

Painkiller Link

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Painkiller linked to 140,000 heart attacks in patients
By Jeremy Laurance, Health Editor

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A blockbuster drug launched five years ago as a revolutionary treatment for arthritis may have caused up to 140,000 heart attacks in US patients of whom 44 per cent died, scientists said yesterday, making it the world's worst drug disaster.

Vioxx, a new type of painkiller launched in 1999, was one of the most heavily promoted drugs in history, with sales in 80 countries and a global market of 80 million patients.

More than 400,000 patients were taking it in Britain, where it could have caused up to 1,000 heart attacks and deaths.

Last September, the manufacturer, Merck & Co, withdrew the drug from the market after evidence emerged linking it with heart problems.

Now, a study of 1.4 million people in California shows that those taking Vioxx had a one-third higher chance of having a heart attack than those taking other painkillers.

David Graham, of the US Food and Drug Administration, and colleagues concluded: "An estimated 88,000 to 140,000 excess cases of serious coronary heart disease probably occurred in the USA over the market life of rofecoxib [Vioxx]. The US national estimate of the case-fatality rate was 44 per cent, which suggests that many of the excess cases attributable to rofecoxib use were fatal." The results, published online by *The Lancet*, will be seized on by critics of the pharmaceutical industry as evidence of the failure of the drug regulatory system to protect the public. Dr Graham had earlier estimated that Vioxx may have caused up to 27,000 heart attacks but the new study caused him to upgrade the estimate by five times.

Doctors on both sides of the Atlantic have warned of a public health emergency over other painkillers in the same class, known as Cox-2 inhibitors, which could also pose a risk.

Deadly Drug

A report in *The New England Journal of Medicine* last October said studies since 1999 had repeatedly indicated a danger with Vioxx. Drug regulators made Merck include a warning in the drug package but never ordered a definitive trial.

Professor David Webb, of the clinical pharmacology unit at the University of Edinburgh, says in *The Lancet*: "It falls to the manufacturers, under the careful review of the regulatory authorities, to provide evidence that this class of drugs is safe."

Asked if this was the worst drugs disaster in history, Professor Webb said: "Quite possibly because these drugs were very widely used."

The previous worst disaster involved the drug Tambocor (flecainide) prescribed to patients with irregular heartbeats. It was estimated to have killed 50,000 patients in the Seventies and Eighties.

The European Drug Safety Agency is conducting an urgent safety review of all the Cox-2 inhibitors, which have a combined global sale of \$10bn (£6bn). Last month, the UK Medicines and Health Care Products Regulatory Agency advised all patients still taking Vioxx, estimated at 750,000, to review their treatment with their doctor.