



THE FIRST AMENDMENT DOES NOT UNDERMINE THE PREEMPTION OF MEDICAL-DEVICE FAILURE-TO-WARN SUITS

by Andrew Tauber

As the U.S. Supreme Court confirmed in 2008, federal law expressly preempts most failure-to-warn claims arising from injuries allegedly caused by medical devices that have received premarket approval (PMA) from the Food and Drug Administration (FDA). Since that decision, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the plaintiffs' bar has been working to chip away at the preemption defense.

The bar's most recent effort argues that recent decisions expanding First Amendment protection for commercial speech have undermined the basis for federal preemption. The plaintiffs' bar is wrong. Even if manufacturers have a constitutional right to truthfully promote off-label uses of their products, as certain courts have lately held, federal law still expressly preempts most failure-to-warn claims involving PMA devices.

Medical devices that have received premarket approval from the FDA are subject to 21 U.S.C. § 360k(a), which expressly preempts any state-law safety or effectiveness requirement that is "different from, or in addition to," the federal requirements imposed on the device. When the FDA grants premarket approval to a medical device, the agency dictates the warnings that must accompany the device. Under federal law, the manufacturer is not required—and generally not permitted—to issue warnings other than those the FDA has approved. Thus, as the Supreme Court has held, § 360k(a) "[s]urely ... would preempt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings." *Riegel*, 552 U.S. at 329.

Hoping to evade this clear limitation on failure-to-warn claims involving PMA devices, some members of the plaintiffs' bar argue that recent First Amendment jurisprudence has undermined *Riegel*'s interpretation of § 360k(a). The starting point for their argument is the decision of the U.S. Court of Appeals for the Second Circuit in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). Relying on the Supreme Court's decision in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011)—which held that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment"—and applying the doctrine of constitutional avoidance, the Second Circuit held that the Food, Drug, and Cosmetic Act cannot be construed to prohibit a manufacturer from engaging in truthful off-label promotion of a product (*i.e.*, truthful promotion of the product for uses other than those indicated on its FDA-approved warning label).

Andrew Tauber, a Partner in Mayer Brown LLP's Washington, DC office, frequently litigates preemption issues on behalf of medical-device manufacturers, railroads, and other defendants in heavily-regulated industries. John Lewis, a Mayer Brown Associate, provided invaluable research assistance.

Caronia, which was decided as a matter of statutory interpretation, was subsequently extended by *Amarin Pharma, Inc. v. U.S. Food & Drug Admin.*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). The district court, ruling on a preliminary-injunction motion, held that Amarin would likely prevail on its claim that it possessed a First Amendment right to engage in truthful speech promoting the off-label use of an FDA-approved product. Plaintiffs cite *Caronia* and *Amarin* when arguing that if a manufacturer has a constitutional right to engage in truthful speech regarding a device, then nothing can prevent the manufacturer from issuing truthful warnings, even if they are different from or in addition to those approved by the FDA. Consequently, plaintiffs have reasoned, failure-to-warn claims brought in connection with medical devices that have received premarket approval from the FDA are no longer preempted.

That suggestion, which ignores the plain text of § 360k(a), has no merit. The mere fact that the manufacturer of a PMA medical device might have a First Amendment right to issue warnings beyond those that the FDA requires does not mean that the manufacturer is under a federal obligation to do so. The manufacturer's only duty under federal law is to distribute the FDA-mandated warnings. Thus, any state-law requirement that the manufacturer issue other warnings would be a requirement "different from, or in addition to," the federal requirement—and therefore squarely foreclosed by § 360k(a).

Indeed, the courts have already so held, albeit in response to a slightly different argument. Although the manufacturer of a PMA medical device is generally prohibited from altering the device's warning label without prior FDA approval, there are—pursuant to the "changes being effected" regulation codified at 21 C.F.R. § 814.39(d)—limited circumstances under which a manufacturer may provisionally change a label to warn of newly discovered risks without first obtaining agency approval. Plaintiffs have argued that a manufacturer's ability to issue such warnings eliminates any conflict between the manufacturer's obligations under federal law and its state-law duty to warn, and that state-law tort claims predicated on a manufacturer's failure to avail itself of that possibility therefore avoid preemption.

Courts have consistently rejected that argument because 21 C.F.R. § 814.39(d) "*permits* a device manufacturer to make a temporary change to a label" but does not "*require* such a change," *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 783 (D. Minn. 2009), and 21 U.S.C. § 360k(a) prevents states from requiring an act that federal law "permits, but does not require," *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005). As the Supreme Court has held in the context of a similarly-worded statute, the express preemption of any state-law requirement different from or in addition to the applicable federal requirements precludes a state-law requirement that would transform a federal "may" into a state-law "must." *Nat'l Meat Ass'n v. Harris*, 132 S. Ct. 965, 969–71 (2012).

This case law and § 360k(a)'s unambiguous text contradicts the contention that a manufacturer's constitutional right to engage in truthful speech about its product saves state failure-to-warn claims implicating PMA devices from express preemption. It is immaterial whether it is the First Amendment or 21 C.F.R. § 814.39(d) that purportedly permits device manufacturers to issue truthful warnings other than those previously approved by the FDA. The fact remains that federal law does not *require* the manufacturer of a device that has received premarket approval to issue any such warnings, and that any state-law duty to issue such warnings would therefore be "different from, or in addition to," the federal requirements and thus expressly preempted by § 360k(a).

Plaintiffs' latest misguided argument originated in the generic-drug context. In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court, applying conflict-preemption principles, held that federal law preempts any state-law requirement that the manufacturer of a generic drug issue warnings different from those issued by the brand-name manufacturer. The federal statute governing generic drugs requires that their warning labels be identical to those of their brand-name equivalents. This duty of "sameness" forbids the manufacturer of a generic drug from changing the drug's warning label unless and until the FDA approves such a change for its brand-name equivalent.

Therefore, if state law requires that the manufacturer of a generic drug issue a warning that has not been approved by the FDA for the generic's brand-name equivalent, the manufacturer cannot comply with state law without violating federal law. Given the impossibility of simultaneous compliance with state and federal law, state law must, under the Supremacy Clause, yield to federal law. Hence, the *Mensing* Court held, federal law impliedly preempts any failure-to-warn claim based on a generic manufacturer's failure to issue a warning that the FDA did not approve for the drug's brand-name equivalent.

According to Lou Bograd, a leading member of the plaintiffs' bar, *Sorrell, Caronia, and Amarin* "undermine *Mensing*," because "[i]f the First Amendment protects [manufacturers'] right to truthfully promote the drugs they sell, it also must protect their constitutional right to provide truthful warnings about their products' risks, even if the FDA has not approved those warnings." L. Bograd, *Be Careful What You Wish for: Drugmakers, The First Amendment, and Preemption*, 51 TRIAL 24 (Nov. 2015). Under this theory, if manufacturers have a constitutional right to issue truthful warnings, then federal statutes cannot prohibit such warnings. Simultaneous compliance with federal law and a state-law duty to warn is therefore possible, and state-law failure-to-warn claims are not impliedly preempted.

Although Bograd suggests that a "'constitutional right to warn' may affect a variety of drug and device cases," he, unlike some other members of the plaintiffs' bar, tacitly recognizes that this theory applies, at most, to "failure-to-warn claims involving generic prescription drugs."¹ Why do failure-to-warn claims involving PMA medical devices remain preempted even if otherwise identical claims involving generic drugs do not? Devices, unlike drugs, are covered by 21 U.S.C. § 360k(a). In the absence of an applicable express-preemption provision, failure-to-warn claims implicating drugs can only be *impliedly* preempted. In practice, that means such claims are preempted only if they conflict with federal law. By contrast, § 360k(a) expressly preempts "*any*" state-law requirement that is "different from, or in addition to," the federal requirements applicable to a device with premarket approval. In other words, it "covers not just conflicting, but also different or additional state requirements." *Nat'l Meat Ass'n*, 132 S. Ct. at 971. Therefore, even if medical-device manufacturers have a constitutional right to issue truthful warnings about their devices, § 360k(a) preempts any tort claim involving a device with premarket approval that is predicated on a state-law duty to disseminate a warning that is not required by the FDA.

¹ James Beck, a leading member of the defense bar, has argued in his influential *Drug and Device Law* blog that Bograd's theory fails on various grounds even as to generic drugs. In Beck's view, even if there is a First Amendment right to issue truthful warnings, the FDA may—as a constitutionally permissible time/place/manner restriction—require that manufacturers submit such warnings for review prior to any labeling change. See "When They Don't Have Anything, They'll Try Anything," DRUG AND DEVICE LAW (Dec. 9, 2015, 9:50 AM), <http://druganddevicelaw.blogspot.com/2015/12/when-they-dont-have-anything-theyll-try.html>. According to Mr. Beck, given the requirement of agency review, manufacturers are not unilaterally able to change their labels. If so, failure-to-warn claims would still be preempted under conflict-preemption principles, because, as the Supreme Court held in *Mensing*, the relevant question for implied preemption purposes is "whether the private party could independently do under federal law what state law requires of it." 131 S. Ct. at 2579.

As the FDA itself recognizes, off-label use of PMA devices is frequently the accepted standard of treatment. If device manufacturers must fear criminal or regulatory enforcement actions when discussing off-label uses, they will avoid discussing such uses. As a result, doctors will be without the benefit of relevant information and patients will suffer accordingly. The courts' recent recognition of expanded commercial-speech rights under the First Amendment reduces the threat of such pernicious results. It would be paradoxical if the recognition of those same rights were used by the plaintiffs' bar to undermine the protection afforded manufacturers by § 360k(a)—protection that spurs the development of innovative medical devices and patients' access to such devices. Fortunately, the statutory text and the case law interpreting it preclude such a negative outcome.

Past WLF Publications on Related Issues

***Reed v. Town of Gilbert* Portends a Positive Sign for First Amendment Arguments Regarding Off-Label Speech**

By **James M. Beck** and **Lisa M. Baird**, Counsel with Reed Smith LLP in its Philadelphia, PA and Los Angeles, CA offices, respectively, and **Raffi Kassabian** and **Gillian H. Clow**, Associates in the Los Angeles office.

Federal Preemption: Origins, Types and Trends in the U.S. Supreme Court

By **Frank Cruz-Alvarez** and **Jennifer Voss**, Partners, and **Jared Sherr** and **Talia Zucker**, Associates, with Shook, Hardy & Bacon LLP. Foreword by **Daniel E. Troy**, Senior Vice President and General Counsel, GlaxoSmithKline. Mr. Troy is also a member of WLF's Legal Policy Advisory Board.

To Tweet or Not to Tweet: How FDA Social Media Guidelines Violate the First Amendment

By **Kirby T. Griffis**, a Partner, and **Tamara Fishman Barago**, an Associate, with Hollingsworth LLP in Washington, DC.

Ninth Circuit Bucks Supreme Court Again on Medical Device Preemption

By **Matthew A. Reed**, an Associate with Sedgwick LLP in its Los Angeles, CA office.

The First Amendment and the Emerging Tort of Off-Label "Promotion"

By **Michael A. Walsh**, a Partner with Strasburger & Price LLP in Dallas, TX.

All WLF publications are available online at www.wlf.org