SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-1359-14T4
A-1361-14T4
A-2581-14T4
A-2582-14T4

KRISTY BRECKE,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

GREGORY LUONGO,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

JAMES ALBERT BOERMA, JR.,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

BRIAN THOMAS ZIMPFER,

Plaintiff-Appellant,

v.

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

Defendants-Respondents.

Argued December 12, 2017 – Decided January 30, 2018

Before Judges Fisher, Sumners and Moynihan.

On appeal from Superior Court of New Jersey, Law Division, Atlantic County, Docket Nos. L-1453-10, L-4094-11, L-0901-08 and L-1910-07.

William F. Cash, III (Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, PA) of the Florida bar, admitted pro hac vice, and Bruce D. Greenberg, argued the cause for appellants (Lite, DePalma Greenberg, LLC, Seeger Weiss LLP, Sugarman Law, LLC and William F. Cash, III, attorneys; David R. Buchanan, Barry Sugarman, Michael D. Hook and Stephen F. Bolton (Hook & Bolton) of the Florida bar, admitted pro hac vice, and Mary Jane Bass (Beggs & Lane) of the Florida bar, admitted pro hac vice, on the brief).

Paul W. Schmidt (Covington & Burling LLP) of the District of Columbia bar, admitted pro hac vice, argued the cause for respondents (Gibbons PC, and Paul W. Schmidt, attorneys; Michelle M. Bufano, of counsel and on the brief; Michael X. Imbroscio (Covington & Burling LLP) of the District of Columbia bar, admitted pro hac vice, and Paul W. Schmidt, on the brief).

PER CURIAM

In these consolidated appeals, four plaintiffs — Kristy Brecke, Gregory Luongo, James Albert Boerma, Jr., and Brian Zimpfer — who claim injuries from their use of Accutane, which is manufactured and sold by defendants, argue that the trial judge erred in finding their claims to be time barred. Because our standard of review compels deference to the judge's findings of fact, Cole v. Jersey City Med. Ctr., 215 N.J. 265, 275 (2013), and because the judge correctly applied the principles of Lopez v. Swyer, 62 N.J. 267 (1973), in applying the two-year statute of limitations, N.J.S.A. 2A:14-2, we affirm the dismissal of all four complaints.

To explain, we provide a few brief comments about Accutane, followed by a discussion of the applicable legal principles and our standard of review, and then a separate analysis of each of these four cases.

I

In 1982, the Food and Drug Administration (FDA) approved defendants' new drug application to market Accutane, "known generically as isotretinoin, for the treatment of recalcitrant nodular acne." McCarrell v. Hoffman-La Roche, Inc. (McCarrell II), 227 N.J. 569, 577 (2017). The drug is a retinoid, derived from vitamin A, and is highly effective in treating severe acne. Kendall v. Hoffman-La Roche, Inc. (Kendall I), 209 N.J. 173, 180 (2012). It is undisputed 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 also evidence that Accutane has an effect on the gastrointestinal tract. McCarrell v. Hoffman-La Roche, Inc. (McCarrell I), No. A-3280-07 (App. Div. Mar. 12, 2009) (slip op. at 6, 23-26).

These Accutane cases, and others currently pending in this multicounty litigation, concern the alleged propensity of the drug to cause inflammatory bowel disease (IBD), a chronic disease that primarily manifests as one of two diseases: Crohn's disease or ulcerative colitis. Kendall I, 209 N.J. at 181. Ulcerative colitis (plaintiffs' diagnosed condition), primarily involves inflammation

of the lining of the colon (large intestine), while Crohn's disease can occur in any part of the digestive tract, although it primarily manifests in the small intestine (the ileum) and the colon. The peak onset of IBD occurs during adolescence — the same period during which individuals are likely to take Accutane. Ibid. Both forms of IBD share the same core symptoms including abdominal pain, frequent and often bloody bowel movements, and rectal bleeding. Ibid. These symptoms, however, are also associated with other less serious and curable diseases. Although the cause of IBD remains largely unknown, several triggers are associated with a statistically increased rate of IBD, including family history, infections, antibiotics, smoking, and possibly the use of oral contraceptives and nonsteroidal anti-inflammatory drugs. Ibid.

The FDA did not require a warning about IBD on the 1982 Accutane launch label. But, shortly after obtaining FDA approval, defendants received reports of IBD in patients taking Accutane.

In March 1984, defendants amended the "Warnings" section of the Accutane package insert (or label) made available to physicians but not patients, that remained in effect until 2000, to provide:

> 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.

The 1994 Accutane patient brochure that was provided to three of the four plaintiffs — Luongo, Boerma, and Zimpfer — did not specifically refer to IBD, but warned users that during treatment:

> YOU SHOULD BE AWARE THAT ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS SIDE EFFECTS. BE ALERT FOR ANY OF THE FOLLOWING:
>
> • HEADACHES, NAUSEA, VOMITING, BLURRED VISION
>
> • CHANGES IN MOOD
>
> • SEVERE STOMACH PAIN, DIARRHEA, RECTAL BLEEDING
>
> • PERSISTENT FEELING OF DRYNESS OF THE EYES
>
> • YELLOWING OF THE SKIN OR EYES AND/OR DARK URINE
>
> IF YOU EXPERIENCE ANY OF THESE SYMPTOMS OR ANY OTHER UNUSUAL OR SEVERE PROBLEMS, DISCONTINUE TAKING ACCUATNE AND CHECK WITH YOUR DOCTOR IMMEDIATELY. THEY MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD POSSIBLY RESULT IN PERMANENT EFFECTS.

The same warnings were reprinted on the blister packaging, which contained the individual Accutane pills. At that time, the "patient information/consent" form was limited to warning about the risks of birth defects if a woman became pregnant while taking the drug.

In May 2000, the FDA approved an amendment to the "WARNINGS"

section of the package insert or label, provided to physicians, but not patients, strengthening the warnings by removing the word "temporally," and warning that:

> Inflammatory Bowel Disease: Accutane has been associated with inflammatory bowel disease (including regional iletis) 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).
>
> [(Emphasis added).]

The "ADVERSE REACTIONS" section of the label provided:

> ADVERSE REACTIONS: Clinical Trials and Postmarketing Surveillance: The adverse reactions listed below reflect the experience from investigating studies of Accutane, and the postmarketing experience. The relationship of some of these events to Accutane therapy is unknown. Many of the side effects and adverse reactions seen in patients receiving Accutane are similar to those described in patients taking very high doses of vitamin A (dryness of the skin and mucous membranes, e.g. of the lips, nasal passage, and eyes).
>
> . . . .
>
> Gastrointestinal inflammatory bowel disease (see WARNINGS: inflammatory bowel disease) . . . bleeding and inflammation of the gums, colitis, ileitis, nausea, and other nonspecific gastrointestinal symptoms.

Beginning in January 2001, pharmacists provided Accutane

patients with a "Medication Guide," which described some of the symptoms of IBD, but did not specifically refer to the disease, warning instead that "Accutane has possible serious side effects," including:

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

Commencing in January 2002, physicians were also required to provide patients with a patient brochure presented as a bright pink colored metal ring binder entitled "Be Smart/Be Safe/Be Sure Accutane Pregnancy Prevention and Risk Management Program for Women." See Kendall I, 209 N.J. at 183. The "binder materials primarily focused on the dangers of becoming pregnant while taking Accutane." Ibid. The binder's first section, entitled "Patient Product Information: Important information concerning your

treatment with Accutane (isotretinoin)," warned, without specifically referring to IBD, that:

> You should be aware that certain SERIOUS SIDE EFFECTS have been reported in patients taking Accutane. Serious problems do not happen in most patients. If you experience any of the following side effects or any other unusual or severe problems, stop taking Accutane right away and call your prescriber because they may result in permanent effects.
>
> . . . .
>
> Abdomen (stomach area) problems. Certain symptoms may mean that your internal organs are being damaged. These organs include the liver, pancreas, bowel (intestines), and esophagus (connection between mouth and stomach). If your organs are damaged, they may not get better even after you stop taking Accutane. Stop taking Accutane and call your prescriber if you get severe stomach, chest, or bowel pain; have trouble swallowing or painful swallowing; get new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.
>
> [(Emphasis added.)]

The ninth edition of the "Be Smart, Be Safe, Be Sure" binder included consent forms to be removed and signed by patients, requiring them to acknowledge that they understood the risks of serious birth defects and would stop taking Accutane if they experienced any symptoms of depression; it did not specifically refer to IBD. Patients were also required to acknowledge they had read and understood "the Patient Product Information, Important

Information Concerning your treatment with Accutane© (isotretinoin) and other materials my prescriber gave me containing important safety information about Accutane."

Similar warnings to patients were included on the blister packaging, which again primarily warned about birth defects and depression, but also warned, without specifically referring to IBD, that:

> Other serious side effects to watch for[.] Stop taking Accutane and call your prescriber if you develop any of the problems on this list or any other unusual or severe problems. If not treated they could lead to serious health problems. Serious permanent problems do not happen often.
>
> . . . .
>
> Severe stomach pain, diarrhea, rectal bleeding, or trouble swallowing . . . .

These were, in general, the relevant communications provided to physicians and patients at or about the time these four plaintiffs were taking Accutane or were experiencing difficulties following their course of Accutane.

II

The timeliness of plaintiffs' complaints — as well as the complaints filed by seven other plaintiffs[1] — were the subject of

[1] The judge also dismissed two of these other seven; five were found timely filed. The other two plaintiffs whose complaints were dismissed have not appealed.

Lopez hearings that occurred in 2014. All four of these plaintiffs were diagnosed with their ailments more than two years prior to the filing of their complaints.

Because a product liability action "generally accrues on the date of injury," Cornett v. Johnson & Johnson, 211 N.J. 362, 377 (2012), abrogated on other grounds by McCarrell II, 227 N.J. at 591 n.9, and the Legislature requires that such actions be commenced within "two years . . . after the cause of any such action shall have accrued," N.J.S.A. 2A:14-2,[2] plaintiffs' complaints could only survive through a proper application of equitable tolling principles embodied within the discovery rule, Lopez, 62 N.J. at 272.

This discovery rule is a rule of equity; it tolls the statute of limitations "until the injured party discovers, or by an exercise of reasonable diligence and intelligence should have discovered . . . a basis for an actionable claim." Lopez, 62 N.J. at 272; see also McCarrell II, 227 N.J. at 578. This equitable principle "avoid[s] the harsh results that otherwise would flow from mechanical application of a statute of limitations," Vispisiano v. Ashland Chem. Co., 107 N.J. 416, 426 (1987), and

[2] The parties do not dispute that New Jersey's statute of limitations jurisprudence applies to the claims of these out-of-state plaintiffs. See McCarrell II, 227 N.J. at 575.

"balances the need to protect injured persons unaware that they have a cause of action against the injustice of compelling a defendant to defend against a stale claim," Kendall I, 209 N.J. at 193.

The party claiming the discovery rule's indulgence is saddled with the burden of persuasion. Lopez, 62 N.J. at 276. Although a judge's application of legal principles is subject to de novo review, Manalapan Realty L.P. v. Twp. Comm. of Manalapan, 140 N.J. 366, 378 (1995), a judge's factual findings and assessment of witness credibility are entitled to deference on appeal unless lacking support in the record, Cole, 215 N.J. at 275; Rova Farms Resort, Inc. v. Inv'rs Ins. Co. of Am., 65 N.J. 474, 483-84 (1974).

The question posed in these four cases is "whether the facts presented would alert a reasonable person exercising ordinary diligence" that the alleged injury was "due to the fault of another." Hardwicke v. Am. Boychoir Sch., 188 N.J. 69, 110 (2006) (quoting Martinez v. Cooper Hosp.-Univ. Med. Ctr., 163 N.J. 45, 52 (2000)); see also Kendall I, 209 N.J. at 191. The standard is objective: whether the plaintiff "knew or should have known" of facts sufficient to equitably justify the commencement of the statute of limitations. Martinez, 163 N.J. at 52. The determination is "highly fact-sensitive," Catena v. Raytheon Co., 447 N.J. Super. 43, 54 (App. Div. 2016), appeal dismissed, __ N.J. __ (2017),

varying "from case to case, and . . . from type of case to type of case," Vispisiano, 107 N.J. at 434.

Factors to be considered include: the nature of the injury; the availability of witnesses and written evidence; the elapsed time since the alleged wrongdoing; whether the delay was deliberate or intentional; and whether the delay peculiarly or unusually prejudiced the defendant. Lopez, 62 N.J. at 276. When "fault is not self-evident at the time of injury, a plaintiff need only have 'reasonable medical information' that connects an injury with fault to be considered to have the requisite knowledge for the claim to accrue." Kendall I, 209 N.J. at 193 (quoting Vispisiano, 107 N.J. at 435).

The Court in Kendall I held that in pharmaceutical cases a judge must also consider the rebuttable presumption of adequacy of an FDA-approved warning under N.J.S.A. 2A:58C-4 "where the question is what a reasonable person knew or should have known about the risks of a product for discovery rule purposes." 209 N.J. at 179-80. In the discovery rule setting, unlike when liability is the issue, the Court adopted a "middle-of-the-road approach," and held that the presumption should be treated as a standard presumption "capable of being overcome by evidence which 'tends to disprove the presumed fact, thereby raising a debatable question regarding the existence of the presumed fact.'" Id. at

197 (quoting Shim v. Rutgers, 191 N.J. 374, 386 (2007)). The plaintiff may overcome the presumption of adequacy with evidence to show that despite the product's warnings "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 held that Kendall's suit could proceed because the evidence not only overcame the presumption but also established she was reasonably unaware defendants caused her injury until less than two years before she filed suit. Id. at 198. The Court reached that conclusion because: (1) Kendall was twelve years old when she began taking Accutane; (2) her treating physicians had never warned her or her parent of the risk of IBD because they were unaware of its relationship to Accutane; (3) she suffered no gastrointestinal symptoms during her first four courses of Accutane; (4) her dermatologist, in consult with her gastroenterologist, agreed to prescribe a fifth course of Accutane in 2000 despite the diagnosis of ulcerative colitis in 1999; and (5) during her sixth course of Accutane, from 2003 to 2004, she received a stronger warning and experienced some increased diarrhea, but no other gastrointestinal symptoms. Id. at 198-99. The Court found:

> Although we can conceive of circumstances in which the 2003 warning might have been sufficient to alert a plaintiff of the connection between Accutane and her disease, it was certainly not sufficient, in these circumstances, to cause Kendall to doubt her physicians or to disregard the advice and information that had been imparted to her by them for the prior six years. That is particularly so in light of the lack of a discernable link between Kendall's symptoms and the ingestion of the drug.
>
> [Id. at 199.]

We are also mindful of McCarrell II, where plaintiff's claim was found timely filed, evidence having revealed he began taking Accutane in 1995, when he was twenty-four years old, during which he did not experience any gastrointestinal symptoms. 227 N.J. at 576. He received a copy of the 1994 Accutane patient brochure. Id. at 577. His physicians never warned him that Accutane can cause IBD. Ibid. He experienced symptoms of IBD in August 1996, ten months after he stopped taking Accutane, and was diagnosed with IBD in November 1996. Id. at 576. McCarrell testified during a Lopez hearing that he made the connection between the drug and IBD in May 2003, when his grandmother showed him an advertisement for a law firm. McCarrell I, slip op. at 106-07.

With this guidance from our Supreme Court, we separately examine the disposition of the four complaints in question in these consolidated appeals.

III

A. Gregory Luongo

On December 17, 1996, Luongo — then two months shy of his eighteenth birthday — was prescribed Accutane by a Massachusetts dermatologist. Prior to taking Accutane, Luongo received three courses of antibiotics; all were ineffective in treating his acne. Luongo received, along with his mother, the dermatologist's advice regarding Accutane's potential common side effects. The dermatologist testified it was her practice to discuss potential gastrointestinal effects, including abdominal pain, nausea, vomiting, diarrhea, and rectal bleeding, but she did not specifically warn about IBD because it was not known to be a common side effect. Luongo, who participated in medical decisions in collaboration with his mother, could not recall the details of this discussion, but he maintained the dermatologist did not inform him that Accutane could cause ulcerative colitis because the first time he heard the term was in 2003, when he was diagnosed with the disease. Luongo's mother, then employed as a staff physical therapist, confirmed she too first became aware of the term when her son was diagnosed with the disease.

When prescribing Accutane, the dermatologist provided Luongo and his mother with a copy of the 1994 Accutane patient brochure,

which as observed earlier, did not specifically warn about IBD but warned that, "[d]uring your treatment," "ACCUTANE MAY CAUSE SOME LESS COMMON, BUT MORE SERIOUS SIDE EFFECTS" and advised patients to be "ALERT" for "SEVERE STOMACH PAIN, DIARRHEA, [and] RECTAL BLEEDING." Luongo testified he "likely" read the materials "thoroughly." Those warnings were also included on the Accutane blister packaging.

During his Accutane treatment between December 1996 and June 1997, Luongo experienced no gastrointestinal side effects. In 1999, two years later, Luongo experienced "[s]ome diarrhea and cramping," which he then attributed to a virus or "stomach bug" but now relates to his ingestion of Accutane. He did not then seek medical treatment because the symptoms did not persist. His symptoms "infrequently" reoccurred, but he did not report those symptoms to his primary physician during an annual physical in May 2002.

In February 2003, six years after he completed Accutane treatment, Luongo's symptoms progressed and he thought it might be something more serious. For several months, Luongo experienced persistent and worsening diarrhea, rectal bleeding, and abdominal pain and cramping — symptoms he admittedly was warned in 1996 were side effects of taking Accutane.

Luongo's family physician referred him to a

gastroenterologist, who, in March 2003, diagnosed Luongo as suffering from ulcerative colitis. None of Luongo's treating physicians told him that Accutane was a cause of his IBD. Although Luongo had not heard of ulcerative colitis before his diagnosis, he testified that as of March 2003 he understood "ulcerative colitis . . . meant symptoms of abdominal pain, diarrhea [and] rectal bleeding." He admitted his dermatologist had told him Accutane's side effects included abdominal pain, diarrhea and rectal bleeding — the symptoms he had been experiencing. And he admitted that if shown the patient brochure in March 2003 he would have suspected Accutane as a nexus:

> Q. So if in March 2003 after you had been diagnosed you had gone home and you . . . found that brochure lying around . . . and you had read that, that would have been notice to you that, whoa, maybe Accutane had something to do with my ulcerative colitis. Right?
>
> A. It's possible if I had seen that at that time, yes.
>
> Q. Essentially what you're saying today is that in March 2003, you simply forgot what you had been told by [the dermatologist] and what you had read in the brochure back in 1996 and 1997?
>
> A. That's correct.

Luongo asserted, however, that his understanding of the warning was that the gastrointestinal symptoms would arise while taking Accutane, not six years later, and that if he had developed those

symptoms while taking the drug and had been treated, the symptoms would have ceased and not have led to chronic, irreversible IBD.

Luongo testified at the Lopez hearing that he first drew a connection between Accutane and IBD in early 2011 when he saw a television commercial which advised compensation was available for those who had taken Accutane and developed IBD. He acknowledged, however, he learned nothing new from the lawyer's advertisement, only that it was the first time a connection between his diagnosis and Accutane had been expressed to him.

Luongo's complaint was filed on June 9, 2011, more than eight years after the March 2003 diagnosis of ulcerative colitis. During discovery, defendants obtained medical records from all Luongo's physicians except a pediatrician he saw prior to 1993. In accordance with his office policy, that pediatrician had destroyed Luongo's medical records, which would have revealed whether Luongo took antibiotics as a child. At his deposition, Luongo admitted this pediatrician may have prescribed antibiotics for him as a child for ailments such as ear infections, strep throat, and sinus infections.

To summarize the essential facts, it is undisputed Luongo experienced IBD symptoms in 1999, was diagnosed with ulcerative colitis in 2003, and did not file his complaint until June 9, 2011, more than eight years after the diagnosis. In considering

the timeliness of the complaint, the critical question is whether Luongo knew, or a person in his circumstances should reasonably have known, before June 9, 2009, enough information to believe he had developed ulcerative colitis because he took Accutane.

The trial judge found Luongo to be "generally credible" and concluded Luongo had reason to know "very early on that something was wrong and that the something may well have been his ingestion of Accutane." The judge explained that Luongo "had symptoms that would have prompted action by a reasonable person," and Luongo's "failure to act within two years of his diagnosis of [ulcerative colitis] in March 2003, is fatal to his claim." The judge found that:

> Luongo admits that if he had read the warnings of the brochure in March 2003, he would have believed Accutane may have caused his [ulcerative colitis]. Luongo also concedes that in March 2003, he forgot what [the dermatologist] had told him and what he had read in the Accutane brochure. Plaintiff conceded that the warnings in the literature he received described the symptoms he had been experiencing for years. Luongo claims that it wasn't until eight years after his diagnosis that he first made the connection between Accutane and [ulcerative colitis] when he saw a [television] commercial in early 2011. Interestingly, on cross[-]examination, Mr. Luongo conceded that he didn't learn any new information from the lawyer solicitation on television that he hadn't previously learned from the warning literature.

The judge additionally found that the delay in filing suit

prejudiced defendants:

> Most striking about Luongo's case is the long period of time between being diagnosed with [ulcerative colitis] and filing his claim. . . . This is especially troubling because multiple records from his medical/health history no longer exist. The need for complete medical records in these types of claims is imperative. The lack of those records unfairly prejudices [d]efendant's ability to investigate other potential causes of Mr. Luongo's [ulcerative colitis].

Considering those factors deemed relevant in Kendall I, we note, as the judge recognized, that Luongo was seventeen when he began taking Accutane and suffered no gastrointestinal symptoms during his treatment. But, Luongo developed some non-persistent gastrointestinal symptoms two years after he stopped treatment, and was diagnosed with ulcerative colitis more than eight years before he commenced suit. Regardless of the fact that Luongo did not receive the stronger 2003 warnings quoted earlier, his testimony permitted the judge's finding that the 2011 legal ad — the event that allegedly triggered Luongo's connection between Accutane and his ailments — did not inform Luongo of anything he did not already know.

To be sure, although Luongo forcefully argues that the factual circumstances should have led to a different determination — particularly asserting that it is not reasonable to conclude that someone in Luongo's position would likely go back and re-read the

warnings in search of a link between Accutane and the diagnosis received years later — the judge was entitled to make findings based on his own appreciation of the evidence. In addition, the judge's findings and ultimate determination to dismiss the complaint finds further support in the evidence of prejudice to defendants. Although defendants were able to marshal considerable evidence of Luongo's medical history and Accutane usage, the passage of time deprived defendants of a pediatrician's treatment of Luongo up until 1993, three years before Luongo began taking Accutane.

Consequently, in deferring to the judge's findings, which are well-supported by the evidence, we affirm the dismissal of Luongo's complaint.

B. James Boerma

On February 17, 1998, Boerma, then thirteen years old, was prescribed Accutane by a Florida dermatologist. Prior to taking Accutane, Boerma had undergone a three-month course of antibiotics, which was not effective in treating his acne.

Before prescribing Accutane, the dermatologist advised Boerma and his mother of the "possible risks and benefits of Accutane therapy" and said he typically discussed with patients the risk of developing "pseudotumor cerebri, headaches, mood

swings, depression, hair loss, visual disturbance, . . . arthraigias, photosensitivity, flare of acne resulting in scarring, and hypertriglyceridemia." The dermatologist did not discuss IBD or diarrhea, and Boerma did not remember receiving written or verbal warnings about those things from the dermatologist. Boerma's recollection, however, was not very reliable since he also could not remember where the dermatologist's office was, what the dermatologist looked like, or even when he had taken Accutane. Boerma's mother, who made medical decisions on her son's behalf at that time, recalled that the dermatologist warned of the risk of getting pregnant while taking the drug and of developing dry lips.

The dermatologist provided Boerma and his mother with a copy of the 1994 Accutane patient brochure, which, as we have noted, warned of serious side effects during Accutane use, and alerted patients to the potential for severe stomach pain, diarrhea, and rectal bleeding. Boerma's mother testified at her deposition that it was her practice to read written information about medications, but she only recalled seeing the warnings in the brochure about pregnancy and the drawings depicting common birth defects associated with Accutane use during pregnancy. Boerma similarly only recalled having seen the drawing of the pregnant woman on the individual pill packaging.

During his treatment, between February and April 1998, Boerma experienced dry skin and chapped lips but no gastrointestinal symptoms. Four years later, in the summer of 2002, Boerma — then seventeen years old and living in Louisiana with his father — experienced diarrhea, abdominal pain, and rectal bleeding.

In July 2002, a gastroenterologist determined Boerma was suffering from ulcerative colitis. None of Boerma's physicians told him or his mother that Accutane was a cause of his IBD. In fact, the gastroenterologist testified that if a patient asked how he had developed IBD, he would reply, "[b]ad luck, being related to the wrong people if somebody else had the disease in their family; that it just happens, rarely, occasionally." Boerma's mother testified she had "probably" researched the disease at that time by using a dictionary or an encyclopedia.

Boerma testified at the Lopez hearing that he first made a connection between Accutane and IBD "[t]owards the end of the year 2006," when his mother telephoned him from Pensacola, Florida to inform him she had learned there may be a relationship. In his fact sheet, Boerma asserted he first contemplated retaining an attorney "in December 2006," but, when questioned at the Lopez hearing, Boerma said "it was September time" when he "started working" at Times Bar & Grill and toward "the end of [his] culinary school training." In his fact sheet, Boerma asserted he began

working at the Times Bar & Grill in March 2006. Consequently, Boerma later admitted at the Lopez hearing that these discussions about a link between his illness and Accutane occurred during "the beginning of 2006." Boerma also admitted he had confused other dates on his fact sheet and employment applications.

Nonetheless, Boerma persisted in fixing the date of the phone call from his mother with the fact that he was living in an apartment in Louisiana with a roommate in the fall of 2006. He also recalled that when his mother came to Louisiana for Thanksgiving in 2006, they discussed the connection between Accutane and ulcerative colitis and the fact that a Pensacola law firm was pursuing such cases:

> Q. And did she tell you then that she learned of this connection from any kind of advertisement in the Pensacola paper?
>
> A. No, sir.
>
> Q. What was your impression then in Thanksgiving as to how she learned this?
>
> A. That she had done research or read -- just done research on it. I didn't know where she got it from.

Boerma's mother, who was employed as a paralegal in a bankruptcy law firm, testified during her deposition that she first learned of a possible connection between Accutane and ulcerative colitis when she read an advertisement in the Pensacola

News Journal. She said she talked to her son about the advertisement and "probably" suggested he call the attorney listed, but she could not recall when she saw the advertisement or when she talked to her son.

During discovery, Boerma produced copies of Pensacola News Journal attorney advertisements but these advertisements ran only during the month of August 2003, not in 2006.[3] Boerma's mother testified that sometime "much later" — after she read the advertisement — she conducted internet research on ulcerative colitis; she could not recall if she read anything about a connection between Accutane and IBD or in what year she conducted the research. Boerma stated he never saw the advertisement, nor did his mother tell him about it — she only told him she "learned there was a connection" without explaining "where she got this connection."

Boerma learned he had developed IBD in July 2002 but did not file his complaint until March 19, 2008. The critical question is whether Boerma knew, or a person in his circumstances should reasonably have known, before March 19, 2006, of enough information

[3] The advertisement for two local attorneys, read in part, "ACCUTANE USERS YOU MAY HAVE A CLAIM. If you are taking or have taken the acne drug Accutane and have suffered from side effects such as . . . inflammatory bowel disease including [C]rohn's disease and ulcerative colitis . . . contact . . . [us]."

to believe he had developed IBD because he took Accutane.

The trial judge found that "the details surrounding . . . Boerma's awareness that Accutane may have caused his [ulcerative colitis] are unclear and, at times, not sufficiently credible." For example, "Boerma claimed that his mother called him in September 2006 and made him aware of the connection between Accutane and [ulcerative colitis]." To substantiate that claim, he "correlated the telephone call with his mother to his recent employment at Times Bar and Grill." But, in his fact sheet, Boerma set forth that he had been working at the Times Bar and Grill since March 2006, and thus "acknowledged" that his testimony during the Lopez hearing "was inaccurate."

Boerma also testified his mother made the connection between Accutane and IBD "by doing independent research." But Boerma's mother testified at her deposition "that she did not know if her son's recollection of her research was accurate," and that "she first did non-computerized research on her son's [ulcerative colitis] around the time of his diagnosis, and any computer based research would have been conducted in the recent past." She also "could not remember coming across anything in her research regarding the connection between Accutane and [ulcerative colitis]."

Instead, Boerma's mother said she first made the connection

between Accutane and her son's ulcerative colitis when she read a lawyer's advertisement in the Pensacola News Journal. She could not recall when she saw the advertisement and claimed, in contrast to her son's testimony, she discussed it with him.

Prior to the Lopez hearing, the trial court ordered "that all lawyer advertisements placed by firms representing and referring plaintiffs on or after January 1, 2004 be produced. The attorneys who entered an appearance were also required to advise if any referring attorneys refused to produce any such ads." No such advertisements were produced, nor was there any suggestion of non-compliance. Thus, the trial judge found "there is no evidence of any post-January 1, 2004 Accutane lawyer's advertisements in the Journal" and that "lack of evidence . . . supplement[ed] [Boerma's mother's] poor recollection as to when she first saw the advertisement."

The trial judge also found Boerma was "not credible" for a number of reasons:

> He often confused the dates of his employment and education. Furthermore, at his deposition, Mr. Boerma testified that his mother never told him to contact an attorney and she did not help him find an attorney. However, Mr. Boerma changed his testimony at the Lopez hearing and stated that his mother did recommend Hook & Bolton. [His mother]'s deposition confirms that she had a friend who worked at Hook & Bolton, and was actively involved in helping him find an attorney.

The judge concluded:

> Credibility matters, especially when the [c]ourt is asked to apply the equitable discovery rule to delay running the [statute of limitations] for a plaintiff's claim. Here, Mr. Boerma has the burden to establish that a reasonable person in his circumstances would not have been aware by March 18, 2006 of the connection between Accutane and his [ulcerative colitis] diagnosis. The lack of evidence regarding post January 1, 2004 lawyer advertisements in the Journal is telling.
>
> It is the conclusion of the [c]ourt that . . . Boerma, has failed to meet his burden of proof with the quality of the testimony he presented and is not entitled to equitable relief. . . .

These credibility determinations and findings of fact are well-supported by the record and are, therefore, entitled to our deference. Consequently, we reject Boerma's arguments and affirm the dismissal of his complaint.

C. Brian Zimpfer

On December 7, 1999, Zimpfer, then seventeen years old, was prescribed Accutane by a dermatologist in Colorado. Beforehand, Zimpfer took several courses of antibiotics, which were ineffective in treating his acne. Although he had input from his parents, Zimpfer testified it was his decision to begin treatment with Accutane.

The dermatologist advised Zimpfer of several possible side

effects, including diarrhea, nausea and vomiting, but he did not discuss IBD. Zimpfer recalled discussions with the dermatologist about "pregnant women stuff" and that he would have "to get blood drawn." The dermatologist provided Zimpfer with a copy of the 1994 Accutane patient brochure quoted earlier. Zimpfer recalled receiving written literature, which he said he would have read, but he did not specifically recall receiving the patient brochure. He recalled there were warnings on the blister packaging but testified the language in the patient brochure and on the blister packaging would not have warned him that he could develop ulcerative colitis years after taking Accutane.

Zimpfer's Accutane treatment, which started in December 1999, continued until May 2000. He suffered no gastrointestinal side effects during treatment. During each monthly follow-up visit, the dermatologist repeated and discussed the risks and side effects of Accutane.

On January 22, 2004, approximately three-and-a-half years after he stopped taking Accutane, Zimpfer went to the emergency room at Poudre Valley Hospital in Fort Collins, Colorado, complaining of an acute onset of severe rectal bleeding and stomach cramps he initially thought related to a recent snowboarding fall. He was diagnosed as suffering from hemorrhoids and was not admitted. Zimpfer returned to the emergency room two weeks later,

but was not admitted; he complained at the time of the same symptoms and was instructed to follow up with a gastroenterologist. On February 10, 2004, Zimpfer saw a gastroenterologist who performed a colonoscopy and diagnosed ulcerative colitis.

Ten months later, in December 2004, Zimpfer returned to the dermatologist for acne treatment. The dermatologist initially treated him with antibiotics, which were discontinued after Zimpfer experienced a flare-up of ulcerative colitis. In seeking approval from Zimpfer's insurance carrier for an alternative acne treatment, the dermatologist wrote that Zimpfer "has tried Accutane in the past with a severe flare" and has "been diagnosed with [u]lcerative colitis which could worsen with [A]ccutane." The dermatologist did not send Zimpfer a copy of the letter but Zimpfer was aware of this possible alternative treatment and mentioned it to his primary care physician. Zimpfer testified that neither the dermatologist nor any treating physician told him of a connection between Accutane and IBD.

Zimpfer, who had majored in computer science in college, testified at the Lopez hearing that he first made the connection between the disease and Accutane in October 2005, approximately eighteen months after his diagnosis, when he was admitted to Poudre Valley Hospital for severely worsening ulcerative colitis symptoms. He testified that during his two-week stay in the

hospital from October 23 to November 12, 2005, his mother, who Zimpfer said was essentially computer "illiterate," told him that while conducting an internet search she found "some information about a lawsuit with Accutane . . . causing ulcerative colitis." During his deposition, Zimpfer testified he could not recall when his mother discussed her research with him other than to acknowledge it occurred when he was "at Poudre Valley"; he was unable to remember "which stay it was."

In his fact sheet, Zimpfer stated he first contemplated hiring an attorney in July 2005 — months before he alleged he learned of the connection between Accutane and IBD. He admitted he knew when he filled out the fact sheet that his suit would be barred if he knew or had reason to know of the connection before June 7, 2005. Nevertheless, he explained he and his mother, who helped him complete the fact sheet, listed the date his mother first learned about the connection between the drug and the disease — a date four months before she allegedly told her son. In explanation, Zimpfer claimed his mother "does that a lot. She'll make up her mind about something and then not tell anyone."

Zimpfer's mother testified, however, that she thought she had searched for information about ulcerative colitis closer in time to February 2004 when her son was "diagnosed with ulcerative colitis," because she had never heard of the disease and knew

nothing about it. She could not recall exactly when she conducted the internet search, what websites she visited, or whether she discussed her research with her son. She also did not recall finding any research revealing or suggesting an association between Accutane and IBD.

As observed above, Zimpfer was diagnosed with IBD on February 10, 2004, but he did not file his complaint until June 7, 2007. The question for the trial judge, and now us, concerns whether Zimpfer knew, or a person in his circumstances should reasonably have known, before June 7, 2005, of information sufficient to believe he had developed IBD because of Accutane.

The judge responded to that question with thorough findings. He found that Zimpfer testified

> his mother told him of the connection while he was at Poudre Valley Hospital. His mother testified that she made the connection around the time of her son's initial gastrointestinal problems and [ulcerative colitis] diagnosis in February 2004. Coincidently, Mr. Zimpfer went to Pourde Valley Hospital on January 22nd and February 4, 2004.
>
> Likewise, Mr. Zimpfer's vague testimony at his deposition discredits his assertion at the Lopez hearing that he was told of the connection in October-November 2005 [during his] stay at Poudre Valley Hospital. Although Mr. Zimpfer claims his mother is computer illiterate, she made the causal connection between Accutane and [ulcerative colitis] for him. Mr. Zimpfer cannot repeatedly testify regarding his lack of memory and ask this

> [c]ourt to doubt his mother's reasonable assertion that she researched her son's disease around the time of the diagnosis. This is especially true considering that the dates of her research match two distinct dates when Mr. Zimpfer was at Poudre Valley Hospital, where he claimed she told him of the connection. Furthermore, it is not believable that Mr. Zimpfer would wait more than a year and a half to inform her son of the connection.
>
> . . . Zimpfer [failed] to meet his burden of proof with the quality of the testimony he presented and is not entitled to equitable relief. Accordingly, the filing of his [c]omplaint on March 19, 2008[,] was untimely and must be dismissed with prejudice.

The judge's findings, largely the product of his credibility determination, require our deference. Zimpfer, like Luongo, presented conflicting testimony as to when his mother told him about the connection between Accutane and IBD, and the judge was entitled to conclude this connection was drawn at an earlier point than argued — a point more than two years prior to the filing of the complaint. Consequently, we affirm the dismissal of Zimpfer's complaint.

D. Kristy Brecke

On September 9, 2003, Brecke, then twenty-three years old, was prescribed Accutane by a dermatologist in Minnesota. Brecke, who the judge found to be a candid and credible witness, testified she was warned of the risks of birth defects, suicide, and dry

eyes, lips, and skin, but she was not warned of IBD or gastrointestinal symptoms.

When Brecke was prescribed Accutane, she was also provided with a copy of the binder entitled "Be Smart/Be Safe/Be Sure Accutane Pregnancy Prevention and Risk Management Program for Women" (9th ed. 2002), which primarily focused on the dangers of becoming pregnant. The binder, however, contained a warning about "Abdomen (stomach area) problems," and cautioned that "[c]ertain symptoms may mean that your internal organs are being damaged" and "may not get better even after you stop taking Accutane." This binder instructed users to cease taking Accutane and call their prescriber if they experienced severe stomach or bowel pain and new or worsening diarrhea or rectal bleeding. Brecke signed the consent form acknowledging she read and understood this written material.

At the Lopez hearing, Brecke testified that she recalled receiving the binder and admitted she probably read it "thoroughly." She testified, however, that none of the written material, including the binder, medication guide, and blister packaging, warned that Accutane could cause ulcerative colitis or IBD.

On December 4, 2003, while still taking Accutane, Brecke experienced some rectal bleeding and mucus in her stool, but no

other gastrointestinal side effects. She described what she characterized as a "very mild symptom." A nurse from the dermatologist's office advised her to stop taking Accutane and see a physician; she complied.

On December 8, 2003, Brecke saw her primary care physician and reported she had been taking Accutane and was suspicious it may have caused her rectal bleeding. The physician diagnosed a superficial rectal fissure and prescribed a topical cream. Brecke understood that a fissure was "a crack in the skin in [her] anus"; she did not know that anal fissures are a symptom of IBD. She testified the physician told her he did not think she had developed the fissure from taking Accutane. No other physician told her there was a connection. From this, Brecke felt it was safe to continue taking Accutane. She returned to the dermatologist's office on January 26, 2004, and reported on her treatment with the physician. The dermatologist was satisfied the fissure had resolved and was unrelated to Accutane use, and the Accutane prescription was renewed. Brecke testified she did not think the dermatologist would have continued to prescribe Accutane if she thought the rectal bleeding was an Accutane-related side effect.

Brecke continued taking Accutane until March 8, 2004, at which time she continued to experience rectal bleeding but no other gastrointestinal symptoms. After ending her treatment,

Brecke continued to experience rectal bleeding, which she reported to her physicians.

Beginning in late September 2004, six months after she stopped taking Accutane, Brecke, who held a doctorate in marriage and family therapy, worked for eighteen months as a therapist in a wilderness program for teenagers in Oregon. She experienced some rectal bleeding during this time, which, while "embarrassing," did not restrict her strenuous activity, including hiking mountains carrying a sixty-pound backpack.

Prior to starting work with the program, Brecke reported the rectal bleeding during a physical examination with her primary care physician; she was not then suffering from any other gastrointestinal symptoms. Brecke was again diagnosed with an anal fissure and given a prescription for a topical medication. The physician suggested she return for a follow-up examination if her symptoms did not resolve in three months. She did not do so, however, due to a lack of health insurance.

During a physical exam on August 3, 2005, Brecke reported she was experiencing rectal bleeding almost every day; she was again diagnosed with "anal fissures with bleeding." During a wilderness trek in December 2005, she experienced "some urgency and looser stools."

In January 2006, Brecke took a two-month backpacking trip in

Southeast Asia during which she experienced a bout of constipation and bloating that resolved. In March 2006, a few days after she returned from the trip, Brecke experienced for the first time "some pretty severe symptoms," including cramping, urgency and extreme nausea.

On April 3, 2006, Brecke returned to her primary care physician complaining of bloody diarrhea. The physician gave her samples of an antibiotic, which did not resolve her symptoms. Three weeks later, on April 26, 2006, she returned complaining of bloody diarrhea, constipation, and urgency; she received another prescription, which did not resolve her symptoms.

On May 9, 2006, Brecke went to an emergency room suffering from abdominal pain, nausea, vomiting, diarrhea, and incontinence. There, on May 10, 2006, Brecke was diagnosed as suffering from ulcerative colitis, which she had never heard of until this diagnosis. She testified that none of her treating physicians ever told her what caused her to develop the disease. And she did not relate her symptoms to her use of Accutane approximately two years earlier because her symptoms were so "drastically different" than the anal fissure symptoms she had experienced while taking the drug.

Despite all these physical concerns and complaints, Brecke testified she did not make the connection between Accutane and IBD

until October 11, 2009, when, at a nurse's suggestion, she read the Mayo Clinic's webpage on IBD for information about her disease. The "Risk Factors" section of the website described Accutane as:

> a powerful medication sometimes used to treat scarring cystic acne or acne that doesn't respond to other treatments. Although cause and effect hasn't been proved, studies have reported the development of inflammatory bowel disease with isotretinoin use.

Brecke then realized she had exhibited ulcerative colitis symptoms during her use of Accutane. Brecke, who was "shocked" and "overwhelmed with emotions," emailed her mother on October 11, 2009, to report that discovery.

To summarize, Brecke learned she had developed IBD on May 10, 2006, but did not file her complaint until nearly four years later, on April 5, 2010. The critical question, therefore, is whether Brecke knew, or a person in her circumstances should reasonably have known, before April 5, 2008, of enough information to claim she developed IBD because of Accutane.

The trial judge was impressed with Brecke's "candor" during the Lopez hearing and "found her testimony generally credible." But he questioned:

> what type of person with persistent rectal bleeding makes a two-month backpacking trip throughout Southeast Asia without first consulting with her physician on how to safeguard against a worsening condition while in a foreign country? Someone who is oblivious

> to her health. Rectal bleeding was one of the very risks Plaintiff was advised of, and it began early, and Accutane was suspected early, yet Ms. Brecke never took it seriously or explored the potential of a claim against [d]efendant.
>
> So, when the circumstances of [p]laintiff's medical history are considered in light of the burden of proof required at a Lopez hearing, viz., where the relationship between plaintiff's injury and defendant's fault is not self-evident, plaintiff must prove that a reasonable person in her circumstances would not have been aware of such fault in order to receive the benefit of the discovery rule, Kristy Brecke's claim is found wanting.
>
> A reasonable person in her circumstances would have concluded very early on that something was wrong and that the something may have been her ingestion of Accutane. Plaintiff had persistent symptoms that clearly would have prompted action by a reasonable person. Her failure to bring a legal claim within two years of her diagnosis of IBD on May 12, 2006, is fatal to her lawsuit. . . .

The judge was entitled to view the evidence as demonstrating that Brecke had reason to know her IBD may have been caused by Accutane earlier than April 5, 2008. She was a well-educated, twenty-three year old when she began taking Accutane and suffered gastrointestinal symptoms during her treatment — a circumstance suggesting a discernable link between the drug and her disease. Although her dermatologist did not specifically warn of the risk of IBD, Brecke (unlike the other plaintiffs here) received a copy of the stronger warnings contained in the 2002 patient binder—

warnings the Court in Kendall I found "might have been sufficient to alert a plaintiff of the connection between Accutane and her disease." 209 N.J. at 199.

Moreover, as early as December 2003 Brecke in fact suspected Accutane may have caused her rectal bleeding. Although her primary care physician diagnosed her at that time with a rectal fissure, and her dermatologist continued her prescription for Accutane, Brecke suffered from rectal bleeding while taking Accutane and continued to suffer from worsening rectal bleeding for approximately three years. In light of these circumstances, the judge's finding that Brecke had failed to sustain her burden of persuasion is entitled to our deference.

IV

The orders dismissing the complaints in these four matters are affirmed.