IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SAMUEL WONIEWALA, Plaintiff, v. MERCK & CO., INC., et al., Defendants.	CIVIL ACTION NO. 15-3089

OPINION

Slomsky, J. **August 7, 2017**

I. INTRODUCTION

In this action, Plaintiff Samuel Woniewala claims that MiraLAX®, an over-the-counter laxative, failed to warn the medical community about the risks associated with the product, which allegedly caused him to develop oxalate nephropathy.[1] (Doc. No. 49 at ¶ 7.) The MiraLAX® label cautions against using the product if a patient, like Plaintiff, has kidney disease, unless it is under the advisement and supervision of a physician. (Doc. No. 71-7 at 3.)

Defendants have filed a Motion for Partial Summary Judgment on the claims of failure-to-warn, express warranty, and strict liability design defect. (Doc. No. 71.) Plaintiff has filed a Response in Opposition (Doc. No. 73), and Defendants have filed a Reply. (Doc. No. 75.) The Motion is now ripe for decision. For reasons that follow, the Motion for Partial Summary Judgment (Doc. No. 71) will be denied without prejudice.

[1] Oxalate nephropathy is an acute renal injury, a form of serious kidney damage, characterized by deposits of ethylene glycol in the kidneys. (Doc. No. 49 at ¶¶ 7, 74, 79(c).)

II. BACKGROUND

Plaintiff Samuel Woniewala was diagnosed with Stage III chronic kidney disease. (Doc. No. 49 at ¶ 22.) Back in 2009, Plaintiff experienced problems with constipation. (Id. at ¶ 23.) On March 23, 2009, Plaintiff's primary care physician, Dr. Karen Bowles, M.D., prescribed MiraLAX® to treat the constipation. (Doc. No. 71-2 at ¶ 10.) MiraLAX® is a laxative containing polyethylene glycol 3350 ("PEG 3350"), which increases water in the colon to cause bowel movements and unblock constipation. (Doc. No. 71-1 at 3.)

A. MiraLAX® Federal Drug Administration Approval and Label

In February 1999, the Federal Drug Administration ("FDA") approved MiraLAX®'s original application to be sold by prescription only. (Id. at 8.) In October 2006, the FDA approved MiraLAX® to be sold over-the-counter. (Id. at 9.) MiraLAX® is used to treat occasional constipation in adults. (Doc. No. 71-2 at ¶ 11.) The directions on the label instruct the patient to dissolve 17 grams of powder in a beverage, and drink it once a day for no more than seven days. (Doc. No. 71-7 at 3.) Additionally, MiraLAX®'s label advises patients with kidney disease to take the laxative under medical supervision. (Id.) The label at issue provides in full as follows:

<table>
<tr>
<td>Drug Facts
Active ingredient (in each dose) Purpose
Polyethylene Glycol 3350, 17 g……..Laxative</td>
<td>Drug Facts (continued)
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</td>
</tr>
<tr>
<td>Use
• relieves occasional constipation (irregularity)
• generally produces a bowel movement in 1 to 3 days</td>
<td>Directions
• do not take more than directed unless advised by your doctor
• adults and children 17 years of age and older:
  • stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
  • use once a day
  • use no more than 7 days
• children 16 years of age or under: ask a doctor</td>
</tr>
<tr>
<td>Warnings
Allergy alert: Do no use if you are allergic to polyethylene glycol</td>
<td>Other information
• Store at 20º - 25ºC(68º - 77ºF)
• Tamper-Evident: Do not use if foil is open or broken</td>
</tr>
<tr>
<td>Do not use if you have kidney disease, except under the advice and supervision of a doctor</td>
<td>Inactive ingredients none</td>
</tr>
<tr>
<td>Ask a doctor before use if you have
• nausea, vomiting or abdominal pain
• a sudden change in bowel habits that lasts over 2 weeks
• irritable bowel syndrome</td>
<td rowspan="4">Questions or comments?
1-800-XXX-YYYY</td>
</tr>
<tr>
<td>Ask a doctor or pharmacist before use if you are taking a prescription drug</td>
</tr>
<tr>
<td>When using this product you may have loose, watery, more frequent stools</td>
</tr>
<tr>
<td>Stop use and ask a doctor if
• you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.
• you get diarrhea
• you need to use a laxative for longer than 1 week</td>
</tr>
</table>

(Id.)

B. Plaintiff's MiraLAX® Usage

Plaintiff took MiraLAX® every day from March 2009 until May 2013. (Doc. No. 71-11 at 2-3; Doc. No. 71-8 at 6:18-7:23.) As noted, in 2009, Plaintiff experienced problems with constipation. (Doc. No. 49 at ¶ 23.) His primary care physician, Dr. Bowles, who was aware of his history of chronic kidney disease and was monitoring his creatinine levels[2], prescribed the use of over-the-counter MiraLax® to treat Plaintiff's constipation. (Id.) On July 10, 2009, Plaintiff's creatinine level was 1.47 mg/dl[3] compared to a normal value level of 0.5 to 1.3 mg/dl. (Id. at ¶ 24.) Both his primary care physician, and his nephrologist, Dr. Michael Rudnik, continued to prescribe and recommend MiraLAX® to be taken as needed for Plaintiff's chronic constipation. (Id. at ¶ 26.) Plaintiff continued to use MiraLAX® at the advice of, and under the supervision of, his physicians. (Id.) Throughout 2010, Plaintiff's doctors tested and documented his creatinine levels, which ranged between 1.31 to 1.81 mg/dl. (Id. at ¶ 28.)

In 2011, Plaintiff continued to experience problems with constipation, and his nephrologist continued to prescribe over-the-counter MiraLAX® to treat this condition. (Id. at ¶ 29.) The MiraLAX® label instructs adults to fill the bottle cap to the indicated line, which measures to 17 grams of powder, dissolve the powder in four to eight ounces of liquid, and drink the mixture once a day. From 2009 until approximately December 2012, Plaintiff ingested one capful of MiraLAX® daily. (Doc. No. 71-8 at 6:18-7:2.) From December 2012 until May 2013,

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[2] "Creatinine is a waste product in your blood that comes from muscle activity. It is normally removed from your blood by your kidneys, but when kidney function slows down, the creatinine level rises." (Doc. No. 73 at 3 n.3 (citing National Kidney Foundation Website at www.kidney.org/atoz/content/understanding-your-lab-values).) "Generally, a high creatinine level means that your kidneys aren't working well." Creatinine test, MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH (Jan. 27, 2016), http://www.mayoclinic.org/tests-procedures/creatinine-test/details/results/rsc-20179431.

[3] "mg/dl" is an abbreviation for milligrams per deciliter.

his physician increased his daily dosage to one and one-half to two capfuls of MiraLAX®. (Id. at 7:4-23.)

"Beginning in February 2013, Plaintiff noted some left-sided abdominal flank pain," and on March 15, 2013, he told his primary care physician about the pain. (Id. at ¶ 38.) On May 6, 2013, Plaintiff was admitted to Mercy Hospital in Philadelphia, Pennsylvania, complaining of various symptoms, including nausea and abdominal pain. (Id. at ¶ 39.) When Plaintiff was admitted to the hospital, his creatinine level was measured at 8.3 mg/dl, which is about eight times the normally accepted level. (Id. at ¶ 40.)

On May 13, 2013, Plaintiff was transferred to the Hospital of the University of Pennsylvania. (Id. at ¶ 41.) There, Plaintiff's creatinine level at admission was 7.68 mg/dl. (Id. at ¶ 42.) Plaintiff was diagnosed with an acute kidney injury, and the doctors noted during his admission that he had been taking MiraLAX® daily to treat his chronic constipation. (Id. at ¶ 43.) Plaintiff continued to experience constipation while an inpatient at the Hospital of the University of Pennsylvania. (Id. at ¶ 44.) During that time, the hospital continued to prescribe MiraLAX® and administer the laxative to him to treat his continuing constipation. (Id.) In June 2013, a renal biopsy was performed, and the specimens were submitted to the Mayo Clinic for examination. (Id. at ¶ 46.) The Mayo Clinic reported that the specimens confirmed the presence of oxalate nephropathy.[4] (Id. at ¶ 47.)

C. Procedural History

Plaintiff Samuel Woniewala initiated this suit in state court, alleging negligence, strict product liability, and breach of express and implied warranties in connection with his use of

[4] As noted, oxalate nephropathy is an acute renal injury, a form of serious kidney damage, characterized by deposits of ethylene glycol in the kidneys. (Doc. No. 49 at ¶¶ 7, 74, 79(c).)

MiraLAX®. (Doc. No. 1-1.) Defendants removed the action to this Court from the Court of Common Pleas of Philadelphia County. (Doc. No. 1.)

The parties thereafter proceeded to discovery. On February 8, 2016, at the request of the parties, discovery was bifurcated—or split—into two phases. (Doc. No. 58.) "Phase I" was limited to the issue of proof of injury and medical causation.[5] (Id. at ¶ 1.) "Phase II" will address liability issues including pre-emption, adequacy of the warning, breach of warranty, and design and manufacturing defects. (Id.) To date, the parties have not yet entered "Phase II" of the discovery plan. (See Doc. No. 80 at 45:19-47:2.)

On February 13, 2017, Defendants filed a Motion for Partial Summary Judgment on Plaintiff's failure-to-warn, express warranty, and strict liability design defect claims. (Doc. No. 71.) On February 23, 2017, Plaintiff filed a Response in Opposition. (Doc. No. 73.) On March 2, 2017, Defendants filed a Reply. (Doc. No. 75.)

III. STANDARD OF REVIEW

Granting summary judgment is an extraordinary remedy. Summary judgment is appropriate "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). In reaching this decision, the court must determine whether "the pleadings, depositions, answers to interrogatories, admissions, and affidavits show there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Favata v. Seidel, 511 F. App'x 155, 158 (3d Cir. 2013) (quoting Azur v. Chase Bank, USA, Nat'l Ass'n, 601 F.3d 212, 216 (3d Cir. 2010) (quotation omitted)). A disputed issue is "genuine" only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party. Kaucher v. Cnty. of

[5] The parties agreed that "[m]edical causation is the threshold issue in this case." (Doc. No. 55 at 1.) At oral argument, the parties explained that the "Phase I" question is therefore "Did the drug cause the harm?" (Doc. No. 80 at 7:5-6.)

Bucks, 455 F.3d 418, 423 (3d Cir. 2006) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). For a fact to be considered "material," it "must have the potential to alter the outcome of the case." Favata, 511 F. App'x at 158. Once the proponent of summary judgment "points to evidence demonstrating no issue of material fact exists, the non-moving party has the duty to set forth specific facts showing that a genuine issue of material fact exists and that a reasonable factfinder could rule in its favor." Id. (quoting Azur, 601 F.3d at 216 (internal quotation marks omitted)).

In deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Id. (quoting Chambers ex rel. Chambers v. Sch. Dist. of Philadelphia Bd. of Educ., 587 F.3d 176, 181 (3d Cir. 2009) (quotation omitted)). The Court's task is not to resolve disputed issues of fact, but to determine whether there exist any factual issues to be tried. Anderson, 477 U.S. at 247-49. Whenever a factual issue arises which cannot be resolved without a credibility determination, at this stage the Court must credit the non-moving party's evidence over that presented by the moving party. Id. at 255. If there is no factual issue, and if only one reasonable conclusion could arise from the record regarding the potential outcome under the governing law, summary judgment must be awarded in favor of the moving party. Id. at 250.

IV. ANALYSIS

Defendants contend that partial summary judgment is warranted on Plaintiff's design defect claims, which include failure to warn, express warranty, and strict liability claims. (Doc. No. 71-1.) In particular, Defendants argue that Plaintiff cannot satisfy his burden of proving that any alleged inadequacy of MiraLAX®'s warnings proximately caused his injuries because Plaintiff admitted he never read the MiraLAX® label. (Id. at 9.) Additionally, Defendants argue that Plaintiff's express warranty claim fails because no express warranty was a "benefit of the

bargain" when Plaintiff purchased MiraLAX®. (Id. at 12.) Finally, Defendants argue that Plaintiff's design defect and warranty claims are preempted by federal law. (Id. at 13.)

In contrast, Plaintiff contends that the Motion for Partial Summary Judgment is premature. (Doc No. 73.) Specifically, Plaintiff argues that the parties have not completed the necessary discovery on these claims to determine whether a genuine issue of material fact exists. (Id. at 6.) Plaintiff proffers that any decision on the Motion should be deferred until the conclusion of the next phase of the litigation, since "Phase I" is limited to "the issue of medical causation." (Id.) The court agrees with Plaintiff.

Defendants' Motion for Partial Summary Judgment is premature in "Phase I" because the parties stipulated to a bifurcated discovery plan that included two phases. (See Doc. No. 55-1 at 1.) Pursuant to a scheduling order, "Phase I" is "limited to only the issue of proof of injury and medical causation." (Doc. No. 58 at ¶ 1.) Under Federal Rule of Civil Procedure 29, parties may agree to separate discovery into phases. Rule 29 allows for stipulations about discovery procedure:

> Unless the court orders otherwise, the parties may stipulate that: (a) a deposition may be taken before any person, at any time or place, on any notice, and in the manner specified—in which event it may be used in the same way as any other deposition; and (b) other procedures governing or limiting discovery be modified—but a stipulation extending the time for any form of discovery must have court approval if it would interfere with the time set for completing discovery, for hearing a motion, or for trial.

Fed. R. Civ. P. 29.

Here, the parties previously agreed to bifurcate discovery to promote judicial economy. (Doc. No. 55-1 at 1.) In the Joint Rule 26(f) Report, the parties represented as follows:

> The Parties propose that discovery in this case shall proceed in two distinct phases. Discovery in Phase 1 would address whether Mr. Woniewala had oxalate nephropathy and, if so, whether the laxative drug, MiraLax®, caused the disease. Phase 1 would consist of fact and expert discovery, followed by potentially

> dispositive and Daubert motions, all limited to the issue of proof of injury and medical causation. Assuming the case cannot be resolved at the conclusion of Phase 1, the case would proceed to Phase 2, followed by trial if necessary. Discovery in Phase 2 would cover issues of liability, including negligence and proximate cause. While there may be some degree of minor overlap in the issues pertaining to liability and causation, the parties believe that bifurcation of this case will promote judicial economy. Irrespective of the outcome of "Phase 1", all parties agree that resolving the causation issues prior to the liability issues will likely expedite resolution of the case.

(Id. (emphasis added).)

At this stage, the parties should adhere to the stipulated bifurcated schedule of discovery. "The rule in this circuit since 1972 has been that the decision to bifurcate *vel non* is a matter to be decided on a case-by-case basis and must be subject to an informed discretion by the trial judge in each instance." Lis v. Robert Packer Hosp., 579 F.2d 819, 824 (3d Cir. 1978) (citing Idzojtic v. Pennsylvania Railroad Co., 456 F.2d 1228, 1230 (3d Cir. 1971)).

"Phase I" of discovery is limited to the issue of proof of injury and medical causation. (Doc. No. 56.) Pursuant to the Court's Order "Phase II" will address liability issues including pre-emption, adequacy of the warning, proximate cause, design and manufacturing defects, and breach of warranty. (Doc. No. 58.) Plaintiff will be afforded the opportunity to take discovery and produce expert reports in support of his causation claims. (Doc. No. 73 at 2.)

The instant Motion would be more appropriate when the record is fully developed at the conclusion of "Phase II" of discovery because "Phase II" will address the adequacy of the warning, design and manufacturing defects, and breach of warranty. Therefore, the Motion for Partial Summary Judgment (Doc. No. 71) will be denied without prejudice.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion for Partial Summary Judgment (Doc. No. 71) will be denied without prejudice. An appropriate Order follows.