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Attorneys for Defendants
Hoffmann-La Roche Inc. and
Roche Laboratories Inc.

IN RE: ACCUTANE® LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

CASE NO.: 271

CIVIL ACTION

ACCUTANE® LITIGATION

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT BASED ON LACK OF PROXIMATE CAUSE BECAUSE PLAINTIFFS' PRESCRIBERS ARE DECEASED OR UNABLE TO BE LOCATED

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

IT IS on this 12th day of October 2016,

ORDERED as follows:

1. Defendants' Motion is hereby granted;

2. Plaintiffs' Complaints in the matters listed on the accompanying Schedule A are hereby dismissed with prejudice in their entirety;

3. Plaintiffs' Complaints in the matters listed on the accompanying Schedule B are hereby dismissed with prejudice in their entirety;

4. A copy of this Order shall be served on all counsel within 5 days of receipt by Defendants' counsel.

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

[✓] Opposed
[ ] Unopposed

Third Amended Schedule A: Deceased Prescribers

Plaintiff Name	Docket Number
ARNOLD, JOSEPH R.	ATL-L-006624-11
BISTANY, KURT ROY	ATL-L-004480-11
BOISSELLE, JAKE ANDREW	ATL-L-002484-11
BROCK, RONALD CHRISTOPHER	ATL-L-007284-11
BUCEK, CHRYSTALL M	ATL-L-000802-11
CARMICHAEL, COURTNEY CLAIRE	ATL-L-006703-11
CARO, ALISON ANN	ATL-L-001040-12
CARTWRIGHT, JOHN KEITH	ATL-L-004668-11
CHATELAIN, JILL S.	ATL-L-005534-11
CHILDERS, ANDREA MARIE	ATL-L-004330-11
*COHEN, TRACY L. *(Case also on Schedule B)*	ATL-L-004709-11

Total: 45

FLETCHER, DEBRA L.	ATL-L-004160-11
FOLSE, HEATH F.	ATL-L-009500-11
FONSECA, NICHOLAS R.	ATL-L-005358-10
FOX, NANCY L.	ATL-L-006803-05
GIOVENGO, ANTHONY MARK	ATL-L-002869-12
GWYN, BRADLEY MONROE	ATL-L-004599-11
HAHN, JASON E.	ATL-L-004233-11
HEALY, JENNIFER L.	ATL-L-007681-11
HOFFMAN, JASON L.	ATL-L-006828-12
KERFUS, LORI ANN	ATL-L-005632-11
KERR, JOHN RYAN	ATL-L-006106-11
KOSTOSS, CHRISTOPHER M.	ATL-L-005688-11
LAMONS, DEREK TREMAYNE	ATL-L-006143-11

LEJEUNE, AARON DALE	ATL-L-004351-12
MAPEL, ROBERT M.	ATL-L-000422-12
MCLAIN, RALPH TIMOTHY	ATL-L-005562-11
MILLER, CYNTHIA LORRAINE	ATL-L-003211-12
ORISINO, JOSEPH G.	ATL-L-006006-11
PIQUERO, CAROLYN	ATL-L-006411-11
PRUTTING, ANTHONY LAWRENCE	ATL-L-006567-11
RODGERS, WES AUSTIN COLE	ATL-L-005842-11
ROEDEL, ROBERT NICHOLAS	ATL-L-002609-12
SCHUSTER, LAURA I.	ATL-L-006903-11
SELF, BOBBIE NELL	ATL-L-002194-12
SINICK, MICHAEL	ATL-L-002651-12
STILES, QUENTIN	ATL-L-000206-11

SULLIVAN, R. LENORA	ATL-L-004379-12
SVIHLA, TERRI JOANN	ATL-L-007245-11
TREON, MARGARET EDNA	ATL-L-002054-11
VARBONCOUER, MARY PATRICIA	ATL-L-007313-11
WALSH, JEROME E.	ATL-L-007344-11
WHITAKER, AMANDA REEVES	ATL-L-005972-11
WILKIE, CHRISTOPHER D.	ATL-L-006737-12
WOODS, KIMBERLY R	ATL-L-007497-10

Third Amended Schedule B: Prescribers Unable to Be Located

Plaintiff Name	Docket Number
BAKER, AMMON J.	ATL-L-007795-10
BLEA, CHARLES ANTHONY	ATL-L-004482-11
BONNER, GERALDINE	ATL-L-000803-11
BRADY, MATTHEW WILLIAM	ATL-L-002756-08
CHARO-MURRIETTA, MIRIAM SABRINA	ATL-L-007725-11
CICHACKI, LORIANN H.	ATL-L-000578-12
*COHEN, TRACY L. *(Case also on Schedule A)*	ATL-L-004709-11
CORTIZO, JASON M.	ATL-L-006925-11
DONOHOE, BENJAMIN A.	ATL-L-005129-11

Total: 42

EDWARDS, DIANA RENEE	ATL-L-004142-11
FRANKOS, MARIE	ATL-L-000902-08
GAINES, JAMES AARON	ATL-L-000163-13
GAITHER, NANNETTE M.	ATL-L-002653-12
GOLDTHWAITE, RICHARD CLARK	ATL-L-001627-08
HENRY, JOANNA	ATL-L-005513-11
HILTON, CRAIG A.	ATL-L-005290-11
IRBY, JOSEPH CHARLES	ATL-L-003719-09
JAMESON, BOBBIE	ATL-L-010041-11
JULIANA, MARGARET	ATL-L-009558-11

JULKOWSKI, JAMES H.	ATL-L-007707-11
KEANE, MICHAEL G.	ATL-L-000107-12
LAWRENCE, WILLIAM EDWARD	ATL-L-004332-12
LEAVITT, TYLER	ATL-L-007255-11
MARTIN, TRENTON EUGENE	ATL-L-002554-12
MCLEMORE, JAMIE NICOLE	ATL-L-001305-12
NAPOLES, JOHN L.	ATL-L-001071-12
NOVICK, JON SCOTT	ATL-L-004459-11
PERKINS, ANGELA KAY	ATL-L-007948-11
PETERSON, BRAD HOBSON	ATL-L-002671-11

PLETTA, STEVEN E.	ATL-L-000421-12
ROSE, KIMBERLY A.	ATL-L-003174-12
SPARROW, LISA D.	ATL-L-010397-11
STAPLES, JASON E.	ATL-L-008169-11
SWAFFORD, BRADLEY WILLIAM	ATL-L-003016-11
SYME, CRYSTA JEANNE	ATL-L-007045-11
THOMAS, TOINETTE CORA	ATL-L-006665-11
VAN PATTEN, ZACHARY J.	ATL-L-000936-12
WADE, PATRICIA B.	ATL-L-002654-12
WALKER, TRACY LYNN	ATL-L-010006-11

WATSON, WILLIAM B.	ATL-L-000935-12
WATTS, GINGER R.	ATL-L-003906-12
WATTS, KERRY G.	ATL-L-007409-11

SUPERIOR COURT OF NEW JERSEY

NELSON C. JOHNSON, J.S.C.

1201 Bacharach Boulevard
Atlantic City, NJ 08401-4527
(609) 594-3384

MEMORANDUM OF DECISION ON MOTION
Pursuant to Rule 1:6-2(f)

RE: ACCUTANE LITIGATION
CASE NO.: 271

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT BASED ON LACK OF PROXIMATE CAUSE BECAUSE PLAINTIFFS' PRESCRIBERS ARE DECEASED OR UNABLE TO BE LOCATED

CASES: SCHEDULES A & B

DATE: OCTOBER 12, 2016

APPEARANCES:

PLAINTIFFS:	DEFENDANTS:
DAVID R. BUCHANAN, ESQUIRE MICHAEL L. ROSENBERG, ESQUIRE MARYJANE BASS, ESQUIRE BILL CASH, ESQUIRE STEPHEN M. BOLTON, ESQUIRE DANIEL C. LEVIN, ESQUIRE PETER SAMBERG, ESQUIRE PAUL L. SMITH, ESQUIRE WENDY ELSEY, ESQUIRE MORRIS DWECK, ESQUIRE ROBERT J. EVOLA, ESQUIRE RICK M. BARRECA, ESQUIRE DIANE M. COFFEY, ESQUIRE LON WALTERS, ESQUIRE ALLISON E. WHITTEN, ESQUIRE SCOTT C. GREENLEE, ESQUIRE GREGORY BROWN, ESQUIRE ANN RICE ERVIN, ESQUIRE JUSTIN JENSON, ESQUIRE W. LEE GRESHAM, III, ESQUIRE LISA ANN GORSHE, ESQUIRE	PAUL W. SCHMIDT, ESQUIRE MICHAEL X. IMBROSCIO, ESQUIRE RUSSELL L. HEWITT, ESQUIRE BRANDON E. MINDE, ESQUIRE CHRIS MCRAE, ESQUIRE ERIC SWAN, ESQUIRE MARK A. DREHER, ESQUIRE CORTNEY M. GODIN, ESQUIRE DIMPLE DESAI SHAH, ESQUIRE

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

Nature of Motion and Procedural History

This matter comes before the Court via an Omnibus Motion filed by the Defendants, Hoffman-LaRoche, et al. (hereinafter "the Defendants") based upon the purported lack of proximate cause in a total of one hundred and twelve (112) cases, wherein Defendants assert that the learned intermediary is either deceased or unable to be located. Without testimony from such learned intermediaries, Defendants argue that Plaintiffs' claims fail for lack of proximate cause. As a consequence of further review and discussion among counsel, there are now only eighty-six (86) cases, from thirty-five (35) jurisdictions, subject to this Motion, the captions and docket numbers for which are attached hereto as "Schedule A" and "Schedule B". The Court received the benefit of the excellent oral arguments from counsel on August 22, 23, and 24, 2016, and now makes its ruling.

Additionally, Defendants filed Motions for Summary Judgment based upon an alleged lack of proximate cause in sixteen (16) states. Those Motions are addressed in another Memorandum of Decision of same date.

Findings of Fact

After reviewing the submissions of all parties and having received the benefit of oral argument during the week of August 22, 2016, the Court makes the following findings of fact:

1. On March 29, 2016, Defendants requested that Plaintiffs voluntarily dismiss their Complaints in these cases, 112 cases total. Plaintiffs refused to voluntarily dismiss any of the cases at that time or failed to respond.
2. Defendants have provided evidentiary support in each case where they allege that the physician for each of the Plaintiffs in question is deceased.
3. As evidence of the deaths of the aforesaid physicians, Defendants provided either an obituary, medical license status, correspondence from Plaintiffs' counsel, the Plaintiff's Fact Sheet, or a combination thereof.
4. Plaintiffs concede that their prescribing physicians are either deceased or unable to be located and that those physicians have not previously given testimony in this litigation.
5. No Plaintiff has filed individual opposition papers, and so the case-specific facts presented by Defendants are undisputed and admitted, namely, that each of Plaintiffs' physician(s) is either deceased or unable to be located, as listed on the attached Schedules A and B.

6. As a result of both stipulated dismissals and withdrawn Complaints, eighty-six (86) of the original 112 claims remain.

Movant's Contentions

Defendants: Defendants argue that in a pharmaceutical products liability action alleging failure to warn, a plaintiff must show that a different warning would have altered their physician's decision to prescribe the medication in order to satisfy proximate cause. In the Schedule A and B cases associated with this Motion, testimony is lacking from the Plaintiffs' physicians who are either deceased or unable to be located, and so, there is no testimony. Defendants assert that there are forty-six (45) Plaintiffs with deceased physicians and forty-two (42) Plaintiffs with physicians that are unable to be located, making a total of eighty-six (86) cases lacking physician testimony. [NOTE: *Tracy L. Cohen vs. Hoffman-LaRoche, Inc.*, Docket No.: ATL-L-4709-11 has both a deceased and missing physician and appears on both Schedule A and Schedule B.]

Defendants argue that without the testimony of the deceased or missing physicians, Plaintiffs cannot establish that Accutane would not have been prescribed given a different warning and thus they cannot satisfy proximate cause. *See Strumph v. Schering Corp.*, 133 *N.J.* 33 (1993), *rev'ing on dissent,* 256 *N.J. Super.* 309, 323 (App. Div. 1992) (Skillman, J.A.D., dissenting) (under New Jersey law, plaintiffs were required to show that adequate warnings would have altered his or her physician's decision to prescribe Accutane). Absent physicians' testimony, Defendants argue that the causal link to injury is broken. Even if the proximate cause standard were as Plaintiffs claim – that their prescriber might hypothetically have altered their risk discussion somehow if only Roche had warned differently – Defendants assert that physician testimony is still needed.

Defendants argue that injury-state law should govern. *See Cornett v. Johnson & Johnson,* 211 *N.J.* 362, 377-78 (2012) (applying injury-state law where no true conflict exists and agreeing with the Appellate Division's decision to apply injury-state law even if conflict does exist). *See also Gaghan v. Hoffman-La Roche Inc.*, Nos. A2717-11, A-3211-11, & A-3217-11, 2014 *N.J. Super.* Unpub. LEXIS 1895, at *38 (App. Div. Aug. 4, 2014) (applying injury-state law to the issue of proximate cause). Regardless of which state's law is applied, Defendants

assert that the result would be the same because Plaintiffs lack evidence to establish their failure to warn under any state's law.

Plaintiffs: In opposition to Defendants' motion, Plaintiffs argue that the testimony of the prescribing physicians is not required to establish proximate cause under either New Jersey or Plaintiffs' ingestion states' laws. Plaintiffs aver the following:

First, New Jersey's heeding presumption precludes summary judgment. Plaintiffs argue that the Court must view the adequacy of Roche's warnings in the light most favorable to Plaintiffs' and hence accepts Plaintiffs' evidence of inadequacy to reach proximate causation. Plaintiffs argue that Defendants have not put forth any evidence to rebut that presumption.

Plaintiffs argue that the New Jersey Supreme Court has held that there is a rebuttable presumption that the recipient of an adequate warning in a failure-to-warn case would have heeded the warning. *Coffman v. Keene,* 133 *N.J.* 581, 602-03 (1993). Plaintiffs assert that this presumption has been upheld in pharmaceutical failure to warn cases. *See McDarby v. Merck & Co., Inc.,* 401 *N.J. Super* 10, 80-92 (App. Div. 2008); *In re Diet Drug Litigation,* 384 *N.J. Super.* 525, 530 (Law Div. 2005). According to Plaintiffs, *In re Diet Drug* held that the patient, as well as the learned intermediary, plays a role in the proximate cause determination. *Id.* at 540-41. Plaintiffs argue that the heeding presumption can be rebutted with evidence that a health care professional who is provided an adequate warning would have still prescribed the drug at issue or "would not have communicated the risk information" to the plaintiff. *Id.* at 544-45. Plaintiffs assert that because Defendants have not presented evidence to rebut the presumption that the prescribing physicians would have heeded a stronger warning.

Second, Plaintiffs assert that there is a like presumption in other states, whether it be express or implicit in the states' adoption of Section 402A of the *Restatement (Second) of Torts* (hereinafter "Section 402A"), comment j. Comment j states that, "[w]here warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." Plaintiffs have provided case law from twenty states, in addition to New Jersey, implicated within Defendants' Motion and argue that the law supports their contention that a heeding presumption applies in all of those states. The law of those states, as analyzed by Plaintiffs, is as follows:

1. **Arkansas:** There is a presumption that a user would have heeded a warning if it were provided. *Bushong v. Garman Co.*, 311 *Ark.* 228, 234 (Ark. 1992). The heeding presumption applies in pharmaceutical failure-to-warn cases. *In re Prempro Products Liability Litig.*, 586 *F.*3d 547, 569 (8th Cir. 2009).

2. **Idaho:** Section 402A was expressly adopted by the Court in *Shields v. Morton Chemical Co.*, 518 *P.*2d 857 (Id. 1974).

3. **Illinois:** Section 402A was adopted by the Illinois Courts. *See Brand v. Holmes Air Taiwan, Inc.*, 500 *F. Supp.* 2d 1043, 1047 (S.D. Ill. 2007); *Suvada v. White Motor Co.*, 32 *Ill.*2d 612 (1965).

4. **Indiana:** In a pharmaceutical failure-to-warn case, the Court relied upon Section 402A comment (j), which provides "a presumption of causation" if the warnings are inadequate. *Ortho Pharm. Corp. v. Chapman,* 388 *N.E.*2d 541, 555-56 (Ind. Ct. App. 1979).

5. **Kansas:** In *Vanderwerf v. SmithKline Beecham Corp.*, 529 *F. Supp.* 2d 1294 (D. Kan. 2008), the Court held that if the plaintiffs proved that defendant failed to provide a proper warning, Kansas law then presumes that a doctor would have heeded a proper warning. *Citing Wooderson v. Ortho Pharm. Corp.*, 235 *Kan.* 387, 407 (1984).

6. **Kentucky:** The Court in *Snawder v. Cohen,* 749 *F. Supp.* 1473, 1476 (W.D. Ky. 1990), denied summary judgment on the grounds that Kentucky's adoption of Section 402A makes clear that Kentucky would follow the presumption, if not rebutted, that a consumer would have heeded an adequate warning.

7. **Louisiana:** The Courts in Louisiana have adopted the heeding presumption doctrine. *Bloxom v. Bloxom,* 512 *So.*2d 839, 850 (La. 1987). The presumption has been extended to apply in pharmaceutical failure to warn cases. *Sharkey v. Sterling Drug, Inc.*, 600 *So.*2d 701, 711 (La. App. 1992). *See also Burks v. Abbott Laboratories,* 917 *F. Supp.* 2d 902, 918 (D. Minn. 2013).

8. **Maine:** The Courts in Maine have adopted Section 402A, comment (j). *Bernier v. Raymark Indus.*, 516 *A.*2d 534, 538 (Me. 1986).

9. **Maryland:** Maryland Courts follow the principle that "plaintiffs [would have heeded] a legally adequate warning had one been given." *United States Gypsum Co. v. Mayor and City Council of Baltimore,* 647 *A.*2d 405, 413 (Md. 1994).

10. **Massachusetts:** "The law permits the inference that a warning, once given, would have been followed." *Harlow v. Chin,* 545 *N.E.*2d 602, 606 (Mass. 1989). In *Knowlton v. Deseret Medical, Inc.*, 930 *F.*2d 116 (1st Cir. 1991), the Court held that it was incumbent upon defendant medical device manufacturer to rebut the presumption favoring plaintiff with evidence that the physician would not have heeded an adequate warning on the dangers of the device.

11. **Minnesota:** The Court in *Levaquin Products Liability Litig.*, 700 *F.*3d 1161 (8th Cir. Minn. 2012), held that "generally [w]here warning is given, the seller may reasonably assume that it will be read and heeded," (internal citations omitted).

12. **Missouri:** Missouri follows the heeding presumption doctrine. *Winter v. Novartis Pharmaceuticals Corp.*, 739 *F.*3d 405 (8th Cir. 2014).

13. **New Mexico:** Section 402A was expressly adopted by the Courts in New Mexico. *Stang v. Hertz Corp.*, 497 *P.*2d 732 (N.M. 1972).

14. **New York:** The Courts in New York have adopted the heeding presumption doctrine. *Union Carbide Co. v. Affiliated FM Insurance Co.*, 955 *N.Y.S.*2d 572, 575 (N.Y.A.D. 2012). *See also Adesina v. Aladan Corp.*, 438 *F. Supp.* 2d 329, 338 (S.D.N.Y. 2006); *In re Fosamax Prods. Liab. Litig.*, 924 *F. Supp.* 2d 477, 486 (S.D.N.Y. 2013); *Hoffmann-Rattet v. Ortho Pharma Corp.*, 516 *N.Y.S.*2d 856, 861-62 (N.Y.Sup.Ct. 1987).

15. **North Dakota:** When a warning is not given, the plaintiff is entitled to the benefit of a presumption that an adequate warning, if given, would have been read and heeded. *Butz v. Werner*, 438 *N.W.*2d 509, 517 (N.D. 1989). Where the presumption is not rebutted, proximate cause is established. *Crowston v. Goodyear Tire & Rubber Co.*, 521 *N.W.*2d 401 (N.D. 1994).

16. **Ohio:** The Court in *Seley v. G.D. Searle Co.*, 423 *N.E.*2d 831, 838 (Ohio 1981), held that there is "a presumption that an adequate warning, if given, will be read and heeded. . . However, where no warning is given, or where an inadequate warning is given, a rebuttable presumption arises. . . that the failure to adequately warn was a proximate cause of the plaintiff's ingestion of the drug."

17. **Texas:** Texas Courts have held that there is a rebuttable presumption that the failure to give an adequate warning is the cause of an injury. *Dresser Industries, Inc., v. Lee*, 880 *S.W.*2d 750 (Tex. 1993). *See also American Tobacco Co., Inc. v. Grinnell*, 951 *S.W.*2d 420 (Tex. 1997) (holding that where there is no warning, there is a rebuttable presumption that the user would have read and heeded the warnings). The Court in *Ackerman v. Wyeth Pharmaceuticals*, 526 *F.*3d 203, 212 (5th Cir. 2008), held that the heeding presumption has not been applied by Texas Courts in pharmaceutical failure-to-warn cases where a learned intermediary was involved. *See also Ebel v. Eli Lilly & Co.*, 321 *Fed. Appx.* 350 (5th Cir. Tex. 2009).

18. **Utah:** The heeding presumption has been adopted by the Courts in Utah. *House v. Armour of Am., Inc.*, 886 *P.*2d 542, 551 (Utah Ct. App. 1994), *aff'd*, 929 *P.*2d 340 (Utah 1996).

19. **Wisconsin:** Wisconsin Courts have adopted the presumption that a warning would have been read and heeded. *Tanner v. Shoupe*, 596 *N.W.*2d 805, 817 (Wis. App. 1999).

Third, Plaintiffs argue that Defendants are not entitled to sanctions, which are only imposed under *Rule* 1:4-8 when "an assertion is deemed 'frivolous'" and "'no rational argument can be advanced in its support, or it is not supported by any credible evidence, or it is completely untenable.'" *United Hearts, L.L.C. v. Zahabian*, 407 *N.J. Super.* 379, 389 (App. Div. 2009) (internal citations omitted). Additionally, Plaintiffs argue that Defendants' e-mail dated March 29, 2016, does not satisfy written notice and demand pursuant to *R.* 1:4-8(b).

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NOTE: As discussed with counsel during oral argument, the Court will not consider Defendants' Motion for counsel fees because no formal "Notice and Demand" as contemplated by *R.* 1:4-8 was served upon Plaintiffs. Without need for further discussion this Motion shall be DENIED.

Defendants: In reply to Plaintiffs' opposition, Defendants aver the following:

First, the heeding presumption does not eliminate Plaintiffs' burden of proving a *prima facie* case. Defendants assert that while Plaintiffs may receive favorable factual inferences, they are still charged with the duty to provide credible evidence to support every element of their claims, including proximate cause, in order to advance beyond summary judgment. *See R.* 4:46-2; *Brill v. Guardian Life Ins. Co. of Am.,* 142 *N.J.* 520 (1995). Contrary to Plaintiffs' contentions, Defendants argue that heeding a risk warning in the learned intermediary context does not equate with a decision by the physician to not prescribe the drug. If it did, given that every medicine has risks, heeding those warnings would result in medications never being prescribed. In order to prove proximate cause in these cases involving a learned intermediary, Defendants assert that Plaintiff must prove that their prescribers would not have prescribed Accutane to them. Additionally, Defendants argue that the heeding presumption does not apply in cases where the manufacturer provided a warning. Plaintiffs rely on comment (j) of the Section 402A, which was eliminated in the *Restatement (Third) of Torts* as this unintended expansion was referred to as "unfortunate". Thus Defendants argue that even if comment (j) applies, Defendants may reasonably assume that Plaintiffs' prescribing physicians heeded the warning and still prescribed Accutane to Plaintiffs. Therefore, Defendants argue that not only do Plaintiffs lack evidence to prove that the physicians would not have prescribed Accutane, but the evidence available is to the contrary.

Second, this Court should not extend the heeding presumption to apply to the present cases under New Jersey Law. Four of the Plaintiffs subject to this motion ingested Accutane in New Jersey and would thus be subject to New Jersey law. However, Defendants argue that New Jersey Courts have not extended the heeding presumption to the learned intermediary context where the manufacturer did in fact provide a warning. Defendants argue that the public policy reasons leading the Court to adopt the heeding presumption in *Coffman*, to prevent use of unreliable, and self-serving testimony and encourage manufacturers to warn of risks, do not exist

in the present cases. The Legislature has determined that manufacturers of medicines bearing FDA-approved warnings are entitled to protection from failure-to-warn lawsuits. *See N.J.S.A.* 2A:58C-4. The Accutane warnings were FDA approved and so Defendants argue that the public policy considerations in pharmaceutical product liability cases involving FDA-approved warnings weigh against alleviating Plaintiffs' burden of proving all of the elements of their claims.

Defendants argue that *In re Diet Drug Litigation* is a Law Division case that is not binding upon this Court, and, furthermore, it is a no-warning case that does not justify extending the heeding presumption to learned intermediary cases where the manufacturer did provide a warning. The Court in *In re Diet Drug Litigation* even made such a distinction; "[t]here is a difference in the use of the heeding presumption in no-warning cases such as *Coffman, supra* at 581, and these phen-fen cases as opposed to inadequate warning cases where the manufacturer made some attempt to provide this information but it is claimed that the information[.]" *In re Diet Drug, supra* at 540 n.11. Defendants assert that the *McDarby* case discusses, *in dicta,* that, "in appropriate circumstances, a heeding presumption may be applicable to claims of failure to warn of the dangers of pharmaceuticals." *McDarby, supra* at 80. Those aren't the facts here.

Third, even if the heeding presumption applies, Plaintiffs' claims fail because there is evidence to rebut the presumption. Defendants assert that The American Academy of Dermatology ("AAD") and The American Academy of Pediatrics ("AAP") both issued statements approving the continued use of Accutane or isotrentinoin for the treatment of acne. AAD's original statement was issued in 2009, with amendments being made in 2003, 2004, and 2010. The AAP's statement was issued in 2013. The AAD's statement confirms the lack of association between isotrentinoin and IBD and states that physicians should continue to prescribe the medicine while being aware of the risk. Given these prescribing standards, Defendants argue that the premise underlying Plaintiffs' position, that any mention of some marginal additional IBD risk would inescapably result in no physicians ever prescribing Accutane, is incorrect.

Fourth, Plaintiffs' claims fail under injury-state law. The motions at hand implicate thirty-five jurisdictions, however Plaintiffs have failed to address fifteen in their opposition brief, thus failing to provide heeding presumption cases and conceding that proximate cause cannot be proven under the law of those states. In the remaining jurisdictions (less New Jersey, discussed

above), Defendants assert that Plaintiffs do not distinguish between pharmaceutical products liability cases involving the absence of a warning and those in which a warning was provided. Defendants analyze the law of the jurisdictions in contention below:

1. **Arkansas:** While the Arkansas Supreme Court has adopted the heeding presumption in the context of an employee using cleaning products at work in *Bushong,* it "has yet to consider the presumption in a pharmaceutical case." *Scroggin v. Wyeth (In re Prempro Prods. Liab. Litig.),* 586 *F.*3d 547, 569 (8th Cir. 2009).

2. **Idaho:** Defendants are unaware of any authority holding that Idaho has adopted the heeding presumption at all, let alone in a pharmaceutical warning case. The *Shields* case adopted the Section 402A rule of strict liability, but takes no position on the "unfortunate" reading of comment (j) related to the heeding presumption. *Shields, supra* at 859.

3. **Illinois:** The *Brand* case does not apply the heeding presumption, but rather, the Court held that "the warnings presented were adequate, and if the warnings had been read and heeded, [the plaintiff]'s injuries would not have occurred." *Brand, supra* at 1047. The Federal Court in *Brand* granted the defendants' motion for summary judgment.

4. **Indiana:** In Indiana, a heeding presumption establishes that a warning would have been read and obeyed. *Kovach v. Midwest,* 913 *N.E.*2d 193, 199 (Ind. 2009). Moreover, the presumption works in favor of the manufacturer when there is an adequate warning. *Ortho Pharm. Corp. v. Chapman,* 388 *N.E.*2d 541, 555 (Ind. Ct. App. 1979).

5. **Kansas:** Kansas has adopted a heeding presumption in a no-warning case. *See Wooderson v. Ortho Pharm Corp.,* 681 *P.*2d 1038, 1057-58 (Kan.), *cert. denied,* 469 *U.S.* 965 (1984); *Vanderwerf, supra* at 1309-10. Plaintiffs have not cited, and Defendants are not aware of, any state court authority applying the heeding presumption to a risk warning in the learned intermediary context.

6. **Kentucky:** The Court in *Snawder* stated that, "this Court can find no Kentucky case which affirmatively applies this presumption." *Snawder, supra* at 1480. The Court speculated that Kentucky would adopt the heeding presumption because the state had adopted Section 402A of the Restatement. *Id.* The language of Section 402A, but makes no mention of the comments, including comment (j). *See Dealers Transp. Co. v. Battery Distrib. Co.,* 402 *S.W.*2d 441, 446-47 (Ky. 1965). Plaintiffs have not cited, and Defendants are not aware of, any Kentucky authority applying the heeding presumption to a risk warning in the learned intermediary context.

7. **Louisiana:** Louisiana has adopted the heeding presumption in the non-prescription pharmaceutical context. *See Sharkey v. Sterling Drug, Inc.,* 600 *So.*2d 701, 711 (La. Ct. App.), *cert. denied,* 605 *So.*2d 1100 (1992). Plaintiffs have not cited, and Defendants are not aware of, any Louisiana authority applying the heeding presumption to a risk warning in the learned intermediary context.

8. **Maine:** Defendants are unaware of any Plaintiff subject to this Motion who allegedly took Accutane while residing in Maine.

9. **Maryland:** The *Gypsum* case specifically acknowledges that Maryland has adopted a heeding presumption as to plaintiffs, but makes no mention of prescription products or a learned intermediary. *Gypsum, supra* at 413. Plaintiffs have not cited, and Defendants are unaware of, any State Court authority applying the heeding presumption to a risk warning in the learned intermediary context.

10. **Massachusetts:** Plaintiffs have not cited, and Defendants are not aware of, any State Court authority applying the heeding presumption to a risk warning in the learned intermediary context.

11. **Minnesota:** The case law that Plaintiffs cite demonstrates that the heeding presumption does not exist in Minnesota. In an unpublished opinion, a Minnesota Appellate Court found that the heeding presumption "is contrary to Minnesota law." *Yennie v. Dickey Consumer Prods.*, No. C1-00-89, 2000 *Minn. App.* LEXIS 819, at *4 (Ct. App. Aug. 1, 2000). The Minnesota Supreme Court has declined to address the issue. *Kallio v. Ford Motor Co.*, 407 *N.W.*2d 92, 99 (Minn. 1987). The *Schedin* case cited by Plaintiffs, while citing comment (j) of Section 402A, does not adopt a heeding presumption. *Schedin, supra,* 700 *F.*3d 1168-69.

12. **Missouri:** Plaintiffs misstate the heeding presumption in Missouri, because it does not arise automatically. "[A] preliminary inquiry before applying the presumption is whether adequate information is available absent a warning." *Arnold v. Ingersoll-Rand Co.*, 834 *S.W.*2d 192, 194 (Mo. 1992). Where Defendants have provided a warning, the presumption does not arise automatically and plaintiffs have the burden of showing a lack of prior knowledge. *Moore v. Ford Motor Co.*, 332 *S.W.*3d 749, 762 (Mo. 2011).

13. **New Mexico:** The Court in *Stang* adopted Section 402A, but made no mention of comment (j) nor of a heeding presumption. *Stang, supra* at 734. New Mexico has not adopted the heeding presumption.

14. **New York:** The heeding presumption in New York is more akin to a permissible jury inference. *See Raney v. Owens-Ill., Inc.*, 897 *F.*2d 94, 95 (2d Cir. 1990) ("Appellate somewhat misstates the matter by asserting that New York recognizes a 'heeding presumption,' but she is correct in contending that in some circumstances, New York permits the trier to infer that a warning would have been heeded and thereby to conclude that the absence of a warning that was reasonably required to be given was a proximate cause of injury. Appellee cites no New York decision that refers to a 'presumption' of heeding."). It is a plaintiff's burden to prove that a defendant's failure-to-warn was a proximate cause of his injury, including adducing proof that the user of a product would have read and heeded a warning had one been given. *Sosna v. Am. Home Prods.*, 748 *N.Y.S.*2d 548, 549 (App. Div. 2002) (internal citations omitted).

15. **North Dakota:** North Dakota has adopted the heeding presumption in a no-warning case. *Butz v. Werner,* 438 *N.W.*2d 509, 517 (N.D. 1989). In the learned intermediary context, the presumption may be rebutted by evidence that the prescriber knew of the risks of prescribing and continued to do so. *See Ehlis v. Shire Richwood, Inc.*, 233 *F.Supp.*2d 1189, 1196 (D.N.D. 2002), *aff'd,* 367 *F.*3d 1013 (2004).

16. **Ohio:** Ohio recognizes a heeding presumption, which a defendant can rebut. *Seley v. G.D. Searle & Co.*, 423 *N.E.*2d 831, 838-39 (Ohio 1981); *Daniel v. Fisons Corp.*, 740 *N.E.*2d 681, 685 (Ohio Ct. App. 2000).

17. **Texas:** Plaintiffs admit that the heeding presumption does not apply in Texas cases involving a learned intermediary. *See* Plaintiffs' Brief at p. 11.

18. **Utah:** Utah adopted the heeding presumption in the context of use warnings, but not in the context of risk warnings. *House*, 929 *P.*2d at 347.

19. **Wisconsin:** Recent Wisconsin case law establishes that the state does not follow the heeding presumption as articulated by Plaintiffs. *Kurer v. Parke, Davis & Co.*, 679 *N.W.*2d 867, 876 (Wis. Ct. App.), *review denied*, 684 *N.W.*2d 137 (2004). A Wisconsin statute establishes that the heeding presumption does not exist in that state. *Wis. Stat. Ann.* § 895.047(1)(e) (stating that the "claimant" must establish that "the defective condition was a cause of the claimant's damages.")

Standard for Review of Summary Judgment

R. 4:46-2(a) provides,

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

Additionally, *R.* 4:46-2(c) provides that summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." All inferences of doubt are drawn against the movant in favor of the non-movant. *See Brill vs. Guardian Life Ins. Co. of Am.*, 142 *N.J.* 520 (N.J. 1985). "[A] determination whether there exists a 'genuine issue' of material fact that precludes summary judgment requires the motion judge to consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact finder to resolve the alleged disputed issue in favor of the non-moving party." *Brill*, 142 *N.J.* at 540. Accordingly, "when the evidence is 'so one-sided that one-party must prevail as a matter of law,' the trial court should not hesitate to

grant summary judgment." *Id.* (citation omitted). Where a motion under this rule is not rendered upon the whole action and a trial is necessary, the Court when hearing the motion will "make an order specifying those facts and directing such further proceedings in the action as are appropriate." *R.* 4:46-3(a).

Standard for Heeding Presumption and the Court's Analysis

The policy behind the heeding presumption "... serves to reinforce the basic duty to warn-to encourage manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings." *McDarby v. Merck & Co., Inc.,* 401 *N.J. Super.* 10, 81 (App. Div. 2008) (citing *Coffman v. Keene,* 133 *N.J.* 581, 599 (1993)). Comment (j) of *The Restatement (Second) of Torts* § 402A lends support to the heeding presumption, it states that, "[w]here warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." In failure-to-warn cases, the heeding presumption "... undergirds our doctrine of strict product liability. ... [it] ... accords with the manufacturer's basic duty to warn; it fairly reduces the victim's burden of proof; and it minimizes the likelihood that determinations of causation will be based on unreliable evidence." *Coffman, supra* at 603.

The heeding presumption is not a "natural" or "logical" presumption, but one that is based upon policy considerations. *Coffman, supra* at 597. The policy underlying comment (j) is clear; the Courts wish to avoid claimants' use of unreliable, and self-serving testimony and wish to encourage manufacturers to warn of the risks associated with their products. Comment (j) presumes that warnings provided by the seller *have been heeded.* However, in the absence of a warning, the heeding presumption operates as a presumption of causation, i.e. but-for the absence of a warning, the plaintiff would not have taken the drug and become injured. *Coffman, supra* 594. Adoption of the heeding presumption in no-warning cases protects plaintiffs from the defense that, *even if we did provide a warning, it would not have been followed.* This presumption slices both ways.

The *Coffman* case is a no-warning case; defendant had not provided a warning to consumers of the health risks associated with asbestos products. *Coffman, supra* at 590. The jury in *Coffman* was charged with finding whether the absence of a warning was a proximate cause of the plaintiff's injury. *Id.* at 592. Such is not the case here where a warning was provided. The Court recognized that the manufacturer or seller "would benefit [from the heeding presumption] when a warning was provided," and the corollary is that the buyer benefits "where a warning is *not* given." *Id.* at 596 (internal citations omitted). The heeding presumption is not intended to work in the corollary where a warning was provided.

Likewise, the *In re Diet Drug* case also involves a manufacturer who did not initially provide a warning. 384 *N.J. Super.* 525 (Law Div. 2005). The Court in that case held that the heeding presumption was applicable in "pharmaceutical cases such as th[o]se." *Id.* at 530. Our Courts have held that the heeding presumption, "in appropriate circumstances. . . may be applicable to claims of failure to warn of the dangers of pharmaceuticals." *McDarby, supra* at 80. These cases are factually dissimilar to the present cases; they lacked any warning from the manufacturer and, as in *McDarby,* involved misrepresentations where dangers were known and not disclosed. Additionally, these Courts all recognized that the heeding presumption would only extend to pharmaceutical cases under certain circumstances, and so a blanket statement that the heeding presumption applies to all pharmaceutical failure-to-warn cases is misleading.

This Court, faced with arguments surrounding the heeding presumptions, is in a somewhat singular position, because the adequacy of Defendants' provided warning is squarely at issue. Regardless, the Court is persuaded by Defendants' arguments that the heeding presumption within a learned intermediary context does not equate with a decision by the physician to not prescribe the drug. If it did, medications would never be prescribed when accompanied by warnings because of the various risks associated with their use.

As noted by Findings of Fact #s 4 and 5 hereinabove, Plaintiffs concede that their physicians are deceased or otherwise unavailable, and they have offered nothing by way of individual opposition papers. Rule 4:46-5(a) obligates Plaintiffs to "respond by affidavit ... setting forth specific facts showing there is a genuine issue for trial." They have not done that. Accordingly, the case-specific facts presented Defendants are undisputed.

Plaintiffs' reasoning is flawed, especially when one considers the slew of risks associated with and heeded by Accutane users and prescribing physicians. Notably, application of the heeding presumption in the context of a pharmaceutical learned intermediary case where a manufacturer provided a warning and its adequacy remains in issue is not reflected within any of the cited case law.

Were the Court to deny Defendant's Motion, Plaintiffs' claims would go before a jury with testimony from Plaintiff that she/he ingested Accutane but no testimony from the prescribing physician. The jurors would be left to speculate as to what the prescribing physician considered of the warning(s). Though Plaintiffs may receive favorable factual inferences, they still have the burden of proof for every element of their claim. Heeding the warning of a risk in the context of the learned intermediary doctrine does not equate with a decision by the physician to not prescribe the drug. If it did, given that every prescription medication has associated risks, heeding those warnings would result in medications never being prescribed. While that may be Plaintiffs' counsels' hopes, it is not reality.

Even if the heeding presumption were to apply, it is rebuttable by Defendants, such as in a case where a defendant can show that the injured person (or in this case, learned intermediary) was otherwise aware of the dangers. *Coffman, supra* at 603. In *McDarby,* the defendants argued that one cannot presume that an additional risk accompanying a pharmaceutical product would lead the prescribing physician to avoid the drug, and the Court agreed. *McDarby, supra* at 81-82. According to the Court, this circumstance is recognized by the rebuttable nature of the heeding presumption, allowing a "drug manufacturer to counter a plaintiff's causation argument with contrary evidence[.]" *Id.* The prescribing physician in *McDarby* testified that plaintiff had various cardiovascular risk factors, and so given a cardiovascular warning, he would not have prescribed Vioxx to the plaintiff. *Id.* at 83. In the present cases, no Plaintiff-specific evidence has been presented that leads this Court to believe that a stronger IBD risk would have altered the physician's decision to prescribe Accutane to the individual.

Defendants have proffered evidence to rebut the presumption, namely, the recommendations of the medical community. During the time(s) in question, both the AAD and AAP issued statements approving the continued use of Accutane or isotrentinoin due to an

alleged lack of association between the drug and IBD. They stated that while physicians should continue to prescribe the drug, they should also be aware of the risk of IBD.

This Court does not find it reasonable to believe that a prescribing physician would cease to prescribe Accutane or isotrentinoin when (1) the medical community issued statements urging continued use, (2) there is evidence that the learned intermediaries were otherwise aware of the risk of IBD, and (3) no evidence has been provided supporting the notion that one additional risk factor would lead the prescribing physicians to avoid this drug. Additionally, this is *not* a no-warning case. All prescribing physicians were aware of *at least* a risk of "temporal association" with IBD. Sufficient evidence has been presented to rebut the heeding presumption, were it to apply in any of these cases.

Accordingly, the Court finds that under New Jersey law, a heeding presumption does not apply in cases such as these, and even if it did, Defendants' FDA approved warning carries a presumption of adequacy until rebutted by Plaintiffs. *McDarby, supra* at 62. Under the heeding presumption, a warning, if adequate, is presumed heeded by the user. *Coffman, supra* at 596. Where the application of the heeding presumption depends upon the adequacy and/or existence of a warning, it cannot apply in cases where the adequacy remains squarely in issue. Neither policy nor reason warrant the extension of the heeding presumption to these cases.

The Court's ruling of July 24, 2015, regarding Plaintiffs' petition for MCL Designation applies to choice of law questions raised by Defendants' Motions. "Applying New Jersey law to the proximate cause issue in the Accutane MCL cases at issue thus meets the Court's objectives and is appropriate under New Jersey's principles on conflicts and choice of law." Notwithstanding the aforesaid, the Court has reviewed the law on proximate cause in each of the thirty-five injury states. The rulings in other states reflect similar policy considerations as in New Jersey and are analyzed below:

1. **Arkansas:** While Arkansas adopted the heeding presumption in *Bushong v. Garman Co.*, 311 *Ark.* 228, 234 (Ark. 1992), the Federal Court in *Scroggin v. Wyeth (In re Prempro Prods. Liabl. Litig.),* 586 *F.*3d 547, 569 (8th Cir. Ark. 2009), stated that "Arkansas has yet to consider the presumption in a pharmaceutical case." The *Wyeth* Court speculated that, "[g]iven the current application of the heeding presumption in Arkansas and the majority view," Arkansas Courts would require the Defendants to rebut the presumption in cases involving pharmaceutical products. *Wyeth* is a no-warning case. *Id.* at 545-55.

While the Court's analysis and decision in *Wyeth* is persuasive, it is not binding Arkansas precedent. In looking at policy, Arkansas law, and the circumstances of *Wyeth* being a no-warning case, this Court does not find that a heeding presumption applies in the present Arkansas cases. Plaintiffs have not offered any case law where the Arkansas Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiff who ingested Accutane in Arkansas.

2. **Idaho:** In *Shields v. Morton Chemical Co.,* 518 *P.*2d 857, 859 (Id. 1974), the Court adopted Section 402A in terms of strict liability *only.* In *Shields,* the Court makes no reference to the heeding presumption nor to Section 402A comment (j). Plaintiffs have not presented any Idaho case law where the heeding presumption was adopted, let alone discussed.

This Court, applying Idaho law, does not find that the heeding presumption applies to the Idaho cases. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Idaho.

3. **Illinois:** The Courts in Illinois have adopted a heeding presumption. *Brand v. Holmes Air Taiwan, Inc.,* 500 *F. Supp.* 2d 1043, 1047 (S.D. Ill. 2007); *Suvada v. White Motor Co.,* 32 *Ill.*2d 612 (1965).

This Court seriously doubts that the Court in *Brand* intended the heeding presumption to apply in the present, and very different, pharmaceutical circumstances. Plaintiffs have not offered any case law where the Illinois Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Illinois.

4. **Indiana:** The Indiana Court has held that, based upon Section 402A comment (j), the heeding presumption shall apply in pharmaceutical cases only where the warnings are deemed inadequate. *Ortho Pharm. Corp. v. Chapman,* 388 *N.E.*2d 541, 555-56 (Ind. Ct. App. 1979). The Court in *Ortho* did not apply the heeding presumption, evidence presented on proximate cause had been left to the trier of fact. *Id.* at 557. In *Ortho,* the defendant manufacturer had not provided a warning regarding the statistically significant relationship between the use of or oral contraceptives and thrombophlebitis. *Ortho, supra* at 560 (Lowdermilk, J., dissenting).

Plaintiffs have offered no case law where the Indiana Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the

manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Indiana.

5. **Kansas:** Kansas has adopted a rebuttable heeding presumption in no-warning cases. *Wooderson v. Ortho Pharm. Corp.*, 681 *P.*2d 1038, 1057-58 (Kan.), *cert. denied,* 469 *U.S.* 965 (1984); *Vanderwerf v. SmithKlineBeecham Corp.*, 529 *F. Supp.* 2d 1294 (D. Kan. 2008).

Plaintiffs have offered no case law where the Kansas Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Kansas.

6. **Kentucky:** Plaintiffs have stipulated that the Court did not apply the heeding presumption, but argued that it "makes clear that Kentucky would follow the presumption." *Snawder v. Cohen,* 749 *F. Supp.* 1473 (W.D. Ky. 1990). The Court stated that it could "find no case which affirmatively applies this presumption." *Id.* 1479.

Plaintiffs have offered no case law where the Kentucky Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Kentucky.

7. **Louisiana:** Louisiana has extended the heeding presumption to pharmaceutical cases. *See Sharkey v. Sterling Drug, Inc.*, 600 *So.*2d 701, 711 (La. Ct. App.), *cert. denied,* 605 *So.*2d 1100 (1992); *Burks v. Abbott Laboratories,* 917 *F. Supp.* 2d 902, 918 (D. Minn. 2013).

Plaintiffs have offered no case law where the Louisiana Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Louisiana.

8. **Maine:** The Court is also unaware of any Schedule A or B Plaintiff who ingested Accutane in Maine.

9. **Maryland:** The Court in *United States Gypsum Co. v. Mayor and City Council of Baltimore,* 647 *A.*2d 405, 413 (Md. 1994), applied the heeding presumption in a property damage case recognizing the policy that plaintiffs would heed an adequate warning.

Plaintiffs have offered no case law where the Maryland Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Maryland.

10. **Massachusetts:** The Federal court, applying Massachusetts law in *Knowlton v. Deseret Med., Inc.*, 930 *F.*2d 116, 123 (1st Cir. 1991), adopted Section 402A comment (j). The Court held that where an adequate warning is provided it will benefit the manufacturer, but and a rebuttable presumption arises in the case of an inadequate warning and is sufficient to satisfy proximate cause. *Id.*

Plaintiffs have offered no case law where the Massachusetts Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Massachusetts.

11. **Minnesota:** The heeding presumption does not exist in Minnesota. In an unpublished decision, a Minnesota Appellate Court held that the heeding presumption "is contrary to Minnesota law." *Yennie v. Dickey Consumer Prods.*, No. C1-00-89, 2000 *Minn. App.* LEXIS 819, at 4* (Ct. App. Aug. 1, 2000). The Minnesota Supreme Court has declined to address the issue (as stipulated by Plaintiffs). *Kallio v. Ford Motor Co.*, 407 *N.W.*2d 92, 99 (Minn. 1987). The other case relied upon by Plaintiffs does cite Section 402A comment (j), but does not adopt a heeding presumption. *See Schedin v. Ortho-McNeil-Janssen Pharms., Inc. (In re Levaquin Prods. Liab. Litig.)*, 700 *F.*3d 1161 (8th Cir. 2012).

Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Minnesota.

12. **Missouri:** The heeding presumption has been adopted in Missouri but does not arise automatically. *Arnold v. Ingersoll-Rand Co.*, 834 *S.W.*2d 192, 194 (Mo. 1992). A preliminary inquiry as to whether adequate information is available absent a warning is required. *Arnold, supra* at 194. Before applying the heeding presumption, there must be inquiry into there was adequate information about the risks otherwise available and obviating the need for a warning. *Moore v. Ford Motor Co.*, 332 *S.W.*3d 749, 762 (Mo. 2011). If the heeding presumption does arise, it is rebuttable. *Moore, supra* at 762.

Plaintiffs have offered no case law where the Missouri Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Missouri.

13. **New Mexico:** The heeding presumption has not been adopted in New Mexico. The Court in *Stang v. Hertz Corp.*, 497 *P.*2d 732 (N.M. 1972), adopted Section 402A in terms of strict liability, but made no mention of comment (j) nor of a heeding presumption.

Plaintiffs have offered no case law where the New Mexico Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in New Mexico.

14. **New York:** In New York, "it remains plaintiff's burden to prove that defendant's failure to warn was a proximate cause of his injury and this burden includes adducing proof that the user of a product would have read and heeded a warning had one been given." *Sosna v. Am. Home Prods.*, 748 *N.Y.S.*2d 548, 549 (App. Div. 2002) (internal citations omitted). "Failure to warn law includes a presumption that 'a user would have heeded warnings if they had been given, and that the injury would not have occurred.'" *Adesina v. Aladan Corp.*, 438 *F. Supp.* 2d 329, 338 (S.D.N.Y. 2006) (internal citations omitted). New York's heeding presumption dictates that a user would have heeded a provided warning. *Scheinberg v. Merck & Co., Inc. (In re Fosamax Prods. Liab. Litig.)*, 924 *F. Supp.* 2d 477, 486 (S.D.N.Y. 2013).

The *Fosamax* case involves facts most similar to the present facts of this case. *Id.* While an updated warning was provided for Fosomax in 2005 after the plaintiff began taking the drug, its adequacy was in issue. *Id.* The Court referred to the heeding presumption, but did not apply it as Plaintiffs argue for here, i.e. it was not presumed that the plaintiff would have taken *Fosamax* if an allegedly better warning was provided in 2005.

Plaintiffs have offered no case law where the New York Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in New York.

15. **North Dakota:** North Dakota has adopted the heeding presumption in a no-warning case. *Butz v. Werner,* 438 *N.W.*2d 509, 517 (N.D. 1989).

Plaintiffs have offered no case law where the North Dakota Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in North Dakota.

16. **Ohio:** Ohio recognizes a rebuttable heeding presumption. *Seley v. G. D. Searle & Co.*, 423 *N.E.*2d 831, 838-39.

Plaintiffs have offered no case law where the Ohio Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Ohio.

17. Texas: As conceded by Plaintiffs in their brief, the heeding presumption has not been applied by Texas Courts in pharmaceutical failure-to-warn cases where a learned intermediary was involved. *Ackerman v. Wyeth Pharmaceuticals,* 526 *F.*3d 203, 212 (5th Cir. 2008).

Plaintiffs have offered no case law where the Texas Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Texas.

18. Utah: Utah has adopted the heeding presumption in the context of use warnings, but not in the context of risk warnings. *House v. Armour of Am., Inc.,* 886 *P.*2d 542, 551 (Utah Ct. App. 1994), *aff'd,* 929 *P.*2d 340 (Utah 1996). *See Thomas v. Hoffman-LaRoche, Inc.,* 949 *F.*2d 806, 813-14 (5th Cir. 1992) (the Court held that the heeding presumption should apply only to preventable risk warnings where there is choice of using a product safely or unsafely, not to unavoidable risk warnings where choice is not between safe and unsafe but between using or not using the product).

Plaintiffs have offered no case law where the Utah Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Utah.

19. Wisconsin: As quoted by both parties, "[e]ven in the event that a warning is inadequate, proximate cause is not presumed." *Kurer v. Parke, Davis & Co.,* 679 *N.W.*2d 867, 876 (Wis. App. 2004) (internal citations omitted).

Plaintiffs have offered no case law where the Wisconsin Courts have applied the heeding presumption in the context of a pharmaceutical learned intermediary case where the manufacturer provided a warning. Regardless, Defendants have presented sufficient evidence to rebut a heeding presumption.

Defendants' Motion for Summary Judgment is GRANTED as to the Plaintiffs who ingested Accutane in Wisconsin.

As to the remaining sixteen jurisdictions listed below, Plaintiffs have not opposed Defendants contentions regarding the law of these states as is required to avoid the dismissal of their claims on Summary Judgment pursuant to *R.* 4:46-2(a) and *Brill, supra* at 520. "Causation is a fundamental requisite for establishing any product-liability action." *Coffman, supra* at 594. As such, Defendants contentions regarding the Plaintiffs who ingested Accutane in the below states remain unopposed and are deemed admitted by the Court.

As a consequence of Plaintiffs failure to proffer any case law for the remaining sixteen jurisdictions on proximate cause or the heeding presumption to combat the proximate cause arguments made by Defendants, the Motions for Summary Judgment are granted as to the Schedule A and B Plaintiffs in the remaining jurisdictions: (1) Alabama; (2) Arizona; (3) California: (4) Connecticut; (5) Colorado; (6) Florida; (7) Georgia; (8) Mississippi; (9) Nevada; (10) North Carolina; (11) Oregon; (12) Pennsylvania; (13) South Carolina; (14) Tennessee; (15) Virginia; (16) Washington.

Accordingly, Defendants' Motion for Summary Judgment is hereby GRANTED against all remaining Schedule A and B Plaintiffs. An appropriate order has been entered. Conformed copies accompany this Memorandum of Decision.

Finally, the Court has found that sanctions are not warranted here where Plaintiffs' contentions are not "frivolous" with "no rational argument" to be advanced in their support, thus, as noted hereinabove, said Motion is DENIED.

NELSON C. JOHNSON, J.S.C.

Date of Decision: October 12, 2016

Third Amended Schedule A: Deceased Prescribers

Plaintiff Name	Docket Number
ARNOLD, JOSEPH R.	ATL-L-006624-11
BISTANY, KURT ROY	ATL-L-004480-11
BOISSELLE, JAKE ANDREW	ATL-L-002484-11
BROCK, RONALD CHRISTOPHER	ATL-L-007284-11
BUCEK, CHRYSTALL M	ATL-L-000802-11
CARMICHAEL, COURTNEY CLAIRE	ATL-L-006703-11
CARO, ALISON ANN	ATL-L-001040-12
CARTWRIGHT, JOHN KEITH	ATL-L-004668-11
CHATELAIN, JILL S.	ATL-L-005534-11
CHILDERS, ANDREA MARIE	ATL-L-004330-11
*COHEN, TRACY L. *(Case also on Schedule B)*	ATL-L-004709-11

Total: 45

FLETCHER, DEBRA L.	ATL-L-004160-11
FOLSE, HEATH F.	ATL-L-009500-11
FONSECA, NICHOLAS R.	ATL-L-005358-10
FOX, NANCY L.	ATL-L-006803-05
GIOVENGO, ANTHONY MARK	ATL-L-002869-12
GWYN, BRADLEY MONROE	ATL-L-004599-11
HAHN, JASON E.	ATL-L-004233-11
HEALY, JENNIFER L.	ATL-L-007681-11
HOFFMAN, JASON L.	ATL-L-006828-12
KERFUS, LORI ANN	ATL-L-005632-11
KERR, JOHN RYAN	ATL-L-006106-11
KOSTOSS, CHRISTOPHER M.	ATL-L-005688-11
LAMONS, DEREK TREMAYNE	ATL-L-006143-11

LEJEUNE, AARON DALE	ATL-L-004351-12
MAPEL, ROBERT M.	ATL-L-000422-12
MCLAIN, RALPH TIMOTHY	ATL-L-005562-11
MILLER, CYNTHIA LORRAINE	ATL-L-003211-12
ORISINO, JOSEPH G.	ATL-L-006006-11
PIQUERO, CAROLYN	ATL-L-006411-11
PRUTTING, ANTHONY LAWRENCE	ATL-L-006567-11
RODGERS, WES AUSTIN COLE	ATL-L-005842-11
ROEDEL, ROBERT NICHOLAS	ATL-L-002609-12
SCHUSTER, LAURA I.	ATL-L-006903-11
SELF, BOBBIE NELL	ATL-L-002194-12
SINICK, MICHAEL	ATL-L-002651-12
STILES, QUENTIN	ATL-L-000206-11

SULLIVAN, R. LENORA	ATL-L-004379-12
SVIHLA, TERRI JOANN	ATL-L-007245-11
TREON, MARGARET EDNA	ATL-L-002054-11
VARBONCOUER, MARY PATRICIA	ATL-L-007313-11
WALSH, JEROME E.	ATL-L-007344-11
WHITAKER, AMANDA REEVES	ATL-L-005972-11
WILKIE, CHRISTOPHER D.	ATL-L-006737-12
WOODS, KIMBERLY R	ATL-L-007497-10

Third Amended Schedule B: Prescribers Unable to Be Located

Plaintiff Name	Docket Number
BAKER, AMMON J.	ATL-L-007795-10
BLEA, CHARLES ANTHONY	ATL-L-004482-11
BONNER, GERALDINE	ATL-L-000803-11
BRADY, MATTHEW WILLIAM	ATL-L-002756-08
CHARO-MURRIETTA, MIRIAM SABRINA	ATL-L-007725-11
CICHACKI, LORIANN H.	ATL-L-000578-12
*COHEN, TRACY L. *(Case also on Schedule A)*	ATL-L-004709-11
CORTIZO, JASON M.	ATL-L-006925-11
DONOHOE, BENJAMIN A.	ATL-L-005129-11

Total: 42

EDWARDS, DIANA RENEE	ATL-L-004142-11
FRANKOS, MARIE	ATL-L-000902-08
GAINES, JAMES AARON	ATL-L-000163-13
GAITHER, NANNETTE M.	ATL-L-002653-12
GOLDTHWAITE, RICHARD CLARK	ATL-L-001627-08
HENRY, JOANNA	ATL-L-005513-11
HILTON, CRAIG A.	ATL-L-005290-11
IRBY, JOSEPH CHARLES	ATL-L-003719-09
JAMESON, BOBBIE	ATL-L-010041-11
JULIANA, MARGARET	ATL-L-009558-11

JULKOWSKI, JAMES H.	ATL-L-007707-11
KEANE, MICHAEL G.	ATL-L-000107-12
LAWRENCE, WILLIAM EDWARD	ATL-L-004332-12
LEAVITT, TYLER	ATL-L-007255-11
MARTIN, TRENTON EUGENE	ATL-L-002554-12
MCLEMORE, JAMIE NICOLE	ATL-L-001305-12
NAPOLES, JOHN L.	ATL-L-001071-12
NOVICK, JON SCOTT	ATL-L-004459-11
PERKINS, ANGELA KAY	ATL-L-007948-11
PETERSON, BRAD HOBSON	ATL-L-002671-11

PLETTA, STEVEN E.	ATL-L-000421-12
ROSE, KIMBERLY A.	ATL-L-003174-12
SPARROW, LISA D.	ATL-L-010397-11
STAPLES, JASON E.	ATL-L-008169-11
SWAFFORD, BRADLEY WILLIAM	ATL-L-003016-11
SYME, CRYSTA JEANNE	ATL-L-007045-11
THOMAS, TOINETTE CORA	ATL-L-006665-11
VAN PATTEN, ZACHARY J.	ATL-L-000936-12
WADE, PATRICIA B.	ATL-L-002654-12
WALKER, TRACY LYNN	ATL-L-010006-11

WATSON, WILLIAM B.	ATL-L-000935-12
WATTS, GINGER R.	ATL-L-003906-12
WATTS, KERRY G.	ATL-L-007409-11