American Enterprise Institute for Public Policy Research

September 2005

Junk Science Reigns

By John E. Calfee

The recent verdict in a case involving the pain reliever Vioxx demonstrates how junk science can corrupt drug litigation. Reporting on the trial and the broader controversy over the drug exacerbates the problem and discourages patients from taking reasonable risks to relieve pain.

If we know anything about the American tort liability system, we know that it works badly when it gets infected by junk science. The recent Vioxx verdict in Angleton, Texas, is a case in point. The jury awarded $253 million to the widow of a man who died after taking the now-infamous pain reliever. The award will almost certainly be reduced to something like $5 million or $10 million because it ignored statutory limits on punitive damages, and it may eventually get thrown out because of mistakes by the judge. But even at "only" $10 million a case, a string of adverse Vioxx decisions would prove an expensive example of the triumph of the junk lawsuit over science.

Most press accounts portray the jury's decision as simply a reflection of medical science, which supposedly has indicted and convicted Vioxx of causing excess heart attacks. This view prevailed in the four months after September 30, 2004, when Merck voluntarily pulled Vioxx from the market. Those months saw vituperous debate and criticism of both Merck and the Food and Drug Administration in leading medical journals. A renegade FDA staffer testified at congressional hearings along with other critics.

Yet as the recriminations continued, FDA officials and some medical academics quietly started accumulating evidence that painted a very different picture. The FDA immediately pointed out that Advil and older prescription and over-the-counter arthritis treatments (called non-steroidal anti-inflammatory drugs or NSAID) had not been subjected to long-term clinical trials like the one that seemed to reveal heart problems with Vioxx.

Comparative Risks

There is little evidence that Cox-2 inhibitors (the drug class that includes Vioxx and its competitor, Celebrex) are significantly more dangerous for the heart than the older anti-inflammatories they tended to replace. Moreover, Cox-2 inhibitors offer a good trade-off for many patients who suffer from arthritis pain. NSAID users are at risk for ulcers (which kill some 15,000 people a year), and the Cox-2s tend to prevent ulcers. Just last month, a Canadian expert panel voted eleven to one to bring Vioxx back to the market so patients could take advantage of that benefit.

Even if Cox-2 inhibitors carry greater cardiac risks, there is some evidence that more traditional medicines are equally risky. What looked at first like a Vioxx problem, or maybe a Cox-2 problem, might be a problem with anti-inflammatories in general. The FDA now requires strong heart warnings for all these drugs, including the ones that the plaintiff attorneys think should have been used in place of Vioxx.

Much of this new thinking emerged when the FDA convened an advisory committee meeting

John E. Calfee is a resident scholar at AEI. A version of this article appeared in the *New York Sun* on August 22, 2005.

this past February. By a tight margin, that group voted to return Vioxx to the market, and by a thirty-one-to-one vote to keep Celebrex on the market, because its benefits exceeded its risks. The group also endorsed the view that the older drugs are probably equally dangerous for the heart. In April, the FDA formally set forth its assessment of anti-inflammatories, including the failure of the evidence to indicate significant extra heart risk from the Cox-2s and the necessity of heart warnings for all these drugs, new and old. The popular press paid little attention to the events of February and April. None of the papers seems to have retracted the bitter editorials they ran a few months earlier attacking the FDA and Merck or to have covered the new information about risks associated with traditional drugs.

Junk Science and the Texas Case

Which brings us to the Texas case. It should have been difficult for the plaintiff to win. The lawyers had to surmount the views of FDA and Canadian expert panels that Vioxx was safe enough to return to the market; evidence that, to the extent that Vioxx was dangerous, it was not necessarily any more dangerous than other drugs; and the inconvenient fact that the deceased in the case had died of heart arrhythmia, a cardiac problem not associated with Vioxx.

But when the case went to trial, Texas law opened the door to junk science, inviting the jury to overlook all three of those facts. The judge instructed the jury: "You can have 49 percent doubt, and cast your vote where the 51 percent is." Faced with expert testimony on both sides, the jury endorsed scientifically dubious propositions about whether a victim of heart arrhythmia was actually the victim of a heart attack—which might be a side effect of Vioxx—that left no physical traces and whether Vioxx actually caused this particular heart attack if indeed it had even occurred.

Unfortunately, the anti-Vioxx frenzy in the press has left the public inclined to regard the Texas jury's decision with precious little suspicion. Republican Senator Charles E. Grassley of Iowa, for example, went so far as to tell the *Washington Post* that "the Food and Drug Administration was also negligent in the Vioxx case." Junk science now threatens to reign supreme in drug litigation, which is very bad news indeed for patients waiting for new pain relievers and other medicines.