The future of preemption

For FDA-regulated companies, federal preemption can provide a potentially powerful defense to state tort claims.

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For FDA (Food and Drug Administration)-regulated companies, federal preemption can provide a potentially powerful defense to state tort claims. In recent years, the U.S. Supreme Court has decided numerous preemption cases, each emphasizing the highly context-sensitive nature of the inquiry. Determining when preemption applies and how to deploy it to limit claims and to manage discovery requires a keen awareness of evolving doctrine and the regulatory record for the product at issue.

Preemption stems from the Supremacy Clause of the U.S. Constitution, which precludes state law from conflicting with federal law on the same subject. Preemption may be *express*—where a provision of federal law explicitly displaces state law, as in the case of certain medical devices — or *implied* — where state and federal law are incompatible. In general, the greater the regulatory oversight of a matter, the stronger the foundation for a potential preemption defense.

For brand-name prescription drugs and over-the-counter drugs, the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), establishes a framework for evaluating implied preemption of failure to warn claims. For preemption to apply, there must be "clear evidence that the FDA would not have approved" the warning plaintiffs urge. *Id*. at 571. Courts have applied *Wyeth* with varying results. In *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010), plaintiff claimed that Children's Motrin should have contained warnings about toxic epidermal necrolysis (TEN), a rare condition, even though FDA "decided not to require such a warning [against TEN] because it would confuse rather than inform." *Id*. The 7th Circuit held plaintiff's claims preempted because "it would be odd to think that [defendant] had a legal duty to guarantee against a risk that the FDA thought not worth warning against." *Id*. More recently, however, faced with essentially the same warning claims for the same product, the Massachusetts high court rejected preemption, upholding a $63 million verdict. *See Reckis v. Johnson & Johnson*, 471 Mass. 272 (2015). In so doing, the court posited that FDA might have permitted other phrasing about the risks of TEN had defendants proposed it, and that phrasing would have averted injury. *Id.* at 285.

Classwide warnings may provide another basis for preemption. In *Dobbs v. Wyeth Pharms.*, 797 F. Supp. 2d 1264, 1277-80 (W.D. Okla. 2011), the FDA rejected warnings specific to the drug at issue "in favor of uniform language applicable to all" drugs in the class, thereby supplying "clear evidence" that FDA would not have approved drug-specific warnings. *Id*. Preemption may also supply a strong defense where plaintiffs challenge the location of warnings in labeling. *In re Fosamax*, 951 F. Supp. 2d 695 (D.N.J. 2013), found that "preemption is warranted because there is clear evidence" that FDA rejected requests to add warnings to the "Precautions" section of the labeling, permitting them only as "Adverse Reactions." *Id.* at 701-05.

These cases underscore the importance of a painstaking review of the regulatory record, and companies should be mindful of memorializing the agency's safety determinations to better facilitate potential future preemption defenses.

For generic drugs, given requirements that generics generally have "the same" warnings as the brand, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court rejected claims that generics have a duty to provide other warnings. In *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Court also rejected, as incompatible with preemption, calls for generics to stop selling the product if they cannot amend warnings. *Mensing* explains that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." 131 S. Ct. at 2581. This holding may reinvigorate future preemption arguments beyond generics if FDA's prior approval is needed before warnings can be changed (*e.g.*, prior approval supplements, labeling highlights).

The FDA has responded by proposing regulatory amendments to allow generics to amend warnings on their own. State law also has responded with a few decisions permitting claims against the innovator even where the patient took only the generic drug. *E.g.*, *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014).

How preemption will play out for recently approved biosimilars — which may be biologically distinguishable from the reference product, but may have the same FDA approved labeling as the brand — remains uncertain and may be a hybrid of these approaches.

For medical devices, *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), held that claims against premarket-approved (PMA) devices — subject to the highest level of FDA scrutiny — are expressly preempted under 21 U.S.C. § 337(a) to the extent they impose requirements that are different from, or in addition to, federal requirements. *Riegel* dispensed with claims that attack the FDA-approved design, warning, or manufacturing process for PMA devices, but it left open the possibility of "parallel claim[s]" if devices deviate from PMA requirements. *Id*. at 330; *e.g.*,*Bryant v. Medtronic, Inc.*, 623 F.3d 1200 (8th Cir. 2010). A similar express preemption provision, 21 U.S.C. § 379r, may bar consumer fraud claims against over-the-counter drugs. *See Carter v. Novartis Consumer Health, Inc*., 582 F. Supp. 2d 1271, 1290 (C.D. Cal. 2008) (dismissing claims).

Where a complaint's allegations are insufficient to state a parallel claim, preemption combined with the heightened pleading standards of *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), may support an early motion to dismiss. *E.g.*, *Scianneaux v. St. Jude Med. S.C., Inc.*, 961 F. Supp. 2d 808, 813 (E.D. La. 2013) (dismissing claims against PMA device where "complaint is light on factual allegations and heavy on conclusory statements"). Even if a complaint attempts to plead a non-preempted claim, an early summary judgment motion may help the parties to phase the litigation and narrow discovery. *Pinsonneault v. St. Jude Med., Inc*.,2014 WL 2879754, at *2 (D. Minn. June 24, 2014), recognized a "first phase of discovery" limited to preemption. Defendant served its preemption summary judgment motion near the outset of discovery "[t]o help focus that discovery" and summary judgment ultimately was granted to defendant.

The 9th Circuit held that federal law did not impliedly preempt Arizona state law failure-to-warn claims premised on a manufacturer's alleged failure to "'report to the FDA any complaints about the product's performance'" allegedly linked to plaintiff's injury and about which the labeling is silent.

Stengel v. Medtronic Inc., 704 F.3d 1224, 1232 (9th Cir. 2013) (en banc), *cert. denied* 134 S. Ct. 2839 (2014). This result came notwithstanding the Supreme Court's ruling that state-law claims predicated on alleged failures in reporting duties owed to FDA are impliedly preempted, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (21 U.S.C. § 337(a)).

Preemption continues to be a vital defense in life sciences litigation. Counsel should consider deploying preemption at each phase of litigation, including pleadings-based motions, summary judgment, discovery management, trial, and appeal. Companies also should remain attuned to efforts by Congress to revisit statutory preemption, often in the wake of significant preemption decisions.

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