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N.J. Determines to What Extent the Product Liability Act's Presumption of Adequacy Applies to Toll the Statute of Limitations

Pharmaceutical Law Update

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Statutes of limitations have traditionally served a critical function in the judicial system. Not only do they compel a person to file an action within reasonable time so that the opposing party has fair opportunity to defend the case, but they also protect against the litigation of stale claims. The discovery rule is an equitable measure that was crafted out of the desire to avoid the "harsh" effects that might otherwise result from a rigid application of a statute of limitations. In the context of drug and medical device litigation, the application of the discovery rule can be a delicate balance taking into consideration a number of factors including the information set forth in a product's label. The New Jersey Supreme Court's recent decision in *Kendall v. Hoffman-LaRoche, Inc*., No. A-73-2010, 2012 N.J. LEXIS 160 (N.J. Feb. 27, 2012), provides some important considerations for pharmaceutical manufacturers seeking to dismiss a suit as time-barred by analyzing the extent to which the New Jersey Product Liability Act's (PLA) presumption of adequacy might impact the tolling of a statute of limitations.

In *Kendall*, the plaintiff, Kamie Kendall, filed suit against Hoffman-LaRoche, Inc., and other associated entities (defendants) for injuries allegedly sustained through her use of Accutane, a prescription medication used to treat recalcitrant nodular acne. Kendall was first prescribed Accutane in January 1997. Between that time and 2003, she received six courses of the medication. Approximately seven months after her third course of Accutane, in April 1999, Kendall experienced a severe case of bloody diarrhea, abdominal pain and cramping, and was diagnosed with ulcerative colitis. Since approximately 1983, the defendants warned, to varying degrees, of the potential relationship between Accutane and inflammatory bowel disease (IBD.) Ulcerative colitis, the disease with which Kendall was diagnosed, is one of the ways that IBD is manifested. On December 21, 2005, Kendall filed suit against the defendants asserting a failure to warn theory of liability, namely, that the warnings she and her doctors received concerning Accutane were inadequate and failed to sufficiently disclose the risk contracting IBD.

At the close of discovery, the defendants filed a motion seeking to dismiss the complaint asserting that the suit was filed out of time. Pursuant to the procedures enunciated in *Lopez v. Swyer*, 62 N.J. 267 (1973), the trial court held an evidentiary hearing to determine whether the complaint was timely filed. At the close of the hearing, the trial judge denied the motion determining that by December 2003 the plaintiff did not know the potential correlation between her ulcerative colitis and Accutane, and that a reasonable person in her shoes similarly would not have known.

After the completion of trial, the defendants filed an appeal seeking reconsideration on the issue of whether the trial court erred in denying their motion to dismiss the suit as time-barred. In addition, they raised the issue whether the "presumption of adequacy" set forth in the PLA governs the statute of limitations analysis. Specifically, under New Jersey law, compliance with FDA regulations provides compelling evidence that a manufacturer satisfied its duty to warn about the dangers of its product. See *Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 24 (1999). Moreover, "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive" of failure-to-warn claims. Id. at 25. Based on that premise, the question became whether this statutory presumption plays a role in evaluating whether "a plaintiff supplied with those warnings acted reasonably in delaying the filing of his or her lawsuit." In considering the issue, the Appellate Division recognized that if "FDA-approved warnings that a consumer received 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" that manufacturer. Despite making this determination, the Appellate Division upheld the trial court's decision that the plaintiff's delay in filing suit beyond the applicable two-year statute of limitations was reasonable.

Thereafter, an appeal was filed with the New Jersey Supreme Court. After considering all of the issues, in a 5-1 decision, the Supreme Court affirmed the Appellate Division's decision, and found that the plaintiff could proceed because the evidence not only overcame the presumption, but established that under all the circumstances, the plaintiff was reasonably unaware that Accutane may have caused her injury until after December 21, 2003.

With respect to the PLA's presumption of adequacy, the Supreme Court determined that a "middle-of-the-road" approach was justified. In the *Lopez* setting, the presumption of adequacy is not a "virtually dispositive" super presumption. Instead, the presumption can be overcome by evidence that "'tends to' disprove the presumed fact, thereby raising a debatable question regarding the existence of the presumed fact." "If, in the face of the evidence, reasonable people would differ regarding the presumed fact, the presumption will be overcome." The burden, however, remains on a plaintiff to demonstrate "that a reasonable person in [his or] her circumstances would not have been aware, within the prescribed statutory period, that [he or] she had been injured" by the defendant's product.

The Supreme Court's decision in *Kendall* provides important considerations for drug and medical device manufacturers seeking to dismiss a claim based on the statute of limitations. Companies should evaluate the relationship between the PLA's presumption of adequacy and the discovery rule in developing a strategy for seeking to dismiss a case based on the statute of limitations, and take into consideration this relationship during the discovery process to help demonstrate that claims are untimely filed.

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