Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals

Mark C. Levy
Gregory J. Wartman
Amicus Curiae Efforts to Reform Product Liability at the Food and Drug Administration: FDA’s Influence on Federal Preemption of Class III Medical Devices and Pharmaceuticals

Mark C. Levy *
Gregory J. Wartman **

I. Introduction

With all of the federal and state legislative proposals aimed at tort reform, the Food and Drug Administration’s (FDA’s) efforts to change existing tort law might go unnoticed. FDA has used amicus curiae briefs in pharmaceutical and medical device litigation to assist courts in decision-making and, in turn, has fueled a trend in favor of preemption of common law claims against manufacturers. Although FDA is an independent governmental body, the recent use of amicus briefs to reform product liability can be attributed, to some extent, to politics. Efforts to provide drug and device manufacturers with greater preemption protection began when President George W. Bush took office in 2000. Because preemption is a matter of broad public interest, amicus briefs have been permitted as a non-legislative attempt to reform existing law.

As this article will explain, FDA’s amicus briefs have been most successful in the medical device context as evidenced by several recent court of appeals decisions. These cases have focused on the preemptive effects of the Medical Device Amendments of 1976 (MDA), 21 U.S.C. §§ 360 et seq., on state common law tort claims. FDA also has weighed in on numerous prescription drug cases, but with mixed results. Those latter efforts represent much more of an uphill battle for FDA.

FDA’s amicus curiae briefs not only have had important reform effects on the state common law tort system through their judicial influence, but they also have important implications for medical device and pharmaceutical drug manufacturers. The pervasiveness of FDA’s influence in medical device litigation has created business incentives for medical device manufacturers to pursue more stringent FDA approval processes in the hopes of gaining tort liability protection through compliance with these processes. Though the effects of amicus curiae briefs in pharmaceutical drug litigation have not been as well received, the briefs in this area have provided drug manufacturers with at least a framework to argue against liability for some common law tort claims. Overall, FDA’s amicus curiae briefs have afforded manufacturers in both fields some protection from liability—only time will tell whether this trend will continue.

II. An Explanation of Preemption

A. Preemption Generally

The preemption of state law is a particularly complex area that arises under Article VI of the U.S. Constitution, the “Supremacy Clause.” The Supremacy Clause states, “This

---

* Mr. Levy is a Partner with the law firm of Saul Ewing LLP, Philadelphia, PA. He is Chair of the firm’s Litigation and Risk Management Life Sciences Industry Service Team.
** Mr. Wartman is an Associate with the law firm of Saul Ewing LLP, Philadelphia, PA. He is a member of the firm’s Litigation and Risk Management Life Sciences Industry Service Team.
Constitution, and the Laws of the United States which shall be made in Pursuance thereof ... shall be the supreme Law of the Land ... ." Defendants use this clause as a basis to argue that if Congress has enacted legislation within a particular field, then that legislation is supreme to any state statute or common law in that field and, thus, any state remedy is preempted by the federal action. Whether federal law displaces state law requires an analysis of congressional intent. Because the "assumption [is] 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," relevant statutory schemes should be analyzed against an underlying presumption against preemption.

B. Express Preemption

Preemption may be either express or implied. Express preemption exists when Congress' intent is "explicitly stated in the statute’s language or implicitly contained in its structure and purpose." When Congress legislates according to one of its enumerated powers, Congress may include as part of the statutory scheme a preemption clause or clauses. This clause, read in conjunction with the Supremacy Clause, would expressly preempt all state laws within the scope of the preemption provision. If no express preemption clause exists, or if the clause is ambiguous in scope, determining Congressional intent poses a problem for courts.

C. Implied Preemption

By definition, implied preemption is preemption that occurs not when Congress expressly supersedes state law but rather when Congress' intent to supersede additional or different state law can be inferred. The Supreme Court has held that four factors must be analyzed to find implied preemption. The four relevant factors are: 1) the aim and intent of Congress as revealed by the statute itself and its legislative history; 2) the pervasiveness of the federal regulatory scheme as authorized by the legislation and as carried out by the administrative agency; 3) the nature of the subject matter regulated and whether it is one that demands exclusive federal regulation in order to achieve uniformity vital to national interests; and 4) whether state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Implied preemption is divided into conflict of laws preemption and occupation of field preemption.

1. Conflict of Laws Preemption

Conflict of laws or "conflict preemption" makes it physically impossible to comply with both state and federal law. Also called partial or defensive preemption, conflict

---

1 U.S. CONST., art. VI, cl. 2.
3 Id. at 107-91.
6 MOORE, supra note 2, ¶ 107.14[4][b], at 107-91.
7 Id.
8 Id.
10 MOORE, supra note 2, ¶ 107.14[4][b], at 107-91.
11 Id.
12 See Cipollone, 505 U.S. at 516.
preemption provides a defense to state claims and does not independently create federal question jurisdiction. In cases of conflict preemption, the Supremacy Clause gives precedence to federal law regardless of whether Congress has expressly preempted the law, or whether Congress has included the law in the scope of its preemptive power.

2. Occupation of Field Preemption

If federal law so thoroughly occupies a legislative field “as to make reasonable the inference that Congress left no room for the States to supplement it,” state law is considered preempted through occupation of the field. By legislating within a given field, Congress’ intent to occupy the entire field preempts any attempt to claim a remedy outside the congressional scheme, even if no direct conflict with state law exists. Also referred to as super or complete preemption, preemption through occupation of a field is rare.

D. Scope of Preemption

By determining the preemptive scope of federal laws, courts help define the proper balance of legislative powers between Congress and the states. Often the intent of Congress to preempt is clear, whether through an express preemption provision or a form of implied preemption. Even when Congress’ intent to preempt is evident, however, the scope of that preemption may be ambiguous. Courts have considered statutory language, legislative intent, policy implications, and a host of other factors when faced with the problem of defining the scope of preemption.

III. AMICUS EFFORTS IN FAVOR OF MDA PREEMPTION

FDA has targeted its amicus curiae efforts at product liability reform in the medical device industry. Through amicus curiae briefs, FDA has urged courts to rule that the MDA preempts state common law tort claims against medical device manufacturers. As will be discussed, courts have given FDA significant deference, thus making FDA’s efforts largely successful.

A. The Preemption Scheme of the MDA

The Food, Drug, and Cosmetic Act (FDCA), and its subsequent amendments provide guidelines for FDA approval of medical devices. Enacted by Congress in 1976, the MDA created a federal program to enhance “the safety and effectiveness of medical devices intended for human use.” The MDA creates three distinct classes of medical devices with each class representing a progressively higher risk of injury to the user or recipient. Class I devices pose little or no risk to consumers and are subject to only

13 Moore, supra note 2, ¶ 107.14[4][b], at 107-92.
14 Cipollone, 505 U.S. at 516 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. at 230, 67 S. Ct. at 1152).
15 Moore, supra note 2, ¶ 104.14[4][b], at 107-93.
16 Id.
minimal regulation.\textsuperscript{20} Class II devices are potentially more harmful than Class I devices and are subject to federal performance regulations.\textsuperscript{21} Presenting a “potential unreasonable risk of illness or injury,” Class III devices are the most strictly regulated under this scheme and include devices such as pacemakers, replacement heart valves, silicone gel-filled breast implants, and implanted cerebella stimulators.\textsuperscript{22}

FDA approval is required before a manufacturer can market a Class III medical device. Of the three approval routes that exist under the MDA, the “premarket approval” or “PMA” process provides the primary method for obtaining approval. The PMA process requires a manufacturer of a Class III device to file a PMA application in which detailed and specific information about the design, labeling, manufacturing, components, and purpose of the device, as well as data obtained through studies and clinical trials that demonstrate the safety and efficacy of the device is provided to FDA.\textsuperscript{23} As the Supreme Court has noted, the PMA process is a “rigorous” process during which FDA spends an average of 1,200 hours reviewing each submission.\textsuperscript{24}

Manufacturers of Class III devices who determine the PMA process is too time consuming and costly may utilize two alternative, expedient, forms of approval. The first is the investigational device exemption (IDE), which applies to Class III medical devices intended for investigational use.\textsuperscript{25} The IDE allows devices representing innovative technology to be used in human trials.\textsuperscript{26} The second option, the 510(k) process, allows a manufacturer to market and sell a device that is “substantially equivalent” to a device in the commercial market prior to 1976.\textsuperscript{27} The 510(k), or substantial equivalence process, is much less rigorous than the PMA process.\textsuperscript{28} A device that is submitted under either the IDE or substantial equivalence process is said to be “cleared” as opposed to “approved” by the agency under a PMA.

Preemption in the medical device field is based on 21 U.S.C. § 360k(a) of the MDA, which provides:

\begin{quote}
[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. [W]hich is different from, or in addition to, any requirement applicable under this chapter to the device, and

2. [W]hich 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.
\end{quote}

FDA also has promulgated an implementing regulation, which states:

State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements

\begin{itemize}
\item\textsuperscript{20} Lohr, 518 U.S. at 477 (citing 21 U.S.C. § 360c(a)(1)(A)).
\item\textsuperscript{21} Id. (citing 21 U.S.C. § 360c(a)(1)(B)).
\item\textsuperscript{22} Id. (quoting 21 U.S.C. § 360c(a)(1)(C)); see also 21 C.F.R § 870.3610 (1995).
\item\textsuperscript{23} 21 U.S.C. § 360e(c)(2)(A).
\item\textsuperscript{24} Lohr, 518 U.S. at 477.
\item\textsuperscript{25} 21 U.S.C. § 360j(g).
\item\textsuperscript{26} Kemp v. Medtronic, Inc., 231 F.3d 216, 222 (6th Cir. 2000).
\item\textsuperscript{27} 21 U.S.C. § 360(j).
\item\textsuperscript{28} See Lohr, 518 U.S. at 479 (explaining time required for section 510(k) process (average of only 20 hours) and full PMA process).\
\end{itemize}
Critical issues concerning the interpretation of the express preemption provision in the MDA arise in determining 1) whether a state common law jury verdict constitutes a state “requirement”; and 2) whether FDA’s process for approving new devices establishes a device-specific federal “requirement” that would trigger the preemption of later common law claims for the same device. Although it is evident that Congress intended to expressly preempt state law tort actions in certain circumstances, the scope of the preemption has posed a problem of interpretation.

In 1996, the Supreme Court’s plurality opinion in Medtronic, Inc. v. Lohr discussed the preemptive scope of the express preemption provision, section 360k(a). At issue in Lohr was a Class III pacemaker device approved through FDA’s “substantial equivalence” process. The Lohr Court held that common law tort claims against the manufacturer of a pacemaker approved pursuant to the abbreviated 510(k) approval process were not preempted by the MDA’s express preemption provision. According to the Court, the 510(k) approval process was not a specific federal requirement. Under the guidance of this fractured opinion, federal and state court judges have encountered difficulty in applying the Court’s analysis to establish the scope of the preemption provision for other FDA approval processes. Not surprisingly, courts have significantly differed in their interpretations of the scope of the MDA preemption provision.

B. Legal Precedent Addressing Preemption Under the MDA

Historically, FDA has endorsed a strong presumption against preemption under the MDA. For a number of years, the government assumed the position that 21 U.S.C § 360k(a) did not preempt state tort claims against FDA-approved device manufacturers. During the Clinton Administration, FDA’s Chief Counsel Margaret Jane Porter repeatedly endorsed this position, which supported the state tort system as an independent operating layer of consumer protection.

---

[29] 21 C.F.R. § 808.1(d).
[30] Lohr, 518 U.S. 470 (holding that FDA’s 510(k) substantial equivalence process does not trigger preemption of state common claims under the MDA’s preemption provision).
[31] Id. at 478-79.
[32] Id. at 490.
[33] The preemption provision at issue was 21 U.S.C. § 360k(a) of the MDA.
[34] See, e.g., Brooks v. Howmedica, Inc., 273 F.3d 785, 795-96 (8th Cir. 2001) (en banc), cert. denied, 535 U.S. 1056 (2002) (finding PMA process imposes specific requirements on medical device manufacturers and common law claims against manufacturers are preempted to extent that state claims impose specific requirements that differ from federal requirements imposed by PMA process); Martin v. Medtronic, Inc., 254 F.3d 573, 584 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002) (holding that PMA process creates device-specific requirements and preempts state law claims against manufacturer of medical device to extent that state claims present substantive requirements contrary to federal requirements); Kemp v. Medtronic, Inc., 231 F.3d 216, 227 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001) (finding PMA process creates specific requirements sufficient to trigger preemption provision of MDA); Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997), cert. denied, 523 U.S. 1020 (1998) (holding that PMA process can constitute specific requirements that may give rise to preemption of state tort claims). But see Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1375-80 (11th Cir. 1999) (finding that PMA process does not impose specific requirements on medical device manufacturers and, therefore, that the MDA does not preempt state law tort claims based on defects in Class III devices); Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997) (holding failure-to-warn claim was not subject to preemption under the MDA).
This view of the state common law tort system as complementary to the regulatory function of FDA appeared in the agency’s amicus curiae brief in *Smith Industrial Systems, Inc. v. Kernats* in which FDA advocated against preemption of the plaintiff’s claims.\(^{37}\) *Kernats* involved common law tort claims against the manufacturer of a PMA process-approved catheter that had inflicted prenatal injuries.\(^{38}\) FDA’s amicus curiae brief directly argued that the PMA process neither conflicted with state law nor frustrated the purpose of Congress.\(^{39}\) Arguing that section 360k(a) did not expressly preempt the tort claims, FDA stated, “[A]llowing respondents’ suits to proceed will not erode the federal policy expressed in the MDA.”\(^{40}\) Considering the PMA and IDE approval processes as only a “minimum standard,” FDA interpreted section 360k(a) as not creating any specific federal requirement necessary for preemption.\(^{41}\)

Under the leadership of the Bush Administration’s former FDA Chief Counsel Daniel Troy, FDA made a 180-degree change in position—rejecting the minimum standards approach presented in its *Kernats amicus curiae* brief. The *amicus curiae* briefs submitted by FDA in recent medical device and pharmaceutical cases take an aggressive stance that sides with the medical device and pharmaceutical industry.\(^{42}\) As there has been no intervening event, statutory or legislative change, new FDA regulation, or decision by the Supreme Court interpreting the MDA to prompt the change in FDA’s opinion, the agency’s *amicus curiae* efforts may be a reaction to increased judicial recognition of the deference FDA deserves regarding its own regulations. Although the Supreme Court held in *Lohr* that the section 510(k) substantial equivalence approval process did not preempt state tort actions, it generally recognized the need for preemption of state common law tort claims to preserve FDA’s authority.\(^{43}\)

FDA’s reversal in position is reflected by preemption arguments set forth in recent *amicus curiae* briefs—most notably its *amicus curiae* letter brief in *Horn v. Thoratech, Inc.*\(^{44}\) At issue in *Horn* was a PMA-approved heart pump implant that allegedly caused the death of a patient when a suture wore out.\(^{45}\) In response to the Third Circuit Court of Appeals’ request for FDA’s views on the preemption of design defect, strict liability, negligence, and failure-to-warn state tort claims, FDA rejected its previous minimum standards approach and instead asserted that FDA approval “sets a ceiling as well as a floor.”\(^{46}\) In *Horn*, FDA maintained that section 360k(a) preempted state common law claims because they would impose a requirement “different from” or “in addition to” federal requirements imposed by FDA regulations.\(^{47}\) Insisting the PMA process created specific federal requirements, this brief represented a drastic departure from the view presented in *Kernats*.\(^{48}\)

---

\(^{37}\) Brief of Amici Curiae FDA, at 13, *Kernats* (No. 96-1405).


\(^{39}\) Brief of Amici Curiae FDA, at 13-14, *Kernats* (No. 96-1405).

\(^{40}\) Id. at 14.

\(^{41}\) Id.


\(^{43}\) See *Lohr*, 518 U.S. 470 (holding that the section 510(k) substantial equivalence approval process did not preempt state tort actions, but also noting that similar claims would be preempted against products that had undergone the rigorous FDA PMA process); see also *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (holding that fraud on FDA claims was impliedly preempted by federal authority of FDA).

\(^{44}\) Brief of Amici Curiae FDA, *Horn v. Thoratech*, No. 02-4597 (3d Cir. 2004).

\(^{45}\) *Horn*, 376 F.3d at 164.

\(^{46}\) Brief of Amici Curiae FDA, at 29, *Horn* (No. 02-4597).

\(^{47}\) Id. at 1.

\(^{48}\) Id. at 1, 16.
In finding the claims in *Horn* preempted, the Third Circuit gave substantial weight to the analysis in the *amicus curiae* brief.\(^{49}\) Although the dissent concluded that FDA’s brief was entitled to “near indifference” because it represented a departure from its prior position, the majority depended heavily on FDA’s view, which focused on the thoroughness and safety-oriented function of the PMA process.\(^{50}\) The court’s two-pronged analysis followed FDA’s well-reasoned arguments to establish that both a federal and state requirement existed. Agreeing with the *amicus curiae* arguments, the court concluded that FDA “imposes federal requirements based on the highly detailed and prescriptive nature of the PMA process,”\(^{51}\) and that a state law judgment in favor of *Horn* “would necessarily rest upon an implicit [state] requirement that this device be designed, manufactured or marketed in a way that differs from the way approved by FDA.”\(^{52}\)

To find that federal law preempted the claims in *Horn*, the court had to distinguish the Supreme Court’s holding in *Lohr*. First, the court distinguished *Lohr* on the basis that the federal requirement of the PMA process in *Horn* was of greater specificity than the 510(k) substantial equivalence process at issue in *Lohr*.\(^{53}\) Second, the Third Circuit addressed Justice Breyer’s concurring opinion statement in *Lohr* that “it is apparent that few, if any, common-law duties have been preempted” by the MDA’s express preemption provision.\(^{54}\) FDA’s *amicus curiae* arguments had a strongly persuasive effect in creating a background concern of public safety against which to diminish the importance of the *Lohr* Court’s statement. Quoting FDA’s statement that “[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices,” the court noted that “individualized redetermination of the benefits and risks of a product” could harm public health by “resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments.”\(^{55}\) Overall, FDA’s persuasive policy argument to protect public health had a substantial influence on the *Horn* court’s capacity to distinguish *Lohr*.

**C. Implications of FDA’s Amicus Curiae Brief and the Horn Decision**

Following *Horn*, three other courts also have used the same rationale to find Class III medical device claims preempted. As a critical influence on the *Horn* court’s analysis, the effects of FDA’s *amicus curiae* brief can be seen in these opinions. Two circuits did oppose the rationale of *Horn* and adopted the view that the PMA process does not preempt state claims, but both of those cases were decided before *Horn* was announced.\(^{56}\) Several cases decided after *Horn*, however, indicate the preemptive trend that has evolved from FDA’s influence in *Horn*. These cases are discussed below.

1. **McMullen v. Medtronic, Inc.**

In *McMullen v. Medtronic, Inc.*, decided in August 2005, the Seventh Circuit Court of Appeals ruled that a post-sale failure-to-warn claim against a Class III device manufac-

---

\(^{49}\) *Horn*, 376 F.3d at 167. FDA’s *amicus curiae* brief posed that the process “submitted under Section 510(k) is thus entirely different from a PMA, which must include data sufficient to demonstrate to the FDA that the device is safe and effective.” *Id.* (quoting Brief of Amici Curiae FDA, at 25, *Horn* (No. 02-4597)).

\(^{50}\) *Id.* at 170-71.

\(^{51}\) *Id.* at 171.

\(^{52}\) *Id.* at 177-78.

\(^{53}\) *Id.* at 169-73.

\(^{54}\) *Id.* at 174-78.

\(^{55}\) *Id.* at 178.

\(^{56}\) See *Oja*, 111 F.3d 782; see also *Goodlin*, 167 F.3d 1367.
turer was expressly preempted by the MDA.\textsuperscript{57} At issue in \textit{McMullen} was “Activa,” a medical device implanted in the brain to relieve the symptoms of Parkinson’s Disease.\textsuperscript{58} FDA required Medtronic to generally warn physicians of certain risks associated with two procedures—electrocautery and diathermy—in patients using the device, which Medtronic did. The plaintiff was implanted with the device in 2000.\textsuperscript{59}

In January 2001, Medtronic learned that a recipient of the device was injured after being treated with diathermy following oral surgery. Medtronic investigated the incident and, in May 2001, sent letters to doctors and patients who had already received the device warning them of this potential risk from diathermy. Pursuant to its continuing FDA obligations, Medtronic also submitted a PMA supplement that sought approval of the device with a new warning.

In March 2001, not having been warned of the specific dangers of undergoing diathermy or electrocautery treatments, the patient in \textit{McMullen} underwent such treatments during a routine dental procedure and allegedly suffered severe brain damage, permanent disfigurement, and disabling injuries.\textsuperscript{60} The patient sued, alleging that Medtronic breached its post-sale duty to warn of dangers arising from those procedures. Medtronic moved for summary judgment on the grounds that this state law claim was preempted by the MDA. The district court agreed and awarded Medtronic summary judgment on the plaintiff’s failure-to-warn claim.\textsuperscript{61}

The Court of Appeals for the Seventh Circuit recently affirmed.\textsuperscript{62} The court’s rationale for preemption under section 360k paralleled that presented in \textit{Horn}.\textsuperscript{63} The \textit{McMullen} court reasoned that both the PMA process and post-sale requirements imposed by FDA constitute “specific federal requirements.”\textsuperscript{64} Because a post-sale failure-to-warn claim would be premised on the fact that Medtronic had additional state law duties beyond the PMA process and the PMA supplement process—with which Activa complied—the claim was preempted.\textsuperscript{65}

2. \textit{Cupek v. Medtronic, Inc.}

In 2005, the Sixth Circuit Court of Appeals followed the \textit{Horn} and FDA \textit{amicus curiae} brief reasoning and preempted common law post-sale failure-to-warn and post-sale failure-to-recall claims.\textsuperscript{66} The plaintiffs in \textit{Cupek v. Medtronic, Inc.} claimed that the manufacturer was aware that defects existed in already-purchased pacemaker leads, which had been approved pursuant to the PMA and PMA supplement process.\textsuperscript{67} Noting that FDA had the authority to determine if a recall was necessary,\textsuperscript{68} and that FDA could require device manufacturers to report adverse device events,\textsuperscript{69} the court determined that any common law failure-to-warn or failure-to-recall claims would impose a state requirement “different from” or “in addition to” the federal PMA application re-

\textsuperscript{57} McMullen v. Medtronic, Inc., 2005 WL 2043827 (7th Cir. Aug. 26, 2005).
\textsuperscript{58} Id. at ’2.
\textsuperscript{59} Id. at ’1-2.
\textsuperscript{60} Id. at *2.
\textsuperscript{62} McMullen, 2005 WL 2043827, at ’7.
\textsuperscript{63} See id. at *5-6.
\textsuperscript{64} Id. at ’5.
\textsuperscript{65} Id. at ’6.
\textsuperscript{66} Cupek v. Medtronic, Inc., 405 F.3d 421, 423 (6th Cir. 2005).
\textsuperscript{67} Id. at 422-23.
\textsuperscript{68} 21 C.F.R. § 810.10.
\textsuperscript{69} Id. § 803.50.
quirements. Accordingly, the Sixth Circuit found no error in denying plaintiffs leave to amend their complaint, holding that the proposed amendments were futile because the claims were preempted.


In *Baker v. St. Jude Medical, S.C., Inc.*, the Texas Court of Appeals ruled that claims of negligence, product liability, and breach of warranty were preempted under the *Horn* court’s preemption theory. The court’s determination was based on citation to *Horn* and other federal cases that agree with the reading of the *Lohr* plurality as indicating that a state law tort claim can be a state requirement and can be expressly preempted by section 360k(a). Refusing to distinguish a PMA-approved device and a PMA-approved device that also has a PMA supplement, the court reasoned similar to *Horn* that FDA’s imposition of specific conditions, labeling, and precise manufacturing standards through the PMA approval and supplement processes imposed specific federal requirements. Because state-imposed requirements would nullify FDA’s approval through the PMA approval and supplement processes, the court held the plaintiff’s claims were preempted.


In *Morton v. Centerpulse Orthopedics, Inc.*, the U.S. District Court for the Eastern District of California joined the majority of courts to rule that PMA approval of a medical device “results in preemption of state common law claims to the extent those claims seek to impose requirements that are different or in addition to those required by federal law.” The court, therefore, granted summary judgment against the majority of the plaintiffs’ claims, but refused to grant summary judgment on the plaintiffs’ negligence claim because the defendant manufacturer did not set forth specific facts showing that it “complied with the FDA-approved design.”

5. Cupek Petition for Certiorari

On June 29, 2005, the *Cupek* plaintiffs filed a petition for certiorari with the U.S. Supreme Court, asking the Court to resolve the split between the opinions of the Third Circuit (*Horn*) and Sixth Circuit (*Cupek*) Courts of Appeals, on the one hand, and the Tenth and Eleventh Circuit Courts of Appeals, on the other hand. Specifically, the petitioners asked the Court to hear their appeal of the Sixth Circuit’s decision and to rule

---

70 *Cupek*, 405 F.3d at 424.
71 See id.
73 Id. at ’4-5.
74 Id. at ’6-7.
75 Id. at ’8-9.
77 Id. at ’4.
78 Although a majority of courts have found federal preemption with respect to MDA devices, the Tenth and Eleventh Circuits have held that the MDA does not have a preemptive effect on state common law tort claims. In an early post-*Lohr* but pre-*Horn* decision, the Tenth Circuit in *Oja v. Howmedica, Inc.* held a common law failure-to-warn claim was not subject to preemption under the MDA. The Eleventh Circuit also held, in *Goodlin v. Medtronic, Inc.*, that simple approval of a PMA application imposes no federal “requirements.” Even though neither circuit has reversed its decision as of yet, no case has affirmed the *Oja* or *Goodlin* courts’ rationale post-*Horn* either.
that the PMA approval process does not preempt additional or different state law tort claims. This case was docketed as M.R. Knisley et al. v. Medtronic, Inc., 05-22.

On September 6, 2005, Medtronic filed a brief in opposition to the petitioners’ petition for certiorari. Medtronic urged the Court to deny the petition contending that “a clear and growing consensus has emerged” that premarket approval of a medical device preempts additional or different state law claims “arising from the design, manufacture, distribution, and labeling of such a device.” Medtronic further argued that, in the last four years, the Supreme Court had denied two “virtually identical” petitions for certiorari in Martin v. Medtronic, Inc. and Kemp v. Medtronic, Inc. 79

Medtronic also relied heavily on FDA’s amicus curiae brief in Horn for support that preemption in this case is well established. 80 Medtronic argued that “there is no need for this Court to grant review in this case” because FDA provided “clear guidance” of its position in Horn. 81 The device manufacturer posited that “FDA’s reasoned analysis is entitled to substantial weight as the agency’s fair and considered judgment on the matter in question.” 82 As further evidence of the influence of FDA’s amicus brief, Medtronic contended that “[t]here is simply no reason to believe that those few courts that misinterpreted Lohr soon after it was decided will not now take heed of the FDA’s amicus curiae brief in Horn.”

On October 11, 2005, the Supreme Court denied the petition for certiorari. While this denial cannot be interpreted as approval of the Sixth Circuit’s ruling in favor of preemption, it does represent an important victory for medical device manufacturers as it leaves undisturbed the court of appeals’ rulings in their favor. 85

IV. FDA INVOLVEMENT IN PHARMACEUTICAL LITIGATION

FDA’s amicus curiae reform efforts have not been limited to the medical device context, but instead have extended to the liability of pharmaceutical manufacturers as

---

79 Brief for Respondent in Opposition at 1, Knisley v. Medtronic, Inc., No. 05-22 (U.S. Sept. 2005).
80 Id. at 1.
81 Id.
82 Id. at 23.
83 Id.
84 Id.
85 Trial Magazine, an American Trial Lawyers Association publication, recently published an article in which the author signaled a sea change in federal preemption jurisprudence. Leslie A. Bruecker, A Turning of the Tide for Preemption, Trial Mag., Nov. 2005, at 28. This article encourages the plaintiffs’ bar to argue that the Supreme Court’s recent decision in Bates v. Dow Agrosciences LLC can be read to defeat preemption challenges in all products liability cases. We respectfully disagree with this position and believe that the Bates decision should be limited to its facts.

In Bates, the Court ruled that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) did not preempt a series of state tort claims brought against a pesticide manufacturer by a group of peanut farmers. The Court reasoned that the state tort claims did not impose “requirements” that were different from or in addition to FIFRA’s misbranding provisions. 125 S. Ct. 1788, 1800 (2005). In issuing this ruling, the Court rejected the Environmental Protection Agency’s (EPA’s) interpretation of FIFRA and ruled that where there are two equally plausible interpretations of a statute, the Court has a “duty to accept the reading that disfavors pre-emption.” Id. at 1801.

If arguing in favor of federal preemption post-Horn, expect your opponent to argue that FDA’s position with respect to the PMA process should similarly be rejected and a presumption be imposed against preemption. FIFRA is easily distinguished, however, from the PMA process at issue in Horn and the PMA supplement process at issue in Baker. As the Court stated, FIFRA is a “relatively decentralized scheme that preserves a broad role for state regulation.” See id. at 1802. Indeed, EPA has taken a very hands off approach to pesticide manufacturers and, therefore, had little support for the argument that FIFRA should preempt state tort claims. The PMA process, on the other hand, involves a comprehensive FDA review process that provides a strong basis for federal preemption. FDA also has broad enforcement powers diminishing the need for additional regulation. Accordingly, we respectfully conclude that Bates should be limited to its facts and should not have the broad-sweeping effect envisioned by the plaintiffs’ bar.
well. Similar to Class III medical device preemption, FDA has been using *amicus curiae* briefs to press courts to preempt claims involving prescription drugs. This illustrates the extent of FDA’s efforts to reinterpret its own regulations and reform product liability without formal rulemaking. Despite these efforts, the judicial influence and reform effects have not been nearly as far reaching on the tort system for pharmaceutical companies as they have been for Class III medical device manufacturers.

FDA actions in prescription drug litigation are especially aggressive because the sections of the FDCA applicable to prescription drugs do not contain a preemption provision. As a medical device regulation, the MDA contains a very specific express preemption provision. 86 Though the scope may be ambiguous, the provision declares a clear intent to preempt some forms of claims. In contrast, the sections of the FDCA applicable to prescription drugs contain no such provision or expression of intent. Current FDA regulations still require a manufacturer to submit a labeling change to FDA, but permit a manufacturer to “add or strengthen a contraindication, warning precaution, or adverse reaction” without prior approval by FDA.87

Although courts have endorsed FDA regulations regarding medical devices as a floor as well as a ceiling,88 pharmaceutical drug regulations appear to align with more of a minimum standards approach. The minimum standards approach is embodied in current FDA statutes and regulations and their court interpretations. Governing pharmaceutical drug labeling, 21 U.S.C. § 352(f) requires a manufacturer to provide “adequate warnings.” The term “adequate” may imply a minimum standard, as an over-inclusive warning cannot be considered inadequate.89 Most courts have agreed with the minimum standards interpretation of the regulations, stating, “FDA regulations are generally minimum standards of conduct[,]”90 and “[a]n FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.”91 Explaining the need for preemption of pharmaceutical drug claims, recent FDA *amicus curiae* briefs have argued against this interpretation of the relevant regulations.92

In *Motus v. Pfizer*, FDA submitted an *amicus curiae* brief to support Pfizer’s argument that the plaintiff’s failure-to-warn claim should be preempted.93 The plaintiff in *Motus* alleged that the Zoloft warning inadequately indicated the relationship between Zoloft and suicide.94 The *amicus curiae* brief presented two alternative arguments to support preemption.95 First, under the theory of conflict preemption, FDA argued Pfizer would not be able to comply with both state and federal laws because they conflicted.96 FDA argued that Pfizer could not have strengthened the Zoloft warning because three different times the agency had considered and rejected claims that Zoloft and other similar antidepressant drugs cause suicide.97 Because FDA would have disapproved of a warn-

---

87 21 C.F.R. § 314.70(c)(6)(iii)(A).
88 *Horn*, 376 F.3d at 186.
90 *Hill v. Searle Labs., Inc.*, 884 F.2d 1064, 1068 (8th Cir. 1989).
91 *Wells v. Ortho Pharm. Corp.*, 788 F.2d 741, 746 (11th Cir. 1986).
92 *See Brief of Amici Curiae FDA, Motus v. Pfizer, Inc., Nos. 02-55372 & 02-55498 (9th Cir. 2002); Brief of Amici Curiae FDA, Dowhal v. SmithKline Beecham Consumer Health Care, LP, No. S109306 (Cal. 2003); Brief of Amici Curiae FDA, In re Paxil Litig., No. 01-07937 (C.D. Cal.).
93 *See Brief of Amici Curiae FDA, Motus v. Pfizer, Inc. Nos. 02-55372 & 02-55498 (9th Cir. 2002).
95 *See Brief of Amici Curiae FDA, at 15-23, Motus (Nos. 02-55372 & 02-55498).
96 *Id.*
97 *Id.* at 13.
ing linking Zoloft and suicide, the warning could not have been strengthened without violating the FDCA and FDA regulations.

The *Motus amicus curiae* brief also presented a second, much broader argument for preemption. Because the FDCA seeks to ensure a drug’s optimal use by requiring that manufacturers disseminate only truthful information, imposing liability on the basis of a failure-to-warn claim would “prevent the accomplishment and execution of the full purposes and objectives of Congress.”98 Basing the argument on FDA’s power to decide which warnings are scientifically substantiated, the brief seeks to preserve FDA authority over drug regulation. Because this argument does not depend on FDA having made any prior determination as to a specific warning, the implications of preemption on these grounds are much broader.

Even though the court in *Motus* refused to find preemption of the failure-to-warn claim, two pharmaceutical cases post-*Horn* have relied on the *amicus curiae* brief in *Motus* to find preemption of failure-to-warn claims. Both *Needleman v. Pfizer Inc.* and *Dusek v. Pfizer Inc.*, involved plaintiffs who committed suicide while under the influence of the prescription drug Zoloft.99 In both instances, plaintiff’s failure-to-warn claims sought a stronger warning that would specifically identify a link between Zoloft and suicide. In *Needleman*, the court relied on the *Motus amicus curiae* brief’s argument that any relationship between Zoloft and suicide would be deemed “false and misleading,” and would preempt the state warning claim because it was in conflict with the FDCA.100 Noting the deference given to the *Motus amicus curiae* brief, the court in *Dusek* also found the plaintiff’s failure-to-warn claim preempted under the same conflict preemption argument presented in FDA's brief.101

The majority of courts have not accepted FDA’s perspective, however. Two pharmaceutical cases post-*Horn* have rejected FDA’s preemption arguments—one court has even used *Horn* to distinguish between pharmaceutical and medical device claim preemption.102 In both *Zikis v. Pfizer Inc.* and *Cartwright v. Pfizer Inc.*, plaintiffs alleged the defendant failed to warn patients taking the prescription drug Zoloft of the danger of self-harm.103 In *Zikis*, the court rejected the defendant’s reliance on the *Motus amicus curiae* brief and refused to preempt the plaintiff’s claims because FDA regulations allow pharmaceutical manufacturers to “add or strengthen a contraindication, warning, precaution, or adverse reaction ….” without prior FDA approval.104 The *Cartwright* court similarly reasoned that “[t]he FDCA and FDA’s regulations do not conflict with Texas’ failure-to-warn law because they merely set minimum standards with which manufacturers must comply; they expressly do not prohibit a manufacturer from ‘add[ing to] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction.’”105

Reinforcing the decision not to preempt plaintiffs’ failure-to-warn claim, the *Cartwright* opinion continued on to distinguish *Horn*. Discussing Congress’ intent to prohibit stricter state law requirements for medical devices in section 360k(a), the *Cartwright* court noted that prescription drug regulations pose the exact opposite intent by allowing the strengthening of warnings without prior FDA approval.106 Distinguishing *Horn*

98 Id. at 23-4 (quoting *Jones*, 430 U.S. at 543).
100 *Needleman*, 2004 WL 1773697, at *4 (noting that a label which is “false and misleading” is in direct contradiction of the FDCA).
104 *Zikis*, 2005 WL 1126909, at *2 (quoting 21 C.F.R. § 314.70(c)(6)(ii)(A)).
105 *Cartwright*, 369 F. Supp. 2d at 882 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)).
106 Id. at 882-83.
in this fashion creates a different congressional intent against which to analyze pharmaceutical drug and medical device claims. This difference in congressional intent places possible restrictions on the future scope of preemption in pharmaceutical drug litigation.

The acceptance of the Horn rationale regarding preemption of common law tort suits may indicate that FDA briefs submitted in other fields eventually may expand preemption of tort claims in medical device and prescription drug litigation. While FDA's amicus curiae briefs have encouraged pervasive tort reform in medical device litigation through the use of judicial influence, their influence has yet to be accepted as widely, however, in other fields. For pharmaceutical drug litigation, the lack of an express preemption provision in the FDCA creates a significant bar to FDA's amicus curiae preemption efforts. The amicus curiae briefs submitted in support of pharmaceutical cases also tend to be more fact specific, relying on FDA's previous rejection of a proposed stronger warning or indication. In contrast, the Horn brief espoused a broader conflict preemption theory—an argument that created a broader scope of preemption in the medical device field.

Overall, future implications of the influence of FDA amicus curiae briefs for pharmaceutical manufacturers are uncertain. The Horn reasoning and FDA's arguments still could apply to prescription drugs because the new drug approval (NDA) process to approve pharmaceuticals is similar to the PMA process for medical devices. The NDA and PMA processes have been described as “equally rigorous.” Because courts have focused on the rigoroussness of the PMA process as creating a federal requirement, the possibility still exists to expand the scope of preemption of pharmaceutical tort claims. Under the guidance of present decisions, however, tort liability still is a significant possibility for pharmaceutical manufacturers that comply with existing FDA regulations. In the future, the existing split in court decisions regarding preemption may indicate that the Supreme Court may clarify preemption standards and, in turn, could clarify the scope of protection for pharmaceutical manufacturers.

V. IMPLICATIONS OF THE JUDICIAL INFLUENCE OF FDA’S AMICUS CURIAE BRIEF

The judicial influence of FDA’s amicus curiae brief in Horn represents an effective non-rulemaking effort by FDA to reform existing tort law. The substantial deference given to FDA in Horn played a critical role in the Third Circuit’s decision to preempt the state common law tort claims.

FDA’s recent amicus curiae efforts to influence judicial determinations, both in Horn and in various pharmaceutical cases, go beyond the agency’s normal sphere of influence. The standard FDA rulemaking process for any change to its regulatory scheme is lengthy. FDA must publish a proposed regulation in the Federal Register, must leave it open for a “comment period” that typically spans at least sixty days, and must go through other legislative and political “red tape” in order to promulgate a new regulation. FDA even follows the same drawn out regulatory process for guidance documents (i.e., issuing a draft guidance on which the public can comment before issuing a final guidance). The Horn amicus curiae brief not only circumvented this lengthy administrative process to change the interpretation of its regulations, but also reformed longstanding precedent without rulemaking.

FDA’s amicus curiae efforts are a valid use of the authority granted to the agency. Courts historically have cited to the validity of their reliance on and deference to the 

\[107\] Cartwright, 369 F. Supp. 2d at 885.
expertise of an agency regarding matters the agency regulates. Created for the purpose of protecting the public’s health, FDA has incomparable topical experience in regulating medical devices and is in the best position to evaluate what regulatory actions would best benefit public safety. In addition to topical expertise, FDA also should be entitled to deference regarding the scope of its own regulations. FDA’s power to circumscribe the scope of the MDA’s preemption provision is rooted in the fact that the agency itself promulgated the preemption provision. FDA’s efforts to convince courts of the preemptive effects of the FDCA, however, are based, not on an FDA-promulgated preemption provision, but on an implied conflict preemption theory. Accordingly, these efforts represent a much more uphill battle.

Although the intervention of FDA in *Horn* and the resulting effects on the tort system have been perceived as a drastic reversal of position, the agency’s recent actions are consistent with its role in protecting public health. FDA’s position on preemption of Class III medical device claims and the reformatory effects of the agency’s *amicus curiae* briefs on the U.S. tort system have many beneficial effects for society at large. Allowing tort suits to conflict with thoroughly researched and established FDA medical standards risks supplanting the agency’s pervasive oversight of safety and accumulated expertise. For example, allowing failure-to-warn claims to proceed even though a product has met the stringent FDA labeling requirements can harm the public’s health by encouraging manufacturers to withdraw products or to issue new warnings that overemphasize the risks and lead to “underutilization of beneficial treatments.”

By limiting additional or different state common law claims, courts have deferred to FDA’s knowledge and have refused to displace scientifically substantiated product approvals—a result that would be detrimental to the public.

FDA’s actions to reform existing products liability may be challenged on the basis that consumers are injured by retardation of the innovation process and reduced incentives for safety. Even though it may appear that innovation is slowed due to the extended timeframe of the PMA process as compared to other approval processes, FDA’s reform efforts actually can avoid retardation of innovation. Affording some security to manufacturers encourages growth, development, and advancements. Creating manufacturer liability for products that already have been approved as “safe and effective” may make companies less likely to market approved products with life-saving benefits. Companies may be induced to remove already-approved products from the market if they fear large losses from possible tort liability.

In the medical device industry, FDA’s *amicus curiae* efforts create a business decision for manufacturers: choose to pursue the expensive, time-consuming PMA process; obtain approval through the abbreviated 510(k) process; or do not pursue innovation at all. After *Horn*, there is a strong basis for manufacturers to subject their products to the increased level of FDA scrutiny through the PMA process. Sound risk management counsels in favor of following this process when there arguably is such a strong protection from litigation costs. There is firm logic to the theory that FDA’s

---

108 “When a statute speaks clearly to the issue at hand, courts ‘must give effect to the unambiguously expressed intent of Congress,’ but when the statute ‘is silent or ambiguous,’ courts must defer to a reasonable construction by the agency charged with its implementation.” Barnhard v. Thomas, 540 U.S. 20, 124 S. Ct. 376, 380 (2003) (quoting *Chevron U.S.A. Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 843, 104 S. Ct. 2778 (1984)); *Houston Police Officers’ Union v. City of Houston, Tex.*, 330 F.3d 298, 302-03 (5th Cir. 2003) (noting that the appellant “fortified[d]” its interpretation of a statute by arguing that it is advocated by the Department of Labor in an *amicus curiae* brief, as well as certain regulations and an opinion letter). The Court does not accord *Chevron* deference to the *amicus curiae* brief, as it is unclear whether the “pronouncement[] [is] sufficiently authoritative to merit *Chevron* deference.” *Houston Police Officers’ Union*, 330 F.3d at 305. The Court does, however, place weight, though not dispositive weight, on the agency’s view as expressed in the *amicus* brief.

109 *Horn*, 376 F.3d at 178.
position on preemption benefits consumers in the form of safer products as much as it benefits manufacturers.

By using *amicus curiae* briefs and avoiding lengthy, time-consuming regulatory process, FDA has in effect reformed tort law: the agency has crafted a spectrum of protection and a sword for medical device manufacturers by providing the ability to end a common law tort claim at its inception based on the preemption doctrine.