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Presumption-of-Adequacy Defense Is Clarified and Reinforced

December 7, 2011 by James J. Ferrelli and Paul M. da Costa

On Sept. 29, the Appellate Division took a significant step forward in clarifying and reinforcing the presumption-of-adequacy defense provided to manufacturers of prescription drugs under the New Jersey Product Liability Act (PLA). N.J.S.A.2A:58C-1 to -11. In *Bailey v. Wyeth, et al.*, the court affirmed summary judgment in favor of the defendant drug manufacturers, dismissing the plaintiffs' claims for violations of the PLA. Those claims sought recovery for personal injuries based on allegations that the plaintiffs had sustained breast cancer from ingesting hormone replacement therapy (HRT) drugs. The plaintiffs asserted that the drug manufacturers failed to provide adequate warnings on the risks of breast cancer allegedly associated with HRT.

Under the PLA, a pharmaceutical company "that communicates adequate information on the dangers and safe use of the [prescription drug] product, ... taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician" will not be liable for failure to warn. N.J.S.A.2A:58C-4. Beyond this general statutory language, the PLA provides specific deference to the federal Food and Drug Administration's (FDA) determination of appropriate labeling for prescription drugs, by including a rebuttable presumption of adequacy in the statute. In other words,

companies that comply with FDA labeling regulations are granted a rebuttable presumption that their labeling is adequate as a matter of law. N.J.S.A.2A:58C-4.

The PLA expressly states: "If the warning or instruction given in connection with a drug ... has been approved or prescribed by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act,' ... a rebuttable presumption shall arise that the warning or instruction is adequate." N.J.S.A.2A:58C-4.

There was no dispute in *Bailey* that the PLA provides a rebuttable presumption of adequacy based on FDA approval of drug labeling. Rather, the issue in *Bailey* was the effect and operation of the rebuttable presumption under the PLA, as applied to the facts of the case.

The plaintiffs in *Bailey* appealed the trial court's finding that the presumption of adequacy applied such that the HRT drugs' warnings were adequate as a matter of law. They contended that the presumption could not apply prior to 1995 "because the combined use of estrogen and progesterone constituted an offlabel use of the drugs." *Bailey v. Wyeth, Inc., et al.*, No. L-0999-06-MT (App. Div., p. 4, Sept. 29, 2011). Moreover, they argued that the trial court misconstrued the controlling case law regarding the application of the presumption of adequacy under the PLA.

The Appellate Division, however, affirmed substantially on the basis of "the well-considered and exhaustive opinion of Judge Happas."

On the defendant drug manufacturers' motions for summary judgment, the plaintiffs did not disagree that the PLA afforded the defendant drug manufacturers a rebuttable presumption of adequacy. Rather, they asserted that the presumption of adequacy "follows N.J. [Rule of Evidence] 301, whereby a plaintiff can rebut the presumption by showing some evidence tending to disprove the adequacy." The plaintiffs also contended that once they established there was some evidence tending to disprove the

adequacy of the drug label, the presumption would become moot, thereby "leaving them with the burden of proving the label's inadequacy."

On the other hand, the defendants contended that N.J.R.E. 301 does not "purport to identify the substantive evidence required to overcome the presumption of adequacy under the PLA. Therefore, plaintiffs' reliance on expert opinions that defendants' warning should have said something different is misplaced because those opinions are not based on the evidentiary predicate required to overcome the presumption of adequacy."

In granting the defendants' summary judgment motions, the trial court emphasized that a plaintiff must proffer certain types of evidence demonstrating intentional misconduct by a defendant in order to rebut the presumption of adequacy. The court explained that this principle is rooted in three New Jersey cases: *Perez v. Wyeth Lab., Inc.*, 161 N.J. 1, 24 (1999); *Rowe v. Hoffmann-LaRoche, Inc.*, 189 N.J. 615, 626 (2007); and *McDarby v. Merck*, 401 N.J. Super. 10, 63 (App. Div. 2008). These cases establish that the evidence necessary to rebut the presumption of adequacy must establish one of two exceptions:

- deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects (the "*Perez/Rowe exception*") or
- manipulation of the postmarket regulatory process (the "*McDarby exception*").

Among the plaintiffs' contentions were that the drug manufacturer should have done more to study the risks of combining the hormones estrogen and progesterone, studied the risk of breast cancer following increased use of the combined hormones and conducted additional studies. The court rejected this argument as too open-ended, as well as inconsistent with both the PLA and prior case law.

The court stressed that if it were to accept the plaintiffs' theory that the defendant drug manufacturers:

failed to test before filing its [new drug application], then in any failure to warn case, the presumption of adequacy accorded an FDA-approved drug labeling could be nullified by a plaintiff contending that the FDA would have approved a different warning had the defendant manufacturer done additional tests before filing its [new drug application].

Likewise, the court rejected the argument that evidence of a label's being strengthened following FDA approval was sufficient to rebut the presumption of adequacy. In particular, the court noted that inherent in the drug approval process is "the expectation that warnings will be revised and often strengthened over time." The court could not conclude that the legislature was oblivious to the fact that an approved drug's label could, and likely would, be strengthened the longer it is in the marketplace.

Additionally, the plaintiffs asserted that post-market regulatory manipulation was evidenced by (1) representations in the labeling that the manufacturer allegedly knew to be untrue, (2) alleged minimization and discounting of studies showing an increased risk of breast cancer, and (3) the manufacturers' involvement in "ghost writing" articles. The court determined such evidence was insufficient to establish intentional misconduct. Rather, the documentary evidence revealed that "the FDA actively exercised its regulatory authority and took prompt and effective action" in response to information and studies submitted to it.

With respect to purported "ghost written" medical articles, there was no dispute that the articles were subjected to "a rigorous peer review process and were factually and medically sound." Further, the court found that the FDA was well aware of the off-label use of the products, and the products' off-label prescription and usage did not rebut the statutory presumption. In sum, the court granted the defendant drug manufacturers' motions for summary judgment after concluding that the plaintiffs had not presented compelling evidence that would enable the presumption of adequacy to be rebutted.

In addition to the presumption-of-adequacy defense, *Bailey* also reaffirmed the expansive scope of the PLA, holding that the plaintiffs' Consumer Fraud Act, fraudulent-

misrepresentation and negligent-misrepresentation claims were subsumed under the PLA. Quoting the Supreme Court's opinion in Sinclair v. Merck & Co., 195 N.J. 51, 66 (2008), the court reaffirmed that "despite the broad reach [it] give[s] to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product."

The *Bailey* decision solidifies the presumption-of-adequacy defense, which defendant drug manufacturers are likely to employ in all failure-to-warn cases involving a prescription drug approved by the FDA. Consequently, this decision appears to be a significant setback for plaintiffs seeking to bring failure-to-warn claims against drug companies in New Jersey.

Nevertheless, *Bailey* does not signal an end of all pharmaceutical products liability litigation in New Jersey. The court went to great lengths to distinguish the case from *McDarby*, noting that the FDA had been actively involved in the labeling and monitoring of the HRT drugs at issue "for several decades," and was well-informed of "the prevalent practice" of off-label prescriptions of HRT. The court also stressed that the risk of breast cancer was not "newly discovered" after FDA approval of the drugs, but was reflected previously in worldwide medical literature. Finally, the court found that the FDA remained "actively involved in regulating, monitoring, and requesting changes in the labeling" of HRT drugs, and there was no evidence that the defendants actively sought to dilute the labeling or intentionally withheld any risk information from the FDA.

Following *Bailey*, the availability of the presumption of adequacy as a defense will continue to be a highly fact-intensive inquiry. Extensive and detailed fact discovery will likely be a prerequisite to a summary-judgment motion based on the presumption of adequacy.

Therefore, both plaintiffs and defendant drug manufacturers should be prepared to engage in exhaustive fact discovery and should prepare their clients accordingly. Discovery will focus on facts pertinent to the two categories of intentional misconduct identified by Perez and its progeny: the drug manufacturer's deliberate concealment or

failure to disclose after-acquired knowledge of harmful effects, and the drug manufacturer's "economically-driven manipulation of the post-market regulatory process."

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