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Supreme Court Dismisses HRT Punitive Damages Appeal

The state Supreme Court has thrown out the appeal of a drug company seeking to overturn an $8.6 million punitive damages award in a hormone replacement therapy products liability case brought by a woman who developed breast cancer while taking Prempro.

P.J. D'Annunzio

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The state Supreme Court has thrown out the appeal of a drug company seeking to overturn an $8.6 million punitive damages award in a hormone replacement therapy products liability case brought by a woman who developed breast cancer while taking Prempro.

In an order Monday, the justices dismissed as improvidently granted Wyeth Pharmaceuticals' appeal in *Daniel v. Wyeth Pharmaceuticals*, determining allocatur never should have been granted in the case.

Oral arguments for the case were heard by the court Sept. 11, 2012, in Philadelphia. During arguments, counsel for Wyeth contended that punitive damages were not warranted for a drug approved by the federal Food and Drug Administration when there was no evidence the pharmaceutical company misled or withheld information from the FDA.

Baltimore-based attorney Robert K. Jenner of Janet, Jenner & Suggs represented plaintiffs Mary and Thomas Daniel in the case and told The Legal he felt the Supreme Court ruled properly in the matter because the appeal was not worthy of the court's attention.

"Wyeth argued that there was insufficient evidence for a jury to find punitives on Wyeth's behalf, but I think the [justices] realized this was not a question for the Supreme Court," Jenner said.

"The question for any Supreme Court should involve a serious policy matter or somehow resolve inconsistencies in court rulings that have significant public policy repercussions," Jenner added. "That was simply not the case here. The Supreme Court, after due consideration, concluded that we were right, that the jury ruled as it ruled, and it let the Superior Court do its job."

Robert C. Heim of Dechert represents Pfizer, which owns Wyeth. Heim told The Legal that he was surprised and disappointed with the Supreme Court's order.

"The court had received extensive briefs and heard oral argument on the issue of whether there can be punitive damages when a product has been approved by the FDA, and so we were disappointed with the order," Heim said. "The trial court had found that the company complied with all federal regulations and there was no evidence of any willful misconduct on the part of the company."

Heim said during arguments there was "no deception, no hiding the ball, and there is evidence that the company has done a lot of testing."

If punitive damages were to be allowed in a case in which the company is argued to not have done enough testing, then Heim said he questioned how a lawyer would ever advise a drugmaker on when it has done enough testing.

Heim's appellate co-counsel, Sheila L. Birnbaum of Quinn Emanuel Urquhart & Sullivan in New York, said during the argument that, as a matter of policy, allowing punitive damages on the basis of the retrospective opinion of one plaintiff's expert—when the entire FDA process had resulted in Prempro's approval—would negatively affect the public interest.

And Chief Justice Ronald D. Castille said during the argument that such a liberal approach to punitive damages could result in Pennsylvania being labeled a "judicial hellhole," an appellation that is handed out by one "tort reform" advocacy group in its policy papers.

Howard Bashman, a Willow Grove, Pa., solo practitioner who argued on behalf of the Daniels, told the justices that state law requires a higher standard of behavior than the FDA does, and that the FDA's approval process does not get into Wyeth's "state of mind." The FDA's "ex parte" process is incapable of testing a drugmaker's sincerity, Bashman said at argument.

The Daniels' case was not put forth as a test case on the issue of whether FDA regulation of drugs can box out punitive damages, and deciding that issue only on the volumes of evidence in the Daniels' case, if it was done by the legislature, would "clearly represent a case of legislative malpractice," Bashman argued.

Justice Debra M. Todd asked if Wyeth was seeking a blanket rule against allowing punitive damages for drug products liability cases in which drugmakers had complied with the FDA rules.

While Heim said that was not so, Bashman argued the court ruling in this case would indeed result in such a blanket prohibition, and the legislative branch, not the judicial branch, should decide if FDA approval of a prescription drug automatically blocks punitive damages.

The state Superior Court panel of Judges Christine L. Donohue and Cheryl Lynn Allen and Senior Judge James J. Fitzgerald III restored the punitive damages after the trial court judge had thrown them out. Fitzgerald wrote a concurring opinion.

While the late Philadelphia Court of Common Pleas Judge Myrna Field granted judgment notwithstanding the verdict regarding punitive damages, Field did have the jury consider punitive damages in case she was reversed by an appellate court. Field's JNOV on punitive damages was reversed by the Superior Court.

Heim had said at argument that the panel did not review all of the circumstances of the trial when finding that punitive damages were indeed warranted, and it was not clear what standard of review they used to reverse Field.

Bashman had said at argument that the trial judge was reviewed de novo or under plenary review, which is "the most wide-ranging appellate empowerment available."

The Daniels were awarded $1.5 million in compensatory damages.

Mary Daniel took Prempro, a combination of estrogen and progestin, a synthetic form of progesterone, for less than 18 months from 1999 until Aug. 9, 2001, when she was diagnosed with breast cancer.

P.J. D'Annunzio *can be contacted at 215-557-2315 or pdannunzio@alm.com. Follow him on Twitter @PJDannunzioTLI. •*