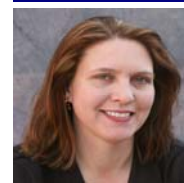


A multi-disciplinary approach to hazard communications.

## ***RIEDEL V MEDTRONIC: PRE-EMPTION OF CERTAIN CLASS III MEDICAL DEVICES*** **No. 06-179, SLIP OP. (U.S.S.C. FEBRUARY 20, 2008)**

**Court's Decision in Riegel.** In *Riegel v. Medtronic*, the United States Supreme Court considered whether the pre-emption clause in the Medical Device Amendments (MDA) of 1976, 21 U.S.C. § 360(k), bars common law claims typically filed in state court that challenge the safety and effectiveness of the device, particularly where the device has been given Pre-Market Approval (PMA) by the Food and Drug Administration (FDA). The Court determined that the 1976 MDA pre-empted state law claims for certain types of Class III medical device products. In this case, the U.S. Supreme Court asked and decided what pre-emption is allowed Class III medical devices given FDA authority pursuant to a Pre-Market Approval (PMA) application.



Lori Hardaway's principle legal work is food, drug, and medical device matters, including regulatory compliance, patent prosecution, and infringement opinions.

She discusses here pre-emption given FDA authority pursuant to a PMA application. Ms. Hardaway is a 2001 graduate of Sandra Day O'Connor School of Law and holds a Ph.D. in medicinal chemistry and a Pharm.D. from the University of Arizona College of Pharmacy.

Specifically, the Supreme Court held that plaintiffs did not have claims against Medtronic that it had violated New York common law in its design, labeling, or manufacturing of the catheter because those claims would impose state requirements on the medical device where it had been specifically regulated by federal law. The Court held that instead of violations of state law, the Riegels could have alleged violations of federal law, which would have claimed specifically that Mr. Riegel's catheter violated the requirements of the Pre-Market Approval authorized by the FDA. The Riegels did not make these allegations and for that reason, their claims were dismissed. Also, the Supreme Court affirmed that the FDA has exclusive authority over the safety and effectiveness of medical devices granted PMA authorization.

**Pre-emption in *Riegel*.** In *Riegel*, the subject pre-emption at issue was expressly stated in the federal MDA statute, U.S.C § 360(k), as follows:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
- (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

The U.S. Supreme Court found that this 1976 MDA statute specifically called for federal oversight of medical device products, the most extensive of which is reserved for Class III devices that must receive PMA from the FDA before these products may go to market. The FDA's PMA requirements allow Class III devices to be commercially available to consumers only after the FDA has reviewed and approved the design, labeling, and manufacturing specifications for these products and has determined that such specifications provide a reasonable assurance of safety and effectiveness. After that decision is made by the FDA, the device manufacturer may not make changes to the device unless they first seek and obtain permission from the FDA. *Slip Op.* at 3-5.



The pre-emption considered and decided in *Riegel* applies to a medical device product that must gain Pre-Market Approval (PMA) before it may be manufactured, labeled, or advertised, or sold to consumers. *Id.* at 8-12. PMAs are typically considered for Class III devices and obtaining PMA authority from the FDA “is a ‘rigorous’ process.” *Id.* at 4. After submittal of an application, the FDA evaluates the product’s “safety and effectiveness” under the conditions set forth on the product’s proposed labeling and grants the application only upon finding a “reasonable assurance” that such safety and effectiveness exists. *Id.* at 4-5 *citing* §360c(a)(2)(B) and §360e(d). In *Riegel*, the medical device product was an Evergreen Balloon Catheter that was inserted into Mr. Riegel’s coronary artery to attempt to dilate a blocked artery. *Id.* at 6.

**Other Medical Devices Not Subject to Pre-emption.** By contrast, other Class III medical device products are given FDA authority for commercial distribution via 21 U.S.C. §510(k) based on substantial equivalence. In those instances, the medical devices are approved via §510(k) but their approval is based on the demonstration of a substantial equivalence of the product to a similar legally marketed device (i.e., a predicate device). The United States Supreme Court in *Lohr* held that devices cleared for commercial distribution via § 510(k) were *not* subject to pre-emption. *Lohr v. Medtronic, Inc.*, 518 U.S. 470 (1996). Specifically, the Court in *Lohr* held that negligent design claims and plaintiff’s manufacturing and labeling claims were not pre-empted by the FDA regulatory scheme because Lohr’s Medtronic pacemaker was a Class III medical device subject to approval via a substantial equivalence test under § 510(k). *Id.* It was not a medical device subject to a PMA process. *Id.*; *Riegel*, Slip Op. at 8-10.

Thus, although pre-emption was not applied to medical devices approved for commercial distribution pursuant to § 510(k) based on substantial equivalence, as in *Lohr*, pre-emption was recognized and applied to medical devices approved for commercial distribution by a PMA pursuant to § 360e, as in *Riegel*. *Riegel*, Slip. Op. at 4-6, 8-10. The Court in *Riegel* distinguished between the two types of Class III medical devices and found that devices authorized under a PMA had been held to “federal requirements” that comprised a federal safety review. *Id.* at 9. As support for this finding, the Court in *Riegel* noted that in 2005 “the FDA authorized the marketing of 3,148 devices under §510(k) and granted premarket approval to just 32 devices.” *Riegel*, Slip Op. at 4.

**The Effect of Pre-emption.** The residual effect of pre-emption will vary. Depending on the language of the federal statute and the specific facts at issue in a case, pre-emption will have different applications under different circumstances. Generally, pre-emption is a rule of law that where the federal government has enacted legislation through Congress on a specific subject matter, that legislation shall be controlling over state laws in a way that will preclude the state from enacting laws on the same subject. Essentially, pre-emption is the displacing affect that federal laws have over state laws where Congress has specifically stated the federal law will occupy the field. In applying pre-emption, U.S. federal courts have developed a large and complicated body of case law to resolve conflicts between federal and state laws. Typically, federal courts will attempt to reconcile inconsistent state and federal laws and if the laws may not be reconciled, then the federal law will generally preempt the state law only to the extent of the inconsistency. Where there is federal law on the subject matter at issue in the case, the federal law pre-empts application of state law and displaces or supplants it.

Pre-emption may affect different products in different ways. For example, the effect of pre-emption in *Riegel* precluded a state court from ruling on negligence, strict liability, or warning issues made by a plaintiff about a medical device that had been awarded FDA authority following the review, consideration, and ruling on the manufacturer’s PMA application. Conversely, in *Lohr*, the effect of pre-emption was to allow a state court to rule on negligence, strict liability, and warning issues made by a plaintiff about a medical device that was awarded FDA authority following submittal by a manufacturer based on a Section 510(k) application, which is based on review and consideration of the device because it is “substantially equivalent” to another device already approved by the FDA.



**Specific Comments About *Riegel*.** Some media have reported that medical device manufacturers are now “immune from suit” or that pending lawsuits alleging defective medical device products will be dismissed. See “*Supreme Court Shields Medical Device Manufacturers from Consumer Lawsuits*,” February 25, 2008, NaturalNews.com; see also “*Medical Device Ruling Redraws Lines on Lawsuits*,” New York Times, February 22, 2008; also compare “*Interpreting the Supreme Court’s Medical Device Decision*,” U.S. News & World Report, February 22, 2008.

Only a small subset of medical device products—those authorized by a PMA—were the subject of the ruling in *Riegel*. Even then, that subset of medical devices remain subject to a lawsuit where the device failed the specifications required by the PMA or where the device otherwise violated the requirements of the federal regulations governing the PMA. Class I and Class II devices were not subject to the ruling. Also, Class III devices that gain clearance for commercial distribution pursuant to a mechanism other than a PMA (e.g. by 510(k) clearance) are not the subject of the ruling. The ruling may be expanded at a later time to include additional medical device products, but another, subsequent ruling must apply and expand the *Riegel* decision.

**Preemption Allows Consistent Application of Law and Standards to Medical Device Manufacturers.** Also, the U.S. Congress could change the result in the case. If the Congress passed legislation changing whether pre-emption was available to medical device manufacturers in a lawsuit, that decision would affect more or all medical device products and device lawsuits going forward. Some U.S. congressional representatives have threatened such an action. See “*Medical Device Ruling Redraws Lines on Lawsuits*,” New York Times, February 22, 2008; “*Interpreting the Supreme Court’s Medical Device Decision*,” U.S. News & World Report, February 22, 2008.

**FDA Regulatory Compliance Is Prerequisite to Any Preemption.** Finally, the obvious but prerequisite requirement of FDA regulatory requirements must be noted. Medtronic gained preemption in *Riegel* because it had properly obtained FDA authorization to proceed with the manufacturing and marketing of its catheter following the successful review and consideration of the PMA by the FDA. Had Medtronic been acting outside the scope of their approved PMA (e.g. by altering manufacturing, labeling or the like) the outcome would have been different. Thus, eligibility for pre-emption begins with strict compliance with applicable FDA regulations.

**Additional Medical Device Products May Be Impacted By Legislation.** Finally, displacement of state law with federal law is typically a favorable development for manufacturers because it improves the standards under which the manufacturer is held accountable. It makes applicable standards consistent and uniform, and it applies the law evenly from case to case. Too often, the application of state law by state courts, and even the application of state law by federal courts in certain circumstances is uneven and is given random application, especially where the subject application is the common law torts claiming negligence or the varying language of individual state statutes addressing strict product liability.

*NOTE: This article is informational only and does not provide or seek to provide legal advice. Similarly, this article and its information does not create or in any way establish an attorney-client relationship. Consult a lawyer about your products, medical devices, and applicable pre-emption of federal law governing those products before making business, legal, or strategic decisions in your company.*

Lori A. Hardaway, Pharm.D., Ph.D., J.D.

AVERTURE

Two CityPlace Drive, Suite 200  
St. Louis, Missouri 63141

Main: 314.862.7878

Cell: 623.326.0194

Facsimile: 314.862.7882

Email: [lori.hardaway@averture.net](mailto:lori.hardaway@averture.net)

[www.averture.net](http://www.averture.net)

