The Legal Intelligencer

ALM Properties, Inc.
Page printed from: *The Legal Intelligencer*

Back to Article

Supreme Court Mulls Punitive Damages in HRT Case

As the state Supreme Court on Tuesday considered a punitive damages award of $8.6 million for a breast cancer survivor who took Wyeth's hormone replacement therapy drug Prempro, Justice Seamus P. McCaffery asked during oral arguments in Philadelphia whether it would be absurd to allow punitive damages in the case of a drug approved by federal authorities.

Amaris Elliott-Engel

2012-09-12 12:00:00 AM

As the state Supreme Court on Tuesday considered a punitive damages award of $8.6 million for a breast cancer survivor who took Wyeth's hormone replacement therapy drug Prempro, Justice Seamus P. McCaffery asked during oral arguments in Philadelphia whether it would be absurd to allow punitive damages in the case of a drug approved by federal authorities.

McCaffery asked how great a burden should there be placed on drugmakers when every human body is different, when there are risks and benefits to using prescription drugs, and there is not a "smoking gun," as he said there was in the tobacco litigation, to show that Wyeth Pharmaceuticals, now a wholly owned subsidiary of Pfizer, chose to hide the increased risks of breast cancer from taking its hormone replacement therapy drugs from the consuming public.

Robert C. Heim, an attorney with Dechert who argued on behalf of Wyeth, told the justices that punitive damages were not warranted for a drug approved by the federal Food and Drug Administration when there was not evidence that the pharmaceutical company misled the FDA or withheld information from the FDA.

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

If punitive damages are allowed in a case in which the company basically 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 Skadden, Arps, Slate, Meagher & Flom in New York, said 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 that it would result in Pennsylvania being labeled a "judicial hellhole," which

is the appellation given by one conservative group in favor of changing tort law to Philadelphia and other so-called plaintiff-friendly jurisdictions.

"Your words, not mine," Birnbaum said in response.

Howard Bashman, a Willow Grove, Montgomery County, solo practitioner who argued on behalf of plaintiffs Mary and Thomas Daniel, said 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.

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

While Heim said that was not so, Bashman said that 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 Judge Christine L. Donohue, Judge 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.

There is a procedural quirk in the case.

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 said 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 said 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.

Wyeth said the issue, according to the Supreme Court's order granting allocatur, 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."

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

Trial counsel was Mark R. Cuker and Esther Berezofsky of Williams Cuker Berezofsky in Philadelphia.

Amaris Elliott-Engel *can be contacted at 215-557-2354 or aelliott-engel@alm.com. Follow her on Twitter @AmarisTLI.*