Supreme Court Upholds Express Preemption of State Law Product Liability Claims For Medical Devices Given FDA Pre-Market Approval

The United States Supreme Court has confirmed that state law product liability claims against manufacturers of medical devices given pre-market approval by the U.S. Food and Drug Administration (“FDA”) are preempted, pursuant to the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq.

Medical device companies have reason to celebrate the decision in Riegel v. Medtronic, Inc., No. 06-179, ___ U.S. ___ (Feb. 20, 2008), which is the Court’s first device preemption pronouncement since it denied preemption for devices cleared through the 510(k) process 12 years ago. See Medtronic v. Lohr, 518 U.S. 470 (1996). The Riegel decision effectively insulates medical devices that pass the FDA’s pre-market approval process from most product liability lawsuits challenging the safety of the device.

In Riegel the plaintiff sued Medtronic over a catheter that had ruptured in Charles Riegel’s coronary artery, claiming damages under various state law causes of action including strict liability, breach of implied warranty, and negligence. The Medtronic catheter at issue was a Class III medical device and had been cleared by the FDA pursuant to its “rigorous” pre-market approval (“PMA”) process under the Medical Device Amendments.

When Congress enacted the Medical Device Amendments, it expressly preempted any state law “requirement which is different from, or in addition to, any requirement applicable . . . to the device” under federal law. 21 U.S.C. § 360k(a)(1). The Court first held that the PMA process imposes “requirements” under federal law, because a PMA involves the FDA making a specific determination that a particular device “offers a reasonable assurance of safety and effectiveness.” Because state law tort claims can—through the imposition of liability—establish their own “requirements” for the safety and effectiveness of medical devices, the Court held that such claims are preempted to the extent they require any characteristic different than what the FDA requires in a PMA. In practical terms, the Court’s ruling barred all of the plaintiff’s causes of action against Medtronic.
Though *Riegel* provides liability protections for medical devices approved through a PMA, it is important to note that it did not establish preemption immunity for all medical device claims. First, state law tort claims are permitted under *Riegel* to the extent the state requirements are “parallel” to—and not “different from, or in addition to”—the FDA’s PMA requirements, such as when a state law allows tort recovery for violation of FDA regulations. For example, a plaintiff can still pursue a state law claim that a manufacturer failed to comply with the FDA’s specifications or labeling rules. Second, as the Supreme Court ruled in *Lohr*, medical devices cleared for marketing under the FDA’s alternative, more lenient 510(k) process do not receive the preemption protection against tort liability afforded under *Riegel*. The 510(k) process, named after the section of the statute that authorizes it, generally requires that a Class III device be “substantially equivalent” to a previously approved device, and does not involve the same oversight or particularized determinations as a PMA.

The vast majority of new Class III devices are authorized under the more forgiving 510(k) standard (for example, 3,148 in 2005 versus 32 under a PMA). Although only a small percentage of regulated devices are required to go through the PMA process, those that do are typically the devices that pose the greatest risks and thus are likely litigation targets. Whereas in the past companies favored the 510(k) process over the PMA process due to the significant cost savings, it remains to be seen whether companies will now embrace the PMA in order to help insulate them from a possible mass tort scenario.

*Riegel* is the first of three highly anticipated Supreme Court rulings this term addressing preemption in the drug and device context. In *Levine v. Wyeth*, No. 06-1249, the Court will address whether FDA prescription drug labeling requirements preempt state law tort claims alleging inadequate warnings and instructions. In *Warner Lambert v. Kent*, No. 06-1498, set to be argued on February 25, 2008, the Court will address whether federal law preempts a state law imposing liability against manufacturers for committing fraud on the FDA in seeking approval of a pharmaceutical product, even if the FDA itself finds no such fraud.

While these three actions involve the pharmaceutical and medical device industry, the Court’s pronouncements in *Riegel*, *Levin*, and *Kent* are sure to impact the product liability landscape for manufacturers of other products as well. In addition, whatever the outcome in *Levin* and *Kent*, these decisions will likely generate a flurry of legislative action as both opponents and proponents of preemption seek to modify the landscape that ultimately results.

[Click here for a copy of the opinion.]
If you have any questions or would like additional information, please contact your Alston & Bird attorney or any of the following attorneys.

Scott A. Elder  
404.881.7592  
scott.elder@alston.com

Trenton A. Hamilton  
404.881.4977  
trent.hamilton@alston.com

Victoria Davis Lockard  
404.881.7786  
victoria.lockard@alston.com

Bernard Taylor, Sr.  
404.881.7288  
bernard.taylor@alston.com

Jane Fugate Thorpe  
404.881.7822  
jane.thorpe@alston.com

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