

Medical Device Safety: Federal Vs. State Power

Sports coaches often say offense wins games but defense wins championships. Medical device firms play offense by launching new products, innovating and feeding their R&D pipelines. They play defense by shielding themselves from the financial costs of product liability. One component of this defense in recent years has been the doctrine of federal pre-emption. Federal pre-emption is the notion that, if the FDA approves a medical device, injured patients should not be able to sue product manufacturers by alleging defective warnings.

By way of background, in 1976, Congress passed the Medical Device Amendment (MDA) to the Federal Food, Drug and Cosmetic Act. This expanded the FDA's authority to ensure medical devices are safe and effective. Congress recognized that national, uniform regulations encourage emerging new technologies.

By contrast, overlapping federal and state rules could stymie innovation and undermine the public health. Imagine 50 state agencies ruling on medical device safety and effectiveness. That is the basis for pre-emption in product liability cases involving medical devices.

Riegel v. Medtronic Reinforces Pre-emption

In mid-2007, the Supreme Court agreed to consider federal pre-emption in the case of *Riegel v. Medtronic*. At issue: is whether the MDA pre-empts common law tort claims against medical devices that entered the market pursuant to the FDA's premarket approval PMA process. *Riegel* involved an Evergreen balloon catheter, a PMA device used during angioplasty to open clogged arteries. *Riegel*'s heart was blocked after his doctor unsuccessfully tried to dilate a partially occluded coronary artery. The FDA had approved this catheter after a multi-year vetting process. The Evergreen

balloon catheter was contra-indicated for patients like *Riegel*, whose coronary artery was diffusely diseased and heavily calcified. Calcifications often have hard edges, and the device's end point is a balloon. Despite the product's warning label, *Riegel*'s doctor over-inflated it, pumping it to 10 atmospheres, instead of the recommended eight.

In January 2008, in an 8-1 decision, the Supreme Court held that federal pre-emption bars state law claims that challenge the safety or effectiveness of medical devices receiving FDA premarket approval. The court's decision hinged largely on its finding that FDA's PMA approval of a Class III device does, indeed, impose federal requirements on the device. Also, successful state law tort claims would impose device requirements different from—or in addition to—those already imposed on the device by the PMA process.

Much lawyer, consumer and editorial outrage erupted after the ruling. However, *Riegel* affects only a narrow slice of medical device claims and lawsuits—those involving PMA devices. Most devices do not come to market through the PMA path. In 2005, for example, the FDA authorized 3,148 devices under 510(k) but gave premarket approval to just 32 devices. The Court's decision bars certain claims for injuries that result from aspects of the device that were scrutinized during PMA review.

Most claims—suits against non-PMA devices—will still survive, as will claims for manufacturing defects. Plaintiffs can also sue makers of devices not conforming to the specifications or safety processes approved during PMA review. They can also sue manufacturers who deceive regulators by giving false information to gain approval. *Riegel* will not cause a sea change in the medical device product liability landscape.

However, we should not belittle *Riegel*'s impact just because it only applies to PMA



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devices. While Riegel only impacts a handful of devices, that cross-section consists of claims that often have high-dollar values, jumbo reserves, high jury values, high exposure and high legal costs. PMA devices, by their nature, are often life-supporting and life-sustaining. If they do not work as intended, a patient death or catastrophic

injury often ensues. These are expensive cases, carrying large claim reserves and settlement values.

If Riegel removes many claims against PMA devices, the financial impact of these cases—which are high severity claims—may be disproportionate to their stick count. Thus, the Riegel decision is finan-

cially significant for a subset of the medical device universe.

Case May Make Things Tougher on Outsourcing

In some ways, Riegel could create new challenges for device firms involved in outsourcing. Public perceptions—fueled by the media and the plaintiff's bar—are that Riegel gave device companies a “free pass” on safety and weakens consumer protections. Couple this with the spotlight shone on some heralded instances of outsourcing hazards and challenges compound. For example, the scare over tainted heparin that Baxter faced after outsourcing to China. While not drawn from the device arena, kid's toys outsourced for overseas manufacture raised safety and health concerns. Even the term “outsourced” has negative connotations to many consumers. Many American workers hear the term outsourced just before they hear the word layoffs. American consumers can be skeptical when it comes to outsourcing.

Combine that with the notion of outsourcing medical devices and consumers may wrongly perceive that outsourcing is a way to do things “on the cheap,” at a lower quality. This can become a dangerous association when the subject is healthcare. When viewing an adverse patient outcome involving an outsourced product, or a key component made by an outsourcing company, consumers and jurors may “buy” claims of defect, using a jury trial as a way to “right the perceived wrongs” wrought by Riegel. Thus, Riegel might create new challenges for medical device outsourcing firms.

Why Riegel Decision Could Have Only a Limited Effect

The Riegel decision may have a limited shelf-life for three reasons.

First, some outraged lawmakers are seeking to overturn Riegel. In mid-2008, Reps. Frank Pallone and Henry Waxman introduced The Medical Device Safety Act of 2008-HR 6381. In July, Sens. Patrick Leahy and Ted Kennedy introduced simi-

lar legislation. Given the November election results, many predict that Democrats will push legislation to “neuter” pre-emption and broaden consumer access to courts for damages against device companies.

Second, Barack Obama's victory may give anti-pre-emption proposals some legs. For example, an Obama administration may produce an FDA with a more circumscribed view of federal pre-emption. Two of the top candidates being discussed for FDA commissioner are gadflies who have been sharp critics of the agency.

Third, the Supreme Court heard arguments in December 2008 in a case pitting Wyeth against a guitarist who lost part of an arm after she was improperly injected with the anti-nausea drug Phenergan. The doctor accidentally hit an artery while injecting the drug, causing gangrene that required forearm amputation. A Vermont jury awarded Diana Levine \$7 million in damages. Her attorneys argued

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that Wyeth should have given stronger warnings about the dangers of administering Phenergan. (At the time, Phenergan's label had four separate warnings about the risk of improper IV administration.)

The key issue: whether the FDA-approved label pre-empts state product safety laws, as Wyeth and other drug companies argue. They say state juries looking at one patient's experience don't

have the expertise to decide if a drug has proper warnings.

If the court again rules like it did in Riegel v. Medtronic, and favors pre-emption, congressional Democrats have pledged to push legislation to preserve a patient's right to sue under state law.

If Riegel did not solve the product liability problems faced by medical device companies, what then should these companies do now to boost their corporate immune systems from financial loss? This topic we will address next month.

This is one in a two-part series. ❖

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