Vioxx: Who's Responsible?

By ACSH Staff — August 24, 2005

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Last week's news that a jury found the pharmaceutical company Merck negligent in its marketing of the painkiller Vioxx, awarding $229 million in punitive damages, is bad news for all consumers who hope that pharmaceutical companies will continue to develop new drugs -- to address not only their aches and pains but life-threatening conditions like cancer, heart disease, and diabetes.

Specifically, the jury declared that Merck must pay more than $253 million to the family of a Texas man who died after taking the company's Vioxx painkiller. This is the first personal-injury case over the drug to come to trial. There will be more such cases, including in Britain, where some families are considering taking legal action -- and if similar verdicts are the result, we have a classic case of killing the goose that is laying the golden eggs.

Jurors awarded $24.4 million in actual damages and $229 million in punitive damages to the family of Robert Ernst, whose lawyers argued that Merck rushed Vioxx to market without proper safety testing, to compete with Pfizer Inc.’s Celebrex painkiller. The family, who claimed Ernst developed an irregular heartbeat because of Vioxx, said the company played down the drug's potential for causing heart attacks and strokes.

In reality, Vioxx underwent years and years of study and evaluation. It was approved by the U.S. Food and Drug Administration. The FDA reviewed all available data and agreed that Vioxx should be marketed. All drugs have risks as well as benefits. The FDA decided that the benefits of Vioxx outweighed the risks. That approval was based on current, state-of-the-art knowledge about the safety and efficacy of Vioxx.

Such safety and efficacy studies are, by necessity, based on examination of results on a relatively small number of patients. Only post-surveillance data (that is, reports of benefits and risk after the drug is approved and used by large numbers of patients) can pick up unforeseen problems like, in the case of Vioxx, increased risk of heart disease in some highly vulnerable users.

If pharmaceutical companies are held liable for unpredicted consequences of pharmaceuticals that receive FDA blessing, what is the incentive for the companies to produce new drugs? If liability costs (a substantial portion of which are paid directly to plaintiffs' lawyers) wipe out the company's potential to recoup the hundreds of millions of dollars (in some cases, over a billion) spent in researching, developing, and testing a drug, why would a company even bother to pursue new pharmaceutical innovations?
The time has come to consider providing legal immunity to pharmaceutical companies who are granted FDA approval. Otherwise, we are holding them accountable and responsible for effects that (a) may not actually be validated or (b) were not known at the time the drug was approved. Not to consider this option threatens the health of all of us, our children and our grandchildren, who look to research pharmaceutical companies to provide the blockbuster drugs of the future.

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