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Court Split Over Medical Device Claims Persists

Law360, New York (February 10, 2014, 6:04 PM ET) -- A Jan. 27, 2014, decision by the California Court of Appeal is the latest contribution to the deepening judicial divide over preemption of state law tort claims in cases implicating Class III medical devices.

In Coleman v. Medtronic Inc., the California Court of Appeal held that the plaintiff's claims of negligence per se and strict liability failure to warn — based upon allegations that Medtronic violated federal regulations requiring it to submit adverse events reports to the U.S. Food and Drug Administration and prohibiting Medtronic from promoting its products for off-label use — were neither expressly preempted by the Medical Device Amendments, 21 U.S.C. § 360k(a), nor impliedly preempted pursuant to Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Moreover, the court rejected preemption of the plaintiff's manufacturing defect claim, concluding that the plaintiff was entitled to "some opportunity to conduct discovery" before the preemption issue should be decided. The court's rulings fell in line with those of the Ninth Circuit in Stengel v. Medtronic, 704 F.3d 1224 (9th Cir. 2013) — a decision the United States Supreme Court may soon hear on appeal.

Background

Plaintiff John Coleman underwent a posterior lumbar interbody fusion surgery in April 2009. During the procedure, his surgeon used Medtronic's Infuse — a Class III medical device used to strengthen the spines of individuals with degenerated vertebral discs. The FDA had granted premarket approval of Infuse for use in anterior lumbar interbody fusion surgeries only; the surgeon's use of the product in plaintiff's posterior fusion was therefore an off-label use. Following the surgery, the plaintiff developed unwanted bone growth near his surgical site.

In 2011, the plaintiff filed suit against Medtronic, alleging claims of strict liability failure to warn, negligence per se and manufacturing defect, among others. Because Infuse is a Class III medical device subject to premarket approval, Medtronic filed a series of demurrers contending plaintiff's claims were preempted by federal law. Medtronic contended two types of preemption applied to the plaintiff's claims:

- First, that the plaintiff's claims were expressly preempted by the Medical Device Amendments ("MDA") of the Food, Drug & Cosmetics Act because they sought to impose requirements upon Infuse that were "different from, or in addition to" the requirements imposed by the FDA in the premarket approval process.
- Second, that the plaintiff's claims were impliedly preempted, pursuant to Buckman, because they were based upon Medtronic's alleged violations of federal regulations not privately enforceable.

The trial court granted Medtronic's third demurrer, dismissing the plaintiff's complaint with prejudice. The plaintiff appealed, arguing that his strict liability failure to warn, negligence per se and manufacturing defect claims were neither expressly nor impliedly preempted because they were based on state law duties that paralleled federal requirements. Specifically, the plaintiff contended that Medtronic violated state common law and parallel federal requirements by: (1) failing to report adverse event information about Infuse to the FDA; and (2) promoting the off-label use of Infuse in Posterior Fusion surgeries.

The Court's Decision

The Court of Appeal recognized the general rules for express and implied preemption, namely: (1) that a state law claim is expressly preempted if it seeks to impose requirements "different from, or in addition to" the requirements imposed by the FDCA; and (2) that a state law claim is impliedly preempted pursuant to Buckman if it exists "solely by virtue" of the requirements imposed by the FDCA.

To survive both express and implied preemption, the court observed, "a plaintiff 'must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by [the MDA]), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under Buckman).'" In other words, a state law claim "must be premised on conduct that both: (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA."

Applying this standard, the court upheld the plaintiff's negligence per se and strict liability failure to warn claims because, based on the plaintiff's allegations that Medtronic violated federal regulations by: (1) failing to report adverse events to the FDA and (2) promoting Infuse for off-label purposes, the plaintiff's claims sought to enforce state law duties that paralleled the requirements of the FDCA.

The court upheld the plaintiff's negligence per se claim on both theories. Under California's negligence doctrine, the court observed, Medtronic owed the plaintiff a duty of reasonable care, and in a negligence per se action, the federal standards established under the FDCA can be adopted as the applicable standard of care. In Medtronic's case, FDA regulations required it to report adverse events to the agency, and prohibited it from engaging in off-label promotion.

Because the plaintiff alleged these specific regulatory violations, and because the requirements established by the regulations could be adopted as the applicable standard of care for purposes of the plaintiff's negligence per se claim, the court concluded the plaintiff's claim permissibly imposed "parallel" requirements, and was therefore not expressly preempted. Nor was the claim impliedly preempted under Buckman, the court concluded, since California law imposed a duty of reasonable care upon Medtronic independent of the applicable FDA regulations.

The court likewise upheld the plaintiff's strict liability failure to warn claim, but only on the theory that Medtronic failed to report adverse events to the FDA. California law imposes upon manufacturers a duty to warn of risks that were known or knowable at the time of manufacture and distribution. Because FDA regulations required Medtronic to report adverse events to the FDA (i.e., warn the FDA that its products could be associated with certain adverse events) the court concluded that Medtronic's alleged failure to do so could support a breach of its state law duty to warn.

The court rejected Medtronic's contention, based on the learned intermediary doctrine, that its duty to

warn extended only to physicians, not the FDA, reasoning that "the duty to warn should not be so narrowly defined as to exclude a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers." Specifically, the court concluded that the duty to warn a third party, like the FDA, who reasonably can be expected to warn the consumer supports a failure to warn claim.

The court concluded that the plaintiff's off-label promotion theory was expressly preempted in the failure to warn context. In the court's view, this theory would require the plaintiff to argue that Medtronic, by promoting Infuse in an off-label manner, incurred an additional duty to warn about the risks of such use. However, "[b]ecause Medtronic has already complied with federal requirements for warnings and labeling, any state law requirement to provide additional warnings would be different from, and in addition to, federal requirements," and therefore expressly preempted.

Significantly, although the court upheld the plaintiff's negligence and strict liability failure to warn claims against Medtronic's preemption challenges, the court prognosticated that these claims would face significant causation hurdles down the line:

To prevail, [plaintiff] will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached [the plaintiff's] doctors in time to prevent his injuries.

Nevertheless, because the plaintiff's allegations must be taken as true at the pleadings stage, the court concluded that the complaint stated sufficient allegations to support the plaintiff's negligence and strict liability failure to warn claims against Medtronic's motion to dismiss.

With regard to the plaintiff's manufacturing defect claim, the court observed that such claims impose parallel requirements, and are therefore not preempted, when the complaint alleges that a device "failed to comply with either the specific processes and procedures that were approved by the FDA or the ([c]urrent [g]ood [m]anufacturing [p]ractices) themselves and that this failure caused the injury."

Medtronic challenged plaintiff's manufacturing defect claim because the plaintiff did not specify which processes, procedures or current good manufacturing practices the device contravened. The court overruled this challenge as premature, concluding that the plaintiff was entitled to "some opportunity to conduct discovery" before the issue of preemption could be addressed.

Analysis

The Coleman decision is the latest installment of competing judicial opinions defining the circumstances when a state law claim can permissibly impose "parallel" requirements, so as to avoid express and implied preemption in cases implicating Class III medical devices.

Traditionally, pursuant to Buckman, a state law claim premised entirely upon the violation of federal regulations would be impliedly preempted and subject to dismissal. Following the Supreme Court's interpretation of the MDA's express preemption clause in Riegel v. Medtronic, 552 U.S. 312 (2008), however, some courts, like the Coleman court, have been hesitant to deprive plaintiffs completely of all recourse and have applied a narrow interpretation of Buckman, allowing common law negligence and/or strict liability claims to proceed as "parallel" when an alleged violation of federal regulations can serve as the effective breach of a state law duty of care. See, e.g., Stengel, 704 F.3d 1224; Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011).

Other courts have applied Buckman more broadly, dismissing state law claims premised upon violations of federal regulations in the absence of state laws affirmatively recognizing parallel requirements. These courts have declined to uphold state law claims premised solely upon violations of federal regulations, on the grounds that they "are simply an attempt by private parties to enforce the MDA." See In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1205-06 (8th Cir. 2010); see also, e.g., Caplinger v. Medtronic, 921 F. Supp. 2d 1206 (W.D. Okla. 2013).

The scope of Buckman preemption in this context is critically important for the medical device industry, because if courts continue to apply the narrow interpretation favored by Coleman and like cases, the violation of almost any FDA regulation could potentially provide a basis for common law negligence and/or strict liability claims under state law.

Moreover, as courts like Coleman continue to relax plaintiffs' pleading requirements to provide some opportunity for discovery, plaintiffs may escape preemption at the pleadings stage by simply invoking a purported violation of an unidentified FDA regulation. This would render Buckman effectively meaningless, and would allow plaintiffs to circumvent the MDA's express preemption clause, simply by focusing on unspecified conduct purportedly violating unidentified federal regulations.

If courts continue to validate these tactics, the medical device industry could feasibly see a surge in the number of claims implicating Class III medical devices, as well as the number of such claims surviving preemption challenges at the pleadings stage. While some cases will continue to be dismissed on preemption grounds, others will survive, requiring a greater investment in discovery and motion practice. Although, later on, such cases likely will be vulnerable to summary judgment challenges on causation grounds, as the Coleman court observed, an influx of claims of this type will no doubt raise the industry's overall costs of defense and, in turn, potentially increase costs to patients.

The judicial split on this issue, and the negative externalities flowing therefrom, are receiving more attention as state and federal courts continue to issue competing opinions. A year ago, the Ninth Circuit issued its en banc decision in Stengel, adopting the same narrow interpretation of Buckman favored in Coleman, and upholding the plaintiff's Arizona negligence claim based on the defendant's alleged failure to report adverse events to the FDA. That decision was appealed to the Supreme Court and it is expected to decide soon whether it will hear the case.

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