Merck faces ongoing claims after Texan ruling on rofecoxib

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The drug company Merck may face thousands of lawsuits over its cyclo-oxygenase-2 inhibitor rofecoxib (Vioxx) after losing a court case concerning the death from an arrhythmia of a fit 59 year old man from Texas who was taking the drug. The jury awarded his widow \$253.4m (£140m; €206m)—\$24.4m for economic loss and emotional anguish and \$229m in punitive damages. However, the award will be reduced under Texan law to about \$26m. Merck has said it will appeal.

But Merck faces at least 4200 state and federal lawsuits in the United States by people or their relatives who say they were harmed by the drug.

People elsewhere—the United Kingdom and other European countries, Australia, New Zealand, Israel, and Brazil—are also planning lawsuits. About 400 000 people in the UK are reported to have taken Vioxx (*Observer*, “Vioxx Britons queue up to sue”, 21 Aug, <http://observer.guardian.co.uk>).

The next US case will go to trial in Merck's home state of New Jersey this month. The case is being brought by a Vietnam veteran who had a heart attack, but survived, after taking rofecoxib for two months.

A third case, in a federal court, where rules are stricter than in state courts, will begin in November in New Orleans. The case concerns a man who died from a blood clot after he had taken the drug for a month.

The UK law firms of MSB in Liverpool and Irwin Mitchell in London are representing British people who say they were damaged by the drug. A solicitor for Irwin Mitchell said that the firm was considering suing in the US, where awards are often higher than in the UK.

About 20 million people worldwide are thought to have

taken rofecoxib, which was promoted to doctors and the public as being safer than aspirin and non-steroidal anti-inflammatory drugs because it did not cause gastrointestinal bleeding.

Kenneth Frazier, Merck's senior vice president and general counsel, has said that Merck would appeal the Texan case. He said the case was flawed: the risks of traditional non-steroidal anti-inflammatory drugs and rofecoxib were similar, and no evidence has been shown that rofecoxib caused cardiac arrhythmias.

Each case, Mr Frazier said, presented a different set of facts. He told the *New York Times* (Aug 26; sect A: 1) that it would consider settling suits brought by people who had taken rofecoxib for a long time and had few risk factors for heart disease but that it did not plan to enter a broad settlement. Merck has set aside \$675m to fight the suits.

Financial analysts have estimated that Merck faces liabilities of \$10bn to \$50bn.

Rofecoxib was approved by the US Food and Drug Administration in 1999. It was withdrawn from the market in September 2004 after a study showed that it doubled the risk of heart attack or stroke if it was taken for longer than 18 months. The risk was thought to be due to blood clots. Since then Merck's share price has almost halved.

News reports suggested that the Texan case was considered weak because the autopsy report for Robert Ernst said the cause of death was a cardiac arrhythmia, not a heart attack or stroke. Mr Ernst, a produce manager at the local branch of a supermarket chain and a triathlete who ran marathons, died in his sleep in May 2001. He had been taking rofecoxib for eight months to ease pain in his hands.

Mark Lanier, the winning

Robert Ernst, who died in his sleep in May 2001, had taken rofecoxib (Vioxx) for eight months

lawyer in the case, brought the pathologist who did the autopsy, Maria Araneta, back from the United Arab Emirates, where she currently lives, to testify. She said that she didn't report a blood clot but that it might have been dislodged by cardiopulmonary resuscitation and that she was unaware of

the risk from cyclo-oxygenase-2 inhibitors at the time.

Her testimony was challenged by Craig Pratt, director of research at the Methodist-DeBakey Heart Center in Houston, Texas. He said he didn't think the patient had a clot and he didn't think the death was due to rofecoxib. □