NOT FOR PUBLICATION WITHOUT THE
APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-2717-11T2
A-3211-11T2
A-3217-11T2

GILLIAN GAGHAN,

Plaintiff-Respondent,

v.

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

Defendants-Appellants.

JAMES DAVID GREENBLATT
a/k/a JAMES DAVID MARSHALL,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

KELLY ANDREWS,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

Argued February 10, 2014 – Decided August 4, 2014

Before Judges Ashrafi, St. John, and Leone.

On appeal from Superior Court of New Jersey, Law Division, Atlantic County, Docket Nos. L-3319-04, L-3361-04, and L-1246-06.

Paul Schmidt (Covington & Burling L.L.P.) of the Washington D.C. bar, admitted pro hac vice, argued the cause for appellants in A-2717-11 and respondents in A-3211-11 and A-3217-11 (Gibbons P.C. and Mr. Schmidt, attorneys; Michelle M. Bufano, on the briefs; Mr. Schmidt and Michael X. Imbroscio (Covington & Burling L.L.P.) of the Washington D.C. bar, admitted pro hac vice, of counsel and on the briefs).

David R. Buchanan argued the cause for respondent in A-2717-11 and appellants in A-3211-11 and A-3217-11 (Seeger Weiss L.L.P., Michael D. Hook (Hook & Bolton, P.A.) of the Florida bar, admitted pro hac vice, Mary Jane Bass (Beggs & Lane) of the Florida bar, admitted pro hac vice, and William F. Cash, III (Levin Papantonio) of the Florida bar, admitted pro hac vice, attorneys; Mr. Buchanan, on the brief).

PER CURIAM

These consolidated appeals arise from a single jury trial. Plaintiffs allege that the acne drug Accutane caused their

development of inflammatory bowel disease (IBD), and that defendant drug companies (Roche[1]) failed to give an adequate warning of IBD as a potential side effect of their drug. Roche appeals from a verdict of $2,125,617 in favor of plaintiff Gillian Gaghan, and plaintiffs Kelley Andrews and James David Greenblatt, who is also known as James David Marshall, appeal from the jury's verdict in favor of Roche. Having considered the record and the parties' arguments, we reverse the verdict in favor of Gaghan (A-2717-11) and affirm the verdicts in favor of Roche (A-3211-11, A-3217-11).

I.

The seven-week trial was similar in many respects to earlier Accutane trials that have been completed and appealed as part of the Accutane Mass Tort Litigation designated in New Jersey for consolidated case management in Atlantic County. As of the time of the notices of appeal in these cases, almost 8,000 complaints were pending in the Accutane Mass Tort Litigation alleging that the drug caused injury to the complainant plaintiffs. Several juries in the completed trials have found that Accutane caused IBD, although some of those

[1] Defendants are Hoffman-La Roche Inc. and related companies. The parties refer to defendants collectively as "Roche." We will use the same designation in this opinion.

verdicts have been reversed on appeal on issues of law. Roche maintains that recent case studies published in medical journals prove that Accutane does not cause IBD, and that plaintiffs' causation expert in the mass tort litigation, gastroenterologist David Sachar, M.D., selectively ignores the results of the case studies.[2]

Much of the evidence at the trial of these three cases pertained generally to Accutane and the allegation that it causes IBD, and it was similar to the evidence presented in the earlier trials. We therefore repeat our narrative of the general facts from a prior unpublished decision of this court, Sager v. Hoffman-La Roche, Inc., Nos. A-3427-09, A-3428-09, A-3702-09 (App. Div. Aug. 7, 2012), certif. denied, 213 N.J. 568

[2] Two of the studies predated the trial in this case and were used as evidence in the trial — Charles N. Bernstein et al., Isotretinoin Is Not Associated With Inflammatory Bowel Disease: A Population-Based Case-Control Study, 104 Am. J. Gastro-enterology 2774, 2777 (Nov. 2009); Seth D. Crockett et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study, 105 Am. J. Gastroenterology 1986, 1988-89, 1991 (Sept. 2010). Roche contends that the results of two more studies announced since the time of the trial confirm the same conclusions — A. Racine et al., Abstract, Isotretinoin Use and Risk of Inflammatory Bowel Disease: A Case-Control Study from the French National Health Insurance System, 6 J. Crohn's & Colitis S176-S177 (Supp. 1) (Feb. 2012); Mayhar Etminan, Final Progress Report, Isotretinoin and Risk of Inflammatory Bowel Disease: A Case-Control Study, available at http://www.broadmedical.org/asset/1406-finalprogressreport-etminan.pdf. Plaintiffs object to any reliance on the two new studies because they are not part of the trial record.

(2013), dispensing with quotation marks or other attribution to our prior decision and making changes for the present appeals. The Sager decision, in turn, used descriptions of Accutane and its alleged injurious side effects from the Supreme Court's decision on the appeal of another similar trial, Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173 (2012).

Accutane, the brand name for the prescription drug isotretinoin, is an oral medication for acne that Roche developed and began marketing in the 1980s. Id. at 180-81. The drug is used to treat recalcitrant nodular acne that has not responded to other regimens. Id. at 180. Roche stopped selling Accutane in 2009. Id. at 180 n.3. However, isotretinoin continues to be sold by generic drug manufacturers and prescribed by dermatologists.

The present plaintiffs, Gaghan, Andrews, and Marshall, are all residents of California. They used Accutane in the 1990s as prescribed by their respective dermatologists. At the time of their treatment with Accutane, the warnings Roche provided with the drug included a statement that it had been "temporally associated" with inflammatory bowel disease. Roche deleted the word "temporally" from the warning in 2000 and further modified the warning in 2003, but by that time each plaintiff had

discontinued taking Accutane and each had been diagnosed with IBD.

Plaintiffs Gaghan and Andrews filed their complaints against Roche in 2004 and plaintiff Marshall in 2006. Plaintiffs alleged that Roche was liable to them for their ongoing IBD symptoms because the product warnings were inadequate. Roche denied liability, and contended that plaintiffs' IBD conditions were not caused by their short-term use of Accutane. It also asserted, among other things, that the warnings it provided were reasonably adequate and had been approved by the United States Food and Drug Administration (FDA).

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 is diagnosed either as ulcerative colitis or as Crohn's disease — "chronic incurable diseases characterized by inflammation of the intestine." Id. at 181. Ulcerative colitis

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 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, and the precise causes 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 non-steroidal anti-inflammatory drugs. Ibid.

The FDA first approved the use of Accutane in 1982. At that time, the FDA did not require Roche to provide a label warning of possible gastrointestinal side effects. Ibid. 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. [Roche is] . . . 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. 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.]

That warning was approved by the FDA and remained in place until 2000, ibid., that is, throughout the time in the 1990s that plaintiffs in these cases used Accutane.

In 1994, Roche issued a patient brochure. 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. The 1994 patient brochure remained in effect until 1999, ibid., and was available to two of the plaintiffs in these appeals, Gaghan and Andrews. 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.

As previously stated, in 2000 Roche amended the physician warnings to remove the term "temporally" from the 1984 version of its warning and added to its 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.

II.

We first address the appeals of the two plaintiffs that did not prevail before the jury.

A.

In July 1992, Marshall, a twenty-four-year-old actor who had appeared in movies and television shows, was prescribed a very low dose of Accutane by his dermatologist, Gary Carlson. Dr. Carlson did not warn Marshall about the risk of developing IBD. During his first thirty-day treatment, Marshall did not experience any gastrointestinal effects.

In May 1993, eight months after Marshall had completed taking Accutane, he experienced rectal bleeding, left lower quadrant abdominal pain, diarrhea, fatigue, and weight loss. On May 12, 1993, Theodore Stein, a gastroenterologist, diagnosed Marshall with ulcerative colitis.

Before ever being prescribed Accutane, Marshall had experienced symptoms consistent with ulcerative colitis, and

Marshall's father, who had also been diagnosed with ulcerative colitis in his late twenties, had also been treated by Dr. Stein and had undergone a colectomy.

In June 1993, one month after the diagnosis by Dr. Stein, Marshall returned to Dr. Carlson for acne treatment, but did not inform Carlson that he had been diagnosed with IBD. Dr. Carlson prescribed another thirty-day course of Accutane, again a low dose, and did not warn Marshall about the risk of IBD. Dr. Carlson testified that if he had known Marshall had been diagnosed with IBD, he would not have prescribed Accutane without the approval of a gastroenterologist. During his 1993 treatment, Marshall did not experience any gastrointestinal upsets or IBD flares.

On August 30, 1994, Dr. Stein sent Marshall for a consult with Dr. Joe Chen. Dr. Chen wrote:

> [Marshall's] disease activity initially presented seven years ago when he experienced abdominal distention, diarrhea, fever, abdominal pain lasting approximately three to four weeks with complete resolution; therefore, he did not seek medical attention. He had several smaller attacks, approximately one to two per year, thought to be secondary to IBS [inflammatory bowel syndrome] versus IBD.

Dr. Stein testified that he relied on Dr. Chen's report in concluding there was "a likelihood" that Marshall's symptoms of

ulcerative colitis presented six or seven years before his diagnosis of IBD in 1993.

Marshall's disease periodically flared after Dr. Stein's diagnosis in 1993. He subsequently had a colectomy, ileostomy (attachment of small intestine to anal canal), and surgical placement of an ileostomy bag. In November 1995, Dr. Stein referred Marshall to Robert Beart, a surgeon, for the surgical removal of the ileostomy bag. In response to a question inquiring when his IBD "started," Marshall responded that his "[f]irst major attack" occurred in 1985 when he was eighteen years old, the "second attack" occurred in 1993 when he was twenty-five years old and was diagnosed by Dr. Stein, and the "[t]hird attack" occurred in 1995 when he was twenty-eight years old and required emergency surgery. Based on this history, Dr. Beart concluded that Marshall had suffered from ulcerative colitis since 1985, when he was eighteen years old.

In January 2005, Marshall's wife showed him an article in a magazine about a man who had taken Accutane and was later diagnosed with IBD. Marshall filed suit in February 2006.

The jury answered only one of four questions on a verdict form pertaining to Marshall. In response to the question: "Was Accutane a substantial factor in James Marshall developing IBD," the jury answered "no" by a vote of six to one. In denying

Marshall's motion for a new trial, the trial court concluded that the evidence supported the jury's verdict. The court stated:

> This plaintiff's father also had IBD and there was evidence that genetics is a factor in a person developing IBD. There is no question IBD can develop in persons without use of Accutane. In addition, there was evidence that James Marshall had symptoms of IBD before taking Accutane. The court finds that the verdict was one that properly could be rendered by a reasonable jury based on the evidence in the case.

On appeal, Marshall argues that the verdict was tainted by the improper argument of the defense that stress causes IBD, and specifically that it triggered Marshall's IBD. He contends there was no evidence to support that contention.

Roche's expert gastroenterologist, Brian Dieckgraefe, testified without objection that stress can cause a flaring of IBD. He also testified that "stress is . . . one of the major triggers for inflammatory bowel disease," and that the medical records confirm that when Marshall experienced a stressful situation, his IBD symptoms flared. During cross-examination, Dr. Dieckgraefe admitted that a peer-reviewed scientific article states that stress was initially thought to be a trigger for IBD but subsequent research had "failed to identify psychological stress as an important etiological factor."

Defense counsel then played for the jury a portion of Dr. Stein's videotaped testimony. The videotape included a question and answer that the trial court had previously ruled were inadmissible because Dr. Stein had admitted his answer was speculative. The disputed segment was as follows:

> Q: It also indicates here on May 3rd [1993] that [Marshall] was under increasing stress, correct?
>
> A: That is correct.
>
> Q: And, Doctor, stress can trigger a flare of ulcerative colitis in people with existing disease, correct?
>
> A: I would agree with that statement.
>
> Q: And people who do not have a diagnosis of ulcerative colitis, but have a genetic propensity to develop it can present with ulcerative colitis under circumstances of stress, correct?
>
> A: I would agree with that. That's a speculative comment. But I think people who have a predisposition who are stressed are more likely to present with their disease than if they were not stressed.

Plaintiffs' counsel objected to the last answer from Dr. Stein being played for the jury. Defense counsel conceded that the excluded question and answer should not have been played and apologized. The court acknowledged the error and instructed the jury to disregard the last question and answer.

Defense counsel then pursued further testimony on the potential effect of stress on the manifestation of IBD symptoms, and defense counsel argued in summation that stress was an important factor in the flare-up of Marshall's condition.

Marshall argues on appeal that the videotape error and the closing argument constitute misconduct by defense counsel that entitles him to a new trial. We disagree.

Rule 4:49-1(a) provides that a court shall grant a motion for a new trial "if, having given due regard to the opportunity of the jury to pass upon the credibility of the witnesses, it clearly and convincingly appears that there was a miscarriage of justice under the law." The decision whether to grant the motion for a new trial is within the trial court's discretion. Crawn v. Campo, 136 N.J. 494, 511-12 (1994). "A jury verdict should be set aside 'only in cases of clear injustice.'" Little v. KIA Motors Am., Inc., 425 N.J. Super. 82, 92 (App. Div. 2012) (quoting Boryszewski v. Burke, 380 N.J. Super. 361, 391 (App. Div. 2005), certif. denied, 186 N.J. 242 (2006)). We defer to the trial "judge's determination of the extent to which the prejudice, if any, may have contributed to an unjust result." Hill v. N.J. Dep't of Corrs., 342 N.J. Super. 273, 302 (App. Div. 2001), certif. denied, 171 N.J. 338 (2002).

Here, the inadvertent admission of a brief videotaped clip, followed by a curative instruction to the jury to disregard a specific part of the testimony, was not clearly capable of producing an unjust result. We presume the jury followed the court's instruction. See State v. Smith, 212 N.J. 365, 409 (2012), cert. denied, ___ U.S. ___, 133 S. Ct. 1504, 185 L. Ed. 2d 558 (2013).

Throughout the trial, Roche's position, supported by evidence, was that Marshall had developed ulcerative colitis seven years before his brief exposure to Accutane in 1992 and 1993, and that the flaring of his IBD symptoms in 1993 and 1994, was due to stress, not his use of Accutane. We disagree with Marshall's contention that the defense argued, without evidential support, that stress caused Marshall's IBD, as opposed to triggering the flaring of symptoms of an existing condition.

There was ample evidence from which the jury could rationally conclude that Marshall's IBD symptoms predated his first use of Accutane, and therefore, the use of Accutane was not a substantial factor in his developing IBD or causing the manifestation of symptoms. The trial court did not err in denying Marshall's motion for a new trial.

B.

Kelley Andrews was first prescribed Accutane in December 1997, when she was sixteen years old. Before taking Accutane, Andrews had developed acne while still in elementary school, and she had suffered from cystic nodular acne for more than a year. She attempted several remedies, including a series of antibiotics. Her mother, Laura Andrews, was very concerned about the physical and emotional toll acne was taking on her daughter, and was frustrated by her inability to find an effective treatment for the condition.

In July 1997, while on antibiotics and before Accutane, Kelley experienced gastrointestinal symptoms, including diarrhea, heartburn, and abdominal pain, but the symptoms resolved when she discontinued taking antibiotics. In December 1997, after Kelley suffered another bout of gastrointestinal upset from antibiotic use, Kelley and her mother decided that she would try Accutane.

Before Kelley's dermatologist, Laura Tenner, prescribed Accutane, she had a "long discussion" with Kelley and her mother about Accutane's side effects, including the risk of birth defects if she were to become pregnant, dry skin, chapped lips, severe depression, and severe headaches, but Dr. Tenner did not mention IBD. In accordance with her customary practice, Dr.

Tenner gave Kelley and her mother a copy of the Accutane patient brochure, which had been issued in 1994. The brochure warned that patients should be alert for severe stomach pain, diarrhea, and rectal bleeding, and advised patients to discontinue Accutane and consult with a doctor if they had those symptoms. Kelley, however, only recalled being told not to get pregnant, and remembered seeing the blister packaging, which contained a depiction of a pregnant woman within a circle with a line through it. Kelley and Laura Andrews did not read all the warnings on the blister packaging of the drug.

During Kelley's Accutane treatment, which ran from December 1997 to June 1998, she experienced dry skin, dry mouth, chapped lips, and some eczema, and she also had some abdominal pain in the left upper quadrant.

In September 1998, about three months after she stopped taking Accutane, Kelley had chronic abdominal pain, diarrhea, nausea, and vomiting. In late September 1998, Nathan Kam, a gastroenterologist, diagnosed Kelley with Crohn's colitis. Subsequently, Kelley underwent multiple surgeries, including an ileostomy, placement of an ileostomy bag, ileocecal resection, and removal of the ileostomy bag. She suffered nerve damage and developed anemia as a result of the surgeries, and continued to experience IBD symptoms to the time of the trial.

Kelley testified she did not make a connection between her use of Accutane and IBD until July 2004, when her mother showed her an advertisement in a magazine. Kelley filed suit in 2004.

Dr. Tenner testified that she continued to prescribe isotretinoin at the time of trial. She testified that the drug was "the most successful medication" that she prescribed and was "extremely well-tolerated." Kelley Andrews was the only patient she had treated who had developed IBD. Nonetheless, the doctor testified that if Roche had warned her that Accutane could cause IBD, she would have informed Kelley and her mother. Laura Andrews testified that if she had known that Accutane could cause IBD, she would "[a]bsolutely not" have allowed Kelley to take it.

The jury found by unanimous votes that Accutane was a substantial factor in Kelley Andrews developing IBD and that Roche failed to provide an adequate warning about the risks of IBD. However, the jury voted six to one that Roche's failure to warn was not a substantial factor in Kelley Andrews' decision to take Accutane, in other words, that Kelley Andrews had failed to prove the inadequate warning proximately caused her IBD.

Andrews argues that the trial court erred in denying her motion for a new trial because the jury finding on proximate cause was against the weight of the evidence. When ruling on

Andrews' motion, the trial court expressed surprise at the verdict in comparison to Gaghan's favorable verdict, but then stated:

> Based on the evidence presented, the jury could have found Kelley Andrews was more vulnerable and under more social pressure and psychological distress because of her acne. The jury did not have to believe the testimony of her and her mother that she would not have taken Accutane if she knew of the risk of IBD. The jury could have found that Andrews just did not carry the burden of proof on this issue.

There was substantial evidence from which the jury could have found that Andrews would have taken Accutane even if Dr. Tenner had received and passed on to her and her mother a stronger warning in the form recommended by plaintiffs' expert witnesses. Laura Andrews testified that her daughter was upset and embarrassed by her acne, disgusted with the way she looked, and becoming socially withdrawn. The mother was very concerned about the detrimental physical and emotional effect acne was having on her daughter. Moreover, neither Kelley nor Laura Andrews read the warning material that was provided to them, thus suggesting that a more strongly-worded warning would not have been heeded.

We conclude there was no abuse of discretion in the trial court's denial of Kelley Andrews' motion for a new trial.

Crawn, supra, 136 N.J. at 511-12; Hill, supra, 342 N.J. Super. at 302; R. 4:49-1(a).

III.

We now turn to Roche's appeal from the verdict in favor of Gillian Gaghan. Roche makes four arguments: (1) that the trial court erred in admitting the testimony of plaintiffs' general causation expert, Dr. Sachar; (2) that the IBD warnings issued by Roche were adequate as a matter of law because they were approved by the FDA; (3) that Gaghan did not have sufficient evidence that Roche's alleged inadequate warnings caused her to take Accutane and develop IBD because her dermatologist would have prescribed the drug even if stronger warnings had been given; and (4) that Gaghan's complaint was barred by the statute of limitations. We find merit in the last two arguments, and therefore, need not address the first two, which have been addressed in our prior unpublished decisions.

A.

Prior to taking Accutane, Gaghan had suffered from cystic nodular acne for approximately five years, for which she was prescribed a series of antibiotics. In June 1995, her dermatologist, Paul Hartman, first discussed Accutane as a treatment option with Gaghan and her mother because he was concerned about permanent scarring caused by Gaghan's acne.

Gaghan decided not to undergo the treatment at that time because of the risk of birth defects and hair loss. She continued a course of antibiotics, to no avail. In 1998, when she was twenty-two years old, Gaghan decided to try Accutane.

Before Dr. Hartman prescribed Accutane in May 1998, he again discussed its side effects with Gaghan, including the risk of birth defects if she were to become pregnant, elevated triglycerides, dry skin, chapped lips, bloody nose, headaches, and hair loss. Although he had read and was familiar with the product label and brochure, Dr. Hartman did not discuss the risk of IBD with Gaghan because it was such a "rare event."

Gaghan testified that she only recalled being told not to get pregnant. But unlike many plaintiffs in these cases, Gaghan testified that she fully read the warnings and patient brochure given to her about the potential side effects of Accutane. As set forth previously, the 1994 brochure warned that patients should be alert for severe stomach pain, diarrhea, and rectal bleeding, and advised that patients "discontinue" Accutane and consult with a doctor if they experienced any of those symptoms. Gaghan signed a consent form acknowledging that she had received and read the patient brochure.

During her treatment from May to October 1998, Gaghan experienced dry lips and headaches, but no gastrointestinal

effects or swelling. But in December 1998, less than two months after she finished taking Accutane, Gaghan had severe and frequent bloody diarrhea. On January 20, 1999, James Reed, a gastroenterologist, diagnosed her with ulcerative colitis.

In March 1999, Dr. Hartman saw Gaghan again. Her acne had mostly cleared up at that time, but Dr. Hartman learned that she had been diagnosed with IBD. According to Gaghan and her mother, Dr. Hartman re-read the Physician's Desk Reference (PDR) at the time of that visit and told them that Accutane was not the cause of her IBD.

Dr. Hartman wrote in his notes regarding the March 1999 office visit that the PDR states Accutane has been "temporally associated" with IBD, but that Gaghan had never had any IBD symptoms while on Accutane, and had not been diagnosed with ulcerative colitis until after she stopped treatment.[3] Dr. Hartman testified that he understood the phrase "temporally associated" in Roche's warning to mean that IBD might "occur while people are on" Accutane, "simultaneously."

There was also evidence that Gaghan herself read the package insert as published in the PDR at or near the time of her March 1999 visit with Dr. Hartman. She testified she

[3] Dr. Hartman's office notes were incorrectly transcribed from dictation as "temporarily associated."

thought "temporally" meant "it was just temporary. It would go away if it was treated." Dr. Hartman's testimony left no doubt that he, of course, knew the difference between the meanings of "temporally" and "temporarily."

In February 2000, Gaghan requested and received from Dr. Hartman a copy of her medical file kept by him.

After her diagnosis, Gaghan took several medications to treat her IBD. She was hospitalized several times for episodes of bloody diarrhea, nausea, fatigue, vomiting blood, anorexia, and a rapid heartbeat. According to Gaghan, smoking helped her IBD symptoms.[4]

In December 2000, Gaghan saw Jonathan Terdiman, another gastroenterologist, who diagnosed her as suffering from Crohn's colitis. Dr. Terdiman testified that an IBD diagnosis is generally based on the distribution of the inflammation, and that a clear case of Crohn's disease involves inflammation that extends beyond the colon into the small intestine. If the inflammation is limited to the colon, as in Gaghan's case, the diagnosis is more difficult to make because it could be either Crohn's colitis or ulcerative colitis. He explained that it was not clear which form of IBD Gaghan had because her biopsies had

[4] Roche states that cessation of smoking is believed to be a risk factor for the development of ulcerative colitis.

"always been consistent with ulcerative colitis," but she had some slight "patchiness to the inflammation in her colon that is a bit more common in patients with Crohn's." Dr. Terdiman acknowledged that the patchiness could have resulted from IBD treatment, which can cause differential healing, and would therefore not be an indication of Crohn's disease. He said that "[u]sually the most accurate diagnosis is the initial diagnosis," which in Gaghan's case was ulcerative colitis.

Dr. Terdiman explained that given the indeterminate nature of Gaghan's IBD, he assigned her a Crohn's colitis diagnosis so that her insurance would cover the cost of a prescription for Remicide — an immunosuppressant drug which had then only been FDA-approved for Crohn's disease, but which was also very effective and has now been approved for treating ulcerative colitis. Throughout Gaghan's medical records, Dr. Terdiman consistently referred to her IBD as Crohn's disease. The doctor admitted he had not spent a lot of time trying to discern which kind of IBD Gaghan had because the treatments were "nearly identical."[5]

[5] The significance of Dr. Terdiman's diagnosis of Crohn's disease rather than ulcerative colitis is that some of the case studies referenced in footnote 2 of this opinion are definitive in their conclusions that isotretinoin has not been shown to cause Crohn's disease. Also, Dr. Sachar concluded that Gaghan's (continued)

During the next several years, Gaghan saw Dr. Hartman occasionally for mild resurgence of acne and other conditions. He did not prescribe Accutane for her again but treated her conditions with other medications.

In 2004, Gaghan's mother showed her an advertisement in a magazine stating that the reader should contact a named lawyer if he or she suffered from Crohn's or colitis and had taken Accutane. Gaghan filed suit on October 22, 2004.

At the time of trial Gaghan was taking an immunosuppressant and her drug-induced lupus (which had been caused by Remicide), had resolved, but her IBD symptoms waxed and waned, as is often the course of the disease. Although her disease was in remission, she still had three to five bowel movements a day, was fatigued, had an increased risk of colon cancer, and had suffered bone loss.

Dr. Hartman, who at the time of trial continued to prescribe isotretinoin for patients and understood that there was a possible relationship between IBD and the drug, was asked by defense counsel: "[I]f a lady . . . walked in the door today with the same history as Ms. Gaghan back in 1998, [and] our label said that 'Accutane can induce IBD,' would you still be

---

(continued)
correct diagnosis is ulcerative colitis despite Dr. Terdiman's records and despite Dr. Sachar's never having treated Gaghan.

willing to prescribe it to that patient . . . who has severe recalcitrant nodular acne?" Dr. Hartman answered "yes."

Dr. Hartman said he would have wanted to know that there was a latency effect and that Roche had received positive rechallenge[6] reports of IBD because "[t]hat's significant," but that such information would not necessarily have changed his prescribing habits. He also said he discussed major serious side effects with patients, but did not routinely discuss IBD because it was extremely rare. He agreed that the patient ultimately decides whether to take the drug.

Gaghan testified that if she had been warned that Accutane can cause IBD, she would not have taken it.

On the verdict form pertaining to Gaghan, the jury answered "yes" to the questions inquiring whether Accutane was a substantial factor in causing Gaghan to develop IBD, whether Roche's warning was inadequate, and whether the inadequate warning was a substantial factor in Gaghan's development of IBD, the last of these questions by a vote of five to two. The jury awarded $2,000,000 in monetary compensation to Gaghan, which was added to a fixed amount of $125,617 for past medical expenses. The trial court denied Roche's motion for a judgment

[6] A rechallenge report refers to whether an adverse reaction that coincided with the taking of a drug ceased after use of the drug stopped and then returned if the use was resumed.

notwithstanding the verdict and a new trial, and entered judgment for Gaghan for the amount of the jury award plus interest and costs.

B.

Roche contends the trial court erred in denying its several motions for summary judgment, directed verdict, and judgment notwithstanding the verdict because Gaghan did not and could not prove that Roche's allegedly inadequate warning was the proximate cause of her developing IBD. Roche argues that, under the applicable California law, the issue is whether a stronger warning from the manufacturer of the drug would have caused the doctor not to prescribe the drug. Here, Dr. Hartman testified he would still prescribe Accutane for Gaghan's condition even with the additional warning that the drug may or does cause IBD in rare cases.

Gaghan contends that California product liability law on medication warnings is not limited to the doctor's decision to prescribe the medication but recognizes that the ultimate decision belongs to the patient, who must be fully informed about serious side effects. She cites general product liability and medical malpractice cases to support her contentions. Gaghan points to Dr. Hartman's testimony that he would have

wanted to know about all serious side effects of the drug and would have passed that information on to the patient.

Motions for judgment at the close of the plaintiff's case, R. 4:37-2(b), at the close of the evidence, R. 4:40-1, and after the verdict, R. 4:40-2(b), are governed by the same standard: "[I]f, accepting as true all the evidence which supports the position of the party defending against the motion and according [her] the benefit of all inferences which can reasonably and legitimately be deduced therefrom, reasonable minds could differ, the motion must be denied." Verdicchio v. Ricca, 179 N.J. 1, 30 (2004) (quoting Estate of Roach v. TRW, Inc., 164 N.J. 598, 612 (2000)). On appeal, we apply the same standard to the resolution of such motions as the trial court. Estate of Roach, supra, 164 N.J. at 612.

When the trial court in this case denied Roche's motion for summary judgment, it stated that "[p]roximate cause is almost always a jury issue." At the close of the evidence, the court was more specific and identified as "very uniquely up to the jury, not the court" questions as to whether the doctor would have informed the patient about the risk if the doctor had been given a different warning, and whether a patient would then have taken the drug.

In denying Roche's post-trial motion for judgment notwithstanding the verdict, the court essentially agreed with Gaghan's view of the pertinent California law. The court noted that, although Dr. Hartman testified that a different warning would not have changed his decision to prescribe Accutane, the jury could determine in accordance with the doctor's testimony that he would have passed on to Gaghan a warning that Accutane causes or may cause IBD, and that Gaghan would not have taken the drug if that warning had been given.

This focus on the decision of the patient also conformed to the instructions the trial court gave the jury on proximate cause. The instructions placed the burden on plaintiffs to prove that Accutane and the failure of Roche to provide an adequate warning were a substantial factor in causing their IBD, but the instructions also included the following explanation of substantial factor: "failure to warn is a substantial factor if you find that a stronger warning would have resulted in the plaintiff not being prescribed Accutane or would have resulted in that plaintiff not taking Accutane." (Emphasis added). Thus, the trial court viewed the proximate cause question as tied to the patient's decision to accept or decline Accutane, not just to the doctor's decision to recommend and prescribe it or not to do so.

Under general products liability law in California, "manufacturers have a duty to warn consumers about the hazards inherent in their products." O'Neil v. Crane Co., 266 P.3d 987, 997 (Cal. 2012); Anderson v. Owens-Corning Fiberglas Corp., 810 P.2d 549, 559 (Cal. 1991). However, in prescription drug cases, California recognizes and applies, in accord with the majority of the states including New Jersey, the "learned intermediary" doctrine. Carlin v. Superior Court, 920 P.2d 1347, 1354 (Cal. 1996); Brown v. Superior Court, 751 P.2d 470, 477-78 (Cal. 1988); see Restatement (Third) of Torts: Products Liability, §6(d) (1998); N.J.S.A. 2A:58C-4; Perez v. Wyeth Labs., Inc., 161 N.J. 1, 10 (1999).

Under the "learned intermediary" doctrine, a drug manufacturer's "duty to warn runs to the physician, not to the patient." Carlin, supra, 920 P.2d at 1354; see also Valentine v. Baxter Healthcare Corp., 81 Cal. Rptr. 2d 252, 263 (Cal. Ct. App. 1999) (physician stands in shoes of "ordinary user" because patient learns of properties and use of drug or implant from physician). The rationale for the doctrine is that:

> "(1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse

> possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient."
>
> [Carmichael v. Reitz, 95 Cal. Rptr. 381, 400-01 (Cal. Ct. App. 1971) (quoting Rheingold, Products Liability -- The Ethical Drug Manufacturer's Liability, 18 Rutgers L. Rev. 947, 987 (1964)).]

Thus, a prescription drug manufacturer fulfills its duty to warn if it provides adequate warnings to the prescribing physician, and it has no duty to ensure that the warning reaches the patient. Brown, supra, 751 P.2d at 477-78; Stevens v. Parke, Davis & Co., 507 P.2d 653, 661 (Cal. 1973); see also Carlin, supra, 920 P.2d at 1354 (manufacturer discharged duty if warning to physician was adequate, and cannot be held liable where physician did not read the warning). The manufacturer's duty is to the doctor because "the prescribing physician is the party who must read and understand the medication's uses and contraindications." Evraets v. Intermedics Intraocular, Inc., 34 Cal. Rptr. 2d 852, 860 (Cal. Ct. App. 1994).

Applying the substantive law of California, the United States Court of Appeals for the Second Circuit stated in Plummer

v. Lederle Laboratories, 819 F.2d 349, 356 (2d Cir.), cert. denied, 484 U.S. 898, 108 S. Ct. 232, 98 L. Ed. 2d 191 (1987):

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.
>
> [(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)).]

Gaghan relies on general products liability law and medical malpractice cases to support her contention that an inadequate warning is a proximate cause of the injury if the patient would decline to use the medication upon learning of the potential side effect that should be disclosed to her by her doctor. In physician malpractice cases, the courts of California, like our Supreme Court in New Jersey, have held that a physician has the duty under the "doctrine of informed consent" to disclose to the patient "all information relevant to a meaningful decisional process." Cobbs v. Grant, 502 P.2d 1, 9-10 (Cal. 1972); accord Arato v. Avedon, 858 P.2d 598, 607 (Cal. 1993); Hahn v. Mirda, 54 Cal. Rptr. 3d 527, 532 (Cal. Ct. App. 2007); Largey v. Rothman, 110 N.J. 204, 212 (1988). "The scope of a physician's

duty to disclose is measured by the amount of knowledge a patient needs in order to make an informed choice." Truman v. Thomas, 611 P.2d 902, 905 (Cal. 1980). Ultimately the "patient still retains the sole prerogative to make the subjective treatment decision based upon an understanding of the circumstances." Ermoian v. Desert Hosp., 61 Cal. Rptr. 3d 754, 788 (Cal. Ct. App. 2007).

However, the case before us does not allege the malpractice of the treating dermatologist in failing to give adequate advice about the serious side effects of Accutane and in failing to obtain Gaghan's informed consent. A product liability claim against the manufacturer of a prescription drug requires that the plaintiff establish that the warning to the prescribing doctor was inadequate. Plummer, supra, 819 F.2d at 358; Rutherford v. Owens-Illinois, Inc., 941 P.2d 1203, 1214 (Cal. 1997).

Since the warning is directed to the doctor, adequacy of the warning must be measured from the doctor's point of view. Cf. N.J.S.A. 2A:58C-4 ("An adequate product warning or instruction is 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 . . . in the case of prescription

drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician."). The issue in this case is whether Roche's warnings directed to Dr. Hartman in 1998 were inadequate from the doctor's perspective. If they were, the resulting question is whether the inadequate warnings were a substantial factor in Gaghan's development of IBD because Dr. Hartman could not make an informed decision.

No published decision of a California court that has been brought to our attention establishes whether the substantial factor requirement can be satisfied by proof that the doctor would have passed a stronger warning on to the patient rather than by proof that the doctor's decision to prescribe the medication would have been altered by a stronger warning.

Roche relies on several federal court decisions, some unpublished, holding that the pertinent question under California law is whether the doctor would nevertheless have recommended and prescribed the drug even with the stronger warnings. Most notably, the United States District Court for the Central District of California so held in Motus v. Pfizer Inc., 196 F. Supp. 2d 984, 991-92 (C.D. Cal. 2001), and the Ninth Circuit Court of Appeals affirmed, relying on the District Court's analysis of California law, Motus v. Pfizer Inc., 358 F.3d 659, 661 (9th Cir. 2004). Also, the United States Court of

Appeals for the Second Circuit, applying California law, has reached the same conclusion. See Misouria v. Eli Lilly & Co., 394 Fed. Appx. 825, 826-27 (2d Cir. 2010); Neal v. Eli Lilly & Co., 394 Fed. Appx. 823, 824-25 (2d Cir. 2010).

In Motus, supra, 196 F. Supp. 2d at 986, the plaintiff's husband committed suicide shortly after being prescribed Zoloft, an antidepressant. The plaintiff claimed that Pfizer Inc., the drug's manufacturer, was liable because it failed to provide adequate warnings of the potential for suicidal thoughts and actions caused by the drug. Ibid. The district court granted summary judgment to Pfizer, finding the plaintiff failed to establish causation because the prescribing doctor admitted he had not read the warnings before prescribing the drug, and thus there was no evidence that an adequate warning would have changed his conduct. Id. at 996. As the court described the record, the plaintiff's counsel had asked the doctor:

> "If you had been told that Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, is that the kind of information you would pass on to your patients?" Dr. Trostler responded, "Yes." Plaintiff argues that this response creates a genuine issue as to whether Dr. Trostler would have changed his behavior had Pfizer provided adequate warnings. The Court does not agree. Given that this case is about the sufficiency of the warnings accompanying Zoloft, the appropriate question would have been: "If Zoloft's package insert had contained a warning that

> Zoloft can cause an increased risk in suicide during the first few weeks of drug treatment, would you have prescribed Zoloft to Mr. Motus?" But Plaintiff's lawyer did not ask this question . . . . The testimony Dr. Trostler did give does not establish that if that warning had been provided, he would not have prescribed Zoloft or would have told Mr. Motus something other than what he did say.
>
> [Id. at 997.]

In affirming the district court's decision, the Ninth Circuit agreed that:

> a product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician. On the record adduced during discovery, Motus failed to establish proof that stronger warnings would have changed her husband's medical treatment or averted his suicide.
>
> [Motus, supra, 358 F.3d at 660 (citations omitted).]

The question of law is whether the conduct of the doctor that would be altered by a stronger warning is limited to the doctor's prescribing decision or, as the trial court concluded here, also includes the doctor's decision to provide a stronger warning to the patient. In the absence of a decision by a California appellate court contradicting the holdings of the federal courts, we conclude that California law focuses on the prescribing decision of the doctor as the learned intermediary.

A number of other jurisdictions have held similarly that the relevant conduct that would be altered by a stronger warning is the doctor's decision to prescribe the drug. See Ackermann v. Wyeth Pharms., 526 F.3d 203, 213-14 (5th Cir. 2008) (Texas law); Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 976-77 (10th Cir. 2001) (Kansas law); Wheat v. Pfizer, Inc., 31 F.3d 340, 343 (5th Cir. 1994) (Louisiana law); Hoffman-La Roche Inc. v. Mason, 27 So. 3d 75, 77 (Fla. Dist. Ct. App. 2009) (Florida law), review denied, 37 So. 3d 848 (Fla. 2010).

Our own Supreme Court in New Jersey has reached the same conclusion. See Strumph v. Schering Corp., 133 N.J. 33 (1993), rev'ing on dissent, 256 N.J. Super. 309, 323 (App. Div. 1992) (Skillman, J.A.D., dissenting) (under New Jersey law, plaintiff must show adequate warnings would have altered physician's prescribing decision). But cf. Niemiera v. Schneider, 114 N.J. 550, 565-66 (1989) (under New Jersey's learned intermediary doctrine, doctor's responsibility is to inform patient about information that enables patient to use product safely); In re Diet Drug Litig., 384 N.J. Super. 525, 541 (Law Div. 2005) (leaving prescribing decision solely in hands of learned intermediary runs afoul of New Jersey's public policy).

Here, defense counsel asked Dr. Hartman directly whether stronger warnings on the Accutane label would change his decision to prescribe Accutane for Gaghan:

> Q. [E]ven if the label said "Accutane may cause IBD," would you still be willing to prescribe this drug —
>
> A. Yes.
>
> . . . .
>
> Q. So if a lady who walked in the door today with the same history as Ms. Gaghan back in 1998, [and] our label said that "Accutane can induce IBD," would you still be willing to prescribe it to that patient . . . who has severe recalcitrant nodular acne?
>
> A. Yes

Gaghan failed to prove that Dr. Hartman would have altered his decision to recommend and prescribe Accutane for her severe scarring acne that could not be adequately treated with other medications.

In addition, while Gaghan argues, and the trial court concluded, that the jury could determine that Dr. Hartman would have conveyed the stronger warnings to Gaghan, his testimony was ultimately equivocal on that subject. On direct examination, Dr. Hartman testified he would have wanted to know that Accutane can cause serious or permanent side effects, that there had been reports of positive rechallenges where IBD had been diagnosed

for an Accutane patient, and that there might be a latency effect of Accutane rather than simultaneous manifestations of the digestive tract symptoms. But Gaghan's counsel could not get Dr. Hartman to testify that he would have warned Gaghan of an IBD side effect if the Roche warnings had been as plaintiffs' evidence and argument would have required.

Dr. Hartman's direct examination included the following testimony:

> Q. And if a drug could cause serious or permanent side effects, is that something that you would like to know in order to take into account in your prescribing decision?
>
> . . . .
>
> A. Sure.
>
> Q. Okay. Would you consider a permanent disease to be a serious side effect?
>
> A. Yes.
>
> Q. And would you consider a disease that needed — that could lead to surgery to be a serious side effect?
>
> A. Yes.
>
> . . . .
>
> Q. If a disease could lead people to require a lifetime of medical care, would that be a serious side effect that you would want to know about?
>
> A. Of course.

Q. [T]aking all of this into account, what side effects would you have warned Gillian about at the time you prescribed Accutane in 1998?

. . . .

A. I — I warned her about as many as I thought were the major side effects. And the consent form also had a lot of listing of the side effects in it, which she was able to read and she signed.

So between my conversation and the consent form, I thought that most side effects would be covered by that.

Q. . . . But can you tell us what those major side effects would have been?

A. The major side effects are usually the chapped lips, the bloody nose, headaches. People get very dry skin. Some people get some hair loss. Those are the main ones that I've seen in most people.

I mean, hers is extremely rare. Like I say, that's not something I've heard of that was mentioned in the PDR, but it's not something I had ever seen before. So it's not something that I would routinely mention.

Q. So you never warned Gillian that Accutane might cause inflammatory bowel disease?

A. No. But there are so many of these side effects that are in the PDR. We could go down the list. I could probably give her three pages of side effects, and it's just not practical to go through the PDR and read from the PDR every time that you give someone a drug.

So we try and give the major side effects: the not getting pregnant; the elevation in triglycerides, cholesterol,

> liver function tests. These are the main ones that show up on patients.
>
> I have seen those show up and, in my experience, those are the main ones that I have seen and had to stop the medicine for that, that were manageable. But ulcerative colitis was not one that usually would be mentioned, since it's such a rare event.

Despite the efforts of plaintiffs' counsel to equate IBD with a serious, permanent condition about which Dr. Hartman was obligated to warn and would have warned Gaghan, the doctor's final answers to this line of questioning repeated his earlier testimony that IBD was such a rare occurrence that he did not believe it was necessary to warn the patient about its potential occurrence.

Gaghan's attorney did not ask Dr. Hartman directly in this line of questioning whether if he had been informed that Accutane can cause IBD, he would have conveyed that warning to Gaghan. He did not ask Dr. Hartman whether he would or would not have prescribed Accutane if the stronger warnings had been provided.

As we stated, however, defense counsel did ask the latter question. On cross-examination, Dr. Hartman testified that the stronger warnings would not have dissuaded him from recommending and prescribing Accutane because the side effects were rare, the drug was highly effective, and a patient with severe acne who had tried other medications would benefit greatly by its use.

He testified that Gaghan was the only patient among approximately 200 that he had treated with Accutane who had experienced IBD or similar side effects.

Thus, even if California law did focus on the decision of the patient rather than the decision of the doctor, there was insufficient evidence in the record from which the jury could rationally conclude that stronger warnings would have altered Dr. Hartman's treatment of Gaghan in the sense of conveying the stronger warnings. Gaghan did not establish that stronger warnings would have changed Dr. Hartman's conduct.

In sum, the evidence was not sufficient for the jury to conclude that Roche's allegedly inadequate warnings were the proximate cause of Gaghan's taking Accutane and her development of IBD.

C.

Roche also contends the trial court erred in denying its motion to dismiss Gaghan's adequacy-of-warning claim as time-barred, and in applying equitable principles and the discovery rule of Lopez v. Swyer, 62 N.J. 267, 272 (1973), to toll the applicable two-year statute of limitations.

"New Jersey courts long have employed the equitable principle of the discovery rule to avoid the potentially harsh effects of the 'mechanical application' of statutes of

limitations." Guichardo v. Rubinfeld, 177 N.J. 45, 51 (2003) (quoting Vispisiano v. Ashland Chem. Co., 107 N.J. 416, 426 (1987)).[7] "Under the discovery rule . . . the limitations period does not commence until the injured party actually discovers or should have discovered through reasonable diligence the fact essential to the cause of action." R.A.C. v. P.J.S., Jr., 192 N.J. 81, 98 (2007); see also Fox v. Millman, 210 N.J. 401, 415 (2012) ("until the injured plaintiff discovers, or should have reasonably discovered, 'a basis for an actionable claim.'") (quoting Guichardo, supra, 177 N.J. at 51).

Gaghan learned she had developed IBD on January 20, 1999, but she did not file her complaint against Roche until October 22, 2004. Her complaint is barred by the two-year statute of limitations unless the discovery rule was properly applied so that her cause of action did not accrue until two years or less

[7] Roche states in a footnote that the trial court erred in applying New Jersey law to its motion to dismiss Gaghan's claim on statute of limitations grounds. See Cornett v. Johnson & Johnson, 211 N.J. 362, 373-74, 378 n.6 (2012). But Roche also concedes that the error had no effect on the court's decision. California, like New Jersey, has a two-year statute of limitations for personal injury claims, Cal. Civ. Proc. Code § 335.1 (2013), and California also applies an equitable discovery rule, see Norgart v. Upjohn Co., 981 P.2d 79, 88-89 (Cal. 1999). We have not been informed of any difference between California's and New Jersey's discovery rules. Consequently, there is no need for us to make a choice-of-law decision. See P.V. ex rel. T.V. v. Camp Jaycee, 197 N.J. 132, 143 (2008); Rowe v. Hoffman-La Roche Inc., 189 N.J. 615, 621 (2007).

before she filed her complaint. The critical question is whether Gaghan knew before October 22, 2002, or a person in Gaghan's circumstances should reasonably have known, enough information to believe she had developed IBD because she took Accutane. See, e.g., Martinez v. Cooper Hosp.-Univ. Med. Ctr., 163 N.J. 45, 52 (2000).

Gaghan testified she did not have any gastrointestinal symptoms associated with IBD during the time that she was taking Accutane from May to October 1998. Dr. Hartman had not advised her of the risk of IBD. However, Gaghan received and read the patient brochure and the blister pack warnings, which warned that she should be alert for severe stomach pain, diarrhea, and rectal bleeding, the symptoms that she suffered less than two months after finishing her course of Accutane.

Although her testimony at the Lopez hearing was contradictory on the subject of what warnings she did read and when, it is clear that at some point before October 2002, she had also read the physician's warning contained in the PDR, which specifically referred to IBD as being "temporally associated" with the taking of Accutane. So, more than two years before she filed her complaint, she had read the information provided by Roche that referred to both IBD, or its symptoms, and Accutane.

Important to the trial court's decision on the discovery rule, however, was that Gaghan and her mother saw Dr. Hartman in March 1999, expressed their suspicion about the role of Accutane in causing her IBD symptoms, and were assured by Dr. Hartman that his reading of the product warnings indicated that Accutane did not cause her IBD. Gaghan testified that she felt "relieved" that Accutane was not related to her diagnosis of ulcerative colitis.

Nonetheless, Gaghan, who also worked in the medical field, testified that either during or after the March 1999 office visit, she read the PDR and was thus aware of its warning that "Accutane has been temporally associated with inflammatory bowel disease." She said she thought the term "temporal association" meant that "it was just temporary" and "would go away if it was treated." The testimony about her misunderstanding of the word "temporally," however, does not explain why Gaghan would not have inquired further once it became apparent to her that her IBD was not temporary and had not gone away.

In 2000, Gaghan requested and received Dr. Hartman's records of her treatment, and, upon reading the records, she would have seen Dr. Hartman's reference to Accutane and IBD in his notes. Nonetheless, she claimed that she did not make the connection between Accutane and IBD until mid-2004, when her

mother showed her an advertisement in a magazine listing a lawyer's telephone number to call if the reader suffered from ulcerative colitis and had taken Accutane.

In ruling on Roche's motion to dismiss Gaghan's complaint, the trial court found that Gaghan was not credible in much of her testimony. The court stated:

> And by that I mean she was all over the place. She said she saw the PDR. She said she didn't see the PDR. She said she saw . . . the nurse's PDR. She said her mother showed her the PDR, she said her mother didn't show her the PDR. She said she discussed it with the doctor, she said she didn't discuss it with the doctor. She was everywhere.

In considering this comment of the court, it is important to recall that a plaintiff who seeks application of the discovery rule bears the burden of proving at a Lopez hearing that equitable principles should extend the normal statute of limitations for her cause of action. See Kendall, supra, 209 N.J. at 197-98; Vispisiano, supra, 107 N.J. at 432.

On the other hand, the trial court found there was "some truth to the fact" that Gaghan had no understanding that Accutane had caused her injury, although she may have had a "suspicion," because she and her mother asked Dr. Hartman about a possible connection. Overall, the court viewed this to be "a close case" on the application of the discovery rule, but

concluded there was sufficient evidence that Gaghan did not realize there was a connection between Accutane and IBD when she read the PDR or reviewed Dr. Hartman's notes. The court stated that, although Gaghan and her mother might have suspected a connection, the facts were similar to Vispisiano, supra, 107 N.J. at 424-25, 434, where the Court concluded that suspicion of a connection between a product and an illness is not sufficient to trigger the accrual of a cause of action and the running of the two-year statute of limitations.

In its written opinion after the trial, the court rejected Roche's argument that Gaghan should have known about the alleged connection between Accutane and her IBD because she had read the warnings issued by Roche. The court was persuaded that Gaghan did not know she had a cause of action against Roche until she saw the lawyer's advertisement because the jury had found Roche's warning to be inadequate to alert the consumer of the possible connection between IBD and Accutane.

Whether a cause of action is barred by a statute of limitations is determined by the court, not by the jury. Lopez, supra, 62 N.J. at 272. In reviewing the trial court's findings and conclusions pertaining to application of the discovery rule, we defer to the trial judge's first-hand assessment of witness credibility and the weight of evidence, unless it lacks

substantial support in the record. See Rova Farms Resort, Inc. v. Investors Ins. Co., 65 N.J. 474, 483-84 (1974). However, we exercise plenary review of the trial court's application of the relevant legal principles, see Manalapan Realty, L.P. v. Twp. Comm. of Manalapan, 140 N.J. 366, 378 (1995), and also, "[t]he judge's determination of the legal consequences of established facts is not due any special deference from us," Estate of Hainthaler v. Zurich Commercial Ins., 387 N.J. Super. 318, 325 (App. Div.), certif. denied, 188 N.J. 577 (2006).

"The discovery rule prevents the statute of limitations from running when injured parties reasonably are unaware that they have been injured, or, although aware of an injury, do not know that the injury is attributable to the fault of another." Baird v. Am. Med. Optics, 155 N.J. 54, 66 (1998). "Although the discovery rule does not require 'knowledge of a specific basis for legal liability or a provable cause of action,' it does require 'knowledge not only of the injury but also that another is at fault.'" Guichardo, supra, 177 N.J. at 51 (quoting Martinez, supra, 163 N.J. at 52). "Once a person knows or has reason to know of this information, his or her claim has accrued since, at that point, he or she is actually or constructively aware 'of that state of facts which may equate in law with a

cause of action.'" Abboud v. Viscomi, 111 N.J. 56, 63 (1988) (quoting Burd v. New Jersey Tel. Co., 76 N.J. 284, 291 (1978)).

"At the heart of every discovery rule case is the issue of 'whether the facts presented would alert a reasonable person exercising ordinary diligence that he or she was injured due to the fault of another.'" Kendall, supra, 209 N.J. at 191 (quoting Hardwicke v. Am. Boychoir Sch., 188 N.J. 69, 110 (2006)). "The standard is basically an objective one — whether plaintiff 'knew or should have known' of sufficient facts to start the statute of limitations running." Martinez, supra, 163 N.J. at 52 (emphasis added) (quoting Baird, supra, 155 N.J. at 66).

After the trial in this case, the Supreme Court in Kendall, supra, 209 N.J. at 179-80, held that a trial court must consider the presumption of adequacy of an FDA-approved warning under N.J.S.A. 2A:58C-4 in determining whether to apply equitable tolling principles to extend the limitations period for the filing of a lawsuit. That holding of Kendall is particularly important in this case, where the trial court found the application of the discovery rule was a "close question," and further found, without referring to the statutory presumption, that the warning was not adequate to "put [Gaghan] on notice of a potential claim."

The Court in Kendall adopted a "middle-of-the road approach," and held that the presumption should be viewed as a standard presumption that can be overcome by evidence which "'tends to' disprove the presumed fact." Kendall, supra, 209 N.J. at 197 (quoting 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 that analysis, the Court concluded 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." Id. at 198. The Court reached that conclusion based on the following facts, which were important to its evaluation of the record: 1) Kendall was twelve years old when she was first prescribed Accutane; 2) her dermatologist and gastroenterologist had never warned her or 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 consultation with her gastroenterologist, prescribed a fifth course of Accutane despite the fact that Kendall 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. Id. at 198. The Court noted that Kendall had not received any warning that specifically mentioned IBD and had no reason to doubt her doctors or to disregard their advice. Ibid.

Applying the factors discussed in Kendall to this case, we conclude that Gaghan had reason to know her IBD may have been caused by Accutane substantially earlier than in October 2002. First, Gaghan was a twenty-two-year-old adult when she started taking Accutane. Second, she was diagnosed with IBD only six weeks after she stopped treatment, presumably while the warnings she had read — to be alert for stomach pain, diarrhea, and rectal bleeding — were fresh in her mind. Third, Gaghan actually read the PDR and physician package insert long before October 2002, and those sources specifically referred to IBD as

associated with Accutane. In fact, Gaghan and her mother suspected a connection and discussed it with Dr. Hartman in March 1999. Although Dr. Hartman assured them there was no connection, he never prescribed Accutane for her again, as the dermatologist in Kendall had done with the approval of Kendall's gastroenterologist. Furthermore, Gaghan pursued additional information about her medical history by obtaining Dr. Hartman's records in February 2000, and she presumably read his notes, which repeated the warning of a "temporal[] associat[ion]" between the drug and IBD.

Added to these facts that distinguish Gaghan from the circumstances in Kendall, the trial court did not consider the significance of FDA approval of Roche's warnings in the context of the discovery rule. The jury's finding that the warning was inadequate before Gaghan took Accutane and experienced IBD symptoms does not eliminate the question of whether the warning was nevertheless adequate to prompt Gaghan to investigate the cause of her IBD condition after she had been diagnosed. The fact that the FDA found Roche's warning label to be adequate to warn of the potential side effect of the drug in connection with IBD is relevant on that issue – specifically, whether an ordinarily diligent patient would have been alerted to

sufficient facts to learn that her IBD might be connected to her use of Accutane.

Viewing the same uncontradicted evidence that was before the trial court, and deferring to the court's mixed credibility determination with respect to Gaghan's testimony and that of her mother, we conclude that Gaghan knew or should have reasonably known before October 2002 that her IBD symptoms may have been caused by her use of Accutane. Her filing of a complaint in October 2004, therefore, was barred by the two-year statute of limitations.

Reversed on A-2717-11. Affirmed on A-3211-11 and A-3217-11.