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Panel Eyes Impact of Punitives in Hormone Therapy Cases

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Pa Superior Court Judge Kate Ford Elliot

A Pennsylvania appellate judge wondered during oral argument Tuesday what the "breaking point" is for a drug manufacturer facing 1,000 Philadelphia lawsuits where plaintiffs are seeking punitive damages based on the same evidence of alleged wrongdoing.

Superior Court Judge Kate Ford Elliott said that the same evidence on punitive damages will need to be presented in 1,000 drug products liability cases pending in Philadelphia Common Pleas Court against Pfizer on injuries allegedly caused by two of its divisions' hormone-replacement therapy drugs. Women are suing two of Pfizer's divisions, which have merged into the drug company, on the theory that their use of hormone-replacement therapy caused their breast cancer.

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At the end of the argument, Ford Elliott also wondered why the Philadelphia trial court had not held one global trial regarding punitive damages that could apply to all HRT plaintiffs and what impact repetitious litigation over punitive damages would have on the Superior Court.

The court's decision on punitive damages in the cases of two Illinois women could affect the 1,000 HRT cases still pending in Philadelphia.

Plaintiff counsel Michael J. Quirk of Williams Cuker Berezofsky in Philadelphia, who is representing plaintiff Connie Barton, told Ford Elliott that a defendant alone must raise the issue of its possible exposure as an argument to limit punitive damages, and Wyeth has only noted that it is facing a large number of cases.

Under Illinois law, Quirk said that punitive damages can be found to be too much in light of the defendants' possible exposure; in light of the defendants' worth, which in the case of Pfizer's unit Wyeth was over $19 billion; and in light of the relative enormity of the defendants' wrong. Illinois law was applied in both cases because it is the plaintiffs' home-state law.

No one has shown that Wyeth Pharmaceuticals or Pharmacia & Upjohn Co. made misrepresentations to the federal Food and Drug Administration or withheld information from the FDA, said Robert C. Heim, counsel for the companies now owned by Pfizer. Instead, the plaintiffs argued that the drugmakers didn't test for the risk of breast cancer, he said.

But Heim said that under Illinois law a plaintiff only can win punitive damages against a drugmaker if he or she can show that the drugmaker failed to warn of a known risk.

Joining Ford Elliott on the panel were Senior Judges Stephen J. McEwen Jr. and William H. Platt.

The Superior Court is considering *Barton v. Wyeth* , in which a Philadelphia jury awarded in 2009 $78.7 million in damages, including $75 million in punitive damages. Philadelphia Common Pleas Senior Judge Norman Ackerman remitted that award to $10.6 million.

The court is also considering *Kendall v. Wyeth* , in which a Philadelphia jury in 2009 awarded $34.3 million in damages, including $28 million in punitive damages. Philadelphia Common Pleas Court Senior Judge Victor J. DiNubile Jr. remitted the punitive damages award to $1 million. In the *Kendall* case, Wyeth was found 60 percent liable, and co-defendant Upjohn was found 40 percent liable.

Reducing the award by 96.5 percent in *Kendall* was not required under Illinois law because Illinois does not require a certain ratio between compensatory and punitive damages, said Howard Bashman, a Willow Grove, Pa., solo practitioner who is appellate counsel for plaintiff Donna Kendall.

"What the defendants did was put profits ahead of patients' health," Bashman said. Bashman is a columnist on appellate litigation for *The Legal* .

Quirk said that juries are better at assessing punitive damages than judges.

Drugmakers Wyeth and Upjohn disputed that the evidence of the companies' sales strategies, including alleged off-label use marketing of HRT to physicians, should have been allowed in as evidence at the *Barton* and *Kendall* trials unless it could be shown such marketing influenced the particular plaintiffs' prescribing physicians.

Both judges, particularly Ackerman, allowed the plaintiffs, defense counsel Robert C. Heim said, "to introduce evidence, a torrent, and if I was being up-to-date, a tsunami of evidence totally unconnected" with the plaintiffs' prescribing physicians' decisions to prescribe them HRT.

"If you can't connect it up to causation, then it can't come in," said Heim, of Dechert in Philadelphia.

Ford Elliott, however, said that such evidence could be relevant to a jury deciding punitive damages and could be used to show a drugmaker's motives not to test for all of the risks of a blockbuster-selling drug being marketed for off-label use.

Bashman said that the Superior Court has found in another HRT case that Wyeth's decision to not test regarding the risks of breast cancer was a conscious disregard of known risk.

Both of the plaintiffs' doctors prescribed HRT because of their patients' severe menopausal symptoms, not because of any use not given approval by federal regulators in the drug's warning label, Heim said.

However, Bashman said that Kendall's physician did testify about a perception that HRT was good for a woman's heart and the jury was allowed to infer that was part of why the doctor did prescribe HRT. Quirk said that both his client and her physician remembered that off-label uses were part of the prescribing decision in her treatment.

Heim said that the FDA couldn't have approved Prempro in 1994 had drug regulators not concluded that there was adequate testing to show that the drug was safe and effective for use.

Quirk countered that the FDA's approval of Prempro was conditional and FDA approval couldn't be used as immunity from punitive damages.

There were warnings that HRT could increase risk of breast cancer, Heim said, including with higher doses or lower doses taken for several years.

The scientific community had differing opinions on whether HRT was correlated to a higher risk of breast cancer, Heim said, and he disputed there was ever any evidence that the label failed to accurately set forth the state of scientific knowledge. •

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