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APR 2 2015

NELSON C. JOHNSON, J.S.C.

COURT INITIATED

IN RE: ACCUTANE LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY CIVIL ACTION NO.: 271 (MCL) ACCUTANE® MULTICOUNTY LITIGATION **ORDER**

THIS MATTER having come before the court on Defendants' Motion for Summary Judgment asserting that Defendants' post-April 10, 2002 warnings for the prescription medication Accutane are adequate; and the court having reviewed the parties' pleadings and conducted a hearing on March 19, 2015, at which time the court heard from Russell Hewitt, Esquire, Paul W. Schmidt, Esquire, and Michelle M. Bufano, Esquire, on behalf of Defendants in support of their application; and Plaintiffs' opposing this Motion, David R. Buchanan, Esquire, and MaryJane Bass, Esquire, appearing; and the court having received oral argument of counsel; and for the reasons stated in the Memorandum of Decision of even date herewith; and for good cause shown;

IT IS ON THIS 2nd **DAY OF** April, 2015, **ORDERED**:

1. Defendants' Motion for Summary Judgment is hereby GRANTED. The effect of this Order is expressly limited by the terms of the court's Memorandum of Decision of even date herewith.

2. Defense counsel shall prepare a form of Order reciting those New Jersey lawsuits effected by this ruling – including Captions and Docket Numbers - and submit the same to the court on or before April 17, 2015. Said Order will not be entered until Plaintiffs' counsel have an opportunity to be heard on the form of the same, particularly the precise Captions and Docket Numbers.

3. On or before April 24, 2015, counsel shall submit legal briefs articulating their position regarding the following issues: (1) all those jurisdictions in which claims arise under the post-April 2002 warnings, delineating the same by state, name of Plaintiff and Docket Number; (2) of said jurisdictions, which ones recognize the learned intermediary doctrine and permit the adequacy of drug labels to be decided as a matter of law; and (3) of those jurisdictions, which ones have a heavier burden of proof than New Jersey.

4. The Court shall convene a Plenary Hearing to finalize the impact of this Ruling on May 11, 2015, at 10:00 a.m. and will continue the same, day-to-day until concluded.

NELSON C. JOHNSON, JSC

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APR -2 2015

NELSON C. JOHNSON, J.S.C.

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

IN RE: ACCUTANE LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY CIVIL ACTION NO.: 271 (MCL) ACCUTANE® MULTICOUNTY LITIGATION

OPINION

RE: PLAINTIFFS WHO INGESTED ACCUTANE ON OR AFTER APRIL 10, 2002

DECIDED: APRIL 2, 2015

APPEARANCES: DAVID R. BUCHANAN, ESQUIRE, PLAINTIFF
MARYJANE BASS, ESQUIRE, PLAINTIFF

RUSSELL L. HEWITT, ESQUIRE, DEFENDANT
PAUL W. SCHMIDT, ESQUIRE, DEFENDANT
MICHELLE M. BUFANO, ESQUIRE, DEFENDANT

NELSON C. JOHNSON, J.S.C.

HAVING CAREFULLY REVIEWED THE MOVING PAPERS AND ANY RESPONSE FILED, TOGETHER WITH ORAL ARGUMENT OF COUNSEL, I HAVE RULED ON THE ABOVE CAPTIONED MOTION AS FOLLOWS:

I. NATURE OF MOTION

Defendants, Hoffmann-La Roche, Inc. and Roche Laboratories, Inc. ("Defendants" and/or "the manufacturer"), bring this Motion for Summary Judgment asserting that Defendants' post-April 10, 2002 warnings (hereinafter "the labeling" and/or "the warnings") for the prescription medication Accutane are adequate as distributed to physicians prescribing the

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medication. Defendants assert that, as a matter of law, the warnings contained in their literature comply with the New Jersey Products Liability Act, *N.J.S.A.* § 2A-58C ("NJPLA").

Plaintiffs oppose this motion and argue, in part, that prior rulings of the previous trial judge in this MCL on omnibus and case-specific motions regarding the adequacy of the warnings establish the law of the case, and that this court is bound by such prior rulings. Plaintiffs' opposition is also based upon their contention that given the number of claims potentially affected by Defendants' Motion, that the court would err were it to act without first conducting a case-specific choice of law analysis.

Finally, in her correspondence to the court of February 4, 2015, Michelle M. Bufano, Esq. advises that a significant number of claims are impacted by Defendant's Motion. "There remain well over 800 cases where plaintiffs first ingested Accutane after April 10, 2002, and where plaintiffs were thus subject to the warning system addressed by this motion." The court believes that because of the magnitude of claims affected, various issues must be addressed sequentially, namely, which/whose claims are affected by this ruling.

II. QUESTION PRESENTED

As the court understands the primary issue framed by the pleadings, the question presented is whether or not the warnings issued to prescribing physicians via Defendants' warning system were adequate to alert them that Inflammatory Bowel Disease (hereinafter "IBD") was a risk associated with the ingestion of Accutane? *Or,* framed consistent with the intent of the Legislature as expressed in the NJPLA, the question presented is, "taking into account the characteristics of, and the ordinary knowledge common to the prescribing physician" did the warnings communicate adequate information of the danger that IBD was a risk associated with the ingestion of Accutane?

III. PROCEDURAL HISTORY

The adequacy of the post-April 10, 2002 Accutane warnings were considered by this court's predecessor on several occasions. To the best of this court's knowledge, there has been no appellate review of any of the five rulings previously entered by the predecessor judge presiding over the Accutane MCL. The five prior rulings are discussed hereinafter.

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First, on March 20, 2008, Defendants' Omnibus Motion for Summary Judgment on the adequacy of the May 2000 Accutane warning label, otherwise known as the Physician package insert, was denied. The trial judge found that, as a matter of law, the warnings were not adequate under the NJPLA.

Second, the adequacy of the Accutane warnings following the adoption of the Medication Guide in January 2001 were presented to the court. In her Memorandum of Decision of December 10, 2008, the judge stated that the decision focused "on the addition of the Medication Guide to the package insert, and whether this addition renders the warnings sufficiently clear and unambiguous to a reasonable dermatologist with ordinary knowledge to take the issue away from the jury." That motion was denied.

Third, Defendants filed yet another Omnibus Motion on the adequacy of the warnings as to all New Jersey Plaintiffs. In addition to the warnings previously considered by the trial judge, the decision also addressed the *Be Smart/Be Safe/Be Sure* brochure. On January 16, 2009, that motion was denied. In her Memorandum of Decision, this court's predecessor rejected Defendants' argument and the case law they cited, instead relying upon *N.J.R.E.* 301, concluding that there was nothing in the plain language of the NJPLA to suggest the rebuttable presumption is any different from other rebuttable presumptions in New Jersey law.

A *Fourth* motion of the Defendants filed in *Tanna v. Hoffmann-La Roche Inc., et al.,* Case No. ATL-L-3366-04 was denied. Ultimately, that matter was concluded by Plaintiff's counsel opting to voluntarily dismiss the claim with prejudice following inconclusive/unsuccessful jury deliberations. Plaintiffs' counsel referenced the failed jury negotiations in their pleadings and at oral argument, but the court believes that *Tanna* warrants no further discussion.

Fifth, Defendants filed a similar motion for summary judgment in *Falco v. Hoffmann-La Roche Inc.*, et al., Case No. ATL-L-2646-08. Suffice it to say, the court applied North Carolina law and denied Defendants' motion on December 20, 2012. Such is the pedigree of prior dispositions on motions involving the warning system distributed to physicians prescribing Accutane.

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IV. LAW OF THE CASE

The court will not belabor this issue. Whatever force the law-of-the-case doctrine may have, it does not control on this motion because new facts and law eclipse the record on which prior rulings were based.

R. 4:42-2 provides that in the absence of a direction that an issue is separate and certified as a final judgment, any order or form of decision which adjudicates fewer than all the claims as to all the parties shall not terminate the action as to any of the claims, and it shall be subject to revision at any time before the entry of final judgment in the sound discretion of the court in the interest of justice. Furthermore, the "law of the case doctrine requires judges to respect unreversed decisions made during the trial by the same court or a higher court regarding questions of law." *Sisler v. Gannett Co.*, 222 *N.J. Super.* 153, 159 (App. Div. 1987), *certif. denied*, 110 *N.J.* 304 (1988). "Prior decisions on legal issues should be followed unless there is substantially different evidence at a subsequent trial, new controlling authority, or the prior decision was clearly erroneous." *Ibid.* The doctrine is discretionary and should be applied flexibly to serve the interests of justice. *Id.* at 159-160; *State v. Reldan,* 100 *N.J.* 187, 205 (1985).

Here, the predecessor judge in this MCL did not have the benefit of the reasoning set forth by Judge Happas in *Bailey v. Wyeth, Inc.*, 424 *N.J. Super.* 278 (Law Div. 2008). In *Bailey*, the trial court granted defendants' summary judgment motion with regard to plaintiffs' NJPLA claims because plaintiffs failed to provide the specific type of evidence necessary to overcome the rebuttable presumption of adequacy afforded to the United States Food and Drug Administration ("FDA") approved labeling on the hormone replacement therapy products. Therefore, the warnings on the labels were deemed adequate as a matter of law. *Id.* at 285. Judge Happas addressed the issues considered by this court's predecessor which are now before this court in assessing the adequacy of the labeling herein. One of those issues is whether or not *N.J.R.E.* 301 is controlling on Plaintiffs' burden for overcoming a rebuttable presumption. The *Bailey* decision found that *N.J.R.E.* 301 does not control and was affirmed on appeal as "legally unassailable" in *DeBoard v. Wyeth, Inc.*, 422 *N.J. Super.* 360, 362 (App. Div. 2011), *certif. denied*, 211 *N.J.* 274 (2012). Both *Bailey* and *DeBoard* were approved for publication on September 29, 2011.

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This court is satisfied that *Bailey* and *DeBoard* are "new controlling authority" in this matter. In light of this new and relevant controlling legal authority, and to serve the interests of justice, the decisions of the predecessor judge in this MCL cannot, and will not be followed.

V. CHOICE OF LAW

The court is in general agreement with the position expressed by Plaintiffs at pages 2-3 of their Brief, namely, "Where the facts of the case implicate competing state laws, the court must first engage in a choice of law analysis to determine what law to apply. New Jersey rules on choice of law call for an issue-by-issue analysis, which starts with the presumption that, when there is a true conflict of laws, the law of the place of injury [generally] should apply." *See P.V. ex rel. T.V. v. Camp Jaycee,* 197 *N.J.* 132, 143 (2008).

That said, the court would be derelict in the performance of its duties were it to make no decision at this time, instead approaching this issue plaintiff-by-plaintiff, state-by-state, case-by-case, on an individual basis as appears to be the recommendation of Plaintiffs' counsel. No one's interest would be served by such an approach. An estimated 800+ claims have been filed in the Accutane MCL wherein the post-April 2002 warnings are applicable. Both sides to this dispute are entitled to a ruling by the court on the adequacy of the warnings contained in literature distributed by Defendants to physicians prescribing Accutane. Both sides benefit from a decision on this petition to guide them going forward in this litigation.

As discussed with counsel during oral argument on March 19, 2015, the court believes it is prudent to first make a ruling under New Jersey law; then proceed in a deliberate fashion to the remaining states in which these claims arise. As confirmed by "Appendix A- Multi-State Survey of Adequacy Law" which accompanies Defendants' Reply Brief of March 13, 2015, it appears that there may be a significant number of jurisdictions which agree with the standard created by NJPLA and our Supreme Court's decisions interpreting the same. Unfortunately, what is not before the court is a state-by-state breakdown of the claims affected by this ruling. That analysis *must* be done. As noted hereinafter, counsel are directed to make their own inquiry and submit those findings to the court.

Nonetheless, the court acknowledges that learning all those states which embrace the learned intermediary doctrine may not complete the inquiry. It may be necessary to examine both

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the statutes on pharmaceutical claims and court decisions of multiple states in order to determine precisely all those jurisdictions which are in harmony with New Jersey law. In any event the court needs to learn: (1) all those jurisdictions in which claims under the post-April 2002 warnings arise; (2) of those jurisdictions, which ones recognize the learned intermediary doctrine and permit the adequacy of drug labels to be decided as a matter of law; and (3) of those jurisdictions, which have a heavier burden of proof than New Jersey, in which case a choice of law analysis is not necessary because those claims must fail. Preliminarily, it appears that the states of New York, Connecticut, Pennsylvania, Maryland, Ohio, Illinois, Florida, California, and Massachusetts may compare favorably to New Jersey law. Additionally, it appears that Michigan and Texas may require a heavier burden of proof than New Jersey.

Accordingly, at this juncture in these proceedings, the prudent thing to do is to limit the effect of this ruling to New Jersey Plaintiffs only.

VI. LEGAL STANDARD

Summary Judgment is appropriate where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." *R.* 4:46-2. A "determination whether there exists a 'genuine issue' of material fact that precludes summary judgment requires the motion judge to consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party." *Brill v. Guardian Life Ins. Co.,* 142 *N.J.* 520, 540 (1985). If there exists a single, unavoidable resolution of the alleged disputed issue of fact, that issue should be considered insufficient to constitute a genuine issue of material fact for purposes of *R.* 4:46-2. *Ibid.* The thrust of *Brill* is that "when the evidence 'is so one-sided that one party must prevail as a matter of law,' . . . the trial court should not hesitate to grant summary judgment." *Ibid.*

Further, in order to defeat a motion for summary judgment, a party must show that there are genuine issues of material fact. *Ibid* at 540. "Bare conclusions in the pleadings, without factual support in tendered affidavits, will not defeat a meritorious application for summary

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judgment." *United States Pipe and Foundry Co. v. American Arbitration Ass'n.*, 67 *N.J. Super.* 384, 399-400 (App. Div. 1961); *See* also *Brae Asset Fund v. Newman*, 327 *N.J. Super.* 129, 134 (App. Div. 1999) and *Baran v. Clouse Trucking, Inc.* 225 *N.J. Super.* 230, 234 (App. Div. 1988).

In addition to *Brill*, the court receives guidance from *Anderson v. Liberty Lobby, Inc.*, 477 *U.S.* 242 (1986) which cites *Improvement Co. v. Munson*, 14 *Wall* 442, 448 (1872). In *Anderson*, *supra,* 477 *U.S.* at 251, our Supreme Court quoted *Munson* and admonished trial judges that,

> ...before the evidence is left to the jury, there is a preliminary question for the judge, not whether there is literally no evidence, but whether there is any upon which a jury could properly proceed to find a verdict for the party producing it, upon which the onus of proof is imposed.

The Court in *Anderson* also stated,

> In sum, we conclude that the determination whether a given factual dispute requires submission to a jury must be guided by the substantive evidentiary standards that apply to the case ... The trial judge's summary judgment inquiry as to whether a genuine issue exists will be whether the evidence presented is such that a jury applying that evidentiary standard could reasonably find for either the plaintiff or the defendant. *Id.* at 255.

Moreover, a drug manufacturer that communicates adequate information on the dangers and safe use of prescription drugs, "taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician," will not be liable for a failure to warn under the NJPLA. *N.J.S.A.* § 2A:58C-4. Additionally, if the warning or instruction given in connection with a drug has been approved or prescribed by the FDA, "a rebuttable presumption shall arise that the warning or instruction is adequate." *Ibid.*

Further, as noted by the court in *Banner v. Hoffman*, 383 *N.J. Super* 364, 377-378 (App. Div. 2006), notwithstanding the general rule that "the question of whether a warning is adequate is one for a jury to resolve...[citations omitted]... That principle, however, is not a rigid mantra, to be applied inexorably in all situations and contexts. Even in the context of prescription drugs, the adequacy of a warning may be determined as a matter of law."

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VII. WARNINGS CONTAINED IN LITERATURE

S.M.A.R.T. Guide to Best Practices

Working in cooperation with the FDA, Defendants developed a new prescribing procedure called the System to Manage Accutane Related Teratogenicity, or S.M.A.R.T., which was set forth in mailings to prescribing physicians and pharmacists in January 2002. Accordingly, in order to continue prescribing Accutane after April 10, 2002, each physician was required to read a booklet called "S.M.A.R.T. Guide to Best Practices," which gave him or her further instructions on how to prescribe Accutane. The Guide advised physicians:

> ABOUT ACCUTANE
>
> ...
>
> Therapy with Accutane should not be undertaken before conventional treatment has been tried first, including the use of systemic antibiotic therapy, and the patient has been fully counseled about the warnings and precautions in the Accutane package insert.
>
> ...
>
> Accutane use is associated with other potentially serious adverse events, as well as more frequent, but less serious side effects.
>
> ...
>
> Adverse Event Warnings include...inflammatory bowel disease...
>
> ...
>
> Patients should be reminded to read the Medication Guide, distributed by the pharmacist at the time the Accutane is dispensed.

The S.M.A.R.T. guide also required physicians to sign and return to Defendants a letter of understanding affirming that they understood the safe and effective use of Accutane as described in the S.M.A.R.T. Guide, Physician package insert and other educational resources before they could receive their Accutane Qualification Stickers. Physicians were required to affix the Qualification Stickers to each prescription. Pharmacists were also instructed not to dispense Accutane without the Qualification Stickers or Medication Guide.

Physician Package Insert

The FDA-approved Accutane Physician package insert, or label, is the primary means by which pharmaceutical companies communicate the risks and benefits of their medicines to the

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medical community. Defendants have included information about IBD in the WARNINGS section of the package insert since 1984. At all relevant times, the Physician package insert contained the following language:

> **WARNINGS:**
> ...
> *Inflammatory Bowel Disease:* Accutane has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after Accutane treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately (see ADVERSE REACTIONS: *Gastrointestinal).*

Supporting language also appeared in the package insert under the ADVERSE REACTIONS section:

> **ADVERSE REACTIONS:** ***Clinical Trials and Postmarketing Surveillance:*** The adverse reactions listed below reflect the experience from investigational studies of Accutane, and the postmarketing experience. The relationship of some of these events to Accutane therapy is unknown.
> ...
> *Gastrointestinal:* inflammatory bowel disease (see WARNINGS: *Inflammatory Bowel Disease)...*

This IBD warning language remains in place through this date, including after the manufacturer chose to stop selling Accutane in the United States in 2009.

Medication Guide

The Medication Guide was developed in conjunction with the FDA in January 2001. Pharmacists were required to provide patients with the Medication Guide each time an Accutane prescription was dispensed. Defendants also drafted a letter to all prescribing physicians requesting that they utilize the Medication Guide in all discussions with patients who were contemplating the use of Accutane. The 2001 Medication Guide stated in pertinent part:

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> **Accutane has possible serious side effects**
>
> ...
>
> **Abdomen (stomach area) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the...bowel (intestines)...If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach or bowel pain, diarrhea, rectal bleeding...
>
> ...
>
> Serious permanent problems do not happen often. However, because the symptoms listed above may be signs of serious problems, if you get them, stop taking Accutane and call your provider. If not treated, they could lead to serious health problems. Even if these problems are treated, they may not clear up after you stop taking Accutane.

This language was in effect as of April 10, 2002 and was revised in June of 2002 only to add the esophagus to the list of organs and "trouble swallowing" as a symptom.

Patient Brochures

The manufacturer also provided physicians with patient brochures. The Eighth and Ninth Edition patient brochure became available in January and November 2002, respectively. In all relevant respects, the warnings provided in the Eighth Edition patient brochure are identical to those provided in the Ninth Edition brochure. Both brochures are titled *Be Smart/Be Safe/Be Sure*. Furthermore, both brochures warned the following in their first section entitled *Patient Product Information: Important information concerning your treatment with Accutane (Isotretinoin):*

> Accutane can cause serious side effects. Before you decide to take Accutane, you must discuss with your prescriber how bad your acne is, the possible benefits of using Accutane, and its possible side effects...Your prescriber will ask you to read and sign a form or forms to show that you understand some of the serious risks of Accutane. Please read this brochure carefully and ask your prescriber any questions you may have.
>
> ...
>
> WHO SHOULD NOT TAKE ACCUTANE?

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...
Do not take Accutane unless you completely understand its possible risks and are willing to follow all of the instructions in this brochure. When you pick up your Accutane prescription at the pharmacy, you should receive a copy of the Accutane Medication Guide with your Accutane.

...

DURING YOUR TREATMENT: WHAT SHOULD YOU AVOID WHILE TAKING ACCUTANE?

...

You should be aware that certain SERIOUS SIDE EFFECTS have been reported in patients taking Accutane. Serious problems do not happen in most patients. If you experience any of the following side effects or any other unusual or severe problems, stop taking Accutane right away and call your prescriber because they may result in permanent effects.

...

- **Abdomen (stomach area) problems.** Certain symptoms may mean that your internal organs are being damaged. These organs include the...bowel (intestines)...If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach or bowel pain, diarrhea, rectal bleeding...

The Eighth and Ninth Edition brochures also included consent forms to be removed and signed by patients to affirm that they had read and understood the first section of the brochure and other materials provided by their prescribers regarding important safety information about Accutane. Consent forms also included a signature line for prescribers to confirm that they had fully explained the benefits and risks of Accutane treatment.

Blister Packaging

Defendants made Accutane available in a 10-pill blister packaging that contained warnings accessible when patients removed their Accutane pills. The blister pack warned, in pertinent part, as follows:

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Other serious side effects to watch out for

Stop taking Accutane and call your prescriber if you develop any of the problems on this list or any other unusual or severe problems. If not treated, they could lead to serious health problems. Serious permanent problems do not happen often.

...

- Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing.

...

Other important information is found in the Medication Guide and in the booklets from your prescriber.

VIII. FINDINGS OF FACT

Based upon the legal briefs, certifications and exhibits filed with the court, together with the arguments of counsel at the hearing on March 19, 2015, the court makes the following Findings of Fact:

1. The physicians prescribing Accutane, generally dermatologists, have known since in or about 1984 that IBD is a potential risk of Accutane.

2. As a consequence of Accutane's known pregnancy risk, the Defendant manufacturer developed a controlled prescribing procedure, or warning system, which alerted dermatologists and pharmacists to ensure that patients were fully counseled and monitored throughout their course of treatment with Accutane.

3. That procedure, called "System to Manage Accutane Related Teratogenicity," (hereinafter "S.M.A.R.T.") was set forth in a packet of literature mailed to all prescribing physicians and pharmacists in January 2002 and formally went into effect in April 2002.

4. As a condition precedent to a physician's ability to prescribe Accutane after April 10, 2002, every physician was required to read a booklet called "S.M.A.R.T. Guide to Best Practices" and all related literature in the warning system which gave them further instructions on how best to prescribe Accutane.

5. The guide reminded physicians that "[t]herapy with Accutane should not be undertaken before ... the patient has been fully counseled about the warnings and precautions in the Accutane package insert," among which it expressly listed IBD as an adverse event.

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6. Further, those dermatologists, and any other physicians, prescribing Accutane were required to sign and return to Defendant a letter of understanding affirming that they understood the risks associated with it, including IBD, which read, in pertinent part: "I acknowledge that by completing this form I demonstrate my understanding of the safe and effective use of Accutane as described in ... the Accutane package insert."

7. Pharmacists were instructed not to dispense Accutane unless a prescription was accompanied by a sticker from Roche, affixed to the prescription by the prescriber, indicating that the prescriber had complied with the S.M.A.R.T. requirements.

8. Upon Accutane becoming available for physicians to prescribe, the manufacturer provided them with patient brochures and other literature explaining the key characteristics of Accutane so that they could use the same in counseling their patients.

    a. The aforesaid brochures and accompanying literature were modified and updated through the years, with a major reworking of the form and structure going into effect with the Eighth Edition in January 2002.

    b. The brochures and accompanying literature comprising the warning system are discussed in greater detail in Finding of Fact #12 hereinafter.

9. In January of 2001, Defendant implemented a comprehensive Medication Guide for Accutane that was required by federal law to be provided to every patient by the pharmacist every time the patient renewed an Accutane prescription.

10. As set forth in a letter from the manufacturer to prescribing physicians when the medication guide first became available (A "Dear Health Care Provider" letter), prescribers were expressly directed to use the Medication Guide in *"all prescriber discussions with patients"* contemplating the use of Accutane.

11. Since 1990, Defendant has made Accutane available only via "blister packaging" which likewise contained significant warnings and reminders for patients regarding Accutane.

12. The literature and warning system utilized by Defendant in the distribution of Accutane is significant. (See Exhibits J-1 thru J-11, marked into evidence at the time of oral argument, also known as Exhibits 6, 7, 8, 10, 11, 12, 15, 16, 21, 22, and 24 of Defendant's pleadings.) With regard to the "Be Smart/Be Safe/Be Sure" brochure and accompanying literature, the court concludes as follows:

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a. The warnings contained in the "Be Smart/Be Safe/Be Sure" brochure are clear, accurate and unambiguous. They advise of potential risks in a manner that portrays seriousness of purpose in advising dermatologists and any other physicians as to the steps to be followed prior to prescribing Accutane.

b. The "Be Smart/Be Safe/Be Sure" brochure is a document designed to attract the attention of any physician reading the same and focus doctors on the seriousness of the medication they are considering to prescribe to a patient in hope of treating severe acne.

c. The content of the literature is such that the reasonable physician, including dermatologists, of ordinary education, training and experience will immediately understand that Accutane has been associated with life-altering side effects.

d. The brochure's design alone signals seriousness of purpose. Held together by a metal ring binder (comparable to students' notebooks) this brightly colored brochure measures 10" x 11" and is a hefty document. The text of the brochure contains 50+ pages and is separated by 3 heavy tabs.

e. The requirement that no physician can issue a prescription for Accutane until he or she first counsels the patient on the warnings accompanying the medication reinforces the manufacturer's seriousness of purpose in issuing the warning literature.

f. The physician's knowledge that Accutane is tendered to the patient in a blister package made of thick paper wherein each pill has its own vessel for storage made of aluminum foil and plastic, which the patient must break open in order to take the pill, likewise reinforces the manufacturer's seriousness of purpose in issuing the warning literature.

13. As recently as May 2012, the FDA approved Absorica, a new type of isotretinoin with the same indication as Accutane and its generic counterparts. The FDA-approved package insert for Absorica contained the identical warning language regarding IBD as was included in the June 2002 Accutane Physician Package Insert.

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IX. ANALYSIS AND RULING

Roles of FDA and Manufacturers on Labels

At times, our society seems to have made a Faustian bargain with the pharmaceutical industry. We have limited patience with illnesses and high expectations for quick cures. Our faith in science is such that we assume there is a medication for every physical malady; everything from heartburn, colds and acne to high blood pressure, urinary difficulties, and cancer. In short, ours is a culture which believes there should be a pill for every ill. Under the statutory and regulatory scheme by which new pharmaceutical products enter the marketplace, the FDA is the gate keeper. Only the FDA is empowered to initially assess all new medications, whether prescription or over-the-counter. It is likewise the FDA, alone, which approves the labels by which medications are presented to consumers, and once a label has been approved for marketing the drug to the public, anyone making a claim for injury purportedly arising from a medication has a significant burden of proof.

The FDA has exclusive control of the introduction of new drugs to the American public and all drugs must be approved by that agency before marketing in the U.S. 21 *U.S.C.A.* § 355(a). The FDA is responsible for "promot[ing] the public health by promptly and efficiently reviewing [drug manufacturers'] clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 *U.S.C.A.* § 393(b)(1). All new drugs must be tested for safety prior to marketing. 21 *U.S.C.A.* §§ 301-399. The results of a manufacturers' testing are submitted to the FDA as part of a New Drug Application ("NDA"), and the FDA is responsible for ensuring that all new drugs are both "safe and effective" prior to marketing to the public. *See* 21 *U.S.C.A.* § 393(b)(2)(B).

To initiate the approval process, a manufacturer submits a NDA to the FDA, which, among other things, reports on the investigation into the safety and effectiveness of the drug, the components and production methods used in the drug's manufacturing, together with draft language proposed for the labeling of the drug. *See* 21 *C.F.R.* § 314.50. Once the drug is approved, the manufacturer remains obligated to report to the FDA adverse drug experiences and any "significant new information . . . that might affect the safety, effectiveness, or labeling of the drug product." 21 *C.F.R.* § 314.81(b)(2)(i). In the event a manufacturer seeks approval of additional indications for a drug, it must submit a supplemental new drug application ("SNDA").

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The FDA reviews the SNDA, including the data from clinical studies supporting the change, with the same degree of scrutiny as the original NDA. 21*C.F.R.* § 314.125(b)(4).

In the context of prescription drugs, "[t]he term 'labeling' means all labels and other written, printed or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 *U.S.C.A.* § 321(m). In 2006, the FDA codified the longstanding policy that labeling must "adequately inform users of the risks and benefits of the product and [be] truthful and not misleading." 71 *Fed. Reg.* 3922 (Jan. 24, 2006). Labeling proposed by a manufacturer is submitted as part of the NDA and reviewed by the FDA; the "labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug," including, among other things, potential safety hazards associated with use of the drug. 21 *C.F.R.* § 201.56(a). The NDA must include a "summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling." 21 *C.F.R.* § 314.50(d)(5)(viii). Finally, in the event revisions to the labeling are deemed necessary by the FDA prior to reaching final approval, "the labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 *C.F.R.* § 201.80(e)

Learned Intermediary Doctrine

In prescription drug cases where the "learned intermediary doctrine" applies, it is the physician who is viewed as the user. The intended "audience" of the labeling and warnings are medical doctors, not patients.

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 v. 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 learned intermediary doctrine 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 learned intermediary doctrine, the question in evaluating the adequacy of a warning is whether it is sufficient to apprise the

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reasonable practicing physician of the medication's risk in order to allow a sufficient risk-benefit analysis before the drug is prescribed. *See Prince v. Garruto et al.*, 346 *N.J. Super.* 180, 190 n.2 (App. Div. 2001).

The learned intermediary doctrine 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 v. Hoffmann-La Roche Inc.*, 383 *N.J. Super.* 364, 375 (App. Div. 2006), *certif. den.* 190 *N.J.* 393 (2007). 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 v. Wyeth* 313 *N.J. Super.* 511, 515-516 (App. Div. 1998), *rev'd. on other grounds*, 161 *N.J.* 1 (1999).

In *Perez,* despite Justice Pollack's dissent, the Supreme Court overrode the learned intermediary doctrine in the case of prescription drugs mass marketed to the public. *Perez, supra,* 161 *N.J.* at 20-21. But that is not the situation here and when a drug is marketed only to physicians, as Accutane was, the learned intermediary doctrine controls. The NJPLA also provides that where a drug manufacturer has FDA approval for its warning, it benefits from a "rebuttable presumption" of adequacy; that is the question before the court.

Finally, at page 40 of Plaintiffs' Reply Brief, counsel argues that "the court cannot summarily dispose of these cases without considering testimony of the prescribing physicians." Implicit in this urging is Plaintiffs' desire to have the court engage in a case-by-case, subjective review of the Accutane warnings, doctor by doctor, with each Plaintiff's prescribing physician opining on the labeling. The FDA's approval of a drug label is entitled to a presumption of adequacy for which Plaintiffs have the burden of proof to demonstrate that the approved label is inadequate. Counsel ignores the fact that the approved labeling language for Accutane continues to this day via the FDA's approval of the Absorica label. For Plaintiffs' counsel, the FDA's approval would be secondary to the prescribing physicians' subjective opinions. The court's Findings of Fact recited hereinabove obviate the need for such an exercise.

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Rebuttable Presumption Under the NJPLA

A manufacturer "that communicates adequate information on the dangers and safe use of the [prescription drug] product . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician" will not be liable for a failure to warn under the NJPLA. *N.J.S.A.* 2A:58C-4. In an effort to level the floors of our State's courtrooms, the New Jersey Legislature accorded deference to the FDA's determination of appropriate labeling of prescription drugs by including a rebuttable presumption in the NJPLA. As characterized by our Supreme Court in *Kendall v. Hoffman-La Roche, Inc.*, 209 *N.J.* 173, 195 (2012), that presumption is a "super-presumption" and "only in the 'rare case' will damages be assessed against a manufacturer issuing FDA-approved warnings." (quoting *Perez, supra,* 161 *N.J.* at 24).

It is the public policy of this State that manufacturers who comply with FDA regulations are granted a rebuttable presumption of adequate labeling. *N.J.S.A.* 2A:58C-4 specifically provides: "If the warning or instruction given in connection with a drug . . . has been approved or prescribed by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act,' a rebuttable presumption shall arise that the warning or instruction is adequate." Our State Legislature adopted this presumption to insure even-handed treatment of claims against New Jersey manufacturers of pharmaceutical products. By doing so, the Legislature demonstrated special concern for "an industry with a significant relationship to [New Jersey's] economy and public health." *See Rowe v. Hoffman-La Roche Inc.* 189 *N.J.* 615 at 626 (2007). It is clear to this court that in enacting the NJPLA, "The Legislature intended for the Act to limit the liability of manufacturers..." *See Zaza v. Marquess & Nell* 144 *N.J.* 34, at 47 (1996). The NJPLA, and the presumption it accords drug manufacturers, "accepts FDA regulation as sufficient, a least in part, to deter New Jersey pharmaceutical companies from manufacturing unsafe prescription drugs." *Rowe, supra,* 144 *N.J.* at 625.

New Jersey Courts require that before the FDA warning presumption will be deemed rebutted, the plaintiff must produce a specific type of evidence demonstrating intentional misconduct by the manufacturer. *See* William A. Dreier, *New Jersey Products Liability & Toxic Torts Law* § 15:4 at 465 (2015). Our Supreme Court first defined the specific type of evidence needed to overcome the presumption of adequacy granted by the NJPLA in *Perez, supra,* 161

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N.J. at 24. The exception to the presumption of adequacy crafted in *Perez* was reaffirmed by the Supreme Court in *Rowe, supra*, 189 *N.J.* at 626.

The *Perez* Court held "for all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" of a failure to warn claim. *Perez, supra*, 161 *N.J.* at 25, ("[a]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling"); *See* also *Rowe, supra*, 189 *N.J.* at 626. Several years ago the Appellate Division discussed an additional basis for overcoming the presumption of adequacy set forth in the NJPLA, namely, a pharmaceutical company's "economically-driven manipulation of the post-market regulatory process." *McDarby v. Merck*, 401 *N.J. Super.* 10, 63 (App. Div. 2008).

Presently, the presumption of an adequate warning based on compliance with FDA regulations will be deemed rebutted only if the following proof is presented: (a) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ("*Perez/Rowe* exception"), or (b) manipulation of the post-market regulatory process ("*McDarby* exception") *Rowe, supra*, 189 *N.J.* at 626; *Perez, supra*, 161 *N.J.* at 25; *McDarby, supra*, 401 *N.J. Super.* at 63. The Court in *Perez*, explained that compliance with FDA regulations provides "*compelling evidence* that the manufacturer satisfied its duty to warn the physician." *Perez, supra*, 161 *N.J.* at 24 (emphasis added). Thus, the presumption in favor of the adequacy of FDA-approved warnings will not be deemed rebutted unless plaintiffs produce the type of evidence identified in *Perez, Rowe*, or *McDarby*.

Plaintiffs have failed to produce the type and quality of evidence required by the aforementioned case law. Counsel asserts at page 41 of Plaintiffs' Brief that "there was economically-driven manipulation of the post-marketing regulatory process" and that Defendants' "strategy to downplay the IBD risk has been proven to be deliberate ...". This court asks to whom were such assertions *proven to be deliberate?* Time and again at the two *McCarrell* trials and the *Kendall* trial, this court's predecessor expressly found that the necessary proofs to support such assertions did not exist. In short, the proofs required by *Perez, Rowe* and *McDarby* are not before the court, despite ample opportunity to present them at prior trials.

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Ruling

This is not the "rare case" where a claimant is entitled to damages against a manufacturer which has marketed a prescription medication utilizing "FDA-approved warnings." Based upon the Findings of Fact set forth hereinabove, the Court concludes the Plaintiffs have failed to provide the type and quality of evidence required by our Supreme Court. Plaintiffs' submission cannot overcome the rebuttable presumption of adequacy under the NJPLA afforded to the FDA-approved labeling utilized by these Defendants in the marketing of Accutane.

As noted by Finding of Fact #12, the court requested that originals of the warning literature be marked into evidence and be available for physical examination by any reviewing panel. Both the substance and form of the warning literature issued to prescribing physicians by Defendants emanates a very forceful seriousness of purpose; driving home the message to physicians of ordinary skill, care and diligence that is clear, accurate and unambiguous, namely, *You are about to prescribe a medication that is associated with risk of serious side effects. You are responsible for counseling your patients of these risks.*

Taken as a whole, the warning system crafted by Defendants conveys a meaning as to potential risks and consequences that is unmistakable. It is inconceivable to this court that the reasonable dermatologist (or any physician, generally) of ordinary education, training and experience could examine the materials comprising the warning literature and not immediately conclude that Accutane has been associated with life-altering side effects, including IBD. At multiple points, IBD is explicitly communicated to the prescribing physician as a potential risk of Accutane ingestion.

Findings of Fact #s 5, 6, 9, 10 and 12 in particular, along with the other findings, demonstrate that the labeling and all the warning literature issued to physicians by the manufacturer very ably disclose with ample detail and intensity the risks associated with taking Accutane. Viewed objectively, it is a striking package of information for introducing a medication to a prescribing physician. Any physician of ordinary skill, care and diligence who ignored the Defendants' warning system did his/her patients a disservice. Such warnings are entitled to the benefit of our state's rebuttable presumption of adequacy and are deemed adequate as a matter of law. Accordingly, Defendants' Motion for Summary Judgment is GRANTED.

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Finally, as noted in the discussion on the Choice of Law at page 5 above, the court hereby directs counsel to submit legal briefs articulating their position on or before April 24, 2015, regarding the following issues: (1) all those jurisdictions in which claims arise under the post-April 2002 warnings, delineating the same by state, name of Plaintiff and Docket Number; (2) of said jurisdictions, which ones recognize the learned intermediary doctrine and permit the adequacy of drug labels to be decided as a matter of law; and (3) of those jurisdictions, which ones have a heavier burden of proof than New Jersey. In an effort to finalize a precise list of all lawsuits impacted by this Ruling, the court shall convene a Plenary Hearing commencing on May 11, 2015, at 10:00 a.m. and will continue the same, day-to-day until concluded.

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

NELSON C. JOHNSON, J.S.C.

Date of Decision: April 2, 2015

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