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Control No. 15022221

Filing Date: February 17, 2015
Response Date: March 23, 2015

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March 23, 2015

VIA ELECTRONIC FILING
The Honorable Arnold L. New
Complex Litigation Center
622 City Hall
Philadelphia, PA 19107

Re: ***In re: Risperdal Litigation*, March Term 2010, No. 296**
N. Murray v. Janssen Pharmaceuticals, et al., April Term 2013 No. 1990

PLAINTIFF'S RESPONSE IN OPPOSITION TO THE MOTION FOR SUMMARY JUDGMENT OF DEFENDANTS JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON AND JANSSEN RESEARCH AND DEVELOPMENT, L.L.C.

TABLE OF CONTENTS

Dear Judge New:

This is Plaintiff's Response in Opposition to the Motion for Summary Judgment of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research and Development, L.L.C. (collectively, "Janssen" or "J&J").

I. EXECUTIVE SUMMARY

Janssen, without citation to a single Maryland state court case, asks this Court to make a blanket finding that Plaintiff's failure to warn claim is barred as a matter of law because Risperdal was prescribed off-label. Janssen relies solely upon a distinguishable federal, trial court decision, *Robak v. Abbott Labs.*, 797 F. Supp. 475 (D. Md. 1992) in support of its argument. Even if this Court accepts Defendants novel "no duty to warn" proposition for off-label usage, a failure to warn claim is still actionable as there is question of material fact whether the Plaintiff was prescribed Risperdal both off-label and for an approved indication. This Court, however, should reject Defendants' proposition. Unlike *Robak*, the issue in this case is not whether a physician may unilaterally prescribe a drug off-label, but whether Maryland law permits a failure to warn claim, where a manufacturer promotes a drug off label (and even knows that the drug is being prescribed off-label) and fails to warn of a reasonably anticipated and foreseeable use. Maryland law, akin to Pennsylvania law, provides that a duty to warn extends to all foreseeable uses. There is no question Janssen was aware (and in fact encouraged and predicted) that doctors would prescribe Risperdal to children and adolescents. Thus, Janssen had a duty to warn of the known risks associated with pediatric and adolescent use, including gynecomastia.

Plaintiff's claims are not barred by the learned intermediary doctrine. The Nanty-Glo rule precludes summary judgment under learned intermediary principles because Janssen relies

solely on the testimony of Dr. Langfitt. Janssen was engaged in a scheme designed to take Plaintiff's treating physician out of his role as "learned intermediary." Additionally, there is a genuine issue of material fact that Dr. Langfitt would not have prescribed Risperdal to Mr. Murray had he known information regarding the dangerous propensities of the drug. Dr. Langfitt's prior knowledge of a remote risk does not warrant summary judgment on the issue of causation under learned intermediary principles.

Plaintiff's claim for strict liability should survive summary judgment as Maryland law permits strict liability claims against pharmaceutical manufacturers. In the 39 years that have elapsed since Maryland has adopted strict liability, no Maryland court has ever held that the doctrine of strict liability does not apply to prescription drugs. The only case that Janssen relies upon for this proposition is a highly distinguishable opinion, *Miles Lab., Inc. Cutter Labs. Div. v. Doe*, 556 A.2d 1107 (Md. 1989), that involved blood products contaminated with HIV at a time where there was no reliable testing. Even if the Court were to hold that the "Comment K" exception of the Restatement (which applies to "unavoidably unsafe" products) extends to prescription drugs then Janssen would still be subject to strict liability because that exception is only implicated when the manufacturer properly marketed and provided adequate warnings.

Summary judgment is not warranted on Plaintiff's breach of express warranty claims under either Pennsylvania or Maryland law. Unlike the case law Janssen relies upon, the Plaintiff suffered personal injuries and has alleged various false warranties and representations that amount to more than a mere recitation of the UCC. The Plaintiff only needs to show reliance on the part of the prescribing physician. Summary judgment is inappropriate because there is sufficient evidence brought to indicate Janssen failed to disclose all known information relating to Risperdal and gynecomastia. Likewise, Plaintiff's implied warranty claim survives

summary judgment under Pennsylvania and Maryland law. Whether a product is merchantable is a question for the jury, and there are genuine issues of material fact as to whether Risperdal was fit for its intended purpose.

Janssen argues that a manufacturer of prescription drugs cannot be held liable as a matter of law under Maryland's Consumer Protection Act ("MCPA"), relying on *dicta* from a single, unpublished trial court opinion, *Agbebaku v. Sigma Aldrich, Inc.*, No. 24-C-02-004175, 2003 WL 24258219 (Md. Cir. June 24, 2003) which dismissed the plaintiff's claims for lack of standing. Defendant urges this Court to take the learned intermediary doctrine a step further and find that it precludes Plaintiffs from *stating a claim altogether* under a consumer protection law. Case law from Maryland and the plain language of the MCPA does not support this proposition.

Plaintiff fraud claim survives summary judgment since Plaintiff's mother and prescribing physician relied on the misrepresentations and omissions of Janssen which in turn led to Plaintiff's injuries. Plaintiff's negligent design claim also survives summary judgment because it is not preempted by federal law. Janssen only relies upon *dicta* from an unreported federal trial court opinion in support of its argument that Plaintiff's claim for design defect is legally deficient under Maryland law. *King v. Pfizer Pharm. Co., N*o. RWT 11CV00127, 2011 WL 3157305, at *2 (D. Md. July 25, 2011). *King*, however, only involved a failure to warn, not design defect claim, and therefore, Janssen's reliance on *King* is unpersuasive.

Lastly, Plaintiff's claim for medical expenses is not subject to summary judgment because there are material issues of fact surrounding a recognized exception under Maryland law. For all of these reasons, summary judgment at to these claims should be denied.

II. SUMMARY OF FACTS

A. Plaintiff's Personal Background and Risperdal Usage

This case is about Plaintiff Nicholas Murray, a young man from Maryland who ingested Janssen's drug, Risperdal, as a minor and developed large, female-like breasts as a result, mentally wounding him deeply and creating a condition that may last for the rest of his life. Plaintiff was born on December 25, 1993 in Chestertown, Maryland. *See* Exhibit1, Pl.'s Fact Sheet, at II. Plaintiff was first seen by Shore Pediatrics for medical attention for Attention Deficit Hyperactivity Disorder (ADHD) in 1997. *See* Exhibit 2, Plaintiff's Fact Sheet at p. 8. He was later diagnosed with Asperger's Syndrome and Pervasive Development Disorder; both are which considered Autism Spectrum Disorders. *See* Exhibit 1, Pl.'s Fact Sheet at 7; Exhibit 2, Medical Records from Shore Pediatrics, April 17, 2000 at 19-20, 22; Exhibit 3, Dep. Mark S. Langfitt, M.D. December 17, 2014 (hereinafter "M. Langfitt Dep.") at 149:2-13.

Plaintiff first presented to Dr. Engstrom, a pediatrician at North Shore around April 10, 1998. Exhibit 2, Medical Records from Shore Pediatrics, at NEM:SP:0009-0011. On or around November 22, 1999 Plaintiff was prescribed Risperdal for a short period of time. Exhibit 2, Medical Records from Shore Pediatrics, at NEM:SP:0016; Exhibit 3, M Langfitt Dep. at 39:15-40:7. Dr. Mark S. Langfitt, M.D. ("Dr. Langfitt") began seeing Plaintiff at North Shore Pediatrics around June 16, 2000 and continued to see him on a regular basis until October 31, 2014. Exhibit 3, M. Langfitt Dep. at 33:12-19, 70:2-4. On March 13, 2003, Dr. Langfitt prescribed Plaintiff Risperdal. *Id.* at 37:8-12; 38:4-6; 38:16-39:8. Beginning sometime around November 13, 2003, at the age of 9, Plaintiff for the first time saw a psychiatrist Arvoranee B.

Pinit,[1] M.D., for Asperger's Syndrome and ADHD at the Kennedy Krieger Children's Hospital. *See* Exhibit 1, Pl.'s Fact Sheet at III; Exhibit 3, M. Langfitt Dep. at 49:5-17; Exhibit 4, Medical Records from Kennedy Krieger Children's Hospital at NEM:KKI:0035. Dr. Langfitt continued to see the Plaintiff on a regular basis until October 31, 2014. Exhibit 3, M Langfitt Dep. at 70:2-4.

Dr. Langfitt and Dr. Pinit prescribed Risperdal to Plaintiff for his ADHD and for his symptoms associated with Pervasive Development Disorder and Asperger's Syndrome, which included among other things, his changing moods, temper tantrums, and self-injurious behavior. *See* Exhibit 3, M. Langfitt Dep. at 40: 8-17, 65: 7-21, 151: 12-24, 152:1-24, 153:18-23, 155:4-17, 157:18-158:1-8, 203:6-14; Exhibit 4, Kennedy Krieger Children's Hospital, NEM:KKI:0021-0034, NEM:KKI:0023, NEM:KKI:0027; Exhibit 2, NEM:SP:0020-0021. Dr. Langfitt testified that when he first started prescribing Risperdal he did not have an understanding that Risperdal elevated prolactin nor that Risperdal was associated with gynecomastia. M. Langfitt Dep. at 19:8-14. Dr. Langfitt stated if he had been advised to take a serum prolactin level from NM at that time, he would have taken the instruction under advisement. *Id.* at 64:8-65:4. As of October of 2006, Risperdal became approved in children for symptoms associated with Autism. *See* Exhibit 5, October 6, 2006 Risperdal Label. Plaintiff remained on Risperdal until on or around February 2008. Exhibit 3, M Langfitt Dep. at 53:14-55:9; 58:24-59:2; Exhibit 6, Dep. of Joy Murray October 15, 2013 (hereinafter "J. Murray Dep.") at 74:18-20.

[1]The whereabouts of Dr. Pinit, whose testimony, as the only psychiatrist to prescribe Plaintiff Risperdal, still remains unknown. Plaintiff continues to undertake substantial effort in locating Dr. Pinit.

B. Janssen's Conduct and Knowledge of Gynecomastia

Prior to the Risperdal label being approved for children, Janssen sales representatives were promoting off-label use of Risperdal to pediatric and adolescent populations. Beginning in 1992, Janssen devised a strategy to promote Risperdal to children and adolescents with Excerpta Medica. *See* Exhibit 7, Excerpta Medica's February 2003 marketing handout, at EMRISP0396639. From 1992 until 2003, Excerpta Medica working in concert with Janssen devised a strategic publication plan to market Risperdal to the pediatric and adolescent population as evident from the "Strategic Publication Planning for Risperdal: Child and Adolescent Use." *Id*. at EMRISP0396625; Exhibit 8, Strategic Publication Planning for Risperdal at EMRISP0131382. This document, dated November 2, 2001, and "prepared by Excerpta Medica at the request of Janssen," describes a suggested child and adolescent publication plan for Risperdal. *Id.* The purpose of the "Publication Plan" was to "establish Risperdal as the best novel antipsychotic medication to use in children" and suggests articles for various target audiences, including pediatricians and child psychiatrists. *Id.* at EMRISP0131384. At this time, Risperdal was not approved by the FDA for use in children and adolescents. *See id.* at EMRISP0131387-88. Other evidence of off-label promotional activity, includes, but is not limited to, corporate meetings to orchestrate Janssen's off-label marketing to the pediatric population, s*ee, e.g,* Exhibit 9, "Risperdal Pediatric Market Opportunity" (JJPHD00004880), at JJPHD00004896, and the ghostwriting of articles touting the safety of Risperdal in children, *see, e.g*. Exhibit 10, Pediatrics Status Report (MRISP0150866), at EMRISP0150867.

Prior to December 13, 2004, Janssen sales representatives received incentives for sales related to pediatric and adolescent populations. Mr. Gilbreath, a Janssen sales representative, testified in another Risperdal matter that it was not until December 13, 2004 that Janssen removed incentive measures for Risperdal sales related to pediatric and adolescent populations.

See Exhibit 11, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al,* Gilbreath Testimony (February 4, 2015) at 51:3-19. A 2001 training document entitled "Addressing Prolactin With Your Customers" instructed sales representatives to misinform doctors on elevated prolactin, and misrepresented incidences of prolactin-related adverse events. *See* Exhibit 12, at JJRIS00236367 (JJRIS00236366). And a 2004 internal training document tells sales representatives to sell Risperdal to doctors because the risk of side effects from prolactin was so low. *See* Exhibit13, JJRE00394271. Janssen even created children's Lego toys stamped with Risperdal to be left behind in numerous pediatrician and psychiatrist offices around the country. *See* http://www.nytimes.com/2010/09/02/business/02kids.html?_r=3. Janssen made a significant profit from sales of Risperdal to the pediatric and adolescent populations. *See* Exhibit 14, Risperdal "Children and Adolescent Market Segment," 2002 Business Plan Summary, JJRErev00041039, JJRErev00041049; Exhibit 15, "Child and Adolescent & Other New Business" 2003 Business Plan (July 29, 2002), at JJRE02399406- JJRE02399410.

J & J has repeatedly been found guilty of inappropriate off-label and otherwise fraudulent marketing of Risperdal. In South Carolina in 2011, J&J was found liable by a judge in a bench trial and ordered to pay a verdict of $327 million. In 2012, J&J was forced to settle a case by the State of Texas for $158 million. In addition, on November 4, 2013, the Department of Justice announced that J&J agreed to pay more than $1.391 Billion to resolve civil investigations against it relating to off-label promotion of Risperdal and Invega . J&J also pleaded guilty to a criminal information on November 4, 2013 in which it admitted that it promoted Risperdal® to health care providers for off-label use. It agreed to a plea agreement under which it would pay a total of $400 million. As part of its settlement with the government, J&J and its subsidiaries also agreed to the imposition of a Corporate Integrity Agreement ("CIA") with the Department of Health and

Human Services Office of Inspector General. *See* Exhibit 16, Corporate Integrity Agreement. The CIA is intended to increase accountability and transparency and prevent future fraud and abuse. *Id.*

Following the FDA's approval for Risperdal in October of 2006 in pediatric and adolescent populations for symptoms associated with Autism, Janssen devised a marketing policy wherein all sales representatives were instructed to give out brochures referred to in the industry as a "Leave-Behind" regarding the new autism approval for children. *See* Exhibit17, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Gilbreath Testimony (February 4, 2015) at 70:16-25-76:11. Sales representatives were instructed to advise physicians that Risperdal is now approved for the treatment of irritability associated with autistic disorder in children and adolescents. *Id.* at 76:12-13. Sales representative were further advised to state that:

> This unique indication is supported by well-controlled clinical trials demonstrating significant efficacy, safety, and tolerability data, and dosing guidelines that can all be found in the package insert.

Id. at 77:14-25. Janssen representatives were instructed to provide physicians with the Leave-Behind along with the 2006 package insert. *Id.* at 78:13-80:7. The Leave-Behind, however, failed to contain the new safety information from the updated label and actually contained information that was directly opposite of the 2006 label. *Id.* at 82:1- 86:22, 100:15-118:25; Exhibit17, Autism Leave Behind, JJRE13972932. For instance, the Leave-Behind failed to mention the word gynecomastia, which a study of 1,885 patients found that gynecomastia occurred in 2.3% and provided:

> As with other drugs that antagonize dopamine-2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration.

Id. The Leave-Behind, unlike the 2006 label, did not mention that Risperdal elevates prolactin more than any other antipsychotic (and indeed, suggested that elevated prolactin was a class-effect). . *Id*; Exhibit 5, October 6, 2006 Risperdal Label. Unlike the 2006 label, the Leave-Behind also failed to mention that gynecomastia was observed in 2.3% of patients in study of 1,885. *Id*. Upon information and belief, on or around November 14, 2006, Janssen provided Dr. Pinit with the Autism, new indication Leave-Behind. Exhibit18, Janssen Call Notes, at JJPMURNE00000070.

Janssen knew of Risperdal's propensity to elevate prolactin in children and adolescents and to cause gynecomastia. Interim results from a long-term open-label trial, RIS-INT-41, which was the only pediatric trial out of five that paid "special attention" to prolactin-related side effects, showed that 4.1% of the boys taking Risperdal developed gynecomastia. *See* Exhibit 19, (JJRE08408869-12146) at JJRE08408916; Exhibit 20, (JJRIS02562360-447) at JJRIS02562429. The following October, Janssen confirmed Risperdal's propensity to cause gynecomastia in the final results of this trial, which showed that 5.5% of the boys on Risperdal had developed this condition. Exhibit 21, (JJRE08408869-12146) at JJRE08408950 -8953.

In a long-term study, RIS-INT-70 – a study "of special interest" to Janssen–Defendants observed an even higher rate of gynecomastia in boys taking Risperdal. Exhibit 22, (JJRE08398771-08400028) at JJRE08398810-8817. That study was a one-year extension trial comprised of 48 children, 42 boys of which were in the RIS-INT-41 trial. *Id.* Gynecomastia was reported by 14.3% of the boys in this trial; half of them either developed it or it worsened during this additional year on Risperdal. Exhibit 23, (JJRE08398771-08400028) at JJRE08398830-8834.

Janssen also had additional information which statistically linked elevated prolactin levels in children taking Risperdal with an increased risk of developing gynecomastia. Exhibit 24, JJRE14076752-770. Janssen acquired this information while conducting a meta-analysis of the prolactin results in children and adolescents from five trials. The goal was to "investigate prolactin levels" in these pediatric patients "and explore any relationship with side effects hypothetically attributable to prolactin (SHAP)." Exhibit 25, JJRE00115170-98 at -5172. As reported in Table 21 from this meta-analysis, the data revealed a statistically significant association ($p = 0.0158$) at weeks 8-12 of Risperdal use in the children and adolescents whose prolactin levels were above the upper limit of normal with the risk of subsequently developing gynecomastia. Exhibit 24 at JJRE14076765; see also Exhibit 27, *P.P., et al v. Janssen Pharmaceuticals, Inc., et al*, Kessler Testimony, January 30, 2015, Morning Session at 64:25-65:8.

Janssen, however, never reported the critical safety findings from this analysis or the analysis to the FDA during its' nearly three-year back-and-forth application process for the pediatric autism-related indication, nor was it provided to the FDA in any of the Risperdal standard annual or safety reports. *See* Exhibit 28, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Caers Testimony, February 10, 2015 at 58:10-21, February 11, 2015 at 58:10-21, 114: 22-23, 115:13-116:11; Exhibit 29, Trial Exhibits P34 and P34 A. Also, as evidenced by the documents, senior executives at Janssen advised that this critical safety finding – and a recommendation to conduct blood tests to monitor for prolactin elevation – be omitted based on concerns over increased costs to insurers that would make Risperdal less attractive as compared to competitors. *See* Exhibit 25 JJRE00115170; Exhibit 30, JJRE14088096. In fact, Janssen reported the opposite to the FDA, stating there was no correlation between elevated prolactin

levels and prolactin-related side effects in this pediatric population. Exhibit 31, (JJRE11084197-208) at - JJRE11084202, Exhibit 32, JJRE11084209-53 at JJRE11084224; Exhibit 33, (JJRP00782826-4889) at JJRP00782862. Moreover, this statistically significant association was never included in the Janssen-sponsored journal article discussing the results of this analysis. Exhibit 34, JJRE03839224-31.

On March 20, 2013, in response to a citizen petition filed by Stephen A. Sheller, the FDA sent an Information Request to Janssen, which was not made public, stating:

> We remind you of your obligations pursuant to section 505(k) of the FDCA to submit to FDA "data relating clinical experience and other data and information," as well as those set forth in 21 CFR Part 314, with respect to the drugs that are the subject of the above referenced NDAs. To the extent that you have any data in your possession relevant to the use of risperidone or paliperidone in children and adolescents that you have not previously provided to the Agency, please do so, or otherwise respond to this letter, within 30 days of receiving this letter.

See Exhibit 35, Janssen Response to FDA Information Request. In response, Janssen submitted certain documents to the FDA on April 19, 2013. *Id.* Janssen represented that "[w]e have not identified any data that were required to be submitted pursuant to section 505(k) of the FDCA or 21 CFR Part 314 but was not." *Id.* Janssen further represented that its response was based on "a review of all data in our possession relevant to the use of risperidone or paliperidone in children and adolescents." *Id.*

However, in February of 2015, a Janssen Vice President, Ivo Caers, Ph.D., testified in another Risperdal matter, that Janssen had still failed to submit key documents to the FDA or the public. *See* Exhibit 28, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Caers Testimony, February 10, 2015 at 58:10-21, February 11, 2015 at 58:10-21, 114: 22-23, 115:13-116:11; Exhibit 29, Trial Exhibits P34 and P34A. Some of the key data included documents which

showed that elevated prolactin levels during a critical period from 8 to 12 weeks after a patient starts taking Risperdal are a predictor of significantly increased risk of gynecomastia. *Id.*

C. Relevant Risperdal Labeling

Prior to when Plaintiff Mr. Murray was prescribed the drug, Janssen's Risperdal labeling failed to convey a risk of gynecomastia.

The 2000 Risperdal label:

a. Did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the WARNINGS section.

b. Did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the ADVERSE REACTIONS section; and

c. Claimed that various "Endocrine Disorders", including gynecomastia and male breast pain, were "*Rare*." *See* Exhibit 36, 2000 Risperdal Label

The 2002 Risperdal label:

a. Did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the WARNINGS section.

b. Did not contain any pediatric-specific warning, although Janssen knew that Risperdal was the largest atypical antipsychotic prescribed most to children and adolescents.

c. Did not contain any mention of gynecomastia, hyperprolactinemia, and/or precocious puberty in the ADVERSE REACTIONS section and;

d. Claimed that various "Endocrine Disorders", including gynecomastia and male breast pain, were "Rare."

After Risperdal was approved for pediatric use on October 30, 2006, the Risperdal label included several minor, but still insufficient changes.

a. Contained the indication for Irritability Associated with Autistic Disorder.

b. For the first time, contained mention of gynecomastia and hyperprolactinemia in the WARNINGS section, but only because "WARNINGS" and "PRECAUTIONS" were combined into a single section, and

c. In the "USE IN SPECIAL POPULATIONS" section, under "Pediatric Use", J&J

> made the following misleading statement about the propensity for young boys and girls to develop gynecomastia – "In clinical trials . . . gynecomastia was reported in 2.3% of RISPERDAL®-treated patients." *See* Exhibit 37 2007 Risperdal Label.

This updated label never appeared in an annual or monthly update edition of the PDR. Exhibit 38, 2007 & 2008 annual PDR and January 2007 monthly update.

Under the FDA regulations at the time, a drug company had a duty to revise its labeling to include a warning as soon as there was reasonable evidence of an association of a serious hazard with a drug *even if a causal relationship had not been proved*. 21 C.F.R. § 201.57(e) (2004) (stating, "[t]he labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."). FDA regulations at the time also required Janssen to describe in the "contraindications" section those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit and include patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it. 21 C.F.R. § 201.57(d) (2000). Under these regulations, based on the knowledge it possessed before 2006, Janssen should have promptly strengthened its Risperdal label without prodding or requiring approval from the FDA.

III. SUMMARY JUDGMENT STANDARD

In Pennsylvania, the granting of summary judgment is only proper where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact." Pa.R.C.P.1035.1. A court may grant a motion for summary judgment only where the right is clear and free from doubt. *Pennsylvania State University v. County of Centre*, 615A.2d303,304 (Pa. 1992)."The record must be viewed in the light most favorable to the non-moving party." *Marks v. Tasman*, 589 A.2d 205, 206 (Pa. 1991). Finally, all doubts as to the presence of a genuine issue of

material fact must be resolved against the moving party. *See County of Centre*, 615A.2d at 304.

IV. LEGAL ARGUMENT

A. Choice of Law

Pennsylvania's choice of law analysis consists of two parts. *See Troxel* v. *A.I. DuPont Inst.*, 636 A.2d 1179, 1180 (Pa. Super. 1994); *Griffith v. United Air Lines Inc.*, 203 A.2d 796 (Pa. 1964) (Pennsylvania's hybrid and flexible choice-of-law regime combines a "government interest analysis" with a "significant contacts" analysis). First, the court looks to see whether a "false conflict" exists. *See Cipolla v. Shaposka*, 267 A.2d 854 (Pa. 1970); *Wurtzel v. Park Towne Place Associates Ltd. Partnership*, 2002 WL 31487894, *17 (Phila. Com. Pl. 2002); *LeJeune v. Bliss-Salem, Inc*., 85 F.3d 1069, 1071 (3d Cir. 1996). A false conflict exists where "only one jurisdiction's interests are impaired by the application of the other jurisdiction's law, or if there is basically no difference between the laws of the jurisdictions." *Harsh v. Petroll*, 840 A.2d 404, 418 (Pa. Commw. 2003) (*citing Lacey v. Cessna Aircraft Co.*, 932 F.2d 170, 187 (3d Cir. 1991)). "'False conflict' really means 'no conflict of laws.' If the laws of both states relevant to the set of facts are the same, or would produce the same decision in the lawsuit, there is no real conflict between them." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 659 n. 20 (1985) (quoting R. Leflar, American Conflicts Law § 93, p. 188 (3d ed 1977)).

When a false conflict exists, the court need not decide the choice of law issue, and the court may rely interchangeably on the laws of both states. *Lucker Mfg. v. Home Ins. Co.*, 23 F.3d 808, 813 (3d Cir. 1994). If there is no false conflict, that is, if there is a true conflict, the court next must determine which state has the greater interest in the application of its law. *LeJeune*, 85 F.3d at 1071. In an action for personal injuries, "the law of the state where the injury occurred normally determines the rights and liabilities of the parties of the parties, unless another state,

applying the contacts test, has a more significant relationship to the occurrence and parties. "

Laconis v. Burlington

As Defendants concede "Maryland has the strongest ties to this case" and thus, the law of Maryland law should apply where a true conflict exists. In the instant case, as to Plaintiff's claims for negligent failure to warn, only a false conflict exists because the laws of both Maryland and Pennsylvania would produce the same result or are substantially similar. *Williams v. Stone*, 109 F.3d 890, 893 (3d Cir. 1997) (noting that a false conflict exist when each states law would produce the same result). Maryland and Pennsylvania law is also substantially similar or would produce the same result with respect to Plaintiff's warranty claims. To the extent Pennsylvania and Maryland warranty law differs, this Court should apply Maryland law. There are material differences between law in Maryland and Pennsylvania for strict liability and design defect. [2] Therefore, this Court should apply Maryland law to those issues.

B. Janssen Cannot Seek Maryland Law at this Late Date

Defendants' have waived any right to assert Maryland law applies to all of Plaintiff's claims in this case. Under Pennsylvania law, "[a] party who intends to raise an issue concerning the law of any jurisdiction or governmental unit thereof outside this Commonwealth shall give notice in his pleadings or other reasonable written notice." 42 Pa.C.S. § 5327. *See Commonwealth v. Manley*, 985 A.2d 256 (Pa. Super. 2009) (party's failure to provide timely notice of non-Commonwealth law precluded use of that law); *Tucker v. Whitaker Travel*, Ltd., 620 F. Supp. 578 (E.D. Pa.1985,), *aff'd*, 800 F.2d 1140 (3d Cir.), *cert. denied*,479 U.S. 986 (1986) (state law would be applied to civil action for personal injuries sustained in Bahamas,

[2] Defendants also state that there are differences between Pennsylvania and Maryland negligent design defect claims which under Pennsylvania law, Defendant argues requires showing that it is "too dangerous. " *See* Def.'s Mot. at 15 n. 6

where parties had not argued that Bahamian law applied nor had they submitted information about requirements of Bahamian law); *Maya v. Benefit Risk Mgmt*., 2012 Phila. Ct. Com. Pl. LEXIS 449 (Pa. C.P. 2012) (Quiñones Alejandro, J.) (defendant failed to confirm to the requisite notice requirement through vague references to Tennessee law, and thus this defense was waived). In this case, Janssen provided no such notice to the Plaintiff that they intended to seek the application of Maryland law into this matter. Accordingly, Janssen has waived its opportunity to assert Maryland law due to lack of notice.

C. Maryland Law Does Not Preclude Plaintiff's Failure to Warn Claims

Without citation to a single Maryland case, Janssen argues that under Maryland law, a manufacturer cannot be held liable as a matter of law on a failure to warn theory for drugs prescribed for off-label indications. Instead, Janssen cites to a single distinguishable case from a federal trial court opinion, *Robak v. Abbott Labs.*, 797 F. Supp. 475 (D. Md. 1992). Janssen's argument is flawed.

1. Plaintiff was Prescribed Risperdal for Both On-Label and Off-Label Indications and Therefore Janssen's Argument Fails as a Matter of Law

The testimony of Dr. Langfitt, Plaintiff's prescribing physician, and Plaintiff's medical records demonstrates that Plaintiff was taking Risperdal for both off-label and approved indications. Plaintiff was diagnosed with Attention Deficit Hyperactivity Disorder ("ADHD"), Obsessive Compulsive Disorder ("OCD"), Pervasive Development Disorder ("PDD") and Asperger's Syndrome. Both PDD and Asperger's Syndrome are considered Autism Spectrum Disorders("ASD"). Plaintiff was prescribed Risperdal for irritability associated with these two Autism Spectrum Disorders, which is an approved indication of Risperdal as of October of 2006. In particular, the October 2006 label provides that:

> "Risperdal is indicated for the treatment of irritability associated with autistic disorder in children and adolescents, including symptoms of aggression toward others, deliberate self-injuriousness, temper tantrums, and quickly changing moods."

Hence, even if Defendants had no duty under Maryland law to warn Plaintiff or the public of the dangers potentially caused by the use of Risperdal for off-label use, Plaintiff's failure to warn claim is still actionable as there is a sufficient issue of material fact that Plaintiff was prescribed Risperdal for an approved indication.

Plaintiff's prescribing doctor's testimony and Plaintiff's medical records demonstrate that Plaintiff was prescribed Risperdal for an approved indication. Dr. Langfitt testified that one of his jobs as the Plaintiff's pediatrician was to prescribe medicine to manage Plaintiff's symptoms of Asperger's, a diagnosis Dr. Langfitt made on numerous occasions and which he confirmed with further evaluations and consultations. *See* Exhibit 3, M. Langfitt Dep. 149: 11-21. Dr. Langfitt also testified that he prescribed Risperdal to manage and deal with Plaintiff's symptoms associated with ASD. *See* Exhibit 3, M. Langfitt Dep. 40: 8-17,151: 12-24, 152:1-24, 153:18-23, 155:4-17, 157:18-158:1-8, 203:6-14. Dr. Langfitt testified that he prescribed Risperdal to Plaintiff for symptoms of ASD such as quickly changing moods and temper tantrums. *Id.* at 65: 7-21, 157:18-158:1-8. Dr. Langfitt further testified that when he initially prescribed Risperdal for Plaintiff's symptoms of ASD it was off-label, but that he began to prescribe the drug to the Plaintiff on-label once the drug was approved for this indication in October of 2006. *Id.*

Likewise, Plaintiff's medical records confirm that Plaintiff was prescribed Risperdal for both off-label and approved indications. In multiple medication reports from Kennedy Krieger Children's Hospital, Plaintiff's prescribing physician, Dr. Arvoranee Pinit, listed Encephalopathy – Pervasive Developmental Disorder NOS and ADHD as a condition for which Plaintiff was prescribed Risperdal. *See* Exhibit 4, Kennedy Krieger Children's Hospital, 1/8/2004 thru

8/21/2008, NEM:KKI:0021-0034. These medical records indicate that the symptoms of ASD for which Plaintiff was prescribed Risperdal, included, among others, self-injurious behaviors, such as picking at his fingers and lips, and quickly changing moods. *Id.* at 10/11/2007 NEM:KKI:0023 (noting that "mood is broad"), 3/13/2008, NEM:KKI:0027 (same); NEM:KKI:0027 ("easily frustrated"); *See* Exhibit 2, NEM:SP:0020 (noting "started picking again (lips/fingers)"); NEM:SP:0021 (same). Risperdal was approved for treatment of irritability associated with ASD in children and adolescents, including symptoms, among others, of self-injuriousness behavior and quickly changing moods as of October of 2006. Because there is a sufficient issue of material fact that Plaintiff was prescribed Risperdal both off-label and for approved indications, Janssen's argument that a failure to warn claim is not actionable under Maryland law for off-label usage does not constitute a sufficient basis for summary judgment in Janssen's favor.

2. Janssen was Promoting and Profiting from Pediatric Sales, Knew of this Off-Label Usage and Thus Had a Duty under Pennsylvania and Maryland Law to Warn Regarding Risks Associated with this Foreseeable Use

Janssen asks this Court to make a blanket finding that a manufacturer (who promotes off-label uses, derives revenues from off-label uses and knows that its product is being used for off-label uses) should not have a duty to warn regarding known risks associated with off-label use. In essence, Janssen argues that manufacturers who comply with federal law may be subject to state failure to warn claims, whereas those that violate federal (as well as Maryland statutory provisions prohibiting off-label marketing) are not liable under Maryland law for any personal injuries caused by their violations and breaches.

Janssen fails to cite a single Maryland state court case to support its novel "no duty to warn" proposition.[3] Instead, Janssen relies on a single trial court opinion from the United States District Court for the District of Maryland, *Robak v. Abbott Labs.*, 792 F. Supp. 475 (D. Md. 1992) which addressed the learned intermediary doctrine as it pertains to off-label use. There, the court held that the plaintiff's failure to warn claim was not actionable under the learned intermediary doctrine because the plaintiff's physician unilaterally decided to prescribe the drug for off-label use. *Id*. at 475–476. The only authority the *Robak* court relied upon in support of this proposition was another decision from the United States District Court for the District of Maryland, *Weinberger v. Bristol-Myers*, 652 F. Supp. 187 (D. Md. 1986). However, the *Weinberger* decision did not discuss "off-label" failure to warn claims; rather, the *Weinberger* Court merely held that the defendant's warning was adequate since the label warned that the drug was associated with the risk at issue. *Id.* at 190-91.

Maryland state courts have never adopted the reasoning in *Robak* in over a decade following that decision. The reason that Janssen cannot cite to single Maryland state case is because Maryland law, akin to Pennsylvania law, provides that a duty to warn extends to all foreseeable uses which includes uses that are reasonably anticipated. *Moran v. Faberge, Inc.*, 332 A.2d 11, 15-16 (Md. App. 1975) (the duty of the manufacturer goes beyond the precise use contemplated by the producer and extends to all those which are reasonably foreseeable); *Dougherty v. Hooker Chemical Corp..*, 540 F.3d 174, 179 (3rd Cir. 1978) (applying Pennsylvania law in holding that manufacturers have a duty to warn of all foreseeable uses); *Colegrove v. Cameron Machine Co.*, 172 F. Supp. 611, 626 (same); *see also State v. Fox*, 79 Md. 514, 29 A.

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[3] Aside from the fact that Janssen has failed to cite to any Maryland state court opinion, Janssen has failed to cite to any Appellate decision from *any court* –to support its contention. In fact, Plaintiff's counsel is not aware of any appellate decision from any jurisdiction that supports Janssen's contention that it did not have a duty to warn regarding foreseeable off-label uses.

601, 603 (1894) (vendor who sells a dangerous product is liable for damages sustained by innocent third-parties); *see also Pennwalt Corp. v. Nasios*, 314 Md. 433, 455-56 (1988) (outlining elements of medical products liability under Maryland law); *Polakoff v. Turner*, 385 Md. 467, 478, 869 A.2d 837, 844 (2005) (landlord may be held liable for violation of housing code); *State, to Use of Schiller v. Hecht Co.*, 165 Md. 415, 169 A. 311, 313 (1933) (defendant can be held liable for violation of elevator safety ordinance).

Maryland has never immunized manufacturers for off-label promotion and usage. Janssen cannot escape liability simply because Plaintiff was prescribed Risperdal for some off-label indications. Janssen was obligated to obtain FDA approval for all of the uses for which it intended to promote (i.e. for unapproved uses in children) and once Janssen chose to intentionally promote Risperdal for unapproved uses, it resulted in a violation of both state and federal law. 21 U.S.C. §§331(a) and 352(f) (federal law prohibiting the sale and promotion of misbranded drugs); Md. Code Ann., Health-Gen. § 21-217 (Maryland stating that a drug is misbranded if it fails to contain adequate directions for use or does not have adequate warnings); Md. Code Ann., Health-Gen. § 21-256 (Maryland law prohibiting the sale and promotion of misbranded drugs); *McCormick v. Medtronic*, 101 A.3d 467, 474 (Md. App. 2014) ("Off-label promotion by a manufacturer…stands on different footing from off-label use by a healthcare practitioner, because off-label promotion may constitute "misbranding," a criminal violation of the FDCA."). Janssen proposes a counter-intuitive argument that would allow manufacturers and their representatives to ignore Maryland and federal law, which prohibits off-label promotion. *See McDonald-Lerner* 2103 Md. Cir. Ct. LEXIS * 24 (holding in the context of defendant's preemption arguments that the plaintiff's failure to warn claims were actionable

cogently noting the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the Judgment of Congress, needed more stringent regulation).

Indeed, Maryland state courts have held that failure to warn claims against manufacturers are actionable notwithstanding off label usage and do not distinguish product liability claims based on the use of the product. *See McCormick v. Medtronic, Inc.*, 101 A.3d 467, 487-88, 490 (Md. App. 2014) (Holding that plaintiffs claim for failure to warn with regard to off-label usage was actionable, despite defendants motion in to dismiss on preemption grounds and with regard to off-label promotion stating that "**products liability law concerns products, not the use of products")** (emphasis added); *McDonald-Lerner v. Neurocare Assocs., P.A.*., 2103 Md. Cir. Ct. LEXIS 1, * 2, *6, * 25 (Md. Cir. Ct. 2013) (denying defendants motion to dismiss because the plaintiff stated a viable cause of action for design defect, failure to warn, negligence, strict liability and fraud stemming from injuries the plaintiff suffered as a result of an Infuse medical device which was implanted for an off-label use and also rejecting defendant's preemption argument). Maryland courts have also subjected manufacturers to liability where Maryland misbranding provisions have been violated. *Flaccomio v. Eysink*, 100 A. 510, 515 (1916) (a plaintiff is entitled to compensation from a manufacturer who sold a misbranded product or violated a statute).

Likewise, Pennsylvania case law has held that failure to warn claims are actionable against a drug company for off-label promotion and usage. *Simon v. Wyeth Pharmaceuticals, Inc.*, 989 A.2d 356 (Pa. Super. 2009) (holding that the learned intermediary doctrine did not apply where a drug manufacturer promotes a drug for off-label use and fails to warn the prescribing physician of associated risks); *see also Kendall v. Wyeth, Inc.*, 2012 WL 112609 at *6 (Pa. Super. Jan. 3, 2012) ("Although physicians were free to prescribe [Provera], it was an off-label

use and Upjohn was forbidden from promoting or advertising for it."); *Hahn v. Richter, 427 Pa. Super.* 130, 628 A.2d 860 (1993) aff'd, 673 A.2d 888 (1996) (making no suggestion that the trial court should have dismissed the claims against the drug manufacturer for injuries caused by an off-label use). Federal and state courts throughout the country who have considered similar arguments as those advanced by Janssen have been nearly universal in rejecting such arguments. *See, e.g. Medics Pharm. Corp. v. Newman,* 378 S.E.2d 487 (Ga. App. 1989) (a manufacturer has a duty to warn of risks associated with foreseeable off-label uses)*; Richards v. Upjohn Co*., 625 P.2d 1192 (N.M. App. 1980) (drug manufacturers are liable for failure to warn of risks associated with reasonably foreseeable off-label drug uses); *Miles Labs., Inc. v. Superior Court*, 133 Cal. App. 3d 587, 184 Cal. Rptr. 98 (Ct. App. 1982) *(*a manufacturer will be liable for failure to warn of risks of an off-label drug use if the manufacturer knew or should have known of the off-label use and that use accounted for a significant portion of the manufacturer's sales of the drug.); *Knipe v. SmithKline Beecham*. 583 F. Supp. 2d 602 (E.D. Pa 2008) (applying New Jersey law, in holding that a drug manufacturer has a duty to warn of the risks associated with off-label drug uses); *Meharg v. I-Flow Corp.*, No. 1:08-cv 184-WTL-TAB, 2010 WL 711317 (S.D. Ind. Mar. 1, 2010) (holding that even when manufacturer does not engage in off-label promotion, that they have to warn if they know off-label use occurs and knows that the off-label risk carries a risk of harm); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009) (held that a manufacturer does not have a duty to warn of known risks associated with an off-label use); *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006) (manufacturers that substantially profit from off-label uses of their products must warn physicians of the risks associated with those off-label uses); *Upjohn Co. v. MacMurdo,* 562 So. 2d 680 (Fla. 1990) (standing proposition that a manufacturer is liable for failure to warn of a risk associated with an off-label drug use if the

general medical community accepted the use as appropriate therapy); *see also Proctor v. Davis*, 682 N.E.2d 1203 (Ill. Ct. App. 1997) (the learned intermediary doctrine did not apply when a manufacturer openly promoted an off-label use); *Smith v. Pfizer, Inc*., 714 F. Supp. 2d 845 (M.D. Tenn. 2010) (a manufacturer who actively promotes an off-label use must warn physicians of risks associated with that use). Despite this overwhelming body of case law and near universal consensus, Janssen erroneously asks this Court to hold that Plaintiff's failure to warn claims are barred as a matter of law based on a single federal, trial court opinion *Robak v. Abbott Labs.*, 792 F. Supp. 475 (D. Md. 1992).

But even if this Court was somehow persuaded by *Robak*, Janssen's reliance on *Robak* is misplaced. In *Robak* there was no evidence of off-label promotion by the manufacturer, or that the manufacturer reasonably anticipated the off-label use. There was also no evidence that the manufacturer possessed any information regarding the dangers of the off-label use which would impose a duty to warn *vis-a-vie* the learned intermediary. In the present case, the question is not whether Maryland law provides a cause of action for failure to warn when a drug is unilaterally prescribed by a physician off-label as in *Robak*. *See McDonald-Lerner*, 2103 Md. Cir. Ct. LEXIS *7-8 (noting that the defendants improperly framed the issue); *McCormick*, 101 A.3d at 485 (noting "off-label promotion by a manufacturer, however, stands different footing"). Rather, the issue presented in this case is whether Maryland law permits a failure to warn claim, where a manufacturer promotes a drug off label (and even knows that the drug is being prescribed off-label) and fails to warn of a reasonably anticipated and foreseeable use. *Robak* simply does not answer that question and does not provide any authority on this point.

The record throughout the course of this mass tort litigation establishes a myriad of off-label promotional activities to promote Risperdal in treating children and adolescents. The decision to improperly market and promote Risperdal to children and adolescents began no later than

1992. *See* Exhibit 7, Excerpta Medica's February 2003 marketing handout, at EMRISP0396639. From 1992 until 2003, Janssen devised a strategic publication plan to market Risperdal to the pediatric and adolescent population as evident from the "Strategic Publication Planning for Risperdal: Child and Adolescent Use." *Id*. at EMRISP0396625; *See* Exhibit 8, Strategic Publication Planning for Risperdal (EMRISP0131382). This document, dated November 2, 2001, and "prepared by Excerpta Medica at the request of Janssen", describes a suggested child and adolescent publication plan for Risperdal. *Id.* Further, the "Publication Plan" had a commercial benefit for Janssen – "establish Risperdal as the best novel antipsychotic medication to use in children." *Id.* at EMRISP0131384. The "Plan" continues by suggesting articles for various target audiences, including pediatricians and child psychiatrists. At this time, Risperdal was not approved by the FDA for use in children and adolescents. *See id.* at EMRISP0131387-88.

Pharmaceutical sales representatives working for Janssen, and certainly sales managers knew, based on a nationwide qualifying customer initiative that tracked doctors' prescriptions, Risperdal was being prescribed to children. Not only did Janssen know that Risperdal was being prescribed to children, but until November of 2004, its bonus and compensation policy depended on how much the doctors' were prescribing to children in addition to adults. *See* Exhibit 39, *W.C., et al. v. Janssen Pharmaceuticals et al.*, William Overholt Testimony, at 52:1-66:4. It was not until the Federal Government got involved that this policy changed. In fact, Janssen's conduct was so egregious that numerous states filed actions against Janssen as a result of its illegal campaign to promote Risperdal off-label.

Other evidence of off-label promotional activity, among others, includes corporate meetings to orchestrate Janssen's off-label marketing to the pediatric population, s*ee, e.g*, Exhibit 9, "Risperdal Pediatric Market Opportunity" (JJPHD00004880), at JJPHD00004896, and the ghostwriting of articles touting the safety of Risperdal in children, *see, e.g*. Exhibit 10, Pediatrics

Status Report (EMRISP0150866), at EMRISP0150867. Janssen made a significant profit from sales of Risperdal to the pediatric and adolescent populations. *See* Exhibit 11, Risperdal "Children and Adolescent Market Segment," 2002 Business Plan Summary, JJREv00041039, JJREv00041049; Exhibit12, "Child and Adolescent & Other New Business" 2003 Business Plan (July 29, 2002), at JJRE02399406- JJRE02399410.

In the instant case, Janssen was well-aware that Risperdal was being used by children, reaped substantial profits from pediatric and adolescent usage, and even encouraged this off-label usage. Prior to and during the course of Plaintiff's ingestion, Janssen had knowledge regarding the increased risk of gynecomastia to children taking Risperdal, yet instead of issuing a warning, Janssen ruthlessly and unconsciously promoted Risperdal to be used in children and adolescents. There is no question that it was foreseeable (and in fact encouraged and predicted by Janssen) that doctors would prescribe Risperdal to children and adolescents. Thus, Janssen had a duty to warn of the known risks associated with pediatric and adolescent use.

Accordingly, Janssen's motion for summary judgment on the basis of Plaintiff's failure to warn claims should be denied

D. Plaintiff's Claims are Not Barred by the Learned Intermediary Doctrine

1. Maryland Has Not Expressly Adopted the Learned Intermediary Doctrine.

Defendants argue that Maryland recognizes the learned intermediary doctrine. In support of this proposition Defendants cite an intermediate appellate court decision, *Gourdine v. Crews*, 177 Md. App. 471, 935 A.2d 1146 (2007), which relied on *Nolan v. Dillon*, 261 Md. 516, 523, 276 A.2d 36 (1971) and a federal trial court case, *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, (D. Md. 2006). However, as made clear on appeal of *Gourdine v. Crews*, to Maryland's

highest court, the Maryland Court of Appeals noted that the cases relied upon by the lower court did not expressly adopt the learned intermediary doctrine and declined to answer that question:

> Seminally, however, we note our divergence from the duty analyses of the trial court and the Court of Special Appeals, because both relied on the "learned intermediary" doctrine, with citation to *Nolan v. Dillon,* 261 Md. 516, 523, 276 A.2d 36, 40 (1971), to determine that Lilly did not owe a duty to Mr. Gourdine…. that case clearly lacks the express adoption of the "learned intermediary" doctrine undertaken by other courts… The "learned intermediary" doctrine, thus, is not an issue that we need to explore in the present case.

Gourdine v. Crews, 405 Md. 722, 744 (Md. 2008) (declining to apply the learned intermediary doctrine and finding that the pharmaceutical company did not owe a duty to an unforeseeable third party). While other Maryland District Courts have applied the learned intermediary doctrine in various contexts, Maryland state appellate courts have declined to do so. Thus, under Maryland law, the learned intermediary doctrine does not apply and Defendants' motion for summary judgment should be denied.

2. <u>The *Nanty-Glo* Rule Precludes Summary Judgment Under the Learned Intermediary Doctrine Because Janssen Relies Solely on Testimony of a Non-Party, Dr. Langfitt.</u>

Janssen contends that each of Plaintiffs' claims is barred by the "learned intermediary doctrine." The Pennsylvania Supreme Court in *Nanty-Glo* held that a court may not enter summary judgment where the evidence depends upon oral testimony. The court stated that "[h]owever clear and indisputable may be the proof when it depends on oral testimony, it is nevertheless the province of the jury to decide, under instructions from the court, as to the law applicable to the facts." *Nanty-Glo v. American Surety Co*., 136 A. 523, 524 (Pa. 1932). *See, also White v. Owens-Corning Fiberglas Corp*., 668 A. 2d 136, 142-143, 145 (Pa. Super. 1995) (the credibility of testimony from the plaintiff's treating physician is a matter for the jury, not the

judge); *Drapeau vs Joy Technologies, Inc.*, 670 A.2d 165, 168 (Pa. Super. 1996) ("[b]ased upon the *Nanty-Glo* rule, a case should not be summarily decided solely on the basis of a non-party's testimony."); *Evans v. Penn Mut. Life Ins. Co.*, 186 A. 133, 141 (Pa. 1936) (under *Nanty-Glo* rule, credibility is in the purview of the jury).

In *White v. Owens-Corning Fiberglas Corp*. the Pennsylvania Superior Court found that the trial judge violated the *Nanty-Glo* rule in the statute of limitations context, when it concluded that it expired based solely upon the testimony of the physicians. 670 A.2d at 142-143. Specifically, the parties disputed when the plaintiff learned that his injuries were asbestos-related. *Id*. The plaintiff suffered from shortness of breath for many years, and he claimed that he did not know his symptoms were asbestos related until a late diagnosis by his physician. *Id*. The lower court relied upon the testimony of his doctor and found that the plaintiff knew about the asbestos-related medical condition more than two years prior to bringing his lawsuit. *Id*. The appellate court reversed, finding that the credibility of the doctor and his testimony were a genuine issue of material fact. *Id*. The court noted that the certified record contained no non-testimonial evidence whatsoever to indicate what the plaintiffs knew or should have known. *Id*.

Akin to *White*, Plaintiff's prescribing doctors' testimony and their credibility are genuine issues of material fact that are not properly decided on summary judgment. While Dr. Langfitt stated he would have discussed the risk of gynecomastia with Nicholas' mother, he had no independent recollection of doing so. *See* Exhibit 3, M. Langfitt Dep. at 43:5-10, 102:1-105:10. Similarly, there are no medical records indicating such a conversation took place. Plaintiff and his mother's affidavits definitively confirm they were never warned of the side effect of gynecomastia. *See* Exhibit 40, Affidavit of Joy Murray.

While *Lineberger v. Wyeth*, 894 A.2d 141 (Pa. Super. 2006) found that the *Nanty-Glo*

rule did not apply in a pharmaceutical case, nearly all of the court's discussion was dictum without any precedential value because the plaintiffs did not raise the *Nanty-Glo* issue at the trial level and therefore the Superior Court ruled that it was waived on appeal. Therefore, *Lineberger* does not apply to this case. Additionally, in *Lineberger*, the certified record included evidence that a different warning would not have altered the prescribing physician's actions. *Id.* at 150. Specifically, the physician testified that even if the drug's literature had included a specific warning, he still would have prescribed the drug in question. *Id.* Such facts do not exist here, and therefore *Lineberger* is distinguished.

In sum, Dr. Langfitt's testimony is a matter of credibility for the jury to decide under the *Nanty-Glo* rule and its interpreting case law. Because Janssen relies solely on testimony of Dr. Langfitt, Janssen's Motion for Summary Judgment based on learned intermediary principles must fail.

3. The Learned Intermediary Doctrine is Inapplicable to Plaintiff's Claims as Janssen was Engaged in a Scheme Designed to Take Plaintiff's Treating Physicians Out of Their Role as a "Learned Intermediary."

The learned intermediary doctrine only applies if the facts support the conclusion that a drug manufacturer adequately warns doctors of a drug's dangers; it does not shield drug manufacturers from liability if the warnings they provided to physicians would not permit the physicians to adequately advise their patients. *See Colacicco v. Apotex*, 432 F. Supp.2d 514, 546 (E.D. Pa. 2006) (emphasis added). Indeed, "[p]hysicians become learned intermediaries only when they have received adequate warnings from the drug manufacturer." *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) (emphasis added); *Wyeth, Inc. v. Weeks*, 2013 Ala. LEXIS 2, CCH Prod. Liab. Rep. P19 (Ala. Jan. 11, 2013) (if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for

the injuries sustained by the patient). *See also Meridia Prods. Liab. Litig. v. Abbott Lab*s., 447 F.3d 861, 867 (6th Cir. 2006); *Amore v. G. D. Searle & Co.*, 748 F. Supp. 845, 850 (S.D. Fla. 1990).

The learned intermediary doctrine presumes that the drug manufacturer provides the prescription physician with honest, accurate, and complete information regarding the drug's efficacy and safety. Where that presumption is unfounded, the learned intermediary doctrine cannot shield the drug maker or the concerted action of others from liability; in such a case, no adequate warning ever reaches the physician from which s/he may advise his or her patients - which is the foundational premise of the learned intermediary doctrine. *See, e.g., Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1154 (Pa. Super. 1996) ("a prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient" and weigh "the benefits of any medication against its potential dangers"). *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006)(where the label is inadequate it "could be a "producing" cause of the injury, because it effectively sabotages the function of the intermediary."

Here, the facts permit the conclusion that Janssen failed to adequately warn Dr. Langfitt, Dr. Pinit, and the public, including Nicholas and his family, concerning the dangers of Risperdal; and that Janssen engaged in a scheme devised to remove Dr. Langfitt and Dr. Pinit from their role as learned intermediary. Janssen withheld and concealed pertinent studies and other information revealing that Risperdal caused weight gain, hyperprolactinemia, gynecomastia, diabetes mellitus, metabolic syndrome, and a host of other adverse effects; therefore, Plaintiffs' physicians could not have had sufficient information to "adequately advise [their] patients." *Colacicco v. Apotex, Inc.*, 432 F. Supp.2d 514, 546 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir.), *cert. granted, vacated on other grounds*, 129 S. Ct. 1578 (2009).

Hence, because the Defendants failed to adequately warn Dr. Langfitt and Dr. Pinit as to the dangers of the drug and engaged in a scheme to deceive such providers out of their role as learned intermediary, this doctrine does not apply.

4. <u>There is a Genuine Issue of Material Fact that Dr. Langfitt Would Not Have Prescribed Risperdal Had He Possessed Information Regarding the Dangerous Propensities of the Drug.</u>

The testimony of Dr. Langfitt, Plaintiffs' prescribing physician, and Nicholas Murray's mother, Joy Murray, demonstrates that had Dr. Langfitt been informed of the true risks of Risperdal, he would have provided Nicholas and his mother with a more definite warning about the increased risk of gynecomastia and Nicholas would not have ingested the drug.

The recent case of *Daniel v. Wyeth*, 15 A.3d 909 (Pa. Super. Ct. 2011) is on point here. There the prescribing physician testified at trial that it was his practice when prescribing hormone therapy drugs to engage in a discussion of the benefits and the risks with the plaintiff-patient, and to allow the patient to make the final decision on whether to take the drugs. *Id*. The doctor further testified that when he prescribed Prempro to the Plaintiff, he warned her of certain risks (e.g., headaches, nausea, vaginal bleeding), but not of the risk of cancer. *Id*. at 924. He stated that, in his view, the physician's package insert did not, at the time he prescribed Prempro to the plaintiff, provide him with any basis to conclude that the drug posed any significant risk of breast cancer to her, since its warnings in this regard appeared to be limited to cases of higher doses or doses for a prolonged period of time (ten years or more). *Id.* at 925. In turn, the plaintiff testified that his prescribing doctor never informed her of the risk of breast cancer from taking Prempro, and that if she had known of the risk of breast cancer associated with Prempro, *she would not have taken the drug*—even if her doctor had recommended it. *Id.* The court found that this constituted sufficient evidence of proximate causation, permitting a jury to find that if

the drug manufacturer had issued warnings of risk of breast cancer to the prescribing doctor, he would have altered his prescribing practices. *Id.*

Like the *Daniel* case, Nicholas' prescribing doctor testified regarding his prescribing practices with Plaintiffs, the doctor's lack of exposure to any warning regarding gynecomastia or the like, and that he would have included discussions of the risks of gynecomastia with Nicholas and his mother. Dr. Langfitt testified he was not aware that Risperdal was associated with elevated prolactin. *See* Exhibit 3, M. Langfitt Dep. at 62:19-22. He did not recall knowing that gynecomastia was a side effect definitely related to elevated prolactin. *See* Exhibit 3, M. Langfitt Dep. at 78:12-19. Dr. Langfitt unequivocally stated that he did not associate gynecomastia with Risperdal before he began prescribing Risperdal to Nicholas. *See* Exhibit 3, M. Langfitt Dep. at 79:3-13.

Further, Dr. Langfitt testified that the label in effect at the time he began prescribing Risperdal for Nicholas would have informed him that gynecomastia was "rare" or occurring in less than 1/1000 patients. *See* Exhibit 3, M. Langfitt Dep. at 83:14-84:11. Internally, J&J knew that Risperdal had a much more dangerous effect on prolactin than the other atypical antipsychotics and the risk of gynecomastia was "frequent" rather than "rare." For example, in a 2003 email shown to Dr. Langfitt, a J&J scientist admitted that Risperdal causes higher prolactin elevations than other antipsychotics. *See* Exhibit 3, M. Langfitt Dep. at 91:22-94:1, 85:7-86:9; *See* Exhibit 41, (M. Langfitt Dep. Exhibit 6) (January 28, 2003, email from Olga Mittelman to John Jacoppi), *See* Exhibit 42, (M. Langfitt Dep. Exhibit 8) (Prolactin: From Mechanisms to Sequelae, A White Paper from Janssen Medical Affairs, LLC, Prolactin Taskforce, August 2004). Even as far back as October 1994, J&J admitted internally that Risperdal was vulnerable to its competitors because of its propensity to elevate prolactin more than the other atypicals. *See*

Exhibit 43, October 1994 "Risperdal's future in the new competitive environment", at JJRIS01914456 (emphasis added). Janssen was concerned that this vulnerability would be exploited by its competitors. In another confidential document entirely devoted to the company's strategy concerning prolactin, J&J reported that prolactin was a "unique" problem for Risperdal. *See* Exhibit 44, "Strategic Proposal: Prolactin" at JJRE07809442 . And a February 2000 Executive Summary concerning "Risperdal and the Pediatric Market" analyzed the use of other atypical antipsychotics in the child and adolescent market and acknowledged that Risperdal "may have a problem according to prolactin levels." *See* Exhibit 45, February 28, 2000 "Executive Summary: Risperdal And The Pediatric Market", at JJRE01476166.

After reviewing the label, Dr. Langfitt agreed that there was nothing in the 2003 label stating that Risperdal elevates prolactin more than other antipsychotics. *See* Exhibit 3, M. Langfitt Dep. at 94:16-96:4. He stated that if the pharmaceutical company had advised him to monitor prolactin levels, he would have taken that under advisement. *See* Exhibit 3, M. Langfitt Dep. at 62:23-65:5.

Here, Dr. Langfitt also testified he did not have a specific recollection of what warnings he gave Nicholas and his mother about Risperdal, but it was his general practice to have such a conversation with her. *See* Exhibit 3 M. Langfitt Dep. at 43:5-10, 162:4-8. He stated that if he had known what Janssen knew, (that 4.8 percent of patients in a Risperdal safety study were found to have gynecomastia, he would have discussed it with Dr. Pinit and then expressed his or Doctor Pinit's concerns to Nicholas' mother. *See* Exhibit 3, M. Langfitt Dep. at 102:1-105:7; *See* Exhibit 3, M. Langfitt Dep. at 109:10-110:3).

Dr. Langfitt did not recall reading the 2006 label and stated that while he did his best to update his knowledge of medications, he did not check the label each time he prescribed

medication. *See* Exhibit 3, M. Langfitt Dep. at 158:23-160:9. Further, he stated several times that he would have consulted with Dr. Pinit (Nicholas' only psychiatrist and other prescribing physician) regarding his prescriptions for Nicholas Murray. *See* Exhibit 3, M. Langfitt Dep. at 52:14-53:1, 62:23-63:9, 102:1-105:7. Upon information and belief, on or around November 14, 2006, Janssen provided Dr. Pinit with the Autism, new indication Leave-Behind. As described above that document did not convey that Risperdal elevates prolactin more than any other anti-psychotic (and indeed, suggested that elevated prolactin was a class-effect), nor did it convey that gynecomastia was observed in 2.3% of patients in study of 1,885. *Id*; Exhibit 5, October 6, 2006 Risperdal Label.. Exhibit18, Janssen Call Notes, at JJPMURNE00000070.

Plaintiffs are still attempting to locate Dr. Pinit, and presently Dr. Pinit has not been deposed. Courts have found a Doctor's statement that he would have relied upon medical experts and the medical community in conducting a risk-benefit analysis as to the label's adequacy creates a question of fact for the jury, not susceptible to summary judgment. *See, e.g. Linnen v. A.H. Robins Co.*, 1999 Mass. Super. LEXIS 552, 13 (Mass. Super. Ct. 1999) ("Assuming that the warning was inadequate, defendants have failed to establish that [the plaintiff's doctor's] decision to prescribe fen-phen 'would not have been affected ... by communication of an adequate warning' to the medical community"). Defendants have failed to establish that Dr. Langfitt's prescribing habits would not have been affected by an adequate warning by Dr. Pinit and thus summary judgment is not appropriate.

Additionally, Plaintiff's mother, Joy Murray, testified that her son Nicholas **would not have ingested Risperdal had she discussed those warnings of gynecomastia with Dr. Langfitt or Dr. Pinit**. She further stated that had she received adequate or additional warnings about the endocrine side effects of Risperdal, including the fact that Risperdal causes

hyperprolactinemia more than other antipsychotic medications, and that clinical studies, especially long-term clinical studies, had shown that gynecomastia was not a "rare" occurrence, but occurred in 4.8% or more of patients taking Risperdal, and that there was a statistically significant association between Risperdal, elevated prolactin and gynecomastia, prior to Nicholas being prescribed Risperdal, she would have either asked for a different medication or closely monitored Nicholas for sides effects like gynecomastia while he was taking Risperdal. *See* Exhibit _ Affidavit of Joy Murray. Thus, Ms. Murray has unequivocally stated that she would not have allowed Nicholas to take Risperdal had she known of the risks from Janssen or her son's physician. Janssen relies on *Fripps v. Wyeth*, July Term 2004 No. 0925, 2012 WL 1452556 (Phila. Ct. Com. Pl. April 19, 2012) (Moss, J.). There, the court found the prescribing physician offered no testimony to suggest she would have changed her prescribing habits if warned of the breast cancer risk caused by Prempro. In fact, the alleged prescribing doctor did not remember the plaintiff, nor the last time she treated her, nor why she was on Prempro in the first place. The doctor also testified she did not recall having a risk benefit analysis discussion with the plaintiff. She testified *only hypothetically* that she would have conveyed the risk of breast cancer had the plaintiff asked. The court concluded, therefore, that it could not infer that the plaintiff would not have ingested Prempro had the prescribing doctor known of the dangers *vis a vis* a warning label. While the plaintiff testified that a "definite warning" would have prevented her from taking the drug, there was no indication in the record she could have learned this from the label or the doctor.

The facts of the present case differ from *Fripps* on several grounds. First, Dr. Langfitt had an ongoing relationship with Plaintiff and knew precisely why he was on Risperdal. Second, Dr. Langfitt testified that he would have discussed the risk of gynecomastia with Dr. Pinit,

Plaintiff and/or his mother had he been aware. Third, Plaintiff's mother testified by both sworn affidavit and deposition testimony that she asked about Risperdal's side effects and that had she known that her son was at an increased risk of developing gynecomastia, a frequent side effect, she would not have allowed her son to ingest Risperdal.[4] Under these circumstances, Dr. Langfitt would have changed his prescribing habits with Plaintiff since he a) would have discussed the risk of gynecomastia and b) plaintiff definitively would have opted to reject Risperdal as a treatment for his psychiatric disorder. These are the elements missing in *Fripps* which permit this Court to find sufficient evidence of proximate causation.

Likewise, in *Lineberger v. Wyeth*, 894 A.2d 141, 151 (Pa. Super. 2006) cited by Janssen, the prescribing physician testified that even if the warnings proposed by plaintiff had been present, he would have still prescribed the drug. In *Lineberger*, the Court noted that the record was devoid of evidence that a different warning would have altered prescribing methods of the physician. *Id.*

Similarly, in *Demmler v. SmithKline Beecham Corp.*, the Court initially found that the serious side effect of which plaintiff complained was covered in the products warnings. 671 A.2d 1151, 1155 (Pa. Super. 1996). The Court then affirmed summary judgment on a second independent reason that the plaintiff failed to show the causal link between the alleged defect and plaintiff's injury. *Id.* In contrast to the present case, *Demmler's* prescribing physician offered uncontradicted testimony that he prescribed the drug to plaintiff "based upon his years of clinical experience and his review of medical literature, rather than any information supplied by [the

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[4] Plaintiff is also entitled to an evidentiary presumption that a warning by Janssen would have been read and heeded. *Pavlik v. Lane Limited/Tobacco Exporters International*, 135 F. 3d 876 (3d Cir. 1998) ("This presumption assists the failure to warn plaintiff in satisfying his burden of showing proximate cause."). *See also, Shouey, by & Through Litz v. Duck Head Apparel Co*, 49 F. Supp. 2d 413, 420 (M.D. Pa. 1999) (holding that a plaintiff need not produce evidence that a warning would have been heeded in order to survive a motion for summary judgment). *See also, Wolfe v. McNeil-PPC, Inc*., 773 F.Supp.2d 561, 569 (E.D. Pa. 2011)(summary judgment inappropriate where reasonable jury could find stronger warning would have been heeded, thus preventing plaintiff's injuries).

drug manufacturer]. *Id*. at 1155-56. Contrary to Janssen's assertions, Dr. Langfitt's testimony sufficiently creates an issue of fact for the jury.[5] Accordingly, Janssen's motion for summary judgment based on learned intermediary doctrine should be denied.

5. Dr. Langfitt's Prior Knowledge of a Remote Risk Does Not Warrant Summary Judgment on the Issue of Causation Under Learned Intermediary Principles.

Janssen argues that Dr. Langfitt had prior knowledge of the "precise side effects about which Plaintiff complains" prior to his prescription of Risperdal to Plaintiff. *See* Def's Mot. at 11. As Plaintiff has argued throughout this brief, in order for Janssen to prevail at trial, the record must demonstrate that Dr. Langfitt was *fully aware* of the risk of bodily injury posed by Risperdal.

Based on the evidentiary record, there are serious doubts that the Dr. Langfitt was sufficiently warned of the dangers of gynecomastia. More specifically, as argued above, the 2000 and 2003 labels appear to give the user no notice of the serious nature of gynecomastia posed by Risperdal. Dr. Langfitt even testified that despite the remote risk of elevated prolactin in the label, he did not remember, "specifically thinking in my mind I've got to think about prolactin." *See* Exhibit 3 M. Langfitt Dep. at 147:7-13; *see also Schilf v. Eli Lily*, 687 F.3d 947 (8th Cir. 2012) (a warning that an adverse effect is "associated" with a medication is not a warning that a causal connection exists; summary judgment in favor of manufacturer was error).

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[5] Plaintiffs further submit that Janssen is estopped from asserting the learned intermediary defense since Janssen off-label marketed Risperdal. The learned intermediary doctrine is unavailable to a defendant manufacturer that off-label promotes its drug. *Vitanza v. Upjohn Co*., 48 F. Supp.2d 124, 130 (D. Conn. 1999) (citing *Proctor v. Davis*, 682 N.E.2d 1203, 1214-15 (Ill. App. Ct. 1997)); see also *Ebel v. Eli Lilly & Co*., 321 F. App'x 350, 356 (5th Cir. 2009) (finding a statutory exception to the learned intermediary doctrine exists where the defendant manufacturer recommends, promotes, or advertises their pharmaceutical product for an off-label use); *Dellinger v. Pfizer Inc*., Civ. A. No. 03-CV95, 2006 WL 2057654, at *6 (W.D.N.C. July 19, 2006) (holding that the learned intermediary doctrine did not bar plaintiffs claim because the defendant manufacturer illegally and fraudulently promoted the off-label use of Neurontin).

The facts in *Schilf v. Eli Lilly*, are similar to those in the present case. There, the plaintiffs alleged that Eli Lilly & Co. ("Lilly") failed to warn of the suicide risks associated with Lilly's antidepressant drug, Cymbalta, which eventually caused the suicide death of their 16-year old son. *Id*. at 948. Lilly moved for summary judgment, arguing that the young man's physician prescribed Cymbalta with knowledge of its risks. *Id*.at 948 However, the appellate court emphasized that while the prescriber was aware of an *association* between Cymbalta and suicide, he was not aware of a causal link between the two, or of clinical trials in which five suicides occurred. *Id.* The prescriber had testified that before prescribing Cymbalta, he would have wanted to know the details of any suicide that occurred during its clinical trials. *Id.* He further testified that he read the package insert which cautioned that "completed suicide" and "suicide attempt" were "infrequent adverse events."[6]*Id*. At his deposition, the prescribing physician did not recall this warning and described himself as interested in "see[ing] the information." *Id* The insert did not state the number of suicides that occurred in the clinical trials, nor did it indicate any way that the "completed suicide" or "suicide attempt" adverse events were more significant than the other events detailed. *Id.* The Eighth Circuit reversed the summary judgment finding of the district court, and held that there were genuine issues of material fact as to whether an adequate warning would have altered the prescriber's behavior. *See id.* at 950.

An argument similar to that advanced by Janssen herein was recently rejected by the Pennsylvania Superior Court in *Singleton v. Wyeth Inc.*, 2012 Pa. Super. LEXIS 1593 (Pa. Super. Ct. July 20, 2012.). There, Wyeth sought to have the trial court give the following proposed jury charge:

> Even if you find that Wyeth failed to provide an adequate breast cancer

[6] The 2004 Cymbalta warning also stated that "a causal role for antidepressants in inducing suicidality has not been established." *Id*. at *4.

> warning to Ms. Singleton's prescribing physician, you must find for Wyeth if her physician did not rely on the label prescribing Prempro to Ms. Singleton, ***or was aware of the risk of breast cancer from any other source.***

Id. at *30 (emphasis added).

The trial court refused to give such an instruction. On appeal, the Superior Court noted that the charge was "an inaccurate statement of the law." Citing to the "read and heed" presumption (recognized in Pennsylvania) and the fact that the prescribing doctor would not have prescribed Prempro had he known of the dangers (just as Dr. Pandya here), the court found the charge "misleading" and upheld the decision of the trial court. *Id.* at *30.

Based on the foregoing, there is ample evidence to put the matter before the jury. The Court must leave the question of causation for the jury. *See Pavlik v. Lane Ltd./Tobacco Exporters Intern*., 135 F.3d 876 (3d. Cir. 1998) (prior knowledge of dangers at hand provides no reason for finding no causation; summary judgment in favor of manufacturer was error); *Czimmer v. Janssen Pharms., Inc.*, 2014 Phila. Ct. Com. Pl. LEXIS 90 at *7 (it was for the jury to decide whether or not physician's office was adequately advised of the risks involved when prescribing Topamax to the mother).

Janssen's cited case law is inapposite to the present action. For instance, in *Anderson v Wyeth*, 2005 Phila. Ct. Com. Pl. LEXIS 277 (Phila. C.C.P. June 7, 2005), a decision that pre-dated the Pennsylvania Superior Court's decision in *Daniel, supra*, the plaintiff produced no deposition testimony from the prescribing physician, (and indeed did not even take the deposition of the doctor), but merely produced an *affidavit* from another doctor regarding what a "reasonable physician" would have done with appropriate knowledge, which the court found inadmissible. *Id.* at *4-5 Such is clearly not the case here. Finally, in *Nelson v. Wyeth*, 2007 Phila. Ct. Com. Pl. LEXIS 316 (Dec. 5, 2007), the plaintiffs' prescribing physician *did not rely on the manufacturer's representations whatsoever*, but only the medical literature and her own

clinical experience. *Id.* at *6.

Defendants' contrary arguments are unavailing. Despite Defendants' protestations and artful use of quotations, Dr. Langfitt clearly testified that he did not know of an association between Risperdal and gynecomastia. Plaintiff has shown through record evidence that he would not have consumed the Risperdal drug had he known of the dangers, which Dr. Langfitt would have decisively discussed with his mother and Dr. Pinit had Janssen provided the additional information. The causal link is present. *See Daniel v. Wyeth*, 15 A.3d 909 (causal link present where plaintiff's injury would have been avoided since plaintiff would have declined the prescription). As such, Janssen's motion for summary judgment on the basis of causation should be denied.[7]

E. Plaintiff's Design Defect Claims are Not Barred under Either *Bartlett* or Maryland Law

Contrary to Janssen's assertions, *Mutual Pharmaceutical Co., Inc. v. Bartlett* 133 S. Ct. 2466 (2013) does not act as a bar to design defect claims. As recent Pennsylvania precedent and case law throughout the country make clear, Plaintiff's design defect clear is not preempted. Janssen also argues based on dicta from single United States District Court opinion that Maryland does not recognize design defect claims as applied to pharmaceutical products. However, that case did not involve a design defect claim and therefore, has no bearing on this matter.

Janssen's argument that a state court should prohibit design defect claims based on *Bartlett*, a case involving a generic product, rests on a view of the role of federal law that the Pennsylvania Superior Court has itself rejected. *Bartlett* involved a New Hampshire design defect claim against a

[7] It is noteworthy that this Court has denied Summary Judgment on the Learned Intermediary Doctrine based on similar physician testimony. *See*, Orders Denying Summary Judgment, *Banks v. Ortho McNeil Janssen, et al* January Term 2010; No. 00618; *AB, et al. v. Ortho-McNeil-Janssen ,et al* January Term 2010, No. 00649; *SB v. Ortho-McNeil-Janssen, et a*l. May Term 2010, No. 003629; *P.P., et al. v. Janssen Pharmaceuticals, Inc., et al*., April Term 2012, No.01997.

generic drug where the state statute utilized a risk-utility test that required that the drug, composed of only one-molecule, be redesigned in order to a claim (a feat which was physically impossible). *Id.* at 2474 -76. Since redesign was not an option in *Bartlett*, the Court examined whether the defendant could have altered the drug's labeling to render it not "unreasonably dangerous," but concluded, that "federal law prevents generic drug manufacturers from changing their labels" based on *Mensing*. *Id*. at 2476.

In *Braden v. Janssen Pharmaceuticals*, No. 239 EDA 2014 (Pa. Super. Ct. March 16, 2015), the Pennsylvania Superior Court rejected Defendant's attempt to argue that the holding of *Mensing* applied to brand-name drugs because it "cannot be held accountable under state law for failing to do something that it could not do without the FDA's prior authorization." *Braden v. Janssen Pharmaceuticals*, No. 239 EDA 2014 at *12 (Pa. Super. Ct. March 16, 2015). Although that case involved a failure to warn claim, notably the Superior Court rejected Janssen's preemption argument stating "PLIVA involved federal preemption of state-law failure to warn claims brought against generic drug manufacturers, and is not applicable to the instant case involving a brand name drug manufacturer." *Id.*

Courts throughout the country have held that in the context of design defect claims, preemption does not extend to brand-name products. *Brown v. Johnson & Johnson*, No. CIV. 12-4929, 2014 WL 6979262 (E.D. Pa. Dec. 9, 2014); *see also Hunt v. McNeil Consumer Healthcare*, No. CIV.A. 11-457, 2014 WL 1116358 (E.D. La. Mar. 11, 2014) (In the context of a design defect claim "I conclude that its preemption cases do not extend to the manufacturers of these products"); *Dopson-Troutt v. Novartis Pharms. Corp*., 8:06-CV-1708-T-24, 2013 U.S. Dist. LEXIS 135834 *22 (M.D. Fl. Sept. 23, 2001) (finding Plaintiff's claims that dosage changes in the product label were not preempted by *Bartlett*); *D.A. v. McKesson Corp*., 1:13-CV-01700-LJO-JLT, 2014 U.S. Dist. LEXIS 6503 *28-29 (E.D. Ca., Mark. 17, 2014) (noting on motion to remand that

preemption doctrine under *Bartlett* did not extend to brand name drug distributors); *In re Reglan/Metoclopramide Litig*., 81 A.3d 80, 91 (Pa. Super. Ct. 2012) (discussing *Bartlett* and finding plaintiffs' claims of strict liability viable and not subject to preemption); *Fraser v. Wyeth, Inc.*, 2014 U.S. Dist. LEXIS 4730 at *41-42 (D. Conn., Mark. 14, 2014) (stating, "*Bartlett* does not hold that a plaintiff cannot bring both a design defect and a negligent failure to warn claim based on improper labeling. Rather, it recognized that the plaintiff's state-law design defect claim was based on a defective warning.").

For instance, in *Estate of Cassel v. ALZA Corp*., defendants argued that *Bartlett* stood for the proposition that "federal preemption bars any state-law claim, including design-defect claims, premised on a manufacturer's failure to market a drug with a new design feature that would constitute a 'major change' or render it a new drug, either of which requires prior FDA approval." 12-CV-771, 2014 U.S. Dist. LEXIS 27924 *12 (W.D. Wi. March 5, 2014). The Court specifically rejected this argument on the grounds that the reading of *Bartlett* was too broad. *Id*. First, since defendants' drug product was brand-name the same restrictions did not apply. *Id*. In addition, defendants' own proposed findings of fact demonstrated that their product was amenable to various designs. *Id*. Moreover, the Court concluded that while the *Bartlett* Court held that federal law does prevent drug companies from taking certain remedial measures that ruling did not apply to tort theories prior to FDA approval. *Id*. at *14 (finding that because plaintiff's theory was that defendants had a duty to employ an alternative design from the beginning, *before* FDA approval, defendants' emphasis on altering their patches *after* FDA approval is misplaced and did not entitle them to summary judgment.

In *Hassett*, the Pennsylvania Superior Court rejected generic-defendants' argument that *Bartlett* preempted all of Plaintiff's claims. *See Hassett*, 74 A.3d at 213, n. 7 citing, Wyeth v.

Levine, 555 U.S. 555, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009). The Court distinguished Plaintiff's claims and noted that the *Bartlett* Court expressly left open the issue whether strict product liability claims for design defect would be preempted. 74 A.3d at 213, citing *Bartlett*, 133 S. Ct. at 2474 n.1 (reserving "for another day the question whether a true absolute-liability state-law system could give rise to absolute-liability pre-emption."). Specifically, plaintiffs asserted that their strict liability and negligence defective design claim was premised upon the generic defendants' sale and marketing of a drug they knew was unreasonably dangerous or defective. *Id*. at 212. Plaintiff further alleged that the drug had never been shown "to be either efficacious or safe when used for long-term treatment." ***Id.*** Also, plaintiffs alleged that the generic manufacturers continued to market their dangerous drugs despite the fact that there were safer and less expensive alternatives available. *Id*.

The *Hasset* Court held that plaintiffs' actions were not preempted as the allegations suggested that the drug, even when used as recommended and with appropriate warnings, was defective and unreasonably dangerous. *Id*. Such averments did not necessarily implicate labeling, but asserted absolute liability based on the sale of a defective or unreasonably dangerous product. *Id*. Finally, the Court noted that "while federal labeling statutes may pre-empt state failure to warn claims, they do not pre-empt claims based upon the marketing of defective products, a lack of due care in testing, or a product's failure to conform to express and implied warranties." *Id*. at 215.

Here, *Bartlett* is inapposite to the facts of this case as the Court specifically addressed strict liability design defect claims against generic brand manufacturers who are constrained by federal labeling requirements unlike the requirements for brand name drug manufacturers. Rather, like the plaintiffs in *Hassett* and *Cassel*, Plaintiff has asserted claims that are not

preempted by *Bartlett*. Specifically, Plaintiff has adduced evidence that Janssen sold and marketed Risperdal to children although they knew it was unreasonably dangerous or defective and that it had not been shown as efficacious or safe when used for long-term treatment, and that Janssen continued to market Risperdal despite the fact that there were safer and less expensive alternatives available. These claims do not invoke impossibility preemption against brand manufacturers who are constrained by federal labeling requirements unlike the requirements for generic drug manufacturers.

Janssen also argues that Plaintiff's claim is legally deficient because under Maryland law, no claim for design defect exists against a pharmaceutical company. Janssen relies upon dicta from an unreported federal district court case. *King v. Pfizer Pharm. Co.*, No. RWT 11CV00127, 2011 WL 3157305, at *2 (D. Md. July 25, 2011).

King, however, only involved a failure to warn, not design defect claim. *See King*, 2011 WL 3157305, at *2 (noting that plaintiff is only asserting a failure to warn claim). Indeed, the *King* court only addressed Plaintiff's failure to warn claim, and only noted under products liability law that there are typically three types of actions: design defect, manufacturing defect, or failure to warn. *Id.* Therefore, Janssen's reliance on *King* is unpersuasive.

F. Plaintiff's Fraud Claim is Actionable

1. Plaintiff and His Prescribing Physician Relied Upon the Statements of Janssen.

Janssen argues that Plaintiff's fraud claim fails due to failure to show reliance upon any representations or conduct by Janssen. Janssen neglects to mention that under Pennsylvania law, silence also constitutes fraud. *See Lange v. Burd*, 800 A.2d 336, 339 (Pa. 2002) (fraud consists of anything calculated to deceive, whether by single act or combination, or by suppression of truth, or a suggestion of what is false, whether it be by speech or silence); *Frost v. Perrigo Co.*, 60 D.&

C.4th 365, 371 (Allegheny C.C.P. 2003) (a drug manufacturer that fails to warn is guilty of fraudulent concealment).

Thus, while Janssen argues that there was no affirmative representation made to Plaintiff or Plaintiff's doctor, it cannot escape the evidence showing an intentional non-disclosure of Risperdal's dangers which altered the behavior of Plaintiff and Plaintiff's doctor.[8] *See supra passim.*

Pennsylvania courts have distinguished between an affirmative representation and an omission. *See Toy v. Metropolitan Life Ins. Co.*, 928 A.2d 186 (Pa. 2007); *In re Glunk*, 455 B.R. 399 (Bkrtcy. E.D. Pa. 2011). However, in the context of non-disclosures, or omissions of material fact, it is "virtually impossible to prove reliance." *Clark v. Pfizer Inc.*, 990 A.2d 17 (Pa. Super. 2010) (citations omitted). Nonetheless, Plaintiffs have adduced evidence of reliance by both the prescribing physician, Dr. Langfitt, and Plaintiff's mother.

Similarly, under Maryland Law reliance at its core is the action or inaction of a party that results from the misrepresentation of another. *Nails v. S & R, Inc.*, 334 Md. 398, 416-17, 639 A.2d 660 (1994) (holding that reliance exists if "the misrepresentation substantially induced the plaintiff to act"). "Reliance can either be direct or indirect, in part depending on whether the misrepresentation was directly made to the individual seeking relief." *White v. Kennedy Krieger Inst.*, 2015 Md. App. LEXIS 28, 51 (Md. Ct. Spec. App. Feb. 26, 2015). Maryland courts have recognized that third parties can successfully bring a misrepresentation claim "even when the

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[8]Defendants rely upon *Leonard v. Taro Pharm USA, Inc*. No 10-1241, 2010 WL 4961647 (W.D. Pa. Dec. 2, 2010), for the proposition that all non-negligence claims against a drug manufacturer are barred in Pennsylvania under *Hahn v. Richter*, 673 A. 2d 888 (Pa. 1996) and its progeny. *See* Def. Br. at 9, fn. 3. In the present case, Janssen's reliance on *Hahn* does not advance its challenge to Plaintiff's fraud claim. Plaintiff does not attempt to state a claim for failure to warn in Count III. Rather, Plaintiff alleges that Defendants committed fraud by, *inter alia*, promoting their products for uses that had been expressly rejected by the FDA. As such, Plaintiff alleges overt acts that go beyond a mere failure to warn. Because Defendants identify no law supporting the proposition that Pennsylvania bars all claims of fraud in pharmaceutical suits, the motion for summary judgment must fail.

allegedly fraudulent statement at issue was not made to him or her directly," so long as the individual can demonstrate direct or indirect reliance on the false statement. *See Id*.; *Exxon Mobil Corp. v. Albright*, 433 Md. 303, 335-36, 71 A.3d 30 (2013) (" a party is liable to another who indirectly relies only in circumstances where the party either intended or expected the other to act or refrain from acting as a result of the fraudulent misrepresentation"); *Diamond Point Plaza Ltd. P'ship*, 400 Md. at 741-42 (finding that liability extended to Diamond Point because they had reason to expect borrowers in the secondary market would consider, and be influenced by, the fraudulent loan documents); *see also Hill v. Brush Engineered Materials, Inc*., 383 F. Supp. 2d 814, 820-21 (D. Md. 2005) ("'Maryland law has long allowed plaintiffs to sue for injuries caused by fraudulent misrepresentations made to third parties,' so long as the plaintiff could reasonably have been expected to act or refrain from action in reliance upon the misrepresentation.")(quoting *Maryland Nat. Bank v. Resolution Trust Corp*., 895 F.Supp. 762, 772 (D.Md. 1995)); *White v. Kennedy Krieger Inst.*, 2015 Md. App. LEXIS 28, 53-54 (Md. Ct. Spec. App. Feb. 26, 2015).

Contrary to Defendants' assertions, Janssen did make representations to Plaintiff's prescribing physicians about the safety of Risperdal. Upon information and belief, on or around November 14, 2006, Janssen provided Dr. Pinit with the Autism, new indication Leave-Behind as described above which did not convey that Risperdal elevates prolactin more than any other anti-psychotic (and indeed, suggested that elevated prolactin was a class-effect), nor did it convey that gynecomastia was observed in 2.3% of patients in study of 1,885. *Id*; Exhibit 5, October 6, 2006 Risperdal Label; Exhibit 18, Janssen Call Notes, at JJPMURNE00000070.

In addition, Janssen made several material misrepresentations to the medical community and ultimately Plaintiff's prescribing Physician Dr. Langfitt. Ms. Murray relied upon the

statements made by her doctor and Janssen in weighing the risks and benefits of this treatment for her son. Similarly, Prescribing Physician, Dr. Langfitt testified he was not aware that Risperdal was associated with elevated prolactin. *See* Exhibit 3, M. Langfitt Dep. at 62:19-22. He did not recall knowing that gynecomastia was a side effect definitely related to elevated prolactin. *See* Exhibit 3, M. Langfitt Dep. at 78:12-19. Dr. Langfitt unequivocally stated that he did not associate gynecomastia with Risperdal before he began prescribing Risperdal to Nicholas. *See* Exhibit 3, M. Langfitt Dep. at 79:3-13. The 2000 and 2003 labels appear to give the user no notice of the serious nature of gynecomastia posed by Risperdal. Dr. Langfitt even testified that despite the remote risk of elevated prolactin in the label, he did not remember, "specifically thinking in my mind I've got to think about prolactin." *See* Exhibit 3 M. Langfitt Dep. at 147:7-13. He stated that if he had known what Janssen knew, (that 4.8 percent of patients in a Risperdal safety study were found to have gynecomastia, he would have discussed it with Dr. Pinit and then expressed his or Doctor Pinit's concerns to Nicholas' mother. *See* Exhibit 3, M. Langfitt Dep. at 102:1-105:7; Exhibit 3, M. Langfitt Dep. at 109:10-110:3). Both the prescribing physician and Ms. Murray, would have done things differently if they had known all the risks associated with Risperdal. On the other hand, Janssen for its own purpose wanted to promote Risperdal and make a profit, by reaching and influencing the patients of psychiatrists and pediatricians, such as Plaintiff. Janssen sought to promote their product as safe and effective so that pediatricians and psychiatrists would prescribe the drug to their patients by omitting relevant information. Plaintiffs and their prescribing physicians, reasonably relied upon Defendants' representations and omissions. Thus, as a matter of law, Plaintiffs have demonstrated that they relied upon the statements and omissions of Defendants to their own detriment. As such, whether Plaintiffs' reasonably relied upon the representations of Defendants

should be an issue of material fact to be decided by the jury. *See, Drelles v. Mfrs. Life Ins. Co.*, 2005 PA Super 249, 881 A.2d 822, 2005 Pa. Super. LEXIS 1594 (Pa. Super. Ct. 2005) ("We therefore hold that whether or not justifiable reliance has been established is a question of fact for the jury, to depend, inter alia, on the relative position of the parties, their expertise and experience."); *Rempel v. Nationwide Life Ins. Co.*, 227 Pa. Super. 87, 95, 323 A.2d 193, 197 (1974), *aff'd*, 471 Pa. 404, 370 A.2d 366 (1977) (stating that whether reliance is justified is generally an issue of fact for the jury); *Textile Biocides v. Avecia Inc.*, 52 Pa. D. & C.4th 244 (Pa. County Ct. 2001) (Herron, J.) (same); *see also, Phila. Gear Corp. v. Swath Int'l, Ltd.*, 2003 U.S. Dist. LEXIS 6824 at *10 (E.D. Pa. Mar. 26, 2003); *Williams Controls, Inc. v. Parente, Randolph, Orlando, Carey & Assocs.*, 39 F. Supp. 2d 517, 534 (M.D. Pa. 1999) ("The question of justifiable reliance is most appropriately left to the jury. Reasonableness of reliance involves all of the elements of the transaction, and is rarely susceptible of summary disposition.")(citations omitted).

Simply put, to grant Janssen's motion would require this Court to accept Janssen's view of the evidence. That it cannot do. *See Mattia v. Employers Mutual Companies*, 440 A.2d 616 (Pa. Super. 1982) (court in summary judgment views all the evidence in the light most favorable to the non-moving party). As such, Janssen's motion for summary judgment on Plaintiff's fraud claim must be denied.

G. <u>Under Maryland law, Janssen is Strictly Liable</u>

Although Maryland has adopted the doctrine of strict products liability, Janssen argues such liability should not extend to prescription drugs. Janssen's arguments are flawed. *First*, Maryland has adopted the doctrine of strict products liability. *Phipps v. Gen. Motors Corp.*, 278 Md. 337, 352-53, 363 A.2d 955, 963 (1976). In the 39 years that have elapsed since *Phipps*, no

Maryland court has ever held that the doctrine of strict liability does not apply to prescription drugs. [9]

The only case that Janssen relies upon for this proposition is *Miles Lab., Inc. Cutter Labs. Div. v. Doe*, 556 A.2d 1107 (Md. 1989). In *Miles Lab*, the plaintiff was injected with a blood-based product, known as a blood clotting factor concentrate, which was contaminated with HIV. 556 A.2d at 1109. The court commented generally that "where a sale of a product is involved, but Comment K applies, the doctrine of strict liability in tort has no application." *Id.* at 1117. The court did not, however, hold that Comment K applies to all prescription drugs. Rather, it simply held that blood and blood-based products ordinarily were, in 1983, "unavoidably unsafe" under Comment k and therefore not "unreasonably" dangerous under § 402 A. *Miles Lab*, 556 A.2d at 1121. The court elaborated that manufacturers are not strictly liable "when, at the time of distribution of such products, they contained a then unknown and unknowable infectious agent undetectable by any available scientific test." *Id.* The court reasoned that the fundamental purpose of strict liability is to force hazardous products from the market. *Id.* That rationale, however, "has no application to blood or blood products where the manufacturer had no way of knowing that its products . . . were contaminated by an indetectable virus." *Id. Miles* also gave weight to the "unique nature of blood as a *lifesaving*, *life-sustaining* substance *without any apparent substitutes*" 556 A.2d at 1121 (emphasis added). Unlike, *Miles*, where the defendants had no way of knowing whether its product was dangerous based on available technology in 1983, Janssen has direct knowledge, based on confidential studies never disclosed to the FDA – to a statistical degree of certainty – that children and adolescents who have elevated prolactin

[9] To the extent, Janssen relies on Pennsylvania law in arguing that strict liability does not extend to pharmaceutical products, as Janssen concedes, "Maryland has the strongest ties to this case." Thus, this Court should apply Maryland law which permits strict liability claims with regard to prescription drugs. Def.'s Mot. at 8.

levels at weeks 8-12 will go on to develop gynecomastia. *See* Exhibit 28, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Caers Testimony, February 10, 2015 at 58:10-21, February 11, 2015 at 58:10-21, 114: 22-23, 115:13-116:11; Exhibit 29, Trial Exhibits P34 and 34A. Janssen is also fully aware of the high (and indeed frequent) incidences of children taking Risperdal who develop gynecomastia. As distinguished from *Miles*, there are other alternative and effective drugs on the market which do not have this side effect.

Second, even if the Court were to entertain Janssen's invitation and hold that the "Comment K" exception of the Restatement (which applies to "unavoidably unsafe" products) extends to prescription drugs then Janssen would still be subject to strict liability. Notably, Comment K provides that it is only implicated if the manufacturer properly marketed and provided adequate warnings regarding the risks associated with the product. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). In this case, Plaintiff contends Janssen improperly and illegally marketed Risperdal for non-approved uses and that it failed to provide adequate warnings regarding the risks associated with such non-approved uses, thus, even under Comment K, Janssen would still be strictly liable.

H. Summary Judgment is Not Warranted on Plaintiff's Express Warranty Claim

Janssen argues that there are "no facts" to support plaintiff's express warranty claim. In making this argument, Janssen simply cites to a clearly distinguishable case and testimony that Janssen never had any "direct communication" with the Plaintiff. Janssen, in a footnote, also claims that in Pennsylvania express warranty claims are unable against a pharmaceutical manufacturer citing two opinions from the United States District Court for the Western District of Pennsylvania. Janssen's argument is misguided.

The only case that Janssen cite for the proposition that Plaintiff cannot support his

express warranty claims with sufficient facts is *Pulte Home Corp. v. Parex, Inc.*, 923 A.2d 971, 996 (Md. App. 2007). That case does not support Defendants' argument. In *Pulte Home Corp.* the trial court dismissed the plaintiff's claims against one of the defendants for breach of express warranty on a motion to dismiss because (1) there was a lack of privity and (2) the plaintiff failed to do more than mirror the language of the elements for a breach of express warranty. *Id.* at 723. The trial court's decision was affirmed because, the plaintiff failed to allege personal injuries, which was required in order to dispose of the privity requirement. *Id.* at 724-26. Further, the Plaintiff failed to do more than mirror the language of the UCC code for express warranty which was insufficient under the Maryland rules of civil procedure governing pleadings. *Id*. at 725-26. Indeed, all the plaintiff set forth in the complaint was merely a legal conclusion, without citing to any specific warranty made by the defendants. *Id.* In fact, the *Pulte* decision had nothing to do with the evidentiary showing required to establish an express warranty claim, since it was on a motion to dismiss and the court expressly held that at the pleading stage the plaintiff was not "required to make an evidentiary 'showing' that there was an express warranty.'" *Id.*

Unlike *Pulte*, Plaintiff has suffered personal injuries and has actually alleged warranties made by Janssen, instead of a mere recitation of the UCC. Plaintiff has also identified in detail throughout the Complaint and the course of this litigation various false representations and warranties made by Janssen representatives, in the articles ghost-written by Janssen, in the course of off-label marketing Risperdal to pediatric and adolescent populations, in the Risperdal package inserts and labels, and in Risperdal marketing material. One such representation is the Autism-Leave-Behind, which upon information and belief, was given to Dr. Pinit in 2006, falsely and inaccurately warranting that Risperdal is no worse than any other antipsychotic in

terms of prolactin elevation. *See* Exhibit 11, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Gilbreath Testimony, (February 4, 2015) at 70:16-25-76:11-13, 77:14-25, 78:13-80:7, 82:1-86:22, 100:15-118:25; Exhibit17, Autism Leave Behind, JJRE13972932 ; Exhibit 5, October 6, 2006 Risperdal Label; Exhibit 18, Janssen Call Notes, at JJPMURNE00000070.

In fact, Janssen knew that Risperdal elevated prolactin more than any other antipsychotic. Janssen's confidential studies which were not disclosed to public made a statistically significant finding that individuals that had elevated prolactin levels during weeks 8-12 would go on to develop gynecomastia. *See* Exhibit 28, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al,* Caers Testimony, February 10, 2015 at 58:10-21, February 11, 2015 at 58:10-21, 114: 22-23, 115:13-116:11; Exhibit 29, Trial Exhibits P34 and P34A. First, Janssen represented that safety and efficacy in children had not been established, when in fact, these studies showed that the lack of safety in children and adolescent populations had been established, to a statistically significant degree of certainty. Janssen admitted that it failed to provide this information to the FDA and to the public. *Id.* Indeed, a 2004 internal training document tells sales representatives to sell Risperdal to doctors because the risk of side effects from prolactin was so low. *See* Exhibit 13, JJRE00394271. Later, Janssen represented that Risperdal was safe in children, when in fact, Janssen knew it was not safe for children. By way of example, as part of a nationwide marketing strategy, Janssen representatives were instructed to tell physicians when giving the Autism Leave-Behind that:

> This unique indication is supported by well-controlled clinical trials demonstrating significant efficacy, safety, and tolerability data, and dosing guidelines that can all be found in the package insert.

See Exhibit11, *Pledger, et al v. Janssen Pharmaceuticals, Inc., et al*, Gilbreath Testimony, February 4, 2015 at 70:16-25-76:11, 77:14-25.

Janssen is not required to have "direct communication," with the Plaintiff to establish an express warranty. To the extent that Defendants argue that direct reliance by the consumer is required, under Pennsylvania and Maryland law, plaintiff is only required to show evidence of reliance by the treating or prescribing physician. *In Michael v. Shiley, Inc.*, 46 F.3d 1316, 1334-1336 (3d Cir. 1995) abrogated on other grounds, 135 L. Ed. 2d 700 (1996) (holding that there are sufficient grounds for the plaintiff's express warranty claim, that fraudulent misrepresentation, which also require reliance, extend to "those whom the declarant has a special reason to anticipate," and that the "declarant need not know the identity of the eventual plaintiff if the plaintiff is a member of class or persons whom the declarant has reason to expect will act in reliance upon his fraud"); *In re Orthopedic Bone Screw Products Liability Litigation*, No MDL-1014, 1996 WL 900339 at *1 (E.D. Pa. Dec. 3, 1996) (noting that express warranty can be shown by showing that "the plaintiff or the plaintiff's surgeon relied upon the warranty"); Md. Comm. L. Code Ann. § 2-313 ("affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement. The issue normally is one of fact"); *see also Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563 (2006) ("Learned intermediary" doctrine does not preclude a pharmacy from being held liable for breach of express warranty when it provides a package insert that could provide the basis for such a warranty).

In the instant case, Dr. Langfitt testified that he relies upon the representations of pharmaceutical companies, including, but not limited to, the PDR, the label, journal articles, and conferences in making his prescribing decisions. Exhibit 3, M. Langfitt Dep. at 15:20-24, 16:1-

14, 136:19-24, 137:1-6, 147:16-24.[10] There are genuine issues of material fact as to the warranties made by Janssen, and how these warranties were breached. Therefore, this Court should deny summary judgment on Plaintiff's express warranty count.

I. Plaintiff's Implied Warranty Claim Survives Summary Judgment

Janssen argues that Plaintiff's claim for implied warranty of merchantability or fitness for a particular purpose fails as a matter of law because neither Pennsylvania or Maryland recognize implied warranty claims "based on the allegation that a prescription medication is unreasonably dangerous." *See* Def.'s Mot. at 18.

The Third Circuit, applying Pennsylvania law, has recognized claims against a pharmaceutical company based on a theory of implied warranty of merchantability. *See O'Brien v. Eli Lilly & Co*., 668 F.2d 704, 711–12 (3d Cir. 1982) (although dismissing on statute of limitations grounds, finding that there is an implied warranty of merchantability against a pharmaceutical company). Janssen's reliance upon Dougherty v. C.R. Bard, No. 11-6048, 2012 U.S. Dist. LEXIS 100374 at *33 (E.D. Pa. July 18, 2012) is misplaced as the federal Court was following other courts' prediction that the Pennsylvania Supreme Court would decline to recognize such implied warranty claims.

In the present case, a jury question exists as to whether Risperdal is fit for use in children. Plaintiff specifically alleged in his Complaint that Risperdal is not more efficacious than other antipsychotics. *See* Plaintiffs' Third Amended Complaint, ¶¶153, 174. Janssen's efficacy numbers regarding Risperdal are certainly in question. The TEOSS (Treatment of Early Onset Schizophrenia Study in youth) and CATIE (Clinical Antipsychotic Trials of Intervention

[10] As mentioned, upon information and belief, Dr. Pinit was given the Autism-Leave-Behind and Janssen marketing representatives discussed Risperdal with Dr. Pinit. Plaintiff continues to undertake substantial effort to locate Dr. Pinit's whereabouts.

Effectiveness) trials compared Risperdal and other second-generation antipsychotics (SGAs) to a (different) first-generation (FGA) and found that the FGA in each study was just as efficacious, or more so, than the SGAs. *See* http://www.nimh.nih.gov/news/science-news/2010/effectiveness-of-long-term-use-of-antipsychotic-medication-to-treat-childhood-schizophrenia-is-limited.shtml and http://www.nimh.nih.gov/news/science-news/2005/nimh-study-to-guide-treatment-choices-for-schizophrenia-phase-1-results.shtml (last visited December 15, 2014).

Defendants knew long before TEOSS and CATIE that Risperdal's efficacy was questionable. An internal email in March 1999 addressed the realization that there were deficiencies in the quality of the data and that having to delete data from even a single site would cause the efficacy results to be against Risperdal.

See Exhibit 46, at JJRE02439665 ("Apparently there were some serious concerns at one site and discussions are ongoing whether to drop this site for the final study report…dropping this site will cause the efficacy differences between Risperdal and olanzapine observed at 8 weeks to become non-significant on all parameters"). Despite these deficiencies, a few days later, Alex Gorsky, now the CEO of Johnson & Johnson, responded by requesting a "hard look," and that they "continue to drive the momentum" *See* Exhibit 47, (JJRIS00851574-75). Although the re-analyzed, published version of RIS-USA-112 claimed in the Abstract that "Both treatments were well tolerated and efficacious," and that "There was no measure on which olanzapine was superior," this was misleading because the statistics proved that Risperdal was not superior on the total score on the PANSS, the *primary* efficacy rating scale used. *See* RR Conley and R Mahmoud, *A randomized double-blind study of risperidone and olanzapine in the treatment of schizophrenia or schizoaffective disorder,* 158(5): American J. Psychiatry (2001) at 765–774.

The sister trial to RIS-USA-112 was RIS-INT-45 and its efficacy results, known by April 1999, were even more dismal for Risperdal. *See* Exhibit 48, (JJRE 02440863-64). Despite multiple re-analyses, Johnson & Johnson tried to keep these results from being made public; they were never published. *See* Exhibit 49, at JJRE 00431196-200; JJRE 03590485-7; JJRE 00431189-95; JJRE 01128917-8; JJRE 01130295-6. Further, a 2012 review study of pediatric clinical and cohort studies published from 1987 through February 2011 found that there was overwhelmingly only low strength of evidence and, at best, only moderate strength of evidence, to support claims that the second-generation antipsychotics, including Risperdal, were more effective than each other, FGAs, or placebo. The review study also found considerable risk of bias in the published trials and noted that nearly 80% of the trials had been funded by the pharmaceutical industry.

Janssen cites *Miles Laboratories, Inc. v. Doe*, 556 A.2d 1107, 1123 (Md. 1989) for the proposition that implied warranty of merchantability and fitness fails when the corresponding claim for strict liability fails under §402A comment k. However, as discussed, *supra*, the court reached its conclusion based on the specific fact that the blood was contaminated with a viral agent unknown to medical science and not within the seller's control. *Id*. at 1124-25. The public's need for the lifesaving product outweighed the need to impose liability on the seller. *Id*. at 1125. Here, given that Janssen was fully aware of the risks contained with Risperdal, *Miles* is inapplicable.

Janssen represented that Risperdal was safe and effective, and was well tolerated in adequate and well-controlled clinical studies. Plaintiff experienced a reaction (gynecomastia) that Janssen recognizes is caused by Risperdal. Because there is a genuine factual dispute at to

the safety and efficacy of Risperdal, summary judgment is inappropriate on Plaintiffs' breach of implied warranty claim.

J. Plaintiff has Presented a Valid Claim under the Maryland Consumer Protection Act

Janssen argues that a manufacturer of prescription drugs cannot be held liable as a matter of law under Maryland's Consumer Protection Act ("MCPA"). Janssen, instead, relies on *dicta* in support of this proposition from a single, unpublished trial court opinion, *Agbebaku v. Sigma Aldrich, Inc.,* No. 24-C-02-004175, 2003 WL 24258219 (Md. Cir. June 24, 2003). In relying on *Agbebaku*, Janssen argues that since prescription drugs are directed to physicians, who act as a learned intermediary, the MCPA does not apply. Under Janssen's proposition, the reasoning in *Agbebaku* would bar every MCPA action by a consumer against a drug manufacturer, even if the manufacturer had inadequately warned physicians. In essence, Defendant urges this Court to take the learned intermediary doctrine a step further and find that it precludes Plaintiffs from *stating a claim altogether* under a consumer protection law. Case law from Maryland and the plain language of the MCPA does not support this proposition.

Janssen reliance on *Agbebaku v. Sigma Aldrich, Inc.,* is misplaced. In that case, the Plaintiff brought a claim under the MCPA, among other, alleging that her minor child developed autism as a result of a vaccine containing a mercury-based preservative and a hemoglobin product containing the same mercury-based preservative and that this injury was aggravated by coal burning in the area. *Id.* at *1. The plaintiff sued a number of manufacturers of the vaccine, the preservative, and the hemoglobin product as well as energy companies operating in the area.

Curiously, Defendants fail to mention to this Court that *Agbebaku* held the court lacked jurisdiction to entertain the plaintiff's claims against the manufacturers of the vaccine, the preservative, and the hemoglobin product, including J &J. *Id.* at *4-6, * 12. In holding that the

court lacked jurisdiction, the court reasoned that the plaintiff, having failed to first file her claims in the United States Court of Federal Claims (the "Vaccine Court"), had not exhausted her remedies as required by the Vaccine Act. *Id.* The *Agbebaku* court, having found that the court lacked jurisdiction, went on to state, in *dicta*, that Plaintiff did not have a viable cause of action under the MCPA because manufacturers "provi[de] an FDA-approved vaccine to knowledgeable physician who administer the vaccine" and that the "manufacturer is even more attenuated" than the statutes exclusion for "medical or dental provider." Defendants have not identified any appellate decision from *any court* adopting this conclusion.

Janssen's interpretation and reliance on the dicta in *Agbebaku* would dramatically and unjustifiably expand the plain language of the MPCA. The MPCA clearly establishes that a defendant does not necessarily need to be in direct contact with consumers or directly sell them goods to be subject to suit under the MCPA. See Md. Code Ann., Com. Law § 13-101(g) (the CPA defines a merchant as one "who directly or *indirectly* either offers or makes available to consumers any consumer goods, consumer services, consumer realty, or consumer credit") (Emphasis added); *see also State v. Cottman Transmissions Sys., Inc.*, 587 A.2d 1190, 1197 (Md. App. 1991); Md. Code Ann., Com. Law § 13-102(b)(1) (MCPA was enacted to take "strong protective and preventive steps to investigate unlawful consumer practices, to assist the public in obtaining relief from these practices, and to prevent these practices from occurring in Maryland"); *Klein v. State*, 452 A.2d 173, 176 (Md. App. 1982) cert. denied, 295 Md. 440 (1983) (the Consumer Protection Act is concerned with all consumers) (internal citations omitted); Charles B. Shafer, Maryland Consumer Law, § 6.1 (The Act "constitutes a group of laws that are quite broad both in conduct prescribed and businesses covered").

Under the language of the MCPA, the mere presence of a physician does not cut the

causal chord between consumers and drug manufacturers.[11] Janssen requests that this Court adopted a rationale that threatens to swallow up any cause of action brought against a drug manufacturer, as every claim—whether derived from statute or common-law tort— includes an element of causation and every claim against a drug manufacturer also involves a physician. The *Agbebaku* court's seemingly elementary conclusion also belies a dramatic expansion of the learned intermediary doctrine. Even if the learned intermediary doctrine applies to consumer protection claims (and Plaintiff is unaware of any court applying the learned intermediary doctrine to MCPA claims), every claim susceptible to the learned intermediary doctrine has a chain of relationships that must be answered on an individual basis: the duty owed by the manufacturers to adequately warn physicians, who in turn must warn their patients. Thus, the reasoning in *Agbebaku* is fundamentally flawed.

Further, *T-Up, Inc. v. Consumer Prot. Div.*, 801 A.2d 173 (Md. App. 2002), cert. denied, 802 A.2d 439 (Md. 2002), indicates that Maryland appellate courts permit MCPA claims to proceed against drug manufactures. In *T-Up,* the Maryland Court of Special Appeals, affirmed a determination by Circuit Court and the Maryland consumer protection division's that the defendants, manufacturers of an intravenous and topical "drug," had violated the MCPA, by "engaging in false and deceptive trade practices" in advertising that these products were both safe and effective in treating cancer, AIDs, and HIV. *Id* at 439. In a flawed analysis, the *Agbebaku* court attempted to distinguish this case on the basis that in T-Up was "directly dealing with the consumers and victims." *Agbebaku,* No. 24-C-02-004175, 2003 WL 24258219 at * 11. But, even if that was a valid distinction – which it is not for the reasons discussed above and

[11] Contrary to *Agbebaku*, the MCPA's medical provider exception has nothing to do with "attenuation." In Maryland, physicians are already subject to a variety of independent regulatory restrictions. Further, under medical providers are subject to MCPA claims for certain conduct.

because the MCPA applies to direct and *indirect* conduct – that would, if at all, only go to the evidentiary showing required in making a claim under MCPA, not whether such claims are barred as a matter of law against drug manufacturers. The *T-Up* court did not draw this distinction.

There is systematic and overwhelming evidence that Janssen ruthlessly and unconsciously promoted Risperdal to be used in children and adolescents, and that Janssen touted its safety and efficacy without adequately disclosing its risks (and with full knowledge of the lack of safety of this drug in this population). As *T-Up* demonstrates, drug manufacturers are subject to MCPA claims for "unfair and deceptive practices," and that drug manufacturers, when advertising, among other conduct, are "under a duty, before [it] makes any representation which, if false, could cause injury to the health or personal safety of the user of the advertised product, to make a reasonable inquiry into the truth or falsity of the representation." *T-Up, Inc.*, 801 A.2d at 177 (noting that the MCPA looks to the Federal Trade Commission Act for "unfair and deceptive practices") (quoting *Heinz W. Kirchner*, 63 F.T.C. 1282 (1963) *aff'd*, 337 F.2d 751 (9th Cit. 1964).

Thus, Defendant's argument is without merit and this Court should decline to grant summary judgment on Plaintiff's MCPA claim.

K. Plaintiff has a Viable Claim for Medical Expenses

Janssen's argument in support of dismissal of Plaintiff's claim for medical expenses claims because "[Plaintiff's] underlying claims fail." [Def's. Br. at 26] is unavailing. Janssen's conduct implicates the violation of Pennsylvania and Maryland consumer protection law. Because Plaintiff has properly pleaded and adduced sufficient evidence of all claims, including but not limited to those for fraud, negligent failure to warn, strict liability, negligent design

defect, as well as violations of the Pennsylvania and Connecticut consumer protection and deceptive trade practices acts, Plaintiff has established the underlying claims to which his medical expenses relate. In other words, because none of Plaintiff's claims should be dismissed, Plaintiff's claims for medical expenses survive summary judgment. *See, Bentley v. City of New Haven*, 2001 Conn. Super. LEXIS 2505 *50 (Conn. Super. Ct. Sept. 4, 2001) ("because the court has denied the defendant's motion for summary judgment on the other counts, the court also denies its motion for summary judgment on [the medical expenses] count".)

Janssen relies on a single Maryland case, *Garay v. Overholtzer* in support of their claim that Plaintiff cannot recover medical expenses. Janssen fails to note that the Court in *Garay* agreed that a minor child can be liable for medical expenses when the parent or guardian is unable to pay for them; this in turn gives a minor the right to claim medical expenses on his or her own behalf. *Garay v. Overholtzer*, 332 Md. 339, 371 (Md. 1993). Further, the ability of parents to afford necessary medical care is dependent on a variety of factors that most often will be within the purview of the jury to determine.

> Whether or not parents are able to afford necessary medical care for their negligently injured minor child will vary from case to case according to the circumstances of the parties involved, including, but not limited to, parental income, existing financial assets and obligations, the number of children in the family, available insurance coverage, the cost of living and inflation rate, whether or not both parents work, or are even capable of working in light of the child's injuries, and other economic and non-economic factors too numerous to list. It will also vary, of course, on the nature of the injury and the duration and manner of treatment. These infinitely variable factors preclude a bright line rule concerning the standard by which the affordability determination can be made. More often than not, juries will have to decide with the aid of expert and lay testimony when necessary, whether and to what extent an injured child's medical necessaries exceed the financial ability of the parents.

Johns Hopkins Hosp. v. Pepper, 346 Md. 679, 701 (Md. 1997). Thus under Maryland law, Plaintiff may recover medical expenses.

Even if Pennsylvania law applies to the medical expenses claim, Plaintiff may recover the medical expenses incurred by his parents during his minority. *Czimmer v. Janssen Pharms., Inc*., 2014 Phila. Ct. Com. Pl. LEXIS 90 at *16-17 (Pa. C.P. 2014 (holding that as long as there is not double recovery by both the parent and child, the minor should be permitted to recover medical costs during his or her minority. "Why should the child be placed at a disadvantage because the parents did not bring the action?") *See also*, *Shaffer-Doan v. Commonwealth*, 960 A.2d 500, 516 (Pa. Commw. Ct. 2008)). Therefore, Janssen is incorrect that Plaintiff cannot recover medical expenses because his parents were not named in this action.

V. CONCLUSION

For all of the foregoing reasons, Plaintiff respectfully requests that the Motion for Summary Judgment of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research and Development, L.L.C. be denied.[12]

[12] Plaintiff herein respectfully asserts that his claim survives summary judgment. In support thereof, Plaintiff incorporates by reference the following documents: Plaintiffs' Response in Opposition to Janssen's Motion for Partial Summary Judgment on Punitive Damages and Motion for Reconsideration of this Court's May 2, 2014 Order granting partial summary judgment as to Plaintiffs' punitive damages claims. Plaintiff also incorporates arguments made in prior Risperdal cases. *See*, e.g., *P.P., et al. v. Janssen Pharmaceuticals, Inc., et al*., April Term 2012, No.01997.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing pleading was electronically filed with the Court this date and has been served via the court's Electronic Filing System on all Defendants' counsel, and a courtesy copy was forwarded via electronic mail on the counsel listed below:

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