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PHARMACEUTICALS

Stark Choices at the First Vioxx Trial

The attorney for the plaintiff presented simple and emotional stories that strongly contrasted with Merck's appeals to colorless reason.

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On the first day of the nation's first Vioxx trial, in a case brought against Merck by the widow of a man who died of a heart attack that she believes was caused by the painkiller Vioxx, plaintiff's lawyer W. Mark Lanier of Houston gave a frighteningly powerful and skillful opening statement. Speaking in state court in Angleton, Texas without notes and in gloriously plain English, and accompanying nearly every point with imaginative, easily understood (if often hokey) slides and overhead projections, Lanier, a part-time Baptist preacher, took on Merck and its former CEO Ray Gilmartin with merciless, spellbinding savagery.

Which is not to say that Merck necessarily did anything wrong. In Merck's responding opening statement, David C. Kiernan of Washington, D.C.'s Williams & Connolly presented a thorough, meticulous, and seemingly plausible rebuttal of Lanier's contentions. But in contrast to Lanier, Kiernan spoke matter-of-factly of "NSAIDS" and "coxibs" and "cardiothromboembolic" events with only perfunctory stabs at translation. He seemed to read much of his presentation and illustrated it only with stodgy, corporate headshots of Merck officials or hard-to-read excerpts from documents whose meaning was shrouded in medical jargon.

The trial offers jurors a stark choice between accepting Lanier's invitation to believe simple, alluring, and emotionally cathartic stories versus Merck's appeals to colorless, heavy-going, soporific Reason. Lanier is inviting the jurors to join him on a bracing mission to catch a wrongdoer and bring him to justice. "You've got to be the detectives here," he told them. "If this were TV, this would be *CSI Angleton*." Merck, in contrast, is asking the jurors to do something difficult and unpleasant like—well—taking medicine.

Unless you are an insect, Angleton, Texas, is an uninviting place to be in mid-July. It's flat, charmless, humid, and hot. But lawyers and stock analysts from all over the country flocked here for yesterday's arguments in the 1940s-vintage, gray-stone Brazoria County courthouse. They came because they know that the Vioxx debacle may prove to be the biggest pharmaceutical mass tort anyone has ever seen. Close to 4,000 personal injury suits against Merck have already been filed by people alleging injury from its former blockbuster painkiller. And New Jersey state judge Carol Higbee—who presides over

more than 2,000 of these cases—has estimated that the number nationwide could easily grow to 100,000 or more.

The company has also been hit with well over 100 class action suits: by still more personal injury victims seeking compensation; by uninjured Vioxx users suing for consumer fraud; by shareholders suing over deflated stock prices; by employees suing over shrunken 401k's; and by unions, health plans and other third-party payers seeking reimbursement of their Vioxx-related expenditures. Analysts' estimates of Merck's exposures range wildly, from \$4 billion to \$20 billion. And many of Merck's insurers are contesting their coverage obligations.

Merck voluntarily pulled Vioxx from the market on September 30, 2004 after one of its own long-term studies began showing that the drug increased the risk of serious cardiovascular events in patients who took it for longer than 18 months. But critics of the drug had begun warning of such dangers much earlier, and plaintiff's lawyers even began filing suits on that theory as far back as 2001. FDA scientist David Graham—whom plaintiffs lawyers salute as a hero and drug industry lawyers deride as an alarmist—testified before the Senate Finance Committee in November that the FDA's failure to keep Vioxx off the market was “the single greatest drug catastrophe in the history of the world.”

Whether or not the charges prove accurate, the superficial plausibility of the claims carry enormous consequences for Merck. In most states, including Texas, the plaintiff need only convince a jury that Vioxx was *a* substantial contributing cause of the injury—not *the* cause.

Lanier's argument today was on behalf of Carol Ernst, 60, of Keene, Texas, which is about 25 miles south of Ft. Worth. She maintains that Merck killed her 59-year-old, marathon-running husband, Robert, who died in his sleep in May 2001 of sudden cardiac arrest. “The picture of health,” according to Lanier, Ernst had been taking Vioxx for tendonitis for about 7 or 8 months when he died. During the opening, Lanier projected onto a screen photos of Bob running in a race, of Bob and Carol at their wedding, of Bob and Carol competing in a tandem-bike race. “Then things changed,” Lanier said, and the image of Bob Ernst was replaced with an empty outline of Bob's silhouette. “Bob Ernst died.”

Lanier's story line was black and white. Merck was once a good company. But that changed when Ray Gilmartin became CEO in 1994, Lanier argued, and it lost its moral compass. “He took that company and made the needle always point toward the dollar sign,” Lanier told the jurors. Merck's key moneymaking drugs were about to go off patent and it had too few new drugs in the pipeline. When the cardiovascular problems became apparent, they had no choice but to hide them, Lanier said, because “there was no plan B.” “Nothing could stop the Merck marketing machine,” he continued. (A slide displays a steamroller.) “Merck duped the FDA,” he continued. (A slide displays an image of a pair of hands manipulating three walnut shells.)

In response, Merck counsel Kiernan told the seven-man, five-woman jury that the company meticulously tested the drug, always apprising the FDA and public of all known risks, and that Gilmartin voluntarily pulled the drug in 2004 out of an abundance of caution and against the advice of many doctors who wanted to keep it available. He detailed eight years of testing prior to the drug's FDA approval and said that while the FDA requires that a new drug be tested on only 1,500 patients, Merck tested Vioxx in studies involving 10,000 patients, of whom 5,400 took Vioxx for periods up to 18 months. Kiernan also stressed a memo issued after conducting extensive hearings by the FDA on April 6, 2005, which said that the reliable evidence *still* does not show Vioxx to increase cardiovascular risk to any greater degree than any other drugs of its class (like Pfizer's Celebrex) or even than traditional painkillers like ibuprofen (Advil) or naproxen (Aleve).

Kiernan also emphasized a potentially pivotal aspect of the case: The pathologist who conducted Bob Ernst's autopsy concluded that he had suffered from longstanding, undiagnosed hardening of the arteries, and that his sudden cardiac death had actually been triggered by an arrhythmia—an irregularity in the heart beat—rather than by a blood clot (thrombosis). All the questions surrounding Vioxx and other drugs of its class have focused on their alleged propensity to promote blood clot-related events—thrombotic heart attacks and strokes—while none have linked it to arrhythmias, Kiernan claimed. About 200,000 Americans each year suffer sudden cardiac death due to arrhythmias, Kiernan said, and hardening of the arteries is what most commonly triggers them.

In his own statement, Lanier had glossed over that distinction, insisting that Ernst “died of a textbook Vioxx problem,” and suggesting that Ernst *had* had a thrombotic heart attack, and that the autopsy pathologist couldn't have detected it using the techniques she used. In an interview, Lanier explains: “Ninety percent of heart attacks have an arrhythmia. The two are not mutually exclusive. We will also show that Merck knew Vioxx increased risks of arrhythmias.”

Kiernan closed by noting that seven of the high-level Merck officers most involved in the case—including the former and current research chiefs, Edward Scolnick and Peter Kim—used Vioxx personally. He asked jurors to consider whether these officers would knowingly conceal serious safety issues with the drug.

That this difficult case will be decided by a Brazoria County jury was Lanier's choice. In 1998 Lanier won a \$115 million verdict here for 21 steel workers in an asbestos case tried before the same district judge, Ben Hardin, who is presiding over the Ernst case. (The case was later reportedly settled for about \$15 million.) Last year, however, Lanier lost a case in the same courtroom.

Though Brazoria County was once considered a plaintiff's paradise, its demographics have been changing. During jury selection dozens of prospective jurors voiced hostility to abusive lawsuits and expressed queasiness about awarding damages for touchy-feely injuries like “mental anguish.” (Lanier, however, appears to have been able to exclude most of them from the final panel.)

At the same time, nearly half the prospective jurors instantly raised their hands when Merck counsel Lowry asked if anyone considered Vioxx unsafe “simply” because the company had pulled it from the market. Many also raised their hands when she asked if its removal of the drug from the market “means that the company didn’t do enough research.”

If the company hoped to win points with the public for erring on the side of safety—its stated public rationale for having pulled the drug—the wager may have been naïve.

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