FILED

JAN 29 2016

NELSON C. JOHNSON, J.B.C.

SUPERIOR COURT OF NEW JERSEY

NELSON C. JOHNSON, J.S.C.

1201 Bacharach Boulevard Atlantic City, NJ 08401-4521 (609) 594-3384

MEMORANDUM OF DECISION

RE:

ACCUTANE LITIGATION

CASE No.: 271

CASES:

SEE ATTACHED SCHEDULE A

DATE:

JANUARY 29, 2016

APPEARANCES:

PLAINTIFFS:

MARY JANE BASS, ESQUIRE

MICHAEL L. ROSENBERG, ESQUIRE

STEPHEN F. BOLTON, ESQUIRE

BILL CASH, ESQUIRE PAUL L. SMITH, ESQUIRE

PETER SAMBERG, ESQUIRE WILLIAM T. JONES, ESQUIRE

BRADLEY L. RICE, ESQUIRE

CHRISTOPHER L. SCHNIEDERS, ESQUIRE

SCOTT C. GREENLEE, ESQUIRE ALLISON E. WHITTEN, ESQUIRE

JEFF CRAWFORD, ESQUIRE CONRAD ADAMS, ESQUIRE JEFF CRAWFORD, ESQUIRE

W. LEE GRESHAM, III, ESQUIRE

DEFENDANTS:

MICHELLE M. BUFANO, ESQUIRE NATALIE H. MANTELL, ESQUIRE

PAUL W. SCHMIDT, ESQUIRE JOHN DEBOY, ESQUIRE

MICHAEL X. IMBROSCIO, ESQUIRE

RUSSELL L. HEWIT, ESQUIRE BRANDON D. MINDE, ESQUIRE

I. NATURE OF MOTIONS BEFORE THE COURT.

This matter comes before the Court via an Omnibus Motion filed by the Defendants, Hoffman-LaRoche, et al. (hereinafter "the Defendants") based upon lack of proximate cause in a total of sixty-two (62) cases, wherein Defendants assert that the proper application of the Learned Intermediary Doctrine ("LID") requires the dismissal of all the claims subject to their petition. As a consequence of further review and discussion among counsel, the Plaintiff's claims, which are the subject of this Motion, now totals thirty-two (32) claims, the captions and docket numbers for which are attached hereto as "Schedule A. The Court received the benefit of the excellent oral arguments from counsel listed above on January 13th and 14th, 2016, and now makes its ruling.

Additionally, Defendants filed Motions for Summary Judgment based upon the alleged expiration of the Statute of Limitations and Statute of Repose in the below states. These Motions, upon agreement of all counsel, are stayed pending the outcome of *McCarrell v. Hoffman-LaRoche Inc.*, No. A-28-15 (076524), currently pending before the Supreme Court:

- 1. Defendants' Omnibus Motion for Summary Judgment Based on Florida's Statute of Repose;
- 2. Defendants' Omnibus Motion for Summary Judgment Based on North Carolina's Statute of Repose;
- 3. Defendants' Omnibus Motion for Summary Judgment Based on Alabama's Statute of Limitations;
- 4. Defendants' Omnibus Motion for Summary Judgment Based on Idaho's Statute of Limitations;
- 5. Defendants' Omnibus Motion for Summary Judgment Based on Maine's Statute of Limitations;
- 6. Defendants' Omnibus Motion for Summary Judgment Based on Virginia's Statute of Limitations.

II. COMPETING LEXICONS OF THE PARTIES AS ILLUSTRATED BY THE PROOFS PRESENTED BY COUNSEL.

We live in an age of soundbites – tiny bits of information, viz., factoids – presented as the truth of much larger issues. On everything from politics, finance and education, to entertainment, sports and food, we are bombarded by messages discretely cut from the whole and earnestly presented as the entire story. Attention must be paid in such an age.

During the hearings on the thirty-two Motions addressed in this ruling, the Court heard arguments based upon extracts from the depositions of the individual Plaintiff's treating physician presented in context of the relevant state law. The purpose of those oral arguments was to afford counsel the opportunity to highlight testimony relevant to the Court's decision in light of the LID. Those hearings demonstrate that the law is not exempt from the age of soundbites. So much so, that on occasion the Court wondered if one side or the other was mistakenly quoting from the deposition of another doctor. Attention *has* been paid. What follows are examples of kinds of testimony illustrating the divergence in the perceptions of counsel.

In support of their Omnibus Motions for Summary Judgment, Defendants rely upon questions and answers from the depositions of the prescribing physician which purportedly produce the following evidence:

- 1. The prescribing physicians would have prescribed Accutane to Plaintiff even if the word "temporally" had not been included in the label.
- 2. They would have prescribed Accutane even if the label had said that it "can induce" IBD.
- 3. They would have prescribed Accutane even if the label had said that it was "associated" with IBD.
- 4. They would have prescribed Accutane even if the label had said it "can cause" IBD.
- 5. Despite what they know about Accutane now, they would still prescribe Accutane to Plaintiff today if presented in the same manner.

In support of their opposition to Defendants' motions, Plaintiffs have relied upon questions and answers from the depositions of the prescribing physician which purportedly produce the following evidence:

1. If information regarding prevalence and causation were included in the Accutane warning the doctors would have "altered" their prescribing discussion with patients by sharing such information and conveying the risk of IBD.

- 2. Some of them understood "temporally" to mean "temporary."
- 3. If they knew Accutane "would cause" or was "scientifically proven" to cause IBD they would not have prescribed it.
- 4. They would want to know if a cause-and-effect relationship existed between Accutane and a permanent and serious side effect such as IBD.
- 5. They would not have prescribed Accutane to a patient that refused the drug.

III. COMPETING ARGUMENTS OF COUNSEL.

Defendant's Arguments in Support of their Omnibus Motions for Summary Judgment

In support of their Omnibus Motions for Summary Judgment based on lack of proximate cause in certain ingestion cases arising in the States of New Jersey, Kansas, Louisiana, California and Texas, Defendants assert that the testimony of each of the Plaintiffs' prescribing physicians establishes that he or she would still have prescribed Accutane to each Plaintiff even if an allegedly stronger warning about the risk of IBD had been provided. Defendant relies upon the Appellate Division's opinion in *Gaghan v. Hoffman-La Roche Inc. et al.* (Nos. A-2717-11, A-3211-11, & A-3217-11), 2014 *N.J. Super.* Unpub. LEXIS 1895 (App. Div. Aug. 4, 2014) to support its position that Plaintiffs cannot satisfy proximate cause in this failure to warn case.

The *Gaghan* Court, according to Defendants, opined that without proof from Plaintiff that a different warning would have altered their prescribing physician's decision to prescribe the drug, Plaintiffs cannot establish proximate cause in any of the cases and they all fail to establish a prima facie case. Defendants argue that, in the cases subject to these motions, each prescribing physician's testimony is, relatively speaking, indistinguishable from the prescriber testimony that compelled judgment in Defendants' favor in *Gaghan*.

Defendants argue that pursuant to New Jersey choice of law principles, the specific law of each state should apply to the motions presently before this Court. Defendants assert that under the Supreme Court's decision in *Cornett v. Johnson & Johnson*, 211 *N.J.* 362 (2012), the choice of law analysis in a pharmaceutical products liability case begins with the presumption that the law of the state of the injury, typically the Plaintiff's home state, will apply. *Id.* at 377-79. This state-of-the-injury presumption will hold, according to Defendants, so long as there is no "true conflict" between the injury state's law and that of New Jersey. *Id.* at 377-78. Additionally,

Defendants assert that a "true conflict" exists only where the injury-state law is somehow "offensive or repugnant to the public policy of [New Jersey]." *Ibid*.

Plaintiffs' Opposition to Defendants' Motions

Plaintiffs argue that these motions should be denied or rulings reserved until the Appellate Division decides on the proximate cause issue in the July 24, 2015, decision currently pending appeal. Within that appeal, Plaintiffs argue that the Court erred in determining that New Jersey law applies to Plaintiffs' substantive claims. Since the appeal is still pending, Plaintiff argues that the Court should not make a choice of law determination until the Appellate Court rules on the issue within the aforementioned appeal.

In making a choice of law determination, Plaintiffs turn to *P.V. ex rel. T.V. v. Camp Jaycee*, 197 *N.J.* 132, 143 (2008), and argue that the Court is required to conduct a choice of law analysis on an issue-by-issue basis in order to determine whether to apply the law of the state of injury or the law of the forum. Additionally, Plaintiffs have cited language from the Court's July 24th, ruling, which states that New Jersey law will apply to all elements of liability, and accordingly proximate cause, in the interests of "uniformity and predictability." Plaintiffs assert that the Court expressed concern in the July 24th, Order for inconsistent rulings.

Plaintiffs argue that under New Jersey law, the proximate cause analysis turns on the conduct of both the physician and the patient, or his or her decision-makers, because the decision whether or not to take a drug is an inherently collaborative process. Plaintiffs, both through liaison and individual counsel, argue that Defendants skip a critical step in making a proximate cause determination, namely, the decision of the Plaintiff to take or not take the drug.

Plaintiffs, both as individuals and in the omnibus opposition to Defendants' motions, argue that their prescribing physicians' testimony unequivocally shows that given a stronger warning the physician would have altered their discussions with patients and their prescribing practices. In consequence to that altered behavior on behalf of the physicians, Plaintiffs generally assert that they would have asked their physicians more questions about IBD and then ultimately refused the drug had they known it could lead to their present condition and/or permanent injuries.

Plaintiffs further argue that the Court in *Gaghan* is applying California law on the proximate cause issue. At oral argument, Mary Jane Bass, Esquire, argued for Plaintiffs that the *Gaghan* Court was merely expressing its views on California law, *not* New Jersey. According to

Plaintiff, the *Gaghan* opinion identifies New Jersey cases wherein the Courts did not reach the same conclusion as Defendants on proximate cause; i.e. they did not determine that a plaintiff must prove that a stronger warning would have altered the doctor's decision to prescribe a drug, and thus the decision in *Gaghan* does not support Defendant's interpretation of the LID.

Defendants' Reply to Plaintiffs' Opposition

In reply to Plaintiffs' opposition, Defendants argue that Plaintiffs are unable to prove proximate cause because each prescribing physician has testified that they would still have prescribed Accutane to the patient given a stronger warning. Defendants argue that the *Gaghan* Court expressly rejected the contention asserted by Plaintiffs that the Plaintiffs' testimony of whether or not to take a drug factors into the proximate cause analysis. Defendants aver: (1) *Gaghan* controls and confirms that the proximate cause standard is consistent with their contentions in all the relevant jurisdictions; and (2) proximate cause is lacking, under the law of all the relevant jurisdictions, where the prescribing physician's decision to prescribe a drug would not change given a stronger warning.

Gaghan confirmed that the inquiry in such matters is whether a prescribing physician would have changed his/her decision to prescribe, given a stronger warning, and so, according to Defendants, the facts relied upon by Plaintiffs are irrelevant to this inquiry. Defendants argue that the Gaghan Court specifically rejected the argument proposed by Plaintiffs when they opined that the focus is on the prescribing decision of the physician. Defendants assert that Gaghan's status as an unpublished decision does not change the fact that it properly outlines the legal issue of proximate cause in cases that allege inadequate warning on behalf of the drug manufacturer, and that to maintain consistency among the MCL decisions, the Gaghan analysis should control.

IV. THE LEARNED INTERMEDIARY DOCTRINE AND ROLE OF PHYSICIAN vis-à-vis PATIENT.

In prescription drug cases where the LID applies, it is the physician who is viewed as the user. The intended "audience" of the labeling and warnings are medical doctors, not patients. From a reading of the case law, this Court deduces that – as expressed by both the Legislature and the Courts – the public policy concerns supporting the LID are grounded in the following six elements:

- (1) Prescription medications require far more precaution than an over-the-counter ("OTC") drug; they cannot be purchased without the sanction of a licensed health care professional, and may involve side effects peculiar to age, gender and personal health idiosyncrasies of the patient unconnected to the illness to be treated.
- (2) Prescription drugs are often complex medications; a medical expert is needed to properly evaluate the proclivities of a drug as well as the vulnerabilities of the patient.
- (3) As a practical matter, with a prescription drug, it is inconceivable that a manufacturer could fulfill its obligation of a warning sufficiently understandable by the average person, without a knowledgeable person advising the patient.
- (4) The treating physician plays the role of the go-between to the full extent implied by that term. A physician's ethics as well as the standards of medical care demand independent judgment beyond the influence of the drug manufacturers on the part of the doctor.
- (5) Were patients to be provided all the technical information on the adverse effects possibly associated with the use of the drug, it's unlikely they would evaluate it properly, and given their lack of learning, might take drugs they should not, or refuse a drug vital to curing an illness.
- (6) Human nature is what it is, the common law acknowledges that, after the fact, upon diagnosis of a condition said to be associated with a medication, that the patient is likely to testify that she/he would never have taken the medication had they known then, what they know now.

Of necessity, when the language of a drug warning is crafted by the manufacturer, there is a crucial distinction between an OTC medication and a by-prescription-only medication. In the former, the manufacturer's audience is vast, and must contemplate, and provide for, the persons of ordinary knowledge by whom the product will likely be used. In the latter, there is a very different audience for the warning, *viz.*, a licensed healthcare professional who regularly treats illnesses and whose responsibility is to regularly inquire as to the suitability of a particular medication for a particular person, with a particular illness. Once a doctor determines that a medication accompanied by a warning approved by the FDA is suitable for the patient's condition, then the drug manufacturer has no obligation to ensure how, or if, that warning is delivered to the patient. In short, the duty owed is from the manufacturer to the doctor, not the patient.

Prior to the NJPLA, our Courts found that a warning about a prescription drug need be given only to the physician who prescribed the drug. See, e.g., *Niemiera vs. Schnieder*, 114 *N.J.*

550, 559 (1989), wherein the Court stated, "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities."

In *Niemiera*, our Supreme Court ruled that the LID relieved the manufacturer of a DPT vaccine of the duty to warn parents directly of the vaccine's dangerous side effects because the vaccine was administered by a physician who counseled the patient prior to dispensing the medication. *Id.* at 561. Thus, under the LID, the question in evaluating the adequacy of a warning is whether it is sufficient to apprise the reasonable practicing physician of the medication's risk in order to allow a sufficient risk-benefit analysis before the drug is prescribed. See *Prince vs. Garruto et al.*, 346 *N.J. Super.* 180, 190 n.2 (App. Div. 2001).

The LID was incorporated into prescription drug cases via N.J.S.A. 2A:58C-4, which provides that adequate warnings in prescription drug cases are ones which are sufficient to reasonably inform physicians of ordinary education training and experience. See *Banner vs. Hoffmann-La Roche Inc.*, 383 *N.J. Super.* 364, 375 (App. Div. 2006), certif. den. 190 *N.J.* 393 (2007).

N.J.S.A. 2A:58C-4 states, in relevant part:

An adequate product warning...is one that a reasonably prudent person...would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account... the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician (emphasis added).

See also the Legislative comments accompanying the NJPLA, stating that "in the case of prescription drugs, the warning is owed to the physician." Note that the term "physician" used in the statute includes all health care professionals authorized to prescribe drugs, which includes dermatologists. *Perez vs. Wyeth* 313 *N.J. Super.* 511, 515-516 (App. Div. 1998), rev'd. on other grounds, 161 *N.J.* 1 (1999).

More recently, in an unpublished decision arising on appeal from a jury verdict entered before the undersigned's predecessor, the Appellate Division enunciated its understanding of how the LID is to be applied on these type of claims. In *Gaghan, supra*, the Court focused squarely upon the Trial Court's view that "the proximate cause question...[is] tied to the patient's decision

to accept or decline Accutane, not just to the doctor's decision to recommend and prescribe it or not to do so[,]" and rejected such an application of the LID. *Gaghan*, at 31. As stated by the Appellate Division, "...a prescription drug manufacturer fulfills its duty to warn if it provides adequate warnings to the prescribing physician, and it has no duty to ensure that the warning reaches the patient." *Id.* at 33.

As this Court understands the LID, the physician's obligation is one of balancing the benefits of the medication against its potential harms. The choice made is an informed one, a particularized scientific judgment grounded on a knowledge of both the patient's condition and the hoped for benefits from the medication. Accordingly, because the warning is issued to the physician, the adequacy of the warning must be assessed from the treating physician's perspective, not the patient's. The Court is satisfied that the *Gaghan* Court's statement of the law on the LID is the law of New Jersey, not merely California.

Consideration of the deposition testimony of the various treating physicians of the many plaintiffs herein reveals that either: (a) a different warning would not have altered his or her decision to prescribe Accutane, nor the way in which he or she prescribed it; or (b) a different warning would likely have altered their discussions with patients but the physician still would have prescribed the medication to a willing patient. In each claim, there was a "willing patient" who only thought differently upon acquiring new information via the litigation process. Because the doctors, in each and every instance, testified that even with a different warning they still would have prescribed the medication, the manufacturer's duty is fulfilled. Because the warning is directed to the prescribing physician, she/he is afforded the opportunity to engage in "hindsight" and opine on what they would have done had they known then what they knew at the time of their deposition, Plaintiffs are not afforded an opportunity at "hindsight".

Thus, in answer to the Court's question as posed in an email to all counsel (Court Exhibit #1) dated January 8, 2016, "[q]uery, whose conduct is relevant to the Court's inquiry under the learned intermediary doctrine, the treating physician, or the treating physician and the patient?", the answer is the treating physician, *only*. The Court is mindful of the fact that a lay person may view as harsh the lack of the patient's perspective into the process, yet to rule otherwise would eviscerate the statutory immunity granted to drug manufacturers by *N.J.S.A.* 2A:58C-4 and vitiate the common law.

V. CHOICE OF LAW.

In this Court's decision of July 24, 2015, <u>PART ONE</u>, A thru <u>C</u> 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.

Additionally, the court is guided by the wisdom of Justice Long in P.V. ex rel. T.V. v. Camp Jaycee, 197 N.J. 132, 154 (2008) wherein she stated: "The interests of judicial administration require courts to consider issues such as practicality and ease of application, factors that in turn further the values of uniformity and predictability." Resolving the remaining 4,600 (+) cases via the application of the law of each state is neither practical nor without complication for our court system to administer, nor would it promote "the values of uniformity and predictability." Rather, such a process would: (a) place Atlantic County jurors in the incongruous position of hearing claims under another state's law; (b) likely generate inconsistent rulings; (c) as illustrated by the decision in Sager v. Hoffman-LaRoche, Inc., 2012 N.J. Super, Unpub. LEXIS 1885 (App. Div. 2012), likely generate a multiplicity of appeals for which there are no binding precedents; and (d) impose an unreasonable burden upon the resources of the judiciary.

Consistent with that ruling all of the Defendants' Motions will be considered under New Jersey law and our Court's case law construing the LID. Resolving the issues raised by the dozens of Motions before the Court via the application of the law of each state is neither practical nor without complication for our Court system to administer, nor would it promote the values of "uniformity and predictability".

It was the Plaintiffs who requested the MCL designation to determine whether defendant had violated the NJPLA and this Court will apply the case law arising out of *N.J.S.A.* § 2A-58C-4, which codified the LID. The pertinent provisions of the Court's ruling of July 24, 2015, are incorporated herein by reference. Finally as to Kansas, Louisiana, California and Texas, the Court

has analyzed the Defendants' Motions under both New Jersey law and the law of the individual states.

VI. RULING AS TO EACH MOTION.

1. Raymond J. Di'Tomasso [New Jersey].

Defendants' Contentions: Treating physician, Dr. Paull, testified that he would have prescribed Accutane even if the label had stated that it "may cause" IBD. Bufano Ex. 9, P35. Dr. Paull testified that he understood that there was at least a possible risk of IBD temporally associated with Accutane. Id. at 35.

Plaintiff's Contentions: Dr. Paull testified that if Roche had advised that Accutane can cause or induce IBD, or that a connection was "probable or very probable," he would have shared that information with Plaintiff. *Id.* at 83-84. Plaintiff testified that he would not have taken Accutane if he received warnings regarding IBD, even if the risk was less than 1%. *Bufano* Ex. 10, P91-93.

As revealed by his deposition, there is nothing in the testimony of Dr. Paull showing that a different warning would have altered his decision to prescribe Accutane to Mr. Di'Tomasso. The Court relies upon the deposition testimony of Dr. Paull at P35, L5 thru P37, L8; P64, L7 thru 12; and P83, L14 thru P84, L6. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

2. <u>Victoria Conforti</u> [New Jersey].

Defendants' Contentions: Treating physician, Dr. Brodkin, testified that he would have prescribed Accutane to Plaintiff even if the word "temporally" had not been in the warning paragraph, because the Plaintiff had not given him a history of IBD. *Bufano* Ex. 6, P59-60. Dr. Brodkin testified that he would still prescribe Accutane if the package insert warning had said that it was "possibly or probably related" to IBD or that it "can induce" IBD, rather than just stating it was temporally associated with IBD. *Id.* at 65.

Plaintiff's Contentions: Plaintiff argues that this motion is not ripe for summary judgment because there was no time for Plaintiff's counsel to ask questions at the deposition, and the deposition has yet to be completed. The Court takes Plaintiff's counsel at his word regarding the need to complete Dr. Brodkin's deposition.

Defendants' Motion is DENIED without prejudice. Plaintiff has until March 15, 2016, to complete Dr. Brodkin's deposition. In the event a completed deposition transcript is submitted to the Court by March 28, 2016, it will be considered. In the event it is not, Plaintiff's Complaint will be dismissed with prejudice.

3. Mark Hughes [New Jersey].

Defendants' Contentions: Treating physician, Dr. Toome, testified that she would have prescribed Accutane to Plaintiff even if the label stated that it has been "associated with" IBD. Bufano Ex. 17, P75. Dr. Toome expressed that she did not, and does not, view the IBD risk as a probable result of Accutane use that needs to be discussed with patients. Dr. Toome testified knowing of the risks and side effects of Accutane would "never prevent" her from prescribing Accutane to a patient, and she can be sued for malpractice for not offering Accutane to the patient. Id. at pgs. 78-79.

Plaintiff's Contentions: Dr. Toome testified that she was not aware of the 1996 IBD warning at the time Plaintiff was prescribed Accutane. Buchanan Ex. 1, P73. Dr. Toome testified that IBD does not happen often and that she has never seen it happen except allegedly in this patient. Id. Dr. Toome criticized the package insert for not giving the percentage of incident cases when Accutane is taken nor the "causality percentage." Id. at 74. Dr. Toome stated that had Defendants given a more prominent warning, she would have warned Plaintiff of the risk of IBD. Id. at 106. Dr. Toome testified that percentage of individuals experiencing a risk is the type of statistical information she would look for to trigger a warning. Id. at 108. Plaintiff's mother, the medical decision maker at the time he was prescribed Accutane, testified that had she known that diarrhea, rectal bleeding, serious side effects such as psychiatric injury, and IBD were all possible risks of Accutane she would not have let him take it. Buchanan Ex. 2, P87.

As revealed by the deposition testimony of both Dr. Toome and Plaintiff's Mom, Mrs. Ogg, Plaintiff's counsel have not met their burden of showing that a different warning would have altered Dr. Toome's decision to prescribe Accutane to Mr. Hughes. The Court relies upon the deposition testimony of Dr. Toome at P63, L9 thru P65, L15; and P74, L9 thru P81, L6. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

4. <u>Lisa M. Luizzi</u> [New Jersey].

Defendants' Contentions: Treating physician, Dr. Blank, testified that she would have prescribed Accutane to Plaintiff if the label had stated that Accutane has been "possibly or probably related" to, "may induce," or "can cause" IBD. Bufano Ex. 21, P51 and 86. Dr. Blank testified that she knew of and considered the risk that Plaintiff could develop IBD when she prescribed Accutane to Plaintiff. Id. at 44 and 48. Dr. Blank testified that, back in 1991, it was her practice to tell patients to be on the lookout for any changes in bowel habits. Bufano Ex. 21, P48-49. Dr. Blank stated that even with alternatively proposed language she would have prescribed Accutane to this Plaintiff and risk discussions would have been the same, only changing if the person had active IBD. Id. at 52-53.

Plaintiff's Contentions: Plaintiff testified that she was only warned to not get pregnant, of dry eyes, dry nose, and dry hands. Buchanan Ex. 3, P57. Plaintiff testified that prior to taking Accutane she was not aware that it could cause severe stomach pain, diarrhea, and rectal bleeding, nor was she aware that it could result in permanent effects. Id. at 62-64 and 201. Dr. Blank testified that she did not warn of IBD specifically because she did not understand that there was a risk of developing IBD after taking Accutane because "[i]t was not discussed." Buchanan Ex. 4, P93 and 98. Dr. Blank would warn patients of developing bowel problems but not of a permanent condition. Id. at 94. Dr. Blank testified that had she known there was more of a link between IBD and Accutane use, she would have discussed it with the Plaintiff. Id. at 98-99. Dr. Blank stated that ultimately it is up to the patient to decide whether they will take a drug. Id. at 98.

As revealed by her deposition, there is nothing in the testimony of Dr. Blank showing that a different warning would have altered her decision to prescribe Accutane to Ms. Luizzi. The Court relies upon the deposition testimony of Dr. Blank at P47, L8 thru P49, L3; P51, L15 thru P53, L12; and P86, L16 thru P88, L25. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

5. <u>Jeffrey Herman [Kansas]</u>.

Defendants' Contentions: Treating physician, Dr. Allen, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "possibly or probably related to," "can induce," "may cause," or "can cause" IBD. Bufano Ex. 8, P85-86. Dr. Allen was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to

Plaintiff. *Id.* at 57-58 and 65. Dr. Allen testified that his risk discussion with Plaintiff would not have been any different even if there were some evidence that in rare circumstances Accutane caused IBD in some patients. *Id.* at 86. Dr. Allen further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. *Id.* at 86-87.

Plaintiff's Contentions: Dr. Allen testified that he would have wanted to know of a "challenge, dechallenge, rechallenge" process when he prescribed Accutane to Plaintiff. Wagstaff Ex. C, P119-120. Dr. Allen also testified that if he was made aware of a cause-and-effect relationship between Accutane and IBD, he would have passed that along to his patients. Id. at 117 and 121. Dr. Allen testified that he would have passed along knowledge of a causal relationship between Accutane and IBD to Plaintiff, and if Plaintiff in turn had not wanted to take Accutane Dr. Allen would not have prescribed it to him. Id. at 122. Plaintiff testified that he was unaware of the risk of IBD when he took Accutane, but even if he knew the risk was less than 10% or a risk for years after taking Accutane, he would not have taken it. Wagstaff Ex. B, P122, 150, and 154-155.

As revealed by his deposition, there is nothing in the testimony of Dr. Allen showing that a different warning would have altered his decision to prescribe Accutane to Mr. Herman. The Court relies upon the deposition testimony of Dr. Allen at P60, L15 thru P61, L22; P65, L14 thru P67, L2; and P85, L1 thru P87, L3. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

In the alternative, Kansas, like New Jersey, has adopted the LID. *Ralston v. Smith & Nephew Richards, Inc.*, 275 *F.3d* 965, 974 (10th Cir. Kan. 2001). Under the LID, "the manufacturer's duty to warn its customers is satisfied when the prescribing physician is made aware of the risks and dangers of the product[.]" *Ibid. See Humes v. Clinton*, 246 *Kan.* 590, 602 (Kan. 1990) (the learned intermediary exists because prescription drugs are only available through a physician who acts as a learned intermediary between the manufacturer and patient). Thus, if the manufacturer has communicated the warning to the physician, the inquiry then becomes whether that warning was adequate. *Ralston* at 975.

Based upon *Vanderwerf vs. SmithKlineBeecham Corp.*, 529 *F.Supp.2d.* 1294, 1313 (D. Kan. 2008), the Court is satisfied that the Defendants must prevail. In *Vanderwerf*, the altered

behavior the Court considered was (1) the physician not prescribing Paxil, (2) the physician monitoring the patient more closely for suicidal behavior and precursors, and/or (3) warning the patient and his family of the increased risk of suicide. *Ibid*. The burden in *Vanderwerf* then shifted to plaintiff to prove proximate cause by either discrediting the testimony of the prescribing physicians or showing that had a proper warning been given it would have altered the behavior of the prescribing physicians. *Id.* at 1312-1313. The testimony of Dr. Allen is dispositive.

6. John Cardinale [Louisiana].

Defendants' Contentions: Treating physician, Dr. Palomeque, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "associated with," "possibly related to," "can induce," or "may cause" IBD. Bufano Ex. 5, P45 and 67. Dr. Palomeque was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff, and would still prescribe Accutane to Plaintiff today if presented to him in the same manner despite what he now knows about Accutane's risks and benefits. Id. at 40-41 and 67-68. Dr. Palomeque warned his patients that if they experienced any abdominal pain or diarrhea they should stop taking Accutane. Bufano Ex. 5, P 39. Dr. Palomeque testified that a different warning would have only changed his prescribing practice if he knew the patient had a family history of IBD, because then he would let the patient know that they would probably be at a greater risk of that side effect. Id. at 67-68.

Plaintiff's Contentions: Dr. Palomeque testified that whether or not a patient takes a drug he recommends is "strictly regulated by the patient's acceptance." Buchanan Ex. 2, P89-90 and 109. Plaintiff asserts that Dr. Palomeque was not aware that Accutane could cause IBD. Buchanan Ex. 3, P23, 28, and 53. Knowing what he knows now, Dr. Palomeque testified that he would not prescribe Accutane to a patient with Crohn's disease or UC. Id. at 49-50. Dr. Palomeque also testified that he, more likely than not, would have warned his patients if the Accutane label stated that it was "possibly or probably" related to IBD or that it could "induce" IBD. Id. at 61. Plaintiff testified that he would not have taken Accutane if he knew that it could cause permanent stomach pain, diarrhea, or rectal bleeding. Buchanan Ex. 1, P160.

As revealed by his deposition, there is nothing in the testimony of Dr. Palomeque showing that a different warning would have altered his decision to prescribe Accutane to Mr. Cardinale. The Court relies upon the deposition testimony of Dr. Palomeque at P38, L24 thru P45, L11 and P66, L21 thru P68, L7. Based upon the rationale set forth in Parts IV and V, the Court is satisfied

that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

In the alternative, when the law of Louisiana is applied to these facts, the Court is satisfied, based upon *Kampmann vs. Mason*, 921 *So. 2d* 1093, 1096 (La. App. 5 Cir. Jan. 17, 2006), that the Defendants must prevail. In *Kampmann*, if the movant satisfies their burden, the burden then shifts to the non-movant to establish that they will be able to satisfy the evidentiary burden of proof at trial. *Ibid.* In Louisiana, a plaintiff must show that "the product has a potentially dangerous risk which caused him harm and that the manufacturer failed to use reasonable care to provide adequate warning of that characteristic to the doctor." *Ibid.* citing *La. R.S. 9:2800.57*. The plaintiff must be able to establish that the allegedly inadequate warning was a factual cause of the injury. Those facts do not exist here. Accordingly, Defendants prevail.

7. Brittany Baucum [Louisiana].

Defendants' Contentions: Treating physician, Dr. Wampold, testified that she would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "possibly or probably related to" or "can induce" IBD. Bufano Ex. 2, P50-51 and 53. Dr. Wampold was aware of and considered the risk that Plaintiff could develop IBD when she had prescribed Accutane. Id. at 26 and 44-45. Dr. Wampold further testified that despite what she knows about Accutane now, she would still prescribe Accutane to Plaintiff today if she was presented in the same manner. Id. at 17 and 50-51.

Plaintiff's Contentions: Plaintiff was a minor at the time she took Accutane, and her mother testified that she would not have allowed Plaintiff to have taken Accutane if she knew it could cause UC. Sugarman Ex. 3, P99. Dr. Wampold testified that IBD is a serious and irreversible bowel condition, and if she had thought that Accutane would cause Plaintiff to develop IBD she would have at least warned Plaintiff of that fact. Sugarman Ex. 2, P101-103. Dr. Wampold testified that if she thought Accutane definitely caused IBD she would have warned Plaintiff of that. Sugarman Ex. 2, P101-102.

As revealed by her deposition, there is nothing in the testimony of Dr. Wampold showing that a different warning would have altered his decision to prescribe Accutane to Ms. Baucum. The Court relies upon the deposition testimony of Dr. Wampold at P43, L16 thru P45, L45 and P50, L10 thru P53, L11. Based upon the rationale set forth in Parts IV and V, the Court is satisfied

that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Cardinale motion, under Louisiana law, Defendants must prevail.

8. <u>Lisa Harrison</u> [Louisiana].

Defendants' Contentions: Treating physician, Dr. Palomeque, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "associated with," "possibly or probably related to," or "can induce" IBD. *Bufano* Ex. 13, P55-58. Dr. Palomeque testified that he was aware of the risk that Plaintiff could develop IBD when he prescribed Plaintiff Accutane. *Id.* at 46-48. Dr. Palomeque further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if she was presented in the same manner. *Id.* at 58-59 and 89-90.

Plaintiff's Contentions: At the time Dr. Palomeque prescribed Plaintiff Accutane, he stated that he probably would have read the word "temporally" to mean temporary. Buchanan Ex. 6, P54-55. Dr. Palomeque testified that had the warning for Accutane stated that it "had been possibly or probably related to IBD, or that it can induce IBD," it would "perhaps" change the way he counseled his patients about risk. Id. at 61. Dr. Palomeque testified that "more likely than not" he would have included that information in his risk discussion with patients. Ibid.

At the time Plaintiff took Accutane, her mother did not know it was a dangerous drug, nor did she know of all the specific side effects, but if she had she would not have allowed Plaintiff to take it. *Buchanan* Ex. 7, P62-66. Dr. Palomeque did not warn that Accutane could cause IBD. *Id.* at 112. If Dr. Palomeque had warned of IBD, Plaintiff's mother would not have allowed Plaintiff to take Accutane. *Ibid.*

As revealed by his deposition, there is nothing in the testimony of Dr. Palomeque showing that a different warning would have altered his decision to prescribe Accutane to Ms. Harrison. The Court relies upon the deposition testimony of Dr. Palomeque at P55, L4 thru P61, L20 and P88, L11 thru P90, L14. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Cardinale motion, under Louisiana law, Defendants must prevail.

9. Stuart Schavot, Jr. [Louisiana].

Defendants' Contentions: Treating physician, Dr. Applewhite, testified that she would have prescribed Accutane to Plaintiff if the label stated that Accutane is "possibly or probably related to" or "can induce" IBD. Bufano Ex. 17, P44. Dr. Applewhite was aware of the risk that Plaintiff could have gastrointestinal symptoms when she prescribed Accutane to Plaintiff, and she further testified that despite what she knows about Accutane now, she would still prescribe Accutane to Plaintiff today if he was presented in the same manner. Id. at 42 and 45.

Plaintiff's Contentions: Plaintiff's mother, Sheila Englart, testified that though she was leery of her son taking Accutane she allowed it because of her comfort level with Dr. Applewhite. Buchanan Ex. 10, P44. In her deposition, Ms. Englart testified that she would not have let her son take Accutane if she had been told that there was a chance he would develop IBD. Id. at 64. Ms. Englart also testified that the label, as written, made it seem like if you stop taking the drug the symptom (diarrhea) would go away. Id. at 62. Dr. Applewhite testified that she did not understand that the symptoms of stomach pain, diarrhea, and rectal bleeding would be permanent effects of taking Accutane since she thought "temporally" meant temporarily. Buchanan Ex. 9, P67. Plaintiff argues that Dr. Applewhite could not have warned Plaintiff and his mother of the possibility that he would develop IBD if Dr. Applewhite herself did not understand that the condition was permanent.

As revealed by her deposition, there is nothing in the testimony of Dr. Applewhite showing that a different warning would have altered her decision to prescribe Accutane to Mr. Schayot. The Court relies upon the deposition testimony of Dr. Applewhite at P43, L7 thru P45, L14 and P66, L21 thru P67, L14. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Cardinale motion, under Louisiana law, Defendants must prevail.

10. Bridget Ware [Louisiana].

Defendants' Contentions: Treating physician, Dr. Davis, testified that he would have prescribed Accutane to Plaintiff Ware if the label had stated that Accutane is "associated with," "possibly or probably related to," "can induce," or "may cause" IBD. Bufano Ex. 23, P44-47. Dr. Davis testified that he "would think" he was aware of the risk that Plaintiff could develop IBD at

the time Plaintiff took Accutane. *Id.* at 39-40. Dr. Davis testified that if the label had stated that Accutane may cause IBD, he would still prescribe Plaintiff Accutane, even knowing what he now knows about the risks and side effect of Accutane. *Id.* at 47-48. Dr. Davis stated that even if additional information were included in the warning label stating that Accutane is "possibly or probably" related to IBD or "can induce IBD," he would not have done anything more than tell his patients to watch for IBD symptoms. *Id.* at 46.

Plaintiff's Contentions: Plaintiff argues that she has met the burden of demonstrating that a proper warning would have changed the decision of the treating physician and that but for the inadequate warning, the treating physician would not have prescribed the product. Dr. Davis testified that he would have wanted to know that ingestion of Accutane increased the risk of IBD and that he would have discussed this risk with Ms. Ware. Berezofsky Ex. 2, P82-83 and 86. Dr. Davis testified that had Defendants contained additional information in the PDR about latency periods or increased IBD risks, he would have discussed it with Plaintiff. Id. at 86 and 92.

Plaintiff testified that if her doctor had warned her that Accutane would place her at an increased risk of IBD, even years after taking Accutane, she would not have taken Accutane. Berezofsky Ex. 1, P108-109 and 163. Dr. Davis stated he may recommend Accutane but would never force a patient to take it if they had any objections. Berezofsky Ex. 2 at P70. Dr. Davis testified that he would let patients know that if they had any type of abdominal discomfort, nausea, vomiting, diarrhea, cramping, or bloating they should call the office. Bufano Ex. 23, P42. Dr. Davis did not use the term IBD specifically with his patients. Id. at 41.

As revealed by his deposition, there is nothing in the testimony of Dr. Davis showing that a different warning would have altered his decision to prescribe Accutane to Ms. Ware. The Court relies upon the deposition testimony of Dr. Davis at P41, L22 thru P48, L24. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Cardinale motion, under Louisiana law, Defendants must prevail.

11. Julie Williams [Louisiana].

Defendants' Contentions: Treating physician, Dr. Posner, testified that he would have, or probably would have, prescribed Accutane to Plaintiff if the label had stated that Accutane is "possibly or probably related to" or "may cause" IBD. Bufano Ex. 26, P128. Dr. Posner testified

that he was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. *Id.* at 12 and 101-102.

Plaintiff's Contentions: Dr. Posner testified that information regarding causation and the prevalence of IBD in the label of Accutane would have altered his prescribing practice as he would have conveyed the information to Plaintiff. *Berezofsky* Ex. B, P20-21. Ultimately, Dr. Posner would leave the decision of whether or not to take Accutane up to the Plaintiff. *Berezofsky* Ex. B, P14, 38, and 131.

As revealed by his deposition, there is nothing in the testimony of Dr. Posner showing that a different warning would have altered his decision to prescribe Accutane to Ms. Williams. The Court relies upon the deposition testimony of Dr. Posner at P39, L17 thru P48, L14 and P128, L1 thru L15. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Cardinale motion, under Louisiana law, Defendants must prevail.

NOTE: Preliminary to the Court's rulings on Motions 12 thru 20, the record should reflect that this Court is of the opinion that the interpretation and application of the LID by the Courts of California is in harmony with the Courts of New Jersey. Accordingly, it is the analysis of the *Gaghan* Court which controls. Notwithstanding Plaintiff's rejection of *Gaghan*, the Court is satisfied that there is nothing in *Rule* 1:36-3 that prohibits this Court from expressly embracing the reasoning of the *Gaghan* decision and applying it to all the claims arising in California.

12. <u>Darshan E. Campos</u> [California].

Defendants' Contentions: Treating physician, Dr. Magid, testified that he would have prescribed Accutane to Plaintiff even if the label had stated Accutane "can induce" or is "possibly or probably related" to IBD. Bufano Ex. 2, P93 and 95. Dr. Magid also testified that he knew of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff, and that he would prescribe Accutane to Plaintiff today. *Id.* at 49 and 95-96.

Plaintiff's Contentions: Dr. Magid testified that if Defendants had advised that Accutane can cause IBD, that there is a possible or probable connection between Accutane and IBD, that they had numerous positive rechallenge reports, or that there is a latency risk he would have shared all of that information with Plaintiff. Buchanan Ex. 3, P108-109, 111, and 116-120. Dr. Magid stated that the ultimate decision of whether or not to take a medication is with the Plaintiff and that

he would not prescribe a medication to a Plaintiff that refused it. *Id.* at 130. Plaintiff testified repeatedly that if she had received additional warnings regarding the risk of IBD with Accutane use, she would not have taken Accutane. *Buchanan* Ex. 2, P341-344.

As revealed by his deposition, there is nothing in the testimony of Dr. Magid showing that a different warning would have altered his decision to prescribe Accutane to Ms. Campos. The Court relies upon the deposition testimony of Dr. Magid at P49, L20 thru P52, L23; P83, L23 thru P85, L9; and P92, L18 thru P 96, L15. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

13. William R. Gadue [California].

Defendants' Contentions: Treating physician, Dr. Roth, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "associated with," "can induce," or is "possibly or probably related" to IBD. Bufano Ex. 22, P84. Dr. Roth knew of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 81. Dr. Roth stated that, subject to parental consent, he would still prescribe Accutane to Plaintiff today knowing everything he now knows about Accutane, its risk and sides effects, and Plaintiff's lawsuit. Id. at 123-124.

Plaintiff's Contentions: In 1997, Dr. Roth told his patients that they could experience GI side effects with Accutane. Buchanan Ex. 4, P84. Dr. Roth testified that had Roche warned that the risk of IBD was probable rather than temporal, he would have had a different discussion with his patients. Id. at 160-161. Dr. Roth stated that even if the risk of developing IBD was only 1%, he would have shared it with his patients. Id. at 162. Dr. Roth testified that the ultimate decision of whether or not to take a drug is up to the patient/parent. Id. at 122-124. Plaintiff's parents both testified that had they known of the risk of IBD with Accutane use, they would not have let their son take Accutane. Buchanan Ex. 6, P217, Ex. 8, P140.

As revealed by his deposition, there is nothing in the testimony of Dr. Roth showing that a different warning would have altered his decision to prescribe Accutane to Mr. Gadue. The Court relies upon the deposition testimony of Dr. Roth at P81, L1 thru P85, L9 and P122, L15 thru P124, L3. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

14. James Kuklinski [California].

Defendants' Contentions: Treating physician, Dr. Lang, testified that he would have prescribed Accutane to Plaintiff even if the label contained a stronger warning regarding IBD. Bufano Ex. 32, P55-57. Dr. Lang knew of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 41-42. Dr. Lang testified that he would still prescribe Accutane to Plaintiff today knowing everything he does about Accutane and Plaintiff's lawsuit. Id. at 76-77.

Plaintiff's Contentions: Dr. Lang testified that the IBD warning provided by Roche was insignificant to him and that had different language or format been used it would have gotten his attention. Buchanan Ex. 9, P56-57, 97, and 99. Such a different warning or format of the warning probably would have led Dr. Lang to discuss the risk more with his patients. Id. at 82 and 89. According to Dr. Lang, it is ultimately his patient's decision to take or refuse a drug regardless of what he recommends. Id. at 96-97. Plaintiff's mother testified that had she known that Accutane could cause permanent stomach problems, that there was even a small risk of UC, or that it could cause permanent side effects, she would not have let her son take Accutane. Buchanan Ex. 10, P105-106 and 125-126. Plaintiff's mother testified that if she had been told that Accutane was associated with UC, she would "never ever" have allowed her son to take it. Buchanan Ex. 10, P125.

As revealed by his deposition, there is nothing in the testimony of Dr. Lang showing that a different warning would have altered his decision to prescribe Accutane to Mr. Kuklinski. The Court relies upon the deposition testimony of Dr. Lang at P53, L1 thru P57, L5 and P76, L15 thru P77, L8. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

15. Michael T. McFadden [California].

Defendants' Contentions: Treating physician, Dr. Schmidt, testified that she would have offered Accutane to Plaintiff even if the label stated that Accutane is "associated with," "can cause," or "may cause" IBD. Bufano Ex. 36, P63 and 88-91. Dr. Schmidt knew of and considered the risk that Plaintiff could develop IBD when she prescribed Accutane to Plaintiff. Id. at 57, 65, and 69. Dr. Schmidt stated that she would prescribe Accutane to Plaintiff today knowing everything she now knows about Accutane. Id. at 90-91.

Plaintiff's Contentions: Plaintiff admits that Dr. Schmidt considered a risk that Plaintiff could develop IBD, but Plaintiff argues that Dr. Schmidt did not know of and consider the actual risk that Plaintiff could develop IBD from taking Accutane. Dr. Schmidt testified that had Roche advised her of Accutane's latency risk she would not have prescribed it to Plaintiff. Berezofsky Exhibit B, P66-67. Plaintiff argues that the evidence makes clear that had Roche provided Dr. Schmidt with a stronger warning on the risk of IBD with Accutane use, she either would not have prescribed it or would have discussed those risks with Plaintiff. Had Plaintiff known of the IBD risks, he testified he would not have taken Accutane.

As revealed by her deposition, there is nothing in the testimony of Dr. Schmidt showing that a different warning would have altered her decision to prescribe Accutane to Mr. McFadden. The Court relies upon the deposition testimony of Dr. Schmidt at P62, L1 thru P71, L24 and P87, L23 thru P90, L22. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

16. Jordan Satler [California].

Defendants' Contentions: Treating physician, Dr. White, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane "may cause," "can induce," or is "possibly or probably related" to IBD. Bufano Ex. 54, P55-57. Dr. White was aware of the association risk between Accutane and IBD in 2000. Id. at 48-49. Dr. White testified that he would prescribe Accutane to Plaintiff today even knowing of the current lawsuits. Id. at 56 and 61.

Plaintiff's Contentions: According to Plaintiff, the evidence shows that if Roche had warned about the relationship between Accutane and IBD, then Dr. White would have discussed IBD with Plaintiff and his mother, which would have led them to refuse Accutane treatment for Plaintiff. Dr. White testified that he did not believe that the mentioning of Accutane's association with IBD on the label conveyed a causal relationship. Buchanan Ex. 13, P48. Dr. White did not warn of IBD around the time it was prescribed to Plaintiff because he did not believe that it was a common risk. Id. at 150-152. Dr. White probably would have warned his patients of IBD if the label indicated that Accutane could induce IBD. Id. at 155-156. Dr. White testified that the patient is the ultimate decision maker when it comes to deciding whether or not to take a drug. Id. at 56-57.

Plaintiff's mother testified that she would not have allowed her son to take Accutane had she known that it could cause his current condition. *Buchanan* Ex. 14, P90-91.

As revealed by his deposition, there is nothing in the testimony of Dr. White showing that a different warning would have altered his decision to prescribe Accutane to Ms. Satler. The Court relies upon the deposition testimony of Dr. White at P48, L2 thru P49, L17 and P51, L21 thru P56, L15. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

17. Nicole Yas Shamsian [California].

Defendants' Contentions: Treating physician, Dr. Greenberg, testified that he would have prescribed Accutane to Plaintiff even if the label contained a stronger warning regarding IBD, specifically, even if it had stated that Accutane "may cause" IBD. *Bufano* Ex. 58, P65-66. Dr. Greenberg noted that he would prescribe Accutane to Plaintiff today knowing everything he now knows about Accutane and Plaintiff's lawsuit. *Id.* at 104-105.

Plaintiff's Contentions: Dr. Greenberg was well-informed about the warnings in the Accutane label in 1999 and told Plaintiff about every side effect of which he was aware. Buchanan Ex. 16, P13-15, 51-53, and 29. Initially, Plaintiff denied Accutane treatment and when she was ultimately prescribed it later on, Dr. Greenberg discussed all common and "pretty much the uncommon side effects" with Plaintiff of which he was aware. Id. at 78-79. Dr. Greenberg was unaware that IBD was an Accutane side effect at the time he prescribed it to Plaintiff. Id. at 51. Dr. Greenberg testified that his risk discussion with Plaintiff would have been different given a different IBD warning. Id. at 65. Ultimately, his decision of whether or not to prescribe a medication is yielded to the patient's decision. Id. at 105. Plaintiff's mother testified that she absolutely would not have allowed her daughter to take Accutane had she known that it may cause IBD, even if she was told that the risk was small Buchanan Ex. 18, P125 and 127-128.

As revealed by his deposition, there is nothing in the testimony of Dr. Greenberg showing that a different warning would have altered his decision to prescribe Accutane to Ms. Shamsian. The Court relies upon the deposition testimony of Dr. Greenberg at P64, L7 thru P70, L13 and P104, L23 thru P105, L13. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

18. <u>David Tucker</u> [California].

Defendants' Contentions: Treating physician, Dr. Van Meter, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane "can induce" or is "possibly or probably related" to IBD. *Bufano* Ex. 61, P65-67. Dr. Van Meter noted that he would still prescribe Accutane to Plaintiff today knowing everything he now knows about Accutane and Plaintiff's lawsuit. *Id.* at 82-84.

Plaintiff's Contentions: Plaintiff argues that the evidence shows that had a different warning been provided as to the relationship between Accutane and IBD, Plaintiff would not have taken Accutane and suffered his injuries. Dr. Van Meter did not discuss IBD with his patients or even believe that the language within the Accutane label warned of IBD. Buchanan Ex. 19, P56-57. Dr. Van Meter did not believe that his warnings as to GI side effects included a warning of a permanent condition of IBD. Id. at 63-64. If Dr. Van Meter had been informed of Accutane's IBD risk, he would have discussed it with Plaintiff. Id. at 65-67.

As revealed by his deposition, there is nothing in the testimony of Dr. Van Meter showing that a different warning would have altered his decision to prescribe Accutane to Mr. Tucker. The Court relies upon the deposition testimony of Dr. Van Meter at P64, L3 thru P67, Lt and P82, L24 thru P84, L25. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

19. Nicole Phillips [California].

Defendants' Contentions: Treating physician, Dr. Carmel, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane "can induce," "may cause," or is "possibly or probably related" to IBD. Bufano Ex. 43, P139-142. Dr. Carmel knew of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 89-90. Dr. Carmel testified that he would still prescribe Accutane to Plaintiff today knowing everything he now knows about Accutane and Plaintiff's lawsuit. Id. at 140-142.

Plaintiff's Contentions: Dr. Carmel testified that in the late 1990's and early 2000's, it was not his practice to warn his patients of the risk of IBD when taking Accutane. Gresham Ex. A, P157. Dr. Carmel testified that if Roche had determined internally that Accutane causes IBD he would want to know so that he could pass along such information to his patients. Id. pg. 166. Dr. Carmel stated that he would want to know of different harmful Accutane side effects so that he could include them in his discussions with patients. Id. 166-168 and 174-175. Plaintiff testified

that she relied on Dr. Carmel to weigh the risks and benefits of Accutane and that she would not have taken Accutane had she received additional IBD warnings. *Gresham* Ex. B, P190-196, 243, and 345.

As revealed by his deposition, there is nothing in the testimony of Dr. Carmel showing that a different warning would have altered his decision to prescribe Accutane to Ms. Phillips. The Court relies upon the deposition testimony of Dr. Carmel at P139, L17 thru P142, L19. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

20. Michael Rice [California].

Defendants' Contentions: Treating physician, Dr. Herten, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "associated with," "can induce," or is "possibly or probably related" to IBD. Bufano Ex. 51, P77-81 and 93. Dr. Harten knew of and considered the risk that Plaintiff Rice could develop IBD when he prescribed Accutane to Plaintiff. Id. at 74-77. Dr. Herten testified that he would prescribe Accutane to Plaintiff today knowing everything he now knows about Accutane and Plaintiff's lawsuit. Id. at 79 and 93.

Plaintiff's Contentions: Plaintiff argues that Defendants skip a proper step in the proximate cause analysis by ignoring what Dr. Herten and Plaintiff would have done in the face of a proper warning. Dr. Herten testified that if Defendants had provided a warning saying that Accutane could induce IBD, he would have changed his discussion with Plaintiff and other patients. Buchanan Ex. 11, P79-80. Plaintiff testified that in the 1980's, when he took Accutane, he would have been willing to accept the risk of temporary GI side effects but not serious side effects or the developing of life-long conditions. Buchanan Ex. 12, P435-436 and 388. Plaintiff stated that he would not have risked developing IBD even if that risk was small or if doctors were unsure as to whether Accutane causes IBD. Id. at 389. Plaintiff would not have taken Accutane even if the risk of IBD was less than 1%. Id. at 389-390.

As revealed by his deposition, there is nothing in the testimony of Dr. Harten showing that a different warning would have altered his decision to prescribe Accutane to Mr. Rice. The Court relies upon the deposition testimony of Dr. Harten at P77, L4 thru P81, L23. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

21. Timothy J. Bolton [Texas].

Defendants' Contentions: Treating physician, Dr. Fox, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "associated with," "possibly or probably related to," "can induce," or "may cause" IBD. Bufano Ex. 6, P46-47 and 68-69. Dr. Fox was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 47. Dr. Fox testified that he would still prescribe Accutane to Plaintiff today knowing what he now knows about Accutane. Id. at 69-70.

Plaintiff's Contentions: Defendant ignores the role that the patient's decision plays in the physician's prescribing decision. Dr. Fox would not have prescribed Accutane to Plaintiff if he did not want to take it. Plaintiff repeatedly testified that he would not have taken Accutane if he had received additional warnings about the risk of IBD with Accutane use. D'Onofrio Ex. 1, P143 thru 147. Dr. Fox testified that he understood the word "temporally" to mean that a symptom or complication could occur while the patient was taking Accutane, not after stopping the medication. D'Onofrio Ex. 2, P45. Dr. Fox testified that he would have wanted to know if there were case reports concerning the relationship, or potential relationship, between Accutane and IBD, and that information could have affected his decision to prescribe Accutane. Id. at 98-99 and 69-70.

As revealed by his deposition, there is nothing in the testimony of Dr. Fox showing that a different warning would have altered his decision to prescribe Accutane to Mr. Bolton. The Court relies upon the deposition testimony of Dr. Fox at P47, L2 thru L23 and P68, L17 thru P70, L7. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

In the alternative, when the law of Texas is applied to these facts, the Court is satisfied, based upon the reasoning of the Courts in *Ackermann vs. Wyeth Pharmaceuticals*, 526 F.3d.203 (2008); *McNeil vs. Wyeth*, 462 F.3d 364 (2007); and *Pustejovsky vs. Pliva, Inc.*, 623 F.3d 271 (2010), the Defendants must prevail.

As stated by the Court in *Pustejovsky*, at 276, "where the evidence demonstrates that the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the Plaintiff cannot show that the inadequacy of the warning was a producing cause". Finally, as noted by the Court in *Ackermann*, at 208, citing *McNeil*, the failure to warn must be a producing cause of the harm complained of. "In other words, '[u]nder Texas law, a Plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged

inadequacy caused her doctor to prescribe the drug for her." *Id.* at 372. We don't have those facts here, nor in any of the Texas claims.

22. Stephen Thompson [Texas].

Defendants' Contentions: Plaintiff's prescribing physician, Dr. Roth, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "associated with," "possibly or probably related to," "can induce," or "may cause" IBD. Bufano Ex. 58, P60-61 and 78-79. Dr. Roth was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Plaintiff Accutane. Id. at 49. Dr. Roth further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. Id. at 82.

Plaintiff's Contentions: Defendant ignores the fundamental role that the patient's decision plays in the physician's prescribing decision. Plaintiff testified that he would have refused to take Accutane if he had received additional warnings regarding the risk of IBD with Accutane. D'Onofrio Ex. 4, P147. Plaintiff argues that the evidence presents a fact issue as to whether Dr. Roth would have prescribed Accutane to Plaintiff given a stronger warning. Plaintiff asserts that when Defendant stated that Dr. Roth would still prescribe Accutane to Plaintiff today it was a mischaracterization because Dr. Roth stated he would only prescribe it if that is what Plaintiff wanted. D'Onofrio Ex. 3, P82. The risks and benefits that Dr. Roth told his patients in 1999 are different from those that he gives his current patients today. Id. at 79-80. In 1999, Dr. Roth did not typically use the term IBD with his patients. Id. at 96-97. Plaintiff testified that given a stronger warning about the risk of IBD, he would have refused Accutane. D'Onofrio Ex. 4, P147.

As revealed by his deposition, there is nothing in the testimony of Dr. Roth showing that a different warning would have altered his decision to prescribe Accutane to Mr. Thompson. The Court relies upon the deposition testimony of Dr. Roth at P60, L2 thru P61, L1 and P82, L1 thru L13. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rational set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

23. Danna Blumenau [Texas].

Defendants' Contentions: Treating physician, Dr. Sears, testified that she would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "possibly or probably

related to," "can induce," or "can cause" IBD. *Bufano* Ex. 2, P30. Dr. Sears was aware of the risk that Plaintiff could develop IBD when she prescribed Accutane to Plaintiff. *Id.* at 39. Dr. Sears further testified that despite what she knows about Accutane now, she would still prescribe Accutane to Plaintiff today if she was presented in the same manner. *Id.* at 31.

Plaintiff's Contentions: Dr. Sears testified that having complete and accurate information about the drugs she prescribes is important to her. Buchanan Ex. 4, P62. If Dr. Sears had been provided with complete and accurate information about the risks of taking Accutane she would have shared that information with her patients. Plaintiff testified that the Accutane warnings provided to her were inaccurate because they did not say that there was a risk of IBD after a patient stopped taking Accutane. Buchanan Ex. 1, P190-191. Plaintiff testified that had she been warned that she could develop IBD months or years after stopping Accutane use, she would have refused to take Accutane. Id. at 191 and 199.

As revealed by her deposition, there is nothing in the testimony of Dr. Sears showing that a different warning would have altered her decision to prescribe Accutane to Ms. Blumenau. The Court relies upon the deposition testimony of Dr. Sears at P30, L6 thru P31, L20. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

24. Faith S. Cary [Texas].

Defendants' Contentions: Treating physician, Dr. Epstein, testified that she would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "possibly or probably" related to, "can induce," or "may cause" IBD. Bufano Ex. 12, P88-89. Dr. Epstein stated that she believed she was aware of and considered the risk that Plaintiff could develop IBD when she prescribed Accutane to Plaintiff. Id. at 68. Dr. Epstein further testified that despite what she knows about Accutane now, she would still prescribe Accutane to Plaintiff today if she was presented in the same manner. Id. at 89.

Plaintiff's Contentions: According to Plaintiff, Dr. Epstein testified that she only would have continued to prescribe Accutane, given a different warning, if Plaintiff had agreed to take it after reviewing those additional risks and warnings. Eisbrouch Ex. 2, P88-89. Dr. Epstein also stated that even if an additional risk would not change her decision to prescribe a medication she

would explain that risk to a patient who would then make the ultimate decision of whether or not to take a prescription drug. *Id.* at 97. Plaintiff testified that she would have taken into account her doctor's recommendation, along with, paperwork explaining the risks and benefits of the medication, and discussions with her mom. *Eisbrouch* Ex. 3, P160-161 and 230.

As revealed by her deposition, there is nothing in the testimony of Dr. Epstein showing that a different warning would have altered her decision to prescribe Accutane to Ms. Cary. The Court relies upon the deposition testimony of Dr. Epstein at P67, L20 thru P69, L25 and P88, L17 thru P89, L20. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

25. Kristi Harvey [Texas].

Defendants' Contentions: Treating physician, Dr. Jones, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "possibly or probably related to," "can induce," or "may cause" IBD. Bufano Ex. 26, P84-86. Dr. Jones was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 34. Dr. Jones further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if she was presented in the same manner. Id. at 86.

Plaintiff's Contentions: When conducting a risk-benefit analysis for a drug that Dr. Jones is considering prescribing to his patients, he wants to know whether the drug causes serious side effects. Sugarman Ex. 3, P 96-98. Dr. Jones would want to know of the risk of a permanent irreversible disease, like IBD, because it would have an impact on his decision whether to prescribe such a medication. Id. at 106. Dr. Jones testified that if the Accutane label had stated that there was a causal relationship between Accutane and IBD it would have affected his prescribing habits and the prescribing decisions he made. Id. at 105-106. Dr. Jones would not have prescribed Accutane to Plaintiff if he had known that it would cause IBD. Id. at 104.

As revealed by his deposition, there is nothing in the testimony of Dr. Jones showing that a different warning would have altered his to prescribe Accutane to Ms. Harvey. The Court relies upon the deposition testimony of Dr. Jones at P84, L24 thru P86, L24. Based upon the rationale

set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

26. <u>Daniel Majerus</u> [Texas].

Defendants' Contentions: Treating physician, Dr. Miller, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "associated with," "possibly or probably related to," "can induce," or "may cause" IBD. Bufano Ex. 36, P26 and 31-32. Dr. Miller was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 22-23. Dr. Miller further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. Id. at 32-33.

Plaintiff's Contentions: Dr. Miller testified that whether a drug is known to cause a serious, permanent, irreversible disease, such as IBD, is something that would have an impact on whether or not to prescribe that drug. Sugarman Ex. 6, P50. Dr. Miller testified that if he had thought, at the time he prescribed Accutane to Plaintiff, that Accutane would IBD he would not have prescribed it to Plaintiff. Id. at 49. Dr. Miller would have warned patients of a causal relationship between Accutane and IBD if he had thought that one existed. Id. at 48-50.

As revealed by his deposition, there is nothing in the testimony of Dr. Miller showing that a different warning would have altered his decision to prescribe Accutane to Mr. Majerus. The Court relies upon the deposition testimony of Dr. Miller at P26, L2 thru P33, L17. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

27. James Lewis [Texas].

Defendants' Contentions: Treating physician, Dr. Waller, testified that he would have prescribed Accutane to Plaintiff even if the label had stated that Accutane is "possibly or probably related to," "can induce," or "may induce" IBD. Bufano Ex. 29, P29. Dr. Waller stated that even if he had been aware of the risk of Accutane at the time he prescribed it to Plaintiff, he still would have prescribed it believing that the benefits outweighed the risks. Id. at 24-25. Dr. Waller further

testified that, despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. *Id.* at 48-49.

Plaintiff's Contentions: Dr. Waller testified that had he received additional warnings of the risk of developing IBD with Accutane use, he would have warned the patient that IBD is a serious situation. Buchanan Ex. 6, P 29-30. Dr. Waller testified that it is ultimately the patient's decision whether or not to take a prescription drug. Id. at 49-50. If Plaintiff's mother had been warned that UC was reported in patients taking Accutane, she testified that she would not have allowed her son to take it. Buchanan Ex. 7, P71.

As revealed by his deposition, there is nothing in the testimony of Dr. Waller showing that a different warning would have altered his decision to prescribe Accutane Mr. Lewis. The Court relies upon the deposition testimony of Dr. Waller at P22, L10 thru P25, L22 and P28, L16 thru P31, L14. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

28. Bobby Ray Lunn [Texas].

Defendants' Contentions: Treating physician, Dr. Miller, was aware of the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. *Bufano* Ex. 32, P53-56. Dr. Miller further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. *Id.* at 79.

Plaintiff's Contentions: Dr. Miller testified that it was not his practice to warn patients of IBD when taking Accutane but if Roche had advised him of the risk he would have shared it with Plaintiff. Samberg Ex. A, P91-92. Dr. Miller also testified that had Roche warned of the latency risk of developing IBD, he would have likewise shared that information with his patients. Id. at 94-95. Dr. Miller acknowledged that ultimately the decision of whether or not to take a prescription drug is left up to his patient, and he would not prescribe a drug to a patient that did not want to take it. Id. at 86 and 88.

Plaintiff's dad testified that if he had received additional warnings regarding the risk of permanent disease, like UC, with Accutane use, he would not have allowed Plaintiff to take it. Samberg Ex. C., P152. Plaintiff's dad stated that if Dr. Miller told him that Accutane could cause permanent diarrhea, rectal bleeding, or severe stomach pain he would not have allowed Plaintiff

to take Accutane. *Id.* at 148-149 and 151-152. According to Plaintiff's dad, this was not a "life or death case of acne. This was just a case of acne. I would never have subjected him to something like that." *Id.* at 151. Plaintiff also stated that he would not have taken Accutane if warned of the same permanent risks even if physicians were unsure as to whether Accutane can cause IBD. *Samberg* Ex. B., P186-187 and 318-319.

As revealed by his deposition, there is nothing in the testimony of Dr. Miller showing that a different warning would have altered his decision to prescribe Accutane to Mr. Lunn. The Court relies upon the deposition testimony of Dr. Miller at P57, L6 thru P61, L16 and P78, L18 thru P79, L21. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

29. Nathan Post [Texas].

Defendants' Contentions: Treating physician, Dr. Cox, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "possibly or probably related to" or "can induce" IBD. Bufano Ex. 42, P14. Dr. Cox was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 12-13. Dr. Cox further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. Id. at 15.

Plaintiff's Contentions: Dr. Cox testified that different language in the label would have altered his conversation with the Plaintiff. Berezofsky Ex. B, P45-46 and 51-52. Dr. Cox testified that information about the prevalence of IBD with Accutane use would have been important to him and would have altered his prescribing practice as he would have conveyed the information to Plaintiff. Dr. Cox testified that after conveying the risks of IBD, he would have left the decision up to the Plaintiff. Id. at 32 and 46-47. Plaintiff testified that he would never have taken Accutane had he known of the risk of IBD. Berezofsky Ex. A, P211-212.

As revealed by his deposition, there is nothing in the testimony of Dr. Cox showing that a different warning would have altered his decision to prescribe Accutane to Mr. Post. The Court relies upon the deposition testimony of Dr. Cox at P14, L6 thru P17, L20. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

30. Robert Yur [Texas].

Defendants' Contentions: Treating physician, Dr. Stephens, testified that he would have prescribed Accutane to Plaintiff if the label had stated Accutane is "possibly or probably related to," "can induce" or "can cause" IBD. Bufano Ex. 64, P50. Dr. Stephens was aware of and considered the risk that Plaintiff could develop IBD when he prescribed Accutane to Plaintiff. Id. at 34. Dr. Stephens further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. Id. at 51.

Plaintiff's Contentions: Dr. Stephens testified that Defendants' labeling was inaccurate as the word "temporally" indicated to him that the symptoms of IBD could not occur after the patient is off the drug. Berezofsky Ex. B, P101, 104, and 107-108. Dr. Stephens testified that such information would have altered his prescribing practice as he would have explained that Accutane could cause IBD to the Plaintiff. Id. at 109. Dr. Stephens would have left the decision of whether or not to take Accutane up to the Plaintiff. Id. at 111 and 171. Plaintiff testified that he would never have taken Accutane if he had been warned that it carried a risk of IBD. Berezofsky Ex. C, P167, 169, and 170.

As revealed by his deposition, there is nothing in the testimony of Dr. Stephens showing that a different warning would have altered his decision to prescribe Accutane to Mr. Yur. The Court relies upon the deposition testimony of Dr. Stephens at P50, L16 thru P51, L15. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

31. Mark Rinker [Texas].

Defendants' Contentions: Treating physician, Dr. Schmidt, testified that he would have prescribed Accutane to Plaintiff if the label had stated that Accutane is "associated with" or "may cause" IBD. *Bufano* Ex. 46, P102-103. Dr. Schmidt further testified that despite what he knows about Accutane now, he would still prescribe Accutane to Plaintiff today if he was presented in the same manner. *Id.* at 94-95.

Plaintiff's Contentions: Dr. Schmidt testified that IBD is a serious condition to have and that patients should be advised of serious long-term side effects of medication. Buchanan Ex. 9, P122-123. Dr. Schmidt testified that he would not force his patients to take a drug. Id. at 136-137. Plaintiff's mother testified that if she were told that Accutane may or may not cause IBD but that it probably will not, she would not have allowed her son to take Accutane. Buchanan Ex. 10, P164-165. Plaintiff argues that if Roche provided a stronger warning to Dr. Schmidt, Dr. Schmidt would then have relayed that information to Plaintiff and his mother, and Plaintiff and his mother would have decided against Plaintiff's taking Accutane.

As revealed by his deposition, there is nothing in the testimony of Dr. Schmidt showing that a different warning would have altered his decision to prescribe Accutane to Mr. Rinker. The Court relies upon the deposition testimony of Dr. Schmidt at P94, L22 thru P95, L3; P102, L10 thru P105, L19; and P123, L13 thru P125, L17. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based upon the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

32. <u>David Whitworth-King</u> [Texas].

Defendants' Contentions: Treating physician, Dr. Garner, testified that she would have prescribed Accutane to Plaintiff if the label had stated Accutane is "possibly or probably related to," "can induce," or "may cause" IBD. *Bufano* Ex. 61, P36-37 and 73-74. Dr. Garner was aware of and considered the risk that Plaintiff could develop IBD when she prescribed Accutane to Plaintiff. *Id.* at 74. Dr. Garner further testified that despite what she knows about Accutane now, she would still prescribe Accutane to Plaintiff today if he was presented in the same manner. *Id.* at 53-54.

Plaintiff's Contentions: Dr. Garner testified that her understanding of the symptoms of IBD listed in the PDR for 1995 were that they were symptoms that would only be present while the patient was taking Accutane. Buchanan Ex. 19, P60-61. Dr. Garner testified that given a different label, she would have discussed the additional risks with her patient. Id. at 36-38. Plaintiff's mother testified that she would not have let her son take Accutane if Dr. Garner had told her that there was a risk of IBD or UC that may not occur until months after he stopped taking Accutane. Buchanan Ex. 20, P127.

As revealed by her deposition, there is nothing in the testimony of Dr. Garner showing that a different warning would have altered her decision to prescribe Accutane to Mr. Whitworth-King. The Court relies upon the deposition testimony of Dr. Garner at P35, L22 thru P37, L19. Based upon the rationale set forth in Parts IV and V, the Court is satisfied that when the law of New Jersey on the LID is applied to those facts, Defendants' Motion must be granted.

Based on the legal rationale set forth in the Court's ruling on the Bolton Motion, under Texas law, Defendants must prevail.

VII. <u>FINAL RULING</u>

Consistent with the Court's rulings in thirty-one (31) of the above claims, whose captions and docket numbers are attached hereto as "Schedule A", the Court has entered an Order GRANTING Summary Judgment of these matters and thus dismissing them with prejudice. The Motion for Summary Judgment as to *Conforti vs. Hoffman-LaRoche*, et al. Docket No.: ATL-L-6290-05 is DENIED without prejudice as per Part VI, Paragraph 2 of this ruling.

Appropriate Orders have been entered. Conformed copies accompany this Memorandum of Decision.

NELSON C. JOHNSON, J.S.C.

Dated: January 29, 2016

SCHEDULE A

CASES:

Di'Tomasso vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3780-10 Conforti vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-6290-05 Hughes vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-5630-05 Luizzi vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3842-06 Herman vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-830-10 Cardinale vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-2377-07 Baucum vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-730-11 Harrison vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-7601-05 Schayot vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3724-09 Ware vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-4518-11 Williams vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-7113-10 Campos vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3075-09 Gadue vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-4102-10 Kuklinski vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-1987-05 McFadden vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-911-11 Satler vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3848-06 Shamsian vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-1375-08 Tucker vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-8347-05 Phillips vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-6892-10 Rice vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-13680-06 Bolton vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-10021-11 Thompson vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-8989-11 Blumenau vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-4371-10 Cary vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-10049-11 Harvey vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-6112-11 Majerus vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-6108-11 Lewis vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3936-07 Lunn vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3937-10 Post vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-7804-10 Yur vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-5471-10 Rinker vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-3469-08 Whitworth-King vs. Hoffman-LaRoche, et al. Docket No.: ATL-L-4423-10