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Recent Decision Undercuts Device Manufacturers' Pre-emption Defense

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Federal appeals courts have generally held that the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act pre-empt tort claims relating to medical devices that have undergone the Food and Drug Administration's rigorous pre-market approval process, when the tort claim would impose requirements that conflict or interfere with the requirements embodied in the FDA's approval of the device.

But a recent ruling by a federal district court raises the possibility that a medical device manufacturer could lose the benefit of federal pre-emption if a fact-finder determines that the manufacturer failed to disclose a known danger in an approved device. The ruling raises challenging issues regarding the interplay of federal and state law.

The plaintiffs in *In re Medtronic Inc.*, 2006 WL 3478987 (D. Minn. Nov. 28, 2006), brought suit against the manufacturer of a defibrillator, claiming that the battery used in the defibrillator was subject to premature depletion because of a shorting problem. The manufacturer moved for summary judgment on the ground that plaintiffs' claims were pre-empted under 21 U.S.C. § 360k(a), which prohibits a state from imposing any requirement regarding a medical device that is "different from, or in addition to" requirements applicable to the device under the federal statute and that "relates to the safety or effectiveness of the device ..."

The court denied the motion, based on evidence that

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the manufacturer purportedly withheld "critical information" from the FDA in supplemental applications seeking approval of additional models of the defibrillator. The court cited evidence that the battery exhibited a defect that caused it to discharge prematurely in laboratory testing after the device had been approved.

The court also cited evidence that the manufacturer had received field reports of battery depletion, although the manufacturer reported the battery problems through the FDA's medical device reporting system. Subsequently, the manufacturer issued a public warning and sent "Dear Doctor" letters advising that the defibrillator posed a risk of failure, and the FDA directed a recall. The manufacturer had neither been cited for any regulatory violation nor found in violation of any regulatory requirement by the FDA.

The court held that plaintiffs' claims were not pre-empted. First, it ruled that claims the manufacturer failed to comply with FDA regulations were not pre-empted because they sought to impose requirements that were parallel to, not inconsistent with, federal law. But the court went on to suggest that because the manufacturer allegedly failed to



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disclose “its own positive knowledge” of a danger in the device, federal pre-emption might not apply to plaintiffs’ claims at all.

Under this ruling, the fact-finder in a product liability action against a medical device manufacturer may be called upon to determine whether the manufacturer knowingly failed to comply with federal requirements concerning the disclosure of product dangers to the FDA, even if the FDA itself has neither alleged nor found a violation. The U.S. Supreme Court, however, has held that claims under state law that a manufacturer committed fraud on the FDA are preempted, because they would conflict with the FDA’s responsibility to police fraud according to its own policy objectives. *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 350 (2001).

The court in *In re Medtronic Inc.* distinguished *Buckman* on the ground that the plaintiffs did not allege “fraud-on-the-FDA” as a specific theory of recovery; instead, unlike in *Buckman*, they claimed that they had been deceived by the manufacturer’s failure to disclose information regarding product hazard.

Nevertheless, plaintiff’s claims necessarily implicate the sufficiency of the manufacturer’s disclosures to the FDA. Indeed, the court’s ruling invites a plaintiff to seek to nullify the manufacturer’s pre-emption defense, by proving the very same facts that would need to be shown to demonstrate a fraud on the FDA.

Thus, like a claim for fraud on the FDA, the ruling allows the trier of fact to conduct its own analysis of FDA procedures and requirements, and to speculate whether, when and under what circumstances the FDA would have revoked approval for the device in question, even where the manufacturer reported the danger through the medical device reporting system. In contrast, other courts have suggested that a claim that would require proof of fraud on the FDA is pre-empted, even if the claim is not specifically labeled as such. See, e.g., *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 965-66 (6th Cir. 2004); *Kemp v. Medtronic Inc.*, 231 F.3d 216, 234, n.14 (6th Cir. 2000), reh’g denied, 2001

WL 91119 (6th Cir. Jan. 26, 2001), cert. denied, 534 U.S. 818 (2001).

Further, by suggesting the possibility that plaintiffs may avoid federal pre-emption entirely, the court’s ruling opens the way to the imposition of requirements under state law that are “different from” or “in addition” to the requirements of federal law. Federal law sets forth detailed requirements not just for the approval of a device, but also regarding the sale, distribution or use of the device and continuing evaluation, reporting, labeling and records maintenance after the device has been approved. 21 C.F.R. §814.82.

Federal regulations also require a manufacturer to file, within 30 days of discovery, a medical device report with the FDA when a device has exhibited a “malfunction” which “would be likely to cause or contribute to a death or serious injury.” 21 C.F.R. §803.1 et seq. But under the court’s ruling, once a jury determines that a manufacturer knowingly failed to comply with federal requirements, the jury would be free to impose its own requirements (apparently, no matter how different from federal law). The decision thus permits a jury retroactively to impose more stringent standards on manufacturers than under federal law, despite the absence of a determination by the FDA that the manufacturer violated federal requirements.

Because the court’s ruling allows the trier of fact to determine whether a device manufacturer complied with federal law, even in the absence of a finding by the FDA that a violation occurred, it allows the jury to supplant the FDA’s role in enforcing compliance and threatens to impinge on the agency’s role in setting compliance policy. Further, despite the congressional determination that state law may not impose any requirement “different from” or “in addition to” the requirements set by federal law, the ruling may allow that result based on the jury’s findings in any given case.

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