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REASONS

Painkiller verdict shows mistrust of Merck

Carol Ernst and her attorney win their suit against the drug firm Merck following her husband's death.

A court decision against the maker of Vioxx has set off a wave of legal action.

On 19 August a jury in Angleton, Texas, ordered the pharmaceutical firm Merck to pay \$253 million to Carol Ernst, whose husband died after taking the painkilling drug Vioxx.

The amount is almost certain to be reduced, and the company is likely to challenge the decision to go to trial in the first place based on evidence gathered about Vioxx's side-effects. But other plaintiffs are lining up, with more than 4,000 related cases already in preparation (see *Nature* 436, 459; 2005).

"This is the first trial of many," says Alabama attorney Andy Birchfield, who will present the claim of another widow against the New Jersey-based company in a federal court this autumn. "It's just a first step, but it does show that plaintiffs can meet the legal burden of showing that Vioxx caused a particular heart attack or stroke."

Robert Ernst died of an irregular heartbeat — arrhythmia — in 2001 after taking the medication for eight months.

Merck initially developed Vioxx (rofecoxib) as a safer alternative to painkillers for arthritis. Older drugs, such as aspirin and ibuprofen, work by inhibiting cyclooxygenase enzymes, but this can sometimes lead to severe gastrointestinal bleeding. Vioxx is more specific in its target: it inhibits cyclooxygenase-2 (COX-2)

without blocking the related enzyme COX-1.

Researchers thought this would avert gut problems, but some experts fear that inhibiting COX-2 alone can also increase the body's ability to produce heart-stopping blood clots.

Several years ago, studies began to emerge suggesting that people taking Vioxx had an increased risk of heart attack. In 2000, Merck started a study to assess the anticancer potential of Vioxx — it hoped the drug would prevent the formation of colon polyps, which typically overexpress COX-2. But it found that participants taking Vioxx for an average of 18 months experienced twice as many cardiovascular events as those on a placebo.

The company ended the trial prematurely and withdrew Vioxx from the market last year.

Plain speaking

Carol Ernst's case hinged as much on the amount Merck knew about Vioxx's risks before the withdrawal as on whether the drug was the direct cause of her husband's death. Jurors said they felt the drug company was hiding information about Vioxx, and voted accordingly.

It was not easy for lawyers to link Robert Ernst's death to the painkiller. Merck supporters point out that there are no studies associating Vioxx with fatal or non-fatal arrhythmias, adding that Robert Ernst had been taking Vioxx for a far shorter time than

the 18 months that was linked to heart attacks.

His autopsy uncovered no evidence of a blood clot. But the former local coroner testified at the trial that a blood clot could have dissipated before the examination.

Jurors had to feel convinced only that it was more likely than not that Vioxx was linked to Robert Ernst's death. And their decision did not have to be unanimous; in fact, two of the twelve jurors sided with Merck. Some observers believe that the outcome had more to do with sending a message to the pharmaceutical company than pinning down the cause of one particular death. Merck's stock fell by almost 8% after the verdict was announced.

Plaintiffs in other countries, including Britain, are now making plans to come to the United States, where legal conditions are more favourable for their claims.

The Ernst case was not considered the strongest among those pending, but the verdict should not give others carte blanche to launch into Merck, warns Howard Erichson of Seton Hall Law School in Newark, New Jersey. "You can't assume just because one plaintiff won that all plaintiffs will win."

Merck is likely to make a series of legal appeals. Benjamin Zipursky of Fordham University Law School in New York says, "There are many ways this verdict can be challenged." ■

Roxanne Khamisi