

The Interplay Between FDA Approval and Discovery Rule

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Adopting a middle-of-the-road approach that may raise more questions than it answers, the New Jersey Supreme Court has ruled that U.S. Food and Drug Administration (FDA) approval of drug and medical device warnings creates a presumption against application of the discovery rule to a defendant's otherwise-valid statute of limitations defense.

New Jersey's Product Liability Act (PLA) creates a rebuttable presumption that warnings or instructions approved by the FDA are adequate. Indeed, in discussing the impact of this presumption on the merits of a plaintiff's failure-to-warn claim, the state Supreme Court said in its 1999 opinion in *Perez v. Wyeth Labs Inc.* that "absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims."

In its Feb. 27, 2012, opinion in *Kendall v. Hoffman-La Roche Inc., et al.*, the Supreme Court reaffirmed its *Perez* language as "creat[ing] what can be denominated as a super-presumption."

At issue in *Kendall* was whether that super-presumption plays any role in defeating a plaintiff's attempt to assert the discovery rule in response to a defendant's statute of limitations argument.

The plaintiff in *Kendall* began taking the acne medication Accutane in 1997, when she was 12 years old. As a minor, the running of the plaintiff's statute of limitations was tolled until she turned 18 in 2002. The plaintiff received additional courses of Accutane treatment in 1998, 2000 and finally in September 2003.

In December 2005, the plaintiff filed suit against the manufacturer, claiming that Accutane caused the plaintiff to develop ulcerative colitis, a permanent bowel disease.

The defendant argued that the plaintiff's claim was time-barred under New Jersey's two-year statute of limitations because the suit was filed three years after the plaintiff turned 18 and more than two years after her September 2003 treatment, which included what the defendant claimed were adequate, FDA-approved warnings.

The trial court held a Lopez hearing and determined that the discovery rule tolled the statute of limitations because a reasonable person in the plaintiff's circumstances would not have known about the alleged connection between Accutane and the plaintiff's alleged injury.

On appeal, the manufacturer argued for the first time that the PLA's presumption of adequacy should govern the limitations issue. In other words, if the label is sufficient to warn the plaintiff adequately of the product's risks, it certainly is sufficient to put the plaintiff on notice of a potential claim. The Appellate Division held that while the presumption generally applies to the limitations analysis, the facts in *Kendall's* case were sufficient to overcome the presumption.

Before the Supreme Court of New Jersey, the manufacturer argued that the "virtually dispositive" super-presumption established in *Perez* and applicable to the merits of the claim should apply with equal force to the limitations issue.

Conversely, the plaintiff argued that the presumption should not apply at all in discovery rule proceedings and instead should be limited to the liability phase.

The Supreme Court found that both arguments went too far. Instead, it adopted a "middle-of-the-road approach," permitting judges in Lopez hearings to consider the presumption, but allowing plaintiffs to overcome it with evidence showing that a reasonable person under the same circumstances would not have been aware of the claim within the statutory period.

Although it answers and attempts to clarify an important legal question, it is not clear that the *Kendall* opinion will have

much practical impact on Lopez hearings in drug and medical device cases. While the court did hold that the PLA's presumption of adequacy applies to plaintiffs asserting the discovery rule, it specifically held that it did not apply with the virtually dispositive, super-presumption force articulated in Perez.

Indeed, as a practical matter, the standard that the court set for overcoming the presumption is identical to the existing standard for satisfying the discovery rule, i.e., whether a reasonable person in the plaintiff's circumstances would have been aware of the claim within the statutory period.

Nonetheless, defendants should be sure to include a robust discussion of the PLA's presumption of adequacy and its underlying rationale as part of their limitations arguments in New Jersey.

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