Vioxx Jury in N.J. Orders $9 Mil. in Punitive Damages

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A jury in Atlantic City, N.J., yesterday ordered Merck & Co. to pay $9 million in punitive damages to a user of Vioxx, finding the drug maker knowingly withheld data from federal regulators about the painkiller's cardiovascular risks.

After a three-day trial on punitive damages, the jurors found clear and convincing evidence that Merck withheld material information about Vioxx from the Food and Drug Administration and that its conduct was deliberately meant to harm.

The verdict came a week after the jury awarded $3 million in compensatory damages to John McDarby, 77, of Park Ridge, N.J., and $1.5 million to his wife, Irma, for loss of services.

McDarby's lawyer, Robert Gordon of New York's Weitz & Luxemburg, said this is the first punitive damages verdict against a pharmaceutical company under the 1995 New Jersey Product Liability Act, which generally caps punitive damages at five times the amount of compensatory damages.

"The jury found that there was more than ordinary negligence and willful, wanton and reckless conduct," said Frank McClellan, a professor of torts at Temple University's Beasley School of Law. But, he added, "Merck should take some comfort in the fact that the $9 million doesn't reflect great anger, given that they could have awarded $22.5 million."

Under the statute, 2A:15-5.17, the award of punitive damages requires the trial judge, Superior Court Judge Carol Higbee, to refer the case to state or county prosecutors for a criminal investigation.

Lawyers from one Philadelphia plaintiffs firm took depositions in the case that would later be directly presented to the jury at trial.

Thomas Kline of Kline & Specter said that he deposed, on behalf of the plaintiffs, Eric Topol, a key cardiology expert whose testimony bolstered the liability-phase assertions that Merck had engaged in scientific misconduct. During that phase of the trial, the jury viewed a videotape of Kline deposing Topol, who Kline said did not personally appear at the trial.

Kline also said that during the punitive-damages phase in the case, the jury was played a videotaped deposition showing Shanin Specter, Kline's partner, examining a Merck statistician as to whether certain of the company's clinical studies data had been omitted from its FDA filings.

"This jury has sent a message out from the back yard of pharmaceutical land that they take their policing power seriously," said W. Mark Lanier, who represented McDarby's co-plaintiff, Thomas Cona. The jury did not award compensatory or punitive damages to Cona, 60, who had only three Vioxx prescriptions in the two-year period he claimed to have taken the drug.

Merck withdrew Vioxx from the market in 2004 when a study showed it doubled heart attack risk after 18 months of use. The Atlantic City trial was the first involving plaintiffs who had used Vioxx longer than that period of time.

A lawyer for Merck said that the Whitehouse Station, N.J., company was disappointed with the punitive damages verdict and will appeal.

"Merck's actions were proper and did not, in any way, call for this award as defined by New Jersey law," said Chuck Harrell of the Memphis office of Butler Snow O'Mara Stevens & Cannada. "The evidence was clear that we provided the FDA with the information about Vioxx that we were required to provide. And, under New Jersey law, that means punitive damages should not have been awarded."

Merck had argued at trial that the data were statistically invalid and that no FDA regulation requires drugmakers to submit invalid statistics. "They did not engage in deliberate and willful misconduct, deliberate acts that they knew would harm someone else," Merck lawyer Christy Jones told jurors in her closing argument of the

punitive-damages phase. "The doctors and scientists at Merck always acted in a way that they believed was appropriate. Don't label them as killers. Don't label them as guilty of willful and wanton misconduct."

Merck general counsel Kenneth Frazier added, "The jury heard irrelevant and prejudicial information from the plaintiffs' attorneys about Merck and an appeal will be our next step. The evidence is that Merck acted ethically and in a responsible manner - from researching Vioxx prior to approval in clinical trials involving almost 10,000 patients, to monitoring and studying the medicine while it was on the market, to voluntarily withdrawing the medicine when we did."

Merck lawyers say that the appeal will focus on what they call improper restrictions on presenting relevant evidence to the jury, such as orders that:

Prevented Merck regulatory experts from talking about FDA rules and Merck's compliance with FDA regulatory requirements;

Limited Merck's ability to discuss the FDA's most recent findings;

Forbade Merck witnesses to state that they personally used Vioxx in the face of false allegations that they believed the medicine was unsafe;

Stopped witnesses from testifying about scientific studies performed by Merck regarding the cardiovascular safety of Vioxx;

Allowed unsubstantiated conclusions that were irrelevant and/or inflammatory to be presented to the jury by plaintiff witnesses;

Allowed opinion testimony to be given to the jury by witnesses lacking subject matter expertise; and

Allowed opinion testimony that was not based on a reliable scientific basis as required by law.

"We continue to believe that the heart attacks in both these cases were caused by the pre-existing medical conditions of these two men, and not Vioxx," said Harrell. "Proving that Vioxx was a substantial contributing factor for someone's heart attack is an important element in these lawsuits."

"This split verdict reaffirms our commitment to defending each case on a case-by-case basis," added Frazier. "Merck is in this for the long term."

This is the second punitive-damages award against Merck over Vioxx. It lost a $253 million jury verdict last August in Houston, which state law will reduce to $26 million. Merck won a no-cause in New Jersey last November. The company has vowed it will fight each case individually, and has set aside $970 million for that purpose.