SYLLABUS

(This syllabus is not part of the opinion of the Court. It has been prepared by the Office of the Clerk for the convenience of the reader. It has been neither reviewed nor approved by the Supreme Court. Please note that, in the interests of brevity, portions of any opinion may not have been summarized.)

Kamie S. Kendall v. Hoffman-LaRoche, Inc., et al. (A-73-2010) (066802)

Argued October 24, 2011 -- Decided February 27, 2012

LONG, J., writing for a majority of the Court.

The Court considers whether plaintiff Kamie Kendall's lawsuit against the developers and marketers of the prescription drug Accutane (collectively, Hoffman-LaRoche), was barred by the two-year statute of limitations.

Accutane is used to treat nodular acne. Its many side effects include dry skin, lips and eyes and a high risk of birth defects if taken while pregnant. This case concerns Accutane's alleged propensity to cause inflammatory bowel disease (IBD), including ulcerative colitis, which is characterized by frequent and often bloody bowel movements, pain, and other symptoms. The symptoms wax and wane, but the condition is permanent. When the FDA approved Accutane in 1982, it did not require a warning of possible gastrointestinal side effects such as IBD.

Kendall was first prescribed Accutane in January 1997, when she was twelve years old. By that time, the information provided to physicians began to warn of a possible link between Accutane and IBD. The information provided to patients warned to stop taking the drug and consult a doctor if stomach pain, diarrhea and rectal bleeding occurred. In 1998 and 2000, the physician warnings were strengthened with regard to IBD. In 2003, the warnings provided to patients also were strengthened. These included a brochure that focused on the dangers relating to pregnancy, but also warned about "abdomen (stomach area) problems" and damages to the "liver, pancreas, bowels (intestines), and esophagus." It advised patients to stop taking the drug and call a physician if they developed symptoms that included stomach, chest or bowel pain or diarrhea. Patients also were required to sign a consent form and watch a video about contraception. The 2003 warnings did not mention IBD or ulcerative colitis by name.

When Kendall was first prescribed Accutane, her doctor did not mention the risk of IBD because he was not aware of it. Although the patient brochure Kendall was provided warned to be on the alert for stomach pain, diarrhea and rectal bleeding, she did not experience any gastrointestinal side effects. During three additional courses of Accutane--July to September 1997, February to April 1998, and July to September 1998—Kendall also had no gastrointestinal symptoms. However, in April 1999, at a time when she was not taking Accutane, Kendall was hospitalized for bloody diarrhea and abdominal pain and was diagnosed with ulcerative colitis. Although the doctor did not identify a cause, hospital records indicated that Kendall's grandmother also had the disease. Thereafter, Kendall took medication for the condition, and the symptoms disappeared and reappeared frequently, as is usual.

In December 2000, Kendall was again prescribed Accutane after her dermatologist consulted with her gastroenterologist, who had no objection. Kendall did not experience any gastrointestinal side effects. In September 2003, Kendall was prescribed her sixth course of Accutane, which she took until January 2004. She was given the 2003 warnings and signed the consent form agreeing that she had read and understood them and had watched the video on contraception. Kendall later testified that she skimmed over the warnings because she had taken the drug before. This time Kendall had increased diarrhea. In January 2004, Kendall saw a magazine advertisement that listed the risks associated with Accutane, including IBD, and began to think that it may have caused her IBD. In April 2004, Kendall's grandmother told her about a lawyer's advertisement linking Accutane to IBD.

On December 21, 2005, Kendall filed this lawsuit, alleging that Hoffman-LaRoche was liable because the warnings were inadequate by failing to disclose the risk of developing IBD. Hoffman-LaRoche moved to dismiss the lawsuit, asserting that the statute of limitations had expired. The trial court scheduled a hearing to determine whether Kendall had filed her complaint within the two-year statutory period for personal injury actions, pursuant to N.J.S.A. 2A:14-2(a). After the hearing, the judge denied the motion to dismiss. He noted Kendall's age at the time she began taking Accutane, the fact that her doctor prescribed it even after she was diagnosed with IBD, and the fact that the 2003 warnings focused primarily on preventing pregnancy and suicide. The judge concluded that by

December 2003, Kendall did not know that her ulcerative colitis was caused by Accutane and that a reasonable person in her circumstances would not have known, therefore the suit was timely. After a trial, the jury found in favor of Kendall.

The Appellate Division panel remanded the case for a new trial on a different issue, but affirmed the trial court's decision on the statute of limitations. In ruling, the panel considered whether the presumption of adequacy of an FDA-approved warning, as provided in the Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, governs the statute of limitations issue. The panel concluded that if the warnings are presumed sufficient to place an adult consumer on reasonable notice of a drug's risks, they bear on what the consumer reasonably should have known about potential side effects for the purpose of contemplating filing a lawsuit. The panel determined, therefore, that to survive dismissal based on the statute of limitations, a trial court should find that the policies underlying the presumption of adequacy are outweighed by the particular circumstances presented and that the plaintiff has a reasonable basis for overcoming the presumption. The panel found that permitting Kendall's case to go forward did not undermine the policies underlying the presumption because her failure to file a lawsuit earlier was not unreasonable under the circumstances. The Supreme Court granted certification on the issue of the timeliness of Kendall's complaint. 205 N.J. 99 (2011).

HELD: Because a reasonable person in plaintiff Kamie Kendall's situation would not have known by December 2003 of the relationship between Accutane and ulcerative colitis, her December 2005 lawsuit against the defendant developers and marketers of the drug was timely.

1. Statutes of limitations place a time limit on when lawsuits may be filed to penalize dilatoriness and serve as a means of repose. The discovery rule balances the need to protect injured persons against the injustice of compelling a defendant to defend against a stale claim. It postpones the accrual date of a cause of action if the plaintiff is unaware either that he has been injured or that the injury is due to the fault of an identifiable individual or entity. Knowledge of fault and injury may occur simultaneously, but where the relationship between them is not self-evident, a plaintiff can invoke the discovery rule if he establishes that a reasonable person in those circumstances would not have been aware within the statutory period that he was injured through the fault of another. (pp. 19-25)

2. Under the common law, a product may be defective due to a failure to warn or an inadequate warning. In enacting the PLA, the Legislature intended to reduce the lawsuit-related burden on manufacturers of FDA-approved products. In part, the PLA provides that if a warning has been approved by the FDA, a presumption arises that the warning was adequate. Although nothing in the PLA suggests that the Legislature intended to alter New Jersey's long-standing discovery rule jurisprudence, it could be argued that the legislative desire to lessen a manufacturer's potential liability for using an FDA-sanctioned warning would extend to protecting it from defending belatedly-filed lawsuits. Therefore, a judge considering the timeliness of a lawsuit alleging a failure to warn may consider the PLA's presumption of adequacy, but the presumption is not conclusive and can be overcome by evidence. Ultimately, the burden remains on the plaintiff 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 a defendant's product. (pp 25-31)

3. Kendall's lawsuit may proceed because the evidence overcame the presumption and established that Kendall reasonably was unaware that Hoffman-LaRoche caused her injury until after December 21, 2003. When Kendall was first prescribed Accutane, her dermatologist did not warn about IBD because he was not aware of the risk. Kendall took four courses of the drug from 1997 through 1998 with no gastrointestinal symptoms. When Kendall later developed ulcerative colitis, a disease that waxes and wanes, her gastroenterologist did not know of a connection between ulcerative colitis and Accutane. In 2000, her dermatologist consulted her gastroenterologist and they agreed she could be prescribed Accutane. Again, she did not experience gastrointestinal effects. While on her sixth course of Accutane, September 2003 to January 2004, she experienced some increased diarrhea. Kendall, who the trial judge found credible, said that her doctors never advised her not to take Accutane or of the risk of IBD or she would not have taken the drug. The 2003 warning focused on pregnancy and suicide and, although it advised to stop taking the drug if certain symptoms occurred, neither the warning nor the consent form mentioned IBD or colitis. In fact, Kendall never received a warning that specifically mentioned IBD or ulcerative colitis. In these circumstances, the warnings were not sufficient to cause Kendall to disregard six years of physician advice, particularly in light of the lack of a discernable link between her symptoms and her ingestion of the drug. (pp. 31-33)

The judgment of the Appellate Division is **AFFIRMED**.

JUDGE WEFING (temporarily assigned), **DISSENTING,** is of the opinion that the warnings sufficiently advised of the risk, but because Kendall was a minor when she was diagnosed with ulcerative colitis, she was permitted two years beyond her eighteenth birthday, which occurred on January 28, 2002, to file the complaint; therefore her December 2005 complaint was time barred.

CHIEF JUSTICE RABNER and JUSTICES LaVECCHIA, ALBIN, and HOENS join in JUSTICE LONG's opinion. JUDGE WEFING (temporarily assigned), filed a separate, dissenting opinion. JUSTICE PATTERSON did not participate.

SUPREME COURT OF NEW JERSEY
A-73 September Term 2010
066802

KAMIE S. KENDALL,

Plaintiff-Respondent,

v.

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

Defendants-Appellants.

Argued October 24, 2011 – Decided February 27, 2012

On certification from the Superior Court, Appellate Division.

Paul W. Schmidt, a member of the District of Columbia bar, argued the cause for appellants (Gibbons, Dughi & Hewit, and Covington & Burling, attorneys; Mr. Schmidt, Michelle M. Bufano, Russell L. Hewit, and Michael X. Imbroscio, a member of the District of Columbia bar, of counsel; Mr. Schmidt, Ms. Bufano, Mr. Hewit, Mr. Imbroscio and Natalie H. Mantell on the briefs).

David R. Buchanan argued the cause for respondent (Seeger Weiss and Hook & Bolton, attorneys; Mr. Buchanan and Michael D. Hook, a member of the Florida bar, on the briefs).

John Zen Jackson submitted a brief on behalf of amicus curiae The Medical Society of New Jersey (McElroy, Deutsch, Mulvaney & Carpenter, attorneys).

Michael A. Galpern and Jonathan W. Miller submitted a brief on behalf of amicus curiae New Jersey Association for Justice (Locks Law Firm, attorneys).

Stephen C. Matthews submitted a brief on behalf of amici curiae The New Jersey Business and Industry Association, The New Jersey State Chamber of Commerce, and The Commerce and Industry Association of New Jersey (Porzio, Bromberg & Newman, attorneys; Mr. Matthews and Brian P. Sharkey on the brief).

Edward J. Fanning, Jr. submitted a brief on behalf of amici curiae The New Jersey Lawsuit Reform Alliance and The Healthcare Institute of New Jersey (McCarter & English, attorneys; Mr. Fanning and David R. Kott of counsel; Mr. Fanning, Mr. Kott and Maritza Braswell on the brief).

JUSTICE LONG delivered the opinion of the Court.

On December 21, 2005, plaintiff Kamie Kendall filed suit against Hoffman-LaRoche, Inc., Roche Laboratories, Inc., F. Hoffman-LaRoche Ltd., and Roche Holding, Ltd. (defendants), for injuries that allegedly resulted from her use of Accutane, a drug produced and marketed by defendants. Defendants moved to dismiss the action as untimely. The trial judge conducted a Lopez hearing[1] and ruled that Kendall's claim was not time-barred; her delay was reasonable under the circumstances.

[1] Lopez v. Swyer, 62 N.J. 267, 275-76 (1973) (holding trial court should determine applicability of discovery rule in pretrial hearing).

A subsequent jury trial resulted in a large award to Kendall. Defendants appealed, challenging a number of the evidential rulings at trial and again arguing that the suit was barred by the statute of limitations. The Appellate Division declared the action timely, but reversed the award on other grounds. On certification, the sole issue before us is whether Kendall's action is time-barred.

The case requires us to revisit our discovery rule jurisprudence and to assess the place, if any, of the Product Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, in determining whether to countenance a filing delay. In particular, we are asked to decide if the presumption of adequacy of a Food and Drug Administration (FDA)-approved warning, provided in N.J.S.A. 2A:58C-4, affects the application of the discovery rule.[2]

Although that presumption is not a perfect fit for a statute of limitations analysis, we have concluded, as did the Appellate Division, that it cannot be totally ignored where the question is what a reasonable person knew or should have known about the risks of a product for discovery rule purposes. However, in the discovery rule setting, the presumption is not dispositive but may be overcome by evidence that tends to disprove the presumed fact.

[2] We note that that issue was not raised during the Lopez hearing, but was advanced by defendants and decided by the Appellate Division.

With that consideration in place, we are satisfied, as were the trial judge and the Appellate Division, that Kendall reasonably did not appreciate by December 21, 2003, that Accutane had caused or exacerbated her condition and that, therefore, her filing on December 21, 2005, was timely.

I.

The relevant facts are basically uncontroverted.

A. Accutane

Accutane, the brand name for isotretinoin, is a prescription drug developed and marketed by defendants.[3] Physicians' Desk Reference 2848 (59th ed. 2005). The drug is a retinoid, derived from vitamin A, that is used to treat recalcitrant nodular acne that has not responded to other regimens. Id. at 2849. Nodular acne is a condition marked by an accumulation of sebum under the skin, which ultimately ruptures the follicle wall and forms an inflamed nodule. John S. Strauss & Diane M. Thiboutot, Diseases of the Sebaceous Glands, in Fitzpatrick's Dermatology in General Medicine 771-73 (Irwin M. Freedberg et al. eds., 5th ed. 1999). Although much remains unknown about how Accutane treats acne, the drug appears to reduce the production of oil and waxy material in the sebaceous glands. Physicians' Desk Reference, supra, at 2849.

[3] Defendants discontinued the sale of Accutane in 2009.

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. Id. at 2848-49. This case concerns the effect of Accutane on the digestive tract and, in particular, the alleged propensity of the drug to cause inflammatory bowel disease (IBD).

B. IBD

IBD includes several chronic incurable diseases characterized by inflammation of the intestine. Mark Feldman, Lawrence S. Friedman, & Marvin H. Sleisenger, Sleisenger & Fordtran's Gastrointestinal and Liver Disease 2005 (7th ed. 2002). It traditionally manifests as one of two diseases: Crohn's disease or ulcerative colitis. Ibid. Ulcerative colitis, Kendall's diagnosed condition, involves a chronic condition characterized by ulceration of the colon and rectum. Id. at 2039. Individuals suffering from ulcerative colitis experience frequent and often bloody bowel movements. Id. at 2046-47. Accompanying those bowel movements are fatigue, dehydration, anemia, cramping, abdominal pain, and bloating. Ibid.; William S. Haubrich, Fenton Schaffner, and J. Edward Berk, Bockus Gastroenterology 1338 (5th ed. 1995). The symptoms often wax and wane, but the condition is regarded as permanent. The Merck Manual 307 (17th ed. 1999).

The causes of IBD are unclear. Sleisenger & Fordtran's Gastrointestinal and Liver Disease, supra, at 2039. The peak onset of IBD is young adulthood. Id. at 2040. Statistically, it has been linked with family history, prior infections, frequent use of antibiotics, and possibly to use of contraceptives and nonsteroidal anti-inflammatory drugs. Id. at 2009, 2040, 2041; Bockus Gastroenterology, supra, at 1355.

C. Accutane Labels[4]

By way of background, in 1982 the FDA approved the use of Accutane and did not require a label warning of possible gastrointestinal side effects. In 1983 and 1984, defendants revised the warnings on the Accutane label, 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. . . ."

In 1984, defendants issued a "Dear Doctor" letter to prescribing physicians, which explained that:

> Ten Accutane patients have experienced gastrointestinal disorders characteristic of inflammatory bowel disease (including 4

[4] We will not recount here the various studies that led to the original labeling and later relabeling of Accutane. Those studies are relevant to the merits of plaintiff's cause of action. This aspect of the case is only about what plaintiff knew and when she knew it.

> ileitis and 6 colitis). While these disorders have been temporally associated with Accutane administration, i.e., they occurred while patients were taking the drug, a precise cause and effect relationship has not been shown. [Defendants are] . . . continuing to monitor adverse experiences in an effort to determine the relationship between Accutane . . . and these disorders.
>
> [(Emphasis added).]

At that time, defendants also amended the warning section of the Accutane package insert provided to physicians. Specifically, the revised physician's insert included:

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

That warning remained in effect until 2000.

In 1994, defendants issued a patient brochure that 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." Patients who experienced any of those symptoms were advised to "discontinue" Accutane and consult with a doctor. The brochure warned that those symptoms "MAY BE THE EARLY SIGNS OF MORE SERIOUS SIDE EFFECTS WHICH, IF LEFT UNTREATED, COULD

POSSIBLY RESULT IN PERMANENT EFFECTS." That patient brochure remained in effect until 1999. The same warning was printed on the blister packaging, which contained the individual Accutane pills.

Defendants issued another "Dear Doctor" letter in August 1998 to board-certified dermatologists warning that patients taking Accutane should be monitored for several serious adverse events, including IBD. In 2000, defendants amended the warnings provided to physicians to remove "temporally" from the 1984 warning and added that the symptoms of IBD "have been reported to persist after Accutane treatment has stopped."

In 2003, defendants again strengthened the warnings accompanying Accutane. The written materials provided to Kendall included a patient brochure presented as a binder entitled "Be Smart, Be Safe, Be Sure." The binder materials primarily focused on the dangers of becoming pregnant while taking Accutane. The binder also contained a warning about gastrointestinal side effects:

> 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, <u>stop taking Accutane</u> 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 . . . . 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).]

A similar warning was included on the medication guide provided to Kendall by the pharmacy and on the blister pack.

In addition to those warnings, patients were required to sign a "Patient Information/Consent" form, which stated that the patient had read and understood the written patient information and watched a video about contraception. A second "Informed Consent/Patient Agreement Form" listed several side effects of Accutane, including birth defects and the risk of depression and suicide. None of the 2003 patient warnings mentioned IBD or ulcerative colitis by name. The 2003 warnings were in place when Kendall began her final course of Accutane.

D. Plaintiff Kamie Kendall

1. Initial Accutane Treatments

Kendall was first prescribed Accutane in January 1997, by her dermatologist, Dr. Steven Thomson, when she was twelve years old. Prior to taking Accutane, she had suffered from acne for

approximately two years and had received antibiotics therefor. After other treatments failed to control her acne, Dr. Thomson prescribed Accutane.

Before he prescribed Accutane in 1997, Dr. Thomson addressed its side effects with Kendall and her mother (e.g., dry eyes, dry skin, risk of sunburn). He did not discuss the risk of IBD with Kendall because, according to him, he was not aware of its relationship to Accutane. Kendall only recalled being warned not to become pregnant.

In addition to the warnings that Dr. Thomson discussed with Kendall and her mother, he provided Kendall with a copy of the Accutane patient brochure. As noted, the 1994 brochure, in effect in 1997, warned that patients should be alert for stomach pain, diarrhea, and rectal bleeding, and advised that patients "discontinue" Accutane and consult with a doctor if experiencing any of those symptoms. Kendall signed a consent form acknowledging that she had received and read the patient brochure.

During that first treatment period, which ran from January 1997 to May 1997, Kendall experienced dry lips, cracking at the corner of her mouth, bloody noses, dry eyes, and back and knee pain, but no gastrointestinal side effects. Kendall received three more courses of Accutane: July to September 1997, February to April 1998, and July to September 1998. During each

of these courses the warnings on Accutane remained the same. She reported only similar symptoms to those she had experienced during her initial course of treatment. In other words, during four courses of Accutane, Kendall experienced no gastrointestinal symptoms.

2. IBD Diagnosis

Seven months later, in April 1999, Kendall experienced a severe case of bloody diarrhea, abdominal pain, and cramping, for which she was hospitalized. On April 14, 1999, Kendall's pediatric gastroenterologist, Dr. Linda Book, diagnosed her with ulcerative colitis. Although Dr. Book did not identify a cause for Kendall's colitis, hospital records indicated that Kendall's grandmother also suffered from the disease. Dr. Book discussed the use of Accutane with Kendall and her mother. At the time, however, because Dr. Book did not know of a connection between Accutane and ulcerative colitis, she did not raise that issue with the Kendalls.

To treat her ulcerative colitis, Kendall testified to taking various medications. She indicated that the symptoms of IBD disappeared and reappeared frequently, as is often the course of the disease.

3. Additional Accutane Treatments

In October 2000, Kendall returned to Dr. Thomson for acne treatment. Dr. Thomson consulted with Dr. Book before

prescribing Accutane again. During consultation, Dr. Book expressed no objection to Kendall restarting Accutane, provided that Dr. Thomson monitored her liver enzymes. On December 11, 2000, Kendall began her next course of Accutane. Kendall was given a copy of the patient brochure, which was the same as that provided in 1997. Again she experienced several side effects, but no diarrhea or other gastrointestinal side effects. Thus, by 2000, Kendall had taken five courses of Accutane, never experiencing any gastrointestinal symptoms while on the drug.[5]

Three years later, in August 2003, Kendall returned to Dr. Thomson for persistent acne. Before that final course of treatment, Kendall received the 2003 warnings, including the "Be Smart, Be Safe, Be Sure" binder. She signed both consent forms agreeing that she read and understood the written patient information and that she watched a video accompanying the product about contraception. Kendall testified that she "skimmed over the book" because she had taken courses of the drug before. Thereafter, in September 2003, she began her sixth and final course of Accutane, which continued through January 2004. Kendall suffered many of the side effects she had earlier experienced while on the drug and some increased diarrhea.

[5] Kendall was taking medication for her IBD when she started her fifth course of Accutane, and she did not report any diarrhea during this course of treatment.

In January 2004, Kendall saw an advertisement in a magazine that listed the risks associated with Accutane, including IBD. At that point, she "started to think" that Accutane may have caused her IBD. In April 2004, Kendall's grandmother told her that she had seen a lawyer's advertisement linking Accutane to IBD. At some point Kendall called the telephone number of an attorney's office listed in the advertisement.

E. Procedural History

Kendall filed suit on December 21, 2005. In the complaint she alleged that defendants were liable because the warnings on Accutane were inadequate in that they failed to disclose the risk of developing IBD. Prior to trial, defendants filed a motion to dismiss the action due to the expiration of the statute of limitations.

1.

The trial court scheduled a Lopez hearing to determine whether Kendall had filed her complaint within the statutory period. At the hearing, Kendall testified, and deposition testimony of Drs. Thomson and Book was read into the record. Kendall's position was that a reasonable person, in her circumstances, would not have known that Accutane was the cause of her ulcerative colitis by December 2003 because none of the warnings provided to her mentioned ulcerative colitis, IBD, or Crohn's Disease, by name, and because her doctors did not know

of the risk. Individually and in consultation with each other, they continued to prescribe Accutane after her diagnosis.

Conversely, defense counsel argued that Kendall should have known of the connection between her ulcerative colitis and Accutane, at the latest by August 2003, as a result of the 2003 warnings given when she received her last Accutane prescription. In addition, defendants argued that Kendall realized that during her 2003 dosages of Accutane her diarrhea worsened. Therefore, they contended that a reasonable person would have known of a connection between Accutane and colitis, thus accruing the claim, at the latest, in August, September, or October 2003, any of which is more than two years before the filing of the suit.

The trial judge denied defendants' motion to dismiss. After outlining the basic legal principles, the judge turned to the facts presented during the Lopez hearing. She considered Kendall's age at the time she began taking Accutane; the timing of the diagnosis; and the fact that her doctor continued to prescribe Accutane after Kendall was diagnosed. Regarding the warnings provided in 2003, the judge found that the booklet focused primarily on preventing pregnancy and, as a secondary concern, on suicide. Indeed, the judge estimated that of the 3,000 words in the initial pages of the booklet, only 80 were devoted to gastrointestinal side effects and that the booklet did not mention ulcerative colitis and only mentioned the bowel

in a list of all the other organs of the gastrointestinal tract. Likewise, the judge noted that the consent forms focused on pregnancy and suicide and did not mention gastrointestinal side effects, but only referred generally to the other warnings provided in the booklet.

Based on those facts, the judge concluded that by December 2003, Kendall did not know that her ulcerative colitis was caused by Accutane and that a reasonable person, in her circumstances, would not have known. The judge, therefore, concluded that the suit was not barred by the statute of limitations.

2. Jury Trial and Verdict

Kendall's case was tried in April 2008. She testified, along with her mother, Dr. Thomson, Dr. Book, her surgeon, and her husband. In addition, a proverbial battle of the experts ensued with Kendall's expert opining that Accutane "certainly was a cause" of her IBD and defendants' experts declaring that there is no "experimental evidence to support the biological plausibility for Accutane causing IBD."

The jury found in favor of Kendall and awarded her $10.5 million in compensatory damages and $78,500 in past medical expenses. Through special interrogatories, the jury found that: (1) "the use of Accutane [is] a cause of inflammatory bowel disease in some people who take it"; (2) defendants failed "to

provide adequate warning" to Kendall's "prescribing physician about the risks of [inflammatory bowel disease] from Accutane that [defendants] knew or should have known about prior to April 1999"; and (3) defendants' failure to warn was "a proximate cause of [plaintiff] developing [inflammatory bowel disease.]" Defendants moved to set aside the jury verdict on multiple grounds. The trial court rejected the motions in their entirety.

3. Appellate Division

Defendants appealed the verdict and the trial court's ruling at the Lopez hearing. The panel reversed and remanded the case for a new trial because of a separate evidentiary issue, but rejected defendants' challenge to the trial court's decision on the statute of limitations.

In ruling, the panel first considered the newly minted contention that the presumption of adequacy in the PLA should govern the limitations issue. Although recognizing that the presumption does not "stringently apply" in a discovery rule proceeding, the panel nevertheless concluded that if the warnings are presumed "sufficient to place an adult consumer on reasonable notice of a pharmaceutical drug's risks before ingesting it, those warnings also bear upon what that same consumer knew, or reasonably should have known, about the drug and its potential adverse side effects for the purposes of

contemplating potential litigation against the drug manufacturers."

Accordingly, the panel determined that the trial court in the Lopez hearing should "make a preliminary finding that the public policies underlying the presumption of adequacy are outweighed by the particular facts and circumstances presented, and that plaintiff has supplied a reasonable basis for overcoming the presumption for purposes of extending the statute of limitations." According to the panel, it would be for the jury ultimately to determine whether the presumption was overcome.

The panel went on to hold that the trial court's decision to permit Kendall's case to go forward did not undermine the policies underlying the presumption of adequacy because Kendall's failure to act sooner was not unreasonable under all of the circumstances. In particular, the panel restated the findings of the trial court that the 2003 warning materials "alluded to abdominal and bowel problems in a far less conspicuous or pointed manner" than to the effects on a pregnancy; that plaintiff was not informed by doctors of the risks of IBD or abdominal problems; and that Kendall had been repeatedly prescribed Accutane by her doctors, despite her diagnosis of IBD. The panel did not identify exactly when Kendall's claim accrued, instead holding that it had not accrued

more than two years before December 21, 2005, the date on which she filed suit. Relying on those facts, the panel affirmed the trial court's denial of defendants' motion to dismiss the complaint as time-barred.

Defendants filed a petition for certification, which we granted on the issue of the timeliness of plaintiff's complaint. Kendall v. Hoffman-LaRoche, Inc., 205 N.J. 99 (2011). We also granted leave to a number of organizations to appear as amici curiae: (1) New Jersey Lawsuit Reform Alliance (NJLRA) and Healthcare Institute of New Jersey (HINJ); (2) New Jersey Business and Industry Association, New Jersey State Chamber of Commerce, and Commerce and Industry Association of New Jersey; (3) Medical Society of New Jersey; and (4) New Jersey Association for Justice.

II.

Defendants argue that the Appellate Division's decision eviscerates the presumption of adequacy in the PLA and eradicates the carefully-developed limits that have been placed on the discovery rule by omitting consideration of the effect of constructive notice on claim accrual.

Kendall counters that the presumption of adequacy does not apply at all in discovery rule proceedings; that there was, in any event, sufficient evidence to rebut the presumption; and,

that the Appellate Division properly applied the discovery rule in determining that her action was not time-barred.

Amici, NJLRA and HINJ, argue that the decline in New Jersey's important pharmaceutical industry coincides with a rise in pharmaceutical tort litigation and that the presumption of adequacy should be dispositive, absent evidence of fraud.

Amici, the New Jersey Business and Industry Association, New Jersey State Chamber of Commerce, and Commerce Industry of America, contend that the Appellate Division's decision will have a negative impact on the State's business community, attract out-of-state plaintiffs, and foster a hostile legal environment for New Jersey businesses. Amicus, Medical Society of New Jersey, argues that Kendall's claim is barred by the statute of limitations and by classic discovery rule principles.

Amicus, New Jersey Association for Justice, contends that the PLA has no relevance to a statute of limitations analysis; that the presumption of adequacy need not be rebutted in such a proceeding; and that the touchstone of a Lopez hearing remains reasonableness.

III.

Although at common law there was no limit on the time in which a party could institute a legal action, Rothman v. Silber, 90 N.J. Super. 22, 28 (App. Div.) (citing Uscienski v. National Sugar Refining Co., 19 N.J. Misc. 240, 242 (C.P. 1941)), certif.

denied, 46 N.J. 538 (1966), statutes of limitations have since been adopted regarding all causes of action. At issue in this case is N.J.S.A. 2A:14-2(a), which provides that an action for "an injury to the person caused by the wrongful act, neglect or default of any person . . . shall be commenced within two years next after the cause of any such action shall have accrued . . . ."

Statutes of limitation are intended to

> penalize dilatoriness and serve as measures of repose. When a plaintiff knows or has reason to know that he has a cause of action against an identifiable defendant and voluntarily sleeps on his rights so long as to permit the customary period of limitations to expire, the pertinent considerations of individual justice as well as the broader considerations of repose, coincide to bar his action. Where, however, the plaintiff does not know or have reason to know that he has a cause of action against an identifiable defendant until after the normal period of limitations has expired, the considerations of individual justice and the considerations of repose are in conflict and other factors may fairly be brought into play.
>
> [Farrell v. Votator Div. of Chemetron Corp., 62 N.J. 111, 115 (1973) (citations omitted); Fernandi v. Strully, 35 N.J. 434, 438 (1961).]

Those considerations comprise the so-called "discovery rule," the goal of which is to

> avoid [the] harsh results that otherwise would flow from mechanical application of a statute of limitations. Accordingly, the

> doctrine postpones the accrual of a cause of action so long as a party reasonably is unaware either that he has been injured, or that the injury is due to the fault or neglect of an identifiable individual or entity. 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.
>
> [Caravaggio v. D'Agostini, 166 N.J. 237, 245 (2001) (citing Abboud v. Viscomi, 111 N.J. 56, 62-63 (1988) (citations and internal quotation marks omitted)).]

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[.]" 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)).

> Critical to the running of the statute is the injured party's awareness of the injury and the fault of another. 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) (citations omitted).]

Knowledge of fault and knowledge of injury may occur simultaneously:

> Fault is apparent, for example, where the wrong tooth is extracted during surgery, Tramutola v. Bortone, 118 N.J. Super. 503, 512-13, 288 A.2d 863 (App. Div. 1972), or a foreign object has been left within the body after an operation. See Fernandi, supra, 35 N.J. at 452, 173 A.2d 277 [(holding that period of limitations on a patient's negligence cause of action began to run when the patient knew or had reason to know about the foreign object left in her body)].
>
> [Martinez, supra, 163 N.J. at 53.]

However, where the relationship between plaintiff's injury and defendant's fault is not self-evident, it must be shown that a reasonable person, in plaintiff's circumstances, would have been aware of such fault in order to bar her from invoking the discovery rule. See Alfone v. Sarno, 139 N.J. Super. 518, 523-24 (App. Div.), certif. denied, 71 N.J. 498 (1976).

Thus,

> [i]n Lopez, supra, 62 N.J. at 271, 300 A.2d 563, for example, the plaintiff suffered from severe burns, pain, and nausea after undergoing radiation therapy following a radical mastectomy for breast cancer. Plaintiff's husband had previously been told by a physician that "this was not malpractice. This sometimes happens." Lopez v. Swyer, 115 N.J. Super. 237, 244, 279 A.2d 116 (App. Div. 1971). While Ms. Lopez was being treated for her symptoms by another doctor, she overheard him say to colleagues, "[a]nd there you see, gentlemen, what happens when the radiologist puts a patient on the table and goes out and has a cup of coffee." Lopez, supra, 62 N.J. at 271, 300 A.2d 563. The Appellate Division reversed the trial court's grant of summary judgment for the radiologist, and this Court

> affirmed. Although Ms. Lopez knew that her burns were caused by the radiation therapy, the record did not reveal that she knew or should have known, prior to overhearing the "cup of coffee" statement, of the causal connection between her physician's negligent treatment and her injury. Thus her complaint, filed slightly over five years after her injury, but within two years of the "cup of coffee" statement, was ruled timely.
>
> [Caravaggio, supra, 166 N.J. at 247.]

Similarly, in Lynch v. Rubacky, 85 N.J. 65, 67-68 (1981),

> plaintiff injured her ankle and was operated on by defendant. When she did not improve and suffered great pain and disability, the defendant continually assured her that her condition was due to the original injury and the healing process. It was not until after the statute of limitations expired that another physician suggested that plaintiff's problem was due to defendant's negligence. Id. at 69, 424 A.2d 1169. We held that "all of the factors militating against adequate knowledge of physician fault" were present in the case. Id. at 77, 424 A.2d 1169. Included were plaintiff's faith in defendant, his reassurances that the pain and swelling were part of the healing process, and the fact that a physician whom plaintiff later consulted did not suggest defendant's medical negligence until after the statute had run. We held her action to be timely.
>
> [Martinez, supra, 163 N.J. at 53-54.]

Likewise, in Caravaggio, plaintiff's femur-stabilization rod snapped and her surgeon, in good faith, blamed it on a structural defect in the rod. Subsequent metallurgical tests showed the rod was not defective. Plaintiff then sued the

surgeon who moved to dismiss the action as untimely. The motion was granted and the judgment affirmed. We reversed on the ground that plaintiff had no reason to doubt her doctor's assessment of the situation or his conclusion that there was a defect in the rod. Caravaggio, supra, 166 N.J. at 253; see also Gallagher v. Burdette-Tomlin Mem'l Hosp., 163 N.J. 38 (2000) (allowing plaintiff to amend claim after expiration of statute to include after-care physicians belatedly inculpated in adversary's expert report).

As those cases reveal, the discovery rule 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. Lopez, supra, 62 N.J. at 273-74. To be sure, legal and medical certainty are not required for a claim to accrue. See Lapka v. Porter Hayden Co., 162 N.J. 545, 555-56 (2000). Thus, a plaintiff need not be informed by an attorney that a viable cause of action exists, Burd v. New Jersey Telephone Company, 76 N.J. 284, 291 (1978), nor does a plaintiff need to understand the legal significance of the facts. See Lynch, supra, 85 N.J. at 73. Likewise, a plaintiff may not delay his filing until he obtains an expert to support his cause of action. Brizak v. Needle, 239 N.J. Super. 415, 429 (App. Div.), certif. denied, 122 N.J. 164 (1990). In cases in which 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. Vispisiano v. Ashland Chem. Co., 107 N.J. 416, 435 (1987). Temporal proximity of injury with exposure may be sufficient medical information; however, it is not dispositive. Compare Burd, supra, 76 N.J. at 292-93 with Vispisiano, supra, 107 N.J. at 436.

At a Lopez hearing, the burden is on the plaintiff seeking application of the discovery rule to establish that a reasonable person in her circumstances would not have been aware within the prescribed statutory period that she was injured through the fault of another. See Henry v. N.J. Dept. of Human Servs., 204 N.J. 320, 339 (2010) (citing Lopez, supra, 62 N.J. at 274-76). That is the backdrop for our inquiry.

IV.

The PLA, N.J.S.A. 2A:58C-1 to -11, was enacted as a remedial measure to limit the liability of manufacturers by establishing "clear rules with respect to certain matters . . . including certain principles under which liability is imposed and the standards and procedures for the award of punitive damages." N.J.S.A. 2A:58C-1(a). In particular, in enacting the PLA, the Legislature intended to reduce the burden on manufacturers of FDA-approved products resulting from products

liability litigation. Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 626 (2007).

The Act was not intended to codify all issues relating to product liability, N.J.S.A. 2A:58C-1(a), and basic common law principles of negligence and strict liability remain intact, except to the extent that the Act sets new limits on liability and punitive damages. See N.J.S.A. 2A:58C-8 to -11, and N.J.S.A. 2A:15-5.9 to -17.

Under the common law, "[a] product may be unsafe, and therefore defective, because of a failure to warn or an inadequate warning." Feldman v. Lederle Labs., 125 N.J. 117, 144 (1991) (citation omitted); see also Campos v. Firestone, 98 N.J. 198, 205 (1984) (recognizing that no warning, or an inadequate warning, renders a product defective). An adequate warning "includes the directions, communications, and information essential to make the use of a product safe[,]" Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 243 (1981), and reveals "the risks attendant on all foreseeable uses." Id. at 244. Generally, the adequacy of a warning is a jury question. Matthews v. Univ. Loft Co., 387 N.J. Super. 349, 357 (App. Div.), certif. denied, 188 N.J. 577 (2006). In that connection, N.J.S.A. 2A:58C-4 provides:

> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the

> product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. 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, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," . . . or the "Public Health Service Act," . . . a rebuttable presumption shall arise that the warning or instruction is adequate.
>
> [N.J.S.A. 2A:58C-4 (emphasis added).]

Compliance with FDA regulations provides compelling, although not absolute, evidence that a manufacturer satisfied its duty to warn about the dangers of its product. Perez v. Wyeth Labs. Inc., 161 N.J. 1, 24 (1999). Indeed, in Perez we created what can be denominated as a super-presumption: "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims[]"; only in the

"rare case[]" will damages be assessed against a manufacturer issuing FDA-approved warnings. Id. at 25; see also William A. Dreier, Liability for Drug Advertising, Warnings, and Frauds, 58 Rutgers L. Rev. 615, 616 (2006).[6]

V.

At the heart of this appeal is the question of what, if any, role the PLA's presumption of adequacy plays in the judicial analysis of whether plaintiff acted reasonably in delaying the filing of her suit. Defendants urge us to apply the "virtually dispositive" presumption as described in Perez. Kendall counters that the presumption does not apply at all in discovery rule proceedings and is intended solely for the liability phase of the case.

Each of those arguments proves too much. On the one hand, nothing in the language of the PLA or its legislative history suggests, even obliquely, an intention on the part of the drafters to alter our long-standing discovery-rule

[6] In Perez, we also recognized that a case in which the presumption is overcome might only warrant compensatory and not punitive damages, Perez, supra, 161 N.J. at 25, thereby suggesting that circumstances less egregious than deliberate concealment could overcome the presumption. See McDarby v. Merck & Co., Inc., 401 N.J. Super. 10 (App. Div. 2008) (holding defendant's economically-driven opposition to post-market regulatory process not "deliberate concealment or non-disclosure" but sufficient to overcome presumption of warning adequacy), certif. granted, 196 N.J. 597 (2008), certif. dismissed as improvidently granted, 200 N.J. 267 (2009). We need not resolve that issue here.

jurisprudence. Indeed, in its original 1987 form, the PLA did not even mention statutes of limitations. Later, in 1995, a single reference to the subject was added providing tolling of "the applicable statute of limitations" against a product manufacturer once a strict liability action against a seller is instituted. That is the sum and substance of reference to limitations of actions in the PLA. Moreover, nothing in the legislative history of the PLA suggests that, despite its silence regarding its effect on a statute of limitations, it was intended to apply to a timeliness analysis.

Further, in "rebalancing" the law in favor of manufacturers, N.J.S.A. 2A:58C-4 establishes that a product manufacturer "shall not be liable" for failure to warn if an "adequate warning" is given. Ibid. (emphasis added). It is that provision that is the source of the presumption of adequacy. It would thus be fair to say that, by its choice of language, the Legislature signaled that the presumption was only intended to be part of the ultimate liability calculus.

On the other hand, as the Appellate Division aptly noted: "it can be argued that the legislative desire to lessen a drug manufacturer's potential liability for using an FDA-sanctioned warning also would extend to protecting that same manufacturer from an open-ended burden of defending belatedly-filed product liability lawsuits." Further, the gravamen of N.J.S.A. 2A:58C-4

is that an FDA-approved label is presumably adequate to inform a reasonable person of the dangers of a product. Thus, there is something awry about the notion of barring that evidence altogether at a discovery rule hearing at which the very issue is when, in light of the warnings actually received by plaintiff, plaintiff knew or should have known of the dangers of the product.

We are accordingly satisfied, as was the Appellate Division, that a middle-of-the-road approach is justified. That approach permits the judge at a Lopez hearing to consider the presumption of adequacy. However, we see no warrant for viewing the presumption, in the Lopez setting, as a "virtually dispositive" super-presumption. Perez, supra, 161 N.J. at 25. Rather, it should be treated, as would any presumption in the ordinary course, as 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." Shim v. Rutgers, 191 N.J. 374, 386 (2007) (citing Ahn v. Kim, 145 N.J. 423, 439 (1996)). If, in the face of the evidence, reasonable people would differ regarding the presumed fact, the presumption will be overcome. See N.J.R.E. 301; Harvey v. Craw, 110 N.J. Super. 68, 73 (App. Div.), certif. denied, 56 N.J. 479 (1970). 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.

VI.

When that approach is adopted in this difficult case, the result remains that reached by the trial judge and the Appellate Division -- that Kendall's suit may proceed because the evidence not only overcame the presumption, but established that under all the circumstances, Kendall reasonably was unaware that defendants caused her injury until after December 21, 2003.

We reach that conclusion based on the facts, the most important of which are as follows: Kendall was originally prescribed Accutane, when she was twelve years old. At that time, her dermatologist did not warn her or her mother of the risk of IBD because he was not aware of its relationship to Accutane. She took four courses of the drug from 1997 through 1998, with no gastrointestinal symptoms whatsoever. When she later developed ulcerative colitis, a disease that waxes and wanes, her pediatric gastroenterologist did not know of a connection between Accutane and ulcerative colitis. In 2000, when Kendall returned to her dermatologist, he consulted with the gastroenterologist and together they agreed that she could be prescribed Accutane despite her prior bout with colitis.

Again, she did not experience gastrointestinal effects while on the drug.

In September 2003, Kendall returned to the dermatologist, who prescribed Accutane again. While on that sixth course of the drug, from September 2003 to January 2004, Kendall experienced the same side effects she had previously experienced and some increased diarrhea.

Kendall, who the trial judge found to be credible, said her doctors never advised her not to take Accutane or of the risks of IBD and that she would not have taken or continued the drug had they done so. The 2003 warning, which was focused on pregnancy and suicide, indicated that a patient should "stop taking Accutane" (emphasis added) if certain symptoms occurred, but did not mention IBD or colitis. Nor did the consent form Kendall signed. Indeed, she never received a warning which specifically mentioned IBD or ulcerative colitis.

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.

We take no position on whether the January and April 2004 lawyer's advertisements should have spurred Kendall to action. If they had, the December 2005 filing would be timely. Our conclusion is, like that of the Appellate Division -- that a reasonable person in Kendall's circumstances would not have known by December 2003 of the relationship between Accutane and her condition. As such, her December 2005 filing was timely.

VII.

The judgment of the Appellate Division is affirmed.

CHIEF JUSTICE RABNER and JUSTICES LaVECCHIA, ALBIN, and HOENS join in JUSTICE LONG's opinion. JUDGE WEFING (temporarily assigned), filed a separate, dissenting opinion. JUSTICE PATTERSON did not participate.

SUPREME COURT OF NEW JERSEY
A-73 September Term 2010
066802

KAMIE S. KENDALL,

Plaintiff-Respondent,

v.

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

Defendants-Appellants.

Judge Wefing (temporarily assigned), dissenting.

In New Jersey, actions for personal injuries must be commenced within two years of accrual of the cause of action. N.J.S.A. 2A:14-2. If the individual who wishes to commence such an action was a minor at the time the cause of action accrued, the period of limitations is extended until two years after the date the individual attains majority. N.J.S.A. 2A:14-21; Green v. Auerbach Chevrolet Corp., 127 N.J. 591, 592-93 (1992) (noting that although the Legislature did not amend N.J.S.A. 2A:14-21 at the time it reduced the age of majority from twenty-one to eighteen, the period of limitations within which to commence suit for injuries received as a minor is computed from the individual's eighteenth birthday).

Plaintiff Kamie Kendall was born on January 28, 1984. Her eighteenth birthday was on January 28, 2002. Her first course of Accutane treatment commenced in January 1997, and her last course commenced in September 2003. Pursuant to N.J.S.A. 2A:14-21, she had until January 28, 2004, to commence suit for any injuries she reasonably attributed to her use of Accutane while a minor.

My colleagues have determined, however, that her complaint, which was not filed until December 21, 2005, was timely. They reach this result by concluding that the various warnings included with Accutane over the period of her use, each of which was approved by the federal Food and Drug Administration (FDA), did not provide adequate warning to plaintiff of the risk of developing ulcerative colitis. Based upon what they perceive to be inadequate FDA-approved warnings, they conclude that plaintiff is entitled to a further tolling of the period of limitations under the discovery rule. See Lopez v. Swyer, 62 N.J. 267 (1973). I am unable to agree and therefore must dissent.

A review of the facts demonstrates that plaintiff had adequate notice of the risks of receiving Accutane. Plaintiff received her first prescription for Accutane from her treating dermatologist in January 1997 when she was twelve years old. At that time, the patient brochure that accompanied each

prescription included the following warnings regarding side-effects of the 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 ACCUTANE 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.

Plaintiff's physician testified that he gave plaintiff a copy of the brochure when he gave her the first Accutane prescription. Plaintiff signed a consent form acknowledging that she received and read the patient brochure. Those same warnings were repeated on the blister packaging that contained the individual Accutane pills that plaintiff received when she filled the prescription. In addition, the package insert for Accutane included the following statement:

> *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 FDA had approved the contents of the patient brochure, the blister packaging, and the package insert.[1]

Plaintiff's treating dermatologist gave her three more prescriptions for Accutane. She took the drug for three separate three-month periods: July to September 1997, February to April 1998, and July to September 1998. On each occasion, when she received the prescription from her physician and when she had it filled at the pharmacy, she received the same FDA-approved warnings. On each of the visits, as she had been on her first, she was accompanied by her mother.

Plaintiff began to suffer abdominal pain in approximately April 1998. In April 1999 she was hospitalized after experiencing a severe case of bloody diarrhea, abdominal pain, and cramping; and on April 14, 1999, her pediatric gastroenterologist diagnosed her as having severe ulcerative colitis. Thus, by 1999 plaintiff suffered symptoms, which were

[1] It is not immediately apparent from the record whether plaintiff received a package insert each time she had her prescriptions filled. There are two categories of package inserts: physician package inserts and patient package inserts. The examples contained in the record are not identified as to which category they belong.

included in the FDA-approved warnings that accompanied her receipt and use of Accutane.

Inflammatory bowel disease is a condition marked by chronic idiopathic inflammation of the small bowel and colon. Stedman's Medical Dictionary 414 (26th ed. 1995). It traditionally manifests itself as one of two diseases: Crohn's disease or ulcerative colitis. David B. Sachar & Aaron E. Walfish, Overview of Inflammatory Bowel Disease, The Merck Manual Home Health Handbook, Aug. 2006, http://www.merckmanuals.com/home/digestive_disorders/inflammatory_bowel_diseases_ibd/overview of_inflammatory_bowel_disease.html. The latter involves the chronic inflammation of the inner lining of the colon cells. Sachar & Walfish, Ulcerative Colitis, The Merck Manual, supra, http://www.merckmanuals.com/home/digestive_disorders/inflammatory_bowel_diseases_ibd/ulcerative_colitis.html. The symptoms of ulcerative colitis include frequent and often bloody bowel movements accompanied by cramping and abdominal pain, together with other symptoms. Ibid.

In October 2000, plaintiff returned to the physician who was treating her acne condition. He consulted with her pediatric gastroenterologist, who expressed no objection to plaintiff receiving another course of Accutane as long as plaintiff's liver enzymes were monitored. In December 2000,

plaintiff began her fifth course of Accutane. By that time, the package insert that accompanied the pills stated:

> *Inflammatory Bowel Disease:* Accutane has been associated with inflammatory bowel disease (including regional ileitis) 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 . . . .

The only modification to that portion of the package insert from its previous iteration was the deletion of the word "temporally," which had preceded the word "associated" in the earlier package inserts. She again received the patient brochure with its various warnings. The pills were again dispensed in a blister package that also restated the warnings. All of the warnings had been approved by the FDA.

In August 2003, more than a year and a half after turning eighteen, plaintiff again returned to her treating dermatologist for her acne. He decided to prescribe yet another course of Accutane treatment. By this time, the FDA had directed that the warnings that accompanied a prescription of Accutane be strengthened.

In connection with her 2003 prescription, plaintiff received an expanded patient booklet. It stated in pertinent part:

> 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 . . . . 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.

Plaintiff signed an acknowledgement that she received and read the information.

In addition, when she went to the pharmacy to have the prescription filled, she received a medication guide for Accutane. It stated in pertinent part:

> **What are the possible side effects of Accutane?**
>
> . . .
>
> **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, trouble swallowing or painful swallowing, new or worsening heartburn, diarrhea, rectal bleeding, yellowing of your skin or eyes, or dark urine.

In addition to the various warnings delivered to plaintiff over the course of her Accutane treatment, defendants also delivered warnings to physicians prescribing the drug. For example, some years prior to plaintiff's initial prescription, defendants sent a "Dear Doctor" letter to physicians informing them that ten patients who had received Accutane treatment "experienced gastrointestinal disorders characteristic of inflammatory bowel disease." The letter said that defendants would continue to monitor the matter. In 1998, defendants issued another "Dear Doctor" letter warning dermatologists of the importance of monitoring patients on Accutane for inflammatory bowel disease. Plaintiff's dermatologist received those letters.

Plaintiff suffered symptoms of ulcerative colitis with varying intensity from the time she was initially diagnosed with the disease in 1999. It is characteristic of ulcerative colitis that its symptoms will wax and wane over the course of time. The Merck Manual 307 (17th ed. 1999). She acknowledged that her symptoms intensified after completing a course of treatment with Accutane. Indeed, plaintiff's expert with respect to causation,

David B. Sachar, M.D., relied on the fact that her symptoms worsened after several courses of treatment in opining that Accutane was a cause of plaintiff's ulcerative colitis. Plaintiff also acknowledged that her diarrhea worsened with the 2003 treatment. Her symptoms progressively worsened and led to her decision in January 2006 to undergo a proctocolectomy.

In the face of the repeated FDA-approved warnings provided to plaintiff, the warnings provided to her physician, and the intensification of her symptoms, my colleagues have concluded that plaintiff was reasonably unaware by December 21, 2003, two years prior to the filing of her complaint, of a potential link between her ulcerative colitis and her use of Accutane. My colleagues stress that the material she received in 2003 did not use the terms inflammatory bowel disease or ulcerative colitis.

I cannot find that reasoning persuasive for several reasons. The 2003 material, in an effort to be more informative, refrained from diagnostic terms but clearly stated that an individual's intestines could be damaged and that an individual should stop taking the drug if he or she experienced diarrhea or rectal bleeding. Because plaintiff experienced both symptoms, she should have been aware of a potential link. See, e.g., Magistrini v. One Hour Martinizing Dry Cleaning, 109 F. Supp. 2d 306, 315 (D.N.J. 2000) (holding that manufacturer of dry cleaning solvent was required to warn that the substance was

carcinogenic rather than to warn of the risk of contracting a specific form of cancer). Further, plaintiff testified at the Lopez hearing that after receiving the diagnosis of ulcerative colitis in 1999, she engaged in research on the topic and knew that ulcerative colitis was a particular form of inflammatory bowel disease and was a medical term for damage to the bowels.

Plaintiff testified that she "skimmed" the material she received in 2003. At the beginning of the medication guide she received from the pharmacy in 2003, it noted the importance of a patient reviewing the entire document, even if the patient had received an earlier prescription for Accutane because the information may have changed in the interim. Plaintiff should not be relieved of having the information contained in that material imputed to her because she chose not to review it.

Further, I am unable to agree, for purposes of determining whether a complaint has been timely filed, that the statutory presumption contained in N.J.S.A. 2A:58C-4, which presumes FDA-approved labels are adequate, can be overcome by plaintiff's election not to review the material in which the warnings are set forth. Nor can I discern an analytical justification for according the statutory presumption set forth in N.J.S.A. 2A:58C-4 a different weight when the issue is timeliness of the filing of the complaint as opposed to the merits of the claim.

This Court recently recognized that the Legislature enacted N.J.S.A. 2A:58C-4 to "re-balance the law 'in favor of manufacturers.'" Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 623 (2007) (quoting William A. Dreier, N.J. Prods. Liab. & Toxic Torts Law § 15:4 (2007)). One of the underlying purposes of our product liability statute was "'to establish clear rules with respect to specific matters as to which the decisions of the courts in New Jersey have created uncertainty.'" Id. at 624 (quoting Senate Judiciary Committee, Statement to Senate Committee Substitute for S.B. No. 2805 at 1 (Mar. 23, 1987)). In my judgment, the approach adopted here by my colleagues does not further either of those legislative objectives.

As I noted at the outset, a cause of action accrues when a plaintiff knows or should know of a state of facts that possibly equates to a cause of action. The determination of when a cause of action accrues is a question of law for the court. Baird v. Am. Med. Optics, 155 N.J. 54, 65 (1998) (citing Fernandi v. Strully, 35 N.J. 434, 439 (1961)). "The discovery rule delays the accrual of a cause of action until 'the injured party discovers, or by an exercise of reasonable diligence and intelligence should have discovered that he may have a basis for an actionable claim.'" Id. at 66 (quoting Lopez, supra, 62 N.J. at 272). Medical certainty linking the harm and its cause is not the fulcrum for the analysis; rather, "reasonable medical

information" suffices. Vispisiano v. Ashland Chem. Co., 107 N.J. 416, 435 (1987). Certainly, all of the FDA-approved material provided to plaintiff has to be considered "reasonable medical information." Giving plaintiff the most generous reading of the material provided to her, I conclude that she knew or should have known, no later than her August 2003 receipt of yet another prescription for Accutane, of a potential link between her use of the medication and her continuing gastrointestinal problems.

I note that my colleagues "take no position" whether advertisements placed by lawyers in January and April 2004 "should have spurred Kendall to action." (See ante slip op. at 33). Kendall testified that the advertisements caused her to think for the first time that there might be a link between her use of Accutane and her intestinal problems. My colleagues' omission is entirely understandable in light of the fact that the advertisements contained less information than defendants had provided her over the years as she took the medication.

In my judgment, plaintiff's complaint was untimely and should have been dismissed.

SUPREME COURT OF NEW JERSEY

NO. A-73 SEPTEMBER TERM 2010

ON CERTIFICATION TO Appellate Division, Superior Court

KAMIE S. KENDALL,

Plaintiff-Respondent,

v.

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

Defendants-Appellants.

DECIDED February 27, 2012

Chief Justice Rabner PRESIDING

OPINION BY Justice Long

CONCURRING/DISSENTING OPINIONS BY

DISSENTING OPINION BY Judge Wefing (temporarily assigned)

CHECKLIST	AFFIRM	REVERSE
CHIEF JUSTICE RABNER	X	
JUSTICE LONG	X	
JUSTICE LaVECCHIA	X	
JUSTICE ALBIN	X	
JUSTICE HOENS	X	
JUSTICE PATTERSON	----------	----------
JUDGE WEFING (t/a)		X
TOTALS	5	1