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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-3427-09T4
A-3428-09T4
A-3702-09T4

LANCE SAGER,

Plaintiff-Respondent,

v.

HOFFMAN-LA ROCHE, INC., and
ROCHE LABORATORIES, INC.,

Defendants-Appellants,

and

F. HOFFMAN-LA ROCHE, LTD, and
ROCHE HOLDING, LTD,

Defendants.

JORDAN SPEISMAN,

Plaintiff-Respondent,

v.

HOFFMAN-LA ROCHE, INC., and
ROCHE LABORATORIES, INC.,

Defendants-Appellants,

and

F. HOFFMAN-LA ROCHE LTD, and
ROCHE HOLDING LTD,

Defendants.

KELLY MACE,

Plaintiff-Respondent,

v.

HOFFMAN-LA ROCHE, INC., and
ROCHE LABORATORIES,INC.,

Defendants-Appellants,

and

F. HOFFMAN-LA ROCHE LTD, and
ROCHE HOLDING LTD,

Defendants.

Argued March 19, 2012 - Remanded March 23, 2012
Resubmitted June 25, 2012 - Decided August 7, 2012

Before Judges Sabatino, Ashrafi, and Fasciale.

On appeal from the Superior Court of New Jersey, Law Division, Atlantic County, Docket Nos. L-197-05, L-196-05, and L-199-05.

Paul W. Schmidt (Covington & Burling LLP) of the Washington, D.C. bar, admitted pro hac vice, argued the cause for appellants (Gibbons P.C., attorneys; Michael X. Imbroscio (Covington & Burling LLP) of the Washington, D.C. bar, admitted pro hac vice, and Mr. Schmidt, of counsel; Michelle M. Bufano, on the brief).

David R. Buchanan argued the cause for respondents (Seeger Weiss LLP, and Michael D. Hook (Hook & Bolton, P.A.) of the Florida bar, admitted pro hac vice, attorneys; Mr. Buchanan, on the brief).

Alan Klein (Duane Morris LLP) of the Pennsylvania bar, admitted pro hac vice,

argued the cause for the amici curiae Ranbaxy, Inc., Ranbaxy Laboratories, Inc., and Ranbaxy Pharmaceuticals, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., Mylan Bertek Pharmaceuticals, Inc., Cardinal Health, 409, Inc., Barr Laboratories, Inc., and Barr Pharmaceuticals, LLC (Duane Morris LLP, Sills Cummis & Gross, Porzio Bromberg & Newman, P.C., attorneys; Beth S. Rose, Stuart M. Feinblatt, Kenneth R. Meyer, and Brian P. Sharkey, of counsel; Mr. Klein, James J. Ferrelli, John M. Lyons, of the Pennsylvania bar, admitted pro hac vice, and Fletcher W. Moore of the Pennsylvania bar, admitted pro hac vice, on the brief).

PER CURIAM

These three consolidated cases are the latest appeals before this court[1] seeking review of jury verdicts in products liability cases against defendants Hoffman-La Roche, Inc. and Roche Laboratories, Inc. (collectively, "Roche"), manufacturers of the prescription drug Accutane.

The present plaintiffs, Lance Sager, Jordan Speisman, and Kelly Mace, are all residents of Florida. They each started

[1] See McCarrell v. Hoffman-La Roche, Inc., No. A-3280-07 (App. Div. Mar. 12, 2009) (slip op. at 2-3, 105-07) (finding an Alabama resident's New Jersey lawsuit against Roche timely but reversing the judgment for plaintiff because of trial error and remanding for a new trial), certif. denied, 199 N.J. 518 (2009); Kendall v. Hoffman-La Roche, Inc., No. A-2633-08 (App. Div. Aug. 5, 2010) (slip op. at 2, 62) (finding a Utah resident's lawsuit timely but similarly vacating the jury award and remanding for a new trial because of trial error), aff'd, 209 N.J. 173 (2012). We identify these related cases for background purposes only. See R. 1:36-3.

taking Accutane, which had been prescribed by their respective dermatologists, for acne in the late 1990s when they were teenagers. At the time of plaintiffs' treatment with Accutane, the warnings Roche provided with the drug indicated that it had been "temporally associated" with inflammatory bowel disease ("IBD"). The warning was strengthened by Roche in 2003, but by that point Sager, Speisman, and Mace had already discontinued taking Accutane after each had been diagnosed with and treated for IBD.

Plaintiffs alleged that Roche was liable to them under applicable Florida products liability law for their ongoing IBD symptoms because the product warnings supplied with Accutane before 2003 were inadequate. Roche denied such liability. It asserted, among other things, that the warnings were reasonably adequate and had been duly approved by the Food and Drug Administration ("FDA") and that plaintiffs' IBD conditions were not proximately caused by their short use of Accutane. Roche also argued that plaintiffs' lawsuits, which were all filed more than two years after their IBD diagnoses, were time-barred under the New Jersey statute of limitations.

After the trial judge found that all three lawsuits were timely based upon equitable tolling principles, the cases were jointly tried before the same Atlantic County jury in the fall

of 2008. The jury found Roche liable to all three plaintiffs on their failure-to-warn claims, awarding them substantial compensatory damages. Roche now appeals on various grounds.

The two pivotal issues before us are (1) whether the trial court erred in finding plaintiffs' lawsuits timely, particularly in light of the equitable tolling restrictions recently set forth by the Supreme Court in Kendall, supra, 209 N.J. at 196-99; and (2) whether Roche is entitled to judgment under the controlling Florida law of proximate causation, given that each of plaintiffs' treating dermatologists testified that they still would have prescribed Accutane for them even if the product warnings had been stronger.

For the reasons stated in this opinion, we affirm the trial court's renewed conclusion in a remand decision applying Kendall that plaintiffs' complaints were all timely. However, we conclude that controlling Florida precedent, specifically Hoffmann-La Roche, Inc. v. Mason, 27 So. 3d 75 (Fla. Dist. Ct. App. 2009), review denied, 37 So. 3d 848 (Fla. 2010), another Accutane products liability case, entitles Roche to judgment in each of these cases as a matter of law. Consequently, the final judgments are reversed.

I.

A.

Accutane, the brand name for the prescription drug isotretinoin, is an oral medication for acne that Roche developed and began marketing in the 1980s. Kendall, supra, 209 N.J. at 180-81. Roche halted the sale of Accutane in 2009. Id. at 181 n.3. However, isotretinoin continues to be sold by generic drug manufacturers.

As the Supreme Court noted in Kendall, Accutane has several known side effects, which include "dry lips, skin and eyes; conjunctivitis; decreased night vision; muscle and joint aches; elevated triglycerides; and a high risk of birth defects if a woman ingests the drug while pregnant." Id. at 180. The present appeals, like Kendall, concern "the effect of Accutane on the digestive tract and, in particular, the alleged propensity of the drug to cause [IBD]." Id. at 180-81.

IBD refers to "several chronic incurable diseases characterized by inflammation of the intestine." Id. at 181. In general, IBD presents as one of two conditions: Crohn's disease or ulcerative colitis. Ibid.

Ulcerative colitis, the condition with which Speisman and Mace were diagnosed after taking Accutane, is "a chronic condition characterized by ulceration of the colon and rectum."

Ibid. People who suffer from ulcerative colitis have frequent and often bloody bowel movements. Ibid. The bowel movements may be accompanied by fatigue, dehydration, anemia, cramping, abdominal pain, and bloating. Ibid.

Crohn's disease, the condition with which Sager was diagnosed after taking Accutane, is similar to ulcerative colitis in that it causes inflammation and ulcers, but it can occur in any part of the digestive tract from the mouth to the anus, although it mainly occurs in the ileum and the colon. Ileitis is a form of Crohn's disease involving inflammation of the small intestine.

The symptoms of IBD often "wax and wane," but the condition is generally regarded to be permanent. Ibid. Onset of IBD usually occurs during young adulthood. Ibid.

The precise causes of IBD are uncertain. Ibid. However, IBD has been statistically linked with factors such as family history, previous infections, frequent use of antibiotics, and potentially the use of contraceptives and nonsteroidal anti-inflammatory drugs. Ibid.

The FDA first approved the use of Accutane in 1982. Ibid. At that time, the FDA did not require Roche to provide a label warning of possible gastrointestinal side effects. Ibid. However, in 1983 and 1984, Roche revised the warnings on the

Accutane label, which were provided to physicians, to indicate that "'[t]he following reactions have been reported in less than 1% of patients and may bear no relationship to therapy . . . inflammatory bowel disease (including regional ileitis), [and] mild gastrointestinal bleeding[.]'" Id. at 181-82 (alterations in original).

Then, in 1984, Roche issued what is described as a "Dear Doctor" letter to prescribing physicians. Id. at 182. The letter explained:

> Ten Accutane patients have experienced gastrointestinal disorders characteristic of inflammatory bowel disease (including 4 ileitis and 6 colitis). While these disorders have been temporally associated with Accutane administration, i.e., they occurred while patients were taking the drug, a precise cause and effect relationship has not been shown. [Defendants are] . . . continuing to monitor adverse experiences in an effort to determine the relationship between Accutane . . . and these disorders.
>
> [Ibid.]

At that same time, Roche also changed the warning section of the Accutane package insert provided to physicians. Ibid. Specifically, the revised physician's insert stated:

> Inflammatory Bowel Disease: Accutane has been temporally associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. Patients experiencing abdominal pain, rectal bleeding or severe

> diarrhea should discontinue Accutane immediately.
>
> [Ibid. (emphasis added by the Court in Kendall).]

That warning remained in place until 2000. Ibid.

In addition, in 1994, Roche issued a patient brochure. Ibid. The brochure warned, among other things, that "'ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS SIDE EFFECTS' and that patients should 'BE ALERT FOR . . . SEVERE STOMACH PAIN, DIARRHEA, [AND] RECTAL BLEEDING.'" Ibid. (alterations in original). The brochure advised patients who experienced any of these symptoms to "'discontinue'" Accutane and consult a doctor. Ibid. The brochure further warned that such symptoms "'MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS.'" Ibid. This patient brochure remained in effect until 1999. Ibid. The same warning was included on the drug's blister packaging. Ibid.

In August 1998, Roche distributed a different version of the "Dear Doctor" letter to board-certified dermatologists. Id. at 183. This revised letter warned that patients taking Accutane "should be monitored for several serious adverse events, including IBD." Ibid.

Thereafter, in 2000, Roche amended the physician warnings to remove the term "temporally" from the 1984 version and added

a warning that IBD symptoms "'have been reported to persist after Accutane treatment has stopped.'" Ibid. The warnings were again strengthened in 2003, in respects that do not bear upon the present three cases.

Many products liability cases have been filed against Roche, in New Jersey and elsewhere, by patients who used Accutane and developed IBD or other adverse symptoms.[2]

B.

We turn to the discrete facts relating to the three plaintiffs in the cases before us.

Speisman

In November 1999, Speisman, who was then eighteen years old, began treatment with Accutane for inflammatory nodular acne that had been resistant to antibiotic and topical treatment. He initially received a daily dose of 80 mg, later increased to 100 mg. Dr. Betsy Beers, his dermatologist, discussed with Speisman Accutane and its common side effects, including dryness of the lips and eyes, muscle and skeletal aches, and liver toxicity. She also discussed some more unusual, but potentially serious

[2] As of July 2012, there are nearly 8000 cases listed on New Jersey's Accutane mass tort list. Accutane Caselist (July 14, 2012), http://www.judiciary.state.nj.us/mass-tort/accutane/access-2012.port.

side effects, including vision disturbances, abdominal pain, and severe back pain.

Dr. Beers did not warn Speisman about IBD. However, he received the then-existing warnings on the Accutane blister pack stating that patients should be "ALERT" for "SEVERE STOMACH PAIN, DIARRHEA, [and] RECTAL BLEEDING," and that if they experienced any of these symptoms, they should discontinue taking Accutane and check with their doctor immediately because the symptoms "MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS."

Dr. Beers, who had read the warning that "Accutane has been temporally associated with inflammatory bowel disease," testified that she believed the term "temporal association" did not mean that Accutane caused IBD. Instead, she understood that the term meant that developing IBD was a possible risk of taking Accutane and that some patients had developed IBD while taking the drug, or shortly thereafter. As a result, she monitored Speisman for IBD by asking him during his monthly appointments whether he had experienced any abdominal pain or gastrointestinal upset. During the course of treatment, Speisman reported that he experienced nosebleeds, dry skin and lips, and back pain, but no abdominal pain, diarrhea, or rectal

bleeding. Speisman finished his last course of Accutane on April 23, 2000.

Eight months later, in early January 2001, after Speisman returned from a short vacation, he suffered from an onset of IBD symptoms, followed by three weeks of worsening frequent diarrhea with urgency, abdominal pain, and blood in his stool. Beginning on January 31, 2001 and continuing through the time of trial, Speisman was treated by Dr. Charles Sninsky, a gastroenterologist. After reviewing the results of Speisman's colonoscopy, Dr. Sninsky diagnosed him as suffering from ulcerative colitis. Speisman took various medications to treat his IBD, including prednisone, which caused bloating and insomnia, and Remicade, which was administered by I.V. His symptoms waxed and waned, as was typical of the disease. He remained in remission from June 2001 to November 2004, but his symptoms flared in November 2004 and generally worsened through the time of trial.

At the time of trial in 2008, Speisman, who was taking prednisone and receiving regular infusions of Remicade, continued to experience worsening diarrhea with urgency, blood and mucous in his stool, and cramping. He had approximately fifteen bowel movements a day. Dr. Sninsky believed, with a

reasonable degree of medical certainty, that Speisman would ultimately have to undergo surgery to remove his colon.

Speisman testified that if he had been warned that Accutane could cause ulcerative colitis, he would "absolutely" not have taken the drug. In this regard, he noted there was no specific reference to ulcerative colitis in the written warnings on the blister pack, nor had any of his physicians advised him that his Accutane use could have caused his ulcerative colitis.

Sager

In January 1998, Sager, who was then seventeen years old, began treatment with Accutane for cystic and scarring acne, a condition that had not been resolved after treatment with antibiotics. He received a daily dose of 60 mg of Accutane. Dr. Martin Schiff, his dermatologist, discussed Accutane and its common side effects with Sager and his mother, Shelia Sager, who worked as a medical assistant in Dr. Schiff's office. They discussed musculoskeletal aches, elevated cholesterol and triglycerides, joint pain, headaches, decreased night vision, depression, and dry lips and eyes.

Dr. Schiff did not advise Sager or his mother of the risk of developing IBD. Dr. Schiff did, however, give Sager a copy of the Accutane patient brochure, which warned, as set forth above, that he should be alert for severe stomach pain,

diarrhea, and rectal bleeding. Sager also received the warning on the blister pack.

At trial, Dr. Schiff, who had read the Accutane label in existence at the time he treated Sager, testified that he understood that the term "temporal association" did not mean "cause." As Dr. Schiff understood it, the term meant that two things occurred "together close in time," and was a stronger warning than just an "association." His "impression at the time was that [IBD] was not a prominent side-effect," and that there was not "a lot of discussion in the literature or meetings about Accutane and [IBD]." If Roche had warned that there was a causal link between Accutane and IBD, Dr. Schiff would have made his patients, including Sager, aware of that assessment. He also would have wanted to know that Roche had received so-called "positive rechallenge"[3] reports indicating adverse patient reactions.

In February 1998, after approximately one month of treatment, Sager experienced a severe case of abdominal pain and cramping, rectal bleeding, and diarrhea, which lasted for

[3] A "challenge-dechallenge-rechallenge" is a medical protocol in which a patient is given a drug after suffering an adverse effect to determine whether the adverse effect will occur again. If the adverse effect recurs, that is a so-called "positive rechallenge." If the effect does not recur, that is a "negative rechallenge."

several days. Sager could not recall ever having experienced diarrhea and cramps prior to taking Accutane, although there is a note in his medical record that he had exhibited the "same symptoms" the previous summer.

Shelia Sager contacted Dr. Lorne Katz, her son's pediatrician. Dr. Katz, who was aware that Sager was taking Accutane, did not tell him to stop treatment, nor did he tell him that his symptoms may have been caused by Accutane.

Sager's initial symptoms resolved in a few days, but he later had three or four more episodes of loose bowel movements and diarrhea while taking Accutane. He completed his course of treatment with Accutane in June 1998.

In December 1998, Sager experienced very severe stomach cramping, diarrhea, and blood in his stool. About two weeks later, Dr. Douglas Weissman, a gastroenterologist, diagnosed Sager as suffering from Crohn's disease. Sager was then treated by Dr. Barry Ross, a gastroenterologist.

Sager took various medications to treat his gastric symptoms, which waxed and waned. When his symptoms flared, Sager had as many as ten to twenty bowel movements a day. Later, Sager developed anal abscesses, requiring painful treatment, and anal fistulas, which resulted in leakage of fecal matter.

As of the time of trial, Sager continued to experience approximately six instances per year of severe stomach cramping, blood in his stool, diarrhea, and weakness, often lasting four to seven days. He is required to undergo regular colonoscopies because of his increased risk for colon cancer.

Sager testified that if he had been warned that Accutane could cause Crohn's disease, he would not have taken the drug. There was no specific reference to Crohn's disease in the materials he received, although there was reference to gastric symptoms, including rectal bleeding and diarrhea. Sager's treating physicians did not warn him that Accutane was associated with Crohn's disease, or that he should not take Accutane after being diagnosed with the disease.

Mace

In July 1999, Mace, who was then fifteen years old, began treatment with Accutane for cystic and scarring acne, which had not resolved after approximately one year of antibiotic treatment. She received a daily dose of 40 mg of Accutane, later increased to 60 mg. Mace received warnings on the blister pack to be alert for stomach pain, diarrhea, and rectal bleeding, but did not remember reading the warnings.

Dr. Jerome Fairchild, Mace's dermatologist, discussed Accutane and its common side effects with the teenager and with her mother, Donna Mace, including potential birth defects, joint pain, headaches, sun sensitivity, nosebleeds, and dry lips. He did not advise them of the risk of developing IBD, nor could he recall giving them the Accutane patient brochure. Dr. Fairchild, who had read the label, testified that he understood that a "temporal association" did not mean "cause," but meant "associated in time." He stated that if Roche had evidence that there was a causal link between Accutane and IBD, he would have wanted to know that information, and would have made his patients, including Mace, aware of that assessment.

During the initial six-month treatment, Mace experienced side effects from Accutane use, including dry skin, dry lips, and nosebleeds. In December 1999, approximately two weeks before she finished her last dose, she experienced a severe stomach ache and then developed diarrhea and had blood in her stool.

In January 2000, Donna Mace called Dr. Fairchild's office to report her daughter's symptoms. The doctor's records indicate that he recommended that Mace see a gastroenterologist, and he wrote in her chart "[n]ot likely from Accutane. Starting after off medication."

In February 2000, Dr. Robert Dillard, a gastroenterologist, reviewed Mace's colonoscopy results and diagnosed her as suffering from limited ulcerative colitis, a "fairly mild" IBD. Over the next few months, Mace took various medications, and her symptoms waxed and waned. She often experienced painful cramping and bloody diarrhea, and she had as many as six to eight bowel movements a day.

Meanwhile, Dr. Fairchild continued to see Mace, whose acne had not cleared up, until October 2001. At that point Dr. Fairchild determined that he would "hold off on oral medication" because of Mace's "chronic colitis."

From August 2005 to May 2008, Mace was treated at a clinic for weight loss. At that time, Mace told Dr. Deborah Viglione, an internist, that she was not suffering from any symptoms of IBD. Dr. Viglione prescribed appetite suppressant medication for Mace. That weight loss medication had several potential side effects, including gastrointestinal disturbances and diarrhea. Dr. Viglione did not warn Mace that the diet medication could aggravate her ulcerative colitis, nor did Mace experience any increase in flare-ups of the disease while on that other medication.

Thereafter, in July 2008, Mace, who had not sought treatment for her ulcerative colitis since 2006, saw Dr. Mounzer

Soued, a gastroenterologist, for complaints of abdominal pain, bloody diarrhea, and cramping. Dr. Soued determined that Mace's symptoms were consistent with an exacerbation or flare-up of her underlying ulcerative colitis. He opined that there was "[a]bsolutely" a correlation between ulcerative colitis and colon cancer, and thus Mace would have to undergo regular colonoscopies.

Donna Mace testified that if she had been warned that Accutane could cause ulcerative colitis she would not have allowed her daughter to take the drug. None of Mace's treating physicians warned her that Accutane use could be associated with ulcerative colitis.

C.

Plaintiffs filed their complaints in the Law Division on January 6, 2005, alleging, among other things, that Roche was liable to them under products liability law and common-law principles. Before trial, Roche moved to dismiss each of plaintiffs' claims as time-barred under the applicable New Jersey statute of limitations. Plaintiffs countered that their lawsuits were timely and that the applicable limitations periods for each of them should be equitably tolled under the "discovery rule" principles of Lopez v. Swyer, 62 N.J. 267, 272-75 (1973).

Following an evidentiary hearing, at which each of the plaintiffs testified, the trial court concluded that their complaints were timely and therefore denied Roche's motion.

A consolidated trial was held in October and November 2008, with each side calling a series of lay and expert witnesses. Like the claimants in other Accutane IBD cases tried in the Law Division, plaintiffs relied upon the expert opinions of Dr. David Sachar, a gastroenterologist, and Dr. Cheryl Blume, a pharmacologist.

Dr. Sachar, who is board-certified in internal medicine, was chairman of the FDA advisory committee on gastroenterology. He has been specializing in IBD for thirty-eight years. He opined that Accutane in prescribed doses is a cause of IBD in humans and was the cause of plaintiffs' IBD. He supported his conclusions with reference to the information compiled from related scientific studies and literature, which included data from tests involving dogs. Dr. Sachar also reviewed "piles" of internal Roche documents, which reinforced his opinions regarding scientific causation. These documents included an internal Roche memorandum from February 1994, stating that "[i]t is reasonable to conclude from this data that in rare cases, [Accutane] may induce or aggravate a preexisting colitis."

In determining specific causation as to the three plaintiffs, Dr. Sachar reviewed each of their extensive medical histories and examined their individual pathology slides. He admitted that he could not determine by looking at the pathology slides whether plaintiffs' IBD was caused by Accutane. However, he was able to rule out other potential causes of IBD, including prior use of antibiotics, infections, smoking, and non-steroidal anti-inflammatory drug use. He also determined that Mace's use of diet drugs had no effect on her ulcerative colitis.

Dr. Blume, plaintiffs' expert in regulatory affairs and drug labeling, opined that the Accutane label or warning as it existed in 1998 and 1999, when plaintiffs took the drug, did not accurately reflect the knowledge the company had regarding IBD. She explained that Roche had received multiple signals, prior to and after marketing Accutane, which should have alerted it to the need for a stronger warning as to the risks of developing IBD, as well as the need for further post-marketing surveillance and study.

Dr. Blume acknowledged that in 1984, before plaintiffs began taking the drug, Roche amended the warnings section of the label provided to physicians to warn that Accutane had been "temporally associated with inflammatory bowel disease." Thereafter, through its post-marketing surveillance, Roche

received numerous reports of patients who developed IBD following Accutane use, many of which contained positive rechallenge events.

On the whole, Dr. Blume testified that Roche improperly failed to change its label or other written materials to reflect the accumulating number of reports of IBD and also failed to recognize that the reports might indicate that Accutane use could cause IBD. She also criticized Roche for failing to conduct post-marketing clinical or epidemiologic studies adequately to follow up on the reports of IBD.

Dr. Blume further opined that Roche did not comply with the applicable standard of care because the 1998 label in existence when plaintiffs began taking Accutane did not sufficiently and clearly communicate the risks of IBD from Accutane use. She criticized Roche's use of the phrase "temporally associated," explaining that Roche should have warned that IBD is a permanent disease, not a condition that will abate once a patient ceases taking the drug. According to Dr. Blume, Roche also should have informed physicians that patients should undergo gastrointestinal evaluations even after completion of Accutane therapy.

Roche's own labeling expert, Dr. Gerald Faich, a physician specializing in internal medicine, opined at trial that the

Accutane label was adequate. Dr. Faich stated that the various reports and so-called "causality assessments" compiled by the company did not warrant a change in the warning. He contended that the term "associated with," as used in the label, is "very strong language," which sufficiently alerts a physician that "there's already been a link."[4]

On the subject of general causation, Roche's expert gastroenterologist, Dr. Lloyd Mayer, testified that Accutane cannot cause IBD, or serve as a trigger for it. Dr. Mayer asserted that Accutane has an anti-inflammatory effect, not an inflammatory effect, on the cells in the gastrointestinal tract. Similarly, Dr. Lorraine Gudas, Roche's pharmacology expert, opined that there is no biologically plausible mechanism by which Accutane could cause or trigger IBD.

Roche also presented expert testimony from Dr. Jerry Hardisty, a veterinary pathologist, who stated that none of the autopsied dogs in an animal study relied upon by Dr. Sachar had developed IBD or intestinal inflammation. However, Dr. Hardisty admitted there was evidence in the clinical findings in that

[4] On appeal, Roche contends that post-trial scientific articles have defined the possible relationship between Accutane and IBD in terms that are weaker than Roche's warning. We need not address that contention, in light of our dispositions of what prove to be the two pivotal legal issues in the appeal.

study that Accutane caused a slight, dose-related gastrointestinal toxicity in the treated dogs.

With regard to specific causation, Dr. Mayer testified for the defense that Accutane use did not, in his opinion, cause or trigger Speisman's or Sager's IBD. Dr. Richard Blumberg, another gastroenterologist called by Roche, opined that Mace did not have an IBD, but rather had an episode of infectious colitis, which had resolved.

D.

The jury returned separate verdicts in plaintiffs' favor on the product liability claims. In particular, the jury found that Roche failed to provide an adequate warning to plaintiffs' prescribing physicians about the risks of IBD from Accutane; that a stronger warning would have prevented plaintiffs from taking the drug; and that Accutane use is a cause of IBD and was a substantial factor in causing plaintiffs' IBD. The jury awarded Speisman compensatory damages of $8,642,500, Sager $2,625,000, and Mace $1,628,000, later reduced by the court's remittitur to $578,000.

Roche moved for judgment notwithstanding the verdict or a new trial. On December 1, 2008, while Roche's motions were pending, we issued our unpublished opinion in McCarrell, supra. The trial court then entered an order on March 25, 2009, denying

without prejudice Roche's motions, thereby allowing counsel an opportunity to revise their arguments in light of the McCarrell opinion.

After oral argument on the re-filed motions, the trial judge issued a fifty-page opinion and an order on October 28, 2009, denying Roche's motion for judgment notwithstanding the verdict and further denying a new trial.

Meanwhile, on October 27, 2009, the day before the judge issued her written decision in this case, the Florida First District Court of Appeal reversed a judgment entered in a similar Accutane products liability case, based on a finding that the plaintiff had failed to establish proximate cause under Florida law. Mason, supra, 27 So. 3d at 75. The law firms in the present case were also involved in that Florida case. On November 19, 2009, Roche filed a motion for reconsideration of the trial court's October 28, 2009 decision in this case, in light of the Mason decision. Then, on December 10, 2009, the Florida District Court of Appeal denied Mason's motion for rehearing, rehearing en banc, and request for certification.

After oral argument, and at the trial judge's request, Roche submitted copies of the appellate briefs filed in the Mason case, the jury verdict form, and transcripts of various

witnesses. On March 16, 2010, the judge issued an order and a written decision denying the Mason-based motion.

The trial court entered final judgments in the Speisman and Sager cases on March 24, 2010, and a final judgment was entered in the Mace case on April 13, 2010. Roche then appealed. Meanwhile, on May 24, 2010, the Florida Supreme Court denied the plaintiff's application for review in Mason, supra, 37 So. 3d at 848.

E.

Shortly before oral argument on the present appeals, on February 27, 2012, the Supreme Court issued its opinion in Kendall, supra, 209 N.J. at 184-85, another Accutane case involving a plaintiff who developed IBD after using the drug. In its opinion, the Court addressed several pertinent issues concerning the statute of limitations.

Among other things, the Court in Kendall clarified the legal standards applicable to the equitable tolling issues in cases such as this one, where the FDA has approved the product warning for the prescription drug at issue. In particular, the Court held that the rebuttable presumption of the sufficiency of the FDA-approved warning, as reflected in N.J.S.A. 2A:58C-4, is a pertinent but not dispositive factor in evaluating the extent to which any equitable tolling should be allowed. Id. at 196-

99. Applying that "middle-of-the-road" approach to Kendall's circumstances, the Court concluded that her lawsuit was not time-barred, even factoring in the public policies underlying the statutory presumption of adequacy. Ibid. In doing so, the Court highlighted several distinct aspects of Kendall's use of Accutane — particularly her interactions with her physician, her age, and the timing of her IBD symptoms — which, on the whole, justified her delay in filing suit. Id. at 198-99.

After hearing oral argument on the issues raised on appeal, including arguments by amicus curiae counsel for generic makers of isotretinoin, we temporarily remanded the tolling issues to the trial court for re-examination in light of Kendall. Sager v. Hoffman-La Roche, Inc., No. A-3427-09 (Mar. 23, 2012) (slip op. at 5). We gave the trial court discretion on remand to take additional testimony to develop the record, if necessary, on the issues implicated by Kendall, or, alternatively, to choose to decide the remand issues on the existing record. Id. at 6-7.

On remand, the parties agreed to have the post-Kendall issues reconsidered without additional testimony. After hearing oral argument, the trial judge issued a written decision dated May 25, 2012. In that remand opinion, the judge concluded that, even in light of Kendall's middle-of-the-road approach to the statutory presumption of labeling adequacy, "each of the

plaintiffs is entitled to equitable tolling of the statute of limitations and [Roche's] request to dismiss their cases based on the statute of limitations is denied." Roche then amended its appeal to include this newest ruling, and the parties submitted supplemental briefs at our invitation.

II.

The first critical issue that we address is the timeliness of plaintiffs' three lawsuits, which we consider in light of the Court's guidance in Kendall. As we have noted, the Court held that a trial judge may consider the presumption of adequacy of an FDA-approved warning, see N.J.S.A. 2A:58C-4, in determining whether to apply equitable tolling principles. Kendall, supra, 209 N.J. at 179-80. However, the presumption is not dispositive in the equitable tolling setting and "may be overcome by evidence that tends to disprove the presumed fact." Id. at 180. As already noted, the Court agreed with our court's conclusion that Kendall herself had overcome the presumption. Id. at 198-99.

In Kendall, the plaintiff, a Utah resident, took four courses of Accutane beginning in January 1997 when she was twelve years old, was diagnosed with ulcerative colitis in April 1999, took two more courses of Accutane in 2000 and 2003, and filed suit in New Jersey on December 21, 2005. Id. at 184-86.

Kendall had to file her complaint by January 28, 2004, two years after she reached the age of eighteen, unless equitable tolling principles under Lopez applied to extend that time period. Kendall, supra, slip op. at 38-39. Kendall received the 2003 FDA-approved warnings, included in the patient brochures and on the blister packaging containing the individual Accutane pills. Kendall, supra, 209 N.J. at 182-83.[5]

Faced with these circumstances, the Court held that a trial judge may consider the N.J.S.A. 2A:58C-4 presumption of adequacy of an FDA-approved warning in determining whether to apply equitable tolling principles under Lopez. Id. at 179-80. The Court stated that "[a]lthough that presumption is not a perfect fit for a statute of limitations analysis, we have concluded, as did the Appellate Division, that it cannot be totally ignored where the question is what a reasonable person knew or should have known about the risks of a product for discovery rule purposes." Id. at 179-80. The Court explained that

> as the Appellate Division aptly noted: "it can be argued that the legislative desire to lessen a drug manufacturer's potential liability for using an FDA-sanctioned warning also would extend to protecting that same manufacturer from an open-ended burden

[5] In her dissent, Judge Wefing noted that the "FDA had approved the contents of the patient brochure, the blister packaging, and the package insert." Kendall, supra, 209 N.J. at 201 (Wefing, dissenting).

> of defending belatedly-filed product liability lawsuits." Further, the gravamen of N.J.S.A. 2A:58C-4 is that an FDA-approved label is presumably adequate to inform a reasonable person of the dangers of a product. Thus, there is something awry about the notion of barring that evidence altogether at a discovery rule hearing at which the very issue is when, in light of the warnings actually received by plaintiff, plaintiff knew or should have known of the dangers of the product.
>
> [Id. at 197.]

The Court thus adopted what it termed a "middle-of-the-road approach," holding that the presumption should be viewed not as a "'virtually dispositive' super-presumption," but rather as a presumption that can be overcome by evidence which "'[may] disprove the presumed fact, thereby raising a debatable question regarding the existence of the presumed fact.'" Ibid. (quoting Perez v. Wyeth Labs., Inc., 161 N.J. 1, 25 (1999); Shim v. Rutgers, 191 N.J. 374, 386 (2007)). In other words, "[i]f, in the face of the evidence, reasonable people would differ regarding the presumed fact, the presumption will be overcome." Ibid. "Ultimately, the burden remains on the plaintiff seeking application of the discovery rule to show that a reasonable person in her circumstances would not have been aware, within the prescribed statutory period, that she had been injured by defendants' product." Id. at 197-98.

In applying this approach, the Court found that "Kendall's suit may proceed because the evidence not only overcame the presumption, but established that under all the circumstances, Kendall reasonably was unaware that defendants caused her injury until [less than two years before she filed her lawsuit]." Id. at 198. The Court found several factors important to its analysis: (1) Kendall was twelve years old when she was first prescribed Accutane; (2) her dermatologist and gastroenterologist had never warned her, nor had they warned her mother, of the risk of IBD because they were unaware of its relationship to Accutane; (3) Kendall suffered no gastrointestinal symptoms during her first four courses of Accutane, which she took from 1997 to 1998; (4) in 2000, her dermatologist, in consult with her gastroenterologist, agreed to prescribe a fifth course of Accutane despite the fact that she had been diagnosed with ulcerative colitis in 1999; (5) Kendall did not experience gastrointestinal symptoms while taking her fifth course of Accutane; and (6) during her sixth course of Accutane, and after she had received a revised and stronger warning (a warning not given in these cases), Kendall experienced some increased diarrhea, but no other gastrointestinal symptoms. Ibid.

Applying on remand the teachings of Kendall to the present three plaintiffs, the trial judge found that they are likewise entitled to the benefit of equitable tolling of the two-year New Jersey[6] statute of limitations, despite the policies underlying the statutory presumption of adequacy for an FDA-approved warning. We affirm that conclusion, substantially for the cogent reasons set forth in the judge's remand opinion dated May 25, 2012. We need only highlight certain facts and key portions of the judge's analysis.

This is the relevant timeline. Speisman, who was eighteen when he started taking Accutane, was diagnosed with ulcerative colitis on February 6, 2001. If one strictly applied the applicable two-year New Jersey limitations statute, N.J.S.A. 2A:14-1, Speisman would have had to file his complaint by February 6, 2003.

Sager, meanwhile, was seventeen when he started using Accutane, turned eighteen on October 25, 1998, and was diagnosed with Crohn's disease on December 30, 1998. Consequently, in the

[6] Roche had suggested in the March 2012 oral argument before this court that, in light of recent cases on choice of law, the Florida statute of limitations and not the New Jersey statute should apply here. However, Roche withdrew that suggestion on remand. Roche has now stipulated to the application of the New Jersey statute of limitations, which was the statute that all parties and the judge had treated as applicable throughout the trial court proceedings preceding the appeal.

absence of equitable tolling, Sager would have had to file his complaint by December 30, 2000.

Lastly, Mace, who was fifteen years old when she started taking Accutane and was diagnosed with ulcerative colitis on February 22, 2000, would have had to file her complaint, absent tolling, by November 2, 2003, two years after she reached the age of eighteen. See N.J.S.A. 2A:14-21; Green v. Auerbach Chevrolet Corp., 127 N.J. 591, 598 (1992).

Given these timelines, the critical question for purposes of equitable tolling is thus whether by January 6, 2003, which is two years before the actual filing date, these plaintiffs knew or reasonably should have known that they had been injured because of Roche's actions or inactions.

The trial judge carefully considered this tolling issue twice, both before the Supreme Court's opinion in Kendall and again in the post-Kendall remand. The judge properly recognized that the warnings provided to plaintiffs were included in the patient brochure and the blister packaging. The judge found, however, that defendants had argued "without success" that the warnings about "diarrhea and rectal bleeding," should have sufficiently alerted plaintiffs that their IBD symptoms were caused by Accutane. As the judge noted, those warnings did not specifically refer to IBD, Crohn's disease, or ulcerative

colitis. Thus, as the judge put it, when plaintiffs were given their diagnosis of IBD, "there would have been no light bulb going off in their brains to flash back to this language from the patient materials."

The judge explained:

> Almost everyone has had diarrhea at some point in time and often stomach upset and diarrhea are side effects of drugs. IBD is significantly different from temporary diarrhea even with bleeding. While rectal bleeding is a more serious and less common symptom, it is not exclusive to IBD and occurs with infections, food poisoning, hemorrhoids, and other processes. Having temporary diarrhea or rectal bleeding is not IBD. Crohn's and Ulcerative Colitis are specific chronic inflammatory processes which are diagnosed not based on these symptoms alone, but by specifically trained gastroenterologists usually only after a colonoscopy.

The judge also observed:

> The decision in Kendall states that the post 2003 brochure might be adequate in some circumstances, but was not for her. This was not the brochure given to Sager, Mace and Speisman. Looking specifically at each plaintiff, Kendall was twelve, Mace was 15, Sager was 16 and Speisman was 19[7] when they took Accutane. None of them really remember reading the patient warnings in the brochures or on the blister packs in any detail.
>
> The defendants argue the failure to read the patient brochures is dispositive.

[7] Speisman was actually eighteen, not nineteen.

> Two of these plaintiffs were taken by their parent to get the drug. They, like Kendall, reasonably relied upon the doctor and their parent. Speisman was 19, just barely an adult under the law. The court finds it credible that they do not remember reading the materials. Ultimately, the court finds that based on their separate circumstances, the plaintiff[s] have all proved that it is more likely than not that even if they read the materials, they would not have connected their diagnosis to the use of Accutane.

Moreover, the judge found the timing of plaintiffs' IBD symptoms of significance to their equitable tolling claims:

> All three of the plaintiffs were diagnosed with IBD after they were no longer taking the drug. Jordan Speisman had no symptoms while he was on the drug and Mace and Sager developed their first symptoms near the end of their course of use of the drug. Like Kendall who barely read the materials, the three plaintiffs recalled that the emphasis was on the risks of pregnancy while on the drug. None of their dermatologists advised them about the link between IBD and Accutane so as to put them on notice of [a] potential connection. None of them were told by their gastroenterologists there could be a connection.
>
> Even starting the Lopez analysis with the presumption that a warning approved by FDA is adequate, this court finds there is sufficient evidence presented to overcome that presumption in the particular circumstances of each of these cases.

The judge's fact-sensitive determinations warrant our deference, particularly in light of the fact that the judge had the opportunity to evaluate the credibility of all three plaintiffs

at the pretrial Lopez hearing. See Rova Farms Resort, Inc. v. Investors Ins. Co. of Am., 65 N.J. 474, 484 (1974).

We reject Roche's emphasis on the point that all three plaintiffs had not read, or at least could not remember reading, the Accutane product warnings. Plaintiffs all relied on their parents to obtain the drug. Two of them were minors and the other had barely reached adulthood when they began taking Accutane. They were not diagnosed with IBD until after they completed taking the drug, and even then they were not told immediately that their IBD was caused by Accutane. In Speisman's case, he did not suffer any gastrointestinal symptoms while taking Accutane. Unlike the plaintiff in Kendall, none of these plaintiffs received the stronger 2003 Accutane warnings, making their own arguments for tolling even more compelling in that respect.

There is ample justification here to allow plaintiffs to overcome the rebuttable presumption of the adequacy of the pre-2003 warnings. The judge fairly allowed plaintiffs to file their complaints on January 6, 2005, a date which the judge reasonably found was within two years of when plaintiffs knew or should have known that they had a basis for a claim. There was a sound basis for the judge to conclude that a reasonable person in their shoes would not have made a litigational connection

between the drug and their injuries within the ordinary limitations period.[8]

Furthermore, we detect no appreciable prejudice to Roche resulting from plaintiffs' delay in filing. Cf. Mancuso v. Neckles ex rel. Neckles, 163 N.J. 26, 37 (2000) (noting the relevance of prejudice to a defendant in tolling a limitations period); Lopez, supra, 62 N.J. at 276 (same). Roche was able to marshal considerable defense proofs at trial and was able to probe plaintiffs' medical histories and Accutane usage. This is not a matter in which faded memories and absent witnesses made a critical difference in the outcome. Although plaintiffs could not recall at trial some of the details concerning what they were told as teenagers about the drug, their medical treatments were documented, and there is no reason to believe that their recollections would have been significantly better if the lawsuits had been filed a year or two sooner.

[8] We note that this statute of limitations analysis, grounded mainly upon equitable principles, does not dictate whether a product warning was inadequate as a matter of substantive products liability law. In other words, a judge's findings about a warning expressed in the course of a pretrial equitable tolling analysis do not control a jury's subsequent assessment of the warning in the verdict, which must instead be based upon the trial proofs and the applicable products liability standards without concern for equitable factors.

The trial court's denial of Roche's motion to dismiss these three cases as time-barred is consequently affirmed.

III.

We now examine the key issues of proximate causation under the law of Florida, the State which, as the parties agree, provides the governing substantive law in these three cases involving Florida residents.[9]

Under Florida law, manufacturers of dangerous products generally have a duty to convey adequate warnings directly to consumers. Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 822 (Fla. Dist. Ct. App.), pet. for review denied, 407 So. 2d 1102 (Fla. 1981). However, in products liability actions involving prescription drugs, Florida, like the majority of States, including New Jersey, recognizes the "learned intermediary" doctrine, which alters that duty. Felix v. Hoffmann-La Roche, Inc., 540 So. 2d 102, 104 (Fla. 1989); see also N.J.S.A. 2A:58C-4; Perez, supra, 161 N.J. at 10 (1999); Restatement (Third) of Torts: Products Liability § 6(d) (1998).

Under the learned intermediary doctrine, a manufacturer's duty to warn about the dangers of prescription drugs, which

[9] Because the parties agree that Florida substantive law applies here, we need not engage in the choice of law analysis otherwise called for by P.V. ex rel. T.V. v. Camp Jaycee, 197 N.J. 132, 135-36 (2008), examining which State has the most significant relationship to each case.

"'are likely to be complex medicines, esoteric in formula and varied in effect,'" runs to the physician, not the patient or consumer. Buckner, supra, 400 So. 2d at 822 (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S. Ct. 687, 42 L. Ed. 2d 688 (1974)).

The rationale behind the doctrine is that the prescribing physician, acting as a learned intermediary between the manufacturer and the patient as the product consumer, is in the best position to warn the patient, who does not have direct access to prescription drugs, about the risks and benefits of taking a drug. See ibid. The physician's task is to "'inform himself of the qualities and characteristics of those products which he prescribes for . . . his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product.'" Id. at 823 (quoting Terhune v. A. H. Robins Co., 577 P.2d 975, 978 (Wash. 1978)). The physician must tailor the warning about the drug's side effects to the patient in light of his or her specific medical needs and history. Ibid. In turn, the patient relies on the physician's judgment to make an informed choice as to whether to take the drug. Ibid.

However, a physician's duty to warn patients of potential side effects is not absolute under Florida law, and the extent

of disclosure is a matter of medical judgment. Buckner, supra, 400 So. 2d at 823. A physician must "'inform his patient what a reasonable prudent medical specialist would tell a person of ordinary understanding of the serious risks and the possibility of serious harm which may occur from a supposed course of therapy,'" to enable the patient to make an intelligent choice, based on sufficient knowledge, by balancing "'the possible risks against the possible benefits.'" Ibid. (quoting ZeBarth v. Swedish Hosp. Med. Ctr., 499 P.2d 1, 11 (Wash. 1972)). If a physician breaches that duty, the patient may have a claim against the physician for lack of informed consent.

Hence, in a failure-to-warn case brought under Florida law against a drug manufacturer, the plaintiff must prove that the warning to the physician was inadequate, that the inadequacy of the warning proximately caused his or her injury, and that he or she suffered an injury from using the drug. Mason, supra, 27 So. 3d at 77; Colville v. Pharmacia & Upjohn Co., 565 F. Supp. 2d 1314, 1320 (N.D. Fla. 2008). If the warning to the physician is adequate, the manufacturer will have discharged its duty and cannot be held liable even if the physician did not read the warning or convey it to the patient. Felix, supra, 540 So. 2d at 105; see also E.R. Squibb & Sons v. Farnes, 697 So. 2d 825, 827 (Fla. 1997).

A critical issue in the present cases is whether plaintiffs proved by a preponderance of the evidence that Roche's allegedly inadequate warning was, under Florida law, the proximate cause of their injuries. See Colville, supra, 565 F. Supp. 2d at 1322. The "plaintiffs must show that it is 'more likely than not' that the defendant's act was a substantial factor in bringing about the injury." Christopher v. Cutter Labs., 53 F.3d 1184, 1191 (11th Cir. 1995) (quoting Reaves v. Armstrong World Indus., Inc., 569 So. 2d 1307, 1309 (Fla. Dist. Ct. App. 1990)). Because drug manufacturers have a duty to warn the physician, not the patient, "it is the prescribing physician's course of conduct that is most relevant to proximate cause in the prescription drug context." In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 279 (S.D.N.Y. 2009) (applying Florida law). Plaintiffs must therefore show that an adequate warning would have altered their physicians' conduct. See ibid.

Although Florida law on this issue is not extensive, it reflects that a physician's independent knowledge of the risk — which an adequate warning would have communicated — breaks the chain of causation between the inadequate warning and the injury. Christopher, supra, 53 F.3d at 1192 (applying Florida law); Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007); Zanzuri v. G.D. Searle & Co., 748 F. Supp. 1511,

1517 (S.D. Fla. 1990); Dean v. Eli Lilly & Co., 387 Fed. Appx. 28, 29-30 (2d Cir. 2010) (applying Florida law). In other words, a physician's independent awareness of a risk, through personal experience or research, disrupts proximate cause and obviates any liability for a manufacturer's failure to warn. See, e.g., Felix, supra, 540 So. 2d at 103 (finding that any inadequacy in the Accutane product warning could not have been the proximate cause of the child's birth defects because the prescribing physician testified that "he fully understood the warnings and also had prior knowledge of the [] propensity of Accutane" to create the risk of such birth defects).

In the three cases before us, it does not appear that plaintiffs' prescribing dermatologists had independent knowledge of Accutane's claimed potential to induce IBD. The question then becomes whether, under Florida law, the allegedly defective warnings that those physicians received could be the proximate cause of plaintiffs' injuries.

In Mason, supra, 27 So. 3d at 75, a published decision of Florida's intermediate appellate court, an important consideration was identified that bears upon this causation question. That consideration is whether the doctors would have still prescribed the drug to plaintiffs, even if the manufacturer had supplied a more pointed warning. Id. at 77-78.

The facts in Mason are markedly similar to the present cases. The plaintiff, a minor, had seen a Florida dermatologist to treat his severe acne. Id. at 76. After antibiotics and other treatments failed, the dermatologist prescribed Accutane, which the plaintiff took until he was diagnosed with IBD. Ibid. Mason sued Roche in the Florida state court under Florida products liability law, alleging that the warning provided to his doctor was inadequate. Ibid. As in this case, the warning stated that Accutane had been "temporally associated" with IBD. Ibid. Mason contended that the defective warning proximately caused his injuries. Ibid. The Florida jury accepted that claim and awarded Mason damages. Ibid.

Roche appealed the trial court's denial of its motion for judgment notwithstanding the verdict. Id. at 77. The Florida intermediate appellate court reversed, holding that Mason had not established proximate causation under Florida law. Id. at 77-78. In particular, the appellate court found it critical that even if the drug had been marketed with the stronger warning advocated for by Mason's expert, the dermatologist conceded that he would still have prescribed the drug for him. Id. at 77.

We quote in this regard from the dispositive final paragraph of Mason:

> While Appellee presented testimony that the warning label was inadequate to warn physicians that Accutane use could lead to IBD, Dr. Fisher, the prescribing physician, testified that he understood the warning label to mean that there was at least a possibility of a causal relationship between Accutane and IBD. He testified that he would still be willing to prescribe Accutane to his patients even if there was evidence showing that it could cause IBD in rare cases. He also testified that even if the warning label contained all of the information suggested by Appellee's expert, he would still have prescribed the medication for Appellee. Thus, any inadequacies in Accutane's warning label could not have been the proximate cause of Appellee's injury because Dr. Fisher understood that there was a possibility that use of the drug could lead to Appellee developing IBD and he made an informed decision to prescribe the drug for Appellee despite this risk. Because Appellee presented no evidence to establish proximate cause, the trial court erred in denying Appellants' motion for a directed verdict.
>
> [Id. at 77 (emphasis added).]

As previously noted, the Florida Supreme Court declined to review this published appellate opinion. Mason, supra, 37 So. 3d at 848 (2010). No Florida Supreme Court case since then has repudiated or questioned Mason.

Mason is therefore the controlling Florida precedent, which must be applied here on the proximate cause issue. The trial judge here declined, however, to do so. Instead, she undertook an extensive analysis of other Florida opinions and concluded

that Mason is, in essence, an outlier decision. The judge concluded that Mason is at odds with Buckner, supra, 400 So. 2d at 820, and several other prior Florida cases. She found that Mason illogically hinged its proximate cause analysis solely upon the treating doctor's prescribing decision and improperly ignored the possibility that, even if a drug were prescribed, a patient might decline to use it if a stronger warning about IBD were passed along by the physician. The judge also declined to treat Mason as binding Florida precedent because it is a terse, per curiam opinion.

It is not our place, however, to second guess the appellate courts of Florida and the wisdom of their decisions. The published opinion in Mason, short and unsigned as it may be, is binding Florida precedent. See Newmons v. Lake Worth Drainage Dist., 87 So. 2d 49, 50 (Fla. 1956) (instructing that unsigned per curiam opinions published in Florida are precedential). Indeed, Mason was recently cited, albeit not in the learned intermediary context, by another Florida appellate panel. See Union Carbide Corp. v. Aubin, 37 Fla. L. Weekly D 1454 (Fla. Dist. Ct. App. 2012). Only the Florida Supreme Court can overturn Mason or repudiate it. That has not yet occurred. Where Florida precedent governs, it should be applied uniformly

to Accutane plaintiffs, whether they file suit in Florida, New Jersey, or elsewhere.

Because we are thus constrained to treat Mason as the binding law of Florida, we apply it to the present facts. Notably, all three of plaintiffs' dermatologists testified at trial that they would have still prescribed Accutane to the patients even if Roche had provided a stronger product warning about the risks of IBD. The relevant testimony is as follows.

Speisman's dermatologist, Dr. Beers, who continued to prescribe Accutane to other patients as of the time of the 2008 trial, testified that if she saw Speisman in 2008 in the same condition that he had been in 1999, she still would have strongly considered prescribing Accutane. She stated that she would do so because "there's nothing that works as well." Dr. Beers did note that she would have wanted to know if Roche had found a causal relationship between Accutane and IBD and that if the drug was a probable or highly likely cause of IBD, she would have informed a patient of the relationship. Even so, her testimony was unambiguous when asked about whether, if the product warning had been stronger, she would have made the same prescribing decision as to Speisman:

> Q. Even if the warning label in 1999 had [] changed the words associated with to causes, or may cause, am I correct that you

still would have prescribed and recommended Accutane to Jordan Speisman?

A. I guess I am assuming that if it were written that way, there would be studies to make me aware of the relative risk that would be different than the way it was stated. However, I can't say that it would have changed my prescribing practices.

Q. . . . [E]ven if that warning label had been [worded] as [plaintiff] suggests . . . that Accutane . . . may cause inflammatory bowel disease, am I correct that you still would have prescribed it for Jordan Speisman?

A. Yes.

. . . .

Q. [E]ven if the wording of the label had been changed, given what your experience is, what is the probability that even if that wording had been changed that you would have discussed the risks with Jordan any differently than you discussed it with him in terms of asking about G.I. side effects, such as nausea or G.I. upset or abdominal pain?

A. I don't think it would have made any difference.

Sager's treating dermatologist, Dr. Schiff, also was continuing to prescribe Accutane to patients as of the time of the 2008 trial. Dr. Schiff testified that he would still have prescribed the drug to Sager, even in hindsight, so long as Sager had no family history of IBD:

Q. [I]f you saw Lance Sager today, with the same conditions that he had back in 1997

> and 1998, with the same response to treatments that were prescribed in 1997 and 1998, you would recommend Accutane to him today; correct?
>
> A. I would still consider Accutane as a treatment for him. I would inquire about family history of inflammatory bowel disease.
>
> Q. And if he had told you that there was no family history of inflammatory bowel disease, you would recommend treatment with Accutane; correct?
>
> A. I would.
>
> Q. And you would do that today?
>
> A. Yes.

Lastly, Mace's dermatologist, Dr. Fairchild, who likewise was still prescribing Accutane to patients in 2008, testified:

> Q. [T]oday, knowing about this lawsuit and the claims that Kelly Mace is making . . . knowing the risks of Accutane, it's your opinion that Accutane is a good and appropriate medication to treat inflammatory scarring acne of the type that Kelly Mace had, correct?
>
> A. . . . To me, yes, it's good; yes it's effective. And I don't prescribe everybody on it [sic], but in the right situations I have used it and would use it.
>
> Q. Right. And in Kelly's situation, the condition that she had of recalcitrant inflammatory scarring acne, that is the condition that it's indicated for, right?
>
> A. Yes.

> Q. And that's the kind of condition, like Kelly had, that you prescribe it for today, correct?
>
> A. Correct.
>
> Q. And that's the kind of condition where Accutane is a good and appropriate medication, correct?
>
> A. Correct.

This crucial testimony by each of the prescribing dermotologists clearly establishes that all three plaintiffs cannot surmount Mason's binding legal test for proximate cause in a Florida learned intermediary situation. Although the outcome under New Jersey products liability law may well have been different, the inescapable conclusion is that the trial proofs failed in this case to establish proximate causation under controlling Florida precedent.

Because the proofs at trial did not satisfy Mason, Roche was entitled to judgment in its favor in all three cases. We therefore must reverse and direct the trial court to enter new final judgments accordingly.[10]

IV.

Affirmed in part as to the trial court's statute of limitations ruling, and reversed as to the court's denial of

[10] Because we are reversing the judgments and granting dismissal to Roche, we need not discuss the other issues raised by Roche on appeal.

Roche's post-trial motion for judgment based upon Mason. The trial court accordingly shall enter final judgments for defendants in all three cases within thirty days.