

## The Broad Reach Of New 'Failure-To-Warn-FDA' Claims

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Recently, the Ninth Circuit created a new state-law cause of action against medical device manufacturers: “failure to warn the U.S. Food and Drug Administration.” The en banc opinion in *Stengel v. Medtronic Inc.*, \_\_\_ F.3d \_\_\_, 13 C.D.O.S. 365 (9th Cir. 2013), delivered by Judge William Fletcher, held that the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act (FDCA) did not preempt this claim because it paralleled a federal law duty imposed by the MDA.



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This new cause of action opens the door, at least in the Ninth Circuit, to claims against all medical device and drug manufacturers and could defeat *Pliva v. Mensing's* preemption of failure-to-warn claims against generic drug manufacturers.

### The Allegations in the Stengels' Amended Complaint

In October 2000, Richard Stengel had a SynchroMed EL pump and catheter — manufactured by Medtronic — surgically implanted in his abdomen to deliver pain relief medication directly into his spine. In February 2005, Stengel collapsed, reporting heaviness and decreased sensation in his right leg.

At the hospital, Stengel was diagnosed with ascending paralysis. The device was removed, but Stengel became a paraplegic and claimed that the device caused his paralysis.

Plaintiffs alleged that Medtronic became aware of risks associated with the pain pump before Stengel was paralyzed in 2005, but it did not inform the FDA of the risks. The FDA discovered the risks — and that Medtronic knew about them — more than a year after Stengel's injury.

In July 2007, the FDA sent a warning letter to Medtronic stating that Medtronic “misbranded” its pain pump by concealing known risks. In January 2008, Medtronic sent a medical device correction letter, and in March 2008, it recalled the device. Stengel and his wife sued Medtronic, alleging that it violated a state-law duty of care by failing to report the known risks associated with the pain pump to the FDA.

### The Medical Device Amendments

Congress enacted the MDA to extend coverage of the FDCA to medical devices. The MDA divides medical devices into three classes according to user risk. Class III devices are those deemed by the FDA to have the highest risk — they are those that “cannot be determined to provide a reasonable assurance of safety and

effectiveness under Class I or II controls and are marketed either as life-supporting or possibly causing an unreasonable risk of illness or injury.”

Class III devices are subject to the premarket approval (PMA) process of the FDA. 21 U.S.C. § 360c(a)(1)(C).

During the premarket approval process, the FDA performs a risk benefit assessment and determines the adequacy of the manufacturer’s label. The FDA can then approve the application, deny it or approve it with conditions on distribution.

Notably, the MDA contains an express preemption clause, which provides that no state may establish any requirement

“which is different from, or in addition to, any requirement applicable” under the MDA. 21 U.S.C. § 360k(a). Under the U.S. Supreme Court’s decision in *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008), many courts have found that state-law claims concerning PMA devices were preempted.

After the FDA approves a medical device (Class I, II or III), the MDA imposes a duty on the manufacturer to report any information that reasonably suggests that the device may have caused or contributed to a death or serious injury or has malfunctioned and that any recurring malfunction would be likely to cause or contribute to a death or serious injury. 21 C.F.R. § 803.50(a); 21 U.S.C. § 360i(a). It is this reporting duty that formed the basis of the Stengels’ state-law “failure-to-warn-the-FDA” claim.

### **Procedural History**

The U.S. District Court for the District of Arizona dismissed the Stengels’ complaint and denied leave to amend, holding that the MDA preempted all of the Stengels’ claims, including the negligence claim based on Medtronic’s failure to report known risks of the pain pump to the FDA. *Stengel v. Medtronic*, No. CV 10-318-TUC-RCC (D. Ariz. Nov. 9, 2010). The Stengels appealed, and the Ninth Circuit affirmed, granting rehearing en banc. 676 F.3d 1159 (9th Cir. 2012).

### **The Ninth Circuit's En Banc Analysis**

The en banc panel framed the issue as “whether the MDA preempts a state-law claim in which the state-law duty of care ‘parallels’ a federal-law duty imposed by the MDA.” In other words, the court asked, do the MDA’s federal reporting requirements preempt state-law claims based on a medical device manufacturer’s duty to report known risks to the FDA? The answer: a resounding “no.”

The Ninth Circuit started with the usual “presumption against preemption.” The court then considered the three Supreme Court MDA preemption cases: *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001); and *Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008). The Ninth Circuit found support for its conclusion in all three cases.

First, the court noted that in *Lohr*, the Supreme Court found that Florida could impose a state-law duty to warn patients and physicians regarding the risks of a particular pacemaker, despite parallel federal warning requirements under the MDA. The Stengels alleged a similar concurrent duty — violation of the MDA’s post-marketing reporting requirements.

With regards to *Buckman*, the Ninth Circuit noted that plaintiffs there — unlike the Stengels — alleged no state-law claims and instead “were concerned exclusively with alleged fraud on the FDA that had occurred as part of th[e] [premarket] approval process.” Because the Stengels did not allege fraud

during the premarket approval process, their state-law claims were not preempted under Buckman.

The Ninth Circuit's rationale contradicted years of jurisprudence finding that all claims alleging violation of disclosure requirements to the FDA were preempted. See, e.g., *Marsh v. Genentech Inc.*, 693 F.3d 546 (6th Cir. 2012) (under Buckman, courts should not determine adequacy of post-marketing disclosures to FDA); *In re Medtronic Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200 (8th Cir. 2010) (Buckman preempts allegation that defendant "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations").

Finally, concerning Riegel, the Ninth Circuit found that contrary to the Stengels' allegations, the state-law duty alleged by the plaintiffs there directly conflicted with, as opposed to paralleled, the federal duty set forth under the MDA. Therefore, Riegel was easily reconciled with the Ninth Circuit's present holding. In fact, the Ninth Circuit's decision created an end run around Riegel, which held that similar failure-to-warn claims for PMA devices were preempted by the MDA. 552 U.S. at 329.

The court found further support in other circuit court opinions, noting that "[their] sister circuits have uniformly held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty 'parallels' the federal-law duty under the MDA." See *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) cert denied 132 S. Ct. 498 (2011).

These authorities bolstered the court's holding that the Stengels' state-law negligence claim based on Medtronic's failure to report known risks to the FDA was not preempted "insofar as the state-law duty parallels a federal law duty under the MDA."

Judge Paul Watford further emphasized this point in his concurrence, noting, "the Stengels' negligence claim is not expressly preempted because it seeks to hold Medtronic accountable only for failing to do what federal law mandated— nothing more. The state law duty, as alleged by the Stengels, is precisely parallel to the duties imposed by federal law."

Judge Watford also noted that the Stengels, who framed their claim "as they must to avoid express preemption," will likely face a "causation hurdle" as their case progresses. He noted, "[t]o prevail, they 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 Mr. Stengel's doctors in time to prevent his injuries."

### **Significance of the Decision**

Under Stengel, the MDA preemption analysis will turn on whether the state-law duty at issue parallels the MDA-imposed federal duty or conflicts with the MDA-imposed federal duty. Manufacturers should be prepared — this decision effectively allows plaintiffs to bring state-law negligence claims premised on federal standards, so long as the plaintiffs frame the state-law duties as mirroring or "parallel to" those of the MDA.

Even though the Buckman court rejected the notion that "any violation of the FDCA will support a state-law claim," Stengel suggests otherwise for cases in the Ninth Circuit. The broad reach of this newly created failure-to-warn-the-FDA claim should not be underestimated — particularly for its potential to breathe new life into claims against generic drug manufacturers.

The decision will likely aid plaintiffs in overcoming motions to dismiss and may result in manufacturers being flooded with a wave of failure-to-warn-the-FDA-type cases.

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