Strategic Applications

Preemption in Drug and Device Products Litigation

by Jon A. Strongman

Federal preemption is a critical tool in the chest of defenses for pharmaceutical and medical device manufacturers. The concept of preemption—federal law trumping state law—is not a complicated one; applying preemption and maximizing its usefulness, however, is not so simple. But manufacturers (and courts) should not shy from these complexities. Preemption can preclude claims, it can foreclose evidence, and it can win cases.

Prescription drugs and medical devices are regulated by the United States Food & Drug Administration ("FDA"). Before a prescription drug or device ever hits the market, it must pass through the appropriate FDA approval or clearance process. Yet, in the products liability context, plaintiffs often allege that a warning is insufficient or a manufacturing process flawed, despite the fact that such warning or process was approved by the FDA. Moreover, under certain circumstances, manufacturers may be precluded by the FDA from changing the warnings or manufacturing processes as suggested by plaintiffs. It is this potential for plaintiffs to engage in a state-by-state and jury-by-jury second-guessing of the FDA that makes preemption so important. The FDA, recognizing this predicament, has recently endorsed preemption of state-law tort claims under certain circumstances. This position represents a material change for the FDA and reinforces for manufacturers that the preemption defense is alive and well.

This article will discuss the developments of preemption in prescription drug and medical device litigation, including: the roots and background of preemption; express preemption under the Medical Device Amendments; the potential application of implied preemption; and advice on how to best employ preemption in your cases.

Background on Preemption

The doctrine of preemption stems from the Supremacy Clause of the United States Constitution. The Supremacy Clause directs that the laws of the United States "shall be the supreme Law of the Land;... any Thing in the Constitution or Law of any State to the Contrary notwithstanding." Art. VI, cl. 2. Bottom line, federal preemption requires that "state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992).

There are three variations of the federal preemption doctrine: express preemption, implied preemption, and field preemption. Express preemption occurs by the express language in a congressional enactment. When Congress includes an express preemption provision in a statute, the court may not look beyond the language of the statute. *Id.* at 517. Implied preemption, on the other hand, exists by implication due to a conflict between a congressional enactment and a state law. Field preemption, which is really another form of implied preemption, stems from the depth and breadth of a congressional scheme; a federal enactment can be so sweeping as to take an area of regulation out of the states' reach (*e.g.*, regulation of savings and loans). In the drug and medical device context, express and implied preemption are both potential defenses.

Express Preemption and Medical Devices

The Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act ("FDCA") include an express preemption provision. This provision provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a). Stated more simply, preemption under §360k(a) requires: (1) a federal requirement; and (2) a state requirement different from or in addition to the federal requirement.

Congress had two purposes for including an express preemption provision: ensuring that the FDA had sufficient authority to maintain uniformity and minimize risk; and encouraging the development of new and much-needed devices. "[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce will be unduly burdened." H.R. Conf. Rep. No. 853, 94th Cong., 2d Sess. 1, 45 (1976).

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The express preemption provision clearly prohibits states from enacting parallel legislation placing additional or different requirements on the approval and marketing of medical devices. The application of this provision to state tort law, however, is not as clear. To understand just how the express preemption provision of the MDA applies to state tort law claims, a general understanding of FDA regulation of medical devices is necessary.

Regulation of Medical Devices

The FDA's mandate is to ensure that medical devices are safe and effective. *See* 21 U.S.C. §§360c, *et seq.* To this end, the FDA enacts and enforces regulations. Under this regulatory scheme, medical devices are divided into three classes. Class I devices (such as a tongue depressor) are the least dangerous and are subject to manufacturing controls and registration requirements. *Id.* at §360c(a)(1)(A). Class II medical devices would include things such as hearing aids and may be subject to safety performance standards in addition to the Class I requirements. *Id.* at §360c(a)(1)(B). The most stringent regulation is focused on Class III devices—devices used to sustain or support human life, prevent impairment of public health, or which present a potential for unreasonable risk of injury. *Id.* at §360c(a)(1)(C)(ii)(I–II).

To gain approval for a Class III device, the manufacturer must submit a Premarket-Approval ("PMA") application or qualify for one of the two exceptions to the PMA requirement—the §510k process or the Investigational Device Exemption ("IDE"). The PMA process is rigorous. The FDA devotes approximately 1,200 hours to reviewing each PMA submission. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 345 (2001). The FDA then grants approval only if there is "reasonable assurance" that the medical device is "safe and effective." 21 U.S.C. §360c(a)(2),(3). IDE devices, while exempt from the PMA process, also receive stringent regulation. Under IDE review, the manufacturer must still submit a substantial amount of information. *See, e.g., Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095–96 (6th Cir. 1997). Section 510(k) review, on the other hand, is not nearly as rigorous. The §510(k) process requires manufacturers of devices "substantially equivalent" to preexisting devices to submit to a limited form of review, known as premarket notification. As compared to the 1,200 hours required by the FDA in the PMA process, the §510(k) process takes only about 20 hours. *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 221 (6th Cir. 2000).

Express Preemption of State-Tort Claims Involving Class III Devices

There are two key issues when determining preemption of state products-liability claims under the MDA: (1) is the state-tort law a "state requirement" under the statute; and (2) is there a specific "federal requirement." The U.S. Supreme Court added some clarity to these issues in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).

Plaintiff's claims amounted to requirements different from or in addition to the federal requirements.

In *Medtronic*, the Supreme Court addressed for the first time whether §360k preempted state-tort claims. More precisely, the specific question before the Court was whether the MDA expressly preempted state-tort claims involving a Class III device approved through the §510(k) process. The Supreme Court delivered a fractured, plurality opinion holding that none of plaintiffs' claims were preempted as there was no specific preemptive federal requirement with respect to devices approved through the §510(k) process. *Id.* at 501–02. The Court focused on the fact that the §510(k) process was not rigorous and emphasized equivalence as opposed to safety. *Id.* at 492–94. The Court clearly distinguished the §510(k) review process from the PMA process. *Id.* at 477–79, 492–94. Importantly, a majority of the Court did conclude that state-tort law claims could be "state requirements" under the MDA. *Id.* at 504–05, 509 (Justice O'Conner concurring in part and dissenting in part on behalf of four Justices, Justice Breyer concurring in part).

A majority of the circuit courts applying *Medtronic* have likewise concluded that some state-law claims may be preempted by the MDA. Additionally, a majority of the circuit courts applying *Medtronic* have held that, contrary the §510(k) process, the PMA-approval process *does* constitute a preemptive federal requirement under the MDA. For example, after *Medtronic*, the U.S. Courts of Appeal for the Third, Fifth, Sixth, Seventh, and Eighth Circuits have all held that at least some state-law claims were preempted when the device at issue received PMA-approval. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163 (3rd Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001). Some courts applying *Medtronic* have gone as far as to hold that state-law claims involving devices approved through the less vigorous IDE process were preempted. *See Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997).

In direct conflict with the majority of circuits, the Eleventh Circuit has held post-*Medtronic* that the PMA process did *not* constitute a preemptive federal requirement. *See Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

The FDA Speaks

In *Medtronic*, the Supreme Court stated that it gave substantial weight to the FDA's view of preemption under the MDA. 518 U.S. at 496. The Court noted that the FDA's view was particularly significant in a situation where preemption would be dependent on the extent to which the FDA had issued a preempting federal requirement. *Id.* In light of the split among the circuit courts noted above and the importance of the FDA's position, the U.S. Court of Appeals for the Third Circuit in *Horn v. Thoratec* specifically requested the FDA's view on the following question: "With respect to the Thoratec Heartmate, which was reviewed by the FDA, are state common law claims of design defect, labeling, strict liability, negligence, and failure to warn preempted by §360k(a) of the Medical Device Amendments to the Food, Drug and Cosmetic Act?" FDA Brief, *Horn v. Thoratec*, May 14, 2004, 2004 WL 1143720, at *1. The Thoratec Heartmate received PMA approval.

On May 14, 2004, the FDA submitted a letter-brief to the Third Circuit answering

the posed question in favor of preemption. The FDA took the following view:

> [Section 360k(a) of the MDA] does preempt these state law claims because they would impose a requirement different from, or in addition to, the requirements imposed by the FDA in granting premarket approval to the Thoratec HeartMate. The Government believes that this view is compelled in order to achieve Congress's important public health protection purposes, carried out through FDA's implementation of the FDCA.

Id. at * 1–2. In its brief, the FDA conceded that this view represented a change for the FDA. *Id.* at *3. In 1997, the FDA had previously taken the position that such claims were not preempted. *Id.* The FDA, however, emphasized that the change was needed in light of further analysis of legal and policy issues. *Id.* The FDA went on to state: "This change in views has not been taken lightly, and we assure the Court that the filing of this letter taking this position has been authorized by the Solicitor General." *Id.*

The Third Circuit in *Horn* subsequently held that plaintiffs' claims for defective design and failure to warn were preempted. *Horn*, 376 F.3d at 176. The Supreme Court's deference to the FDA's position in combination with the FDA's brief in *Horn* offer hope to manufacturers and defense counsel alike that the Eleventh Circuit's decision in *Goodlin* was an anomaly, and that at least some state-tort claims involving PMA-approved devices will be preempted.

A Recent Example

Within the last year, Judge Kathleen O'Malley, the judge presiding over the Sulzer hip and knee implant multidistrict litigation ("MDL"), held in *Moore v. Sulzer Orthopedics, Inc.*, that plaintiff's claims of strict liability and negligence were preempted under the MDA. *See* MDL Order, Case No. 1:02CV9116 (N.D. Ohio May 18, 2004).

In 2002, Sulzer entered into an expansive class-action settlement agreement with regard to artificial hip and knee implants subjected to a specific manufacturing process. *See generally*, *In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 268 F.Supp.2d 907 (N.D. Ohio 2003). Some plaintiffs, however, brought suits regarding products that were not subject to the settlement. It is in this context that plaintiff brought a products liability action stemming from his Natural Knee II implant. Plaintiff's implant was not subject to the nationwide settlement, but his claim was nonetheless transferred to the MDL Court. The Natural Knee II went through the rigorous PMA process and received PMA approval from the FDA.

Plaintiff alleged that his knee implant contained an improper lubricant. Relying on the Sixth Circuit precedent in *Kemp*, the MDL

Court concluded that the PMA approval created preemptive federal requirements and the state law claims asserted by plaintiff were state requirements for purposes of the MDA. MDL Order, at 8–11. The MDL Court then held that plaintiff could point to no facts to support a determination that Sulzer deviated from the PMA-approved manufacturing process, and as a result, plaintiff's claims amounted to requirements different from or in addition to the federal requirements. *Id.* at 16. Accordingly, defendant's motion for summary judgment was granted. *Id.*

There was one strategic issue of note in *Moore*. Plaintiff's claim was originally filed in Florida state court and was subsequently removed to the Florida federal court. It was then transferred to the MDL Court in the U.S. District Court for the Northern District of Ohio. The Northern District of Ohio sits in the Sixth Circuit while the Florida federal courts fall under the Eleventh Circuit's jurisdiction. The Sixth Circuit has favorable preemption law with respect to PMA-approved devices while—as discussed above—the Eleventh Circuit has unfavorable preemption law. Plaintiff argued that the Eleventh Circuit law should apply while the defendant pushed for the application of Sixth Circuit law. Based on existing authority, the MDL Court concluded that the transferee court should apply the federal law of the circuit in which it sits—here the Sixth Circuit. *Id.* at 14. The transfer of *Moore* to the MDL Court, therefore, was key to prevailing in the case.

Implied Preemption

While there is no express preemption provision in the regulations regarding prescription drugs, preemption of another variety—implied preemption—can be an effective weapon in the defense of drug product liability claims. Implied preemption, as stated above, occurs when there is an inferred conflict between a state law and a federal enactment. Specifically, in the drug and medical device context, implied preemption may be used to counter fraud-on-the-FDA claims, and under certain circumstances, failure to warn claims as well.

Buckman Co. v. Plaintiffs' Legal Committee

Buckman involved allegations that a manufacturer made fraudulent representations to the FDA in order to obtain approval of an orthopedic bone screw. 531 U.S. 341, 343 (2001). The U.S. Supreme Court was presented with the following question: does the FDCA, as amended by the MDA, preempt state law tort actions alleging "fraud-on-the-FDA" claims. *Id.* The Supreme Court answered this question in the affirmative, holding that plaintiffs' claims were impliedly preempted by the FDCA because allowing such claims would "inevitably conflict with the FDA's responsibility to police fraud consistent with the [FDA's] judgment and objectives." *Id.* at 350. The Court noted that:

> "[t]he conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law."

Id. at 348. Although *Buckman* involved a medical device, the Court's analysis is directly applicable to prescription drugs.

Only the United States—not a private litigant—is entitled to sue for noncompliance with the FDCA.

Plaintiffs in drug and medical device cases often claim that the manufacturer misled the FDA or violated FDA regulations. *Buckman*, however, makes it clear that only the United States—not a private litigant—is entitled to sue for noncompliance with the FDCA. *See id.* at 349 n.4. Federal enactments may not be a critical element of plaintiffs' claims. *Id.* at 353.

Moreover, even if plaintiffs do not bring a "fraud-on-the-FDA" claim *per se*, they will inevitably attempt to introduce such evidence to inflame the jury. Importantly, *Buckman* can be enlisted not only to preclude claims, but also to exclude evidence. Multiple courts have relied on *Buckman* to bar any evidence that a defendant misled the FDA. *See, e.g., Bouchard v. Am. Home Prods.*, 213 F.Supp.2d 802, 812 (N.D. Ohio 2002) ("Evidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA.").

Failure to Warn Claims

In *Motus v. Pfizer, Inc.*, another potential application of implied preemption emerged. In *Motus*, plaintiffs claimed that the defendant failed to warn that Zoloft could cause suicide. 358 F.3d 659, 660 (9th Cir. 2004). Yet, the FDA approved the Zoloft warning and even concluded that drugs like Zoloft did not pose a risk of suicide. *See* FDA Brief, *Motus v. Pfizer, Inc.*, Sept. 10, 2002, 2002 WL 32303084, at * 9. As a result, the defendant argued that including such a suicide warning would be false and misleading and would actually render the product misbranded under the Federal law. *Id.* at *13–14. The district court rejected the defendant's argument, but granted summary judgment on other grounds. *Id.* at *4. The case was appealed to the U.S. Court of Appeals for the Ninth Circuit.

Importantly, the FDA intervened on behalf of the drug manufacturer and submitted an *amicus* brief in the Ninth Circuit arguing that plaintiffs' failure to warn claims were impliedly preempted. *Id.* at *1. The FDA reiterated that it has considered the link between suicide and SSRI drugs like Zoloft as many as three times and concluded that there was no evidence to support a suicide warning. *Id.* at *13–14. The FDA further argued that including a warning without sufficient evidence would misbrand a drug—a result prohibited by the FDCA. *Id.* at *16. Moreover, the FDA stated that allowing such a failure to warn claim would hinder the FDA's objectives. *Id.* at *23. The FDA pointed out that including unwarranted warnings could be as much a problem as excluding proper warnings. "Under-utilization of a drug based on dissemination of scientifically unsubstantiated warnings, so as to deprive patients of beneficial, possibly lifesaving treatment, could well frustrate the purposes of federal regulation as much as over-utilization resulting from a failure to disclose a drug's scientifically demonstrable adverse effects." *Id.* This position was a shift for the FDA, which had stood against implied preemption until the Bush administration took office. *See* Gary

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Young, "FDA Strategy would preempt tort suits," *The National Law Journal*, Volume 26, No. 26, March 1, 2004, at p. 12.

The Ninth Circuit eventually affirmed the summary judgment while sidestepping the issue of preemption. *Motus*, 358 F.3d at 660–61. The FDA's position in *Motus*, however, offers great support for manufacturers to argue for implied preemption when the FDA requires one warning while plaintiffs are calling for another.

Practical Guidance

Think of Preemption Early

Drug and device manufacturers, and the counsel representing them, should think of preemption long before any product liability suit is filed. For example, preemption under the MDA requires specific "federal requirements." Accordingly, as early as the PMA or IDE application, a manufacturer could make a point of identifying design and warnings as "specific requirements." Moreover, in communicating with the FDA during the approval process, a manufacturer can characterize information or a change sought by the FDA as a "specific requirement." The correct terminology takes any ambiguity away if a court later has to determine if a specific federal requirement was ever imposed. In the prescription drug context, it is important to know if the FDA denied inclusion of any warnings. An early analysis of the FDA correspondence by counsel can answer this question.

Once a suit is filed—even before answering—counsel should determine if preemption is a possible defense. Analyze the complaint to identify any fraud-on-the-FDA claims or claims where violations of FDA regulations are a critical element. In the device context, counsel should know the law of the circuit where the case is pending as well as the nature of the approval for the device. Both of these issues are central in a preemption analysis.

Think of Transfer

As evidenced by the discussion of *Moore* above, getting a case to the right jurisdiction can be the difference between winning and losing a preemption motion. In federal court, the transferee court will usually apply the law of its own circuit when analyzing issues of federal law. *Menowitz v. Brown*, 991 F.2d 36, 40 (2d Cir. 1993) ("a transferee federal court should apply its interpretations of federal law, not the constructions of federal law of the transferor circuit"). This is true for transfers under both 28 U.S.C. §1404(a) and §1407. *See, e.g., In re Temporomandibular Joint Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) ("[w]hen analyzing questions of federal law, the [MDL] transferee court should apply the law of the circuit in which it is located"); *Hartline v. Sheet Metal Workers' Nat'l Pension Fund*, 286 F.3d 598, 599 (D.C. Cir. 2002) (addressing federal choice of law in §1404(a)).

If your case is in a forum with unfavorable preemption law, analyze the possibility of a transfer based upon the facts. While a transfer is not a possibility in all cases, it can make all the difference under the right circumstance.

Simplify Preemption

Courts may shy away from granting a motion for summary judgment based on preemption due to the complexities involved. Make an effort to simplify the concept and application of preemption in your case as much as possible. A simple, straightforward argument will increase the odds of the court granting the motion.

Conclusion

The FDA has increasingly supported federal preemption in the drug and medical device context, and this endorsement makes the preemption defense more viable than ever. Preemption can be complicated and the scope of its application can be easily overlooked. But for drug and medical-device manufacturers, it pays to know the law on preemption and to proactively include preemption considerations in both regulatory and litigation strategy. **FD**

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on the plaintiff. Every effort should be made to ignore objections of plaintiff's counsel, lest the plaintiff believe that you will change your question every time her counsel objects. Although you may want to cure the objection, if possible and necessary, it is usually advisable to simply tell the plaintiff that she can go ahead and answer the question unless her counsel directs her not to answer. There are only three bases upon which counsel can instruct his witness not to answer: (1) the matter is privileged; (2) a previous court order provides counsel with a basis upon which to direct the witness not to answer; or (3) the question is designed to embarrass or harass the witness. *See* Fed. R. Civ. P. 30(d)(1) ("A person may instruct a deponent not to answer only when necessary to preserve a privilege; to enforce a limitation directed by the court; or to present a motion under Rule 30(d)(4) that the examination is being conducted in bad faith to unreasonably annoy, embarrass or oppress the witness").

When a plaintiff's counsel directs her client not to answer a question, defense counsel would be well advised to get the plaintiff to state on the record that she is refusing to answer the question, which could be used in a future motion to compel. Then, remind plaintiff's counsel that the parties reserved all objections except as to form at the beginning of the deposition (if that is the case). Further, ask plaintiff's counsel for the specific basis for directing her client not to answer and be sure that counsel specifies one of the bases listed herein. Finally, it is often prudent to ask the same objected-to question at the very end of the deposition when there may be less resistance from plaintiff's counsel (who by then may be fatigued by her own obstructionist conduct!). Although you don't want to fight with opposing counsel over her objections, this does not mean that you should give in to opposing counsel's suggestion on how or what to ask. Remember, you are in control of the deposition and your impatience or frustration with plaintiff's counsel should not steer you in a different direction.

In addition to dealing with objections, every defense counsel should be prepared to deal with the plaintiff's counsel who constantly coaches his witness. In this scenario, defense counsel should first make a record that counsel is continually testifying for her client in violation of the rules. *See* Fed. R. Civ. P. 30(d)(1) ("Any objection during a deposition must be stated