

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

NATALIE T. VARGAS,

Plaintiff,

Case No. 1:08 oe 40113

-vs-

MEMORANDUM OPINION

ORTHO-MCNEIL PHARMACEUTICAL, INC.,

Defendant.

KATZ, J.

BACKGROUND

This is a product liability case in which Plaintiff alleges the use of the Defendant's product caused her to suffer various injuries. This case is one of many to arise out of the litigation involving the ORTHO EVRA® birth control patch.

In March 2006, the Judicial Panel on Multidistrict Litigation, pursuant to 28 U.S.C. § 1407, centralized all civil litigation in the Northern District of Ohio, noting the following common allegations:

i) the Ortho Evra contraceptive patch was defectively designed, and ii) plaintiffs received inadequate warnings regarding Ortho Evra's side effects and safety profile. All actions seek damages for personal injury and/or economic damages on behalf of users of Ortho Evra, asserting various state law claims, such as negligence, products liability, breach of warranties, and negligent and/or fraudulent misrepresentation regarding the risks of using Ortho Evra.

In re Ortho Evra Products Liability Litigation, 1:06 cv 40000, MDL 1742 (N.D. Ohio) (Doc. No. 1).

Natalie Vargas ("Plaintiff"), a resident of New York, initiated an action for strict liability, negligence and breach of warranty against Defendant Ortho-McNeil Pharmaceutical, Inc. (now known as Janssen Pharmaceuticals, Inc.) ("Defendant"), a corporation licensed to do business in the state of New Jersey. Plaintiff filed her complaint on August 23, 2007, in the Supreme Court of

New York, Kings County. (Doc. 1.) Defendant removed the case to the Eastern District of New York on September 17, 2007. (*Id.*) The case was then transferred to the multidistrict litigation (MDL) pending before this Court, in March 2008. (Doc. 8.)

Plaintiff asserts that she developed ovarian cysts, a benign ovarian tumor and ovarian torsion as a result of her use of an ORTHA EVRA® patch. Plaintiff went to the emergency room complaining of acute abdominal pain and nausea. (Doc. 53, Attach. 10.) Doctors performed exploratory surgery and determined that Plaintiff had ovarian cysts and ovarian torsion. (*Id.*) Doctors removed the cysts, her ovary and part of the fallopian tube. (*Id.*) One of the cysts removed was a rare, but benign, tumor called a Struma Ovarii. (*Id.*) Plaintiff alleges these injuries were caused by her use of the contraception, ORTHA EVRA®. (Doc. 53, Attach. 5.)

This case has a long procedural history¹ and Plaintiff has been given much latitude and time to comply with the Court's orders². In light of her *pro se* status, the Court granted Plaintiff the following extensions and waivers:

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On February 9, 2009, in response to Defendant's motion to compel, the Court granted Plaintiff until February 20, 2009 to respond. Two show cause orders were then issued by the Court. (Doc. Nos. 12, 15.) Following a hearing on May 12, 2009, the Court dismissed Plaintiff's case for failure to comply with the show cause orders.

On July 9, 2009, Plaintiff faxed a letter to the Court requesting an extension or legal aid. (Doc. 23.) The Court mailed the *pro se* Plaintiff a letter, dated July 13, 2009, directing her to the United States Court of Appeals for the 6th Circuit and referencing Plaintiff's lead counsel, Janet Abaray.

On February 8, 2011, the United States Court of Appeals for the 6th Circuit reversed and remanded, reinstating the case. (Doc. 21, 24.)

Plaintiff was initially represented by counsel in this matter, but on July 11, 2011, she opted to proceed *pro se*. (Doc. 32.)

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After Plaintiff failed to produce timely discovery items the Court asked Defendant to help guide Plaintiff by creating a letter outlining how the case was to proceed. The Defendant complied. (Doc. 53, Attach. 10, Ex. I.)

- On March 28, 2011, Plaintiff was granted additional time to obtain counsel. The Court also vacated the scheduled status conference and rescheduled a telephone conference, per Plaintiff's request. (Doc. 26, 27.)
- On May 5, 2011, Plaintiff was granted an additional 50 days to obtain counsel. (Doc. 30.)
- On October 6, 2011, Plaintiff was excused from attending the status conference in-person. (Doc. 39.)
- On January 19, 2012, Plaintiff was granted an extension of various discovery deadlines. (Doc. 41, 42.)
- On April 19, 2012, Plaintiff was granted additional time to secure a specific causation expert report. (Doc. 47.) The Court advised Plaintiff during that status conference this would be the last extension.
- On June 28, 2012, Plaintiff was granted additional time to obtain reports or a physician's affidavit. (Doc. 49.) The Court made clear this would be the last extension granted to Plaintiff³.

This matter is now before the Court on Defendant's motion for summary judgment in regard to Plaintiff's lack of expert testimony for product liability claims. Also before the Court are Plaintiff's response, Defendant's reply and Plaintiff's sur-reply. This Court has jurisdiction under 28 U.S.C. § 1332. For the reasons stated below, the Defendant's motion for summary judgment is granted.

DISCUSSION

A. Applicable Legal Standards

a. Summary Judgment Standard

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Plaintiff was ordered to file a response to Defendant's motion for summary judgment by September 17, 2012. (Doc. 54.) Plaintiff's response was filed on September 24, 2012. (Doc. 55.)

Summary judgment is appropriate where “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 bears the initial responsibility of “informing the district court of the basis for its motion, and identifying those portions of ‘the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,’ which it believes

demonstrate the absence of a genuine issue of material fact.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The movant may meet this burden by demonstrating the absence of evidence supporting one or more essential elements of the non-movant’s claim. *Id.* at 323-25. Once the movant meets this burden, the opposing party “must set forth specific facts showing that there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986) (*quoting* FED. R. CIV. P. 56(e)).

Once the burden of production has so shifted, the party opposing summary judgment cannot rest on its pleadings or merely reassert its previous allegations. It is not sufficient “simply [to] show that there is some metaphysical doubt as to the material facts.” Rather, Rule 56(e) “requires the nonmoving party to go beyond the pleadings” and present some type of evidentiary material in support of its position. *Celotex*, 477 U.S. at 324; *see also Harris v. General Motors Corp.*, 201 F.3d 800, 802 (6th Cir. 2000). Summary judgment must be entered “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.

“In considering a motion for summary judgment, the Court must view the facts and draw all reasonable inferences therefrom in a light most favorable to the nonmoving party.” *Williams v.*

Belknap, 154 F. Supp. 2d 1069, 1071 (E.D. Mich. 2001) (citing *60 Ivy Street Corp. v. Alexander*, 822 F.2d 1432, 1435 (6th Cir. 1987)). However, “at the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter,” *Wiley v. U.S.*, 20 F.3d 222, 227 (6th Cir. 1994) (quoting *Anderson*, 477 U.S. at 249); therefore, “[t]he Court is not required or permitted . . . to judge the evidence or make findings of fact.” *Williams*, 154 F. Supp. 2d at 1071. The purpose of summary judgment “is not to resolve factual issues, but to determine if there are genuine issues of fact to be tried.” *Abercrombie & Fitch Stores, Inc. v. Am. Eagle Outfitters, Inc.*, 130 F. Supp. 2d 928, 930 (S.D. Ohio 1999). Ultimately, this Court must determine “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52; *see also Atchley v. RK Co.*, 224 F.3d 537, 539 (6th Cir. 2000).

The Federal Rules of Civil Procedure control here, not state procedural cases or rules⁴. FED. R. CIV. P. 1; *see also Willy v. Coastal Corp.*, 503 U.S. 131, 134-135 (1992) (scope of Rules covers all civil actions in district court proceedings, including civil actions removed from state court). “They should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding.” FED. R. CIV. P. 1.

b. Pro Se Litigant Standard

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Plaintiff incorrectly states summary judgment standards from three New York appellate cases should apply here. (Doc. 55 at 2-3.) This is because removal of an action to federal court divests the state court of jurisdiction. 28 U.S.C. § 1446(d). Once removed to federal court, a civil case is subject to the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 81(c) governing removed actions (“These rules apply to a civil action after it is removed from a state court.”)

Pro se complaints are held to “less stringent standards than formal pleadings drafted by lawyers.” *Haines v. Kerner*, 404 U.S. 519, 520 (1972). However, a plaintiff who invokes the right to self-representation does not acquire ‘a license not to comply with relevant rules of procedural and substantive law.’ *Eagle Eye Fishing Corp. v. U.S. Dept. of Commerce*, 20 F.3d 503, 506 (1st Cir. 1994) (quoting *Faretta v. California*, 422 U.S. 806, 835 n. 46 (1975), *cert denied*, 476 U.S. 1172 (1986)). “When a [pro se litigant] chooses to represent himself, he should expect no special treatment which prefers him over others who are represented by attorneys.” *Bass v. Wendy’s of Downtown, Inc.*, 2013 WL 2097359 *2 (2013), quoting *Brock v. Hendershott*, 840 F.2d 339, 343 (6th Cir. 1988).

B. Causation

Generally, under New York law, “whether the action is pleaded in strict products liability, breach of warranty or negligence, it is a consumer’s burden to show that a defect in the product was a substantial factor in causing the injury....” *Tardella v. RJR Nabisco, Inc.*, 576 N.Y.S.2d 965, 966 (3d Dep’t 1991); *see also Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 271 (2d Cir. 2002) (affirming the district court’s grant of defendant’s motion for summary judgment “because of plaintiff’s failure to present any admissible evidence in support of their theory of causation”).

“Expert testimony with reference to proximate causation is not always required” in all products liability cases. *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 110 (1983) (“jury could have found proximate causation from its consideration of the characteristics of the circular saw and plaintiff’s description of how the accident happened”). Where the subject-matter is not within the “common knowledge and experience” of the average juror, then “ordinarily, expert

medical opinion evidence... is required.” *Donovan v. Centerpulse Spine Tech Inc.*, 416 F. App’x 104, 106 (2d Cir. 2011) (quoting *Meiselman v. Crown Heights Hosp.*, 34 N.E.2d 367, 370 (1941)).

When the central issue in a products liability case is a medical question, expert testimony is required to establish causation. *Fane v. Zimmer, Inc.*, 927 F.2d 124, 128 (2d Cir.1991) (applying New York law). In *Fane*, the plaintiff brought products liability claims against the manufacturer of internal fixation device, or key-free device, which had been placed in her hip to help it heal from a fracture. The court found she failed to establish causation between the product and her injuries, and affirmed the lower court’s directed verdict for the defendant. *Id.* at 131 - 132. The panel in *Fane* explained why expert testimony is necessary to prove causation in complex medical cases:

Ordinarily, expert medical opinion evidence, based on suitable hypotheses, is required, when the subject-matter to be inquired about is presumed not to be within common knowledge and experience and when legal inference predominates over statement of fact, to furnish the basis for a determination by a jury of unskilled practice and medical treatment by physicians; but where the matters are within the experience and observation of the ordinary jurymen from which they may draw their own conclusions and the facts are of such a nature as to require no special knowledge or skill, the opinion of experts is unnecessary.

Id. at 131 (quoting *Meiselman*, 285 N.Y. at 396).

Here, the injuries alleged by Plaintiff, just like the injuries in *Fane*, are complex medical issues and not within the common knowledge of jurors. An ordinary juror is highly unlikely to know whether ovarian cysts, ovarian torsion, and Struma Ovarii are commonly caused by use of ORTHA EVRA®. In fact, an ordinary juror is unlikely to have any knowledge of these medical conditions, let alone be familiar with their causes. It is clear that the determination of causation in

this case requires the testimony of medical experts, which Plaintiff has repeatedly failed to provide. (Doc. 53, Attach. 7.)

Plaintiff cites to a variety of cases to assert that expert medical testimony is not necessary. However, the cases she relies upon are distinguishable because the majority of them are workers' compensation cases or they involve products liability cases in which admissible evidence of causation was presented.

For example, in *Marley Const. Co. v. Westbrook*, 234 Miss. 710 (Miss. 1948), a claimant was deemed to establish causation of his injury as the evidence showed his pain began on the day of the accident and the report of Dr. Turner disclosed the probability the pain was due to the accident alleged by the claimant. *Id.* at 722-723. Likewise, in *Nash-Kelvinator Corp. v. Industrial Comm'n*, 253 Wis. 618 (1948), the claimant's award was affirmed because the commission correctly took into account the "facts testified to by lay witnesses" and was not bound by the medical testimony as the medical witnesses were unable to conclusively establish the cause of the claimant's atrophy. *Id.* at 625, 34 N.E.2d at 824.

In another case alleging disability due to a work incident, the district court affirmed a finding of disability despite the absence of medical expert testimony. *Jarka Corp. of Philadelphia v. Norton*, 50 F.Supp. 221, 288 (D.C. Pa. 1943). In examining all of the evidence in the *Jarka* case, the court found evidence sufficient to sustain such finding, including the testimony of a disinterested physician who was a consultant of the public health department who attested to the possibility of an injury occurring in the manner alleged by the claimant. *Id.* The court determined that the commissioner was not required to accept the opinion of the employer's medical expert

given the particular circumstances and facts alleged, including the claimant's credible testimony. Unfortunately for Plaintiff Vargas, the facts in this litigation are not as straightforward as the situation in *Jarka*.

In a products liability action, the defendant in *Wooderson v. Ortho Pharmaceutical Corporation*, 681 P.2d 1038, challenged the jury's verdict on causation regarding the plaintiff's kidney failure. In its review of the evidence, the court found the three medical experts who testified on this issue presented evidence sufficient to support the jury's determination the acute kidney failure was caused by the defendant's oral contraceptive. Specifically, they presented "proof of medical causation [which was][] detailed, logical, and based upon scientific studies." *Id.* at 398, 681 P.2d at 1048.

Plaintiff's reliance upon *Wright v. Ortho-McNeil Corp.*, No. 3:07 oe 40423, 2009 WL 1322982 (N.D. Ohio, 2009), also involving the ORTHO EVRA® patch, is also misplaced. The plaintiffs in *Wright* presented an "affidavit of Dr. Stephen Byron Shohet, M.D. [], to buttress their opposition to the summary judgment motion" and averred "use of the patch was the contributing cause of her pulmonary emboli and resulting treatment." *Id.* at *2. On the basis of this affidavit the Court denied the defendants' motion for summary judgment.

In this case, instead of providing expert medical testimony, Plaintiff has submitted multiple articles from a variety of websites regarding the possible side effects associated with the use of ORTHO EVRA®, including those from attorney websites. (Doc. 53, Ex. G.) Plaintiff has failed to show "by affidavit or declaration that, for specified reasons, [she] cannot present facts essential to justify [her] opposition." FED. R. CIV. P. 56(d). As this case involves complex

medical issues that are beyond the knowledge of the average juror, Plaintiff must produce admissible evidence in the form of expert testimony or a report to show causation.

Having failed to meet this threshold requirement, she has not presented a genuine issue of material fact for submission to a jury. “A fact is ‘material’ for purposes of summary judgment where proof of that fact would have the effect of establishing or refuting an essential element of the cause of action or a defense advanced by the parties.” *Williams v. Belknap*, 154 F.Supp.2d 1069, 1071 (E.D. Mich. 2001) citing *Kendall v. Hoover Co.*, 751 F.2d 171, 174 (6th Cir. 1984).

Having failed to provide sufficient admissible evidence that her injuries were caused by the use of ORTHA EVRA®, it is unnecessary to proceed in the analysis of Plaintiff’s specific claims against Defendants. *See Tardella*, 576 N.Y.S.2d at 966-67 (finding the lack of causation failed to establish a basis of liability for any of the products liability claims).

Drawing all reasonable inferences in Plaintiff’s favor, the Court finds that the Defendant is entitled to judgment as a matter of law because it has met the burden of demonstrating an absence of a genuine issue of material fact on the critical issue of causation. FED. R. CIV. P. 56(a). Due to the lack of expert testimony to establish causation in this medically complex case, Plaintiff has failed to “go beyond the pleadings” *Celotex*, 477 U.S. at 324, and show that her “claims are based upon something more than metaphysical doubt.” *Matsushita*, 475 U.S. at 586.

CONCLUSION

After multiple extensions and opportunities to do so, Plaintiff has failed to present a genuine issue of material fact on causation sufficient to withstand judgment as a matter of law.

For the reasons stated above, the Defendant's motion for summary judgment (Doc. 53) is granted.

This case is closed.

IT IS SO ORDERED.

S/ David A. Katz
DAVID A. KATZ
U. S. DISTRICT JUDGE