

The Winding Path and Pitfalls of Federal Pre-emption

By D. Andrew List

A young neighbor seeks your counsel after her husband dies following a heart attack. She tells you that her husband had a Beat-Without-Fail pacemaker, and that he had taken the pain medication Fix-It-All. The widow is distressed because she has heard news reports that the Beat-Without-Fail and Fix-It-All products may cause heart attacks.

You agree to undertake a preliminary investigation. You quickly determine that the Food & Drug Administration (FDA) is conducting hearings on Fix-It-All, but that the drug remains on the market. You further discover conflicting articles in several medical journals as to whether Fix-It-All causes heart attacks. Finally, you contact a cardiologist who, after reviewing the medical records, tells you that Fix-It-All was likely a contributing – but secondary – cause of death.

At the same time, you confirm that the Beat-Without-Fail pacemaker has been linked to at least a dozen deaths nationally. You discover that the FDA ordered the manufacturer to recall the product within the last thirty days. You make sure that the Beat-Without-Fail pacemaker is explanted during autopsy, and you have it sent to an electrophysiologist who confirms that the device failed shortly before death.

Following this preliminary investigation, do you tell the widow that she has a viable product liability claim against either or both of the manufacturers? On the facts, it is tempting to advise her to proceed against the manufacturer of Beat-Without-Fail. However, the pre-emption issues give you pause, as you study two recent decisions from the United States Supreme Court.

In *Riegel v. Medtronic*,¹ the United States Supreme Court considered claims involving a medical device. Charles Riegel suffered serious injury when a balloon catheter burst while he was undergoing an angioplasty. 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 (FDCA), and that the claims were pre-empted by federal law. The district court granted summary

judgment based upon federal pre-emption, after which the Second Circuit affirmed.

The Supreme Court affirmed. Writing for the majority, Justice Scalia noted that the Medical Device Amendments of 1976 (MDA) to the FDCA contain the following express pre-emption language:

“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.”²

In finding that state law was pre-empted, such that the Riegels could not maintain their injury claim against Medtronic, the Court explained that: State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation. A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.³

Of note, the Riegel decision is limited to medical devices that have been approved by the FDA through its pre-market approval process. To the extent that the pacemaker had been approved prior to the enactment of the MDA, or to the extent that it was “substantially equivalent” to another device that existed prior to the enactment of the MDA, the widow's claims could proceed against the Beat-Without-Fail manufacturer.

A young neighbor seeks your counsel after her husband dies following a heart attack.

She tells you that her husband had a Beat-Without-Fail pacemaker,
and that he had taken the pain medication Fix-It-All.

The widow is distressed because she has heard news reports that the Beat-Without-Fail and
Fix-It-All products may cause heart attacks.

In *Wyeth v. Levine*,⁴ the Supreme Court considered pre-emption under the FDCA in the context of a pharmaceutical claim. Diana Levine, a musician from Vermont, went to a local clinic for treatment of a migraine headache. She was given Demerol for pain and Wyeth's drug, Phenergan, for nausea. The Phenergan was administered via an IV-push. The physician assistant who administered the drug apparently missed Ms. Levine's vein, instead hitting an artery. This resulted in gangrene and the eventual amputation of Ms. Levine's lower arm.

Ms. Levine filed suit, arguing that Wyeth should have strengthened the warning on its label regarding the IV-push method of administering Phenergan. A jury found in favor of Ms. Levine, and the Vermont Supreme Court upheld the verdict. Wyeth appealed to the United States Supreme Court, arguing that the Phenergan label had been approved by the FDA, and that it was impossible to comply with federal drug labeling rules and regulations, while at the same time being subjected to state regulation through jury verdicts.

The Supreme Court rejected Wyeth's argument. Writing for the majority, Justice Stevens stated that:

Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.⁵

In essence, the Court recognized that, unlike the statutory language applicable to medical devices, the FDCA does not contain express pre-emption language with respect to pharmaceuticals. Noting this difference, Justice Thomas, in a concurring opinion, explained that:

***the Court's pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the "purposes and objectives" embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby. Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they "stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives" of federal law [citation omitted] as perceived by this Court.⁶

Thus, the widow's claim against the manufacturer of Fix-It-All will survive a pre-emption defense, although it is factually less attractive than the claim against the manufacturer of the pacemaker.

Pre-emption adds a layer of complexity to many claims. Although these recent decisions involve injury claims, pre-emption issues extend to other areas of law.⁷ For example, a trial court, after rejecting a pre-emption defense, recently found that a pharmaceutical company's marketing practices violated state consumer protection laws.⁸

To properly advise someone such as the widow described above, the careful practitioner must consider the pre-emption pitfalls, in addition to the facts and the law applicable to the underlying claim.

1. *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008).
2. 21 U.S.C. §360k(a).
3. *Riegel v. Medtronic, Inc.*, at 1008.
4. *Wyeth v. Levine*, No. 06-1249, 555 US ____ (2009).
5. *Wyeth v. Levine*, No. 06-1249, 555 US ____ (2009) (slip op., at 14).
6. *Wyeth v. Levine*, No. 06-1249, 555 US ____ (2009) (slip op., at 23-24).
7. At the time of writing, the Medical Device Safety Act had been introduced in the Senate by Senators Kennedy and Leahy (S. 540) and in the House by Representatives Waxman and Pallone (HR 1346). If signed into law, this legislation would abolish the pre-emption language in the MDA.
8. *SER McGraw v. J&J et al*, Civil Action No. 04-C-156. The court assessed civil penalties against Johnson & Johnson for making false and misleading statements about two of its pharmaceuticals to West Virginia physicians. A copy of the decision can be found on-line by clicking "Johnson & Johnson ordered to pay civil penalties" at <http://news.clarkperdue.com>



alist@clarkperdue.com



*D. Andrew List,
Clark Perdue & List
Of Counsel, Anapol Schwartz Weiss Coban
Feldman & Smalley*