

Athletic coaches often say that offense wins games, but *defense* wins championships. Drug and 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. A pillar of this defense in recent years has been the doctrine of federal preemption. Federal preemption is the notion that, if the FDA approves a drug or medical device, injured patients should not be able to sue manufacturers by alleging defective warnings. Preemption's viability has often become an assumption in underwriting coverage for FDA-approved drugs and devices.

Riegel v. Medtronic Reinforces Preemption

In 2007, in *Riegel v. Medtronic*, the Supreme Court agreed to consider the issue of whether federal law preempted common law tort claims against medical devices that entered the market, pursuant to the FDA's premarket approval (i.e., PMA) process. In 2008, the Supreme Court held that federal preemption barred state law claims challenging the safety or effectiveness of medical devices receiving FDA premarket approval. The Court's decision hinged largely on its finding that the FDA's PMA of a Class III device *does*, indeed, impose federal requirements on the device.

Riegel impacted only a narrow slice of claims and lawsuits – those involving PMA devices. Most devices do not come to market through the PMA path, so defective design and failure-to-warn suits against non-PMA devices still survive, as do claims for manufacturing defects. While Riegel only impacts a handful of devices, claims against them are often high severity claims, involving large dollar values, jumbo reserves, high jury values, high exposure and sizable legal costs. Thus, the Riegel decision is financially significant for a subset of the medical device universe, as well as life science insurers.

Wyeth v. Levine Undermines Preemption

In 2008, the Supreme Court heard arguments in a case pitting Wyeth against Diana Levine, a guitarist who lost part of an arm after her doctor improperly injected her with the anti-nausea drug Phenergan. The physician hit an artery while injecting the drug, causing gangrene that required forearm amputation. A Vermont jury awarded Ms. Levine \$7 million in damages. Her attorneys argued that Wyeth should have given stronger warnings about the dangers of administering Phenergan. (At the time, Phenergan's label had four separate warnings about risks of improper IV administration.) The key issue: whether the FDA-approved label pre-empts state product safety laws, as Wyeth and other drug companies argued. They said that state juries reviewing one patient's experience lack the expertise to assess drug warnings.

In 2009, the Court's majority held that regulations applying to branded drugs allow manufacturers to adhere to differing state and federal law obligations. In rejecting preemption for branded drugs, the court relied upon a "Changes Being Effected" (CBE) provision of the FDA regulations, which lets branded drug makers unilaterally add or strengthen warnings and contraindications on a drug label without prior FDA approval. The Court reasoned that the CBE provision lets manufacturers comply with heightened state standards imposed by juries in product liability lawsuits. Many commentators saw this decision as a dismantling of the preemption defense for branded drugs. The Court did not address the issue for generic drugs.

Risk Management Implications for Drug Firms

From a risk management and underwriting standpoint, the implications of *Wyeth v. Levine* could mean that (1) drug companies may no longer count on FDA approval being a solid defense, (2) drug labeling will become more complicated, with the possibility, however remote, that drug companies will need different labels for each state, (3) plaintiff attorneys may sue drug companies with renewed vigor under the belief that the preemption defense is dead and increase venue-shopping to get cases heard in courts more congenial to them, and (4) drug firms may need to alter their FDA submission approach for labels based on new lawsuits or incidents to establish FDA responses prior to a case going to jury.

While *Wyeth v. Levine* addressed preemption for branded drugs, the U.S. Supreme Court has

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not yet addressed the issue with respect to generic drugs. Some lower courts have refused to recognize a preemption defense. While others believe that preemption remains viable for generic drug companies, the theory remains unvalidated. That may soon change, though, as on 12/10/10 the U.S. Supreme Court agreed to hear three cases addressing generic drug preemption. The Court decided to hear the cases, despite an earlier recommendation from the U.S. Solicitor General that the Supreme Court decline review. Regardless of how it rules, the Supreme Court in 2011 is likely to alter the legal landscape of the Federal preemption defense, at least as it applies (or doesn't) to generic drugs.

Clearly, branded drug makers face a challenging legal landscape amidst a tort environment that favors consumers and weighs little the FDA's approval. Pharmaceutical firms must invest in product safety systems, rigorously monitor the product user environment and seek insurance partners conversant with their business challenges and their need for rock-solid financial protection. Underwriters must factor in the shifting legal landscape when considering new accounts. If *Riegel* and *Levine* did not solve the product liability problems that life science companies face, what then should firms do now to boost their corporate immune systems from financial loss? The rulings underscore the need to invest in strong safety and risk management programs. Let us therefore turn our attention to that.

Five Life Science Risk Management Strategies

All the risk management strategies that made sense pre-*Riegel* and pre-*Levine* still apply. Five risk management strategies to consider:

1. Do your due diligence! Carefully investigate and continually re-evaluate business partners and suppliers. At multiple points, conduct visits – perhaps unannounced – of the production process and independently test sample products. Verify that your business partner makes products in accordance with your specifications, with the quality of materials specified. If you face a product liability claim, plaintiff attorneys will scrutinize this in microscopic detail.

2. Create dispute resolution mechanisms before a claim or controversy. Let's say an infusion pump malfunctions. One party thinks the culprit is a manufacturing defect; the other party thinks it received flawed specifications? What if each company points the finger at the other when a patient is hurt and an expensive bodily injury claim arises? Being prepared early on to resolve a claim with your business partner can facilitate a more favorable outcome.

3. Regularly review product instructions with qualified legal counsel. Craft and draft thorough warnings. Properly instruct consumers on the use of medications and medical devices, and warn of product hazards. Get warnings, packaging, labels and ads screened in advance by an attorney *who specializes in product liability*.

4. Keep your regulatory house in order. Know your FDA regulatory and reporting obligations *and follow them to the letter*. Regulatory baggage – recalls, MDR's, warning letters, etc. – will be grist for the plaintiff trial bar. If you have any regulatory sanctions, attorneys will know.

5. Prepare contingency plans for product meltdowns. "Dig your well before you're thirsty." Implement procedures and prepare response plans to handle obligations efficiently in the event of recalls or litigation. Perform crisis simulations, such as:

"The FDA just shut down our Illinois manufacturing plant. What will we do?"

"Two hospitals have reported three patient deaths associated with our drug. What's next?"

"We just got a class action lawsuit in California. What is our first step?"

"Our product was just skewered on the TV news show 'Dateline.' What now?"

Identify, play out and rehearse responses in various scenarios. Be ready to marshal resources to retrieve products or respond to lawsuits in an organized and cost-effective way if a product problem develops.

Drug and device firms cannot control every potential risk factor. Instead, they must focus on what they *can* influence, including the five strategies above. Given the shifting sands of political change, judicial uncertainty and legislative reform, life science firms are best off investing in the "basics" of building strong risk management and safety programs.

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