Don't Overlook a Preemption Defense in Medical Device Cases

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Medical device manufacturers may be missing opportunities to invoke the doctrine of federal preemption as a defense to common law tort claims. Language in the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act ("FDCA") supports the argument that Congress has preempted common law tort claims against makers of medical devices, at least with respect to failure-to-warn claims. The final word is not in, but unless and until the United States Supreme Court or the vast majority of federal courts reject it, attorneys defending medical device cases should seriously consider pressing a preemption defense.

Overview

Congress can preempt state law expressly or implicitly. Usually, Congress regulates part of an area and lets the courts decide whether state action in that area has been implicitly preempted. So-called "implied preemption" is found when the pervasiveness of the federal regulation precludes supplementation by the states; when the federal interest in the field is sufficiently dominant; or when the object sought to be obtained by the federal law and the character of obligations imposed by it reveals the same purpose. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 239 (1947); (quoted in Schmeidewind v. ANR Pipeline Co., 485 U.S. 293, 300, 108 S. Ct. 1145, 1150, 99 L. Ed. 2d 316, 325 (1988). State law is also preempted where "it stands as an obstacle to the accomplishment of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). In general, courts are reluctant to find that state action is implicitly preempted by federal statutes or regulations.

Express preemption occurs when Congress enacts legislation which declares its intention to bar state regulation of the same subject matter. See Hillsborough County v. Automated Medical Laboratories, 471 U.S. 707, 713 (1985). Particularly in the area of product

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liability, express preemption of state regulation of an entire field is rare. The 1976 Medical Device Amendments to the FDCA may be a rare expression of express preemption. Manufacturers of medical devices may therefore have a better claim to preemption than makers of prescription drugs.

Federal Preemption and Medical Devices: 21 U.S.C. § 360k

With these principles in mind, consider the 1976 Medical Device Amendments to the FDCA, codified at 21 U.S.C. §§ 360 et seq. The Medical Device Amendments contain an express preemption provision. Section 360K(a)(1) prevents the enforcement or establishment of any state requirement for a medical device which is either different from, or in addition to, applicable FDA requirements. Section 360k(a)(2) also precludes the establishment or enforcement of any state requirement relating to the device’s safety or effectiveness, or any other matter included in a requirement applicable under the FDCA.

The Food and Drug Administration’s interpretation of the term “state requirement” may afford medical device manufacturers an affirmative defense to common law tort claims. FDA regulations which construe § 360k provide that in addition to statutes, ordinances and regulations, court decisions are state “requirements” for medical devices and therefore proscribed by § 360k. See 21 C.F.R. § 808.1(d). Most federal courts have ratified this interpretation. See, e.g., Stewart v. International Playtex, 672 F. Supp. 907, 909 (D.S.C. 1987) (granting defendant tampon manufacturer’s summary judgment motion since “[p]laintiff’s common law tort claim alleging ‘inadequate warnings’ seeks by definition to establish a tort labeling requirement which could be different from or in addition to the existing and applicable FDA requirement. Therefore . . . the preemption language in 360k applies”); accord Moore v. Kimberly-Clark Group, 867 F.2d 243 (5th Cir. 1989) (affirming district court’s dismissal of plaintiff’s inadequate warning and labeling claims on § 360k preemption grounds); Kraske v. Kimberly-Clark Corp., No. L89-30066CA (W.D. Mich. Jan. 17, 1990) (summary judgment entered for defendant on federal preemption grounds). 688 F. Supp. 475 (S.D. Ind. 1988); Edmondson v. International Playtex, Inc., 678 F. Supp. 1571 (N.D. Ga. 1987). The Washington Supreme Court recently adopted this view in Berger v. Personal Products, Inc., 115 Wash. 2d 267, 797 P.2d 1148 (1990), where the court held that state tort actions based on inadequate labeling and warning statements are preempted by § 360k. The issue is presently before the Supreme Court of Georgia in Poloney v. Tambrands, Inc., No. 90A 1298 (Ga.). In the lower court, the defendant tampon manufacturer, had been granted summary judgment on federal preemption grounds.

Two district courts (Maryland, Wisconsin) have rejected this interpretation of the statute. Callan v. G.D. Searle & Co., 709 F. Supp. 662 (D. Md. 1989); Muzatko v. International Playtex, 1987 U.S. Dist. LEXIS 14281 (ED Wis. May 14, 1987). However, these decisions are in the minority and have doubtful precedential value. Callan involved a product—an IUD—classified by the FDA as a “drug”, not a “device”; interpretation of § 360k was irrelevant to the issues before the court. The Muzatko Court ruled that § 360k does not apply to common law tort claims— notwithstanding the fact that 21 C.F.R. § 808.1 specifically includes “court decisions” in its list of proscribed state “requirements.” Two months after the Muzatko decision was rendered, a court in the Western District of Wisconsin rejected its reasoning and declined to follow it. See Ignace v. Playtex Family Foods, 1987 U.S. Dist. LEXIS 13609 (W.D. Wis. July 28, 1987). Other courts have rejected Muzatko on the ground that its reliance upon Q’Givie v. International Playtex, Inc., 609 F. Supp. 817 (D. Kan. 1985), aff’d in part, rev’d in part, 821 F.2d 1438 (10th Cir. 1987), cert. denied, 486 U.S. 1032 (1988) was misplaced. In Q’Givie, preemption had not been raised before the district or appellate courts and therefore was not in issue. For these reasons, neither Callan nor Muzatko provides substantial authority for rejecting federal preemption of medical device regulation.

The Stewart Court’s systematic preemption analysis is a useful model for courts and practitioners. In Stewart, plaintiff claimed her decedent contracted toxic shock syndrome as a result of using tampons made by International Playtex. Defendant moved to dismiss plaintiff’s failure to warn claims on federal preemption ground. Plaintiff argued in opposition that § 360k did not expressly or impliedly preempt failure to warn claims. After careful analysis, the Court granted defendant’s motion for summary judgment.

The Stewart Court began by acknowledging Congressional authority to adopt federal statutes or authorize federal administrative agencies to promulgate regulations that preempt state law. The Stewart Court
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described § 360k as "reveal[ing] on its face the congressional objective to prohibit, by the doctrine of express preemption, the proliferation of multiple, diverse, state by state device requirements." 672 F. Supp at 909. The Court observed that the product at issue—tampons—was a Class II medical device as defined in the 1976 Medical Device Amendments. The Court further noted that FDA had adopted specific regulations governing tampon labeling for the purpose of assuring safe use. These findings required the Court to conclude that § 360k applied to putative state tort requirements for tampons and barred plaintiff's failure to warn claim.

Plaintiff's claim that South Carolina tort law was not a "requirement" as defined under 21 C.F.R. § 808.1(b), was summarily rejected because the regulation expressly defines "requirement" to include "court decisions." The suggestion that applying § 360k to plaintiff's failure to warn claim would result in impermissible abrogation of a state-created tort remedy was also dismissed. As the Court observed, "[t]he question ... is not the preemption of a remedy, but whether the federal government can impose upon a manufacturer a binding, uniform standard of conduct. The remedy is available to plaintiff, but compliance with federal law protects the defendant from the vagaries of each state's judicial system." 672 F. Supp at 910 (emphasis in original).

Plaintiff's next argument—that federal regulation should be treated as imposing only a minimum standard of conduct because states can request exemption from the regulatory scheme—was also unsuccessful. *Until a state has applied for exemption under § 521(b) of the Act and a finding is made under 21 C.F.R. § 808.1(c), the requirements are the only ones to be imposed. Finally, an analogy to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) was rejected as unpersuasive because FIFRA contains a savings clause permitting state regulation; the Medical Device Amendments do not.

Caveats and Considerations

* Some courts have limited application of § 360 k to claims based upon inadequate warning and labeling. Krause v. Kimberly-Clark Corp., N. L89-30066CA (W.D> Mich. Jan. 17, 1990) (The court found no indication that Congress or FDA intended to preempt all state law tort claims, only state law claims which challenge the adequacy of information provided with tampon packages were deemed preempted); Rockett v. International Playtex Inc., No. 89-0718- LC (W.D. La. Oct. 4, 1989) (claims based on design, composition and construction of tampons are not preempted by federal law); Accord Rinehart v. International Playtex Inc., 688 F. Supp. 475 (S.D. Ind. 1988) (federal law does not preempt design defect claim).

* Note the date of injury when considering a federal preemption defense under § 360 k. One court has declined to apply § 360k retroactively to bar a claim which pre-dated the enactment of the statute. Desmarais v. Dow Corning Corp., Docket No. H-87-486 (D. Conn. May 8, 1989).

* Most courts construe 360k and its regulations as requiring preemption of state law only if the state law addresses precisely the same subject matter as the federal law. For example, tampon manufacturers were able to make strong preemption arguments, in part because the language of their warnings is dictated by specific federal regulations. By contrast, in Smith v. Pingree, 651 F. 2d 1021 (5th Cir. 1981), the United States Court of Appeals for the Fifth Circuit ruled that federal regulation did not preempt Florida laws governing the fitting and sale of hearing aids since "the federal regulation does not address the procedures required for fitting the hearing aid to the patient". (Note that this interpretation of 360k disregards the proscription of state requirements "different from or in addition to any requirement applicable under this chapter to the device" contained in § 360k (a) (1) (emphasis added).

* Manufacturers of new devices—who must now obtain "pre-market approval" for their products pursuant to 21 U.S.C. § 515—may also be able to claim that this additional level of FDA regulation should preempt common law tort claims. Pre-market approval of medical devices, which follows detailed submissions of product designs and proposed packaging and labeling to the FDA, may be treated by some courts as setting a federal standard which should not be subject to the "whims and vagaries" of state courts.

Conclusion

Medical device manufacturers, especially those sued on state-law failure-to-warn theories, should consider asserting the express federal preemption of state law codified at 21 U.S.C. § 360k as an affirmative defense to such claims. Although a few courts have rejected federal pre-emption as a defense to state law design defect claims, others may prove to be more receptive.

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