

## Discovery Battles Heat Up Over Wyeth's Prempro

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*Wednesday, Aug 01, 2007* --- The number of women joining the battle against Wyeth's Prempro drug has increased exponentially since March of 2003, when the Judicial Panel on Multidistrict Litigation consolidated and transferred the first five cases related to Wyeth's Prempro drug to the U.S. District Court in the Eastern District of Arkansas.

Wyeth now faces approximately 5,000 suits over Prempro, with women around the country filing lawsuits against the pharmaceutical giant alleging that the combination hormone therapy caused breast cancer.

According to plaintiffs' attorney Mike Williams of Williams, Love, O'Leary & Powers PC, litigation over Wyeth's hormone replacement therapy Prempro could balloon into one of the largest product liability cases ever.

"I don't think people realize that yet," Williams said.

Williams estimated that hundreds of thousands of women may have unnecessarily developed breast cancer as a result of taking Prempro—and that means, according to Williams, that more and more cases will keep turning up. "I think the scope of this disaster has not been realized," he said.

But for now, discovery is the the name of the game, at least in the multidistrict litigation in Arkansas over Wyeth's Prempro. The sparring has begun in earnest, with both sides trading blows over documents requested by plaintiffs attorneys.

"It never wraps up. There's always more requests. It only wraps up when the referee blows the whistle," said plaintiffs attorney Robert K. Jenner, principal at Janet, Jenner & Suggs LLC, and member of the plaintiffs' steering committee. "The truth is that as we go farther and farther into litigation, more and more information reveals itself."

One of the requests currently under fierce dispute is a plaintiffs' demand that Wyeth produce documents from sales calls made on doctors who prescribed the drug, both before and after plaintiffs actually took the hormone replacement therapy. Wyeth has already agreed to produce call notes recorded during the prescription period.

In a July 27 letter to U.S. District Judge William R. Wilson, Jr., plaintiffs argued that Wyeth has already been ordered to produce its entire sales representative database, and that records of sales calls both before and after

they prescribed the drug to plaintiffs reveal critical information about doctors' evolving attitudes about Prempro.

In the letter, the plaintiffs said that Wyeth was attempting to claim that because the order to turn over call notes was signed on Sept. 9, 2004, "the order encompasses only pre-Sept. 9, 2004 call notes. This constitutes semantics gone awry."

The letter added that Wyeth's position "is tantamount to saying that if a court ordered a defendant to identify all his criminal conduct, the order would encompass only that conduct that occurred before the order was signed, even if trial was a year away and the defendant went on a killing spree in the interim."

In response, attorneys for Wyeth sent a letter to Judge Wilson on July 30, claiming that the plaintiffs letter "is talking legal nonsense when it claims that the court has already ordered the production of the post-September 2004 call notes. Plaintiffs' document request called for, and the court ordered, the product of the call notes then existing, not call notes yet to be created."

Wyeth also asked the judge recognize the scope of a request for both pre and post prescription files. According to the letter, the call notes Wyeth has already agreed to produce involves more than 15 million pages of documents. The files on sales calls from before and after a doctor prescribed hormone therapy, according to the letter, could number an additional 8.5 million pages.

"When the court weighs the borderline relevance of these call notes against the cost of this enormous additional production, the Solomonic answer is, 'enough is enough,'" Wyeth's letter to the judge said.

An additional discovery wrangle focuses on plaintiffs requests for the production of documents about alternative Prempro products. According to the plaintiffs, the documents relate to a theory that patients should have been given alternative products that are superior to Wyeth's synthetic hormones.

Plaintiffs attorney Mike Williams says this is an important new area of the litigation, which could show how and why Wyeth developed and marketed a drug that is allegedly hazardous, and what other routes the pharmaceutical company could have taken when the drug was under development.

In court documents filed July 9th, Wyeth said that the plaintiff's motion to compel the production of those documents should be denied because it was minimally relevant. "The main reason the court should deny plaintiffs' motion is because plaintiffs admit that they never used the products that are the focus of these discovery requests," Wyeth stated.

In a July 27th reply, plaintiffs fired back. "Obviously, Wyeth fails to grasp the concept of a design defect claim: a safer alternative design would have spared plaintiffs from the injuries they suffered," the reply said. An August

status conference could settle both of those discovery issues.

Plaintiffs' interest has also recently been piqued by a study released in late July by Kaiser Permanente's Center for Health Research in Portland, Oregon. That study seemed to strengthen the link between breast cancer rates and hormone replacement therapies—showing that breast cancer rates rose during the years when hormone therapy was frequently prescribed, particularly therapies that used estrogen in combination with progestin.

Prempro uses a combination of estrogens plus a progestin. The study said that breast cancer rates fell significantly after 2002, when news that the drugs had serious risks prompted doctors to stop giving the drugs to patients.

Other studies have reported similar findings, particularly a much-cited study by the Women's Health Initiative in 2002. In that study, a major clinical trial studying the risks and benefits of hormone replacement therapies that used a combination of estrogen and progestin was abruptly stopped three years before it was supposed to end, because researchers said they found an increased risk of invasive breast cancer in healthy menopausal women who were using the drug.

Litigation against Wyeth began soon after study was released.

Two bellwether cases tried in the Eastern Arkansas MDL have resulted in verdicts favoring the defendants. Wyeth won its first federal trial last September when an Arkansas jury found it was not negligent and had adequately warned patients and doctors of Prempro's link to cancer.

The second favorable verdict for Wyeth came on Feb. 15, when a jury in the U.S. District Court in Little Rock found that Prempro did not cause breast cancer in plaintiff Helene Rush, and that Wyeth was not negligent in the matter.

“There were two unfortunate verdicts in the MDL,” said Jenner. “As our evidence is fine tuned and as the evidence continues to mount, I believe that juries will consistently find in favor of the plaintiffs.”

Just this year, two juries in Pennsylvania have gone the other way. In January, a state jury in Philadelphia determined that Prempro caused the breast cancer of plaintiff Mary Daniel, and ordered Wyeth to shell out \$1.5 million in compensation.

In February, Wyeth lost a second trial when a Philadelphia jury awarded breast cancer patient Jennie Nelson and her husband \$3 million. A Pennsylvania appeals court eventually disagreed with the jury's verdict in the Nelson case and tossed out decision and the damages award.

Several other cases involving individual plaintiffs are proceeding around the country. Jenner said he expects at least 4 new jury verdicts by the end of the year.

“We’re very optimistic. These cases are strong. The juries have come back letting us know that hormone therapy causes breast cancer and that the drug companies conduct was wholly inappropriate. We have every reasons to suspect that juries will continue to find in our favor,” plaintiffs attorney Robert Jenner said.

Representatives for Wyeth declined to comment.

The case is In Re: Prempro Products et al., case number 4:03-cv-01507, in the U.S. District Court for the Eastern District of Arkansas.

-- Additional Reporting by Erin Marie Daly, Shannon Henson and Anne Urda