UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

REGINALD S. COLE, JR.,

Plaintiff,

v. Case No. 15-CV-57

JANSSEN PHARMACEUTICALS, INC.,

Defendant.

DECISION AND ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

The plaintiff, Reginald S. Cole, Jr. (Cole), is a Wisconsin state prisoner representing himself. He is proceeding on a products liability claim against the defendant, Janssen Pharmaceuticals, Inc. (Janssen). The Court has jurisdiction of this action under 28 U.S.C. § 1332. This matter is before the Court on Janssen's motion for summary judgment.

FACTS[1]

Cole is an inmate housed at Waupun Correctional Institution (Waupun) in Wisconsin. He has been incarcerated since April 2007. Cole alleges that his ingestion of the prescription drug Risperdal caused him adverse side effects including migraines, swollen and sore chest, cramping, throwing up blood, stomach pains, dizziness, weakness, nausea, and an elevated prolactin level. He also alleges that Risperdal caused him to develop gynecomastia, a condition in which a male experiences an enlargement of breast tissue.

[1] This section is taken from Janssen's Statement of Proposed Material Facts and from Cole's Statement of Proposed Material Facts. ECF Nos. 134, 172. Relevant facts that comply with Federal Rule of Civil Procedure 56(c) are included in this section.

Risperdal is a prescription antipsychotic medication manufactured and distributed by Janssen. It was first approved for sale in the United States by the FDA in 1993 to treat adult schizophrenia patients. Risperdal is generically known as Risperidone. Since its approval and until the present day, Risperdal's FDA-approved label has always disclosed that Risperdal, like other medicines in its class, has been associated with endocrine-related side effects, including reported cases of gynecomastia. The FDA-approved label has also included the following adverse side effects: vomiting, abdominal pain, and nausea.

Janssen lost its patent protection for Risperdal in June 2008. In July 2008, generic Risperidone that was produced, marketed, and sold by many manufacturers (including Janssen) became widely available. Janssen stopped marketing brand-name Risperdal in 2008. By the end of 2009, Janssen's Risperdal sales had declined by 95.5%.

Risperdal, or its generic equivalent, was prescribed for Cole and discontinued at various times between May 2007 and October 2013. Cole's use of Risperdal in particular appears to have been for relatively short periods of time. Risperdal was prescribed to Cole in May 2007. It was discontinued in July 2007 due to Cole's refusal to take it. Risperdal was again prescribed for Cole in September 2007 but again discontinued in December 2007 because Cole refused to take it. Risperdal by name was last prescribed to Cole in February 2008 but discontinued in April 2008.

Risperidone was prescribed to Cole in December 2012. In the fall of 2013, Cole saw a plaintiff's personal injury law firm's ad on television stating that persons who took Risperdal and developed gynecomastia might be entitled to substantial compensation. After watching the ad, Cole suggested to his health-care professionals that he might suffer from gynecomastia.

On September 26, 2013, upon physical examination for gynecomastia, the nurse noted that Cole's exam was "unremarkable," there was "no nipple dimpling or discharge" and "no palpable lumps." Cole's nurse documented that he was a "questionable historian." Cole's nurse concluded that there was no "objective evidence of gynecomastia or breast abnormality." ECF No. 137-1 at 33.

On October 2, 2013, Cole's psychiatrist, Dr. Ralph Froelich, discontinued Cole's Risperidone prescription based on Cole's subjective complaints. Dr. Froelich's Psychiatric Report from the appointment states that Cole complained of breast tenderness and that Cole "is informed that the risperidone he has been on of [sic] several years may be causing the problem and I informed him that I would stop the medication and do some lab work so we can explain it on the basis of increased prolactin." *Id.* at 170.

On October 16, 2013, Cole saw Dr. Froelich and the doctor's Psychiatric Report from that appointment states in relevant part that Cole is "less worried about his breast enlargement" and that the "tenderness is gone." The report also states that Cole "reports no difficulties since [Dr. Froelich] stopped the risperidone." Additionally, the report states that, "[r]ecent laboratory values revealed a prolactin level of 26.8, with a reference range of 4.0 to 15.2. This was ordered because of his complaint of breast tenderness. Although there was no breast enlargment felt on exam, the elevated prolactin could be an explanation for the complaint." *Id.* at 168.

Dr. Froelich's Psychiatric Report from a December 11, 2013, appointment with Cole states in relevant part that Cole "has also had a problem with breast tenderness which may have been related to elevated prolactin and has been discontinued from potential medications causing that which was risperidone." The report also stated that Cole "has managed well without risperidone." *Id.* at 166.

As noted above, a lab test taken in October 2013 revealed Cole had elevated prolactin. The follow-up lab test taken in January 2014 revealed that Cole's prolactin levels had returned to normal. Cole continued to complain about chest pain and "gynecomastia" but subsequent physical exams revealed that Cole's chest continued to be within normal limits.

The word "gynecomastia" appears approximately six times in Cole's medical records. Each time it appears, Cole's health care professionals were either describing Cole's subjective complaints about the same or reporting that there was no objective evidence of the same. He was never diagnosed with gynecomastia. Cole has no medical training and is not licensed to practice medicine. No expert has opined that Risperdal caused Cole's purported injuries.

Throughout Cole's incarceration, he complained about the symptoms he now attributes to Risperdal, even when he was not taking Risperdal. For instance, Cole complained of chest pain during his incarceration numerous times when he was not taking Risperdal. He complained that contaminated milk caused him migraines, chest cramping, throwing up blood, and stomach pains in another case he filed in the Eastern District of Wisconsin. *See Cole v. Thurman, et al.*, E.D. Wis. Case No. 08-C-0695, ECF No. 1 at 4. Cole once reported having breast reduction surgery, though a physical exam and chart review revealed no evidence of breast reduction surgery. During his deposition, Cole denied having had breast reduction surgery.

Cole's medical records reveal that in April 2010, he agreed that his self-report psychotic behaviors were less than genuine. After purportedly attempting to commit suicide by overdosing on Citalopram in May 2010, Cole's medical records note that he acknowledged that he was never suicidal and was simply "having some fun you know how it is." ECF No. 139-1 at 191. Cole's medical history is also replete with complaints about hearing voices, seeing ghosts, trouble sleeping,

chest pain, vomiting, migraines, nausea and various other complaints. Cole admits that he pretended to suffer from mental illness hoping to be transferred from Waupun to the Wisconsin Resource Center, which is a mental health treatment facility within the Wisconsin Department of Corrections.

Cole filed his amended complaint in this matter, naming Janssen as a defendant on May 16, 2015, seeking billions of dollars in damages for his alleged injuries. Cole's sole theory that Risperdal is defective is its potential to cause adverse side effects. No expert has opined that Risperdal is defective as it relates to Cole's ingestion thereof or that it is a cause of any of the symptoms alleged.

SUMMARY JUDGMENT STANDARD OF REVIEW

Under the Federal Rules of Civil Procedure, summary judgment "is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1). Summary judgment is proper if the pleadings, depositions, answers to interrogatories, and admissions on file, together with any affidavits, show that there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322.

As *Celotex* makes clear, the burden that each party carries with respect to a motion for summary judgment under the federal rules varies significantly depending upon which party bears the burden of proof at trial on the issue upon which summary judgment is sought. Where the party

seeking summary judgment does not bear the burden of proof at trial on any element of the claim, it is enough that it inform the court of "the basis of its motion and identif[y] those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any,' which it believes demonstrates the absence of a genuine issue of material fact." *Id.* at 323. There is no requirement that a moving party who does not bear the burden of proof establish that the element does not exist. In other words, a moving party who does not have the burden of proof at trial, (usually the defendant), is not required to prove a negative in order to make a prima facie showing for summary judgment. *Id.*

Once such a showing is made, however, the nonmoving party who does have the burden of proof at trial, (usually the plaintiff), must respond. In the face of a properly supported motion for summary judgment by the defendant, the plaintiff must designate specific facts to support or defend each element of the cause of action, showing that there is a genuine issue for trial. *Id.* at 322–24. Moreover, the party that bears the burden of proof at trial must show that it has admissible evidence to support its claim:

> When as in the present case a defendant moves for summary judgment on the ground that the plaintiff lacks evidence of an essential element of his claim, the plaintiff is required by Fed.R.Civ.P. 56, if he wants to ward off the grant of the motion, to present evidence of evidentiary quality—either admissible documents or attested testimony, such as that found in depositions or in affidavits—demonstrating the existence of a genuine issue of material fact. The evidence need not be in admissible form; affidavits are ordinarily not admissible evidence at a trial. But it must be admissible in content, in the sense that a change in form but not in content, for example a substitution of oral testimony for a summary of that testimony in an affidavit, would make the evidence admissible at trial.

Winskunas v. Birnbaum, 23 F.3d 1264, 1267–68 (7th Cir. 1994) (internal citations omitted). It is for this reason that summary judgment is referred to in federal courts as the "put up or shut up

moment in a lawsuit." *Johnson v. Cambridge Indus., Inc.*, 325 F.3d 892, 901 (7th Cir. 2003) (internal quotes omitted).

DISCUSSION

Janssen contends that the Court should grant its motion for summary judgment because Cole cannot prove that Risperdal caused any of his alleged injuries and because Cole cannot show that Risperdal is defective. Janssen also contends that the statute of limitations bars Cole's claims of injuries from Risperdal in 2007 and 2008, and that Cole cannot show that he took Risperdal in 2012 and 2013. Cole filed a response in which he contends that he can demonstrate a causal link between his injuries and the ingestion of Risperdal. He also contends that Janssen's product is defective.

In product liability claims in Wisconsin, whether under a strict liability theory or a negligence theory, a plaintiff is required to prove that the allegedly defective product caused his injuries. *See Morden v. Continental AG*, 2000 WI 51, ¶ 45, 235 Wis. 2d 325, 611 N.W.2d 659 (negligence); Wis. Stat. § 895.047(1)(e) (strict product liability); *Peters v. AstraZeneca LP*, 224 Fed. Appx. 503, 506 (7th Cir. 2007). To prove causation in a products liability case, a plaintiff ordinarily must provide expert testimony because of the specialized knowledge required. *Peters*, 224 Fed. Appx. at 506. Expert testimony is required if the issue to be decided is outside the common knowledge of a layman. *Johnson v. Mylan Inc.*, 107 F. Supp. 3d 967, 972 (E.D. Wis. 2015) (citing *City of Cedarburg Light & Water Comm'n v. Allis-Chalmers Mfg. Co.*, 33 Wis. 2d 560, 568, 149 N.W.2d 661, 662 (1967)). Cole's claim that the ingestion of a prescription drug injured him is the type of claim where an expert witness is required. *See City of Cedarburg*, 33 Wis. 2d at 568; *Johnson*, 107 F. Supp. 3d at 975; *Peters*, 224 Fed. Appx. at 506–07.

Cole does not have an expert witness. Instead, he points to his medical records and contends that the psychiatric reports from Dr. Froelich as well as the nurse evaluation support his claim that Risperdal caused his injuries. However, Cole's medical records do not support his contention that Risperdal caused him gynecomastia or any other injury. As an initial matter, Cole was never diagnosed with gynecomastia. In September 2013, a nurse examined Cole for gynecomastia and determined that he did not have it. No medical professional opined that Risperdal caused Cole any adverse side effects in 2007 and 2008, when he took Risperdal. And while Dr. Froelich stated in his psychiatric report that the ingestion of Risperidone might explain Cole's breast sensitivity due to an elevated prolactin level, there is no evidence in the record to support a finding that Risperidone or Risperdal caused any breast sensitivity. *See C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 832 (7th Cir. 2015); *Valente v. Sofamore, S.N.C.*, 48 F. Supp. 2d 862, 870 (E.D. Wis. 1999).

"[I]t is the plaintiffs' burden to introduce 'evidence which affords a reasonable basis for the conclusion that it was more likely than not that conduct of the defendant manufacturer was a substantial factor in the injury.'" *Johnson*, 107 F. Supp. 3d at 975 (quoting *Jagmin v. Simonds Abrasive Co.*, 61 Wis. 2d 60, 74, 211 N.W.2d 810, 817 (1973)). Cole has not introduced evidence to show that Risperdal caused him any injury. Nor has he provided any evidence in support of his contention that Risperdal is defective.

Janssen also contends that even if Cole could prove that Risperdal was defective and caused him injury, the statute of limitations would bar the claim because Cole has not shown that he took Risperdal after 2008. The Wisconsin statute of limitations applicable to personal injury claims, such as this, is three years. *See* Wis. Stat. § 893.54. Under Wisconsin law, however, the statute does not begin to run until the plaintiff "discovers, or in the exercise of reasonable diligence should have

discovered, not only the fact of injury but also that the injury was probably caused by the defendant's conduct or product." *Forst v. SmithKline Beechem Corp.*, 602 F. Supp. 2d 960, 964 (E.D. Wis. 2009) (quoting *Nierengarten v. Lutheran Soc. Servs.*, 219 Wis. 2d 686, 580 N.W.2d 320, 324–25 (1998)). Here, the undisputed evidence is not so clear as to allow a determination as to when Cole discovered or should have discovered his claim against Janssen. Accordingly, summary judgment will not be granted on Janssen's statute of limitations defense. But on the merits, as explained above, Cole has failed to demonstrate that he has any evidence on which a properly instructed jury could find that Risperdal is unreasonably defective or that it was a cause of any injury he sustained. Janssen is entitled to summary judgment.

ORDER

IT IS THEREFORE ORDERED that the defendant's motion for summary judgment (ECF No. 132) is **GRANTED**. The Clerk is directed to enter judgment of dismissal.

Dated at Green Bay, Wisconsin this 12th day of December, 2017.

s/ William C. Griesbach
William C. Griesbach, Chief Judge
United States District Court

This order and the judgment to follow are final. The plaintiff may appeal this court's decision to the Court of Appeals for the Seventh Circuit by filing in this court a notice of appeal within **30 days** of the entry of judgment. *See* Fed. R. App. P. 3, 4. This court may extend this deadline if a party timely requests an extension and shows good cause or excusable neglect for not being able to meet the 30-day deadline. *See* Fed. R. App. P. 4(a)(5)(A). If the plaintiff appeals, he will be liable for the $505.00 appellate filing fee regardless of the appeal's outcome. If the plaintiff seeks leave to proceed *in forma pauperis* on appeal, he must file a motion for leave to proceed *in forma pauperis* with this court. *See* Fed. R. App. P. 24(a)(1).

A party is expected to closely review all applicable rules and determine, what, if any, further action is appropriate in a case.