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The Arbino Autopsy: S.B. 80 By Gerald S. Leeseburg .....	10
Arbino Decision Provides Fairness and Predictability By Richard S. Lovering .....	12
From Vioxx to Gadolinium, Along the Preemption Path By D. Andrew List .....	14
<i>Hughes v. Department of Commerce</i> Geese, Ducks, Turkeys and Other Birds of Administrative Law Explained By Jim Leo Page .....	15
Better Lawyer .....	21
Inside Juvenile Court By David W. Hardymon .....	33
Top Ten Things the Court Likes to See from Practitioners By The Honorable C. Kathryn Preston and Kristin A. Wehrmann .....	38
I-9 Compliance: DHS Raises the Bar By Jane Lee and Luba I. Seliavski .....	39
News From Nameless By Lloyd E. Fisher .....	46

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# From Vioxx to Gadolinium, Along the Preemption Path

“I would argue that the FDA, as currently configured, is incapable of protecting America against another Vioxx. We are virtually defenseless.”

Dr. David Graham (November 18, 2004)

By D. Andrew List

A little more than three years ago, Dr. David Graham, Associate Director for Science and Medicine in the Food and Drug Administration’s Office of Drug Safety, gave the above assessment of the FDA in testimony before the United States Senate. Since that time, many other pharmaceuticals and medical devices have been the subject of recalls or warnings, despite having received initial approval from the FDA. Moreover, a recent report from the Department of Health and Human Services confirms that many of Dr. Graham’s concerns are valid today.

Why should these issues be cause for concern? Two reasons. First, as health care consumers, each of us needs to be certain that the drugs and devices provided for our care are safe and effective. The same is true for health care providers—physicians need to know that drugs and devices prescribed to their patients are safe and effective.

Second, as lawyers, we should be concerned that our clients have adequate remedies if they suffer injury as a result of a dangerous drug or medical device. And, it is this subject that will be addressed by the United States Supreme Court in *Riegel v. Medtronic*.

Charles Riegel suffered serious injury when a balloon catheter burst while he was undergoing an angioplasty procedure. He and his wife sued the catheter’s manufacturer, Medtronic, Inc. Medtronic moved for summary judgment, arguing that the Riegels’ claims were barred by the doctrine of federal preemption. In a nutshell, Medtronic argued that the Riegels’ tort claims sought to impose state requirements that differed from the requirements of the Food, Drug and Cosmetic Act, and that the claims were preempted by federal law. The district court granted summary judgment based upon federal preemption, after which the Second Circuit affirmed.

In addition to being a classic federalism battle, preemption raises critical issues of public policy. For example, does the FDA have the resources necessary to effectively monitor and police the safety and effectiveness of pharmaceuticals and medical devices?

In a recent editorial published in the “New England Journal of Medicine,” the authors outlined these policy issues, noting that:

Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society. Is it in the people’s interest to shield medical-device companies from product-liability claims? Would such a decision benefit patients by making more lifesaving devices available, or would there be adverse effects on the overall safety of devices? Is the FDA pre-marketing approval process sufficiently rigorous and comprehensive to justify immunization of the industry against tort claims? And if medical-device manufacturers are shielded from liability, what about drug manufacturers? Or would society be better served if patients retained their right to seek legal redress when they believed they had

been damaged by a faulty medical device? In the long run, would this result in safer medical devices for patients?

By rejecting Medtronic’s plea for immunity, the Supreme Court can act now to protect patients. From time to time, the Court agrees to hear a case that may have major, even momentous, implications for health care. *Riegel v. Medtronic* is such a case.

The Supreme Court’s decision will have far-reaching implications for health care consumers. For example, consider the FDA warnings issued in May, 2007, regarding gadolinium-based contrast agents. These products have been used for more than a decade in magnetic resonance imaging (MRI) scans to enhance the quality of the images.

Without question, gadolinium-based contrasts are an extremely valuable tool to physicians. However, years after being approved by the FDA, a growing body of evidence suggests that patients with kidney insufficiency who receive gadolinium-based agents are at risk for developing a debilitating and potentially fatal disease known as nephrogenic systemic fibrosis. NSF results in the thickening of the skin and connective tissues, inhibiting movement and resulting in broken bones. Thus, the FDA now suggests that patients should be screened for kidney problems prior to receiving an MRI scan that includes a gadolinium-based contrast agent.

The gadolinium example provides a real-world glimpse into the potential impact of Riegel. Should patients who develop NSF after exposure to gadolinium-based contrast agents be allowed to bring tort claims against the manufacturers of these agents? Beyond the law of preemption, the answer likely depends upon whether you believe that manufacturers will always be truthful in their representations to the FDA, and whether you are willing to substitute the judgment of the FDA for the judgment of a jury of your peers. It is a fascinating legal battle, with wide-ranging social implications, that will have a profound impact on patient rights.

1. FDA, *Merck and Vioxx: Putting Patient Safety First?* (United States Senate Committee on Finance, November 18, 2004).
2. *The Food and Drug Administration’s oversight of clinical trials.* Washington, D.C.: Office of Inspector General, Department of Health and Human Services, September, 2007 (document #OEI-01-06-00160).
3. *Riegel v. Medtronic, Inc.*, No. 06-179, was argued before the United States Supreme Court on December 4, 1007.
4. *A Pivotal Medical Device Case*, *New England Journal of Medicine*, January 3, 2008.



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