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March 5, 2008

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When will the drug safety wars end? How will they end? A new president? A Supreme Court decision?

We thought **Tom Lamb** might know. He's an attorney based in Wilmington, North Carolina. Like it or not, lawyers like Lamb are shaping the perceptions of the pharmaceutical industry and clinical trials.

When he's not pursuing drug companies, Lamb writes the **Drug Injury Watch blog**, making him a card-carrying member of not one but *two* untouchable castes (law and journalism). His posts are more timely, unbiased and substantive than much of what you'll read online.

**The Template**

In a chat, it quickly becomes clear that Lamb understands that drug companies do make a contribution to society and public health. "I don't condemn the industry," says Lamb. "They do fine work."

Lamb got his start in drug-related matters with the Baycol (cerivastatin) saga. That heart drug was approved in 1997 and **removed from the market four years later**.

It was the Baycol litigation, in Lamb's judgment, which set the tone for the stance that Merck took with Vioxx (rofecoxib). No one in the industry wanted to be scammed for tens of billions of dollars in the manner that Wyeth had been during the fen-phen litigation.

**History Lesson**

So Baycol plaintiffs who could prove that they had suffered from rhabdomyolysis were compensated for their injuries. Other plaintiffs had tough sledding. "They said they were not going to be part of a money machine like fen-phen," Lamb says of Bayer, Baycol's manufacturer. "That is being embraced by the pharmaceutical industry in terms of how they want to resolve cases. As long as they compensate people who have been injured by their drugs, that's not a bad model."

Lamb doesn't contest a reporter's characterization that Merck won the legal battle over Vioxx. He notes that the association between Baycol and rhabdomyolysis was tighter than the one between Vioxx and the health problems ascribed to it. "Heart attacks and strokes can be caused by a lot of things," Lamb says.

**In Self-Defense**

Still, Lamb suggests that there was a silver lining to the Vioxx cases. He asserts that lawsuits helped doctors and regulators outside Merck understand the nuances of the painkiller. "There is a benefit to the tort system," he says. "I don't think we would have known as much about what was known and when Merck knew it, if not for taking depositions and knowing more than the FDA had known."

Lamb is soft-spoken. But he doesn't feel that the FDA (as presently funded, structured and managed) is fully on the public's side. **Judging by opinion polls, the public agrees.** Lamb cites the high percentage of post-marketing trials that never seem to start, much less get completed. He also mentions the antibiotic Ketek (telithromycin) as an example of a drug that might never have been approved if all the facts had been known in a timely fashion.

**Empowering The FDA**

No doubt aware that the people reading this article may feel differently, Lamb goes

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on to say that it was the pressure from litigation (not existing regulation or oversight) that caused Merck to pull Vioxx from the market in 2004. "The FDA and Merck negotiated the label change for a considerable period of time," says Lamb. "The FDA was not in a position to make Merck make the label change."

Correct or not, the perception that companies can keep drugs on the market despite the misgivings of FDA officials is out there. It is a perception that undermines the industry's collective reputation and the inherently noble act of participating in clinical trials. If the research process isn't legit after all, why participate?

Lamb believes the latest package of federal user-fee legislation, passed last fall and known as FDAAA, may give the agency a bit more power, assuming that such authority is not made moot by a recently proposed regulation. **There is a summary of FDAAA here.** "The FDA needs the power to make a label change without the approval of a drug company," says Lamb.

As he's written **in this post**, Lamb is worried that the proposed regulation presumes that the FDA is working effectively, despite several Congressional and Institute of Medicine reports to the contrary. Lamb readily concedes that the reasons for the FDA's performance are complex, and could be improved with additional funding or structural change. "If the FDA were functioning at 100 percent, that would be one thing," says Lamb. "They're not. There need to be other mechanisms involved to keep the companies accountable." As in lawsuits.

### When You Know It

When clinical trial data is kept out of the medical journals, Lamb says, it may be lamentable in scientific terms. It saddens him. But it also helps plaintiffs who are seeking to convince a jury that some sponsors of clinical trials care about economics more than patients. "There are isolated cases where they are not forthcoming," Lamb says of drug companies. "That's clear in the public perception of them and in their own doing."

One of the key elements in many drug cases, and in the asbestos and tobacco litigation, is the ability to prove a company knew of a significant risk and took no action. "The scientific studies are critical to our establishing liability," says Lamb. "The fact that they may have known something but not disclosed something to the FDA, to the public, is something that is central to these cases."

### Coming To A Courtroom Near You

Lamb says litigation over two contraceptives (**OrthoEvra** and the **NuvaRing**) is looming on the legal horizon as a relatively unheralded area of regulatory and plaintiff interest, especially with regard to deep vein thrombosis, pulmonary embolism and other adverse cardiovascular events.

In general, Lamb does not feel the benefits of medicines are obscured in the legal process, crediting his courtroom adversaries working on behalf of sponsor companies. "The drug companies have some of the best lawyers in the business representing them," he says. "They get to explain that there are risks and benefits."

### High Court Docket

Lamb says an upcoming Supreme Court case, *Wyeth v. Levine*, could shift the landscape between drug companies and their critics. The question is whether manufacturers of drugs can be sheltered from plaintiffs' legal attacks by virtue of the FDA's national authority. The key legal term is "preemption."

If granted by the Supreme Court, preemption would ensure that few lawsuits over future Vioxxes would ever reach *any* state or federal courtroom. The high court's likely ruling is not hard to guess. Why? Because (in a case related to Medtronic) it just granted a blanket preemption to medical device manufacturers. Oral arguments for the *Wyeth* case will be heard later this year, with a decision by the summer of 2009.

As for our initial question about when and how the drug safety wars might end? Lamb didn't have any answers. He predicted the present litigation climate would continue unless political circumstances or new legislation shift the debate in some way.

Your correspondent may be naive. But he hopes that better safety databases, such as **the Quintiles iGuard project**, could shorten the lengthy timelines to sort out drug safety controversies. Quicker resolutions would protect patients—and shareholders—with better things to invest in than billion-dollar class-action settlements.

*Editor's note:* Attorneys with alternative perspectives on drug safety are invited to contact **us**.



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