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N.J. Hormone Replacement Drug Suits Dismissed Under Product Liability Act

By Mary Pat Gallagher

The fate of 168 New Jersey suits against the makers of hormone replacement drugs has been thrown into doubt with the summary dismissal of the first two of the cases slated for trial.

Superior Court Judge Jamie Happas, the designated judge for all N.J. cases alleging hormone replacement therapy (HRT) drugs caused breast cancer, ruled July 11 that the state Products Liability Act's rebuttable presumption of adequate labeling applied and that the plaintiffs failed to surmount it.

She also dismissed the other counts, violation of the New Jersey Consumer Fraud Act and common-law claims of fraudulent and negligent misrepresentation, finding them subsumed by the Products Liability Act claims.

The dismissals came in what were to be the first two HRT cases tried in New Jersey, *Bailey v. Wyeth Inc.*, L-9999-06, scheduled for Sept. 15, and *DeBoard v. Wyeth Inc.*, set for Oct. 27.

Dora Bailey and Loretta DeBoard allege they developed breast cancer as a result of taking three HRT drugs to deal with menopausal symptoms like hot flashes and bone loss: Premarin, Prempro and Provera.

Premarin, an estrogen substitute derived from pregnant mares' urine, and Prempro, a combination of estrogen and progestin, are made by Wyeth, while Provera, a synthetic progestin, is made by Pharmacia & Upjohn Co.

FOLLOWED FDA ADVICE: 'The product liability statute means what it says,' says Pharmacia lawyer Gita Rothschild. 'If you do all the things you're supposed to do, there's a presumption that your label is adequate.'

PHOTO BY CARMEN NATALE

All three drugs have been used for decades, Premarin as early as 1942, and none has ever been withdrawn from the market. But Bailey and DeBoard allege that Wyeth and Pharmacia violated the PLA by failing to provide adequate warning of the breast cancer risk.

In 1992, the Food and Drug Administration determined that estrogen products, including Premarin, should include a breast-cancer warning but did not find sufficient evidence to warrant a warning on progestin products like Provera. When Prempro was approved in 1994, its label carried a breast-cancer warning.

Since the PLA was enacted in 1987, courts have held some sort of intentional misconduct is needed to overcome the rebuttable presumption, under N.J.S.A. 2A:58C-4, that warnings or instructions approved or prescribed by the FDA are adequate.

"The ultimate decision of the FDA to provide or not provide certain information in a prescription drug label can not be criticized unless a plaintiff has provided evidence of the pharmaceutical company's deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects or if the pharmaceutical company was found to have manipulated the post-market regulatory process," wrote Happas.

She found the plaintiffs failed to present such evidence. She rejected

their argument that their expert opinions were sufficient rebuttal under New Jersey Rule of Evidence 301, stating that the statutory presumption would disappear if Rule 301 were applied rather than the stronger presumption created by *Perez*.

She also spurned the argument that Wyeth should have done more studies of Prempro's risks, which would have led to stronger warnings. "If the court were to accept plaintiffs' theory that Wyeth failed to test before filing its NDA [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 testing before filing its NDA," she said.

Happas found 37 articles concerning HRT that were conceived and drafted by Wyeth and published in peer-reviewed journals did not constitute a manipulation of the regulatory process. The articles were "factually and medically sound" and there was no proof they delayed or diluted FDA warnings on Premarin and Prempro, she said.

Based on similar reasoning, Happas found that the post-market manipulation exception also did not apply to Provera, even though it was not initially approved for menopausal symptoms and was widely used off-label for years, with no breast cancer warning until 2007.

Although some of Wyeth's and Pharmacia's conduct "may have been less than exemplary," Happas said, the plaintiffs did not present "compelling or substantial evidence of the type necessary to rebut the presumption of adequacy."

Much of her 57-page opinion in *Bailey* describes the FDA's comprehensive regulation of the pharmaceutical industry and its decision-making with regard to the use and labeling of the HRT drugs. Her two-page letter opinion in *DeBoard* incorporates that analysis.

Happas also concluded that because the PLA was intended to "provide the exclusive remedy for harm caused by a product," the Consumer Fraud Act claim and common-law claims could not go forward.

Pharmacia's lawyer, Gita Rothschild, predicts the court will put the HRT litigation on hold pending appeal. "I believe this was the first time since the PLA was enacted that a judge has taken a close look at the facts and has made a ruling prior to trial that the statutory presumption applies," says Rothschild, of McCarter & English in Newark.

"The product liability statute means what it says," remarks Rothschild. "If you do all the things you're supposed to do, there's a presumption that your label is adequate." Her client "followed to a T" what the FDA told it to do, she adds. Pharmacia, based in Bridgewater, is a subsidiary of Pfizer.

Esther Berezofsky, who represents Bailey and DeBoard and is liaison counsel for all the HRT plaintiffs, says she will appeal.

"It is disappointing that this judge found that it was acceptable for these drug companies to aggressively market these drugs to women without doing the necessary testing that would have made clear the necessity of the warnings that only decades after were put on these labels," says Berezofsky, of Williams Cuker & Berezofsky in Cherry Hill.

Happas' ruling halts the failure-to-warn claims in their tracks, she says, though some that allege a design defect might be able to go forward.

Wyeth's lawyer, Lauren Handler, of Porzio Bromberg & Newman in Morristown, declines comment. A press release from the Madison-based company attributes to Handler the following comment: "We believe the court's ruling was a proper application of New Jersey law and is consistent with a growing body of law around the nation, rejecting challenges to FDA-approved labeling."■