of fraud, regardless of the form of relief sought, that in order to secure redress, the plaintiff must have relied upon the statement or representation as an inducement to his action or injurious change of position. "The recipient of a fraudulent misrepresentation can recover against its maker . . . if, but only if, (a) he relies on the misrepresentation in acting or refraining from action, and (b) his reliance is justifiable." Restatement (Second) of Torts § 537 (1977). See, Scaife Co. v. Rickwell-Standard Corporation, *supra*, 285 A.2d 451, 455-456 (Pa. 1971); Emory v. Third National Bank of Pittsburgh, 162 A. 281, 283 (Pa. 1932); Delahanty v. First Pennsylvania Bank, 464 A.2d 1243 (Pa. Superior Ct. 1983); National Building Leasing, Inc. v. Byler, 381 A.2d 963, 966 (Pa. Superior Ct. 1997); 37 Am.Jur.2d at §§223, 236.

1. The Commonwealth and Janssen Are Sophisticated Business Entities.

During trial and for the first time since 2007, the Commonwealth advised Janssen and the Court that the parties had a "confidential" relationship. Plaintiff claimed it was entitled to a presumption of reliance and it need not affirmatively prove justifiable reliance. In Plaintiff's Memorandum in Opposition to Nonsuit, June 11, 2010, at page 7:

"Additionally, information shared by drug manufacturers with the Commonwealth and relied upon by it for the determination of the amount of rebate it is owed – the "unit rebate amount" – is confidential and may not be disclosed to

anyone else. (Id. at 27, 56-57 (confidentiality) (Ex. P).) Thus, a “special”, “confidential”, and/or “fiduciary” relationship exists between drug manufacturers like Janssen and the Commonwealth that establishes a presumption of reliance by the Commonwealth in its dealings with Janssen and other pharmaceutical companies. See, e.g., Basile v. H.R. Block, Inc., 729 A.2d 574, 582 (Pa. Super. Ct. 1999); Katlin v. Tremoglie, 43 Pa. D. & C.4th 373, 392 (Phila. Com. Pl. Ct. 1999); see also Affiliated Ute Citizens v. United States, 406 U.S. 128 153-54 (1972) (dispensing with requirement of positive proof of reliance, where a duty to disclose material information had been breached, concluding that the necessary nexus between the plaintiffs’ injury and the defendant’s wrongful conduct had been established). Finally, under Pennsylvania law, the simple fact of the misrepresentations themselves (see ¶3, supra) supports a presumption of reliance.”

At oral argument on June 14, 2010, N.T. 37, the Commonwealth further explained that its presumption of reliance argument was grounded on Dr. Cathers’ testimony relating to the confidential “unit rebate amount.” Initially, it must be noted that confidentiality of manufacturers’ propriety and financial materials is statutorily mandated by both the Federal and State entitlement legislation. See 42 U.S.C.A. §1396r-8(b)(3)(D); 72 P.S.C.A. §3761-704(3).

Generally, a “special”, “confidential” and/or “fiduciary” relationship may be found when the parties are not equal. The cases relied on by the Commonwealth do not support its position that it maintained a confidential or fiduciary relationship with Janssen. See, Plaintiff’s Memorandum in Opposition to Nonsuit, June 11, 2010, page 7:

- In Basile v. H & R Block, Inc., 729 A.2d 574 (Pa. Superior Ct. 1999), the Appellate Court determined that a principal-agent relationship existed between the taxpayers and the accounting firm in a class action. Accordingly, a fiduciary relationship was confirmed and reliance by the class plaintiffs was implicit and established by operation of law.
- In Katlin v. Tremoglie, 43 Pa. D. & C.4th 373 (Phila. Com. Pl. 1999), the Court held that the parties were in a doctor-patient relationship. For purposes of class certification, there was a special relationship, that is, a fiduciary relationship where reliance is presumed and a causal connection between the deception and economic loss was ascertainable.
- Affiliated Ute Citizens v. United States, 406 U.S. 128 (1972), involved an interpretation of Rule 10b-5 of the Securities Exchange Act, where the Supreme Court held that reliance and causation were established without positive proof in order to achieve a high standard of business ethics in the securities industry.
- In Zwiercan v. General Motors, 58 Pa. D. & C.4th 251 (Pa. Com. Pl. 2002), the Court noted that when a purchaser of an automobile is unsophisticated, then reliance can be presumed. See also, Drayton v. Pilgrim's Pride Corporation, 2004 U.S. Dist. LEXIS 6691 (E.D. Pa. 2004), a case brought pursuant to the Pennsylvania Uniform Trade Practices and Consumer Protection Law which relied on Zwiercan, *supra*, to find that reliance can be presumed for an unsophisticated consumer of adulterated food.

The Commonwealth has not addressed, either in writing or at oral argument, the significant distinguishing factors in this case, that is, the parties here are independent, sophisticated business and government entities entrusted with equal knowledge of the complicated federal and state legislative mandates. Neither party exemplifies a dominance or dependence or weakness. See, Frowen v. Blank, 425 A.2d 412 (Pa. 1981); Janssen Memorandum in Support of Nonsuit, June 11, 2010, pages 26-27, and cases cited therein. This Court concludes that the Commonwealth has failed to establish that it has a “fiduciary” or “special” or “confidential” relationship with Janssen. The Commonwealth is not entitled to a presumption of reliance on this basis.

2. The Commonwealth’s Fraud on the Market Theory of Recovery Has Been Rejected By Pennsylvania Courts.

In an earlier theory that reliance should be presumed, the Commonwealth suggested that its fiscal injuries came about by reliance on Janssen’s inflated pricing of Risperdal -- which artificially increased everyone’s price.

In its Response in Opposition to the Motion for Summary Judgment to the original Complaint, the Commonwealth stated at page 28, that the In re Zyprexa third party payor decision supports the Commonwealth’s fraud and misrepresentation claims, noting that, “the third-party payors were not required to present individualized proof of causation because they, “were directly injured . . . when each was overcharged a fixed computable amount for each prescription.” 253 F.R.D. 69, 195 (2008); 671 F.Supp.2d 397 (E.D.N.Y. 2009).

Similarly, in its May 28, 2010, precise statement of claims, the Commonwealth stated that as a compelled purchaser of Risperdal, it relied on Janssen for accurate pricing information. The plaintiff stated that Janssen's false representations caused an artificial increase of everyone's Risperdal price, citing, e.g. Clark v. Pfizer, Inc., 990 A.2d 17 (Pa. Superior Ct. 2010).

The Commonwealth was actually asserting that reliance should be presumed because Janssen created a fraud on the market. The Honorable Superior Court recently stated at 990 A.2d 17, n. 4:

“The fraud on the market theory is a judicially created presumption typically employed by plaintiffs in securities class actions to prove the reliance elements of Section 10(b) and Rule 10b-5 under the Securities Exchange Act of 1934. In such a case, a plaintiff is presumed to have relied on material information disseminated to the public due to market efficiency and the notion that the price of the security simultaneously reflects the incorrect information as it is made public; thus, because traders in a public market rely on the market price and the integrity of the market, the traders have ispo facto relied on the misinformation because they would have traded at another price, or not at all, had the truth been known. Borrowing, implicitly or explicitly, from the fraud on the market theory, courts have permitted plaintiffs to use aggregate, statistical proof to establish class-wide causation in consumer fraud cases alleging artificial price information. In these cases, ‘every member of the putative classes was necessarily injured because defendants’ alleged fraudulent marketing caused an increase in a product’s price, meaning everyone who purchased the product paid too much.’ Consequently, the plaintiffs were automatically subjected to a

single source of harm, i.e., the effect of the defendant's conduct on the purchase price, and could recover economic damages arising from the fraudulently-inflated price." (citations omitted).

In Clark v. Pfizer, Inc., *supra*, the Superior Court rejected the theory of fraud on the market where plaintiffs' theory of liability was based on defendant's making an affirmative misrepresentation in actively promoting a drug that allegedly had no beneficial effects/purposes aside from its FDA-approved uses. There, the application of the fraud on the market theory was rejected when the defendants produced evidence that doctors in Pennsylvania prescribed off-label use of Neurontin to class members for reasons wholly unrelated to defendants' alleged fraudulent marketing. The Superior Court held that in order to establish reliance/causation, plaintiffs would have to demonstrate doctor-by-doctor that the defendant's fraudulent misrepresentations or omissions during the off-label promotion caused the doctor to prescribe the medicine.

In, In re Zyprexa Products Liability Litigation, 253 F.R.D. at 201, the Court allowed the presumption of reliance and causation where, unlike here, the evidence demonstrated that the market for the drugs was responsive to the information about safety and efficacy that was allegedly misstated or suppressed by the drug company. The Court explained the presumption as follows:

"The economic analysis undertaken in the instant case contains the features of reliability lacking in [McLaughlin v. American Tobacco, 522 F.3d 215 (2nd Cir. 2008)]. For example in McLaughlin there was a 'lack of appreciable drop in the demand . . . of light cigarettes after the truth about

lights was revealed . . .’ Here, however, there is a remarkable decline in the demand for Zyprexa after only some of the truth was revealed, despite Lilly’s attempt to ameliorate its effects.”

That Court determined that the fact that the Zyprexa market was responsive in terms of numbers of sales to adverse information suggested that the Zyprexa’s price may have been inflated, thus supporting a presumption of reliance. There has been no such evidence in this litigation. See, Janssen’s Memorandum in Support of Nonsuit, June 11, 2010, pages 24-28.

Here, as in In re Neurontin Marketing, Sales Practices and Products Liability Litigation, 618 F.Supp.2d 96 (D. Mass. 2009), the plaintiff was attempting to “salvage” its fraudulent misrepresentation claims. The Massachusetts Court commented on the differences between the prescription drug industry and the securities industry, and concluded the two are “too dissimilar” to permit a rebuttable presumption of reliance. See also, Prohias v. Pfizer, Inc., 485 F.Supp.2d 1329 (S.D. Fla. 2007), which itself cited Heindel v. Pfizer, Inc., 381 F.Supp.2d 364, 380 (D. N.J. 2004), holding that the “price inflation” or “fraud on the market” theories are too speculative in the pharmaceutical drug industry.

In, In re Neurontin, at 618 F.Supp.2d 111-112, the Court stated:

“. . . no court has ever adopted a ‘fraud on the market’ type theory outside the securities fraud context, and the majority of courts which have had occasion to extend the theory to common law fraud have expressly declined to do so.” (numerous citations omitted).

See also, In re Rezulin Products Liability Litigation, (MDL No. 1348), 524 F.Supp.2d 436 (S.D.N.Y. 2007).

To the extent that the Commonwealth may continue to seek a presumption of reliance based on its price inflation/fraud on the market theory, it failed to present economic analysis, aggregate statistical proof, or any other expert evidence. This Court concludes that the Commonwealth was not entitled to a presumption of reliance and causation on this basis.

3. There Was No Evidence Presented That The Commonwealth Relied on a Misrepresentation or Nondisclosure from Janssen.

In Janssen's Memorandum in Support of Nonsuit, June 11, 2010, page 19, it states:

“Thus, the Commonwealth was not a helpless purchaser of prescription drugs. It had multiple committees, which had the assistance of unbiased outside consultants, making independent determinations regarding access to prescription drugs for Medicaid and PACE participants. The absence of any reliance on any alleged misstatements by Janssen could not be more clear.”

See also, Moore v. Steinman Hardware Co., 179 A. 565 (Pa. 1935) where business parties deal at arm's length, the bargaining transactions are not entitled to special circumstances.

The Commonwealth did not present any evidence of justifiable reliance or causation in this litigation, rather it rested on its position that a “special” or “confidential” and/or “fiduciary” relationship exists between drug manufacturers like Janssen and the

Commonwealth. See, Memorandum in Opposition to Nonsuit, June 11, 2010, pages 6-7. The party claiming a confidential relationship bears the burden to establish proof of the existence of such a relationship. See, In Re Trosylol Products Liability Litigation, 2009 WL 577726 (S.D. Fla.). The Commonwealth did not meet its burden of proof in its case-in-chief.

B. The Learned Intermediary Doctrine Is The Law in Pennsylvania

The Commonwealth failed to present any evidence that in the absence of Janssen's purported fraudulent misrepresentations or nondisclosures, any physicians in Pennsylvania would have changed his or her prescription habits.

In Demmler v. SmithKline Beecham Corporation, 671 A.2d 1151 (Pa. Superior Ct. 1996), the Superior Court upheld summary judgment, finding that where a drug is available only by prescription, the adequacy of the warning is not to the public or the patient, but to the prescribing doctor. It is a prescribing physician who considers the unique set of symptoms and tolerances of his or her patient. The Demmler Court stated at 671 A.2d at 1154:

“Where the drug is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.” *Dion v. Graduate Hosp. of Univ. of Penna.*, 360 Pa. Super. 416, 422, 520 A.2d 876, 879 (1987), quoting *Incollingo v. Ewing*, *supra* at 288, 282 A.2d at 220. See also: *Hahn v. Richter*, *supra* at 142, 628 A.2d at 866. ‘As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential

dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.’ *Windham v. Wyeth Laboratories*, 786 F.Supp. 607, 611 (S.D.Miss. 1992), quoting *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S. Ct. 687, 42 L. Ed. 2d 688 (1974). See also: *Hahn v. Richter*, supra; *Mazur v. Merck & Co., Inc.*, 742 F.Supp. 239, 252 (E.D. Pa. 1990). Generally, expert medical testimony is required to determine whether the drug manufacturer’s warning to the medical community is adequate because prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. *Dion v. Graduate Hosp. of Univ. of Penna.*, 360 Pa. Super. at 425-426, 520 A.2d at 881. See generally: *Hamil v. Bashline*, 481 Pa. 256, 267, 392 A.2d 1280, 1285 (1978).”

The Superior Court in *White v. Weiner, M.D.*, 562 A.2d 378, 385-386 (Pa. Superior Ct. 1989) noted that it is the duty of the physician to be fully aware of the characteristics of the drug, the therapeutic dosage, other medications taken by the patient, and side affects associated with the drug, citing *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971); *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 523 A.2d 374 (Pa. Superior Ct. 1987); *Baldino v. Castagna*, 478 A.2d 807 (Pa. Superior Ct. 1984); *Leibowitz v. Ortho Pharmaceuticals Corporation*, 307 A.2d 449 (Pa. Superior Ct. 1973). See also, *Taurino v. Ellen*, 579 A.2d 925 (Pa. Superior Ct. 1990). The plaintiff-Commonwealth’s theory is that it is exempt from the Learned Intermediary Doctrine because it is challenging Risperdal pricing based on Janssen’s alleged misrepresentations or nondisclosures, and not based on warnings given or not given to medical providers. As noted, however, the

Risperdal market share is dependent on physician prescriptions. See, Hearing, June 14, 2010, N.T. 50, l. 12-19.

The plaintiff-Commonwealth cannot escape the necessity of proof needed to establish a nexus between the allegations of fraudulent misrepresentations or nondisclosure of the drug's efficacy and safety and the economic injury it claims. Absent proof that if the defendant manufacturer had issued the proper warning or a different warning then the prescribing physicians would change his or her prescription habits, thus causing a different and lower price, this plaintiff cannot meet its burden and the case cannot go forward to a jury. Coyle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991).

C. The Internal Causal Nexus Quandry

On June 14, 2010, N.T. 67, l. 7-23, this Court stated:

“And then finally just a comment about causation, which I had another concern about the causal nexus, . . . there was no showing that if either the 1993 letter or any of the internal Janssen marketing materials had been provided to the Drug Utilization Committee or the Pharmacy and Therapeutic Committee or any other Medicaid or PACE committees, that there would have been any actions taken that were different. There was no record of whether any recommendations which those committees might have made or could have made or would have made would have been accepted or rejected. There was no evidence of what would have caused a different course of conduct by either DPW, Department of Aging or Medicaid or the PACE departments, so that's an internal causal nexus concern that I have about this whole causation business.”

It has been said that in Pennsylvania, causation has two separate components: (1) causation in fact and (2) proximate causation. Markovich v. Bell Helicopter Textron, Inc., 805 F.Supp. 1231, 1238 (E.D. Pa. 1992) citing, Robertson v. Allied Signal, Inc., 914 F.2d 360, 366 (3d Cir. 1990). Causation in fact or “but for” causation “requires proof that the harmful result would not have come about but for the conduct of the defendant.” The causal requisite applies with equal force to claims grounded in fraud and misrepresentation.

Fraud must be proven by clear, precise and convincing evidence. See generally, Delahanty v. First Pennsylvania Bank, N.A., 464 A.2d 1243 (Pa. Superior Ct. 1983). The essential elements of the tort are misleading information, justifiable reliance, causation and pecuniary loss. Assuming arguendo Janssen conveyed misleading information:

- The trial record is inadequate to establish the fact or circumstances of plaintiff's reliance on Janssen.
- The trial record is inadequate to establish causation, that is, had Janssen made different warnings that any physician would have prescribed differently.
- The trial record is inadequate to establish that prior to 2004 any Medicaid-related department, clinician or committee within the Commonwealth would have taken any action that would have resulted in fewer prescriptions or purchases of Risperdal, which in turn would have reduced the market share and price.

- Between 2005 and the first half of 2008, the record is clear that notwithstanding public knowledge of the CATIE study, public knowledge of the Diabetes Consensus Statement, and public and private meetings held at all levels of state government, no action was taken by the plaintiff-Commonwealth which resulted in fewer prescriptions or purchases of Risperdal.

D. The Magnitude and Complexity of this Case is Beyond the Experience and Understanding of an Average Juror

Pennsylvania law is well-settled that the purpose of expert testimony is to assist the jury to understand complex issues beyond the knowledge, intelligence and experience of the ordinary layperson.

Rule 702 of the Pennsylvania Rules of Evidence states:

“If scientific, technical or other specialized knowledge beyond that possessed by a layperson will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise.”

Expert testimony is routinely heard with regard to financial, economic and regulatory issues. For example, such experts provide relevant, admissible and helpful testimony for both plaintiffs and defendants to opine about earning capacity, future earnings potential and productivity, business evaluations, property assessments, regulations relating to OSHA, ANSI and, of course, much more.

Prior to trial the Commonwealth suggested that “basic arithmetic” is all that this trial jury would need in order to understand and calculate Pennsylvania’s medical assistance programs. This Court concludes that while many numbers were quickly flashed on a power point screen, the damage computations in multiple millions of dollars were not adequately explained or presented to the jury in a manner to enable these ordinary lay persons to understand the underlying data.

In its pre-trial Motion in Limine (Control No. 10051393), Janssen objected at page 9:

“In the present case, at virtually the last possible moment before trial, the Commonwealth states that it intends to seek in excess of *\$160 million* based on: (1) a claim which is absent from its Complaint; and (2) a claim set forth in a *two sentence description* in its Pretrial Memorandum, without any factual support. Having failed to provide any information in support of its new damage theory, the Commonwealth should be precluded from offering any evidence at the time of trial. *Busy Bee Inc.*, 2006 WL 723487, *46-47.” (footnote omitted).

This Trial Court denied Janssen’s Motion to Preclude Evidence of Damages, by Order dated June 3, 2010.

The failure of the Commonwealth to clearly identify and articulate its damage calculation prior to trial served to confuse the jury as early as opening statements when they saw a power point presentation and they were told by counsel that the Commonwealth was seeking \$289 million. One week later they heard Dr. Terri Cathers testify that Janssen owes the Commonwealth \$148.8 million.

The purpose of an expert report is to assist the triers of fact. The jury is entitled to understand the facts and the data upon which the damage calculations were based -- this includes an understandable presentation and explanation of the words, terms and processes involved in economic and financial conclusions. See, Rules 702, 703, 705 of the Pennsylvania Rules of Evidence; Bernstein, 2010 Pa. Rules of Evidence (Gann); Packel and Poulin, Pennsylvania Evidence, Third Ed., (West 2007).

While the Commonwealth's printouts of computer stored information were not challenged for authenticity in this litigation, there was no foundation testimony presented to permit the lay jurors to comprehend the genesis of the damage numbers -- initially, a quarter of a billion dollars. See, Bernstein Rule 702[8]; Packel and Poulin, §727. Generally, business-related damages may be more readily susceptible to proof with quality expert reports and expert evidence, as well as economic and financial data relating to the various statutory algorithms.

This Court denied defendant-Janssen's Motion in Limine (Control No. 10051393) in order to provide the Commonwealth an opportunity to prove the damage portion of its case. Under the circumstances presented here, it would have been error for this Trial Court to permit the jury to engage in conjecture.

E. The Magnitude and Complexity of This Case Required that The Defendant Be Provided With an Accurate Written Expert Report of Damages Claimed Prior To Trial

By letter dated January 8, 2010, the plaintiff-Commonwealth advised Janssen of the damages it was seeking in this lawsuit:

“. . . the difference between the cost of all Risperdal prescriptions and the cost of a cheaper, safer, generic alternative.”

In the First Amended Complaint filed on May 17, 2010, plaintiff-Commonwealth described its damage claim in its Wherefore Statement:

“. . . for excessive expenditures made for Risperdal prescriptions over the value that the Commonwealth would have paid for Risperdal had the drug’s true safety and efficacy profile been disclosed. . . .”

The Commonwealth opposed Janssen’s Motion in Limine to Preclude Evidence of Damages based on the Difference in Price Between Risperdal and Other Medicines, (Control No. 10051393), and stated the recovery it was seeking at page 7:

“recovery for the price differential between Risperdal and a comparable, cheaper, but equally (or more) safe and effective generic clinical equivalent.”

On May 28, 2010, the Commonwealth described the precise nature of the damages it was seeking as follows:

“Commonwealth seeks damages of at least \$150 million for the difference in price between Risperdal prescriptions paid or reimbursed by the Commonwealth and the cost of a cheaper generic clinical equivalent.”

On June 3, 2010, the Commonwealth told the jury, Janssen and this Court of new damage calculations at N.T. 58:

“Again, we spent \$568 million on Risperdal. The evidence will show that the Commonwealth was overcharged a total of \$289 million. So by the end of the trial, you’ll understand why the evidence will force me to ask you for a verdict of \$289 million.”

In its June 11, 2010, Memorandum in Opposition to Nonsuit, the Commonwealth stated:

“The Commonwealth’s evidence is sufficient to establish that it suffered losses through its Medicaid program in the amount of \$148,833,675, which represents the difference between the amount paid for Risperdal and the actual, real, or intrinsic value of the therapeutically equivalent Haloperidol.”

Throughout the trial, the transcript revealed a patchwork of changing damage claims from this plaintiff. Compare June 4, 2010, P.M. Session, N.T. 101-106, with June 8, 2010, A.M. Session, N.T. 104-112.

Of significant note is that the Commonwealth’s failure to present a qualified economic or financial expert caused it to forego its claim for \$20 million for PACE damages when the fact witness became “confused”. June 10, 2010, A.M. Session, N.T. 61.

Finally, it is not clear to this Court that there was evidence or proof that, “the cost of a cheaper generic clinical equivalent” is the same measure of damages as the “intrinsic value of the therapeutically equivalent Haloperidol”. Thus, not only did the time period

of damages fluctuate through the pre-trial and trial, and the calculations of the amount of the damage claim change, but the nature of the damage claim evolved -- to the detriment of the jury and to the prejudice to defendant-Janssen.

III. NONSUIT IS GRANTED TO COUNT II – UNJUST ENRICHMENT

Count II of the Commonwealth's First Amended Complaint is a claim for equitable relief in the nature of unjust enrichment. The plaintiff described the unjust enrichment action in its Memorandum in Opposition to Nonsuit for Unjust Enrichment Claim, June 11, 2010, at page 3:

“The Commonwealth’s unjust enrichment claim is based on the following conduct and circumstances: (1) the Commonwealth’s indirect conferral of benefits on Janssen by reimbursing Medicaid and PACE participants’ Risperdal prescriptions, which resulted in increased Risperdal profits and market share, (2) Janssen’s appreciation of those benefits through the increased Risperdal profits and market share, and (3) the inequity of permitting Janssen to retain those benefits without payment of value in light of Janssen’s repeated false representations regarding Risperdal’s safety and efficacy in comparison to other antipsychotics, which inflated and sustained Risperdal’s price for 14 years, and the Janssen’s false representation of Risperdal’s value in its pricing of the drug ”

The Commonwealth alleges that Janssen has been unjustly enriched in an amount greater than \$150 million -- the value of the benefit conferred.

This Court must concur with Janssen’s position that well-settled Pennsylvania law precludes the availability of this equitable doctrine where, as here, “the relationship between the parties is founded on a written agreement or express contract”. Janssen

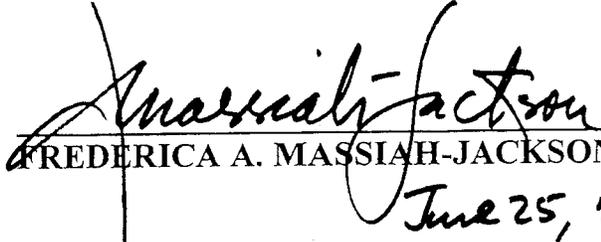
Memorandum in Support of Nonsuit for Unjust Enrichment Claim, June 11, 2010, pages 9-10; e.g. Curley v. Allstate Insurance Co., 289 F.Supp.2d 614, 620 (E.D. Pa. 2003) and numerous cases cited therein; Wilson Area School District v. Skepton, 895 A.2d 1250 (Pa. 2006).

The Commonwealth did not address this issue prior to trial, during trial or in its Nonsuit Memorandum. With this in mind, Janssen's Motion for Nonsuit is granted as to Count II, for failure to present a claim for which relief may be granted.

IV. CONCLUSION

For all of the reasons set forth above, Janssen's Motion for Nonsuit to Count I and Count II of the First Amended Complaint was **GRANTED** on June 14, 2010. Nothing in this Memorandum either explicitly or implicitly is meant to suggest that this Trial Court has reviewed or considered any of the additional grounds for nonsuit identified in Janssen's Motions and Memoranda in Support of Nonsuit filed on June 11, 2010.

BY THE COURT:


FREDERICA A. MASSIAH-JACKSON, J.
June 25, 2010