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Hoffmann-La Roche Inc. and
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ABIGAIL CHRISTINA SAUNDERS,

Plaintiff,

v.

HOFFMANN-LA ROCHE INC., ROCHE LABORATORIES INC., F. HOFFMANN-LA ROCHE LTD., and ROCHE HOLDING LTD.,

Defendants

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO.: ATL-L-13674-06 MT

CIVIL ACTION

ACCUTANE® MULTICOUNTY LITIGATION

**ORDER GRANTING MOTION FOR SUMMARY JUDGMENT BASED ON LACK OF PROXIMATE CAUSE**

This matter having come before the Court on the Motion of Defendants Hoffmann-La Roche Inc. and Roche Laboratories Inc. ("Defendants"), by and through their attorneys, Gibbons P.C., for entry of an Order granting their Motion for Summary Judgment in the above-captioned matter based on lack of proximate cause; and the Court having considered the submission of the parties; and for good cause shown,

**IT IS** on this 21st day of October 2016,

**ORDERED** as follows:

1. Defendants' Motion is hereby granted;

2. Plaintiffs' Complaint in the above-captioned matter is hereby dismissed with prejudice in its entirety;

3. A copy of this Order shall be served on opposing counsel within 7 days of receipt by Defendants' counsel.

Hon. Nelson C. Johnson, J.S.C.

[✓] Opposed
[ ] Unopposed

FILED

OCT 21 2016

NELSON C. JOHNSON, J.S.C

SUPERIOR COURT OF NEW JERSEY

NELSON C. JOHNSON, J.S.C.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
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**MEMORANDUM OF DECISION ON MOTION**
**Pursuant to Rule 1:6-2(f)**

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**RE:** ACCUTANE LITIGATION **DOCKET NO.** ATL-L-13674-06

**NATURE OF MOTION(S): Summary Judgment**

**HAVING CAREFULLY REVIEWED THE MOVING PAPERS AND ANY RESPONSE FILED, I HAVE RULED ON THE ABOVE CAPTIONED MOTION(S) AS FOLLOWS:**

**Nature of Motion and Procedural History**

This matter comes before the Court via Motion filed by the Defendants, Hoffman-LaRoche, et al. (hereinafter "the Defendants") based upon lack of proximate cause, wherein Defendants assert that the proper application of the Learned Intermediary Doctrine (hereinafter "LID") requires the dismissal of Plaintiff, Abigail Christina Saunders' petition.

**Findings of Fact**

Based upon the Court's review of the parties' submissions, the Court makes the following findings of fact:

1. Plaintiff claims injury from the use of the drug Accutane and incorporates by reference the relevant portions of the Master Complaint on file entitled: In Re: Accutane Litigation Case Code Number 271.

2. Defendants manufactured and marketed the drug Accutane.
3. Accutane is prescribed to treat "severe recalcitrant nodular acne."
4. Plaintiff was first prescribed Accutane in the state of Texas; from approximately October 1999 to April 2000 by Dr. Srihari Gopal during his residency at Baylor Family Medicine.
5. Dr. Michael Crouch, A Baylor Family Medicine faculty member, authored the Consent Form that was presented to Ms. Saunders.
6. Plaintiff was prescribed a second course of Accutane by Dr. Adan Ramirez Atriham, another Baylor Family Medicine resident, beginning in January of 2001 for about six months.
7. In July of 2003, Ms. Saunders began having symptoms of fatigue, gas, abdominal cramping, bloating, urge to defecate, loose stool and rectal bleeding.
8. In September 2004, Ms. Saunders was diagnosed with ulcerative colitis.

**Movant's Contentions**

**Defendant's Arguments in Support of their Motion for Summary Judgment:**

Defendants move for summary judgment and dismissal of Plaintiff's complaint, arguing that she is unable to prove proximate causation. In pharmaceutical products liability cases based on an alleged failure to warn, both Texas law and New Jersey law require the Plaintiff to prove that different warning language would have altered his or her physician's decision to prescribe the medicine. Without such testimony, the Plaintiff cannot establish proximate causation, an essential element of the *prima facie case*. Here, in testimony indistinguishable from that discussed in this Court's and the Appellate Division's decisions, the physicians who prescribed Accutane for Plaintiff have affirmatively testified that different warning language would not have altered their decisions to prescribe Accutane for Plaintiff.

Consistent with their choice-of law arguments in prior motions for summary judgment based on lack of proximate cause, Defendants maintain that Plaintiff's home-state law of Texas applies to the issue of proximate cause. *Cornett v. Johnson & Johnson,* 211 *N.J.* 362, 377-79 (2012) (presumptively applying law of Plaintiff's home state); *see also Cornett v. Johnson & Johnson*, 414 *N.J. Super.* 365, 278 (App. Div. 2010), *aff'd as modified*, 211 *N.J.* 362 (2012) ("[T]he

choice-of-law analysis in personal injury cases proceeds with the presumption that the law of the state where the injury occurred will apply..."). Here, Defendants contend that Plaintiff cannot satisfy her burden of demonstrating that Accutane was the proximate cause of her alleged injuries. The causal link to Plaintiff's injury is broken because the physicians who prescribed Accutane to her unequivocally testified that they still would have prescribed Accutane to Plaintiff even with an allegedly stronger warning. In particular, Dr. Gopal testified that he would have prescribed Accutane to Plaintiff even if the medicine label had stated Accutane is "possibly or probably related to," "can induce," or "may cause" IBD. In addition, Dr. Atriham testified he would have prescribed Accutane to Plaintiff if the label had stated Accutane is "possibly or probably related to" or "may cause" IBD. This testimony is indistinguishable from the prescriber testimony that compelled judgment in Roche's favor in this Court's January 29, 2016, Summary Judgment Decision, and the Appellate Division's decision in *Gaghan v. Hoffman-La Roche, Inc.*, 2014 *N.J. Super.* Unpub. LEXIS 1895, 2014 WL 3798338 (App.Div. Aug. 4, 2014), and is dispositive of the issue of proximate cause. As a matter of law, Plaintiff cannot establish that any alleged failure to warn her prescribing physicians proximately caused her injuries given her prescribers' unequivocal testimony establishing that different warning language would not have dissuaded them from prescribing Accutane to Plaintiff. According to Defendants, Plaintiff cannot meet her burden of proving proximate cause and Roche is entitled to summary judgment.

**Plaintiff's Response in Opposition to Defendants' Motion**

Plaintiff disputes the factual averments articulated in Defendant's motion. First, Plaintiff argues that contrary to Roche's assertions, Dr. Gopal did not testify he would prescribe Accutane to a patient, similar to Plaintiff, knowing what he knows today. It is Plaintiff's contention that Dr. Gopal only said that if he were still practicing family medicine today, it would be an option he would discuss with his patients. *(5/11/11 Gopal Dep.)* at 50:22-52:8. Moreover, Plaintiff argues that Dr. Gopal did not unequivocally testify, as Roche asserts, that he would have still prescribed Accutane to Plaintiff even if the label had stated Accutane is "possibly or probably related to," "can induce," or "may cause" IBD. *Id.* at 48:9-49:5. Plaintiff alleges that Dr. Gopal's testimony makes clear that the warnings in effect, when he prescribed Accutane to Plaintiff, did not convey to him the true risk of IBD occurring with Accutane use. According to Dr. Gopal, "association"

does not mean "cause" and hence he was unaware that there was a causal relationship between their drug and a side effect.

Second, Plaintiff contends that Dr. Crouch testified that he would have included information about case reports in his consent form had he been aware of them. If Dr. Crouch had received information whether Roche had positive internal causality assessments or challenge-dechallenge and positive rechallenges, he would have shared that information with his patients. *(4/13/16 Crouch Dep.)* at 105:24-106:14. Plaintiff contends that it may be inferred from Dr. Crouch's testimony that Roche's inadequate warnings did not convey to him the serious risk.

Third, Plaintiff contends that Dr. Atriham testified that if Accutane was a known cause of IBD, he would have wanted to know, and if so warned by the manufacturer, he would have discussed the risk in detail with his patients. Plaintiff concedes that Dr. Atriham did not equivocate in testifying that it is ultimately up to the patient to decide whether to take a drug; however, it is Plaintiff's contention that Dr. Atriham's testimony reveals that had he been adequately informed of the IBD risk, he would have advised Plaintiff of the IBD risk. *(4/14/16 Atriham Dep.)* at 89:15-23, 100:4-8.

Ms. Saunders testified that if she had been warned by her physicians that Accutane caused or may cause IBD, she would have discussed the risk with them and would not have taken the drug if she understood that it could lead to permanent disease.

Plaintiff primarily relies upon the recent Appellate Decision in *Rossitto, Wilkinson v. Hoffma[n] La Roche Inc.,* Nos. A-1236T1, A-1237-13T1, slip op., 58-62 (July 22, 2016). According to Plaintiff, the Court in *Rossitto,* held that under New jersey law, the evidence relevant to the proximate cause inquiry encompasses more than whether stronger warnings would have changed the physician's decision to recommend and prescribe Accutane. Plaintiff asserts that the law of Texas is not in conflict with New Jersey law on this issue and that under either state's law, the evidence in this present case raises genuine issues of material fact that require the Court to deny Roche's motion for summary judgment.

In arguing that there is no true conflict between New Jersey's law on the issue of proximate causation and the law of Texas, Plaintiff reasons that the Texas Supreme Court has established that in a pharmaceutical failure to warn case, "the ultimate decision for any treatment rests with the prescribing physician and the patient." *Centocor, Inc. v. Hamilton*, 372 *S.W.3d* 140, 166 (Tex.

2012) (emphasis added). Plaintiff asserts that in *Centocor*, the Texas Supreme Court's focus on the Plaintiff's actions make it clear that the doctor is not the only decision maker in the risk benefit analysis. Further, the relevant causation inquiry under Texas law is whether "prescribing physicians or [Plaintiff] would have acted differently had ... a different warning been included." *Id.* at 171. Plaintiff asserts that *Rossitto* establishes that the law of New Jersey is in accord with that of Texas as set forth by the Court in *Centocor*. It is Plaintiff's contention that the proximate cause test, under both New Jersey and Texas law can therefore be met with evidence and adequate warning, which Roche allegedly did not provide in this case, would have made a difference in the outcome that resulted in Ms. Saunders not taking Accutane and sustaining her injury.

**Standard**

> *R.* 4:46-2(a) provides,
> The motion for summary judgment shall be served with briefs, a statement of material facts and with or without supporting affidavits. The statement of material facts shall set forth in separately numbered paragraphs a concise statement of each material fact as to which the movant contends there is no genuine issue together with a citation to the portion of the motion record establishing the fact or demonstrating that it is uncontroverted. The citation shall identify the document and shall specify the pages and paragraphs or lines thereof or the specific portions of exhibits relied on. A motion for summary judgment may be denied without prejudice for failure to file the required statement of material facts.

Additionally, *R.* 4:46-2(c) provides that summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." All inferences of doubt are drawn against the movant in favor of the non-movant. *See Brill vs. Guardian Life Ins. Co. of Am.*, 142 *N.J.* 520 (N.J. 1985). "[A] determination whether there exists a 'genuine issue' of material fact that precludes summary judgment requires the motion judge to consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party." *Brill*, 142 *N.J.* at 540. Accordingly, "when the evidence



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is 'so one-sided that one-party must prevail as a matter of law,' the trial court should not hesitate to grant summary judgment." *Id.* (citation omitted). Where a motion under this rule is not rendered upon the whole action and a trial is necessary, the Court when hearing the motion will "make an order specifying those facts and directing such further proceedings in the action as are appropriate." *R.* 4:46-3(a).

**Choice of Law**

In this Court's decision of July 24, 2015, PART ONE, A thru C of that decision, entitled "RULING BASED UPON PLAINTIFFS' PETITION FOR MCL DESIGNATION" concluded, in pertinent part that:

> Given the language of the representations relied upon by the Supreme Court at the time the Order of May 2, 2005 was entered, this court believes it is required to consider all of the remaining claims and issues – in this instance, label adequacy – under New Jersey law. This is so because it was the Plaintiffs who framed the limits of the MCL jurisdiction by asking the court to consolidate all claims on the question of *whether defendant violated the New Jersey Products Liability Act in its marketing and sale of Accutane.* By invoking New Jersey law, Mr. Seeger's letter highlights why New Jersey law should control this MCL. Plaintiffs wanted the benefit of having their claims heard under the NJPLA. How this court's predecessor handled this issue, or the fact that cases were tried under California and Florida law is of no moment. The representations of Plaintiffs' petition for MCL designation are unambiguous, and request a determination(s) under the NJPLA.

Consistent with that ruling, and because counsel agree that there is no conflict between the law of New Jersey and Texas, the Defendants' Motions will be considered under New Jersey law and our Court's case law construing the LID.

**Ruling**

The Court reiterates, and adopts its interpretation of the LID from its previous ruling of January 29, 2016, in full, and deems it unnecessary to list the six elements recited at Part IV. Stated simply, where the LID applies, the testimony of Plaintiff or her medical decision makers is not a part of the proximate cause determination. If it were, the LID would be rendered useless because a proximate cause determination would ultimately come down to what the patient would have done in response to a drug manufacturer's warning, the precise situation which the

Legislature, *viz.*, *N.J.S.A.* 2A:58C-4, sought to avoid. Though Plaintiff argues earnestly that the *Rossitto* decision has changed the rules of the game regarding the interplay of the LID and proximate cause in pharmaceutical litigation, this Court cannot embrace that suggestion. Not only is the *Rossitto* decision unpublished, but the language which Plaintiff relies upon is *dicta.* Counsels' suggestion that the *Rossitto* decision marks a revolutionary change in the proximate cause standard is erroneous.

The Court notes that *Rossitto* involved a successful appeal brought by Defendants wherein the jury returned a verdict awarding $9 million each in compensatory damages to Plaintiffs Rossitto and Wilkinson. Those verdicts were vacated by the Appellate Division and the claims remanded to this trial court. [NOTE: There were no cross-appeal(s) by the two Plaintiffs who were no-caused by the jury.] The primary focus of the reviewing panel's inquiry was errors purportedly made at the time of trial. Various issues were discussed in passing, among them, *briefly*, was the LID. There was nothing about those comments, nor the ruling itself, which indicates that the Court was embarking upon a change in the application of the LID different from the standard articulated by the *Gaghan* decision, and more importantly, that as articulated by Judge Skillman in his dissent in *Strumph.*

That said, *Rossitto* seems to suggest that there are two types of cases where physician testimony is applied differently to the issue of proximate causation. There are instances similar to *Strumph*, where the prescribing doctor's testimony is unequivocal that he or she would have still prescribed the drug even if there were a stronger associated warning; and cases where the prescribing doctor's testimony is not unequivocal that a stronger warning would not have altered his or her discussion with the patient regarding the risks of the drug. The dicta in *Rossitto* suggests that even though a doctor may state that he or she would still prescribe the drug, the trial judge must also consider whether the prescribing doctor would have also provided a stronger warning to the patient. This Court acknowledges that perspective. Nonetheless, these (and prior) proceedings Plaintiff's counsel have done their very best to conflate the LID with the informed consent doctrine. That's simply not the law. When a prescribing physician comprehends the fact that a given medicine is associated with certain potential risks, and exercises his/her medical judgment in deciding whether and how to address those risks with his/her patient, the manufacturer cannot be held responsible for the prescriber's decision.

The Legislature knew full well what it was doing when it adopted *N.J.S.A.* 2A:58C-4. The Court is bound by this state's public policy as enunciated by the Legislature and our Supreme Court, not by Plaintiff's interpretation of an unpublished decision. For the reasons stated in the January 29, 2016, decision, this Court stands by its previous interpretation of the LID and proximate cause in the Accutane litigation.

After reviewing the testimony of the treating physicians in the present matter, this Court is satisfied that all three doctors unequivocally stated that a stronger warning label would not have influenced their decision whether to initially prescribe or recommend Accutane. Any doubt expressed by either expert witness, was the product of hypothetical and contortedly phrased inquiries that were crafted to elicit such a response. Dr. Crouch testified that he would have wanted to know that there was a causal connection between Accutane and IBD if Hoffman-LaRoche had possessed "highly suggestive or convincing evidence." *Ex. F to Mantell Cert. (4/13/16 Crouch Dep.)* at 94:22-23. The FDA has chosen to keep Accutane on the market because the benefits outweigh the risks. *Id.* at 98:25- 99:1-4. The generic form of Accutane [isotretinoin] is still prescribed today. Additionally, Dr. Crouch testified that he allowed his son to undergo the Accutane treatment process and ingest Accutane. *Id.* at 47:3-9.

Dr. Atriham's testimony reaches a similar conclusion. When asked, "[i]f the label said that Accutane was probably related to inflammatory bowel disease, would that have changed the manner in which you prescribed the drug?" Dr. Atriham replied: "[p]robably not." *(4/14/16 Atriham Dep.)* at 90:21-15. Furthermore, when presented with the scenario, "[t]he plaintiffs have an expert in this case who says that the warning should have said that Accutane has been possibly or probably associated with IBD. Would possible or probably related make any difference to –," Dr. Atriham interjected and replied "[n]o." *Id.* at 82:1-6. When asked if the label, "back in 2001 had said Accutane may cause inflammatory bowel disease would that have made any difference in your decisions?" Dr. Atriham again replied "[n]o." *Id.* at 14-17. Thus, this Court finds that Dr. Atriham's testimony is unequivocal that a stronger warning would not have altered his decision to prescribe Accutane.

Dr. Gopal testified that he would have still prescribed Accutane to Plaintiff. *Ex. B to Mantell Cert. (5/11/11 Gopal Dep.)* at 48: 20-25. Dr. Gopal does not concede that a stronger warning would not have changed his discussion with these patients; however, Dr. Gopal does not

believe any such changes would have been critical. When asked if his communication with patients would have changed if the warning had differed to say "may cause" instead of "temporally associated," Dr. Gopal stated: "[w]ell, it would have slightly been changed. Instead of saying has been temporarily associated, probably would have said may have been associated, but essentially it conveyed the same message. *Id.* at 50:17-21. Finally, when asked if he would prescribe Accutane today to a patient with a similar condition to Plaintiff, Dr. Gopal replied, "[t]hat's one of the options, yes." *Id.* at 51:19. Finally, whether under New Jersey law or Texas law, the Defendants prevail. In *Centocor,* the Texas Supreme Court noted that in a pharmaceutical failure to warn case, "the ultimate decision for any treatment rests with the prescribing physician and the patient." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 166 (Tex. 2012). However, the Court in *Centocor* held that "the [learned intermediary] doctrine generally applies within the context of a physician-patient relationship and allows a prescription drug manufacturer to fulfill its duty to warn end users of its product's potential risks by providing an adequate warning to the prescribing physician. *Id.* at 142. Thus, similar to New Jersey law, a Plaintiff in Texas "is required to show that an inadequate warning to the prescribing physician caused the plaintiff's injuries. *Id.* at 143.

In addressing the issue of proximate causation, the court in *Centocor* held that:

> "[w]hile the learned intermediary doctrine shifts the manufacturer's duty to warn the end user to the intermediary, it does not shift the plaintiff's basic burden of proof. *See Medrano*, 28 *S.W.3d* at 94. Doing so would create an anomalous situation where, once the defendant prescription-drug manufacturer invokes the learned intermediary doctrine, the plaintiff would be relieved of proving a key burden in any product warning case –that the product warning was inadequate. The burden on defendants in other industries to show reasonable reliance on an intermediary to effectively deliver a warning has no application in products-liability cases against a prescription drug manufacturer when the plaintiff received the drug through the existence of a physician-patient relationship. *Centocor*, at 166.

Therefore, this Court, mindful of the serious afflictions from which Plaintiff suffers, reaches the conclusion that the three doctors who were deposed in this matter, have unequivocally testified that their decision to prescribe the drug would not have changed despite a stronger warning label for Accutane. Defendants motion for summary judgment is hereby GRANTED.

Accordingly, an appropriate order has been entered. Conformed copies accompany this Memorandum of Decision.

NELSON C. JOHNSON, J.S.C.

Date of Decision: 10-21-16