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A legal update from Dechert's Product Liability and Mass Torts Group

New Jersey Supreme Court Confirms "Super Presumption" of FDA Label

Yesterday, the New Jersey Supreme Court decided the case of *Kendall v. Hoffman-LaRoche, Inc.*, A-73-2010 (066802), in which it held that plaintiff's case was not barred by New Jersey's two-year statute of limitations. While the ultimate ruling was in plaintiff's favor it is also narrow in scope and limited to the particular facts of the case. The underlying analysis of New Jersey's presumption of adequacy for FDA-approved warnings, however, has much broader implications, because it presents an unqualified endorsement of the proposition that New Jersey's presumption of adequacy as to FDA labels is "virtually dispositive" of failure-to-warn claims, and, indeed, a "super presumption."

The case involved the prescription drug Accutane. Plaintiff was first prescribed Accutane in 1997 when she was 12 years old and was prescribed the drug intermittently over the next seven years. In 1999, plaintiff was diagnosed with ulcerative colitis (also known as inflammatory bowel disease (IBD)), a condition which can be treated but is permanent. *Slip op.* at 9-13. The entire time plaintiff was prescribed Accutane, the FDA-approved label accompanying the drug contained a warning of the possible link between Accutane and IBD. *Slip op.* at 6-9. Plaintiff testified that in January 2004 she saw a lawyer advertisement discussing the risks associated with Accutane with IBD and began to think it may have caused her IBD. *Slip op.* at 13. She filed this lawsuit on December 21, 2005.

At the trial level, defendant moved to dismiss the case arguing that the statute of limitations had expired. Following a hearing on the issue, the trial court ruled that plaintiff's claim was not time-barred. A subsequent jury trial resulted in a plaintiff verdict which the defendant appealed on several grounds, including that the case was time-barred. While the Appellate Division reversed the award on evidentiary grounds, it also held that the action was timely. *Slip op.* at 2-3. This was the sole issue before the New Jersey Supreme Court.

More specifically, the question as framed by the court was "what, if any, role the [Product Liability Act]'s presumption of adequacy plays in the judicial analysis of whether plaintiff acted reasonably in delaying the filing of her suit." *Slip op.* at 28. In other words, should an FDA-approved warning that is presumed adequate to satisfy a manufacturer's duty to warn, also be presumed adequate to put a plaintiff on notice to satisfy the discovery rule for purposes of the statute of limitations. In answering that question, the court first examined the presumption itself, which states:

> 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 . . . . 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 . . . a rebuttable presumption shall arise that the warning or instruction is adequate.

N.J.S.A. 2A:58C-4 (*see slip op.* at 26-27). Reaffirming its prior decision in *Perez v. Wyeth Labs, Inc.*, 161 N.J. 1 (1999), the *Kendall* court called this a "super-presumption":

> 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[ ].

Slip op. at 27. The Court dropped a footnote to the effect that the presumption might be overcome by evidence other than "deliberate concealment," citing to the Appellate Division's decision in *McDarby v. Merck*, where the court construed the evidence as showing post-market, economically driven manipulation of information to a level sufficient to overcome the presumption. The footnote further reaffirms the virtual conclusiveness of the presumption, maintaining its conclusiveness save in circumstances perceived as relatively "egregious" and going to the very integrity of the FDA regulatory process.

The *Kendall* court next turned to the issue of the application of the presumption in statute of limitations proceedings, rejecting plaintiff's position that it was irrelevant:

> 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.

Slip op. at 29-30. Distinguishing the applicability and effect of the presumption at the liability phase, the court opted for a "middle-of-the-road" approach, allowing consideration of the presumption during hearings on statute of limitations but not giving it the "virtually dispositive super-presumption" status it affords during the liability phase. *Slip op.* at 30.

Applying that approach to the particular facts of this case, the court concluded, as did the trial and Appellate Division, that plaintiff was reasonably unaware of the link between her alleged injuries and Accutane such that her claims were not time-barred. The court's primary focus was on the fact that plaintiff was a minor for most of the time that she was prescribed Accutane (she was 12 years old when first prescribed, her prescriber did not warn her or her mother of the risk of IBD, her pediatric gastroenterologist was unaware of the link) and that was she prescribed Accutane after being diagnosed with IBD. *Slip op.* at 31. In a well-reasoned dissent on this limited factual issue, Judge Wefing (temporarily assigned) cogently reasoned that the statute of limitations should, therefore, have run from the date plaintiff reached the age of majority, and should have barred this action nonetheless.

Although one could disagree with the majority's ultimate ruling on the merits in this narrow, fact-specific opinion, it is difficult to disagree with its broad and ringing reaffirmation of *Perez*, with its designation of the appellation, "super-presumption", to the presumption of adequacy for FDA-approved warning labels in the liability phase, and with its reminder that "only in the 'rare case[ ]' will damages be assessed against a manufacturer issuing FDA-approved warnings." *Slip op.* at 28.

Practice group contacts

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