

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

IN RE RISPERDAL® LITIGATION :

JOSHUA WINTER :

v. :

JANSSEN PHARMACEUTICALS,  
INC., et al. :

MARCH TERM, 2014

NO. 1170

Control No. 14082046

ORDER

AND NOW this 13<sup>th</sup> day of January, 2015, upon consideration of the Motion for Summary Judgment filed by Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, and the responses thereto, for the reasons set forth in the accompanying Opinion, the Motion is **GRANTED** and Plaintiff's claims as to Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC are hereby **DISMISSED WITH PREJUDICE**.

BY THE COURT:



ARNOLD L. NEW, J.

Winter Vs Janssen Pharm-ORDOP



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**OPINION**

**New, J.**

**January 13, 2015**

For the reasons set forth below, the Court grants the Motion for Summary Judgment filed by Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC and finds, as a matter of law, Plaintiff's claims were not timely filed. The Court finds the statutes of limitation for Plaintiff's warranty claims and unfair trade practices claim began to run on December 31, 1998 and the statutes of limitation for Plaintiff's tort claims began to run, at the latest, on June 30, 2009.

**FACTUAL AND PROCEDURAL HISTORY**

The Food and Drug Administration approved Risperdal, an atypical antipsychotic medication, in 1993 to treat schizophrenia in adult patients.<sup>1</sup> See Second Amended Master Long-form Complaint at ¶ 33.<sup>2</sup> Since 1993, the label has been revised on several occasions;

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<sup>1</sup> Risperdal is the trade name for the generic medication risperidone.

<sup>2</sup> By Order dated May 26, 2010, the In Re Risperdal® Litigation mass tort was formed. . See In Re Risperdal® Litigation, March Term 2010 No. 296, Case Management Order 1, docketed on May 26, 2010. Pursuant to Case Management Order 1, a Master Long-Form Complaint was filed which made allegations common to all plaintiffs in the litigation. See Case Management

some of these label revisions approved Risperdal's use to treat other diseases and a broader population of patients, including children and adolescents. Id. at ¶¶ 34-39.

Plaintiff Joshua Winter was born in May 1980; he was raised in Harrisburg, Pennsylvania, and continues to live and work in Harrisburg. See Defendants' Motion for Summary Judgment at Ex. 1, Plaintiff's Fact Sheet. In 1997, Dr. Nalin Patel prescribed Risperdal to Plaintiff to treat his anger management. Id. Plaintiff continued taking Risperdal until 1998, at which point Dr. Patel discontinued Plaintiff's use of Risperdal for a reason Plaintiff cannot remember. Id. By the end of 1998, Plaintiff noticed, through self-observation, he suffered from gynecomastia, weight gain, diabetes mellitus, and emotional/psychological injuries. See Defendants' Motion for Summary Judgment at Ex. 5, Plaintiff's Short-Form Complaint; Defendants' Motion for Summary Judgment at Ex. 6, Letter dated June 13, 2014 from Plaintiff's Counsel to Defense Counsel (stating "Plaintiff does not recall the exact month [and] day in 1998 in which he became aware of his condition; however, he did become aware in 1998.").

On March 10, 2014, Plaintiff commenced this action against Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Elsevier, Inc., and Excerpta Medica Inc by filing a Short-Form Complaint. The Short-Form Complaint alleges twelve counts, 1) negligence, 2) negligent design defect, 3) fraud, 4) strict liability – failure to warn, 5) strict liability – design defect, 6) breach of express warranty, 7) breach of implied warranty, 8) violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 9) unfair and deceptive trade practices, 10) conspiracy, 11) punitive damages, and 12) medical expenses incurred by parent. See Short Form Complaint at ¶ 11. This matter

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Order 1 at § III(A). Each individual plaintiff was required to file a case-specific short-form complaint, which incorporated the Master Long-Form Complaint by reference and set forth the factual circumstances unique to that individual plaintiff. See Case Management Order 1 at § III(C); see also Short-Form Complaint.

was assigned to the In Re Risperdal® Litigation mass tort program. Accordingly, all of the allegations in Plaintiff's Short-Form Complaint were deemed denied and the respective defendants were deemed to have asserted all applicable affirmative defense, including the statute of limitation defense. See In Re Risperdal® Litigation, March Term 2010 No. 296, Case Management Order 1, docketed on May 26, 2010 at § III(c)(5).

On August 18, 2014, Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC (hereinafter "Moving Defendants") filed a Motion for Summary Judgment, arguing the applicable statutes of limitation bar Plaintiff's claims.<sup>3</sup> Specifically, Moving Defendants argue the statutes of limitation began to run, at the latest, in October 2006, when the Risperdal label was changed to include a precaution that Risperdal has caused gynecomastia in adolescent boys. Plaintiff filed an Opposition to the Motion for Summary Judgment setting forth four arguments as to why the Motion should be denied. According to Plaintiff, the Motion for Summary Judgment must be denied because 1) the discovery rule tolled the statute of limitation until Plaintiff learned of his cause of action in 2013, 2) the doctrine of fraudulent concealment continues to toll the statute of limitation, 3) Plaintiff's individual capacities toll the statute of limitation and 4) discovery has not yet been completed in this matter. For the reasons set forth below, the Court finds the statute of limitation bars Plaintiff's claims.

## **ANALYSIS**

### *I. Standard of Review*

The legal standard for the entry of summary judgment is well established. Rule 1035.2

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<sup>3</sup> It is important to note Moving Defendants' Motion for Summary Judgment incorporates by reference the arguments presented in the Motion for Partial Summary Judgment which was filed on the master docket, In Re Risperdal Litigation, March Term 2010 No. 296. Plaintiff, likewise, incorporates the Response in Opposition to the Motion for Partial Summary Judgment. As such, this Opinion addresses the arguments advanced in both Motions.

provides:

After the relevant pleadings are closed, but within such time as not to unreasonably delay trial, any party may move for summary judgment in whole or in part as a matter of law

(1) whenever there is no genuine issue of any material fact as to a necessary element of the cause of action or defense which could be established by additional discovery or expert report, or

(2) if, after the completion of discovery relevant to the motion, including the production of expert reports, an adverse party who will bear the burden of proof at trial has failed to produce evidence of facts essential to the cause of action or defense which in a jury trial would require the issues to be submitted to a jury.

Pa.R.C.P. 1035.2. The moving party bears the burden of showing no genuine issue of material fact exists and it is entitled to judgment as a matter of law. See e.g. Mountain Village v. Board of Supervisors, 874 A.2d 1, 5 (Pa. 2005). In reviewing a motion for summary judgment, the Court must examine the record in the light most favorable to the non-moving party. See e.g. Swords v. Harleysville Ins. Co., 883 A.2d 562, 567 (Pa. 2005). In the case *sub judice*, Moving Defendants filed a motion for summary judgment in which they argue the relevant statutes of limitation bar Plaintiff's claims. Accordingly, this Court views the evidence in the light most favorable to Plaintiff. Id.

Since Plaintiff resided in Pennsylvania when he ingested Risperdal and when he was injured, there can be no dispute Pennsylvania's statutes of limitation apply. As is noted above, Plaintiff's Short-Form Complaint alleges twelve counts; these twelve counts can be distilled into three types of claims – tort claims, warranty claims, and the unfair trade practices claim.<sup>4</sup> The statute of limitation on tort claims is two years. See 42 Pa.C.S. § 5524(7). Plaintiff's breach of

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<sup>4</sup> Indeed, there is a fourth group into which some of Plaintiff's counts fall. Two counts of Plaintiff's Complaint, punitive damages and medical expenses incurred by parent, are not causes of action; rather, they are specific types of damages. For example, the right to punitive damages is incident to a cause of action and not a cause of action in and of itself. Shanks v. Alderson, 582 A.2d 883, 885 (Pa. Super. 1990).

implied warranty and breach of express warranty claims are subject to a four year statute of limitation. See 13 Pa.C.S. § 2725(a). Finally, Plaintiff's unfair trade practices claim is subject to a six year statute of limitation. Gabriel v. O'Hara, 534 A.2d 488, 495 (Pa. Super. 1987).

With these statutes of limitation in mind, the Court must first determine when Plaintiff's claims accrued. In his short-form Complaint, Plaintiff alleges his use of Risperdal from 1997-1998 caused him to suffer the following injuries: 1) gynecomastia, 2) weight gain, 3) diabetes mellitus and 4) emotional and psychological harm. Plaintiff's Short Form Complaint at ¶ 5. Plaintiff admits he started noticing these injuries in 1998 through visual observation. Defendant's Ex. 1, Plaintiff's Fact Sheet at § VII(B)(1)-(3); Defendant's Ex. 6 (Letter from Plaintiff's counsel stating "Plaintiff does not recall the exact month [and] day in 1998 in which he became aware of his condition; however, he did become aware in 1998"). Accordingly, for the purposes of this Motion, Plaintiff's claims accrued, at the latest, on December 31, 1998 when he had visually observed his injuries. See e.g. Graver v. Foster Wheeler Corp., 96 A.3d 383, 386 (Pa. Super. 2014)(stating for statute of limitation purposes, "accrual occurs when the right to institute a suit arises, typically when the plaintiff suffers harm").

Applying the December 31, 1998 accrual date to the relevant statutes of limitation, the time for filing Plaintiff's claims expired on December 31, 2000 for his tort claims, December 31, 2002 for his warranty claims, and December 31, 2004 for his UTPCPL claim. Plaintiff did not file suit until March 2014, fifteen years after his claims accrued. Therefore, unless the statutes of limitation were tolled, Plaintiff's claims must be dismissed as untimely.

Plaintiff argues the discovery rule and the doctrine of fraudulent concealment toll the statutes of limitation.<sup>5</sup> Before analyzing the applicability of the discovery rule, it is important to

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<sup>5</sup> Plaintiff's third argument, that his mental illness tolled the statute of limitation, will not be discussed in depth in this opinion because it is wholly devoid of merit. Pennsylvania law does

note the discovery rule does not apply in breach of warranty cases. Northampton Cnty. Area Cmty. Coll. v. Dow Chem., USA, 566 A.2d 591, 599 (Pa. Super. 1989). Similarly, the discovery rule does not apply to unfair trade practices claims. See Drelles v. Manufacturers Life Insurance Co., 881 A.2d 822, 831 (Pa. Super. 2005)(statute of limitation on UTPCPL claims “begins to run as soon as the right to institute and maintain suit arises, which generally is when the injury was inflicted”).<sup>6</sup> Therefore, if the discovery rule applies, it would only serve to toll the statutes of limitation as to Plaintiff’s tort claims.

## *II. The Discovery Rule*

Pennsylvania policy favors a strict application of statutes of limitation. Sabella v. Appalachian Dev. Corp., 103 A.3d 83, 92-93 (Pa. Super. 2014). “[A] party asserting a cause of action is under a duty to use all reasonable diligence to be properly informed of the facts and circumstances upon which a potential right of recovery is based and to institute suit within the prescribed statutory period.” Id (internal citations omitted). This obligation is qualified by the “discovery rule” which provides “[T]he start of the statutory limitation on an action in tort may be delayed by plaintiff’s ignorance of his injury and its cause, until such time as he could or should have discovered it by the exercise of reasonable diligence.” Id (internal citations omitted).

As the discovery rule has developed, the salient point giving rise to its application is the inability of the injured, despite the exercise of reasonable diligence, to know that he is injured and by what cause. We have clarified that in this context, reasonable diligence is not an absolute standard, but is what is expected from a party who has been given reason to inform himself of the facts upon which his right to recovery is premised. As we have stated: There are very few facts which diligence cannot discover, but there must be some reason to awaken inquiry and direct diligence in the

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not permit the statute of limitation to be tolled due to mental incapacity. 42 Pa.C.S. § 5533(a); Pearce v. Salvation Army, 674 A.2d 1123, 1126 (Pa. Super. 1996).

<sup>6</sup> Additionally, Plaintiff bears the burden of proving the discovery rule applies, see Gleason v. Borough of Moosic, 15 A.3d 479, 485-86 (Pa. 2011), and Plaintiff has not directed the Court’s attention to any case applying the discovery rule to UTPCPL claims.

channel in which it would be successful. This is what is meant by reasonable diligence. Put another way, the question in any given case is not, what did the plaintiff know of the injury done him? But, what might he have known, by the use of the means of information within his reach, with the vigilance the law requires of him?

Fine v. Checcio, 870 A.2d 850, 858 (Pa. 2005)(internal citations omitted)(quotations omitted).

Generally, the determination of whether a plaintiff exercised reasonable diligence is left to a jury. E.g. Coleman v. Wyeth Pharmaceuticals, Inc., 6 A.3d 502 (Pa. Super. 2010); Simon v. Wyeth Pharmaceuticals, Inc., 989 A.2d 356 (Pa. Super. 2009). However, in some cases, a court may find, as a matter of law, a plaintiff failed to use reasonable diligence to discover the existence of a claim. Pocono International Raceway, Inc. v. Pocono Produce, Inc., 468 A.2d 468, 471 (Pa. 1983). Only where the facts are so clear that reasonable minds cannot differ may the commencement of the limitation period be determined as a matter of law. See Colonna v. Rice, 664 A.2d 979, 980–81 (Pa. Super. 1995). This case falls into the latter classification; it is the type of case in which the facts are so clear that reasonable minds cannot differ and the issue of reasonable diligence must be determined as a matter of law.

Moving Defendants argue if the discovery rule applies at all, it only tolls the statutes of limitation until October 31, 2006. On October 31, 2006, the Risperdal label was changed to include a warning about gynecomastia in adolescents. According to Moving Defendants, the label change put Plaintiff on inquiry notice about the link between his gynecomastia and his Risperdal ingestion. As a result, the discovery rule could only toll the statutes of limitation until at the latest October 31, 2006.

Plaintiff makes two primary arguments in opposition to Moving Defendants' Motion. First, Plaintiff argues the statute of limitation is tolled by the discovery rule because, to date, no medical professional has ever told him his gynecomastia was related to his Risperdal use. This argument is not only unpersuasive, it is wholly contrary to established Pennsylvania case law.



See e.g. Morgan v. Johns-Manville Corp., 511 A.2d 184, 186-87 (Pa. Super. 1986) (“[T]he statute of limitation begins to run even though the plaintiff lacks actual knowledge of an injury and its cause as long as he or she should have been so aware”). Second, Plaintiff argues a jury must determine whether he used reasonable diligence to discover his cause of action. To support this argument, Plaintiff cites two recent opinions from the Superior Court, Simon and Coleman. A review of Simon and Coleman reveals the Superior Court determined the facts of those two cases necessitated a jury to determine whether the respective plaintiffs exercised reasonable diligence; however, neither Simon nor Coleman requires a jury to make such a determination in all cases. Indeed, Pennsylvania precedent explicitly allows a court to determine, as a matter of law, whether a party exercised reasonable diligence. See e.g. Pocono International Raceway, 468 A.2d at 471.

In October 2006, the Risperdal warning label was updated with warnings related to gynecomastia. The October 2006 label indicates:

Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

...

Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin elevating compounds.

...

In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorder treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.35% of risperidone-treated patients.

Defendants’ Ex. “E,” October 2006 Risperdal Label, at p. 3-4. The addition of these warnings put the world, including Plaintiff, on notice as of October 31, 2006 that a potential cause of action exists for Risperdal users who developed gynecomastia. Indeed, one court recently determined, as a matter of law, the October 2006 warnings were legally sufficient such that they defeated a plaintiff’s failure to warn claim. See Apel v. Johnson & Johnson, Case No. 274 (N.J.

Super. Ct. July 25, 2014). Even the Master-Long Form Complaint, which Plaintiff incorporated by reference, appears to concede the October 2006 warnings were sufficient to place Plaintiff on notice of the link between Risperdal and gynecomastia. See Second Amended Master Long-Form Complaint at ¶ 173 (alleging Moving Defendants “deliberately withheld [information concerning the link between Risperdal and gynecomastia] from prescribing physicians and the public *until at least October 2006*, when it appeared in the label for Risperdal and/or Invega”)(emphasis added).<sup>7</sup>

Notwithstanding the fact the label states there is a 2.3% risk of developing gynecomastia as a result of taking Risperdal, Plaintiff argues the label was insufficient to put him on notice of a potential claim because Moving Defendants’ experts, in their depositions, have stated the Risperdal label is not evidence of causation. See In Re: Risperdal, March Term 2010 No. 296, Response to Motion for Partial Summary Judgment at pp. 18-20. It is hornbook law that a defendant need not admit causation before the statute of limitation begins to run. All that is required is a plaintiff know he was injured and have knowledge of a possible cause of said injuries. See e.g. Pocono International Raceway, 468 A.2d at 471. In this case, Plaintiff knew he was injured in December 1998 and in October 2006 the Risperdal label was amended to include sufficient information to allow Plaintiff to know Risperdal may be the cause of his injuries.

Plaintiff also argues the October 2006 label could not have placed him on notice that Risperdal caused his injuries because the label describes the incidence of gynecomastia as “rare,”

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<sup>7</sup> Plaintiff argues the averment in ¶ 173 does not constitute a judicial admission because the averment in ¶ 173 is not a clear and unequivocal admission Moving Defendants told the public about the link between Risperdal and gynecomastia in October 2006. Plaintiff argues ¶ 173 “simply says the information was hidden from the public until at least October 2006. The information could have been hidden longer and, indeed Plaintiffs have alleged this.” Plaintiff’s Response to the Global Motion for Partial Summary Judgment at p. 27 (internal quotes omitted). Plaintiff’s argument is circular and unpersuasive. Logically, if the information was “hidden from the public until at least October 2006,” the information must have been available after October 2006; otherwise, the insertion of a specific time, October 2006, into ¶ 173 is superfluous.

or less than 1/1000, when the 2.3% means the incidence of gynecomastia is “frequent,” or greater than 1/100. This argument is a red-herring. The law charges Plaintiff with using due diligence to discover if Risperdal caused his gynecomastia; it does not charge him with finding the frequency with which Risperdal may have caused his gynecomastia. Therefore, whether the likelihood was less than 1/1000 or greater than 1/100 is irrelevant, the salient point is Risperdal is a potential cause of gynecomastia in adolescents and the October 2006 warning label reflected this fact. Accordingly, the warning label, as of October 2006, was sufficient to place a user on notice of the link between Risperdal use and gynecomastia.

Although this Court agrees with Moving Defendants and finds the October 2006 label changes were sufficient to place a user on notice of the link between Risperdal and gynecomastia, the analysis does not stop at this point. As the Supreme Court noted “there must be some reason to awaken inquiry and direct diligence in the channel in which it would be successful.” Fine, 870 A.2d at 858. Viewing the facts in the light most favorable to Plaintiff, it is possible that immediately after he noticed his injuries, Plaintiff conducted a diligent search into the cause of his injuries, was unable to find evidence of the link between his injuries and his Risperdal use, and by 2006 his diligent search had become stale. When viewed in the light most favorable to Plaintiff, it would be unreasonable to expect him to have continued checking the Risperdal label until October 2006 even though he stopped taking Risperdal in 1998. Put another way, the October 2006 change to the Risperdal label may have been, standing alone, insufficient to have awakened Plaintiff’s inquiry concerning the link between Risperdal and his injuries.

However, because the label change may have been insufficient to awaken Plaintiff’s inquiry in October 2006 does not mean Plaintiff’s inquiry was allowed to lay dormant until December 2013, when a television advertisement about Risperdal litigation alerted Plaintiff of the link between Risperdal and gynecomastia. See Plaintiff’s Affidavit at ¶ 13, attached to

Plaintiff's Response In Opposition to Summary Judgment as Ex. 3 ("I did not know of the link between Risperdal and gynecomastia . . . until my mother informed me of a commercial she viewed in December, 2013 describing the linkage"). Since the determinate factor is not when an individual plaintiff had actual knowledge of the cause of his injuries, see Morgan, 511 A.2d at 186-87, the Court must determine whether, as a matter of law, a person who stopped using Risperdal prior to October 2006 could have discovered the link between Risperdal and gynecomastia through the exercise of reasonable diligence.

In federal multi-district litigations (MDL) and cases from other states, courts have looked at a variety of factors in determining whether a plaintiff should have been on notice of the existence of a claim. In re Avandia, 2012 WL 3205620 (E.D. Pa. August 7, 2012) was an MDL in which plaintiff alleged their use of Avandia resulted in heart attacks and other coronary problems. Judge Rufe relied on five categories of evidence – 1) a groundbreaking study showing Avandia increased the risk of a heart attack by 43% was published in May 2007, 2) in June 2007, numerous physician groups, such as the American College of Cardiology, issued public statements advising Avandia users to contact their physicians, 3) the FDA mandated a label change in November 2007, 4) between May and November 2007, the drug manufacturer sent a series of "Dear Doctor" and "Dear Patient" letters alerting doctors and patients of the existence of the study and the label change, and 5) a plethora of media reports including articles from the New York Times and clips from ABC News – to conclude December 31, 2007 was the latest a reasonable person could have discovered the link between Avandia and increased risk of heart attacks. Id. at \*3-4. Similarly, in the In Re Vioxx MDL, the court ruled plaintiffs were on notice of possible claims when Vioxx was withdrawn from the market on September 30, 2004, triggering "arguably the largest and most-publicized prescription drug withdrawal in this country's history," including "an immediate avalanche of media coverage" and "an onslaught of

front-page stories.” In Re Vioxx, 522 F.Supp.2d 799, 803 (E.D.La. November 8, 2007). In addition to this avalanche of publicity, “Dear Doctor” and “Dear Patient” letters were also sent out by the drug manufacturer. Id. Finally, in Burrell v. Astrazeneca LP, the Delaware Superior Court held a reasonable person could have discovered a link between Seroquel and her alleged injuries because there were various medical and lay publications concerning the link, as well as an updated warning label and two separate “Dear Doctor” letters discussing the updated warning label. Burrell v. Astrazeneca LP, 2010 WL 3706584 (Del. Super. September 20, 2010).

Although their decisions are not binding, the courts of this Commonwealth may adopt the reasoning of federal courts or the courts of sister states when said reasoning is persuasive. NASDAQ OMX PHLX, Inc. v. PennMont Secs., 52 A.3d 296, 303 (Pa.Super. 2012). In the case *sub judice*, this Court finds the reasoning set forth by the Eastern District of Pennsylvania, the Eastern District of Louisiana, and the Delaware Superior Court persuasive. Accordingly, this Court adopts the reasoning set forth in In re Avandia, In Re Vioxx, and Burrell and will examine the factors set forth therein to determine if, and when, Plaintiff should have been on notice of the existence of a claim.

By June 2009, the combination of medical journal articles, print media articles, television media exposure, and lawyer advertising created an environment such that any Risperdal user who exercised even a modicum of diligence should have discovered the link between Risperdal and gynecomastia.

As early as 2003, high volume, national, medical publications such as Current Psychiatry, The Medical Letter, and Drugs, published articles which discussed the link between Risperdal and gynecomastia. Donna A. Wirshing et al., Update On Atypicals: Practical Tips To Manage Common Side Effects, 2 Current Psychiatry 49–57 (2003); Choice Of An Antipsychotic, 45 The Medical Letter 102–04 (2003); Peter M. Haddad & Angelika Wieck, Antipsychotic-Induced

Hyperprolactinaemia: Mechanisms, Clinical Features And Management, 64 *Drugs* 2291, 2292, 2296, 2298–2300 (2004). A review of these articles shows each article clearly references the link between Risperdal use and increased prolactin production, as well as the fact increased prolactin production may result in gynecomastia. *Id.* For example, an article in The Medical Letter states “Of all the atypical antipsychotics, risperidone [Risperdal] causes the highest incidence of hyperprolactinemia, which can cause ... gynecomastia ....” Choice Of An Antipsychotic, 45 *The Medical Letter* 102-104 (2003). Contrary to Plaintiff’s argument, even the existence of medical literature which questions the link between Risperdal and gynecomastia, such as the “Findling Article,”<sup>8</sup> does not result in a tolling of the statutes of limitation. See In Re Avandia, 2012 WL 3205620 \*3-4 (holding a drug manufacturer’s public disagreement with a study linking its products to an increased risk of heart attack did not affect whether a reasonable person could have discovered the existence of a claim).

In addition to the medical journals articles, the mainstream media was also reporting on the link between Risperdal and gynecomastia from 2001. A review of media reports shows the first major media coverage concerning a link between Risperdal and gynecomastia was in May 2001.<sup>9</sup> In May 2001, the Miami Herald ran a multi-day investigative report concerning the use

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<sup>8</sup> A 2003 article authored by, among others, Dr. Robert Findling and published in the *Journal of Clinical Psychiatry* entitled “Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescent” questioned the evidence of a link between Risperdal and gynecomastia. Plaintiff alleges this article severely misrepresented the results of the study and was actually written by Janssen employees for the purpose of disavowing any link between Risperdal and gynecomastia. Assuming *arguendo* the veracity of these allegations, the existence of articles like the “Findling Article” still put Plaintiff on notice of the link between Risperdal and gynecomastia. Articles like the “Findling Article” contribute to the global body of knowledge and alert a reasonably diligent plaintiff to the existence of a possible link between Risperdal and gynecomastia.

<sup>9</sup> In addition to the media coverage cited by Moving Defendants, a court may take judicial notice of press releases news articles and published analyst reports in determining what the market knew. Landow v. Wachovia Securities, LLC, 966 F. Supp.2d 106, 119 (E.D.N.Y. 2013).

of antipsychotic drugs in foster homes; prominent in these articles were references to Risperdal causing adolescent boys to develop breasts. See Miami Herald, Foster Kids Describe Drugs' Effects Prescribed Psychiatric Medications Made "Everything a Blur" for One Girl, 1A (April 23, 2001); Miami Herald, Shocking Tale Fails to Register, 1B (April 24, 2001); Miami Herald Investigation Urged on Antipsychotic Drugs Given to Disabled Floridians, 23A (May 11, 2001). In each of these articles, Moving Defendants denied Risperdal caused the gynecomastia. Additional major coverage came in July 2004 when Janssen sent "Dear Doctor" letters to prescribing physicians concerning certain side effects; newspapers of all sizes throughout the country reported on the release of these "Dear Doctor letters." Although gynecomastia was not mentioned in the "Dear Doctor letters," the link between gynecomastia and Risperdal was mentioned in the articles. See e.g. New York Times, Warning on Schizophrenia Drug, 117 (July 25, 2004); Washington Post, Maker of Schizophrenia Medicine Clarifies Risks, (July 25, 2004); Charleston Newspapers, Drug Firm Admits Misleading Claims, 8 (July 25, 2004); Kansas City Star, Medicine Maker Admits Deception It Downplayed Possibly Fatal Safety Risks, (July 25, 2004). These articles do not contain any comment from Moving Defendants concerning the link between Risperdal and gynecomastia.

The next evidence of significant media coverage on the link between Risperdal and gynecomastia started in early 2008. In February 2008, national newspapers ran reports which mentioned the link between Risperdal and gynecomastia. See Medicaid Kids in Psych-Rx Surge, N.Y. Post, Feb 3, 2008 at 7 ("Stephen Sheller, a Philadelphia lawyer, said he has filed suits in New Jersey on behalf of four boys, ages 14 to 16 – two who underwent mastectomies."); Karl Stark, Tarnished View of Wonder Drugs, Philadelphia Inquirer, February 17, 2008 at E01 ("Research suggests Risperdal . . . can cause an increase in the hormone prolactin, which directs the breasts to enlarge and make milk. Risperdal's label warns about the possibility."). Starting in

late 2008, cable television news programs were discussing the link. See e.g. America's News Headquarters (Jon Scott et al., Fox Television broadcast November 20, 2008). By the spring of 2009, the link between Risperdal and gynecomastia was being regularly discussed on network television, including the evening news. See CBS Evening News: The New Drug of Choice (CBS Television broadcast May 25, 2009). The link between Risperdal and gynecomastia was even being discussed using online platforms. See e.g. Sheller PC, Risperdal®: Has your son experienced breast growth while taking this drug? Youtube (uploaded June 25, 2009) [http://www.youtube.com/watch?v=L\\_wj6-LINIg](http://www.youtube.com/watch?v=L_wj6-LINIg) (last visited January 13, 2015). As a result, this Court determines, as a matter of law, that a potential plaintiff, exercising reasonable diligence, should have discovered the link between Risperdal and gynecomastia no later than June 30, 2009.

In conclusion, the existence of the link between Risperdal use and gynecomastia was discoverable in October 2006 when Risperdal's label was changed to reflect the connection. Furthermore, the link between Risperdal and gynecomastia was so widely discussed in the mainstream media, and in medical journals, that by June 30, 2009, Plaintiff's inquiry should have been awakened and he should have discovered the existence of his claims against Moving Defendants. Accordingly, as a matter of law, the discovery rule can only toll the statutes of limitation until a maximum date of June 30, 2009 for plaintiffs who ingested Risperdal prior to October 2006.

### *III. Doctrine of Fraudulent Concealment*

Plaintiff argues the doctrine of fraudulent concealment also tolls the statutes of limitation. The doctrine of fraudulent concealment is an exception to the requirement that a complaining party must file suit within the statutory period. Where, "through fraud or concealment, the



defendant causes the plaintiff to relax his vigilance or deviate from his right of inquiry, the defendant is estopped from invoking the bar of the statute of limitations.” Meehan v. Archdiocese of Philadelphia, 870 A.2d 912, 921 (Pa. Super. 2005).

Here, Plaintiff argues Moving Defendants misrepresented, and continue to misrepresent, Risperdal was safe for off-label uses, even though such off-label marketing is illegal. According to Plaintiff, Moving Defendants’ scheme of off-label promotion constitutes an affirmative independent act of concealment sufficient to invoke the doctrine of fraudulent concealment. Implicit in Plaintiff’s eloquent argument is the suggestion Moving Defendants engaged in fraudulent concealment because they engaged in fraud and because they engaged in concealment. Plaintiff’s evidence, when distilled to its core, is as follows: Moving Defendants committed fraud by illegally off-marketing Risperdal<sup>10</sup> and Moving Defendants engaged in concealment by omitting or adulterating safety data, such as they did in the “Findling Article,” therefore Moving Defendants committed fraudulent concealment.

Plaintiff’s argument must fail for multiple reasons. First, Plaintiff fails to show how any illegal off-label marketing of Risperdal caused Plaintiff to relax his vigilance in searching for the link between Risperdal and his injuries. Second, Plaintiff cannot point to any statements made to him by Moving Defendants that he relied upon in relaxing his vigilance. See Meehan, 870 A.2d at 922 (general conduct by the church, even systemic general conduct, does not constitute an

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<sup>10</sup> Off-label marketing is the promotion of a drug for a use other than the purpose for which it was approved by the FDA; pharmaceutical manufacturers are prohibited from marketing a drug for “off-label” uses. See e.g. In re Neurontin Marketing and Sales Practices Litigation, 712 F.3d 21 (1<sup>st</sup> Cir. 2013). However, a physician’s decision to use a pharmaceutical for an “off-label” purpose is not only an acceptable practice, but also “an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” Buckman Co. v. Plaintiff’s Legal Committee, 531 U.S. 341, 121 S.Ct. 1012, 1018 (2001). In this case, Plaintiff alleges Moving Defendants engaged in off-label marketing by promoting Risperdal for adolescent use as early as 1998 even though Risperdal was not approved for use in adolescents until October 2006.

affirmative act of concealment which a plaintiff can rely upon for fraudulent concealment purposes; rather, the plaintiff must identify an affirmative and independent act of the church toward the plaintiff that was relied upon). Finally, since October 2006, the Risperdal label has explicitly stated “gynecomastia was reported in 2.35% of risperidone-treated patients.” Assuming *arguendo* Moving Defendants had previously made an affirmative independent statement which caused Plaintiff to relax his vigilance, any such statement was obviated by the October 2006 label change. Indeed, it is disingenuous for Plaintiff to argue Moving Defendants’ fraudulent concealment “continues to this day” when, for the past eight years, Risperdal’s label has explicitly stated “gynecomastia was reported in 2.35% of risperidone-treated patients.” For all of these reasons, the doctrine of fraudulent concealment does not apply.

#### IV. Conclusion

In conclusion, Plaintiff’s claims must be dismissed as untimely. Plaintiff’s claims for breach of warranty and unfair trade practices accrued on December 31, 1998 when he observed his injuries. The statute of limitation period for these claims began to run on December 31, 1998 and expired December 31, 2002 for the warranties claims and on December 31, 2004 on the deceptive trade practices claims. See 13 Pa.C.S. § 2725(a)(four year statute of limitation applies to warranty claims); Gabriel, 534 A.2d at 495 (six year statute of limitation applies to UTPCPL). The discovery rule tolled the statute of limitation on Plaintiff’s tort claims until no later than June 30, 2009. The two year statute of limitation on Plaintiff’s tort claims therefore ran on June 30, 2011. See 42 Pa.C.S. § 5524(7). Plaintiff did not file this case until March 10, 2014. By that time, the statutes of limitation had run on all claims; therefore, all of Plaintiff’s claims should be dismissed as untimely.<sup>11</sup>

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<sup>11</sup> Plaintiff’s final argument is the Motion for Summary Judgment is premature because discovery has not closed. This argument is not persuasive. First, the pleadings are closed; therefore, a

**WHEREFORE**, for the reasons set forth above, this Court grants the Motion for Summary Judgment filed by Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC. An Order dismissing Plaintiff's claims as to Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC is attached hereto.

**BY THE COURT:**



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**ARNOLD L. NEW, J.**

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motion for summary judgment is appropriate. See Pa.R.C.P. 1035.2. Second, Plaintiff had, and utilized, the opportunity to create a factual record to support his claim. For example, Plaintiff submitted an affidavit in support of his Motion for Summary Judgment. If Plaintiff felt he needed additional discovery to support his response, such as deposition testimony, he was free to take said discovery. Finally, no amount of discovery can change the facts of this Opinion. For example, additional discovery would have no impact on the fact Risperdal's label was changed in October 2006 or the media has published multiple articles on the link between Risperdal and gynecomastia since 2001.