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Pharmaceutical/Medical Device Litigation Update

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NEW JERSEY TRIAL COURT DISMISSES HORMONE THERAPY “FAILURE-TO-WARN” CASES, AFFIRMING THE IMPORTANCE OF NEW JERSEY’S PRESUMPTION OF ADEQUACY FOR FDA-APPROVED LABELING¹

In another win for pharmaceutical manufacturers, a New Jersey Superior Court judge recently granted summary judgment in two bellwether hormone replacement therapy (“HRT”) failure-to-warn cases.²

The trial court rejected plaintiffs’ argument that New Jersey’s statutory presumption of adequacy for FDA-approved warnings should be treated in the same way that most rebuttable presumptions are treated under New Jersey Rule of Evidence 301 – that is, once plaintiffs show some rebuttal evidence, the presumption vanishes and plaintiffs are left to prove that defendants’ warning was inadequate. Instead, the court held that the presumption of adequacy is dispositive with only two exceptions, neither of which was met here. The court determined that the presumption can be overcome only if (1) plaintiff has provided compelling evidence of the pharmaceutical manufacturer’s deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects (“Perez/Rowe exception”),³ or (2) if the pharmaceutical manufacturer is found to have manipulated the post-market regulatory process (“McDarby exception”).⁴

The court’s decision validates the oft-made, but never before established, defense argument that the presumption of adequacy is stronger than traditional “bursting bubble” presumptions.

¹ N.J.S.A. 2A:58C-4 specifically provides: 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.”

² The court decided *Bailey v. Wyeth Inc. et al.*, MID-L-0999-06 MT, *slip op.* (N.J. Law Div. July 11, 2008). and a companion case, *Deboard v. Wyeth, et al.*, MID-L-1147-06-MT.

³ “[f]or all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive” of a failure-to-warn claim. *Perez v. Wyeth Lab., Inc.*, 161 N.J. 1, 25 (1999); “[a]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling.” *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 626 (2007). Plaintiff’s claims for fraud and misrepresentation, negligent misrepresentation and violations of the New Jersey Consumer Fraud Act were also dismissed.

⁴ In *McDarby v. Merck*, 401 N.J. Super. 10 (App. Div. 2008), the Appellate Division created a new exception to the presumption of adequacy, holding that a pharmaceutical company’s “economically-driven manipulation of the post-market regulatory process” was an additional basis for overcoming it.

Plaintiffs claimed they developed breast cancer due to their use of Prempro[™] and Premarin,[®] hormone therapy products marketed by Wyeth, and Provera,[®] a progestin product marketed by Pharmacia & Upjohn Company.⁵ The court held that plaintiffs' allegation that the defendants did not warn of the risk of breast cancer failed as a matter of law because (1) the FDA was well aware of the risk of breast cancer, (2) Wyeth followed all FDA directions concerning labeling, and (3) plaintiffs did not present "substantial evidence" that defendants manipulated the post-market regulatory process. Absent such proof, plaintiffs could not overcome the rebuttable presumption of adequacy in the New Jersey Product Liability Act ("NJPLA").

The court also rejected plaintiffs' claim that Wyeth could be liable for not conducting pre-market testing of Prempro,[™] finding that this failure did not constitute "substantial evidence" sufficient to overcome the presumption of adequacy. The court noted that, if it were to accept plaintiffs' theory that Wyeth could be held liable for not conducting additional testing before filing its New Drug Application ("NDA"), then in any failure-to-warn case, the presumption of adequacy accorded FDA-approved drug labeling could be nullified simply by a plaintiff's contention that the FDA would have approved a different warning had the defendant manufacturer conducted additional tests.

The court noted that "[t]he FDA has been actively involved in the labeling and monitoring of Premarin, Provera and Prempro for several decades" and that the "FDA utilized a comprehensive and scientific process to decide whether to approve Prempro and/or change the labeling or approve additional indications for Premarin and Provera." It held that the FDA's decision not to include a more specific breast cancer warning "was both deliberate and informed. Any flaws in the FDA process are the responsibility of the United States Congress and the executive branch to correct, as they are in the best position to evaluate the pharmaceutical regulatory process."

The court also found that there was inadequate proof that defendants diluted the FDA warnings or that "ghost writing articles" on the efficacy of the drugs constituted post-market manipulation intended to delay the implementation of a different warning.

Conclusion

This pro-defense decision comes close on the heels of several favorable decisions by the New Jersey Appellate Division and the New Jersey Supreme Court that have breathed new life into the NJPLA and re-affirmed its statutory purposes – to "re-balance the law 'in favor of manufacturers,'" *Rowe v. Hoffman La Roche*, 189 N.J. 615, 623 (2007), and to "limit the expansion of products liability law by creating absolute defenses and rebuttable presumptions of non-liability." *Shackil v. Lederle Labs.*, 116 N.J. 155, 187 (1989); *See also Sinclair v. Merck*, 195 N.J. 51 (2008); *In re Lead Paint Litigation*, 191 N.J. 405 (2007); *McDarby v. Merck*, 401 N.J. Super. 10 (App. Div. 2008).

⁵ A division of Pfizer Inc.

For further discussion of these significant decisions, please refer to earlier Goldberg Segalla LLP publications, available at www.goldbergsegalla.com/newpub.php

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