

Merck Loss Jolts Drug Giant, Industry

In Landmark Vioxx Case, Jury Tuned Out Science, Explored Coverup Angle 'Shadow' Panel at McDonald's

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ANGLETON, Texas -- In an ominous sign for Merck & Co., it took just an hour for a jury here to blow through the company's principal line of defense: that its painkiller Vioxx couldn't have caused the heart-related death of 59-year-old triathlete Robert Ernst.

Facing thousands of lawsuits over Vioxx, Merck had built its argument in the first suit to go to trial around the nitty-gritty science of heart attacks and what causes them. But after the first hour or so of deliberation Thursday, a majority of the jury had in effect dispensed with the science and started a series of 10-2 votes against Merck that would end in a \$253 million verdict against the drug maker.

Interviews with jurors suggest that many tuned out Merck's arguments and focused instead on evidence they understood: that a big corporation allegedly covered up defects with its product. One crucial document was an email from February 1997 -- two years before Merck started selling Vioxx -- in which a top company scientist, Alise Reicin, wrote that "the possibility of increased CV [cardiovascular] events is of great concern." Merck maintained that it didn't know of Vioxx's potential for heart risk until just before it pulled the drug from the market in September 2004.

"That told me they knew cardiovascular events were possible on this drug, but they failed to tell us about it," said juror Lorraine Blas, a 41-year-old human-resources worker.

The award to Mr. Ernst's widow, Carol, is certain to be reduced, both sides said -- probably to about \$26 million. Jurors set \$229 million of the total as punitive damages, which Texas law requires to be reduced to less than \$2 million.

Merck faces a potential liability from Vioxx litigation that analysts have estimated as high as \$30 billion. Another case is set to begin next month in New Jersey state court and the first federal trial is slated for November.

"I love when a widow from a small town can stand up against one of the largest companies in the entire world, actually get access to their documents and show a jury how they killed her husband," said Mark Lanier, the plaintiff's lawyer, whose folksy manner belied his intense preparation for the case. Mr. Lanier went so far as to convene a "shadow" jury to hear the case and offer its opinions, which he used to fashion a closing argument. In it, he suggested jurors might get national attention if they voted for the plaintiff.

Merck, based in Whitehouse Station, N.J., said it was "disappointed" in the jury's decision and vowed to appeal. In a statement Saturday, Kenneth C. Frazier, Merck's senior vice president and general counsel, said the plaintiff's case was "fundamentally flawed" and that the company has "strong points to raise on appeal." He also said Merck is "steadfast in its legal strategy" to try each of the thousands of other cases one by one. (See Merck statement.)

But the Texas verdict -- and the way the jurors reached it -- offers a worrisome harbinger. Merck argued that Vioxx couldn't have caused Mr. Ernst's death because, according to his death certificate, he died of an arrhythmia or irregular heartbeat, not a heart attack. While scientific evidence suggests Vioxx can promote blood clots leading to a heart attack, no data have linked the drug with arrhythmias.

Jurors who voted against Merck said much of the science sailed right over their heads. "Whenever Merck was up there, it was like wah, wah, wah," said juror John Ostrom, imitating the sounds Charlie Brown's teacher makes in the television cartoon. "We didn't know what the heck they were talking about."

As they assembled around a rectangular wooden table in the jury room, the question of causality -- did Vioxx kill Mr. Ernst? -- caused little trouble for the jurors. The coroner who did the autopsy of Mr. Ernst testified he could have had a blood clot that caused a heart attack but disappeared by the time of the autopsy. That would explain why the death certificate only mentioned arrhythmia.

That speculation about a blood clot was enough for Matthew Pallardy, a 24-year-old juror. "We kind of figured there was one there, but it went away real quick," said Mr. Pallardy. The issue "wasn't a snag. It wasn't a very big debate." Another juror, Derrick Chizer, said as long as the clot existed "for a millisecond" that was enough.

Mr. Ostrom, 49, who has a business remodeling homes, was also disturbed that former Merck Chief Executive Raymond Gilmartin and another top Merck official gave videotaped testimony but weren't in the courtroom. "The big guys didn't show up," said Mr. Ostrom. "That didn't sit well with me. Most definitely an admission of guilt."

William G. Bowen, an outside director at Merck who is on the board's executive committee, said in future trials the company will seek better ways "to make basic scientific points as simple as possible." He also said the company may put different people on the witness stand although no decision has been made about Mr. Gilmartin's testimony.

A spokesman for the Merck defense team said taped depositions are common in trials. Mr. Gilmartin's deposition "demonstrated that Merck's decisions with respect to Vioxx were based on the science and in the best interest of patients," the spokesman said in a statement.

Mr. Bowen said the board held a conference call late Friday afternoon and heard an analysis of the verdict by Mr. Frazier, the general counsel. "We were all extremely disappointed in the court and in the handling of the case and are firmly behind Ken in his decision to appeal," Mr. Bowen said. He added, "Merck is in no way, shape or form going to stand pat." He said the board is mulling whether to put Vioxx back on the market -- partly to blunt plaintiff attorneys' ammunition.

In Mr. Lanier, the widow's lawyer, Merck faced a colorful and formidable adversary. Mr. Lanier won a \$115 million damage award -- later settled for an undisclosed amount -- in 1998 against an asbestos maker on behalf of 21 steelworkers. That victory came in the same courthouse here in Brazoria County and before the same judge who presided over the Vioxx case.

In the Vioxx trial, Mr. Lanier paid a group of local citizens, matched to the jury's demographics, to sit in the courtroom as shadow jurors and give him feedback on the effectiveness of his arguments. The shadow jurors, who made \$125 a day, weren't told who they were working for. Mr. Lanier flew in a PowerPoint expert from California to help him prepare a visual presentation for his closing argument. And he retained Lisa Blue, a psychologist and highly regarded litigator with Baron & Budd, Dallas, to watch the reactions of the real jury as the case unfolded.

From the beginning, Mr. Lanier showed his theatrical flair, speaking loudly and gesturing while roaming the courtroom as if it were a stage. PowerPoint slides in his opening statement portrayed Merck as an automated-teller machine giving cash to executives. Merck's marketing arm was depicted as a bulldozer that would push sales at any cost.

He had workers wheel 157 boxes of paper into the courtroom to show how Merck had inundated the Food and Drug Administration with documents that obscured Vioxx's problems. He finally stopped when Merck lawyer Gerry Lowry objected that the stack obstructed her view of the jury. Mr. Lanier set two trophies Mr. Ernst won for participating in marathons on the witness stand as Mrs. Ernst recounted the day he died. A huge portrait of the couple on their wedding day faced the jury on a large screen.

Plaintiff Carol Ernst

By contrast, the Merck lawyers -- including Ms. Lowry of Fulbright & Jaworski in Houston and David Kiernan of Williams & Connolly in Washington -- were reserved in their presentations. They rarely left the podium when questioning witnesses or addressing the jury.

Tracking Down a Witness

A critical moment came nearly two weeks into the trial, when Mr. Lanier persuaded the judge, over Merck's vehement objections, to allow the testimony of Maria Araneta, the coroner who did the autopsy. Though she wasn't on the initial witness list, Mr. Lanier tracked her down in the United Arab Emirates with the help of two private investigators. Dr. Araneta's testimony that Mr. Ernst might have had a blood clot -- perhaps dislodged during CPR attempts -- was the link Mr. Lanier needed to argue that Vioxx caused Mr. Ernst's death.

Merck presented Thomas Wheeler, interim chairman of pathology at Baylor College of Medicine in Houston, who told the jury that Mr. Ernst's clogged arteries were likely to blame for his heart attack. "He was like a walking time bomb," Dr. Wheeler said. He added, "I think Vioxx had nothing to do absolutely whatsoever with his death."

The two jurors who voted with Merck said they were persuaded by that explanation. "I feel bad he passed away. But I don't feel Vioxx caused it," said Brandon Beaver, 28.

Meanwhile, Mr. Lanier pushed his case that Merck knew about the heart risks of Vioxx long before the drug was pulled from the market. In one 2000 email, Edward Scolnick, Merck's research chief at the time, said it was a "shame" that a study linked Vioxx with increased heart attacks and strokes, "but it is a low incidence and it is mechanism-based as we worried it was."

In a videotaped deposition that appeared damaging to Merck, David Anstice, then the company's head of sales and marketing, said that during an internal probe, he didn't call several academic scientists who said they were being intimidated by Merck executives for speaking out against Vioxx. "So maybe you should have called them?" Mr. Lanier asked. "Perhaps I could've done that," Mr. Anstice said. "I chose not to."

Mr. Lanier's shadow jury met each night at a McDonald's, providing feedback to a consultant about the progress of the trial. Last Monday, two days before closing arguments, the jurors deliberated for more than four hours and provided Mr. Lanier with an early verdict: 9 to 4 in his favor -- with \$115 million in damages. That wasn't good enough. The real 12-person jury would have to vote 10 to 2 for a decision to be valid.

In a strategy meeting held the same evening, Mr. Lanier got a candid assessment from Ms. Blue, the adviser who was watching the real jury. "Four or five are really strong followers" for the plaintiff, she told Mr. Lanier, while "two or three are very bad for us."

She told him that on the issue of whether Merck failed to warn the public about the risks of Vioxx, his case was "good and tight." But that wouldn't matter if the jurors weren't convinced that Vioxx was the culprit. "You're weak on causation," Ms. Blue told him.

She advised him to press hard on "cause" in his closing statement and to stress that the jury only needed to be 51% sure Vioxx was a cause of Mr. Ernst's death. The 51% figure was a way of describing the legal requirement that there be a "preponderance of evidence" in the plaintiff's favor. "Write [51%] on the board twice: Arrhythmia is a cardiovascular event," she instructed him. "That gets you there."

She also urged him to be humble, to play up his role as a Baptist preacher and even to suggest to jurors they might get notoriety if they voted for him. One juror, Ms. Blas, had written in her questionnaire that she loves the Oprah Winfrey show and tapes it. "This jury believes they're going to get on Oprah," Ms. Blue told Mr. Lanier. "They only get on Oprah if they vote for the plaintiff."

Two days later, facing the jury with his final argument, Mr. Lanier kept to his plan. He advised jurors that 51% confidence in Vioxx as a cause of death was good enough. He sprinkled the speech with biblical references, at one point using the tale of Esther to urge the jurors to do the right thing even if they were fearful. And he hammered home the point that they would be sending a message that would be heard widely. "I can't promise Oprah," he said, but "there are going to be a lot of people who'll want to know how you had the courage to do it."

As he made the Oprah reference, Mr. Lanier looked at Ms. Blas in the eye. She says she broke out into laughter and liked the lawyer's attention to her. "That told me he read those profiles and tried to assess each and every one of us," Ms. Blas said.

Ms. Lowry, the Merck lawyer, called Mr. Lanier's presentations "a bunch of cartoons." She added: "The science isn't always as interesting, but that's what this case is about."

A Juror's Prayer

In the jury room at 9 a.m. the next day, the seven men and five women took their seats. Marsha Robbins, a 53-year-old homemaker, who had prayed the night before to be chosen to lead the jury, volunteered and was uncontested to be foreman.

Within a few minutes, Mr. Beaver spoke up to say he didn't believe the science supported the plaintiff's case. He said people die of arrhythmias every day, a fact Merck pointed to. But several other jurors jumped in and told Mr. Beaver that they didn't think Vioxx was the cause of Mr. Ernst's death, but they believed it was a cause. If so, that was enough to find for the plaintiff, according to the judge's instructions.

The discussion on the question was over, jurors say, in about an hour.

The judge had asked the jurors to decide the case by answering a series of questions, the first three of which had to do with whether Vioxx was a cause of death. The vote on the first question, around 10 a.m., was held by a show of hands. It went 10-2 in the plaintiff's favor. Jurors asked for some documents to help them with the second and third questions, and hunted through files in boxes on the table for the evidence that would support

their views. After a bit of stumbling over confusing wording in the second question, by 4 p.m. they had found Vioxx defective and decided that Merck was negligent.

Then it came down to damages. Jurors say the discussion about money was much more passionate than the one about causation. After an hour of debate the first day, they decided to sleep on it and resume discussions in the morning. They settled on a total of \$24.45 million for economic and compensatory damages. The \$229 million for punitive damages came out of a Merck document estimating how much in sales the company stood to lose if new cardiovascular risk information on Vioxx's label were to become effective in October 2001 instead of February 2002. Mr. Lanier mentioned the figure in his closing argument.

A 1995 Texas law, signed by then-Gov. George W. Bush, set strict limits on punitive damages amid business complaints about huge jury awards. The law limits punitive damages to \$750,000 plus twice the economic damages. Factoring in the economic damages in the Ernst case, that means the maximum punitive damages that can be levied against Merck are \$1.65 million. Other states have enacted their own tort reforms.

In interviews, jurors expressed anger and mistrust toward Merck. "If I could say it in one word: hiding," said Mr. Chizer, 43, who works at the Social Security Administration. "Every time a question was asked, any one of [the Merck] witnesses circumvented the questions by going somewhere else. Just give us a straight answer."

David Webb, 20, cited a letter Merck sent to doctors around the country including Mr. Ernst's doctor. Mr. Webb felt it buried information about potential cardiovascular risks. "Who knows, what if they had put the right information and Dr. Wallace had picked up the phone and called Bob Ernst and told him?" he asks.

Even the two men who sided with Merck thought the company should have been more forthright about the heart risk. After the verdict was read, the jurors met briefly with the judge and then were ushered into a nearby building, where they met with the lawyers. Mr. Beaver, one of the two Merck supporters, told Ms. Lowry, the Merck attorney, that if Merck plans on putting Vioxx back on the market, it should place greater emphasis on heart dangers on the label.

When the verdict came in at about 3 p.m. Friday, Merck's Dr. Reicin, whose 1997 email about cardiovascular risks proved influential among the Texas jurors, was giving a deposition in downtown New York for the first federal Vioxx trial in New Orleans, scheduled to start Nov. 28.

Plaintiffs' attorney Thomas Kline of Kline & Specter, Philadelphia, informed Dr. Reicin of the damage award and asked for her reaction. He says she became visibly shaken and left the room. He says, and Merck confirms, that Dr. Reicin's lawyer returned 10 minutes later and said she couldn't continue.