

Judge declares mistrial in federal Vioxx case

Jurors deadlocked in federal trial against pain drug maker Merck

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HOUSTON - A judge declared a mistrial Monday in the first federal lawsuit over the once-popular painkiller Vioxx after jurors were unable to reach a unanimous verdict.

Merck & Co. emerged from its third Vioxx trial Monday with a hung jury when the panel failed, in about 18 hours of deliberations over three days, to side with the drug maker or with the wife of a 53-year-old Florida man who died after taking Vioxx for about a month.

The mistrial means Merck, which already had a one and one record in Vioxx litigation, was unable to gain any momentum in its battle against thousands of other expected lawsuits related to the drug, which was withdrawn from the market last year after being linked to cardiovascular problems.

The nine-member jury was about 20 minutes into its fourth day of deliberations when U.S. District Judge Eldon Fallon called the jurors in and reminded them they had agreed to reach a verdict in a "reasonable time."

"It has now been a reasonable time. We cannot get a verdict," Fallon said, declaring a mistrial. Federal litigation requires a unanimous verdict.

Merck in 'for the long haul'

The judge said he would confer with attorneys next week to set a retrial date. Phil Beck, lead lawyer for Merck, said the retrial would likely be in February in New Orleans. The trial was moved from there to Houston because of hurricane damage.

The jury couldn't decide whether Merck was liable in Richard "Dicky" Irvin's 2001 death and whether the company failed to issue safety warnings that the drug could have serious cardiovascular side effects.

Beck said he had "no clue" what divided jurors or how the panel was split. He said Fallon instructed attorneys not to contact jurors, and "nobody knows what the division was."

Beck, who said Merck was in Vioxx litigation "for the long haul," would present the same defense in a retrial.

But Irvin's wife, Evelyn Irvin Plunkett, said she believed she had to convince a jury that Vioxx was the culprit.

"I knew in my heart my husband had died because of Vioxx and I had to push forward (with a lawsuit) because of that," she said outside the courtroom. "A lot of people have been injured, hurt, died because of that drug."

The jury's decision apparently had nothing to do with news late last week, after deliberations began, that the New England Journal of Medicine said Merck omitted negative results in a report about a 2000 Merck-funded clinical study.

The respected medical journal revealed last week that the report's authors — including Merck's

head of clinical trials — failed to disclose three patients' heart attacks, which made it appear that Vioxx caused four times as many heart attacks as the pain killer naproxen rather than five times as many.

Merck disclosed the full amount of heart attacks to the Food and Drug Administration later that year.

Damaging data withheld

The study in question, called VIGOR, has figured heavily in the first three Vioxx trials to reach juries — one in a Texas state court that Merck lost, another in its home state of New Jersey that the company won, and in the federal case in Houston.

Jere Beasley, one of Plunkett's attorneys, said the revelation showed that Merck withheld damaging data regarding what would become a \$2.5 billion seller before Merck pulled it from the market last year after another study showed Vioxx could double risk of heart attack or stroke if taken for 18 months or longer.

"You can't lie to people like the New England Journal of Medicine and get away with it," he said. "We look forward to the next trial."

Beck said Merck held back nothing. He said Merck gave the Journal the data the company had at the publication's deadline.

"There has been a huge misunderstanding of what came out of the New England Journal's editorial," said Beck, referring to an editorial in the Journal decrying the disparity.

The unexpected outcome leaves Merck with a 1-and-1 record in state trials and an undecided in the first of four federal trials overseen by Fallon. The company faces about 7,000 pending state and federal lawsuits and its liability has been estimated at up to \$50 billion.

In the first case, a Texas state jury slapped Merck with a \$253 million verdict, which will be reduced to \$26.1 million at most because of state caps on punitive damages. Merck is expected to appeal.

In November jurors in Merck's home state of New Jersey absolved Merck of liability, leaving nothing for an Idaho man who survived a heart attack after taking the drug intermittently for two months.

The crux of the federal case was whether Vioxx could be dangerous with short-term use.

Merck argued that Vioxx was not a factor in Irvin's death because he took the drug for a few weeks. The company blamed his death on clogged arteries and a blood clot that led to the heart attack.

Irvin, a former college football player who managed a wholesale seafood company in St. Augustine, Fla., got a prescription for Vioxx from his son-in-law, an emergency-room physician, without a medical checkup.

Plunkett alleged that Vioxx — which inhibits an enzyme that promotes inflammation and thins the blood — led to the clot formation.

Of the 21 witnesses who testified, four testified on Merck's behalf, and none of those were cardiologists. The plaintiff's witnesses included Dr. Eric Topol, chairman of the cardiovascular medicine department of the Cleveland Clinic and a vocal critic of Vioxx, who said the drug can cause heart attacks any time after a patient begins taking it.

Testimony in the federal case ended in less than two weeks, while the state trials lasted three and

four times as long.

Fallon has said he intends to meet with lawyers about perhaps crafting a global settlement of all pending federal Vioxx litigation.

The next federal trials are slated for next year, and the next state trial is scheduled for Feb. 27 in New Jersey.

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