NJ Supreme Court Issues Another Landmark Decision in In re Accutane, this Time Regarding Choice-of-Law and the Presumption of Adequacy for FDA-Approved Warnings

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Nearly two months to the day after the New Jersey Supreme Court issued a landmark decision in the *In re Accutane*® Litigation incorporating the *Daubert* factors into New Jersey law, the court issued another major decision in the same litigation that left no doubt about the strength of the presumption of adequacy for FDA-approved warnings in the New Jersey Products Liability Act (PLA), and applied New Jersey law on the issue of warning adequacy, rather than the laws of plaintiffs' home states, which had been typical in multicounty products liability litigation.

About the Case

In *In re Accutane*, the trial court granted summary judgment for Roche under New Jersey law in 532 cases in which plaintiffs alleged that Accutane caused their inflammatory bowel disease (IBD) and that Roche failed to provide adequate warnings regarding the known risks of that medication. (Slip op. at 2.) Only 18 of the 532 plaintiffs were New Jersey residents, and the remaining 514 were from 44 other jurisdictions. (Id. at 2.) The Appellate Division reversed, and the New Jersey Supreme Court granted Roche's petition for certification. The two issues before the court were (1) "what law governs whether Roche's label warnings were adequate – the law of each of the 45 jurisdictions where plaintiffs were prescribed Accutane or the law of New Jersey where the 532 cases are consolidated for MCL purposes"; and (2) "the adequacy of the label warnings for the period after April 2002." (Id.) Natalie H. Mantell was counsel of record and a member of Roche's litigation team. Edward J. Fanning, Jr. and David R. Kott represented The HealthCare Institute of New Jersey, co-authoring the amicus curiae brief which Ed Fanning argued before the state Supreme Court.

Although many medicines have only a single physician label or package insert containing risk information, Roche had generated a variety of warning materials for physicians, pharmacists and patients related to Accutane, all of which were FDA-approved: (1) a physician package insert, (2) a Best Practices Guide, (3) a Patient Safety Packet and attached informed consent form, (4) a Medication Guide, and (5) the medicine's blister packaging. All of these materials warned of a risk of IBD in medical terminology or lay language. (Id. at 9-13).

If New Jersey law governed the adequacy issue, Roche would have been entitled to a strong presumption that its FDA-approved warnings were adequate as a matter of law. Indeed, the PLA contains a rebuttable presumption of adequacy when a manufacturer's warnings are approved or prescribed by the Food and Drug Administration (FDA), which the state

Supreme Court has previously described as "virtually dispositive" and a "super presumption." N.J.S.A. 2A:58C-4; Rowe v. Hoffmann-La Roche, Inc., 189 N.J. 615, 625-26 (2007); Kendall v. Hoffmann-La Roche, Inc., 209 N.J. 173, 195 (2012). If the laws of each of the 45 jurisdictions applied, however, the PLA's presumption of adequacy would not govern every claim and the standard would vary by state. (See In re Accutane, slip op. at 35).

In analyzing choice-of-law under the most significant relationship test set forth in Camp Jaycee, and the Restatement (Second) of Conflicts of Laws §§ 145, 146 and 6, the New Jersey Supreme Court found that weighing the § 145 contacts yielded mixed results (id. at 40), and emphasized the importance of two § 6 factors to this MCL matter: § 6(f) ("certainty, predictability, and uniformity of result") and § 6(g) ("ease in the determination and application of the law to be applied"). (Id. at 44.) The state Supreme Court noted that applying one state's law on the issue of adequacy to all 532 cases at issue in this MCL appeal "will ensure predictable and uniform results" (id.), and stated, "[t]here can be no question that administrative ease and efficiency favor the application of New Jersey's PLA," (id. at 45). Roche's status as a New Jersey-based corporation, which manufactured and labeled Accutane in New Jersey, also influenced the state Supreme Court's decision. (Id. at 2, 40.) Consequently, the PLA applied to all 532 cases. (Id. at 46.)

Turning to the merits, the court set forth the standards for overcoming the PLA's rebuttable presumption of adequacy. It reiterated the two existing pathways for overcoming the presumption: (1) establishing "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" from the FDA (id. at 56 (citing Perez v. Wyeth Labs., Inc., 161 N.J. 1, 25 (1999)); or (2) proving "economically driven manipulation of the post-market regulatory process." (Id. at 58 (citing McDarby v. Merck & Co., 401 N.J. Super. 10, 63 (App. Div. 2008).) The state Supreme Court, however, added a third pathway for overcoming the presumption that had not yet been articulated in any New Jersey case law – a plaintiff can rebut the presumption if he or she "presents clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the use of the drug and 'a clinically significant hazard' and that the manufacturer failed to update the label accordingly." (Id. at 62 (citing 21 C.F.R. §§ 201.57(c). 314.70(c)).)

Critically, the New Jersey Supreme Court emphasized the heightened nature of the clear and convincing evidentiary standard, and specifically included the definition contained in the Model (Civil) Jury Charges: "[I]t is evidence so clear, direct, weighty in terms of quality, and convincing as to cause [one] to come to a clear conviction of the truth of the precise facts in issue." (Id. at 62 (quoting N.J. Model Civil Jury Charges 1.19).)

In establishing this elevated hurdle for plaintiffs to overcome, the New Jersey Supreme Court acknowledged the preeminent role of the FDA in regulating drugs and medical devices. (Id. at 48.) Indeed, the court spent considerable time detailing the federal regulations that govern a pharmaceutical company's New Drug Application, (id. at 49-54), and made clear that its decision incorporated the "general directive that federal regulations are of the utmost significance in determining whether 'a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its products,'" (id. at 59 (quoting Perez, 161 N.J. at 24).)

Applying the PLA to the facts of these cases, the state Supreme Court found that "plaintiffs have failed to show any of those bases for overcoming the presumption of adequacy" (id. at 65), and Roche's warnings were therefore adequate as a matter of law. The court rejected plaintiffs' arguments that three company documents overcame the presumption and entitled them to trial. The first was a 1994 memorandum in which a Roche physician noted that Accutane "may induce or aggravate a preexisting colitis." (Id. at 67.) The second was another internal document where colitis was identified as a "possible" side effect of the medication. (Id. at 67) Finally, plaintiffs pointed to a 2000 regulatory report in which a physician stated that Accutane "has been found to be causally associated with inflammatory bowel disease, including colitis." (Id. at 68.) As to the first two documents, the state Supreme Court found that the memoranda were "far from clear and convincing evidence that the language 'Accutane has been associated with [IBD]' was an inadequate warning." (Id. at 67.) The court similarly found the 2000 regulatory report insufficient; the statement was made by a single physician while analyzing a single patient's medical history, and there was nothing to suggest "a consensus by other Roche physicians or employees about a causal connection between Accutane usage and IBD." (Id. at 68.) Finally, the New Jersey Supreme Court found no evidence that Roche deliberately withheld information from the FDA or that it engaged in economically driven manipulation of the regulatory process. (Id. at 68-69.)

In light of these findings, the New Jersey Supreme Court dismissed all 532 cases. (Id. at 70.)

What Happens Now?

The decision sets a very high standard for overcoming the presumption of adequacy for FDA-approved warnings, providing significant support for pharmaceutical and medical device manufacturers defending against failure-to-warn claims in New Jersey. Indeed, the court reaffirmed the long-standing principle that FDA review and approval of a product's warnings is virtually dispositive of whether the warnings are adequate as a matter of law. Further, when faced with a complex choice-of-law issue, the state's high court paid particular attention to efficiency and uniform results in the MCL context.

As always, McCarter attorneys are happy to answer any inquiries about the state Supreme Court's decision and, more broadly, its use in the defense of products liability and other litigation in New Jersey. Please contact Edward J. Fanning, Jr., David R. Kott, Natalie H. Mantell, or the McCarter attorneys with whom you normally work for more information or to discuss how this decision applies to your matters.