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Watch your language

HOW EXAMINING FEDERAL PREEMPTION IN COMPLEX TOXIC-TORT CASES AND TAKING GREAT CARE WITH YOUR PLEADING CAN SAVE YOUR LITIGATION

Federal preemption has become a leading defense in products-liability cases. Having a thorough appreciation for the risks of federal preemption before drafting pleadings can protect against damaging and case-ending preemption motions.

This article focuses on how understanding recent U.S. Supreme Court and Ninth Circuit rulings in medical-device regulation have left open the door to many common-law tort claims, even in areas of intense federal regulation. This is also true with regard to another common area for defense arguments regarding preemption, namely toxic exposures to harmful fumes or emissions.

The intent of Congress is presumed to defer to the states

In general, the doctrine of federal preemption is the invalidation of state law when it conflicts with federal law. Courts generally recognize three categories of federal preemption: express, field and conflict preemption. (*Stengel v. Medtronic, Inc.* (9th Cir. 2013) 704 F.3d 1224) (en banc).) In contrast to express pre-emption, the subtypes "field" and "conflict" pre-emption are implied theories of pre-emption. Under all three, "the purpose of Congress is the ultimate touchstone" of pre-emption analysis. (*Cipollone v. Liggett Grp* (1992) 505 U.S. 504, 516.)

In *Cipollone* the Supreme Court addressed cigarette manufacturers' claims that state tort actions were completely vitiated by 1960's-era federal regulations requiring warnings on cigarette packs stating that "cigarettes are hazardous to your health." Writing for the majority, Justice Stevens noted that the U.S. Constitution's Supremacy Clause "starts with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the *clear and manifest purpose of Congress*." (*Id*., 505 U.S. at p. 516, emphasis added.) Accordingly, "[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis." (*Ibid*.)

California courts have repeatedly followed *Cippollone*'s focus. "Given the importance of federalism in our constitutional structure … we entertain a strong presumption that federal statutes do not preempt state laws; particularly those laws directed at subjects – like health and safety – traditionally governed" by the states. (*Frastaci v. Vapor Corp.* (2007) 158 Cal.App.4th 1389, 1395.) Particularly in an area of law traditionally occupied by the states, "Congress's intent to preempt must be 'clear and manifest' to preempt state law." (*Black v. Fin. Freedom Senior Funding Corp.* (2001) 92 Cal.App.4th 917, 926.) [holding that the federal Parity and Truth in Lending Acts did not preempt homeowners' claims that housing creditors violated state laws with marketing of reverse mortgages].)

Therefore, when evaluating a preemption argument, it is critical to start with an examination of whether a "clear and manifest" intent is displayed in the text or history of the federal

law being cited. If not, the presumption remains against pre-emption. (See *Stengel v. Medtronic, Inc*., 704 F.3d at p. 1227.)

Courts are particularly reluctant to preempt common-law tort claims for personal injury where the federal law provides no private right of action. (*Silkwood v. Kerr-Mcgee Corp.* (1984) 464 U.S. 238, 251.) Importantly, in such cases, preemption of the plaintiffs' common-law claims would leave them without the remedy the common law would provide:

> The Court in the past has hesitated to find pre-emption where federal law provides no comparable remedy. See Rabin, A Sociolegal History of the Tobacco Tort Litigation, 44 Stan. L. Rev. 853, 869 (1992) (noting the "rather strong tradition of federal deference to competing state interests in compensating injury victims"). Indeed, in *Silkwood*, the Court took note of "Congress's failure to provide any federal remedy" for injured persons, and stated that it was "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." (464 U.S. at 251.) See also *Id*., at 263 (BLACKMUN, J., dissenting) ("It is inconceivable that Congress intended to leave victims with no remedy at all"). (*Cipollone*, 505 U.S. at p. 541, Blackmun, concurring and dissenting).

The door is still open

Multiple rulings in the area of medical-device regulation and preemption have failed to shut the door on state tort causes of action. In the 1990's and 2000's, the U.S. Supreme Court seemed poised to deliver a severe blow to medical-device-injury litigation. However, the Court has repeatedly refused to close

Peluso, Next Page

Journal of Consumer Attorneys Associations for Southern California
ADVOCATE
February 2017 Issue

the door completely and recent lower court cases may even have completely reversed the tide in favor of plaintiffs' failure-to-warn claims.

In 1996, in *Medtronic, Inc. v. Lohr*, the Supreme Court refused to bar all state-tort claims based on the Food and Drug Administration's ("FDA") power under the Medical Device Amendments to the Food, Drug and Cosmetic Act ("MDA") to regulate medical devices:

> Medtronic's argument is not only unpersuasive, it is implausible. Under Medtronic's view of the statute, Congress effectively precluded state courts from affording state consumers any protection from injuries resulting from a defective medical device. Moreover, because there is no explicit private cause of action against manufacturers contained in the MDA, and no suggestion that the Act created an implied private right of action, Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order "to provide for the safety and effectiveness of medical devices intended for human use," 90 Stat. 539 (preamble to Act). It is, to say the least, "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct," (*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 78 L. Ed. 2d 443, 104 S. Ct. 615 (1984)), and it would take language much plainer than the text of § 360k to convince us that Congress intended that result.
>
> Furthermore, if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it. The statute would have achieved an identical result, for instance, if it had precluded any "remedy" under state law relating to medical devices. "Requirement" appears to presume that the State is imposing a specific duty upon the manufacturer, and although we have on prior occasions concluded that a statute pre-empting certain state "requirements" could also pre-empt common-law damages claims, see *Cipollone*, 505 U.S. at 521-522 (opinion of STEVENS, J.), that statute did not sweep nearly as broadly as Medtronic would have us believe that this statute does. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 487.)

In *Riegel v. Medtronic* (2008) 552 U.S. 312 (2008), the U.S. Supreme Court once again grappled with a different provision of the MDA and once again refused to completely eviscerate state protections.

Wyeth reinforces viability of state-law actions

Next, to the surprise of many court-watchers, the trend to refuse to completely preempt state-tort law claims was solidified in *Wyeth v. Levine* (2009) 555 U.S. 555, 555. The Court in *Wyeth* held that federal law did not fully preempt state-law action by a patient whose gangrene allegedly was caused by injection of drug directly into vein. The court referenced several contrary federal regulations in refusing to find preemption including 44 Fed. Reg. 37437 (1979) ("It is not the intent of the FDA to influence the civil tort liability of the manufacturer"); 59 Fed. Reg. 3948 (1994) ("[P]roduct liability plays an important role in consumer protection"). See also Porter, The Lohr Decision: FDA Perspective and Position, 52 Food & Drug L. J. 7, 10 (1997) (former chief counsel to the FDA stating that the FDA regarded state law as complementing the agency's mission of consumer protection).

One might think that three relatively similar Supreme Court decisions on the same topic would have sufficiently clarified the issue. Not so in the high-stakes world of complex litigation. Importantly, the tide may be swinging even further in plaintiffs' favor. In the *Stengel v. Medtronic, supra,* the Ninth Circuit reversed a district court's grant of a motion to dismiss under FRCP 12(b)(6) based on preemption even with regard to failure-to-warn claims. The case involved the SynchroMed EL Pump and Catheter, an internal pain-medication pump designed to deliver pain medication directly into the spine. Instead of delivering pain relief, the device in question caused complete paralysis in the plaintiff. In reversing the district court the *Stengel* opinion noted continuing differences even post-*Riegel* and *Wyeth* in the Fifth, Seventh and Eighth Circuits. The opinion then held that the Ninth Circuit would join the Seventh and Eight Circuits in holding that state common-law consumer protections under negligence and the federal MDA have "parallel" duties of consumer protection. Even further, the *Stengel* opinion ruled that even failure-to-warn claims did not qualify for federal preemption based on the "parallel" duty of each law.

Manufacturers keep looking to preemption

Manufacturers continue to try to apply express preemption provisions to common-law air quality toxic tort claims, but generally are falling short. Like the MDA, the Clean Air Act (42 U.S.C. § 7401 *et seq*.) ("CAA") gives broad authority to another federal agency, the Environmental Protection Agency (EPA) to establish air-quality standards that adequately protect public health and safety (42 U.S.C. § 7409 (b)(1)*; Lead Industries Ass'n v. Environmental Protection* (D.C. Cir. 1980) 647 F.2d 1130, 1148.) The CAA requires that the EPA develop and enforce a plan broadly regulating sources of air pollution. (42 U.S.C. § 7410(a).) In 1967, amendments to the CAA included the following preemption clause:

> No State or any political subdivision thereof shall adopt or attempt to enforce any standard relating to the control of emissions from new motor vehicles or new motor vehicle engines subject to this part. No State shall require certification, inspection, or any other approval relating to the control

Peluso, Next Page

Journal of Consumer Attorneys Associations for Southern California
ADVOCATE
February 2017 Issue

> of emissions ... as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment.

42 U. S. C. § 7543(a) (or section 209 (a) of the uncodified Act) (*emphasis added*). Commonly in preemption motions, defendants point to Congress' use of the phrase "relating to" for express and "broad preemptive purpose." (See *Morales v. Trans World Airlines, Inc.* 1992) 504 U.S. 374, 383 Airline Deregulation Act of 1978 preempts Texas advertising requirements for disclosure of fare details] and *Engine Mfrs. Ass'n. v. South Coast Air Quality Management District*, 2004) 541 U.S. 246, 248 [state fleet vehicle regulations preempted as efforts to enforce a state emissions standard].)

However, the "relating to" – like all language in preemption statutes – must be read in the context in which it appears. As noted above in the seminal case of *Cippolone*, "*each phrase within* [*a pre-emption*] *clause limits the universe of common-law claims pre-empted by the statute*." (*Cipollone*, 505 U.S. at p. 524 .) (emphasis added). For example, in the case of the CAA, the words "relating to" must be read together with the word "standard." The language of this particular federal statute cannot be read to create a broad exclusion of all common-law claims for tort relief as such claims are simply not 'standards' to control emissions.

> In enacting the CAA, Congress declared that such motor vehicle emission regulations were necessary to "prevent a chaotic situation from developing in interstate commerce in new motor vehicles . . . ." (*Jackson v. GMC* (S.D.N.Y. 2011) 770 F. Supp. 2d 570, 573.) Specifically, section 209(a) is the product of congressional concern that local regulation of emissions standards could unduly burden interstate commerce by subjecting manufacturers to 50 different sets of emissions control requirements. (See H.R. Rep. No. 294, 95th Cong., 1st Sess. 309-10 (Report of the House Committee on Interstate and Foreign Commerce) (1977), reprinted in 1977 U.S. Code Cong. & Admin. News, p. 1388, P.L. 95-95 Legislative History § 221.) The Committee's concern for manufacturers was balanced by its concern that "this preemption (Section 209(a) of the Act) now interferes with legitimate police powers of States…."

(*Ibid*.)

Thus, the test of whether any State law or action falls within the intended scope of section 209(a) pre-emption is the degree to which the State law or action would interfere with the federal regulatory scheme by compelling manufacturers to adapt their products to "different sets of emissions control requirements." (H.R. Rep. No. 294, *supra*.); see also *In re Caterpillar, Inc.*, No. MDL No. 2540, 2015 U.S. Dist. LEXIS 98784, at *47-48 (D.N.J. July 29, 2015).

The precise scope of express preemption

Indeed, in a case involving California's state efforts to regulate air quality, the U.S. Supreme Court elucidated the precise scope of express preemption under 209(a). "The criteria referred to in § 209(a) relate to the emission characteristics of a vehicle or engine. To meet them the vehicle or engine must not emit more than a certain amount of a given pollutant, must be equipped with a certain type of pollution-control device, or must have some other design feature related to the control of emissions." (*Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.* (2004) 541 U.S. 246, 253.) Thus to be expressly preempted a claim must be (1.) related to "a certain amount of a given pollutant," (2.) "a certain type of pollution-control device," or (3.) "some other design feature related to the control of emissions." Aside from wind-resistance coefficients, few motor vehicle "design features" are standards related to emissions. (See *In re Caterpillar, Inc.*, 2015 U.S. Dist. LEXIS 98784, *31 and *Navistar, Inc. v. Jackson* (D.D.C. 2012) 840 F. Supp. 2d 357, 366.) As the claims in *Caterpillar* did not involve "standards" under the preemption rule of section 209(a) but rather a failure to correct a defect, they were not preempted under CAA. *Caterpillar,* 2015 U.S. Dist. LEXIS 98784, *36.

Unlike these cases, the district court in *Jackson v. Gen. Motors Corp.* ruled against plaintiffs on the basis of preemption. The *Jackson* court was confronted with claims of publically-employed bus drivers and mechanics who alleged personal injuries from diesel emissions produced by normally-operating engine, exhaust, and emissions systems. The claims were directly based upon alleged violations of EPA emissions standards and, for this reason, the court found the claims expressly preempted by 209(a). (*Jackson,* 770 F.Supp.2d at 572.)

The *Jackson* court reasoned that the *Jackson* plaintiffs' explicit reference to enforcement in the CAA made clear that "a state common law tort action that questions whether a defendant complied with EPA (or CARB) *standards* promulgated under the CAA is an example of a state attempting to enforce the CAA, and is therefore subject to preemption." (*Id*., at 575, emphasis added). In contrast, the *Caterpillar* plaintiffs did not question whether Caterpillar complied with standards promulgated under the CAA. Nor did the *Caterpillar* plaintiffs contend that they were harmed by the failure of their engines to comply with applicable emissions standards.

Claims like those in *Jackson* are preempted by the CAA, but a personal-injury claim caused by a defect in an engine certified by the EPA is not related to emissions control standards and would not be preempted.

Conclusion

In response to the recent ascent of the preemption defense to products-liability claims, the courts have responded by refusing to foreclose the claims of the injured. Where a product has malfunctioned to cause injury, courts are extremely reluctant to abdicate their power and duty to adjudicate cases that are traditionally their province. As long as it remains the duty of the courts "to say what the law is," courts are indicating their intent to continue to adjudicate injury claims where Congress has not clearly indicated its intent to completely occupy the field. Thus pleading defect and malfunction may immunize the case against an over-reaching preemption attack.

Peluso, Next Page

Journal of Consumer Attorneys Associations for Southern California
ADVOCATE
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