2016 WL 3943335
Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

Kathleen ROSSITTO, Plaintiff–Respondent,
v.
HOFFMAN–LA ROCHE INC. and Roche Laboratories Inc., Defendants–Appellants.
Riley Dean Wilkinson, Plaintiff–Respondent,
v.
Hoffman–La Roche Inc. and Roche Laboratories Inc., Defendants–Appellants.

Argued Feb. 8, 2016.
|
Decided July 22, 2016.

On appeal from the Superior Court of New Jersey, Law Division, Atlantic County, Docket Nos. L–7481–10 and L–1311–08.

Attorneys and Law Firms

Paul W. Schmidt (Covington & Burling, LLP) of the Washington, D.C. bar, admitted pro hac vice, argued the cause for appellants in A–1236–13 and A–1237–13 (Gibbons P.C. and Mr. Schmidt, attorneys; Michelle M. Bufano, on the briefs; Michael X. Imbroscio (Covington & Burling, LLP) of the Washington, D.C. bar, admitted pro hac vice, and Mr. Schmidt, of counsel and on the briefs.).

David R. Buchanan argued the cause for respondents in A–1236–13 and A–1237–13 (Seeger Weiss, LLP, attorneys; Mary Jane Bass (Beggs & Lane) of the Florida bar, admitted pro hac vice, Peter Samberg (Weitz & Luxenberg, P.C.) of the New York bar, admitted pro hac vice, Troy Rafferty (Levin Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.) of the Florida bar, admitted pro hac vice, and Mr. Buchanan, on the brief).

Before Judges SABATINO, ACCURSO and SUTER.

Opinion

PER CURIAM.

***1** This is another appeal involving the prescription acne drug Accutane, the brand name for isotretinoin. Plaintiffs Kathleen Rossitto, Riley Dean Wilkinson, Rebecca Ree Wilkins Reynolds, and Jason Young brought product liability actions against defendants, Hoffman–La Roche Inc. and Roche Laboratories Inc. (collectively "Roche"), the manufacturers of Accutane.

Plaintiffs alleged that the drug caused them to sustain ulcerative colitis, an inflammatory bowel disease ("IBD"). They claimed that the labeling of Accutane that existed at the time failed to sufficiently warn them and their prescribing physicians of the risk of IBD from using the drug. The four cases, which were part of the Accutane multicounty litigation [1], were tried together in 2012.

The jury returned a verdict awarding $9 million each in compensatory damages to Rossitto and Wilkinson, but returned a verdict in Roche's favor as to Reynolds and Young. [2] Roche moved for judgment notwithstanding the verdict and a new trial as to the Rossitto and Wilkinson verdicts, which the court denied.

Roche now appeals, arguing that (1) the court made several prejudicial evidentiary rulings, including the admission of a revision to the Accutane label in 2000 constituting a subsequent remedial measure inadmissible under *N.J.R.E.* 407 and arbitrarily restricting the number of testifying experts on critical subjects; (2) the Accutane product warnings in use when Rossitto and Wilkinson were prescribed the drug were adequate as a matter of New Jersey law; (3) plaintiffs failed to establish proximate cause; and (4) plaintiffs' claims are time-barred under New Jersey law. Rossitto and Wilkinson have not cross-appealed any of the trial court's determinations.

For the reasons that follow, we vacate the final judgment and remand for a new trial.

I.

The basic circumstances involving the characteristics and labeling of Accutane, as well as the reported instances of

IBD in patients who used the drug, have already been canvassed at length in the Supreme Court's opinion in *Kendall v. Hoffman–La Roche, Inc.*, 209 *N.J.* 173, 180–83 (2012),[3] and several unpublished opinions of this court. We will not repeat that entire background except to amplify certain matters that are particularly germane to the present appeal, such as Roche's interactions with the Food and Drug Administration ("FDA") on labeling issues and the course of revisions to the warnings on the Accutane label. We also mention certain evidence that emerged at the current trial to the extent it was not covered in prior Accutane trials or discussed in our previous Accutane opinions.

Accutane

Accutane was originally studied for use in treating cancer. In 1992, the FDA approved a New Drug Application ("NDA"), submitted by Roche under the Federal Food, Drug and Cosmetic Act, 21 *U.S.C.A.* §§ 301–99 ("FDCA"), to market Accutane to treat recalcitrant nodular acne. The acne condition is "marked by an accumulation of sebum under the skin, which ultimately ruptures the follicle wall and forms an inflamed nodule." *Kendall, supra,* 209 *N.J.* at 180.

***2** Accutane is a retinoid, derived from vitamin A. *Ibid.* "Although much remains unknown about how Accutane treats acne, the drug appears to reduce the production of oil and waxy material in the sebaceous glands." *Ibid.* It is well established that Accutane "has a number of known side effects, including 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." *Ibid.*

There is scientific evidence, which the parties sharply dispute in certain respects, that Accutane has an adverse effect on the gastrointestinal tract. Studies prior to the drug's approval by the FDA revealed instances of dose-related gastrointestinal bleeding in dogs treated with the drug.[4] Similarly, in an Accutane clinical study conducted by Roche on 523 patients, 21.6% of them (i.e., 113 patients) suffered gastrointestinal side effects, primarily effects on mucous membranes, including effects such as increased thirst and appetite, nausea, and anorexia, as well as more serious gastrointestinal bleeding. Five patients left the study because of undisclosed gastrointestinal effects, but there were no reported cases of IBD. Gastrointestinal symptoms, but not IBD, were also reported in 34% of the clinical trial patients taking a chemically similar drug (Vesanoid, the brand name for tretinoin), manufactured by Roche to treat leukemia.

Inflammatory Bowel Disease

As in *Kendall* and several other Accutane appeals we have considered, this case concerns "the effect of Accutane on the digestive tract and, in particular, the alleged propensity of the drug to cause inflammatory bowel disease (IBD)." *Kendall, supra,* 209 *N.J.* at 180–81. IBD refers to "several chronic incurable diseases characterized by inflammation of the intestine." *Id.* at 181. The disease occurs when a trigger sets off an abnormal or exaggerated immune reaction, that is, an ongoing inflammatory reaction.

IBD primarily manifests as one of two diseases: ulcerative colitis and Crohn's disease. *Ibid.* Ulcerative colitis, the disease plaintiffs were diagnosed with, is "a chronic condition characterized by ulceration of the colon and rectum." *Ibid.* Crohn's disease 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. Individuals suffering from IBD generally experience abdominal pain, and frequent—and often bloody—bowel movements, resulting in fatigue, dehydration, anemia, fever, cramping and bloating. *Ibid.* The symptoms often wax and wane, but the condition is permanent and there is no known cure. *Ibid.*

The etiology or cause of IBD still remains largely unknown; however, several factors are associated with a statistically increased rate of IBD, including family history, infections, frequent use of some antibiotics, smoking, and possibly the use of oral contraceptives and nonsteroidal anti-inflammatory drugs ("NSAID"). *Ibid.* The peak onset of IBD occurs during adolescence, which is the same period in which patients with acne were likely to have been prescribed Accutane. *See ibid.*

***3** There have been no post-marketing clinical trials to study whether Accutane use causes IBD. Such a study is considered the "gold standard" in assessing causation, but would require a very large clinical trial.[5]

Accutane Labels and Warnings

The 1982 "Launch" Label

The FDA did not require a warning about IBD to appear on the 1982 Accutane "launch label," even though Roche, as the sponsoring pharmaceutical company, had included information in its NDA indicating that the drug had an effect on the gastrointestinal tract. *Kendall, supra,* 209 *N.J.* at 181; *see also* 21 *U.S.C.A* . § 355(b)(1)(A) (requiring NDAs to include reports of investigation into the safety and effectiveness of the drug); 21 *C .F.R.* § 314.50 (same). Nor did Roche, which was required to submit proposed labeling [6] as part of the NDA, propose such a warning. *See* 21 *C.F.R.* § 201.56(a); 21 *C.F.R.* § 314.50(c)(2)(i). Instead, the approved launch label, in accordance with FDA regulations, contained information about other adverse effects under sections headed "Contraindications," "Warnings," "Precautions," and "Adverse Reactions." *See* 21 *C.F.R.* § 201.80(d)-(g); 21 *C.F.R.* § 201.56.

Shortly after obtaining FDA approval for Accutane, Roche began to receive reports of IBD arising in patients who took the drug. As a result, in August 1983, Roche amended the "Adverse Reactions" section of the label to provide that IBD and mild gastrointestinal bleeding had been reported in "less than 1% of patients and may bear no relationship to therapy[.]"

The following month, Public Citizen, a nonprofit consumer advocacy group, petitioned the FDA for enhanced warnings on Accutane about a variety of serious adverse reactions, including IBD. Public Citizen expressed concern that the "potential toxicity" of Accutane had been "seriously under-emphasized" because the drug had been approved on limited data, had received "fast track" approval, and had been over-prescribed by physicians. The group cited to reports of patients developing IBD. It asserted that the number of reported cases likely underestimates the actual occurrence of IBD due to known rates of underreporting and recommended that Roche include a warning about the risk of developing the disease.

The 1984 Accutane Label and Its Warnings

In 1984, Roche amended the "Warnings" section of the Accutane package insert provided to physicians (the warning in effect when plaintiffs here took the drug), [7] as follows:

> 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.
>
> [(Emphasis added).]

The 1984 labeling change, which was reviewed and approved by the FDA and reprinted in the Physician's Desk Reference ("PDR"), remained in effect until 2000, throughout the time that the plaintiffs took the drug. *See* 21 *C.F.R.* § 314.70(c) (regulation governing changes to an approved application).

***4** In March 1984, Roche issued a "Dear Doctor" letter to prescribing physicians, which explained that:

> 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. [Roche is] *continuing to monitor adverse experiences* in an effort to determine the relationship between Accutane ... and these disorders.
>
> [(Second emphasis added).]

At that time, Roche's "Sales Desk Reference," a manual used by sales personnel in answering questions, provided that some patients had experienced symptoms characteristic of IBD, and that "[t]hese disorders have been temporally associated with Accutane administration, that is to say, the symptoms occurred while the patients were receiving the drug. A precise cause and effect relationship has not been shown."

"*Temporally Associated* "

The key term "temporally associated" in the 1984 labeling, which is at the core of the labeling adequacy issues here, was subject to differing and somewhat inconsistent definitions in testimony by Roche's company officials. For example, Eileen Leach, Roche's Medical Director of Dermatology, said that the term "temporal" meant that "during the time that the patient was taking Accutane,

[he or she] developed symptoms, or [he or she] reported symptoms." On the other hand, Dr. Martin Huber, an oncologist and Roche's former Director of Drug Safety, differed with the definition of "temporal" contained in the sales manual, and said it meant a condition that occurs within a "reasonable proximity," and did not have to have occurred at the exact time that a patient was taking the drug. Dr. Alan Bess, Roche's Director of Drug Safety, said that the term "association" was susceptible to different meanings within a label.

In June 1994, Roche issued an FDA-approved patient brochure which Wilkinson's mother received but could not recall having read. Rossitto's mother similarly could not recall having received or read the brochure. The patient brochure did not specifically refer to IBD, but warned 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." Patients who experienced any of those symptoms were advised to "discontinue" Accutane and consult with a doctor. The brochure also warned that those symptoms "MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS." The same FDA-approved warnings were printed on the blister packaging, containing the individual Accutane pills.

Roche's "general data" report concerning the drug stated that it is reasonable to conclude based on available literature that colitis "is a possible side effect of ROACCUTANE [8] in very rare cases, possibly in patients predisposed to inflammatory gastro-intestinal diseases."

The Post–Marketing Period

***5** After receiving FDA approval for Accutane, Roche had a continuing obligation to monitor the drug's safety. This duty included reporting to the FDA any adverse drug experiences and any new information that might affect the "safety, effectiveness or labeling of the drug product," reviewing the scientific literature, and reviewing the data for evidence of potential safety issues that should be included on the product label. *See* 21 *C.F.R.* §§ 314.80–81.

As part of the monitoring process, Roche collected data on adverse drug experiences ("ADE") or events through its call center and through MedWatch, the FDA's voluntary reporting system. As required by 21 *C.F.R.* § 314.80(f), Roche recorded the reports on an FDA form, listing among other information, a description of the event and whether it abated after the patient stopped using Accutane and returned after resuming the drug (referred to as "challenge"/" dechallenge"/"rechallenge").

From 1992 to 1998, Roche recorded several positive rechallenge reports of IBD. Dr. Bess admitted that, in some instances, a single positive rechallenge can be significant enough to warrant inclusion of the event on the label. However, Dr. Huber stated it was "very difficult to interpret" positive rechallenge data for IBD because it is a permanent disease in which the symptoms wax and wane.

In any event, in accordance with 21 *C.F.R.* § 314.80(b), Roche's medical reviewers examined the completed forms and then contacted the patient, doctor, or reporter to supply any missing information. Roche was required under 21 *C.F.R.* § 314.80(c)(1)(i) to report to the FDA "each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than" fifteen calendar days after receipt. Also, in compliance with 21 *C.F.R.* § 314.80(c)(2), Roche submitted annual and periodic ADE reports to the FDA, containing an analysis of the reports and a determination of whether a labeling change was warranted.

The Two FDA Warning Letters, Internal Roche Reports, and Other Developments

In January 1998, while Rossitto and Reynolds were still taking Accutane, Roche received a warning letter from the FDA for deviating from the reporting requirements of 21 *C.F.R.* § 314.80(c)(1) by failing to submit a number of ADE reports generated by their facilities in various countries for Accutane and other drugs "within 15 working days." Although Roche had "initiated corrective actions" to insure efficient processing, according to the FDA, Roche continued to submit "late reports (with some going back to 1989)." The FDA directed Roche to take "prompt action to correct these deviations," and cautioned that failure to do so "may result in regulatory action," including "seizure and/or injunction."

Roche also entered the data from the ADE reports into its internal ADVENT database. The ADVENT database contained a field which reflected the drug company's assessment of "relatedness or causality." Periodically, Roche prepared internal causality reports, which were not required to be submitted to the FDA, evaluating the ADE reports as entered into their database. In one such internal causality assessment, Roche indicated that, from 1982 to 1994, 104 cases of IBD and related syndromes had been reported in Accutane users, of which thirty-three were given a causality rating of " 'possibly' or 'probably' related to the administration of the drug."

***6** Based on this information, Dr. Henry Lefrancq, a physician with Roche, stated in an internal memo dated February 24, 1994, "[i]t is reasonable to conclude from this data that, in rare cases, ROACCUTANE may induce or aggravate a preexisting colitis." Dr. Lefrancq explained it was reasonable to assume that Accutane has the "same effect on the intestinal mucosa as [has been observed] on the other mucosae in the body such as the oral or nasal mucosae." He added, "As these reactions have always been reversible, the colitis which may develop in a relatively limited number of patients can as well be regarded as reversible."

In another internal report from May 2003, Roche stated that there had been 159 reports of adverse events from exposure to Accutane received from worldwide sources. Sixty-four of those patients had Crohn's disease, of which Roche assessed causality as "related" in twenty-seven cases. The remainder were designated either as unrelated or unknown, and twenty-nine had IBD (not otherwise specified), of which it assessed causality as related in thirteen cases, and as unknown in the remaining sixteen cases.

Roche also prepared periodic safety update reports ("PSUR") for European regulators. In a PSUR dated August 17, 1988, Dr. Peter Schifferdecker, a physician and Roche product specialist, reviewed the reports received from patients using Accutane from January 1 to June 30, 1988, and concluded that "[s]ince introduction, ROCHE Drug Safety received 38 case reports of colitis [IBD] and proctitis in association with ROACCUTAN treatment." Twenty-two patients "recovered" after discontinuation of Accutane, but nine patients had persisting colitis or proctitis, and one patient underwent a "total colectomy." In another report dated November 16, 2000, Roche stated that "[i]sotretinoin has been found to be causally associated with inflammatory bowel disease, including colitis." Later, in a January 2003 report, Dr. Daniel Reshef, Roche's Director of Drug Safety, stated that there was "an average event latency after the start of the drug" to when symptoms of IBD manifested "ranging from 23 to 1,219 days."

According to Dr. Bess, in December 1997, while sales of Accutane were escalating sharply, there were differences of opinion between Roche's drug safety and marketing departments about adopting a label change to warn about depression, a different alleged side effect of Accutane. Dr. Bess testified that Frank Condella, Roche's vice president of marketing, "felt very strongly that any label change would hurt U.S. sales." The marketing department's "philosophy was to protect the franchise" and "build the product," and thus Condella, during a "very loud disagreement," "made it very clear that he wouldn't tolerate any action that would hurt the product." Mike Carter, who reported to Dr. Bess, agreed that "[m]arketing was calling the shots."

Dr. Russell Ellison, Roche's former chief medical officer, who was called as a witness at this trial by both sides, acknowledged that there were some "disagreements" between Roche's marketing and drug safety departments. Dr. Ellison asserted, however, that marketing never "called the shots," and that its concerns did not prevail because in February 1998 the Accutane label was changed to include a stronger warning about depression. However, he also stated that Roche had made a significant investment in marketing Accutane, and that its investment strategy was to "[f]eed the goose that lays the golden eggs." Dr. Ellison further noted that before he started working for Roche in 1997, the company had a "negative" image with the FDA (but not specifically regarding Accutane and IBD), which he claimed he had repaired.

***7** On March 5, 1998, Roche received a second warning letter from the FDA in which the agency concluded that Roche's advertising and promotional materials for Accutane were "false or misleading" and promoted "Accutane for an unapproved use." The FDA found that Roche had failed to disclose "that depression may be associated with the use of Accutane," and had "misleadingly" suggested "that Accutane therapy will minimize or improve the patient's psychosocial status, including depression," even though Roche had

"not systematically studied" the ability of Accutane to modify or prevent depression.[9] According to the FDA, Roche's claim was "particularly troublesome in light of information recently presented in a Dear Doctor letter, that Accutane may cause depression[.]" The FDA required Roche to cease this promotional activity and to instruct its sales personnel to stop disseminating the materials.

The 2000 Label Revision

In May 2000, after all of the plaintiffs in this trial had completed their treatment, Roche amended the Accutane warnings section. It removed the term "temporally," and added language about persistent IBD symptoms as follows:

> Inflammatory Bowel Disease: Accutane has been *associated with* inflammatory bowel disease ... in patients without a prior history of intestinal disorders. *In some instances, symptoms have been reported to persist after Accutane treatment has been stopped.* Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue Accutane immediately (see ADVERSE REACTIONS: Gastrointestinal).[10]
>
> [(Emphasis added).]

Despite the label's acknowledgement of an association, Roche's position at trial was that Accutane does not cause IBD.

Plaintiffs' Use of Accutane and Their IBD

Rossitto

Rossitto is a New Jersey resident. In 1992, when she was twelve years old, Rossitto began seeing Dr. James Watt, a dermatologist, for treatment of her acne. Dr. Watt initially prescribed a series of antibiotics and topical creams which did not cause her any gastrointestinal upset, but did not resolve her acne.

In 1997, Dr. Watt recommended that Rossitto, who was then sixteen years old, begin taking Accutane. Dr. Watt, who had read the Accutane label, discussed certain side effects with Rossitto and her mother, including dry skin and lips, effects on the liver, and the risk of birth defects if she became pregnant while taking the drug. The mother testified that Dr. Watt did not discuss the risk of developing IBD, asserting that, if he had, she would not have allowed her daughter to take the drug. The mother also understood from reading the patient brochure, that when you stopped taking the drug, "the side effect would also stop."

Dr. Watt discarded all of his medical records when he retired in 2001. At his de bene esse deposition, he could not specifically recall having treated Rossitto. However, he testified that it was his customary practice in 1997 to only warn patients about the more serious and more common side effects of the drug, including dry skin and lips, and birth defects. Dr. Watt testified that the information provided in the 1984 label did not warn him that Accutane can cause permanent IBD, asserting that if it had, he would have relayed that information to his patients.

***8** In December 1997, Rossitto began taking Accutane with her mother's consent. She completed her treatment in April 1998. During this approximately six-month treatment period, Rossitto experienced dry skin and lips, but no gastrointestinal effects.

In July 1999, about fourteen months after she stopped taking Accutane, Rossitto saw Dr. Richard Eichel, a gastroenterologist, complaining of blood in her stool, diarrhea, and severe abdominal pain. Dr. Eichel diagnosed her as suffering from ulcerative colitis.

Over the next eleven years, Rossitto's IBD symptoms flared and remitted. She underwent numerous colonoscopies, was hospitalized several times, and was treated with a variety of medications, including long-term steroid use. On bad days, she had twenty-five bloody bowel movements a day, and suffered from cramping, fever, and abdominal pain. In June 2011, her colon was surgically removed and her small intestine was brought through a hole in her abdominal wall to drain into an ileostomy bag. In October 2011, she underwent a second surgery to reverse the ileostomy.

None of Rossitto's treating physicians told her that Accutane was the cause of her IBD. Rossitto testified that she instead first learned of the connection between Accutane and IBD in November 2010, when her friend told her about a television commercial that mentioned the disease.

Wilkinson

Wilkinson is a resident of Utah. In January 1993, when he was fifteen years old, Wilkinson began seeing Dr. Robert Orme, a dermatologist, for an acne condition. Like Rossitto, Wilkinson was prescribed a series of antibiotics and creams which proved ineffective but did not cause him any gastrointestinal upset. In October 1993, Dr. Orme gave Wilkinson and his mother a copy of the Accutane patient brochure. In July 1994, Dr. Orme "strongly" recommended that Wilkinson begin taking Accutane, but Wilkinson's mother decided to defer possible Accutane treatment to a later time for various reasons.

In May 1995, Dr. Orme gave Wilkinson and his mother another copy of the patient brochure. Dr. Orme, who had read the 1984 label, discussed with them various side effects of taking Accutane, including dry eyes and skin, photosensitivity, joint pain, headaches, depression, birth defects, and dry mucous membranes, but not IBD. He testified that "[i]n all likelihood," if the label had warned that Accutane had been "possibly or probably associated" with IBD he would still have prescribed the drug for Wilkinson and would not have changed the content of the warnings he gave to Wilkinson. However, Dr. Orme also testified that if Roche had warned that taking Accutane presented a risk of developing IBD, he "[d]efinitely" would have warned them about IBD. Wilkinson's mother confirmed that Dr. Orme had not discussed the risk of developing IBD, stating that, if he had, she would not have allowed her son to take the drug even if Dr. Orme had "highly recommended it."

In May 1995, Wilkinson, then seventeen years old, began taking Accutane with his mother's consent. He completed that course of treatment in October the same year. While taking Accutane he suffered from dry lips and a few nosebleeds, but no gastrointestinal problems.

***9** In May 1996, approximately seven months after he stopped taking Accutane, Wilkinson began experiencing bouts of worsening abdominal pain and bloody diarrhea. The symptoms persisted. In June 1997, approximately twenty months after he stopped taking Accutane, Wilkinson was diagnosed with ulcerative colitis.

Over the next several years, Wilkinson was treated with a variety of medications, including steroids. In May 2001, his colon was surgically removed and he was fitted with an ileostomy bag. He later underwent a second surgery to reverse the ileostomy and replace his colon with a surgically created J-pouch. He subsequently developed bouts of pouchitis caused by J-pouch infections.

None of Wilkinson's treating physicians had ever told him that Accutane was the cause of his IBD. Wilkinson testified that he first learned of the connection between Accutane and IBD in December 2006, when he saw a television commercial on the subject.

Expert and Related Testimony

The parties presented at trial numerous competing liability experts addressing the critical issues of causation and labeling.

Plaintiffs' Experts

Plaintiffs' presented Dr. David Sachar as their causation expert, who linked generally the use of Accutane with IBD and addressed specific causation with respect to plaintiffs' own medical conditions. [11] Dr. Sachar is a board-certified gastroenterologist and internist. He has been a professor at Harvard and Mount Sinai Schools of Medicine. He was also the past chairman of the FDA Gastrointestinal Drugs Advisory Committee, and has authored or co-authored approximately a hundred articles on IBD in peer-reviewed publications.

Relying on a variety of sources, Dr. Sachar opined that Accutane in prescribed doses can cause, trigger or exacerbate ulcerative colitis in humans, and was in fact the cause of plaintiffs' ulcerative colitis in this case. He explained that although Accutane has a half-life of only about ten-to-twenty hours, it acts as a trigger, setting in motion an inflammatory effect that results in the latent development of Accutane-induced IBD.

As to specific causation, Dr. Sachar found that Wilkinson's Accutane use in 1995 had caused his ulcerative colitis. Dr. Sachar noted that Wilkinson had received a high dose for a relatively long period (five months), and had become symptomatic approximately six to twelve months after he had stopped taking the drug, which was well within the latency period. Further, Dr. Sachar ruled out other potential triggers, including family history, prior infections, and NSAID and antibiotic use.

Similarly, Dr. Sachar found that Rossitto's use of Accutane from December 1997 to April 1998 had caused her ulcerative colitis. He explained that Rossitto had

received an "escalated" dose for four months, and was diagnosed with ulcerative colitis approximately fourteen months after she stopped taking Accutane, which was also well within the drug's latency period. Dr. Sachar likewise ruled out other causes of Rossitto's IBD.

***10** Dr. Cheryl Blume, a pharmacologist and consultant, testified as plaintiffs' expert in regulatory affairs, "pharmacovigilance," and drug labeling. Dr. Blume opined, as she had in *Kendall* and in other prior Accutane cases, that the 1984 Accutane label or warning in effect when the present plaintiffs took the drug did not accurately reflect the knowledge that Roche actually had at that time about IBD. Dr. Blume conceded that when the 1984 FDA-approved label for Accutane was first adopted, it appropriately warned about IBD, based on the information Roche had at that time. However, Dr. Blume opined that by the late 1980s the label was no longer accurate because Roche had received, through its post-marketing surveillance, numerous reports of patients who had developed IBD months after taking Accutane. Many of those reports contained positive rechallenge events. According to Dr. Blume, given generally accepted FDA rates of under-reporting, those reports may constitute only one-to-ten percent of the actual incidences of IBD in Accutane patients.

Based on the post-marketing ADE reports and the company's own internal conclusions, Dr. Blume concluded that Roche had deviated from the applicable standard of care on labeling. She testified that the 1984 label, which had remained unchanged for sixteen years, should have contained stronger, more specific language to clearly communicate the risk that taking Accutane can cause IBD. She criticized the label's use of the phrase "temporally associated" as deficient because Roche had received reports of a latency effect, signifying that a patient could develop IBD long after he or she had stopped taking the drug.

Further, Dr. Blume opined that Roche should have recommended in the "Precautions section" that patients who are susceptible to IBD should be given a lower dose of Accutane or not prescribed the drug at all. According to Dr. Blume, Roche should also have referred to the "very important" multiple positive rechallenge events, because there are instances where even a single positive rechallenge is included in a warning label. Dr. Blume also found significant that Roche had received two warning letters from the FDA about the shortcomings of its advertising and promotional materials for Accutane about depression, albeit not about IBD.

Roche's Experts

Roche's experts proffered countering opinions on causation and labeling adequacy. On the subject of general causation, Roche presented Dr. Maria Oliva–Hemker, an expert in pediatric gastroenterology who focused on Rossitto's case. She opined that Accutane in prescribed doses cannot cause or substantially contribute to IBD in humans, and was not the cause of Rossitto's ulcerative colitis. Dr. Oliva–Hemker stated that, although the cause of ulcerative colitis remains unknown, studies have shown that genetics and exposure to certain triggers —but not Accutane—play a role in developing the disease. Dr. Oliva–Hemker stressed that the incidence rate of ulcerative colitis, which has been diagnosed in patients since 1875, had not risen after Accutane came on the market in 1982. As to specific causation, she opined that the most likely trigger of Rossitto's ulcerative colitis was her "extensive exposure to antibiotics" in the five years before taking Accutane.

***11** Similarly, Dr. Brian Dieckgraefe, Roche's expert in gastroenterology and IBD who focused on Wilkinson's case, opined that the available evidence does not support a causal connection between Accutane and IBD. He asserted that "[g]enetics cause" IBD, and that a number of triggers had been reported in the scientific literature and accepted as "exacerbat[ing]" ulcerative colitis, including antibiotics, NSAIDs, and oral contraceptives, but not Accutane. Dr. Dieckgraefe opined that Accutane was not the trigger for Wilkinson's ulcerative colitis because his exposure to the drug was "not proximate" to his developing the disease. The expert could not, however, detect any identifiable known risk or trigger for the onset of Wilkinson's ulcerative colitis. He thus characterized the condition as "idiopathic."

Countering plaintiffs' labeling expert Dr. Blume, Dr. David Feigal testified for Roche that the 1984 Accutane label, in fact, was appropriate. Dr. Feigal is an epidemiologist specializing in drug regulatory affairs, labeling, and pharmacovigilance. He recognized that in 1983 Roche had received nine or ten case reports of patients who developed IBD while taking Accutane and asserted that Roche responded to those reports "rather promptly," noting that during an FDA advisory

committee meeting in October 1983, Roche proposed certain labeling language to "convey that information to physicians[.]" The FDA presented counterproposals, and ultimately approved the language contained in the amended 1984 label.

Dr. Feigal testified that the 1984 label, which is at issue here, contained a "very strong and very effective warning" about IBD. He submitted that the term "temporally associated" used on the label indicates a "strong association," and communicates that IBD is a possible side effect of taking Accutane. Dr. Feigal added that the patient brochure given to plaintiffs was another tool by which a physician could communicate information about Accutane to a patient. Although IBD was not specifically referenced in the patient brochure, the symptoms of the disease were. The brochure instructed a patient to discontinue taking the drug and to check with his doctor if he or she experienced any of those symptoms.

Dr. Feigal agreed that a label should be changed if there is reasonable evidence of an association of a serious hazard with a drug. However, he found no evidence in the ADE reports or the scientific literature of a change in the frequency or severity of IBD, or of a latency effect, sufficient to warrant such a change.

In this regard, Dr. Feigal noted that from 1992 to 1993, Roche received only nine reports of IBD from among the approximately 300,000 Accutane users. From 1992 to 1998, there were about 190 reports of IBD from the approximately eight million Accutane users in the United States. After adjusting for the increased number of patients taking the drug, Dr. Feigal found no change in the frequency of reported cases of IBD, and found only five cases, out of eight million, where the patient experienced a latency effect. Dr. Feigal further stated that the causality reports and epidemiological studies showed only an association, not causation.

***12** On the whole, Dr. Feigal opined that Roche had acted in accordance with FDA standards by conducting post-marketing surveillance, and in complying with reporting and warning letter requirements. Although Dr. Feigal acknowledged that Roche had received a warning letter in 1998 about its failure to timely submit ADE reports to the FDA, he testified that such a failure was not indicative of a "system deficiency," because the late reports had been generated in France and not in the United States.

Dr. Ellison's Testimony

Dr. Feigal's expert opinions on labeling dove-tailed substantially with the factual testimony of Dr. Ellison, who was responsible at Roche for the contents of the Accutane label between 1997 and 2002.

Dr. Ellison maintained that the 1984 label, which provided that Accutane "has been temporally associated" with IBD, was medically accurate and "was the strongest representation" of the risks based on the data that Roche then possessed. He asserted that the term "associated" was a "very accurate way of saying may cause," and that the term "has been" in the label was "very strong" language intended to convey that the potential risk "has been observed."

Dr. Ellison further contended the warning was consistent with the scientific literature, in which authors frequently had used the terms "has been associated" and "temporal relationship" in discussing Accutane and IBD.

According to Dr. Ellison, the 2000 revision to the Accutane label did not alter the "fundamental purpose" of the warning, that is, to warn physicians that there was a risk of developing IBD from taking Accutane. To that end, Dr. Ellison asserted that even if the warning had not been changed, it would still have been medically accurate, appropriately written, and complete. Moreover, he noted that the FDA had not asked Roche to amend the warning to include the information plaintiffs' expert Dr. Blume claimed should have been listed, including positive rechallenges, causality assessments, and a latency effect.

Dr. Ellison acknowledged that, after the Accutane label was amended in 2000, there were discussions about whether the FDA would refer an evaluation of the label to an advisory committee on a variety of side effects, including IBD.[12] An internal Roche "briefing document," dated April 6, 2000, addressed to Kevin Rigby, Roche's vice president of business policy and governmental affairs, noted that Roche had entered into negotiations with the FDA over the label. However, the briefing document further indicated that the discussions had "degenerated," and that the company's responses to the FDA's concerns had "almost uniformly been rejected

[by the FDA] as insufficient." The internal document concluded that Roche had three options: (1) pressure the FDA to prevent an advisory committee; (2) work toward and prepare for a narrowed advisory committee hearing; or (3) prepare for a fairly open advisory committee hearing. Regardless of whether the potential hearing was "narrow" or "open," the document cautioned that "any review of adverse events could lead to questions by committee members on any listed adverse event or members of the public could raise those issues in a *manner likely to prove extremely harmful to Roche.*" (Emphasis in original).

The Verdict and the Present Appeals

***13** After its deliberations, the jury issued a verdict finding that: (1) Roche failed to provide an adequate warning to the prescribing physicians of Rossitto, Wilkinson, Reynolds and Young; (2) Roche's failure to warn was a substantial factor in the decisions of Rossitto and Wilkinson, but not of Reynolds and Young, to take Accutane; and (3) Accutane was a substantial factor in Rossitto and Wilkinson developing IBD. As we have already noted, the jury awarded an identical $9 million in compensatory damages to both Rossitto and Wilkinson. This appeal by Roche ensued. [13]

II.

We begin with a short overview of the governing substantive law. Plaintiffs hinge their claims in this case upon the New Jersey Product Liability Act ("PLA"), *N.J.S.A.* 2A:58C–1 to –11. Although Wilkinson is a citizen of Utah (unlike Rossitto who is a citizen of this state), all parties agree that the PLA and the substantive laws of New Jersey, where Roche is headquartered, govern the liability issues in this case. The product liability laws of Utah and New Jersey, although not identical, are sufficiently similar to justify that choice of law designation. *See P.V. ex rel. T.V. v. Camp Jaycee,* 197 *N.J.* 132, 143 (2008) (applying a "most significant relationship test" to determine the governing choice of law on legal issues); *Rowe v. Hoffmann–La Roche, Inc.,* 189 *N.J.* 615, 621 (2007) (instructing, in the context of an Accutane products liability case, that choice-of-law determinations should be made on an issue-by-issue basis). [14]

The PLA was enacted by our Legislature in 1987 "as a remedial measure to limit the liability of manufacturers by establishing 'clear rules with respect to certain matters relating to actions for damages for harm caused by products,' " and in particular, to "reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." *Kendall, supra,* 209 *N.J.* at 194. In accordance with common-law principles, the PLA provides that a manufacturer shall be liable for harm caused by a product that was "not reasonably fit, suitable or safe for its intended purpose" because it "failed to contain adequate warnings." *N.J.S.A.* 2A:58C–2. A manufacturer "shall not be liable for harm caused by a failure to warn if the product contains an adequate warning," which is defined as

> one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account ... in the case of prescription drugs ... the characteristics of, and the ordinary knowledge common to, the prescribing physician.
>
> [*N.J.S.A.* 2A:58C–4.]

Following FDA approval, a manufacturer has a continuing duty to warn of all known adverse effects of a drug as soon as reasonably feasible based upon actual or constructive knowledge of a danger. *Feldman v. Lederle Labs.,* 97 *N.J.* 429, 456–57 (1984). In this regard, FDA regulations require that "the labeling accompanying a prescription drug 'describe serious adverse reactions and potential safety hazards' and that the labeling 'be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.' " *Rowe, supra,* 189 *N.J.* at 625 (quoting 21 *C.F.R.* § 201.80(e)).

***14** The process of changing an FDA-approved drug label is governed by federal regulation. For example, proposed changes in labeling are generally first submitted to the FDA for approval. However, when a new safety issue emerges, a company may add to the product's labeling on a temporary basis prior to FDA approval by the use of what is known as a "changes being effected" ("CBE") supplement. *See* 21 *C.F.R.* § 314.70(a)-(d). A supplement "is appropriate to amend the labeling for an approved product only to reflect newly acquired information ... to add or strengthen

a contraindication, warning, precaution, or adverse reaction only if there is sufficient evidence of a causal association." *Bailey v. Wyeth, Inc.,* 424 *N.J.Super.* 278, 292 (Law Div.2008) (quoting 73 *Fed.Reg.* 2848 (Jan. 16, 2008)). The FDA defines " 'newly acquired' as 'data, analyses, or other information not previously submitted to the agency.' " *Ibid.* (quoting 73 *Fed.Reg.* at 2850). Ultimately, as it did with respect to Accutane, the FDA reviews all "modified labeling to ensure compliance with FDA regulations." *Id.* at 291–92.

In failure-to-warn claims involving pharmaceuticals, the New Jersey Legislature "recognized the preeminent role of federal regulation of drugs," *Cornett v. Johnson & Johnson,* 211 *N.J.* 362, 387 (2012), by including the following section in the PLA:

> If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," ... *a rebuttable presumption shall arise that the warning or instruction is adequate.*
>
> [*N.J.S.A.* 2A:58C–4 (emphasis added).]

"Compliance with FDA regulations provides compelling, although not absolute, evidence that a manufacturer satisfied its duty to warn about the dangers of its product." *Kendall, supra,* 209 *N.J.* at 195. This "virtually dispositive" statutory "super-presumption" under the PLA is difficult to overcome. *Id.* at 195–197; Dreier, Keefe & Katz, *Current N.J. Products Liability & Toxic Torts Law* § 15:4 at 464–65 (2016). It is "stronger and of greater evidentiary weight than the customary presumption referenced in *N.J.R.E.* 301." *Bailey, supra,* 424 *N.J.Super.* at 314.

To overcome the PLA's "super-presumption," a plaintiff must show either: (1) "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects," *Perez, supra,* 161 *N.J.* at 25; *Rowe, supra,* 189 *N.J.* at 626; or (2) substantial evidence of economically-driven manipulation of the post-market regulatory process, *McDarby v. Merck & Co.,* 401 *N.J.Super.* 10, 63, 66 (App.Div.2008), *certif. dismissed as improvidently granted,* 200 *N.J.* 267 (2009). Compensatory damages are reserved for those "rare cases when the presumption is overcome." *Perez, supra,* 161 *N.J.* at 25.

III.

***15** Roche argues that it was seriously prejudiced in defending this case by several erroneous evidentiary rulings of the trial court. Those challenged rulings included, among other things, (1) allowing plaintiffs' counsel to reveal, when examining Dr. Ellison, that the Accutane label's warning was changed in 2000 after plaintiffs had ceased using the drug, despite the court having previously ruled that the subsequent labeling change would be excluded at trial under *N.J.R.E.* 407; (2) arbitrarily restricting the number of expert witnesses who could testify on a particular subject; and (3) not permitting Roche to introduce into evidence a scientific study that it contends undercuts plaintiffs' causation theories.

We agree with Roche that the trial court misapplied its discretion with respect to the first two of these challenged rulings, which had the cumulative impact of skewing the jurors' fair consideration of this case.

A.

N.J.R.E. 407 directs that "[e]vidence of remedial measures taken after an event is not admissible to prove that the event was caused by negligence or culpable conduct. However, proof of such subsequent remedial conduct may be admitted as to other issues." *Rule* 407 codifies our state's "strong public policy encouraging prompt remedial measures[.]" *Szalontai v. Yazbo's Sports Cafe,* 183 *N.J.* 386, 402 (2005). The Rule recognizes those remedial objectives can be thwarted if a defendant's post-accident corrective actions are admitted as liability proofs in product liability cases. *See In re Petition of S.D.,* 399 *N.J.Super.* 107, 124 (App.Div.2008) (noting that New Jersey has a longstanding public policy favoring the immunization of remedial measures from negative inferences).

Subject to considerations of unfair prejudice and other countervailing factors under *N.J.R.E.* 403, evidence of remedial conduct at times may be admitted under *N.J.R.E.* 407 as to other issues, including efforts to impeach the credibility of a witness. *See Kane v. Hartz Mountain Indus., Inc.,* 278 *N.J.Super.* 129, 148 (App.Div.1994), *aff'd o.b.,* 143 *N.J.* 141 (1996); *Lavin v. Fauci,* 170 *N.J.Super.* 403, 407 (App.Div.1979).

Initially, as it had in other Accutane trials, the trial court barred admission of the 2000 revised label (which, as we have noted, removed the term "temporally" and added language about persistent symptoms) as a subsequent remedial measure disallowed by *Rule* 407. As we will discuss, *infra,* the court reversed course on that ruling later in the case.

A threshold question under *Rule* 407 is whether the 2000 label change qualifies as a subsequent remedial measure. Consistent with the public policy underlying *Rule* 407, the Rule has been "held not to bar evidence of subsequent remedial conduct which was taken under governmental mandate rather than voluntarily." Biunno, Weissbard & Zegas, *Current N.J. Rules of Evidence,* comment 1 on *N.J.R.E.* 407 (2016). For example, in *Harris v. Peridot Chemical (N.J.), Inc.,* 313 *N.J.Super.* 257, 292 (App.Div.1998), we held *Rule* 407's evidentiary prohibition was inapplicable because the safety measures taken by the defendant in that case were not remedial, but rather were mandated by the Department of Environmental Protection. Hence, "admission of the evidence would not violate the policy underlying the Rule." *Ibid.; see also Cepeda v. Cumberland Eng'g Co., Inc.,* 76 *N.J.* 152, 193 n. 11 (1978) (noting that proof of a defendant's installation of a safety device was not barred from evidence as a subsequent remedial measure because it was installed as the result of an official demand, not a voluntary action), *overruled on other grounds, Suter v. San Angelo Foundry & Mach. Co.,* 81 *N.J.* 150 (1979).

***16** We therefore must consider whether the FDA "mandated" the label change in 2000.[15] Dr. Ellison testified that the Accutane label was amended in 2000, in accordance with the FDA's suggestion to take out the word "temporally" and to add language about persistent symptoms. He explained that Roche "effectively agreed" with that suggestion because it did not "dispute it."

If, in fact, the FDA's "suggestion" is deemed to be a mandated label change, then the court's admission of the 2000 label would not violate the policy underlying *Rule* 407 and would not be barred as a subsequent remedial measure. On the other hand, if the label change is deemed voluntary, evidence of that remedial conduct still might be admissible under *Rule* 407 for purposes other than proving culpable conduct or causation. *Kane, supra,* 278 *N.J.Super.* at 148. Nonetheless, "[e]ven where subsequent remedial conduct evidence has relevance to some fact in issue other than negligence, it may be excluded if the prejudicial effect outweighs the probative value." *Ibid.*

Having originally considered the 2000 label change as a non-mandated subsequent remedial measure, the trial court altered its course later in this trial. On the twenty-ninth day of trial, Dr. Ellison testified that the 1984 label was medically accurate and was the strongest representation of the risks based on the data that Roche had at that time. He contended the "temporally associated" warning conveyed causation, and that removing the word "temporally," might "weaken the association in the minds of the doctor," because a doctor might wonder how Roche had determined there was an association. He concluded that "[t]o a degree," inclusion of the term "temporally" made the warning stronger and "was a good thing."

At that point, the court, over Roche's objection, granted plaintiffs' application to admit the 2000 label into evidence under *Rule* 407, for the stated purpose of impeaching Dr. Ellison's credibility. The court subsequently denied Roche's motion for a mistrial on this issue. It instructed the jury that the label change was "admissible only for the purpose of attacking the credibility of the statements of the witness," and was not proof "that the label was inadequate."

In later denying Roche's post-trial motion for JNOV, the trial court found that Dr. Ellison had "opened the door" to justify the admission of the 2000 label. As part of the court's reasoning, it concluded, on reflection, that Roche's assent to the FDA's suggested change to the label in 2000 did not amount to a voluntary "remedial measure" within the ambit of *Rule* 407.

As an appellate court we must afford due deference to the trial court's authority over evidential rulings. *Hisenaj v. Kuehner,* 194 *N.J.* 6, 16 (2008). Nonetheless, we conclude that the court seriously erred in allowing plaintiffs' counsel to divulge to the jury that the Accutane label was altered in 2000 after plaintiffs had already stopped ingesting the drug. The court originally—and correctly—recognized before this trial began the substantial prejudice to Roche in allowing the subsequent post-ingestion labeling change to be considered by the jury. It should not have strayed from that correct determination.

***17** We are not persuaded that the 2000 labeling revision was a "mandated" change. As we have already noted, *supra* note 15, the FDA did not acquire the express regulatory authority to mandate such changes until 2007. We disagree with the trial court's ultimate finding that the FDA's role in proposing the labeling change in 2000 rendered the drug company's adoption of that proposal involuntary. Hence, both the terms and the underlying public policies of *Rule* 407 do pertain here.

Although Dr. Ellison would not concede the point, it is manifestly clear that the 2000 warning did strengthen the label's warning relating to IBD and gastrointestinal disorders by removing the "temporally associated" phrasing that had preceded it. The revelation of the 2000 label change could easily have been viewed by the jurors as "smoking gun" evidence, signifying that the Accutane label that had preceded the 2000 version was deficient.

We disagree with the trial court's assessment that plaintiffs' disclosure of the 2000 label change was justified by *Rule* 407's exception for "other issues" such as witness impeachment. To be sure, Dr. Ellison did maintain that the previous 1984–vintage label was more than adequate, and that inclusion of the word "temporally" was beneficial to patients and their doctors. But such a retrospective defensive posture is a natural aspect of a classic *Rule* 407 factual paradigm, in which defendants and their witnesses are tasked with justifying the sufficiency of past conduct or the benign quality of past conditions that preceded a subsequent remedial change.

In any event, even if we agreed the disclosure of the 2000 label change to the jury fell within an exception to *Rule* 407, the probative value of that impeachment was substantially overcome by the strong prejudice to the defense and by the important public policies underlying the Rule. The court failed to afford sufficient consideration to the offsetting reasons for exclusion under *N.J.R.E.* 403. *See Green v. N.J. Mfrs. Ins. Co.,* 160 *N.J.* 480, 495–501 (1999).

The impact of this error was compounded by plaintiffs' summation. A substantial portion of the summation focused upon attacking Roche's conduct that post-dated plaintiffs' ingestion of Accutane, including an explicit argument that the "stronger" 2000 label change proved the inadequacy of the earlier warning. As part of his closing, plaintiffs' counsel told the jury:

> *Roche failed to provide an adequate warning.* Dr. Blume told you so. I think you know so. *You have seen the information. And this is what you got last week from Dr. Ellison,* his interpretation of the label.
>
> He said, first of all, very important fact, [w]e never made the label weaker. I established that. That was the first point I established with him.
>
> *And then you learned about five minutes later that,* in fact, what they did, after claiming that temporally associated was a stronger warning to patients [and] that [it] conveyed more than association ... was that *in 2000, they took it out of the label. It was removed. And Dr. Ellison, this is the 2000 label change, something you learned about just last week,* removed, and Dr. Ellison told you what it meant, when "temporally" was taken out of the label, *it conveyed to prescribers that this event could develop after somebody stopped taking the drug. Latency. Latency. Not in time for these folks, notwithstanding the company had information on latency years before. Not in time for their doctors.*
>
> ***18** [(Emphasis added).]

This robust and pointed argument shows that, notwithstanding the court's limiting instruction, the 2000 label change was used within plaintiffs' advocacy for its substantive evidential power. Despite the court's instruction, the evidence was obviously not deployed solely as mere impeachment proof to undermine Dr. Ellison. Instead, it was advocated as direct proof of the prior warning's deficiencies, accentuated by counsel's dramatic point that the remedial measure came "too late" for these plaintiffs.

The clear potential for unfair prejudice to Roche was further illuminated by the question the jurors posed as their very first request during deliberations. The jury asked, "Can we see all the evidence or only for 1998 back[?] In reference to the last Accutane brochure showed [sic] in court with the new language." While counsel were discussing with the judge in chambers how to deal with this request, the jury then indicated that "they didn't need an answer, that they found what they were looking for." Roche's counsel argued that the posing of the request suggested that the jury was "talking about the 2000 label change," and that the jury presumably intended to improperly "use the evidence prior to 1998, and then [compare it substantively to] the 2000 label[.]" The judge

responded that the court could not interfere with the jury's deliberation, or speculate as to the reason for the jury's request. We do not share the trial court's confidence that the request was inconsequential, even if it is not totally certain what motivated the inquiry. Instead, it provides further indicia that the improvident admission of the 2000 revised label had the capacity to cause a miscarriage of justice. *R.* 2:10–2.

In sum, the trial court's ill-advised departure from its original ruling to exclude the 2000 label change under *Rule* 407 constituted reversible error. The error was of such a magnitude, particularly coupled with the expert-limitation issue we now address, to warrant relief.

B.

The trial court also misapplied its discretion, albeit without having the benefit of more recent published case law, by curtailing the number of expert witnesses that Roche could present in its behalf on particular subjects.

In *McLean v. Liberty Health System,* 430 *N.J.Super.* 156, 160 (App.Div.2013), an opinion we issued after the verdict in this case, we held that a trial court erred in prohibiting a plaintiff "from presenting the testimony of a second expert witness on the subject of medical malpractice because his testimony would be duplicative." Our opinion explained that:

> *[T]he trial court erred in limiting expert witnesses to only one per side for each relevant field of medicine, in particular, on the crucial issue* of deviation from accepted standards of medical care. *The court's pretrial ruling was a mistaken exercise of its discretionary authority to control the presentation of evidence at the trial. See N.J.R.E.* 611(a) ("court shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence"). Nothing in our rules of evidence, or other laws or rules, gives a trial court authority to balance the number of witnesses presented by each side at the trial. Nor is the trial court authorized by *N.J.R.E.* 403 or any other rule or law to bar crucial evidence merely on the ground that it duplicates another witness's testimony.
>
> ***19** *A trial court would likely abuse its discretion if it imposed a limitation of only one witness for each side to testify on a factual matter that is vital to the resolution of a disputed issue. ...*
>
> Here, the testimony that plaintiff wished to present went to the heart of her case: whether defendant deviated from accepted standards of care for an emergency department physician. Although a second expert would have taken more time at the trial, it might have been time well-spent. In the field of medicine, second opinions are often sought to test the accuracy of a diagnosis or the benefits and risks of proposed treatment. *Surely it cannot be said that additional expert testimony in a case that involved complicated issues of emergency and diagnostic medicine had such low probative value as to be substantially outweighed by its partially repetitive nature.*
>
> [*Id.* at 165–68 (emphasis added).]

We further explained:

> We note that *Rule* 403 does not refer to "duplicative evidence" but to "needless ... cumulative evidence" that might cause undue delay in the trial and a waste of time. *By our holding today, we do not preclude a trial judge from excluding expert evidence when its cumulative nature substantially outweighs its probative value. We hold, however, that two expert witnesses on the central issue of liability in a medical malpractice case do not per se reach the level of needless cumulative evidence that substantially outweighs its probative value.* The trial court mistakenly exercised its discretion in granting defendant's pretrial motion to limit expert witnesses to one on each side on a central disputed issue in the case.
>
> [*Ibid.* (Emphasis added).]

Here, the trial court erred in refusing to allow all four of Roche's experts to testify, as it desired, on the critical subject of general causation. As Roche asserts, it was forced to limit Dr. Dieckgraefe to "a simple net opinion that [p]laintiffs then attacked before the jury by falsely portraying his knowledge on the general cause question," while plaintiffs, on the other hand, were permitted to present general causation evidence through both Dr. Sachar and from another scientist who had commented on a published article addressing the subject. Because of the trial court's announced prohibition on repetitive expert testimony, Roche did not call another expert it had lined up, Dr. Bruce Thiers, a medical school professor who has

prescribed Accutane to over a thousand patients, and had been prepared to address causation issues as well.

To be sure, we are mindful of the practical realities confronting the trial court in presiding over this complicated, lengthy, and hard-fought case. We are equally mindful that the judge did not have at the time the benefit of the guidance we subsequently provided in *McLean.* Nevertheless, in a matter of this complexity on "a central issue of liability," *McLean, supra,* 430 *N.J.Super.* at 168, the court should have allowed the defense freer rein to have overlap in the key causation opinions of its testifying experts. The impact of this error, although it alone might not have required a new trial, adds to the prejudice concerns we have already mentioned.

***20** Although we do not do so lightly, we therefore set aside the verdict because of these two critical and cumulative errors and remand for a new trial. *See Pellicer ex rel. Pellicer v. St. Barnabas Hosp.,* 200 *N.J.* 22, 52–57 (2009) (applying the cumulative error doctrine); *Barber v. ShopRite of Englewood & Assocs.,* 406 *N.J.Super.* 32, 52–53 (App.Div.) (same), *certif. denied,* 200 *N.J.* 210 (2009).

C.

We reject the remainder of Roche's evidentiary arguments. However, one of them is worthy of discussion, as it could bear upon the retrial.

Roche argues that the trial court erred in excluding from evidence the "latest science," which at the time of this trial included a pre-publication abstract of an epidemiological study, later published at Antoine Racine et al., *Isotretinoin Use and Risk of Inflammatory Bowel Disease: A French Nationwide Study, supra,* 109 *Am. J. Gastroenterology* 563 (2014) ("Racine study"). For procedural reasons, the court excluded the study, which largely supports Roche's position of a lack of IBD causation.

The Racine study was published in abstract form in February 2012. During depositions conducted that same month, Dr. Oliva–Hemker testified that she had not relied on the study in forming her opinion because it had not yet been published or presented at a conference. The Racine study was presented at a conference later that spring. A few months later, the court initially ruled that the abstract of the study, which contained only limited information, was admissible, and ordered prompt discovery of the contents.

During this additional discovery, plaintiffs were provided with a series of email conversations between Colleen Hennessey, a defense attorney; one of the Racine authors; and a defense expert who was not called as a witness in this trial. The emails appeared to have been redacted, but were not stamped as such. Pursuant to court order, defense counsel provided plaintiffs with unredacted copies of the emails, which then included a reference to an attachment that was not supplied to plaintiffs. Roche represented that the attachment had been deleted from the email chain and was not available.

Upon questioning by the trial judge during a pretrial hearing on this issue, Hennessey testified under oath that she had not received the attachment because it had been deleted from the email chain by the defense expert, but she represented that the expert had told her the attachment was a copy of the abstract of the Racine study that had already been provided to plaintiffs. A few hours later, however, at the court's direction, defense counsel located the attachment. The attachment was, in fact, a different version of the abstract that had been provided to plaintiffs, in that the abstract listed a different: (1) number of years (2009–2010 vs.2008–2009); (2) number of IBD cases in the general population (7593 vs. 4402); (3) number of IBD cases among people who had taken Accutane (26 vs. 17); and (4) "odds ratio" (0.59 vs. 0.68).

***21** Presented with two conflicting abstracts of the same Racine study, the court ruled that neither abstract was sufficiently reliable to be admissible at that trial, but noted the abstract might be admissible at a future trial once it was determined which version was correct. In later denying Roche's motion for a new trial, raising this issue again, the court further explained that the abstract of the Racine study would have been admitted, but for the conduct of the defense expert, which made it impossible to determine if there were two abstracts, two studies, or whether the abstracts were drafts or redrafts.

As a general proposition, learned treatises may be admissible in evidence under *N.J.R.E.* 803(c)(18), an exception to the hearsay rule, if "established as a reliable authority by testimony or by judicial notice." However, "[m]ere publication does not automatically render a text

a reliable authority." *Jacober v. St. Peter's Med. Ctr.,* 128 *N.J.* 475, 491 (1992).

We concur with the trial court's exclusion of the Racine abstract under these circumstances. The defense, on the verge of trial, had cast doubt on the reliability of the abstract and its actual contents. The court did not abuse its discretion in excluding this evidence, given the procedural setting. *Bd. of Educ. of Clifton,* 409 *N.J.Super.* 389, 430 (App.Div.2009). However, we agree the study may be introduced, subject to any appropriate objections or competing evidence, at a retrial.

IV.

Having set aside the verdict on the grounds we have already discussed, we nonetheless address Roche's additional arguments seeking reversal for sake of completeness and because of their potentially dispositive character.

A.

Roche contends that the 1984 version of the Accutane label was adequate as a matter of law under the PLA. It maintains that plaintiffs failed to present sufficient evidence to overcome the statutory rebuttable presumption of adequacy that flows from FDA approval under *N.J.S.A.* 2A:58C–4.

We previously rejected Roche's categorical argument on this issue in both *McCarrell I, supra,* slip op. at 108 (finding the trial proofs were ample to reasonably support the jury's finding that the 1984 label was inadequate), and in *Kendall, supra,* slip op. at 87. [16]

As in *McCarrell I* and *Kendall,* here there was evidence that the 1984 warning, as it existed when plaintiffs took the drug from 1992 to 1998, was inadequate even though it specifically referred to IBD, because it did not accurately reflect the knowledge the company allegedly had. As we have noted, Dr. Blume testified that during the sixteen years that the label had remained unchanged (from 1984 to 2000), Roche had received information through ADE reports that indicate both a causal relationship between Accutane and IBD and a latency effect, which she asserted was critically important information for a physician to have in making a risk/benefit analysis. Dr. Blume also criticized Roche's use of the term "temporally associated," which was subject to differing definitions by the company's own employees, and which she said meant while a patient was taking the drug. The labeling expert opined that the use of the term "temporally" falsely suggested that the disease was reversible, and that there was no latent effect.

***22** We recognize that the FDA approved the 1984 version of the label. Nevertheless, plaintiffs marshalled sufficient competing evidence upon which a jury reasonably could rely to overcome the rebuttable statutory presumption of adequacy. At a minimum, viewing the record from this trial, as we must, in a light most favorable to the respondents, *see Dolson v. Anastasia,* 55 *N.J.* 2, 5 (1969), there was potentially credible proof of the company's "deliberate concealment *or* nondisclosure of after-acquired knowledge of [Accutane's] harmful effects[.]" *Perez, supra,* 161 *N.J.* at 25 (emphasis added); *see also Rowe, supra,* 189 *N.J.* at 626. On a retrial, the parties are free to continue to litigate the general causation issues bearing upon Accutane's actual "harmful effects" and the adequacy of the 1984 label, with the opportunity to expand the proofs to include more recent scientific studies further addressing those questions.

We need not reach whether the alternative basis for overcoming the presumption, i.e., "economically-driven manipulation of the post-market regulatory process," *McDarby, supra,* 401 *N.J.Super.* at 63, was reasonably shown here. However, if that second prong is placed in issue on a retrial, the company's interactions with the FDA respecting Accutane's effects of depression, as distinct from IBD, would be of some, but only limited, relevance to this case. *See N.J.R.E.* 401 (providing that evidence is relevant if it has a mere "tendency" to prove or disprove a fact of consequence to the case). The depression-related evidence, including Roche's internal briefing document on the subject, would not, in and of itself, be sufficient evidence to surmount that second prong. Instead, if plaintiffs choose to litigate the second prong again, they must present adequate evidence of alleged market manipulation concerning IBD side effects, and not solely of depression; otherwise the depression-related proofs should be excluded.

B.

Roche further argues that plaintiffs failed to present sufficient evidence of proximate causation. It contends that the claims of Rossitto and Wilkinson must be dismissed because their respective physicians would have prescribed Accutane for them anyway, even if the 1984 label had contained a stronger warning. *See Strumph v. Schering Corp.,* 256 *N.J.Super.* 309, 323–28 (App.Div.1992) (Skillman, J., dissenting), *rev'd on dissent,* 133 *N.J.* 33 (1993).

We do not view the evidence in such a conclusive or absolute manner. Viewing the record in a light most favorable to plaintiffs, their prescribing physicians both expressed significant reservations about whether the label sufficiently alerted them to the risks of patient IBD. The evidence is by no means so one-sided that a stronger warning would have had no effect on the doctors' interactions with plaintiffs and their parents, or upon whether the patients would have necessarily agreed to take the drug in spite of a stronger IBD warning.

***23** Under New Jersey law, the inadequacy of a warning cannot be the proximate cause of an injury where there is an intervening cause, that is, that the physician either did not read the warning, or had independent knowledge of the risks. *Perez, supra,* 161 *N.J.* at 28. In order for dismissal of the lawsuit to be warranted on this basis, the evidence must be clear and unequivocal. "Where the plaintiffs' prescribing physicians *unequivocally* testify that they had full knowledge of the dangers associated with a drug and that neither that knowledge nor anything in the enhanced post-injury warnings supplied by the manufacturer would have altered their decision to prescribe it, the plaintiff has failed to show that inadequate warnings are a proximate cause of injury and there must be a verdict for defendant." *See* Dreier, Keefe & Katz, *supra,* § 8:3–2 at 200 (emphasis added). "Where such a statement is not unequivocal the matter is properly for the jury." *Ibid.; see also Strumph, supra,* 256 *N.J.Super.* at 328 (Skillman, J., dissenting) (concluding that "a defendant drug manufacturer may not be held liable for an alleged inadequate warning where the *only evidence* on the issue of causation is the prescribing doctor's *unequivocal* testimony that his or her decision to prescribe the drug was not affected by the warning") (emphasis added).

As to Rossitto, her dermatologist Dr. Watt testified that he understood from reading the warnings, which had remained unchanged for thirteen years, that Accutane was only temporally associated with IBD, meaning to him that the symptoms only occurred while the patient was taking the drug. The 1984 label did not warn that Accutane can cause permanent IBD, or of a latency effect. If it had, Dr. Watt testified that he would have considered that information in conducting a risk/benefit analysis and would have relayed that information to Rossitto. The proofs were sufficient to support a reasonable inference that, if properly warned, Dr. Watt would have communicated the risk of developing IBD to her, and her mother would not have allowed her to take the drug.

Nor, as argued by Roche, was the chain of causation necessarily broken by Dr. Watt's alleged failure to read the warning. Dr. Watt testified that although he could not recall if he had read the Accutane label prior to prescribing the drug for Rossitto, he had, in making a risk/benefit analysis, relied on multiple sources. Those sources included Roche's "Dear Doctor" letter; the PDR, which he kept in his office; drug company representatives, who had been instructed to say that the IBD symptoms occurred while the patient was taking the drug, and that a precise cause and effect relationship had not been established; and his medical training and continuing education classes. There is ample evidence that Dr. Watt read the warning (because it was repeated in the "Dear Doctor" letter) and there was no evidence that he had any independent knowledge that Accutane could cause IBD or that the symptoms would be permanent, not temporary.

***24** We reach the same conclusion as to Wilkinson, although the proofs as to his own prescribing physician, Dr. Orme, are weaker. As we previously noted, Dr. Orme did acknowledge at one point in his testimony that "[i]n all likelihood," if the label had warned that Accutane had been "possibly or probably associated" with IBD, instead of "temporally associated," he "would have still prescribed it to ... Wilkinson with the same communication that [he] did in fact give to [Wilkinson's] parents." However, this evidence is contradicted, at least in part, by other testimony by Dr. Orme stating that if Roche had warned that taking Accutane presented a risk of developing IBD, he "[d]efinitely" would have warned Wilkinson and his mother about the disease. Unlike the circumstances in *Strumph,* this is not a case in which

the prescribing doctor's testimony on this key issue is "unequivocal." *Id.* at 328.

In addition, it is significant that Dr. Orme had multiple discussions with Wilkinson and his mother of the risks and benefits of Accutane over a span of more than a year before the decision to prescribe it was made. There is more than ample evidence to infer that the label's alleged failure to sufficiently discuss the risks of IBD could have affected the prescribing decision and the patient's willingness to take the drug. With a stronger warning passed on by Dr. Orme, the medical decision would then have fallen to Wilkinson's mother, who could have then appropriately considered the IBD risk. As we have noted, the mother testified that if Dr. Orme had warned that Accutane caused IBD, she would not have let her son take the drug, even if Dr. Orme had highly recommended it. Her reluctance in this regard is consistent with her conduct. Dr. Orme raised Accutane as a treatment option in October 1993, and again in 1994, but Wilkinson's mother did not allow her son to take the drug until May 1995.

Viewing this evidence in a light most favorable to Wilkinson, there was sufficient evidence of proximate causation to present to a jury. The "prescribing decision"—insofar as it logically entails both a physician's recommendation and a patient's assent to follow that recommendation after being apprised of the pertinent risks—could have been affected by the absence of a stronger warning. Although a physician can function as a "learned intermediary," *Niemiera v. Schneider,* 114 *N.J.* 550, 559 (1989), it should not be assumed that a doctor will issue a prescription to an informed patient who is unwilling to risk a drug's side effects. The evidence was sufficiently debatable to have the causation issue resolved by the jurors as the fact-finders.

C.

Lastly, Roche argues that the trial court should have ruled that Rossitto's and Wilkinson's claims were time-barred, under the two-year statute of limitations, *N.J.S.A.* 2A:14–2, [17] and should not have permitted their cases to proceed under principles of equitable tolling.

***25** The trial court concluded that both Rossitto, who filed suit in December 2010, and Wilkinson, who filed suit in April 2008, brought their claims within two years of learning of a connection between their use of Accutane and their IBD symptoms. The trial court reached these conclusions after conducting appropriate pretrial evidentiary hearings on the timeliness issues pursuant to *Lopez v. Swyer,* 62 *N.J.* 267, 275–76 (1973), and making associated credibility findings. Having reviewed the proofs developed at those hearings, we are satisfied that there is ample reasonable support for the trial court's findings of timeliness, and that they are consistent with the principles expressed by the Supreme Court in *Kendall, supra,* 209 *N.J.* at 197–98, including the application of the public policies underlying the PLA statute. We affirm those determinations, substantially for the reasons expressed by the trial court.

V.

For the foregoing reasons, we vacate the judgments entered in favor of Rossitto and Wilkinson and remand for a new trial consistent with this opinion.

Affirmed in part, vacated in part, and remanded in part.

All Citations

Not Reported in A.3d, 2016 WL 3943335

Footnotes

1 As of July 9, 2016, there were 3925 cases listed on New Jersey's Accutane mass tort case list. *See Accutane, N.J. Judiciary,* http://www.judiciary.state.nj.us/mass-tort/accutane (last visited on July 11, 2016). Prior to the verdict in this case, decisions were issued in: *McCarrell v. Hoffman–La Roche, Inc. (McCarrell I),* No. A–3280–07 (App.Div. Mar. 12, 2009), *certif. denied,* 199 *N.J.* 518 (2009); *Kendall v. Hoffman–La Roche, Inc.,* No. A–2633–08 (App.Div. Aug. 5, 2010), *aff'd,* 209 *N.J.* 173 (2012); and *Sager v. Hoffman–La Roche, Inc.,* No. A–3427–09 (App.Div. Aug. 7, 2012), *certif. denied,* 213 *N.J.* 568 (2013). After the verdict, decisions were issued in *Gaghan v. Hoffman–La Roche, Inc.,* No. A–2717–11,

A–3211–11, A–3217–11 (App.Div. Aug. 4, 2014) and *McCarrell v. Hoffman–La Roche, Inc. (McCarrell II),* A–4481–12 (App.Div. Aug. 11, 2015), *certif. granted,* 223 *N.J.* 555 (2015).

2 Reynolds, a resident of California, and Young, a resident of New Jersey, did not appeal.

3 Roche's appeal (A–301–14) of a separate $1.578 million jury verdict in favor of Kendall on a retrial of her case was argued back-to-back with the present appeals. That appeal has since been dismissed, as the result of a recent settlement with that individual plaintiff.

4 In an internal document from 1978, Roche noted a call from Dr. Manfred Hein, a pharmacologist with the FDA, in which he expressed concern about the gastrointestinal bleeding observed in the dog studies.

5 Recent epidemiological studies have yielded mixed results regarding the disputed link between Accutane and IBD. For instance, in an article published in 2009, Charles N. Bernstein et al., *Isotretinoin Is Not Associated with Inflammatory Bowel Disease: A Population–Based Case–Control Study,* 104 *Am. J. Gastroenterology* 2774 (2009) (the "Bernstein article"), the authors concluded that "isotretinoin is not likely to cause chronic IBD." Additionally, in an article published in 2010, Seth D. Crockett et al., *Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case–Control Study,* 105 *Am. J. Gastroenterology* 1986 (2010) (the "Crockett article"), the authors found that ulcerative colitis, but not Crohn's disease, is associated with Accutane, but cautioned that a causal association with IBD "remains unproven."

6 "Labeling" is a term of art within the arena of drug regulation. The term refers to "all labels and other written, printed or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 *U.S.C.A.* § 321(m).

7 Plaintiffs Rossitto and Wilkinson took Accutane on various dates from May 1995 to April 1998. When the other two plaintiffs from this trial, Reynolds and Young, are included, the relevant time span of usage expands from November 1992 to November 1998.

8 RoAccutane, also spelled RoAccutan, is the brand name for Accutane in Europe.

9 We discuss, *infra,* the disputed relevance of these depression-related communications to the issues before us that concern IBD.

10 In 2003, the warnings were further strengthened, *Kendall, supra,* 209 *N.J.* at 183, although those 2003 changes were not admitted into evidence at this trial. In 2009, defendants withdrew Accutane from the market, but generic makers continue to manufacture it. *Id.* at 180 n. 3.

11 This court has upheld the admissibility of Dr. Sachar's expert opinions in some of the previous Accutane appeals. Roche has not challenged, in its present appeal, the admission of Dr. Sachar's opinions at the trial of Rossitto and Wilkinson, although the drug company asserts that more recent scientific studies have conflicted with Dr. Sachar's theories of causation.

12 "Advisory committees provide independent advice and recommendations to the FDA on scientific and technical matters related to products ... regulated by the Agency." *New Drug Application (NDA), Food & Drug Admin.,* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ HowDrugsareDevelopedandAppro ved/ApprovalApplications/ NewDrugApplicationNDA (last updated Mar. 29, 2016).

13 Roche has not argued on appeal that the damages the jury awarded to the two prevailing plaintiffs were excessive.

14 There are some differences between New Jersey and Utah law on product liability issues in the prescription drug context, although the parties do not argue that these differences affect the issues now before us on appeal. We do note that Utah, unlike New Jersey, adopted the reasoning of *Restatement (Second) of Torts* § 402A cmt. k (1965), and classifies all prescription drugs "as unavoidably dangerous in design[.]" *Schaerrer v. Stewart's Plaza Pharm., Inc.,* 79 *P.3d* 922, 928 (Utah 2003); *Perez v. Wyeth Labs.,* 161 *N.J.* 1, 10 (1999) (declining to hold as a matter of law that all prescription drugs are unavoidably unsafe). As a result, under Utah law "prescription drugs cannot, as a matter of law, be defective if approved by the United States Food and Drug Administration (FDA) and 'properly prepared, compounded, packaged, and distributed.' " *Schaerrer, supra,* 79 *P.3d* at 928 (quoting *Grundberg v. Upjohn Co.,* 813 *P.2d* 89 (Utah 1991)). However, in Utah, as in New Jersey, manufacturers are not shielded from strict liability claims based on inadequate warnings, which are at issue here. *Ibid.* We should also note that the statutory rebuttable presumptions concerning the effect of FDA approval for a drug differ, in that New Jersey's presumption is stronger and of greater evidentiary weight than a customary presumption, *Kendall, supra,* 209 *N.J.* at 195, while in Utah, "a preponderance of the evidence is sufficient to rebut it." *Egbert v. Nissan N. Am., Inc.,* 167 *P.3d* 1058, 1063 (Utah 2007).

15 The FDA did not acquire the ability to mandate a labeling change until the passage of the Food and Drug Administration Amendments Act of 2007 (FDAA), Pub. Law 110–85, 121 *Stat.* 823. The FDA can now mandate a labeling change based on new information about an approved label. 21 *U.S.C.A.* § 355(o)(4).

16 We cite these unpublished opinions involving the same defendant and the same drug for non-precedential purposes, because they are related cases. *See R.* 1:36–3. In doing so, we need not address whether any principles of issue preclusion or collateral estoppel are applicable, which plaintiffs have not asserted in any event.

17 The parties agree that New Jersey law governs the statute-of-limitations issues, and thus the choice-of-law questions currently before the Supreme Court in *McCarrell II* are not of concern here.