No. 06-___ 061262 MAR 14 2007

In The

Supreme Court of the United States

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED,

Petitioners,

v.

ST. JUDE MEDICAL, S.C., INC., AND ST. JUDE MEDICAL, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The Court Of Appeals Of Texas, First District, Houston

PETITION FOR A WRIT OF CERTIORARI

TIMOTHY D. RILEY
RILEY LAW FIRM
The Civil Justice Center
112 E. 4th St.
Houston, TX 77007-2502
(713) 646-1000
Fax (800) 637-1955

Counsel of Record for Petitioners

JAMES V. PIANELLI
PIANELLI LAW FIRM
The Civil Justice Center
112 E. 4th St.
Houston, TX 77007-2502
(713) 864-3333
Fax (800) 637-1955

Counsel for Petitioners

March 2007

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

BLANK PAGE

QUESTIONS PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), was intended by Congress to preempt state-law product liability suits arising from the use of medical devices that have lost their FDA approval.

Whether the Medical Device Amendments were intended by Congress to preempt all state-law injury suits arising from medical devices that have Pre-Market Approval or Pre-Market Supplement Approval.

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES – Continued

CONSTITUTIONS

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

INTRODUCTION

A confusing and inconsistent body of law has evolved on the question of when, if ever, the express preemption provision of the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act [MDA], should be recognized as preempting state tort suits arising from the use of an FDA-approved medical device. *See, e.g., Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), and *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption). This situation desperately needs correction.

But suppose a particular device is no longer FDA-approved. Would there be any reason or basis in that circumstance to apply preemption? Clearly not:

> This would be a different case if, prior to the instant litigation, the FDA had . . . taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's . . . claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. . . . If the FDA . . . requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme.

Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 354 (2001) (Stevens, J., concurring).

Yet, that is exactly what the Texas appellate court did here. Jean Baker, the 65 year old mother of the petitioners, died a horrible death in February 2000 as a result of a leak in her heart muscle wall caused by the respondents' defective artificial heart valve. The product was classified

as "defective," "adulterated," and "misbranded," and ordered off the market by the FDA in March 2000.

But the case law on the issue of federal preemption has become so distorted and convoluted in the lower courts that the Texas Court of Appeals felt compelled to hold that preemption applied even as to claims arising from products recognized as defective by the FDA and ordered removed. The appellate court here, just as in all of the other cases in which preemption has been found, clearly engaged in a presumption *in favor* of preemption, rather than *against* preemption.

The upshot of the published opinion in this case is that *every* medical device which has *ever* been approved by the FDA under a Pre-Market Approval [PMA], or a PMA Supplement, is *automatically and forever* exempt from civil liability arising from the use of that device. That could not possibly have been the intent of Congress in passing the MDA. Yet, if this Court does not redirect the lower courts, that is precisely where the majority of published appellate decisions will fall.

This Court should step in and clarify definitively when, if ever, preemption should apply under the MDA. The need is pressing.

OPINION AND ORDER BELOW

The decision of the First District Court of Appeals for the State of Texas is published at *Baker v. St. Jude Medical S.C., Inc.,* 178 S.W.3d 127 (Tex.App. – Houston [1st Dist.] 2005, pet. denied.) Appendix at 1a. The petition for review to the Texas Supreme Court was denied under

Cause Number 06-0223. This type of discretionary denial of a petition for review is not published. Official notification of the denial is reproduced in the Appendix at 22a. The order granting summary judgment which underlies this appeal was entered on April 25, 2002, by Probate Court Number One of Harris County, Texas, in Cause No. 312,543-402 (later severed into Cause No. 312,543-402-A). This order is reproduced in the Appendix at 21a.

JURISDICTION

The petition for review was denied by the Texas Supreme Court on December 15, 2006. Appendix at 22a. This Court has jurisdiction under 28 U.S.C. § 1257.

STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 331(a) (Due to volume the statutes and rules are reproduced, in accordance with Sup. C. R. 14(1)(f), at Appendix 23a)

21 U.S.C. § 351(e) (Reproduced at Appendix 23a)

21 U.S.C. § 352(j) (Reproduced at Appendix 23a)

21 U.S.C. § 360c(a)(1)(C) (Reproduced at Appendix 24a)

21 U.S.C. § 360e(d)(2) (Reproduced at Appendix 25a)

21 U.S.C. § 360e(e)(1) (Reproduced at Appendix 25a)

21 U.S.C. § 360k(a) (Reproduced at Appendix 26a)

21 C.F.R. § 7.40 (Reproduced at Appendix 26a)

21 C.F.R. § 7.41(a) (Reproduced at Appendix 28a)

21 C.F.R. § 7.45(a) (Reproduced at Appendix 29a)

21 C.F.R. § 7.46(a) (Reproduced at Appendix 29a)

21 C.F.R. § 803.10(c) (Reproduced at Appendix 30a)

21 C.F.R. § 814.3(g) (Reproduced at Appendix 30a)

21 C.F.R. § 814.47(2) (Reproduced at Appendix 30a)

21 C.F.R. § 870.3925 (Reproduced at Appendix 31a)

21 C.F.R. § 895.1 (Reproduced at Appendix 31a)

STATEMENT OF THE CASE

This petition arises from a state-law wrongful death suit brought in a Texas state court by Keith Baker and Ian Baker, individually and on behalf of the estate of their deceased mother, Jean Baker, against St. Jude Medical, S.C., Inc., and St. Jude Medical, Inc. [SJM]. The petitioners contended that Jean Baker died as the result of a dangerously defective artificial heart valve designed, manufactured, and distributed by SJM.

SJM moved for summary judgment, claiming that, because the subject valve originally had been approved by the FDA under a PMA Supplement, all of the petitioners' claims were preempted by application of the express preemption provision of the MDA, and by the implied preemption doctrine. Appendix at 82a.

The petitioners contended in the trial court that preemption should not be applied to PMA Supplement-approved products in general or with respect to this particular product. The petitioners also contended that the implied preemption doctrine is inapplicable under federal

law. Finally, the petitioners contended that preemption could not possibly apply because this product had been voluntarily withdrawn from the market, and since has been reclassified by the FDA as "defective," "adulterated," and "misbranded," therefore terminating any FDA approval. Absent existing FDA approval, no preemption doctrine can possibly apply.

The petitioners' response to the summary judgment motion was timely filed and relevant portions of the voluminous response are reproduced in the Appendix at 92a. In the court of appeals, the petitioners raised the same contentions, also on a timely basis. The relevant portions of the voluminous briefing filed by the petitioners in that regard are reproduced in the Appendix at 107a. The court of appeals specifically ruled on each of the petitioners' objections. *Baker,* 178 S.W.3d at 134 n.5, 137. These issues were appealed directly by the petitioners to the Texas Supreme Court as well. The relevant portions of the voluminous briefing filed by the petitioners in the Texas Supreme Court are reproduced in the Appendix at 110a.

STATEMENT OF RELEVANT FACTS

In November 1999, Jean Baker was suffering from symptoms of advanced congestive heart failure. Ms. Baker's physicians determined that the patient had a severely leaking cardiac mitral valve, which was causing her problems. CR 928-29.[1]

[1] References to "CR" are to the record in the possession of the Clerk of the First Court of Appeals of Texas. *See,* Sup. C. R. 12(7). As in the federal system, in this state court proceeding the reviewing courts were

(Continued on following page)

Fortunately, prosthetic mitral valves are readily available on the market to correct this malady. Ms. Baker's surgeon selected a market-leading SJM prosthetic mitral valve. CR 2834-35. But, after implant Ms. Baker did not improve. Rather, she deteriorated to a wasting, cachectic state, and finally died in February 2000.

A post-mortem examination revealed that Ms. Baker died as a result of a large hole in her heart, a "paravalvular leak," which had developed where the SJM valve had been sutured to her heart. CR 930-32, 1415-27. Ms. Baker's physicians later learned that they had unknowingly implanted a valve with a new and significant modification – the addition of a thin silver coating to the sewing cuff where it attached to the patient's heart. CR 1401-03.

The original SJM prosthetic mitral valve went through the full PMA process to obtain FDA approval in 1982. CR 2833. This valve generally was successful. However, endocarditis (a cardiac infection), is a rare but known potential complication with every valve replacement surgery. Because silver has anti-microbial qualities in some bodily applications, SJM had the idea that perhaps it could reduce endocarditis by adding a thin silver coating to the fabric sewing cuff. CR 1196. Accordingly, SJM submitted an abbreviated application, known as a "PMA Supplement," to attempt to gain approval to sell its valve with a thin coating of silver, which SJM trademarked as "Silzone." CR 1096-1104.

---

required to: "indulge every reasonable inference in favor of the nonmovant, resolve any doubts in its favor, and take as true all evidence favorable to it." *See, Baker,* 178 S.W.3d at 132. *See also, United States v. Diebold, Inc.,* 369 U.S. 654, 655 (1962).

The Silzone-coated valve was allowed to proceed under a significantly abbreviated process than that normally required for prosthetic valve applications. More specifically, the entire application package for the Silzone-coated valve was only about two inches thick. CR 1086-88, 1103. The product also was approved without the usual FDA Expert Advisory Panel review. CR 1086, 1103. The limited animal studies were cut short at SJM's request, and no human studies were considered or required by the FDA. CR 66-67, 1086, 1089-90, 1099, 1104.

The FDA approved the PMA Supplement for the addition of the silver coating on March 30, 1998. CR 1062. However, because SJM was unable to demonstrate the silver coating had any efficacy whatsoever in reducing endocarditis, the FDA prohibited SJM from marketing the product with any such claims. CR 1091. But the company still wanted to market the product as reducing endocarditis. Accordingly, SJM sponsored a post-approval multicenter human study to attempt to determine efficacy of the product in preventing endocarditis. This trial was known as the Artificial Valve Endocarditis Reduction Trial, or "AVERT." CR 1074, 2847.

SJM began receiving reports very early in the AVERT that enrolled patients were experiencing an unexpected number of life-threatening paravalvular leaks adjacent to the area where the Silzone-coated sewing cuffs attached to the patients' heart muscles. CR 1098. In fact, the rate of paravalvular leaks for patients with the Silzone-coated valves was 2%, compared to .25% for patients with conventional valves, an eight-fold increase in risk. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation,* MDL No. 01-1396, 2004 U.S. Dist. LEXIS 148,

2004 WL 45503 (D. Minn. January 5, 2004) Appendix at 42a, 45a.[2]

In addition to the patients in the AVERT, Silzone-coated valves were implanted unwittingly in 36,000 other patients worldwide, including Jean Baker. CR 1140. In the meantime, though, evidence from the AVERT of Silzone causing paravalvular leaks became overwhelming. SJM became legally obligated to notify the FDA immediately of these results, as the persistent observed development of paravalvular leaks after implant unquestionably involved a significant threat to the lives of implant recipients. *See,* 21 C.F.R. § 803.10(c). Any notification to the FDA of serious complications arising from the use of an approved device inevitably initiates a mandatory investigation and an FDA enforcement action. *See,* 21 C.F.R. §§ 7.45(a),

[2] Around the same time this case was filed in state court numerous materially identical cases – involving the same Silzone allegations against SJM – were filed in various federal courts. On April 18, 2001, the federal Judicial Panel on Multidistrict Litigation consolidated and transferred all of these cases and all later "tag-a-long" cases, pursuant to 28 U.S.C. § 1407, to a federal MDL court in the Minnesota District, Hon. John R. Tunheim presiding. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation,* No. 1396, 2001 U.S. Dist. LEXIS 5226 (J.P.M.L. April 18, 2001). SJM also filed a preemption summary judgment motion in the MDL, but Judge Tunheim determined none of the claims is preempted by federal law. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 01-1396, 2004 U.S. Dist. LEXIS at 148, 2004 WL 45503. Appendix at 42a, 78a. Thus, the incongruent impact of the MDL order is that the Silzone-related claims of citizens of all states filed in federal court are not preempted. However, the claims of Texas citizens filing such suits in Texas courts are deemed preempted, by the state court in *Baker,* by application of federal law. In any event, the incidence of paravalvular leaks found by Judge Tunheim was a comparison of the reported incidence of explants due to paravalvular leaks without infection in AVERT patients who received conventional valves compared to those who received Silzone-coated valves (1/394 compared to 8/398). *Id.* Appendix at 42a, 45a.

814.47(2), and 895.1, *et seq. See also, United States v. Superharm Corp.,* 530 F.Supp. 408, 409-10 (E.D. N.Y. 1981).

To avoid this certain prospect, SJM instead initiated a "voluntary recall" of the Silzone-coated valves on January 21, 2000, and simultaneously notified the FDA of this action, as required by law. CR 1120. This type of recall by a manufacturer *only* occurs when the manufacturer recognizes and acknowledges that the recalled products "present a risk of injury or gross deception *or are otherwise defective.*" 21 C.F.R. § 7.40(a) (emphasis added).

The recall notification compelled the FDA to appoint an ad hoc investigative committee. 21 C.F.R. § 7.41(a). Less than 60 days after notification, on March 20, 2000, the unanimous conclusion of the committee was memorialized into a formal memorandum, the "Fitzgerald Memo." Appendix at 33a.

The Fitzgerald Memo noted that FDA now considered the device: "to be *adulterated and misbranded,* because there is a significantly higher rate of paravalvular leaks with the silver ion (Silzone) coated sewing cuffs leading to valve explants."[3] CR 1183-85, 1186-88 (emphasis added).

On March 22, 2000, these determinations were conveyed to SJM by FDA Acting Regional Director Edwin S. Dee (the "Dee Letter"). Appendix at 37a. SJM was formally notified in the Dee Letter that the FDA found the circumstances and actions of SJM met the formal definition for a

[3] A medical device is deemed "adulterated" only if it is subject to performance standards but fails to conform with such standards, "misbranded" only if it is "health-endangering when used as prescribed." 21 U.S.C. §§ 351(e), 352(j).

"recall." This determination by the FDA was quite significant because it meant that the FDA formally found that the "voluntary recall" was in fact "*an alternative to an FDA legal action to remove the defective products from the market.*" Appendix at 38a (emphasis added).

By law, this meant that SJM's recall was recognized by the FDA as the firm's "removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, *e.g.*, seizure." *See*, 21 C.F.R. § 7.46(a). In other words, this formal recognition of SJM's act as a statutory "recall" means the FDA would seize these devices, but for the fact that the manufacturer recognized them as defective and voluntarily withdrew them from the market, negating the need for an FDA seizure action. *Id.*

The court of appeals implied that the Silzone-coated valves must still be FDA-approved because the PMA Supplement approval was never formally withdrawn. But this clearly is incorrect. *See, In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 01-1396, 2004 U.S. Dist. LEXIS at 148, 2004 WL at 45503 (Appendix at 42a, 77a):

> The Court hesitates to characterize defendant's argument too harshly, however, it is difficult to read the FDA's March 20, 2000 and/or March 22, 2000 correspondence and find any ambiguity. . . . St. Jude appears to recognize that the Silzone valve is not marketable absent additional approval from the FDA. . . . The Court finds persuasive plaintiffs' argument that the Silzone valve no longer has FDA approval.

But the finding of the Texas Court of Appeals also is a meaningless non-sequitur. It is accurate that the FDA can

initiate formal proceedings to withdraw PMA approval if the Secretary unilaterally finds that products are unsafe, misbranded, adulterated, or defective. 21 U.S.C. § 360e(e)(1). Similarly, the FDA can initiate a recall itself when it determines previously-approved products present a risk of illness, injury, or gross deception. 21 C.F.R. § 7.45(a).

But by specific regulation, an FDA-initiated recall can *only* take place when the manufacturer has not initiated a voluntary recall. 21 C.F.R. § 7.45(a)(2). Indeed, both the approval withdrawal and FDA-initiated recall processes become completely unnecessary when the manufacturer voluntarily recognizes that the products present a risk of injury or gross deception or are otherwise defective, and the FDA reclassifies the products as defective, adulterated, and/or misbranded. 21 C.F.R. § 7.40(a).

This is true because it is a criminal act for any person to introduce into interstate commerce a product that the FDA has found to be either misbranded or adulterated. 21 U.S.C. § 331(a); *In re Grand Jury Subpoena,* 220 F.R.D. 130, 154 (D. Mass. 2004). Moreover, product seizure (or the alternative formal classification of a manufacturer's proposed course as a "recall," as occurred here), is the most drastic non-criminal remedy afforded the FDA, as it also makes further distribution of the product illegal. *See, e.g., Superharm Corp.,* 530 F.Supp. at 409-10.

REASONS FOR GRANTING THE WRIT

There are two compelling reasons this petition for writ of certiorari should be granted by this Court. First, there is a significant conflict in authority with regard to whether suits arising from products approved by the FDA under a PMA or PMA Supplement are ever preempted.

Second, this product is no longer approved by the FDA. Accordingly, there is no reason whatsoever to apply preemption when there is no conflicting FDA approval. Not surprisingly, many product liability suits arise from products which have been found defective, and were therefore withdrawn from the market and divested of FDA approval. The opinion of the Texas Court of Appeals is the only published appellate opinion in this country in which a court has directly addressed this issue. The Texas Court of Appeals erroneously and inexplicably held that preemption always applies, even if the product in issue is no longer FDA-approved. This issue should be resolved definitively by this Court.

These issues will be addressed in reverse order.

A. Preemption When the Product is No Longer FDA-Approved

The Texas Court of Appeals analyzed the issue and held that congressional intent in the MDA is to the effect that, if a medical device once-upon-a-time was FDA approved under any PMA process, then the manufacturer will be forever shielded from any liability arising in any way from the use of that product. *Baker,* 178 S.W.3d at 136-37. Under the *Baker* holding, this would be true *even if the PMA Supplement approval were to be voided, or if it should later be determined that the approval was secured through fraud.* This conclusion is outlandish.

As discussed briefly below, the application of preemption under the MDA has had a curious and confusing history. It is well-settled, however, that the express language of the MDA would compel preemption if: (a) there is an ongoing FDA mandatory design specification; and (b) a state later should pass a regulation mandating a different design. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996).

However, the MDA is silent as to whether Congress intended for this preemptive effect also to apply to state common law, developed via case law, or simply to positive statutes or regulations that vary from FDA-imposed obligations.

Case law since 1976 leads to a conclusion that state court judgments in some instances might be considered conflicting requirements so as to invoke express preemption under the MDA and similar statutes. The scope of when these situations might arise was more debatable before the 2005 *Bates* decision, discussed below. However, one aspect of the doctrine has never been subject to debate: The question of whether a state court lawsuit is preempted by the MDA can be determined only by ascertaining whether a state court judgment based on a jury finding could be construed as a "requirement" that conflicts with an existing requirement imposed on the manufacturer by the FDA. *Medtronic,* 518 U.S. at 487.

This analysis assumes that there is some ongoing FDA regulation or finding with which the jury's finding might arguably conflict. Accordingly, it is absurd to suggest that a state court judgment is preempted by the MDA when the product no longer has FDA approval and therefore there is no existing FDA requirement with which the judgment might conflict.

It is important to keep in mind that only an actual, irreconcilable conflict can give rise to preemption:

> As in the typical pre-emption case, the inquiry is whether there exists an irreconcilable conflict between the federal and state regulatory schemes. The existence of a hypothetical or potential conflict is insufficient to warrant the pre-emption of

> the state statute. A state regulatory scheme is not pre-empted . . . simply because in a hypothetical situation a private party's compliance with the . . . [state laws] might cause him to violate . . . [federal] laws.

Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982).[4]

Currently, the only requirements imposed by the FDA with respect to these FDA-determined defective valves are that: (a) all existing stocks be completely and affirmatively removed from the market; and (b) these products no longer be manufactured or sold. Thus, even if a jury verdict in this case could be construed as imposing some type of *requirement*, it is difficult to see how a verdict agreeing with the FDA that the product is defective could possibly conflict with any FDA requirement currently imposed. *Id.*

However, even if one were to analyze this case under the preemption doctrine as if the products were still FDA-approved, the same conclusion against preemption would necessarily be reached under these facts. It is helpful, in analyzing the scope of preemption in this lens, to examine briefly the history of the Medical Device Amendments, as well as the history, purpose, and application of the preemption doctrine.

---

[4] Indeed, as quoted at page 1 above, the very situation which faces this Court today – that preemption cannot possibly apply when FDA approval no longer exists – was foreshadowed and analyzed cogently by a member of this Court. *Buckman,* 531 U.S. at 354 (Stevens, J., concurring).

B. Preemption Under the Medical Device Amendments

1. Legislative Background

It was not until 1976 that the federal government decided to regulate medical devices. Prior to that point, the FDA had only limited authority to seize adulterated and misbranded devices already on the market. However, the FDA lacked the authority to prevent the entry of a new medical device. *Medtronic,* 518 U.S. at 476-77.

It became apparent that this regulatory gap had created hazards to the public health and a hodgepodge of medical device regulations imposed by various states to fill the void. Accordingly, Congress enacted the Medical Device Amendments, bringing medical devices for the first time under the approval umbrella of the long-standing Food, Drug, and Cosmetic Act. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c, *et seq.*). From that point forward, it became illegal for anyone to manufacture and distribute any medical device not already on the market without going through FDA approval. 21 U.S.C. § 331(a); *Medtronic,* 518 U.S. at 577.

2. Regulated Medical Device Classifications

To carry out the regulatory function, the MDA set up three classifications for medical devices. Class I devices pose no reasonable risk of illness or injury. They are subject only to minimal regulation by general controls, and do not require pre-approval for distribution. *Medtronic,* 518 U.S. at 476-77 (quoting 21 U.S.C. § 360c(a)(1)(A)).

More potentially harmful devices are designated Class II. These devices also may be marketed without receiving

advance approval from the FDA. *Id.* at 477 (quoting 21 U.S.C. § 360c(a)(1)(B)).

The most potentially harmful devices are designated as Class III devices. All medical devices which present "a potential unreasonable risk of illness or injury," or that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)). All prosthetic heart valves are Class III devices. 21 C.F.R. § 870.3925.

There is a three-tier process for approval of Class III medical devices. The most rigorous process is known as a Premarket Approval, or "PMA." In this process, manufacturers submit detailed information regarding the safety and efficacy of their devices. Animal studies invariably are required, and there are established protocols for these studies with specific devices, including prosthetic heart valves. CR 1099. Most full PMA applications also require extensive human clinical studies before approval can be obtained. *See,* CR 1101-02.

Once this extensive process has been completed, the FDA then carefully reviews each PMA submission in detail. If the submission passes these rigors, an expert review panel typically is appointed for all new PMA applications, to consider and debate the submitted data and to make recommendations to the agency for or against approval. *See,* FDA, *Panel Review for Premarket Approval Applications, May 3, 1996 (P91-2)* ("In general, all PMAs for the first-of-a-kind device should be taken before the appropriate advisory panel for review and recommendation.").

The typical PMA submission takes an average of 1,200 hours of manpower at the FDA. Document submissions in PMA applications typically are counted by the volumes, if not the boxloads. *See, e.g., Horn v. Thoratec Corp.,* 376 F.3d 163, 169-70 (3d Cir. 2004). *See also,* CR 1088. Ultimately, the FDA is authorized to grant premarket approval for a Class III medical device only if the agency finds that there is "reasonable assurance" that the device is "safe and effective." 21 U.S.C. § 360e(d)(2).

An almost painless alternative to the rigors of the full PMA process is the "510k application." This is a very limited form of review that requires manufacturers to submit nothing more than a "premarket notification" to the FDA. The 510k process was created because devices already on the market prior to the passage of the MDA in 1976 did not require approval to continue to be sold. Accordingly, this limited procedure was designed to allow competitive products, which are found to be "substantially equivalent" to such "grandfathered" products, to enter the market without having to go through premarket scrutiny. *Medtronic,* 518 U.S. at 478-79.

Finally, the MDA also permits manufacturers to seek authorization to modify a previously PMA-approved device and avoid the rigorous PMA process, obtaining approval only for the modification through a "PMA Supplement" application. *See,* CR 1102. *See also,* 21 C.F.R. § 814.3(g). The PMA Supplement review can vary significantly with respect to its thoroughness, specificity, and scope. *See,* 32 C.F.R. § 814.3(g). *See also,* CR 1104. By way of example, while a full PMA approval in 1999 took an average of 12 months, the average time for approval of a PMA Supplement application during the same period was only 4 months. Fischell, R.E., *Regulatory Concerns and Issues:*

Have the Bureaucrats Won?, 13 J. INVASIVE CARDIOL. 139-40 (2001).

3. State Regulatory Efforts as Basis for Statement of Preemption in the MDA

During the MDA enactment process, Congress was informed of various states which had stepped into the regulatory vacuum and required that devices undergo state premarket approval before commercial distribution in those states. *Medtronic,* 518 U.S. at 476-77. Because even non-uniform state premarket scrutiny was preferable to no premarket scrutiny at all, Congress allowed state regulatory programs to remain in place or be implemented until the FDA implemented specific counterpart federal regulations. However, those state requirements would thereafter be preempted by the FDA regulation. *Id.*

4. Types of Recognized Federal Preemption

There are three types of federal preemption, one express and two implied. As a result of application of the Supremacy Clause of Article VI, Clause 2, United States Constitution, any state law is preempted when: (1) Congress expressly preempts ("express preemption"); (2) congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme ("implied field preemption"); or (3) state law conflicts with federal law or its purposes ("implied conflict preemption"). *Gade v. National Solid Wastes Mgmt. Ass'n,* 505 U.S. 88, 98 (1992); *English v. General Elec. Co.,* 496 U.S. 72, 78-79 (1990).

Express preemption occurs only when statutory language clearly and explicitly preempts state law. *Hillsborough Co., Fl. v. Automated Med. Labs, Inc.,* 471 U.S. 707, 712-13 (1985).

Implied field preemption occurs only when a federal law encompasses a field so thoroughly that there is no room for the states to supplement the area. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). The question of implied preemption usually does not arise when preemption is expressed in a statute.[5] *Id.* at 517; *Kemp,* 231 F.3d at 222.

The last category, implied conflict preemption, sometimes is recognized because a manufacturer cannot be obligated to comply with a federal regulation that would subject it to liability under state law.[6] *English*, 496 U.S. at 79.

Under any theory, federal law will be deemed to preempt state law only where Congress intended such a result. *Fidelity Federal Sav. And Loan Ass'n v. de la Cuesta,* 458 U.S. 141, 152 (1982). Thus, preemption will be found to exist only where there is a "clear and manifest purpose of Congress" to foreclose a particular field to state legislation. *Jones v. Rath Packing Co.,* 430 U.S. 519, 525

---

[5] This is not always the case. However, implied field preemption clearly cannot apply here. *See* pages 20-21, *infra.*

[6] Implied conflict preemption has been addressed in an additional subcategory, where the challenged state law stands as an obstacle to the accomplishment and execution of the objectives of Congress. *Gade,* 505 U.S. at 98. However, this has been recognized as indistinguishable from implied field preemption. *See, Crosby v. National Foreign Trade Council,* 530 U.S. 363, 372 n.6 (2000); *Gade,* 505 U.S. at 115 (Souter, J., dissenting); and *English,* 496 U.S. at 79 n.5.

(1977) (quoting *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947)).

In this arena, the courts are required to engage in a strong presumption against preemption. *Bates v. Dow AgroSciences, LLC*, 544 U.S. 431, 449 (2005). This presumption is particularly appropriate in light of the fact that the only reference in the MDA which even arguably gives rise to a preemption argument is in § 360k(a), which states *only* that no state can institute or continue in effect any "requirement" that is different from or in addition to any requirement imposed on the product by the FDA. 21 U.S.C. § 360k(a). Significantly, it is only through implication that § 360k(a) has been found to preempt some state court suits, as neither the words nor the legislative history of the statute indicate any such intent. Because there is no clear and unambiguous expression of an intent to preempt civil tort suits in the MDA, the courts are *compelled* to rule against preemption if there is any cogent argument that preemption in the circumstance presented was not intended. *Bates,* 544 U.S. at 449.

5. Inapplicability of Implied Field Preemption

The inclusion of an express preemption provision in a statute does not necessarily preclude application of the doctrine of implied preemption. *Sprietsma v. Mercury Marine,* 537 U.S. 51, 65 (2002). However, in the face of an express preemption provision, the courts should look primarily to the words of the statute. *Id.* at 62-63; *English,* 496 U.S. at 79.

This Court has recognized an appropriate judicial reluctance to expand federal statutes beyond their terms through the doctrine of implied preemption. *See, e.g.,*

Bates, 544 U.S. at 459 (Thomas, J., concurring in part and dissenting in part); *Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting); and *English,* 496 U.S. at 79. This is based on the fact that preemption must be governed by congressional intent, and the words expressed by Congress in the subject statute are the best gauge of that intent. Otherwise, "a freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is Congress rather than the courts that pre-empts state law." *Gade*, 505 U.S. at 111 (Kennedy, J., concurring in part and concurring in judgment).

With regard to state tort claims brought against manufacturers of defective medical devices, the question of implied field preemption is easily resolved in favor of the petitioners. The federal courts have been quite clear that, when analyzing the preemptive impact of a federal statute with respect to areas traditionally covered by state tort laws, implied field preemption simply does not apply. *See, e.g., Cipollone,* 505 U.S. at 516. *See also, Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984). Thus, reliance on the express preemption language of the MDA to the exclusion of any implied preemption analysis was necessarily and appropriately followed in *Medtronic*, 518 U.S. at 470. This was expressly recognized, first in *Buckman* and later in *Bates*, 544 U.S. at 458 (Thomas, J., dissenting in part and concurring in part).

The claims raised in the case at bar are common law claims, traditionally governed by state law, just as the claims raised in *Bates, Medtronic,* and *Silkwood*. Thus, the doctrine of implied field preemption is inapplicable. *Buckman,* 531 U.S. at 352; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 368 (Tex.), *cert. denied*, 524 U.S. 954 (1998).

6. *Bates v. Dow AgroSciences, LLC*, and the Impact of Jury Verdicts on Preemption

The express preemption doctrine under the MDA has the identical basis and rationale as implied conflict preemption. *See, e.g., Medtronic,* 518 U.S. at 508 (Breyer, J., concurring). That is, the argument concerning the possible application of the express preemption doctrine under the MDA is premised on the prospect that the manufacturer cannot be expected to continue to design and market a product as required by the FDA, if doing so would subject the manufacturer to liability under state law. *Id. Accord, Riegel v. Medtronic Corp.,* 451 F.3d 104, 122 (2d Cir. 2006); *Horn,* 376 F.3d at 176. Not only is this analysis very firmly supported by *Medtronic*, but it also made some logical sense, as the MDA is completely silent with respect to whether Congress intended to preempt civil lawsuits in any respect. *Medtronic,* 518 U.S. at 491.

There once was a question whether the reference in the MDA to conflicting requirements applied only to positive state enactments, such as statutes and regulations, or could also extend to state common law arising from standards imposed by virtue of lawsuits. That question was first answered affirmatively by this Court in *Cipollone*, 505 U.S. at 507, and recently reaffirmed in *Bates,* 544 U.S. at 443-44.

However, according to this Court, the fact that such a federal statute *might* preempt *some unspecified types* of state court lawsuits:

> says nothing about the *scope* of that pre-emption. For a particular state rule to be pre-empted, it

> must satisfy two conditions. First, it must be a requirement. . . . Second, it must impose a . . . requirement that is *"in addition to or different from"* those required under this subchapter.

Id. (quoting 42 U.S.C. § 369k(a)) (emphasis the Court's).

In *Bates,* the Court was addressing an allegedly preempting provision of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (7 U.S.C. § 136, *et seq.*). Texas peanut farmers brought suit against Dow, a pesticide manufacturer, alleging that a pesticide which had been approved by the EPA was nonetheless defective as marketed, and caused damage to their crops. *Bates,* 544 U.S. at 434. Dow moved for summary judgment, contending that the claims were expressly or impliedly preempted by FIFRA. *Id.* at 435. The district court agreed and granted judgment in favor of Dow, which was affirmed by the Fifth Circuit Court of Appeals. *See, Dow AgroSciences, LLC v. Bates,* 332 F.3d 323 (5th Cir. 2003), *rev'd,* 544 U.S. 431 (2005).

The Fifth Circuit held, very similarly to the court of appeals in this case, that a jury verdict would conflict with FIFRA because it would have the tendency to induce the manufacturer to change the marketing of its product to meet the "requirements" implicit in the judgment, rather than the requirements imposed on the product by the EPA. *Compare, Bates,* 332 F.3d at 331 ("For a state to create a labeling requirement by authorizing a claim linked to the specifications of a label, even where the EPA has elected not to impose such labeling requirements, would clearly be to impose a requirement 'in addition to or different from those' required under FIFRA"), *with Baker,* 178 S.W.3d at 137 ("the jury could potentially set a standard of care for

St. Jude that was over and above what the FDA had determined was necessary to produce a safe product.").

But this Court held that the Fifth Circuit was: "*quite wrong* when it assumed that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement." *Bates,* 544 U.S. at 443 (emphasis added). The fact that a manufacturer might face a liability judgment, even though its product was approved by a federal regulatory agency, does not mean that the state will have imposed a *conflicting requirement* on the manufacturer. According to the Court:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.

Bates, 544 U.S. at 445.

Bates explained its distinction from the result reached in *Cipollone.* In *Cipollone,* the plaintiff sued a cigarette manufacturer for alleged defects in cigarette package warnings mandated by federal statute. *Cipollone,* 505 U.S. at 508. The preempting language in issue in that case contained the following language: "No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Id.* at 515. The Court held that this language expressly preempted a state court tort claim, which was based on a contention that the cigarette package warnings were inadequate. *Id.* at 521.

But the *Cipollone* Court noted that: "[t]he phrase 'no requirement or prohibition' sweeps broadly and suggests

no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules." *Id.* This was considered important by the *Bates* Court in distinguishing the scope of preemption as to claims brought under FIFRA. *Bates,* 544 U.S. at 447. Under FIFRA and the MDA, the preemption provision only extends to those state *requirements* which are "in addition to or different from" those imposed by the respective federal regulatory agency. *Id.* Thus, the holding of *Cipollone* cannot be extended to claims arising under FIFRA or the MDA. *Id.*

Beyond injunctions, it is not entirely clear after *Bates* exactly when requirements might be deemed imposed by state court suits so as to run afoul of preemption provisions like those in FIFRA or the MDA. However, *Bates* made one point abundantly clear: even if a jury verdict in a damages claim were to be based on a finding that would conflict with an agency finding, the verdict would *never* support application of the preemption doctrine. This is true because the verdict would not be deemed as imposing a *requirement* on the manufacturer as a matter of law. *Id.* at 445. Further, as the *Bates* Court noted, the statutory language of FIFRA is markedly similar to the preemption provision of the MDA. *Id.* at 447. Accordingly, *Bates* clearly commands the same result under the MDA.

7. *Medtronic, Inc. v. Lohr*

Even if analyzed under false premises that: (a) there is some remaining federal approval of the product in issue; and (b) *Bates* did not relegate to historical significance the "conflicting requirements arising from liability exposure"

argument; the result would be the same under clear law before *Bates*.

Until *Bates,* the dispositive case on this issue was the 1996 opinion of this Court in *Medtronic*. But *Bates* did not overrule the holding of *Medtronic*. To the contrary, the *Bates* Court indicated that its unanimous holding against preemption "finds strong support in *Medtronic*." *Bates,* 544 U.S. at 447.

The medical device manufacturer in *Medtronic* sought preemption from state court liability because its product enjoyed continuing FDA approval under the 510k process. 518 U.S. at 486. The defendant manufacturer contended that any medical devices currently approved by the FDA, regardless of route of approval, should be exempt from all state court liability. Medtronic reasoned that the imposition of liability under state court tort standards would conflict with the federal regulation of the devices under the MDA. Thus, the manufacturer argued that state court remedies were expressly or impliedly preempted under 21 U.S.C. § 360k(a). *Id.*

This Court summarily rejected the claim of express and implied "blanket" preemption regardless of route of approval. *Id.* at 486-87. Rather, to determine whether preemption should even be considered, the Court recognized it would be critical to examine exactly what the FDA approved, and how it was approved, against the supposedly conflicting effect of any necessary finding in a state court judgment. *Id.* at 509.

To hold otherwise would act to deprive all persons suffering injuries as a result of a defective device, whom Congress intended to protect in the MDA, of "most, if not all relief." *Id.* at 487. Consequently, this Court refused to

attribute any intent to preempt state tort claims completely, after observing that such blanket preemption would leave the public, the target of the safety concerns of Congress, without a remedy. Hence, the Court stated: "[i]t is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Medtronic*, 518 U.S. at 487. This Court logically concluded that the manufacturer's blanket preemption argument: "is not only unpersuasive, it is implausible." *Id.* at 487.

Clearly, a compelling reason for rejection of such blanket preemption claims arose from the Court's recognition that: "the FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured consumers, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all." *Id.* at 486 n.7. Subsequently, the Court has recognized the importance of allowing product liability suits against defective products to provide: "an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." *Bates,* 544 U.S. at 450.

The FDA never "required" SJM to put a silver coating on the sewing cuff of its prosthetic heart valves. Thus, even under *Medtronic*, a verdict based on a finding that the silver coating was defective in design could not possibly conflict with any requirement imposed by the FDA. *Medtronic*, 518 U.S. at 487. The fact that this medical device was approved under a PMA or a PMA supplement, rather than a 510k application, makes SJM's blanket preemption argument no more persuasive or plausible than it was in *Medtronic*.

CONCLUSION

The majority of the lower courts have gone far afield from the regulatory preemption language in the MDA to curtail all rights of recourse for innocent victims injured by defective medical devices. This was caused, in part, by the fact that *Medtronic* did not present this Court with an opportunity to address preemption with respect to devices approved through means other than a 510k. By contrast, the instant case presents this Court with a very good clarification opportunity.

Here, the unjustified judicial expansion of the pre-emptive effect of the MDA has been extended to devices that are no longer approved by the FDA. The willingness of the Texas appellate courts to distort this Court's ruling in *Medtronic* to reach such a clearly improper result illustrates the pressing need of the lower courts for further directive as to the scope of such preemption.

This petition for a writ of certiorari should be granted.

Respectfully submitted,

TIMOTHY D. RILEY
RILEY LAW FIRM
The Civil Justice Center
112 E. 4th St.
Houston, TX 77007-2502
(713) 646-1000
Fax (800) 637-1955

Counsel of Record for Petitioners

JAMES V. PIANELLI
PIANELLI LAW FIRM
The Civil Justice Center
112 E. 4th St.
Houston, TX 77007-2502
(713) 864-3333
Fax (800) 637-1955

Counsel for Petitioners

March 2007