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Pfizer Argues Against Punitive Damages in HRT Case

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Howard Bashman

Drugmaker Pfizer is arguing to the state Supreme Court that $8.6 million in punitive damages should not have been awarded in a hormone-replacement therapy case without evidence that its subsidiary misled federal regulators or knew the dangers of the drug were greater than what consumers were warned about.

The Supreme Court granted allocatur in the case of *Daniel v. Wyeth Pharmaceuticals Inc.* Dec. 5 on one issue: whether punitive damages should have been allowed in a drug products liability case for a drug that was reviewed by the federal Food and Drug Administration. There was no evidence, the defendant says, that it misled the FDA about the risk of the drug by hiding scientific facts and data.

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Wyeth is now owned by New York-based Pfizer.

Plaintiff Mary Daniel and her husband, Thomas Daniel, alleged that her hormone-dependent breast cancer was promoted by her use of Wyeth's Prempro and that the warnings for Prempro failed to warn her adequately of the risk of breast cancer incurred by taking the drug.

Prempro combines the hormones estrogen and progestin, a synthetic form of progesterone, and is used to treat menopausal symptoms, according to court papers.

Pfizer argues that punitive damages in the case should not be awarded because Wyeth did not act in subjective appreciation that the risk of using its HRT drug, Prempro, was actually greater than what was acknowledged in its HRT labeling. Pfizer also argues that Wyeth did not act in conscious disregard of that alleged risk.

Pfizer asked the Supreme Court how Wyeth could have acted with a conscious disregard of the risk of harm alleged by plaintiffs from using Prempro when Wyeth complied with all FDA requirements and the FDA rigorously reviewed the testing and labeling of Prempro, according to court papers.

The state Superior Court panel that upheld the punitive damages award said there was sufficient evidence to permit the jury to conclude Wyeth acted intentionally to not perform adequate tests of the risk of breast cancer from using Prempro because it did not want to lose drug sales.

The panel also said that the failure to test was in conscious disregard of the known risk that women using Prempro were at an increased chance of having breast cancer, *The Legal* previously reported.

"The Superior Court's reasoning licenses lay juries that lack scientific expertise to second-guess the FDA on a

matter within its core scientific competence and to punish drug companies whenever a party's retained expert testifies in hindsight that additional studies could have or should have been conducted," Pfizer argued in its brief filed Feb. 16. "Under that rationale, punitive damages could be imposed in any failure-to-warn case against a prescription drug manufacturer. That is not and should not be the law of this state."

Wyeth's brief was written by Sheila L. Birnbaum, Douglas W. Dunham and Ellen P. Quackenbos of Skadden Arps Slate Meagher & Flom in New York, Steven Glickstein of Kaye Scholer in New York and Robert C. Heim and Judy L. Leone of Dechert in Philadelphia.

Pfizer declined comment for this story beyond the brief.

The plaintiffs' attorney, Howard Bashman, a solo practitioner in Willow Grove, Pa., said: "My view of Wyeth's brief is they seek to change the punitive damages standard under Pennsylvania law as that standard currently exists. It allows punitive damages to be awarded both for reckless conduct in addition to intentional wrongdoing and it's Wyeth's position in the brief that where a pharmaceutical company is concerned only intentional wrongdoing should allow punitive damages and furthermore only if that intentional wrongdoing amount to fraud" on federal regulators.

Pfizer is not arguing that the jury was improperly instructed on Pennsylvania law, Bashman said. Bashman writes a column on appellate law for *The Legal* .

The Daniels are also represented by Robert K. Jenner of Janet Jenner & Suggs in Baltimore and Zoe Littlepage of Littlepage Booth in Houston.

The plaintiffs' regulatory expert, Dr. Cheryl Blume, never criticized the FDA for its decision to approve Prempro, Pfizer said.

Pfizer said it is not arguing that punitive damages are federally pre-empted but objecting to the imposition of punitive damages for "undisputed factual circumstances surrounding the FDA's regulation and approval of Prempro."

The plaintiffs argue, however, that in the wake of the U.S. Supreme Court ruling in 2009's *Wyeth v. Levine* that the FDA's approval of a prescription drug warning label does not preclude a state law failure-to-warn claim, "it would make no sense to hold that FDA approval of a drug does not preclude a state law failure-to-warn claim but does categorically preclude an award of punitive damages on such a state law claim."

The legislative branch, not the judicial branch, should decide if FDA approval of a prescription drug automatically blocks punitive damages, the Daniels' lawyers argue in court papers.

Before a pharmaceutical company may market a prescription drug, it must get approval from the FDA of its new drug application and the FDA must determine whether there are enough quality clinical studies "'to permit an evaluation of the drug's effectiveness and safety,'" Pfizer said in court papers.

Prempro was submitted for approval as a new drug in 1992, Pfizer said. The FDA approved the drug in 1994.

The FDA approval process depends upon the good faith of the drug companies because they supply the FDA with 100 percent of the information the FDA relies upon to approve the drug, Bashman said in an interview.

After the drug was approved, Wyeth supported scientific studies to study the risk of breast cancer from using hormone therapy drugs, Pfizer said.

The FDA requested a post-approval study that would assess the risk of breast cancer, and Wyeth pointed out that two large hormone-replacement therapy trials were already under way and Wyeth was providing placebo drugs, as well as active drug products, to those studies, Pfizer said. The FDA agreed that Wyeth's support for those studies would fulfill its request for a post-approval study.

One of those studies, the Women's Health Initiative, received a plethora of attention in 2002 with its findings of an increased risk of breast cancer from the use of HRT; the most severe kind of warning, a "black box" warning, was added to Prempro, according to the plaintiffs' opposition to Pfizer's petition for allowance of appeal.

Pfizer also argues that the WHI would not have even been launched if prior testing done by Wyeth had not "established a safe and effective dose of combination HT" and shown the "feasibility of recruiting investigators and participants to a long-term clinical trial on the scale of the WHI."

The WHI found no increased risk of breast cancer for women like Daniel who used hormone-replacement therapy for less than two years, Pfizer said.

The plaintiffs said in their court papers that the drug Daniel took all but disappeared from the market because Wyeth brought a low-dose, short-duration hormone therapy drug to the market:

"Had the WHI study been performed a decade sooner, Mary Daniel and her doctor would have faced totally different circumstances: i.e., a drug with a black box warning about invasive breast cancer with significant limitations on who should use it and/or the safer Low Dose Prempro. Studies change warnings. Studies furnish more safety data that can then be provided to doctors and women."

After the jury awarded $1.5 million in compensatory damages to the Daniels and $8.6 million in punitive damages,

the late Philadelphia Common Pleas Court Judge Myrna Field granted a judgment notwithstanding the verdict on the punitive damages because Wyeth had complied with federal regulations for the testing and labeling of Prempro and there was no evidence that Wyeth's conduct was "'outrageous, because of an evil motive, or in reckless disregard for patient safety.'"

The state Superior Court panel of Judge Christine L. Donohue, Judge Cheryl Lynn Allen and Senior Judge James J. Fitzgerald III restored the punitive damages. Fitzgerald wrote a concurring opinion.

Wyeth said the issue, according to the Supreme Court's order, is whether "the Superior Court erred in reversing the trial courts' grant of JNOV for Wyeth [respondents'] punitive damages claim under Pennsylvania law, where (a) the FDA extensively reviewed and approved the prescription drug at issue, the sufficiency of the testing for that drug, and the drug's label warnings of the risk of breast cancer, (b) there was no evidence that Wyeth concealed information or misled the FDA or knew that the risk of breast cancer was greater than disclosed in its warnings, and (c) the drug was extensively tested and studied by Wyeth and independent researchers."

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