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### **VIOXX LITIGATION Restructure FDA review**

by George W. Conk; Special to The National Law Journal

Ten years ago, even a leading scholar of products liability law like James A. Henderson Jr. of Cornell Law School, the co-reporter for the *Restatement of the Law Third, Torts: Products Liability*, could describe the Food and Drug Administration (FDA) approval process as one that works "almost perfectly." Today no one would say that.

Late last year, the editors of the *Journal of the American Medical Association* wrote that "the major problem with the current system for ensuring the safety of medications is that drug manufacturers are largely responsible for collecting, evaluating, and reporting data from post-marketing studies of their own products." See Phil B. Fontanarosa, et al., "Postmarketing Surveillance-Lack of Vigilance, Lack of Trust," *JAMA* 292:2647 (Dec. 1, 2004).

In the recent Vioxx case brought by the wife of Robert Ernst, attorney Mark Lanier deployed evidence of the conflict between sales imperatives and public health considerations with devastating effect. He pummeled Merck & Co. Inc. with its advertising material-which trained its sales force to minimize the cardiovascular risks of Vioxx. Merck even used devastating phrases like "Dodgeball" to convey to its sales staff that tough questions were to be avoided, not answered. Such disregard for the health risks of its products led to the huge punitive damages award.

Merck described itself in court as engaging in careful studies and ultimately acting responsibly by withdrawing the drug. But when on Sept. 30, 2004, Merck withdrew Vioxx from the market, Peter Juni and other researchers analyzed all the Vioxx studies and concluded that by the end of the year 2000, the risk of heart attack and other cardiovascular events was more than doubled for those using Vioxx. Their study was published in the *Lancet* in November 2004. The product had remained on the market more than three years after the dangers were well established in the researchers' view.

Since the *Second Restatement of Torts* gave birth to modern products liability law in 1965, many have held that drugs are inevitably dangerous and that nothing can be done to make them safer. Liability has turned on the adequacy of the warnings, not the design. An aspirin is an aspirin. But our experience with Vioxx, Celebrex and other "Cox 2 inhibitors" has shown that manufacturers make design choices and that different designs have different effects. There are significant differences within the class of drugs called Cox 2 inhibitors. Nearly 60% more patients on Vioxx than on Celebrex experienced significant systolic blood pressure elevations. Thus, while Vioxx remains off the market and the FDA asked Pfizer Inc. voluntarily to withdraw Bextra, the FDA concluded in April that "the benefits of Celebrex outweigh the potential risks in properly selected and informed patients."

**'Safe and effective'**

The problem with the drug approval system is that the complexity of drug safety assessment has been underestimated. The Food, Drug and Cosmetic Act commands that a drug be approved for marketing only when it has been shown to be "safe and effective." When the FDA approves a drug, it tells the manufacturer just that in its approval letter. The pharmaceutical companies have taken the view that "that settles it." And the public assumes that is so-the drug is reasonably safe and effective-though you have to watch out for "side effects."

But FDA approval should be seen as but a stage in product development and study. Until now, approval to market has yielded a new stage in product development, which could be called "the poorly controlled mass experiment stage." Millions of people took Vioxx as "super aspirin." Doctors prescribed them widely-despite early suspicions that Cox 2 inhibitors presented cardiac risks.

It was those suspicions that Merck's marketing was designed to allay. The only mechanism in place for studying the effects of drugs once they are mass marketed is VAERS, the Voluntary Adverse Event Reporting System. This haphazard system directs reports of suspected drug-related injuries to the manufacturers themselves for review and analysis. That is the conflict of interest at the heart of the system.

The *Ernst* verdict on Vioxx shows that we need to restructure the premises of our drug marketing and review system along these lines:

The fundamental responsibility of the manufacturers is to be good stewards of their products. From concept development through mass marketing, those who develop products have an obligation to continue to study the products' safety and effectiveness systematically and to report the findings to the government.

Pharmaceutical sales should move from a largely unregulated post-approval free market model to a regulated, licensed public utility model.

FDA premarketing approvals should be conditional, not, as today, essentially unconditional. A five-year approval conditioned on undertaking systematic studies of health effects of newly approved drugs can and should be enacted as a norm by the FDA. The agency has the power without new legislation to impose such obligations.

Although FDA post-marketing review has problems-such as manufacturer capture of FDA review committees-these can be dealt with by political leadership and congressional oversight, without creating the kind of new post-marketing bureaucracy for which some, like FDA in-house whistleblower David Graham, have understandably called.

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