Mass High Tech: The Journal of New England Technology

Tuesday, April 7, 2009

Guest Column

Changing the landscape for FDA approvals

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The U.S. Supreme Court revisited the balance between federal and state authority over drug regulation last month. The result may have long-lasting impacts for drug researchers and manufacturers. By affirming a multi-million dollar verdict in a product liability case -- rejecting a drug maker's argument that a federally approved label bars state law claims -- the court effectively required drug manufacturers to closely monitor side effects even after U.S. Food and Drug Administration approval. This decision deviates a bit from recent case law and deserves an explanation. There may also be implications for device manufacturers.

The case of Wyeth v. Levine involved administering Wyeth's anti-nausea drug Phenergan by the "IV-push" method. Susan Levine, a professional musician, suffered from migraines and received a needle-with-plunger injection of Demerol (for the headache) and Phenergan (for nausea). Because the latter drug accidentally entered one of Levine's arteries – rather than a vein, as advised by the label – gangrene set in that resulted in the loss of Levine's arm, and her livelihood.

Levine sued on state law grounds, and a jury found that because the risk of gangrene and amputation could be almost always avoided by the "IV-drip" (a drip bag using saline solution) rather than the "IV-push" method (as was used). Wyeth was negligent and that IV-push-administered Phenergan was a defective product. Wyeth had been aware of the gangrene risk since at least 1967.

Wyeth's defense relied on FDA approval, and therefore federal "preemption" of state law. The FDA approved Phenergan in the 1950s, subject to labeling that included a general gangrene warning. But over the years, even as Wyeth became aware that the IV-drip method all-but-eliminated the catastrophic risks, the company did not sufficiently update its label. After all, it argued, the label described the risk, and the FDA had approved the language.

The Supreme Court held that Wyeth had a duty to update its labeling to reflect the knowledge that it acquired over the years. (Interestingly, Congress authorized the FDA only in 2007 to compel label revisions in the face of new [adverse] information.) FDA requirements, according to the court, are a "floor" and not a "ceiling" for state regulation.

The Wyeth result -- allowing a tort case to proceed even though there was FDA approval -- initially appears to contradict the Court's decision a year ago in Riegel vs. Medtronic. There, the Court reviewed a different statutory section, which empowered the FDA to review medical devices prior to introduction and explicitly pre-empted state regulation. As a result, the court in the 2008 Medtronic case barred state tort claims arising from damage caused by FDA-approved medical devices. (Further complicating matters, in a 1996 device case involving Medtronic and a still different section of the statute, the court found that state tort claims were not preempted.)

Because the applicable federal pre-emption provision for drugs is narrower, the Wyeth decision came out the opposite way (i.e., against the manufacturer). This means that even after FDA approval, drug makers have a duty to monitor their products and update their

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Finally, there is an unanswered question for device manufacturers: Having obtained FDA approval, what obligations do they have when a defect comes to light after approval? Justice Ginsburg, the sole dissenter in the 2008 Medtronic case, raised that question in her first footnote in that case. The question for the future is whether the court will find the statutory device preemption language (whether-or-not subject to a product recall) or a pattern of post-FDA-approval harm to be more compelling. And for observers who assumed that there is a reliable pro-business majority on the Roberts court, the Wyeth decision suggests a less certain result than the industry might prefer.

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