

Client Alert **Product Liability Law**

Parallel Claims Against Device Manufacturers post-Riegel

In June 2014, the U.S. Supreme Court denied certiorari and let stand the Ninth Circuit's *en banc* ruling in *Stengel v. Medtronic Inc.*, 704 F.3d 1224 (9th Cir. Jan. 10, 2013) that state-law failure to warn claims against a medical device manufacturer that "parallel" federal requirements are not expressly preempted by the Medical Device Amendments ("MDA") of the Food, Drug, and Cosmetic Act. Since the Supreme Court's ruling in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Ninth Circuit is the sixth circuit court to substantively address in a published decision whether state law claims against a medical device manufacturer are preempted or whether they truly "parallel" federal requirements. The Supreme Court's denial of Medtronic's *writ of certiorari* in *Stengel* is significant, because the Court has yet again declined to clarify the contours of "parallel claims" and has left open an approach for plaintiffs to proceed with state law claims against medical device manufacturers.

Section 360k of the Medical Device Amendments expressly prohibits a state from establishing a requirement which is "different from, or in addition to" any applicable federal requirement or relates to the "safety or effectiveness" of a Class III medical device. The U.S. Supreme Court twice addressed express preemption of competing state laws and regulations under § 360k of the MDA and distinguished between 510(k) devices and pre-market approval ("PMA") devices. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that negligent design and failure-to-warn claims against devices approved through the 510(k) process were not preempted by the MDA because

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510(k) devices obtain marketing approval solely based on a showing of substantial equivalency. 510(k) devices do not undergo FDA analysis for safety or effectiveness and therefore, the Court held that “nothing in § 360k” denies recovery for violations of common-law duties when those duties parallel federal requirements. On the other hand, the FDA’s more rigorous PMA process imposes device-specific requirements. As a result, in 2008, the *Riegel* Court held that where claimants bring common law product liability claims against PMA-approved devices, those claims are expressly preempted by the MDA to the extent that the manufacturer has complied with federal law.

What has emerged from these cases is a slim carve-out of state-law product liability claims against PMA-approved Class III medical device manufacturers that escape preemption: specifically, the MDA does not preempt state-law claims against PMA-approved device manufacturers where state duties “parallel,” rather than add to, federal requirements. In other words, the state law claim must be premised on a violation of a federal requirement. However, the Supreme Court has not provided guidance on the particulars of a “parallel” claim sufficient to survive a preemption defense.

To date, six circuits have published opinions considering whether state-law tort claims against manufacturers of medical devices are preempted by the MDA post-*Riegel*.¹ The most recent case is *Stengel*, in which Plaintiff alleged that the catheter manufacturer violated its “duty to use reasonable care” under Arizona negligence law by failing to report adverse events to the FDA as required under the MDA. The district court granted Medtronic’s motion to dismiss all claims, finding the claims preempted by the MDA. Although a panel of the Ninth Circuit affirmed, the Ninth Circuit sitting *en banc* reversed the district court’s dismissal. The court held that since the state-law duty of care “parallels” the MDA-mandated duty to report known risks to the FDA, the state-law claims were neither expressly or impliedly preempted by the MDA. The Ninth Circuit found support for its holding in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. Jan. 21, 2011) and *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. Dec. 23, 2010).

In *Hughes v. Boston Scientific Corp.*, a plaintiff sued Boston Scientific under various Mississippi state-law tort theories. On summary judgment, the district court dismissed all claims as preempted by federal law. The Fifth Circuit affirmed, except for plaintiff’s claim that Boston Scientific failed to comply with federal regulations requiring reports of “serious injuries” and “malfunction” and accordingly failed to provide adequate

¹ The First, Second, Third, Sixth, and Tenth Circuits have yet to weigh in on this issue.

warnings under Mississippi law regarding the risks associated with the device. The Fifth Circuit held that “a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is ‘parallel’ to federal requirements as defined in *Riegel*.” *Id.* at 769. Additionally, because the Mississippi failure-to-warn claim was “a recognized state tort claim” and not a “freestanding federal cause of action” it was not impliedly preempted by § 337(a) as construed by *Buckman Co. v. Plaintiff’s Legal Committee*, 531 U.S. 341, 349, 353 (2000). The *Hughes* court also held that a “formal” finding or enforcement action by the FDA is not an “implicit precondition” to filing a state law claim. Ultimately, the *Hughes* court found that plaintiff’s claim survived preemption because expert testimony in the record showed that Boston Scientific had violated the plain text of the Medical Device Reporting regulations, such that a jury could conclude that Boston Scientific had failed to comply with FDA regulations. This holding implied that a plaintiff need only plead a general violation of a federal regulation as opposed to a device-specific requirement as set forth by the FDA in the PMA approval files. Indeed, the Fifth Circuit clarified this very issue in *Bass v. Stryker Corp.*, 669 F.3d 501, 512 (5th Cir. Jan. 31, 2012): “[I]f a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the [Current Good Manufacturing Practices] themselves and that this failure caused the injury, the plaintiff will have pleaded a parallel claim.”

In *Bausch v. Stryker Corp.*, a plaintiff sued Stryker under Illinois state law theories of negligent manufacturing and strict liability for a defective product, alleging that Stryker’s hip replacement system was manufactured out of compliance with the terms set forth in its premarket approval application and thus in violation of federal law. The Seventh Circuit reversed the district court’s dismissal of claims, finding that state-law claims for manufacturing defects based on a violation of a federal duty under the MDA were not preempted, since such claims would not impose on defendants any requirement “different from, or in addition to, any requirement” imposed by federal law. The Seventh Circuit broadly held that “federal law does not preempt parallel claims under state law based on a medical device manufacturer’s violation of federal law.” *Bausch*, 630 F.3d at 558. Importantly, the Seventh Circuit clarified that plaintiffs did not need to allege violation of “concrete, device-specific” requirements, but could instead allege violation of “general” federal requirements (such as the Quality System Regulations and Current Good Manufacturing Practices) established by the FDA. Also of note is the Seventh Circuit’s discussion of the federal standard of notice pleading (in light of *Twiqbal*) applicable to claims for defective manufacture of a medical device

in violation of federal law: “district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.” *Id.* at 558. Stryker appealed, and the United States Supreme Court denied certiorari.

Although the Fifth, Seventh, and Ninth Circuits have recognized “parallel claims,” the Fourth, Eighth, and Eleventh Circuits have held otherwise. The Eighth Circuit’s opinion in *Sprint Fidelis Leads Prods. Liab. Litig. v. Medtronic, Inc. (In re Medtronic, Inc.)*, 623 F.3d 1200 (8th Cir. Oct. 15 2010) is the most significant. In *In re Medtronic Inc.*, MDL plaintiffs alleged that every person with an implanted Sprint Fidelis Lead was entitled to damages and equitable relief under various state law theories. The district court dismissed all claims. On appeal, two particularly noteworthy issues were discussed: (i) dismissal of claims premised on the manufacturer’s failure to file adverse event reports and (ii) discussion of pleading standards in the context of manufacturing defect claims.

First, the Eighth Circuit affirmed the district court’s dismissal of plaintiffs’ claims premised on the manufacturer’s failure to timely file adverse event reports, as required by federal regulations. The Eighth Circuit affirmed the district court’s conclusion that such claims are “simply an attempt by private parties to enforce the MDA, claims foreclosed by § 337(a) as construed in *Buckman*, 531 U.S. at 349, 353.” *In re Medtronic, Inc.* 623 F.3d at 1205-06. Interestingly, the Eighth Circuit also cited to the district court decision in *Hughes v. Boston Scientific Corp.*, which as noted above, was overturned by the Fifth Circuit. To the extent, then, that the Eighth Circuit’s holding can be construed as rejecting state-law failure-to-warn claims premised on a manufacturer’s failure to comply with FDA reporting regulations, a clear circuit split exists with the Fifth and Ninth Circuits. Unfortunately, the Eighth Circuit disposed of this issue in just over 50 words (not including citations) and did not explicitly cite to or analyze a failure-to-warn claim in connection with an alleged violation of a reporting requirement. Indeed the Ninth Circuit distinguished the holding: “At no point did the court address a state-law claim based on a state-law duty that paralleled a federal duty, and thus *Sprint-Fidelis* is not inconsistent with *Hughes* and *Bausch*.” *Stengel*, 704 F.3d at 1232. Ultimately, this issue remains unclear.

Next, the Eighth Circuit affirmed dismissal of plaintiffs’ manufacturing defect claims. The district court dismissed the claims because plaintiffs generally alleged failure to comply with the Current Good Manufacturing Practices regulations, and did not identify a specific federal requirement in the PMA approval. On appeal, the plaintiffs argued that

this was an impossible pleading standard because, without discovery, PMA approval files are accessible only to the FDA and the manufacturer. Thus, in affirming the district court, the Eighth Circuit appears to have impliedly held that a plaintiff must allege a violation of a device-specific requirement to avoid preemption of a manufacturing defect claim, which is in conflict with the Fifth, Seventh, and Ninth Circuits. However, the Eighth Circuit made clear that its holding was in the context of plaintiffs' allegations that state law entitled every person who had an implanted Sprint Fidelis Lead to damages and equitable relief because all of the devices had an unreasonably high risk of fracture failure. The Eighth Circuit characterized such allegations as a "frontal assault on the FDA's decision to approve a PMA Supplement after weighing the product's benefits against its inherent risks." *In re Medtronic, Inc.*, 623 F.3d at 1207. The Eighth Circuit left itself an opening by also stating that plaintiffs' pleading standard argument "would have considerable force in a case where a specific defective Class III device injured a customer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." *Id.* at 1206.

The Fourth and Eleventh Circuits also appear to require that plaintiff plead a violation of a device-specific requirement set forth in the PMA, rather than a general violation of federal regulations. The Fourth Circuit in *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. Jan. 25, 2012) dismissed state-law claims for negligence, strict liability and breach of warranty after plaintiff conceded that the medical device manufacturer had designed, manufactured, and sold the device in accordance with its premarket approval terms. The Fourth Circuit reasoned that because the accuracy rate referenced in the PMA approval application was not a "formal performance standard," failure to adhere to the specification was not a violation of the premarket approval. Similarly, in *Wolicki-Gables v. Arrow Int'l*, 634 F.3d 1296 (11th Cir. Mar. 8, 2011), the Eleventh Circuit dismissed state-law claims against a pain pump manufacturer for product liability, negligence, vicarious liability, and loss of consortium. The court cited to a Tenth Circuit district court decision when it stated: "To properly allege parallel claims, the complaint must set forth facts' pointing to specific PMA requirements that have been violated." *Wolicki-Gables*, 634 F.3d at 1301 (citing *Parker v. Stryker Corp.*, 584 F.Supp. 2d 1298, 1301 (D. Colo. 2008)). The pump's PMA-imposed requirements were sufficient to preempt the state law claims because the plaintiffs did not allege violation of a specific PMA requirement.

Although the Supreme Court made clear in *Riegel* that state-law tort claims against manufacturers of PMA-approved Class III medical devices are generally pre-empted, the Court left open an exception for "parallel claims." The Circuit Courts are split on

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which state-law claims are preempted and which are not and the Supreme Court has yet to provide guidance on the matter. By denying certiorari in *Stengel*, the Supreme Court is allowing uncertainty regarding the contours of a “parallel claim” to linger, giving plaintiffs a potential escape hatch from *Riegel*.

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