Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Kendall v. Hoffman-LaRoche, Inc. – The Interplay Between the New Jersey Product Liability Act's Presumption of Adequacy for FDA-Approved Warnings and the Discovery Rule in Evaluating a Statute of Limitations Defense

In *Kendall v. Hoffman-LaRoche, Inc.*, No. A-73-2010, 2012 N.J. LEXIS 160 (N.J. Feb. 27, 2012), the New Jersey Supreme Court addressed the interplay between New Jersey's discovery rule, which tolls the statute of limitations until sufficient facts exist placing a reasonable person on notice that she has a cause of action against the defendant, and *N.J.S.A.* 2A:58C-4, the provision of the New Jersey Product Liability Act ("PLA") which establishes a presumption that FDA-approved warnings are adequate. The *Kendall* Court applied a "middle-of-the-road approach" - holding that for discovery rule purposes, the presumption of adequacy applies but can be overcome by evidence that despite the product's warnings, a reasonable person in plaintiff's situation would not have been aware that her injury was caused by the defendant's product.

Kendall involved a product liability lawsuit filed by plaintiff Kamie Kendall on December 21, 2005 against Hoffman-LaRoche ("Roche"). Plaintiff alleged that her use of Accutane caused her to develop ulcerative colitis. Accutane is a medication approved by the FDA for the treatment of recalcitrant nodular acne. Ulcerative colitis is a form of inflammatory bowel disease ("IBD") which can cause a multitude of gastrointestinal symptoms including diarrhea, bloody stool, abdominal pain and cramping, bloating, dehydration and anemia. Since 1983, the labeling and package insert for Accutane has contained language warning about the possible relationship between Accutane and IBD. Over the years, Roche strengthened its Accutane warnings through "Dear Doctor" letters, patient brochures, medication guides, informational videos and patient consent forms.

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Plaintiff was first prescribed Accutane in January 1997 when she was twelve years old. She received the patient brochure but her dermatologist did not mention the risk of IBD because he was unaware of the potential connection. Plaintiff took Accutane over four cycles during 1997 and 1998, and although she experienced several side effects, she never experienced any gastrointestinal symptoms. Approximately six months after her last Accutane treatment, plaintiff began to experience bloody diarrhea, abdominal pain and cramping. On April 14, 1999, her gastroenterologist diagnosed her with ulcerative colitis.

In October 2000, plaintiff's acne returned, and she visited her dermatologist who consulted with her gastroenterologist before prescribing Accutane again. Plaintiff's gastroenterologist had no objection to resuming Accutane treatment, so plaintiff began her fifth cycle of Accutane treatment in December 2000. Once again, plaintiff did not experience any gastrointestinal symptoms while taking the medication. Plaintiff took a sixth cycle of Accutane from August 2003 through January 2004 at which time she received another copy of the patient brochure, watched a video on the potential risks and benefits of the medication and signed a patient consent form. During this last cycle of Accutane treatment, however, plaintiff experienced increased episodes of diarrhea. In January 2004, plaintiff saw a magazine advertisement for Accutane which listed IBD as a potential side effect. Plaintiff alleged that this was the first time she suspected that her ulcerative colitis may have been caused by her Accutane use. In April 2004, plaintiff's grandmother saw an attorney advertisement linking Accutane to IBD. Plaintiff subsequently consulted with an attorney and filed her lawsuit on December 21, 2005, alleging that Roche failed to provide adequate warnings concerning the potential for Accutane to cause IBD.

After discovery was completed, Roche moved for summary judgment arguing that plaintiff's lawsuit was barred by New Jersey's two-year statute of limitations. Plaintiff asserted that the discovery rule applied and argued that a reasonable person in her position would not have suspected that Accutane was the cause of her ulcerative colitis before December 2003. Roche argued that even if the discovery rule applied, a reasonable person would have suspected that her IBD was potentially caused by Accutane by August 2003 at the latest (when plaintiff began her last treatment) because of the IBD warnings in the labeling, patient brochure and informational video for Accutane. After holding a *Lopez* hearing, the trial court denied the defendant's motion. The trial resulted in a jury verdict in plaintiff's favor.

Roche appealed the verdict to the Appellate Division and argued that the statute of limitations issue had been wrongly decided. The defendant argued that *N.J.S.A.*

2A:58C-4, which provides a presumption of adequacy to FDA-approved warnings, should have governed the statute of limitations issue. Essentially, Roche argued that because Accutane's IBD warnings are presumed to be adequate under *N.J.S.A.* 2A:58C-4, those warnings should be deemed sufficient to put a reasonable person on notice that her IBD may have potentially been caused by Accutane for purposes of applying the discovery rule. Although the Appellate Division agreed that the presumption of adequacy should play a role in analyzing whether a plaintiff's claim was timely under the discovery rule, the court held that in this particular case, plaintiff presented sufficient facts to rebut the presumption and demonstrate that a reasonable person in her position would not have linked her IBD to Accutane prior to December 2003.

Roche appealed the decision to the New Jersey Supreme Court. In a 5-1 decision, the Court affirmed. The Court explained that the discovery rule requires plaintiff to establish that a reasonable person in her position would not have been aware that she suffered an injury due to the fault of another during the statute of limitations period. The Court also discussed the history and purpose of the presumption of adequacy afforded to FDA-approved warnings by *N.J.S.A.* 2A:58C-4. With respect to the merits of a failure to warn claim, the Court agreed that the PLA created a "super-presumption" of sorts, and that absent evidence of deliberate concealment from the FDA, the defendant's compliance with FDA standards should be "virtually dispositive" of the failure to warn claim. The Court explained that the statute was designed to "reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." Although the Court did not find any supporting language in the PLA, the Court held that applying the presumption of adequacy in analyzing the discovery rule in a particular case would serve the purposes of the PLA because it would further shield manufacturers of FDA-approved products from "belatedly-filed product liability lawsuits." Therefore, the Court rejected plaintiff's argument that the presumption of adequacy should not play a role in analyzing the timeliness of plaintiff's suit under the discovery rule. On the other hand, the Court also rejected Roche's argument that the FDA's approval of the defendant's warning should be "virtually dispositive" of the statute of limitations issue.

In the end, the Court adopted a "middle-of-the-road approach." The Court held that the trial court must take into consideration the presumption of adequacy afforded to FDA-approved labels when conducting a *Lopez* hearing to determine whether plaintiff's suit is timely under the discovery rule. However, plaintiff can overcome the presumption of adequacy by presenting evidence "that a reasonable person in her

circumstances would not have been aware, within the prescribed statutory period, that she had been injured by defendant's product."

In applying this standard to Kendall's lawsuit, the Court held that the trial court and Appellate Division correctly determined that plaintiff's suit was timely filed. Although the Accutane warnings were approved by the FDA and entitled to a presumption of adequacy, the Court agreed that plaintiff presented sufficient evidence to rebut the presumption and establish that a reasonable person in her circumstances would not have been aware that her IBD may have been caused by her Accutane use prior to December 2003. Some of the facts on which the Court relied included: (1) during five of the six times plaintiff took Accutane she experienced no gastrointestinal problems; (2) neither of her physicians warned her specifically about the potential risk of IBD associated with Accutane; (3) plaintiff's dermatologist, with the approval of her gastroenterologist, prescribed her Accutane even after she had been diagnosed with IBD; (4) although the Accutane labeling and informational materials discussed the potential for severe and permanent gastrointestinal problems, they never used the diagnostic terms IBD or ulcerative colitis; and (5) the Accutane labeling and informational materials focused more on other potential risks, such as birth defects, suicide and depression, than on IBD. Ultimately, the Court concluded that the Accutane warnings were insufficient to cause plaintiff to doubt her physicians and suspect that her IBD was related to her Accutane use.

Judge Wefing (temporarily assigned from the Appellate Division) dissented on factual and legal grounds. With respect to the factual record, Judge Wefing pointed out that although the Accutane warnings did not use the diagnostic term IBD, they did advise users that the medication could damage their intestines and to discontinue use of the product if certain gastrointestinal symptoms appeared. Because plaintiff experienced the symptoms described in the label, she should have been aware of the potential link to Accutane and should not be relieved of having information in warnings imputed to her because she chose not to read them. Legally, Judge Wefing took issue with the majority's analytical justification for giving the presumption of adequacy different weight when the issue was timeliness rather than the merits of plaintiff's claim.

What Does This Case Mean?

The *Kendall* decision is another example of the Court's willingness to give plaintiffs the benefit of the doubt when it comes to the application of the statute of limitations. The Court's decision makes it fairly easy for plaintiffs to rebut the presumption of adequacy

when the timeliness of plaintiff's suit is at issue. For example, the Court stated that "[i]f, in the face of the evidence, reasonable people would differ regarding the presumed fact, the presumption will be overcome." On the other hand, the majority's description of the presumption of adequacy during the liability phase as a "super-presumption" was a welcome affirmation of the high bar a plaintiff must meet to successfully challenge an FDA-approved warning. Interestingly, the Court took no position on whether an attorney advertisement was sufficient to put plaintiff on notice of a potential claim. No doubt these and related issues will be litigated in the years to come. We will continue to monitor and report on any new developments in this important area.

If you would like additional information, please contact:

Beth S. Rose, Esq.
Chair, Product Liability Practice Group
brose@sillscummis.com | (973) 643-5877

Charles J. Falletta, Esq.
Member and Client Alert Editor, Product Liability Practice Group
cfalletta@sillscummis.com | (973) 643-5926

Vincent R. Lodato, Esq.
Associate, Product Liability Practice Group, assisted in the preparation of this Client Alert