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Legal Strategy for Vioxx to Test Merck

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Pharmaceutical giant Merck & Co. vowed to fight every claim filed by plaintiffs who say they were injured by the withdrawn painkiller Vioxx. Now, with 11 cases slated for trial in the next five months, the viability of the company's scorched-earth strategy is likely to become clear.

More than 9,200 lawsuits involving 18,250 plaintiff groups have been filed against Merck, which pulled Vioxx off the market in September 2004. Merck took the action because of a study that showed the drug was associated with increased risk of heart attacks and strokes after 18 months of use. So far Merck's courtroom record is mixed -- one win, one loss and one hung jury, all in cases involving relatively short-term use of the pain drug.

Merck has ruled out the possibility of a mass settlement, at least in public, noting that the studies do not show increased risk until 18 months of use and many plaintiffs had other risk factors for cardiac problems. Even if the company changes its mind later on, its early aggressive strategy could help discourage marginal suits, and a winning streak could persuade other plaintiffs to settle for less.

Another trial is in progress in South Texas in the case of Leonel Garza Sr., a retired auditor who died in 2001. The facts in the case make it relatively defensible for Merck -- Garza was 71, had a history of heart trouble and took samples of Vioxx for less than three weeks before his death, far less than the 18 months flagged by the study. But the proceeding is in the Rio Grande Valley, which has a history of awarding plaintiffs huge verdicts in product liability cases.

"In South Texas, there's a large chance that Merck is going to get hit and hit hard," said Houston trial lawyer David Berg, who is not connected to the case. But the case's long-term cost may not be as bad, Berg said, because the state's highest court has a history of reversing huge judgments.

The real test, outside lawyers said, will come in February, when when the two judges who are presiding over more than 90 percent of the Vioxx cases will begin more of those trials. .

In New Orleans, U.S. District Judge Eldon E. Fallon, who is overseeing nearly 4,100 federal court cases, has scheduled three trials in as many months and has said he hopes to convene broad settlement talks when they are done.

First comes the Feb. 6 retrial of the case of Evelyn Plunkett, whose husband, Richard Irvin, took the drug for about a month before his fatal heart attack. The previous trial, which was held in Houston because New Orleans was still recovering from Hurricane Katrina, ended in a mistrial after the jury split 8 to 1 for Merck. Plunkett's case will be followed shortly by the case of a medium-term Vioxx user, Ellis Diaz, and that of Charles Borowicz, who took the drug for longer than 18 months.

In Merck's home state of New Jersey, Superior Court Judge Carol E. Higbee also is trying to move more than 4,000 cases along. She has consolidated two cases and will hear them together on Feb. 27. Those cases could

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be particularly critical for Merck because they involve the potentially strongest kind of plaintiffs -- long-term users -- and mark the return of plaintiff's attorney Mark Lanier, who won a \$253 million judgment against Merck last fall in a Texas case involving only short-term use of the drug.

"My strategy is, right is right, and wrong is wrong. If you know your drug may kill people, you owe the duty to warn them," Lanier said, adding that he intends to focus again on internal Merck documents that showed concerns about the drug.

The company has set aside \$675 million for legal costs but has not established a reserve for paying damages.

"We do not have a reasonable basis for establishing a liability reserve," said Ted Mayer, one of Merck's outside lawyers. "It's not as simple as you try one case and you know what is going to happen in a whole category." He said the company does not believe there is clear scientific evidence that Vioxx causes heart attacks, even after long-term use. "Our story stays the same from case to case. . . . The company acted in the interest of patient safety."

Outside legal analysts said Merck may be hoping to deter plaintiff's attorneys from filing borderline cases and to avoid the troubles faced by Wyeth after pulling the diet drug "fen phen" off the market in 1997. Wyeth initially underestimated its settlement costs and took repeated hits to its stock price as the costs rose.

"At this early stage you have to take the position you are not settling. Otherwise you bring everybody out of the woodwork," Fordham University law professor Benjamin Zipursky said. The statute of limitations for most state cases will expire in September and has already run out in some jurisdictions, although new plaintiffs may still join the federal litigation.

Outside lawyers also noted that a case-by-case approach is particularly appealing to Merck because so many of the plaintiffs have other risk factors -- age, obesity, previous cardiac problems -- for the injuries they allege Vioxx caused.

Merck could be several years away from making a meaningful estimate on the total cost of Vioxx, mass tort litigation experts predicted. Wall Street analysts have estimated the costs at \$12 billion to \$20 billion.

Two key developments have changed the landscape since the first three trials, lawyers agreed. First, the New England Journal of Medicine published an editorial that accused the drug company of withholding heart attack data from a 2000 article about Vioxx's safety. "It's just not going to play well with a jury," said Charles Rhodes, a law professor at the South Texas College of Law in Houston. "If the jury's not happy with you because they think you're an irresponsible company" they are more likely to find for even a relatively weak plaintiff's case, he said.

Though Merck's lawyers played down the importance of the editorial, they are clearly taking it seriously -- they got Fallon to grant permission to depose two of the journal's editors before the next federal trial.

On the upside for Merck, the Food and Drug Administration announced a new "preemption" policy last week that could undercut Vioxx lawsuits in some states. The FDA said drug manufacturers that follow the FDA's drug approval and labeling requirements should be immune from state lawsuits alleging that the company failed to warn consumers of the dangers of their drugs. While the policy does not have the force of law, it could add weight to Merck's efforts to get cases thrown out before trial or on appeal, said Scott Elder, a lawyer for Alston & Bird who specializes in defending companies against mass product liability claims.