IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

AUGUSTUS HEBREW EVANS, JR.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	**Civil Action No. 14-1316-RGA**
	:	
JOHNSON AND JOHNSON COMPANY, et al.,	:	
	:	
Defendants.	:	

Augustus Hebrew Evans, Jr., James T. Vaughn Correctional Center, Smyrna, Delaware; Pro Se Plaintiff.

Todd C. Schiltz, Drinker Biddle & Reath LLP, Wilmington, Delaware; Daniel J. Brown and Hayley J. Reese, McCarter & English, LLP, Wilmington, Delaware; Counsel for Defendants.

MEMORANDUM OPINION

February 10, 2020
Wilmington, Delaware

ANDREWS, U.S. District Judge:

Plaintiff Augustus Hebrew Evans, Jr., an inmate at the James T. Vaughn Correctional Center in Smyrna, Delaware, who appears *pro se*, filed this action in the Superior Court of the State of Delaware in and for Kent County, raising claims under Delaware law. The matter was removed to this Court on October 16, 2014. (D.I. 1). The First Amended Complaint is the operative pleading. (D.I. 44). Before the Court are the motion for summary judgment filed by Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson (improperly named as Johnson and Johnson Company) and numerous other motions filed by the parties. (D.I. 215, 218, 220, 221, 224, 225, 233, 236).

I. PROCEDURAL AND FACTUAL BACKGROUND

Plaintiff is one of several inmates housed within the Delaware Department of Correction who have filed lawsuits against the manufacturers of Risperdal[1] alleging side effects occurred after taking the medication. Early on, Plaintiff was provided counsel. (*See* D.I. 13). In October 2017, Plaintiff filed a motion to proceed *pro se*. The motion was granted on November 6, 2017, and Plaintiff's counsel withdrew.[2] (D.I. 89).

The First Amended Complaint alleges seven counts: negligence, negligent misrepresentation, breach of warranty, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, breach of express warranty, and fraud by concealment, all arising out of Defendants' development,

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[1] I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

[2] Currently pending are four requests for counsel filed by Plaintiff. (*See* D.I. 218; D.I. 221; D.I. 233; D.I. 236).

marketing, and sale of the drug Risperdal. (D.I. 44.) Plaintiff's First Amended Complaint alleges that he experienced "significant bodily and mental injury, disfigurement, embarrassment, and inconvenience" as a result of taking the drug. (D.I. 44 at ¶¶ 20, 25, 30, 35, 40, 44, 49).

Risperdal is approved for treatment of schizophrenia and bipolar disorder. (D.I. 227-1 at Ex. E. at 55). Janssen is the manufacturer of the brand name drug Risperdal. (*Id.* at Ex. E) Generic versions of Risperdal are referred to as risperidone. (*Id.* at Ex. C). Other drug manufacturers such as Teva Pharmaceuticals USA manufacture and sell risperidone. (*See* D.I. 227-1 at Ex. C [FDA approval of Teva's generic risperidone on June 30, 2008]). Warnings and precautions when taking Risperdal include: cerebrovascular events, neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes mellitus, hyperprolactinemia,[3] orthostatic hypotension, potential for cognitive and motor impairment, seizures, dysphagia, priapism, thrombotic thrombocytopenic purpura, disruption of body temperature regulation, antiemetic effect, suicide, increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies, and diseases or conditions that could affect metabolism or hemodynamic responses. (D.I. 227-1 at Ex. E at 55). The most common adverse reactions in clinical trials were somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva,

[3] Risperdal is associated with higher levels of prolactin elevation than other antipsychotic agents. (D.I. 227-1 at Ex. E at ¶ 5.6). Gynecomastia has been reported in patients receiving prolactin-elevating compounds. (*Id.*). Gynecomastia is the enlargement of the male breast gland due to a hormonal imbalance. *See Trower v. Janssen Pharm., Inc.*, 2019 WL 1571834, at *1 (D. Del. Apr. 11, 2019). Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body. (*See id.*).

constipation, fever, Parkinsonism, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash, akathisia, and dyspepsia. (*Id.*).

Plaintiff testified that he was prescribed Risperdal from approximately April 2007 until April 2008 when he was housed at the Howard R. Young Correctional Institution, although he has no medical records relating to that time period. (D.I. 227-1 at Ex. G at 125-26 [Dep. Tr. at 48, 50]). Plaintiff testified that in deciding to take Risperdal he did not rely on anything from Janssen or Johnson & Johnson; he relied upon his doctor. (*Id.* at 146). His medical records indicate that he was prescribed Risperdal or risperidone from July 23, 2008 through January 14, 2009 and, again, for approximately two weeks in November 2011. (*Id.* at Ex. A at 4-10, 12, 13, 14, 15, 18-19; Ex. B at 26). The July 23, 2008 psychiatric progress note, authored by psychiatrist Anthony Cannuli, indicates that Risperdal was prescribed to treat agitation, that the risks and benefits of the medication were discussed with Plaintiff, that Plaintiff accepted the medication, and that he signed a consent. (*Id.* at Ex. A at 18-19). Medical records indicate that Plaintiff's physicians ordered Risperdal in July and October 2008, January 2009, and November 2011, and specifically note that Plaintiff was given risperidone (not Risperdal) in September, October, November, and December 2008, and November 2011.[4] (D.I. 227-1 at Ex. A at 4, 8, 9, 10, 12, 13, 14; Ex. B at 26). Plaintiff's medical records refer to the administration of Risperdal for a one-month period from August 1 to August 31, 2008. (*Id.* at Ex. A at 15). Plaintiff submitted a medical grievance in June 2014, claiming that "he has increase in his nipples and lumps because of the drug Risperdal."

[4] The parties did not provide Plaintiff's 2009 Medication Administration Records.

(D.I. 230 at 20). The RN's chart review states, "no order in chart for Risperdal since 7/25/13." (*Id.*).

Plaintiff testified that his injuries included "temporary gynecomastia,"[5] weight gain, enlarged and/or elongated nipples, elevated prolactin levels, pituitary tumor,[6] tardive dyskinesia (including allegedly associated tremors and twitches),[7] increased risk of death from heart attack,[8] "diabetes hyperglycemia, and other blood sugar side

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[5] He does not assert that he has ever been diagnosed with gynecomastia. The First Amended Complaint does not make such an allegation. Nor does any declaration of Plaintiff, although in some of his filings he advances a theory that had a temporary form of gynecomastia that caused "super nipples." (See D.I. 90 at 4 [stricken amended complaint]; D.I. 157 at 10 [answering brief in opposing to motion for summary judgment]). Plaintiff submitted a copy of one of his medical grievances in connection with one of his requests for appointment of an expert. The medical grievance was denied on December 3, 2015, with the comment, "I reviewed the past grievances and the available medical record in iCHRT. [Plaintiff] has been complaining of gynecomastia following being prescribed Risperdal. He has been examined numerous times and no gynecomastia has been found. The examiners have described elongated nipples and [Plaintiff] has been recurrently requesting A&D ointment for his dry nipples. He also complains of being told he has a pituitary tumor. In Oct. 2014 Dr. Desrosiers told him he had an elevated prolactin level which was normal on repeat testing." (D.I. 218 at 18).

[6] Plaintiff testified that he noticed the gynecomastia and weight gain no later than 2009. (D.I. 227-1 at Ex. G at 131). Plaintiff testified that his physician told him that his weight gain and "ballooning chest" had nothing to do with the medication he was taking. (*Id.*). Plaintiff testified that Dr. Desrosiers diagnosed that "his pituitary gland and other glands were operating fast." (*Id.* at 134).

[7] Plaintiff testified that he first noticed sporadic and uncontrollable face twitching in 2013. (D.I. 227-1 at Ex. G at 135). He did not raise the problem with his healthcare providers. (*Id.*). Plaintiff testified that Dr. Desrosiers stated there was a possibility that Plaintiff's shoulder, eye, face and/or neck tremors were caused by Risperdal, but that other drugs could have also caused the tremors. (*Id.* at 139).

[8] Plaintiff testified that none of his doctors told him that he had an increased risk of sudden death from heart attack due to Risperdal use. (D.I. 227-1 at Ex. G at 135). Plaintiff testified that he had chest pains before he began taking Risperdal. (*Id.*).

effects,"[9] suicidal thoughts,[10] abdominal pain and decreased activity associated with respiratory infections,[11] dry skin,[12] joint pain,[13] sore throat,[14] headaches,[15] blurred vision,[16] and memory lapse.[17] (D.I. 227-1, Ex. G at 133-144).

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[9] Plaintiff testified that his physicians could not find any medical reason behind his blood sugar issues, and they never associated the problem with Risperdal. (D.I. 227-1 at Ex. G at 136).

[10] When asked if he was bring a claim for suicidal thoughts, Plaintiff replied "yes and no, if that's possible." (D.I. 227-1 at Ex. G at 136). Plaintiff does not know if his feeling of hopelessness is because of Risperdal or something else because he has not seen a specialist who is "willing to seriously diagnose" him. (*Id.* at 137). Plaintiff testified that no doctor told him that Risperdal caused him to be suicidal. (*Id.*).

[11] Plaintiff testified that he had a respiratory infection when he first started taking Risperdal and thought that Risperdal may, or may not, have been the cause of abdominal pain, decreased activity, and respiratory infections. (D.I. 227-1 at Ex. G at 137). Plaintiff testified that Dr. Desrosiers stated that his respiratory infections (he had three) could have come from taking Risperdal. (*Id.* at 140).

[12] Plaintiff testified that he started having dry skin in 2009 and did not have skin issues before taking Risperdal. (D.I. 227-1 at Ex. G at 138). He testified that no physician directly told him that Risperdal caused dry skin, but Dr. Desrosiers stated it is one of the residual effects of the drug. (*Id.* at 139).

[13] Plaintiff testified that he first experienced joint pain in 2013 and was told Risperdal causes joint pain. (D.I. 227-1 at Ex. G at 140). Dr. Desrosiers did not specifically say that Plaintiff's joint pain was caused by Risperdal although she classified it as one of the side effects of the drug. (*Id.*).

[14] Plaintiff testified that he has not been told by a physician that Risperdal caused a sore throat. (D.I. 227-1 at Ex. G at 140, 141).

[15] Plaintiff testified that he experienced headaches soon after taking Risperdal and that Dr. Desrosiers stated that it could be associated with Risperdal but other drugs Plaintiff was taking could have also caused headaches. (D.I. 227-1 at Ex. G at 141). At least five years had passed from the time the headaches started to the time Plaintiff saw Dr. Desrosiers. (*Id.*). A physician Plaintiff saw prior to seeing Dr. Desrosiers did not associate the headaches with Risperdal and thought the headaches could be related to stress or another drug Plaintiff was taking. (*Id.* at 142). Plaintiff testified that he has headaches when he is dehydrated. (*Id.*).

[16] Plaintiff testified that he first experienced blurred vision when he started taking Risperdal, but that it became an issue when he started taking two other drugs – Celexa and Zyprexa. (D.I. 227-1 at Ex. G at 142). Dr. Desrosiers said that blurred vision could be associated with the use of Risperdal and was not necessarily the cause of Plaintiff's blurred vision. (*Id.*).

[17] Plaintiff testified that he noticed memory issues in 2013. (D.I. 227-1 at Ex. G at 143). He was not taking Risperdal at the time. (*Id.*). Dr. Desrosiers told Plaintiff that

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1).

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memory lapse is a possible side effect from taking Risperdal, but no physician has told Plaintiff that his memory lapses are caused by Risperdal. (*Id.* at 144).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

Defendants move for summary judgment on the grounds that: (1) Plaintiff lacks evidence that he consumed Janssen's product, which is the branded drug, Risperdal, as opposed to generic risperidone; (2) the claims are time-barred; (3) Plaintiff does not have the expert testimony that is required to prove causation and to establish a product defect; (4) Plaintiff cannot satisfy the learned intermediary doctrine; (5) Plaintiff does not have evidence of a communication upon which he or his physician relied; (6) Plaintiff has not identified a special purpose in connection with the implied warranty of fitness for a particular purpose claims; (7) Plaintiff's fraud by concealment claim fails because Plaintiff cannot identify an affirmative act of concealment; and (8) Plaintiff's label adequacy arguments are preempted. (D.I. 226).

Plaintiff responds that each of the seven claims is founded upon Defendants' promotion and marketing of Risperdal for off-label purposes for which the drug had neither been tested nor approved and Defendants' failure to warn that the drug should be used as prescribed and not be prescribed for off-label purposes. (D.I. 230 at 6).

III. DISCUSSION

A. Learned Intermediary Doctrine

To succeed on his two negligence-based claims against Defendants, Plaintiff must overcome the learned intermediary doctrine. Defendants argue that Plaintiff cannot satisfy the doctrine.

The learned intermediary doctrine is an exception to the general rule that a manufacturer owes a duty to directly warn a consumer of the risks associated with a product. *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989). Specifically, "a manufacturer of a prescription drug satisfies its duty to provide an appropriate warning about the drug when it gives the patient's physician the necessary information to be disseminated to the patient." *Id.* (emphasis omitted). The doctrine is inapplicable if a warning is "inadequate as a matter of law." *Barba v. Carlson*, 2014 WL 1678246, at *2 (Del. Super. Ct. Apr. 8, 2014). Warnings are not inadequate as a matter of law if there is "a genuine issue of material fact about whether the warnings were adequate." *Id.* at *2-3. To maintain an action against a manufacturer when such a genuine factual dispute exists, a plaintiff must show that an additional warning would have made a difference to the plaintiff's treating physician. *Id.* at *3; *Barba v. Bos. Sci. Corp.*, 2015 WL 6336151, at *6 n.22 (Del. Super. Ct. Oct. 9, 2015) (clarifying that the inquiry employs a subjective test). This is because, if a more complete warning would not have made a difference to the prescriber, a plaintiff is unable to prove but for causation. *See Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014); *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008); *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098-99 (5th Cir. 1991);

In re Plavix Mktg., Sales Practices & Prod. Liab. Litig , 2017 WL 4838842, at *6 (D.N.J. Oct. 26, 2017).

Plaintiff's factual allegations are insufficient to escape the application of the learned intermediary doctrine. Plaintiff argues, without citation to any legal authority, that the Risperdal label was inadequate as it did not warn against off-label prescription and does not warn against "cancerous cellulitis and/or lipoma." (D.I. 230 at 3-4, 15-16). Plaintiff's argument, with nothing more, fails to provide any evidence to establish that Defendants' warnings were inadequate as a matter of law.

Since Plaintiff cannot show inadequacy as a matter of law, he must show that an additional warning would have made a difference to his prescribing physicians. Plaintiff cannot make such a showing. Plaintiff's prescribing physician, Dr. Cannuli, was not deposed. Plaintiff seems to argue that he did not depose Dr. Cannuli because he was confused about discovery deadlines and/or there was a conflict with his prior attorney about deposing the physician. (D.I. 230 at 16).

The record, however, reflects Plaintiff's knowledge of deadlines imposed by the Court. After Plaintiff opted to proceed *pro se*, he was advised in the November 6, 2017 Order that the case would proceed on the deadlines set forth in the July 28, 2017 Order, which included a December 15, 2017 discovery deadline. (D.I. 82; D.I. 89). Following the November 15, 2017 Order, Plaintiff sought discovery from Defendants (D.I. 92). He then proceeded to file a number of motions seeking extensions of time and discovery, many of them complaining about defense counsel's tactics. (*See* D.I. 169 at 2-6).

The record also reflects that when Plaintiff sought to remove his attorney and proceed *pro se*, he made no mention of deposition disputes with his attorney. Rather,

he complained that his attorney withheld information and failed to forward discovery to him. (D.I. 86). When Plaintiff, after the discovery cut-off, on January 17, 2018, sought funds to conduct depositions of "important defendants" (D.I. 132), he made no mention that he sought to depose his own physicians (who are not "defendants.").

Plaintiff has no evidence that, but for the supposedly inadequate warning, he would not have been prescribed Risperdal. Hence, Defendants are shielded from liability by the learned intermediary doctrine. I will grant Defendants summary judgment on this basis on the negligence-based Counts One and Two.

B. Proximate Cause

Plaintiff alleges in Counts One and Two that he was injured as a direct and proximate result of his ingestion of Risperdal when Defendants were negligent in the marketing, distribution, sale, and misrepresentation of Risperdal in failing to warn physicians and users of adverse risks associated with its use and in making false and/or misleading statements regarding the safety of Risperdal. To prevail on his negligence claims, Plaintiff must prove that Risperdal proximately caused him harm. *Culver v. Bennett*, 588 A.2d 1094, 1097-98 (Del. 1991) (discussing Delaware's "but for" rule of proximate cause in negligence cases). A determination of the proximate cause of a specific instance of a disease or medical condition must "rest upon the individualized findings and opinion of a trained physician." *Money v. Manville Corp. Asbestos Disease Comp. Tr. Fund*, 596 A.2d 1372, 1376 (Del. 1991). "General causation" addresses the question of whether a particular substance is capable of causing a particular harm. *Hopkins v. Janssen Pharm., Inc.*, 2019 WL 1567840, at *2 n.3 (D. Del. Apr. 11, 2019). "Specific causation" addresses the related question of whether a particular substance

caused a particular harm to a particular person. *Id.* "A plaintiff's bald assertion that he has a condition and that the condition was caused by a certain drug are insufficient." *Id.* at *2.

Defendants argue that Plaintiff must establish his use of Risperdal was the proximate cause of his alleged injuries.[18] Defendants further argue that because Plaintiff lacks an expert report addressing specific causation (*i.e.*, that his use of Risperdal caused his alleged injuries), summary judgment is appropriate on their behalf. (D.I. 226 at 17-18). I agree.

Plaintiff concedes that he does not have expert testimony and as a matter of law cannot establish causation. (D.I. 230 at 16). Plaintiff argues, however, that the Court did not help him in obtaining an expert witness, which prejudiced his case. (*Id.*). On

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[18] As discussed in footnotes 5 to 17, the evidence of record indicates that: Plaintiff does not have a diagnosis of gynecomastia; his once elevated prolactin levels are now normal; he was told by his physician that his weight gain and "ballooning chest" had nothing to do with the medication he was taking; he was told by his physician there was a possibility that his shoulder, eye, face and/or neck tremors were caused by Risperdal, but that other drugs could have also caused the tremors; none of his doctors told him that he has an increased risk of sudden death from heart attack as a result of using Risperdal; his physicians could not find any medical reason behind his blood sugar issues and they never associated the problem with Risperdal; no doctor told him that Risperdal caused him to be suicidal; he was told by Dr. Desrosiers that his respiratory infections could have come from taking Risperdal; no physician told him directly that Risperdal caused dry skin, but Dr. Desrosiers stated it is one of the residual effects of the drug; Dr. Desrosiers did not specifically say that Plaintiff's joint pain was caused by Risperdal but she classified it as one of the side effects of the drug; he has not been told by a physician that Risperdal caused sore throats; Dr. Desrosiers told him that headaches could be associated with Risperdal but other drugs Plaintiff was taking could have also caused headaches; a physician Plaintiff saw prior to Dr. Desrosiers did not associate the headaches with Risperdal and thought the headaches could be related to stress or another drug Plaintiff was taking; Dr. Desrosiers told him that blurred vision could be associated with the use of Risperdal but it was not necessarily the cause of Plaintiff's blurred vision; and Dr. Desrosiers told Plaintiff that memory lapse is a possible side effect from taking Risperdal, but no physician has told Plaintiff that his memory lapses are caused by Risperdal.

May 8, 2018, the Court addressed the issue of an expert and denied Plaintiff's motion following a review of Plaintiff's filings and finding that he failed to make a sufficient showing to warrant appointment of an expert witness. (D.I. 169 at 6; D.I. 170). Plaintiff did not seek reconsideration of that order. Plaintiff's second motion was denied for the same reasons. (*See* D.I. 212; D.I. 213). At the same time as the second denial, the Court set a new dispositive motion deadline of July 10, 2019. (*See* D.I. 213). Plaintiff filed an interlocutory appeal, but he did not raise the issue of appointment of an expert witness on appeal.[19] (*See* D.I. 214). Nor did Plaintiff seek reconsideration of the denial of his second request for appointment of an expert witness. On June 24, 2019, less than a month before the dispositive motion deadline, Plaintiff filed a renewed motion for appointment of an expert and/or for funds for an expert. (D.I. 218). It is currently pending and, based upon the reasoning denying the first and second motions, will also be denied.

Plaintiff was provided competent counsel who ably represented him, yet Plaintiff opted to proceed *pro se*. Plaintiff has the right to proceed *pro se*, but his decision has negative consequences as evidenced by the lack of an expert witness needed to establish "specific causation." (*See, e.g.*, D.I. 169 at 4) Evidence of only "general causation" is insufficient to establish a negligence claim under Delaware law and, based upon the evidence of record, even that is lacking. Plaintiff's own testimony is that his physicians did not directly connect the use of Risperdal to Plaintiff's medical conditions.

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[19] The appeal was dismissed upon Plaintiff's motion on July 25, 2019. (*See* D.I. 231).

Thus, I will grant Defendants' motion for summary judgment on Counts One and Two for lack of proximate cause.

C. Brand Name Liability for Plaintiff's Use of Generic Risperidone

Defendants seek summary judgment on the negligence claims (*i.e.*, Counts One and Two) on the grounds that Plaintiff cannot establish that his alleged injuries resulted from the use of the brand name drug Risperdal. (D.I. 226 at 14-15). Defendants argue that Plaintiff testified a pharmacy record obtained by his prior counsel documented the use of the brand name Risperdal, but the evidence of record does not support Plaintiff's testimony. (*Id.* at 15). Plaintiff argues that Defendants' agents denied him discovery from 2001 through 2014, the record suggests he was administered the generic brand in 2011 and, in dispute, is whether he was administered the generic brand between 2008 through 2011. (D.I. 230 at 13). Plaintiff also argues that a Delaware law for the substitution of medication did not go into effect until 2014. (*Id.*). Plaintiff relies upon 24 Del. C. § 2549A to support his position. The statute, however, is inapplicable to Plaintiff's claim as it applies to the prescription of biological products.

Under federal law, brand name and generic drug manufacturers are not equally responsible for drug labeling. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (citations omitted). This regulatory reality led the Supreme Court in *PLIVA* to find that federal law preempts state tort liability for a generic drug manufacturer's inadequate label. *Id.* at 623-24.

Delaware is among the states that have passed laws permitting pharmacists to substitute generic drugs without a patient's consent to save costs. *See* 24 Del. C. § 2549. A name brand need be dispensed only if the physician specially directs the patient receive a brand name. *Id.* at ¶ 2549(a)(1) & (c). The law went into effect July 24, 2007, prior to the time Plaintiff was first prescribed Risperdal.

In *Trower v. Janssen Pharms., Inc.*, 2019 WL 1571834, *2-4 (D. Del. Apr. 11, 2019), I examined Delaware's products liability law. As I explained more fully there, Delaware law does not support a claim against a brand name drug manufacturer for a plaintiff's use of a generic drug. *See In re Benzene Litig.*, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007) (to state a claim in a products liability case, a plaintiff must plead facts that identify the defective product and the manufacturer of that product); *Lee v. A. C. & S., Inc.*, 1986 WL 15421, at *2 (Del. Super. Ct. Dec. 15, 1986) ("generic identification of a product is not enough to establish liability absent some other evidence that that generic product was the specific product of a defendant")(asbestos context). *See also Strayhorn v. Wyeth Pharms.*, 737 F.3d 378, 406) (6th Cir. 2014) ("[E]very federal court of appeals to consider this issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug, whether under a state's product-liability act or under general principles of duty.").

The evidence of record is that prescriptions were written for Risperdal. However, the only evidence that Plaintiff was administered Risperdal is the August 2008 medication administration record. The medication administration records for September, October, November, and December 2008, and November 2011 indicate that Plaintiff was administered risperidone. There is no evidence of record of the

medication administered to Plaintiff during 2009, 2010, and January through October 2011.

At most, the record reflects that Plaintiff was given Risperdal during the month of August 2018. Plaintiff's position, without evidentiary support, that he was given Risperdal from 2008 through 2011 does not suffice to defeat Defendants' motion for summary judgment on this issue. Accordingly, I will grant Defendant's motion for summary judgment on Counts One and Two, with the exception of the administration of Risperdal during the month of August 2008.

D. Negligent Misrepresentation, Breach of Express Warranty

Count Two raises a claim for negligent misrepresentation and Count Six raises an express warranty claim. Defendants move for summary judgment on the grounds that there is no evidence that Dr. Cannulli relied on Defendants' judgment or superior skill in deciding to prescribe Risperdal for Plaintiff and there is no evidence that Defendants made an express warranty to Dr. Cannulli.

Counts Two and Six both require evidence of communication and reliance.

To prevail on a negligent misrepresentation claim, Plaintiff must show:

> the defendant had a pecuniary duty to provide accurate information, (2) the defendant supplied false information, (3) the defendant failed to exercise reasonable care in obtaining or communicating the information, and (4) Plaintiff suffered a pecuniary loss caused by justifiable reliance upon the false information.

Dunn v. FastMed Urgent Care, P.C., 2019 WL 4131010, at *12 (Del. Ch. Aug. 30, 2019). A plaintiff cannot sustain a claim of negligent misrepresentation when he has failed to produce any evidence that the defendant supplied false information. *See*

Coleman v. Pricewaterhousecoopers LLC, 2005 WL 1952844, at *3 (Del. Super. Ct. July 29, 2005).

Under Delaware law, claims for breach of an express warranty are governed by the Uniform Commercial Code. *See Bell Sports, Inc. v. Yarusso*, 759 A.2d 582, 592 (Del. 2000) (express warranty provisions of Delaware law are "identical" to UCC provisions).[20] "In order to pursue a claim for breach of express warranty, the consumer must produce evidence of reliance on the express warranty." *Barba v. Carlson*, 2014 WL 1678246, at *5 (Del. Super. Ct. Apr. 8, 2014).

Plaintiff opposes summary judgment on both counts. He argues that there was a confusing discovery schedule, which I addressed at pages 9-10. He also argues, without supporting evidence, that his physician was influenced by Defendants' off-label promotions and that Dr. Cannulli prescribed Risperdal for an off-label condition. "Because the [Food, Drug, and Cosmetic Act] does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012)

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[20] Title 6, section 2–313(1) provides that express warranties of a seller of goods are created as follows:

(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

(b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

(c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model. In addition, 6 Del. C. § 2–313(2) states that: It is not necessary to the creation of an express warranty that the seller use formal words such as "warrant" or "guarantee" or that he have a specific intention to make a warranty, but an affirmation merely of the value of the goods or a statement purporting to be merely the seller's opinion or commendation of the goods does not create a warranty.

(citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (recognizing off-label usage as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.")). There is no evidence that Plaintiff relied upon any representations by Defendants, that Defendants made an express warranty to Plaintiff, or that Defendants made an express warranty to Plaintiff's physicians concerning the use of Risperdal to treat off-label conditions.[21] There simply is no evidence to support Plaintiff's claims. Therefore, I will grant Defendants' motion for summary judgment on the claims of Counts Two and Six.

E. Implied Warranty Claims

Count Three raises a breach of warranty claim (construed as a breach of implied warranty), Count Four raises a breach of implied warranty of merchantability claim, and Count Five raises a breach of implied warranty of fitness for a particular purpose claim.

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[21] The Court takes judicial notice that Janssen, a subsidiary of Johnson & Johnson, entered into a plea agreement with the United States Department of Justice, and pled guilty to promoting Risperdal to health care providers for treatment of psychotic symptoms and associated disturbances exhibited by elderly, non-schizophrenic dementia patients, between March 3, 2002 and December 31, 2003. *See* https://www.justice.gov/usao-edpa/pr/janssen-pharmaceuticals-pleads-guilty-and-sentenced-misbranding (last visited Jan. 29, 2020). The issues to which Janssen pled guilty are not only different from the issues raised by Plaintiff in his Amended Complaint, but also took place during the different time-frame of 2002-03. The Court also takes judicial notice of Janssen's 2012 multi-state (including Delaware) consumer protection settlement, which alleged that Janssen promoted Risperdal, among a class of drugs known as atypical or second-generation antipsychotics, for off-label uses to both geriatric and pediatric populations, targeting patients with Alzheimer's disease, dementia, depression, and anxiety. *See* https://news.delaware.gov/2012/08/30/biden-announces-landmark-settlement-with-janssen-pharmaceuticals (last visited Jan. 29, 2020). The settlement was not an admission of wrongdoing or violation of any law or regulation. *See* https://www.jnj.com/media-center/press-releases/janssen-pharmaceuticals-inc-announces-risperdal-consumer-protection-settlement-with-36-states-and-the-district-of-columbia (last visited Jan. 29, 2020). The issues in the multi-state consumer protection settlement are different from those issues raised by Plaintiff in his Amended Complaint.

Defendants seek judgment on the grounds that Counts Three, Four, and Five are time-barred.[22]

In Delaware, all actions for breach of an implied warranty are limited by the provisions set forth in § 2–725 of Title 6 of the Delaware Code. *Addison v. Emerson Elec. Co.*, 1997 WL 129327, at *3 (D. Del. Feb. 24, 1997) (citing *Johnson v. Hockessin Tractor, Inc.*, 420 A.2d 154, 158 (Del. 1980)). This section provides for a four-year statute of limitations and applies even in cases involving personal injuries. *Id.* The cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge. *LTL Acres L.P. v. Butler Manuf. Co.*, 2016 WL 7336862, at *2 (Del. Super. Ct. Dec. 16, 2016). The breach occurs when the goods are delivered. *Id.*

Plaintiff argues, without evidentiary support, that he last used Risperdal in July 2013. Plaintiff relies upon a June 2014 medical grievance, which states that a chart review indicated that Risperdal had not been ordered for Plaintiff since July 25, 2013. This grievance report, however, does not indicate that Plaintiff was administered Risperdal. The evidence of record indicates that Plaintiff was administered Risperdal in August 2008, and not on other dates. Plaintiff did not commence this action until 2014.

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[22] Defendants also argue that Plaintiff's personal injury claims are time-barred. The Court does not decide summary judgment on this basis given that granting summary judgment is appropriate on other grounds. The Court notes, however, that in 2014, Plaintiff filed a lawsuit similar to this one in the Superior Court alleging that he "suffered adverse side-effects after taking a medication prescribed to him in prison." *Evans v. Genentech, Inc.*, 2015 WL 310248 (Del. Super. Ct. Jan. 23, 2015). He was prescribed medication in 2007 but it was not until 2014 that he became aware his symptoms could have been caused by the medication taken in 2007. The Superior Court dismissed the case as time-barred, noting that as early as 2006 the medical community was on notice of potential side effects resulting from the use of the medication, as was apparent from the drug's packaging insert.

His implied warranty claims are therefore clearly time-barred. I will grant Defendants' motion for summary judgment on these claims.[23]

F. Fraud by Concealment

Count Seven alleges that Defendants knowingly and intentionally concealed, suppressed and/or omitted important information to physicians and consumers regarding the safety of Risperdal. Defendants move for summary judgment on the grounds that there is no evidence of any affirmative action by Defendants to conceal any of alleged side effects Plaintiff claims to have experienced or to conceal any alleged fraud.

To establish a claim for fraudulent concealment or intentional misrepresentation, Plaintiff must show:

> (1) Deliberate concealment by the defendant of a material past or present fact, or silence in the face of a duty to speak; (2) That the defendant acted with scienter; (3) An intent to induce plaintiff's reliance upon the concealment; (4) Causation; and (5) Damages resulting from the concealment.

Nicolet, Inc. v. Nutt, 525 A.2d 146, 149 (Del. 1987).

Plaintiff argues that Defendants' off-label promotions concealed facts that the drug was not tested or approved for uses not listed. He also argues that the warning labels were not adequate. The evidence of record does not support Plaintiff's claim. Notably, Plaintiff testified that he had no communication with Defendants before filing

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[23] Summary judgment is also appropriate on Count Four as Plaintiff lacks the required expert testimony. *See Reybold Grp., Inc. v. Chemprobe Tech., Inc.*, 721 A.2d 1267, 1269-70 (Del. 1998) (In a breach of warranty of merchantability claim, "[i]f the matter in issue is one within the knowledge of experts only and not within the common knowledge of laymen, it is necessary for the plaintiff to introduce expert testimony in order to establish a *prima facie* case" of the "defective" nature of the goods.). The Court addressed Plaintiff's lack of expert testimony at pages 11-12 when discussing proximate cause.

this action and, in deciding to take Risperdal, he did not rely on anything from Janssen or Johnson & Johnson. (D.I. 227-1 at Ex. G at 145, 146). Rather, he relied upon his physician. I will therefore grant Defendants' motion for summary judgment on this issue.

IV. MISCELLANEOUS MOTIONS

There are a number of motions filed by the parties. I will deny Plaintiff's letter/motion for issuance of subpoenas and for a hearing. (D.I. 215). The discovery deadline has passed. For the same reason, I will dismiss as moot Defendants' motion for a protective order for subpoenas. (D.I. 224).

Plaintiff again has filed a motion to appoint an expert. (*See* D.I. 218). I will deny the motion for the reasons set forth in the Court's earlier orders. (*See* D.I. 169; D.I. 170; D.I. 212; D.I. 213). In addition, I note from Plaintiff's deposition testimony that his treating physicians did not directly associate his alleged medical issues with the use of Risperdal.

I will deny Plaintiff's motion for leave to amend and to extend discovery. (D.I. 220). Plaintiff did not comply with the Local Rules of this court in seeking leave to amend. Plaintiff is well aware of this Rule given that the Court referred to it in a 2017 order striking Plaintiff's Amended Complaint that he filed without leave. (*See* D.I. 95). Plaintiff seems to seek to amend based upon "knowledge gleaned" from discovery provided him, but does not indicate which portions of the Amended Complaint he wishes to amend or why it is necessary. In addition, Plaintiff has been given ample time to conduct discovery. Therefore, I will deny his request to extend the discovery deadline.

Plaintiff has filed numerous requests for counsel. (D.I. 218; D.I. 221; D.I. 233; D.I. 236). I will deny his requests. Early in this litigation, the Court referred this matter to the Federal Civil Panel and, on July 28, 2015, the Court recognized the agreement of representation by an attorney for Plaintiff. (*See* D.I. 13; D.I. 17). On October 12, 2017, Plaintiff filed a motion to proceed *pro se*. (D.I. 85). The Court was advised by Plaintiff's counsel that the attorney-client relationship had deteriorated. (D.I. 87). Plaintiff's reasons for returning to *pro se* status were that his attorney withheld information and failed to forward him discovery. This same attorney ably represented several other inmates who filed complaints over their use of Risperdal. After Plaintiff opted to return to *pro se* status, the Court made various rulings to make it possible for Plaintiff to obtain and review the discovery that seemed most important to him. (*See* D.I. 169; D.I. 170, D.I. 194; D.I. 212; D.I. 213).

If the district court determines that a plaintiff's claim has arguable merit in fact and law, the court considers a number of additional factors that bear on the need for appointed counsel including: (1) the plaintiff's ability to present his own case, (2) the complexity of the legal issues, (3) the degree to which factual investigation will be necessary and the ability of the plaintiff to pursue investigation, (4) the plaintiff's capacity to retain counsel on his own, (5) the extent to which a case is likely to turn on credibility determinations, and (6) whether the case will require expert witness testimony. *See Tabron v. Grace*, 6 F.3d 147 (3d Cir. 1993).

As observed by Delaware courts, Plaintiff is "a prolific litigant who has gained notoriety among the Delaware courts." *Evans v. Genentech, Inc.*, 2015 WL 310248, at *1 (Del. Super. Ct. Jan. 23, 2015). He has filed eleven additional federal lawsuits in this

Court since the instant case was removed to this Court. Plaintiff testified that prior to his incarceration he graduated from a paralegal course. (*See* D.I. 223-1 at 70-71). Although certain issues raised by Plaintiff would have required supportive expert testimony in order for Plaintiff to have been able to proceed, Plaintiff's own deposition testimony is that none of his physicians determined his medical conditions were necessarily related to the use of Risperdal, which supports my conclusion that Plaintiff's claims do not have arguable merit in fact. In addition, Plaintiff was afforded counsel, but opted to proceed *pro se*. He is a frequent litigator and has the ability to present, and has ably presented, his own case. Furthermore, viable claims of the type he raises are the sort that lawyers routinely take on a contingency basis. Plaintiff probably knows this. (*See* D.I. 218 at 9 ("Free Risperdal Lawsuit Evaluation: If you or a loved one has been injured by Risperdal, you should contact our law firm immediately. You may be entitled to compensation by filing a lawsuit and we can help." (emphasis in original))). Plaintiff could have sought counsel of his own choice; there is nothing in the record that he ever tried. In light of the foregoing, I will deny Plaintiff's requests for counsel.

V. CONCLUSION

Based upon the above discussion, the Court will: (1) deny Plaintiff's letter/motion for issuance of subpoenas and for a hearing (D.I. 215), motion for appointment and/or funds for expert (D.I. 218), motion for leave to amend (D.I. 220), and requests for counsel (D.I. 218; D.I. 221; D.I. 233; D.I. 236); (2) dismiss as moot Defendants' motion for protective order (D.I. 224); and (3) grant Defendants' motion for summary judgment (D.I. 225).

A separate order shall issue.