No. 06-1262

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

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether, consistent with *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), the Texas court of appeals correctly held that 21 U.S.C. § 360k(a) preempts petitioners' state law damages claims involving St. Jude Medical, Inc.'s Class III medical device?

CORPORATE DISCLOSURE STATEMENT

Respondent St. Jude Medical, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns ten percent or more of this respondent's stock.

Respondent St. Jude Medical, S.C., Inc. is a wholly owned subsidiary of St. Jude Medical, Inc. No other publicly held company owns ten percent or more of this respondent's stock.

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

Petitioners contend this case presents a good vehicle for the Court to clarify *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and address two questions: whether, under 21 U.S.C. § 360k(a), FDA premarket approval (PMA) of a Class III medical device preempts conflicting state law claims arising from the device's design, manufacture, and labeling, and whether preemption still holds if that approval is subsequently "lost."

But the reasons for denying certiorari in this case are significant. The primary question presented in the petition is whether medical devices that have lost their FDA approval give rise to preemption. Yet that issue depends on an

assertion—that FDA approval was lost—lacking any support in the record. Throughout this case, petitioners have argued that statements in two documents (the "Dee letter" and the "Fitzgerald memo") conclusively establish that the FDA withdrew approval for the medical device in question. But the Texas probate court excluded those statements, and the Texas court of appeals did not disturb that ruling. Opp'n App. 1a-2a, 8a; Pet. App. 1a, 5a-6a & n.4, 11a n.5 (*Baker v. St. Jude Medical S.C., Inc.*, 178 S.W.3d 127, 132 & n.4, 134 n.5 (Tex. App. 2005)). Instead, as the court of appeals expressly recognized, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted." Pet. App. 6a. This discrete and correct evidentiary ruling does not warrant this Court's review, and petitioners' failure to inform this Court of it alone is sufficient reason to deny the petition under Rule 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition.").

Moreover, petitioners' assertions of a "conflict" in the relevant preemption authority do not withstand analysis either. In Texas state courts there is no such split. The controlling preemption analysis, set forth in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.), *cert. denied* 524 U.S. 954 (1998), was followed by the courts below. More broadly, the overwhelming majority of federal and state cases follow *Worthy*'s analysis. Accordingly, this Court previously has declined to review cases applying preemption principles to Class III medical devices,[1] and there is no reason, as the

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[1] *See, e.g., McMullen v. Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley v. Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks v. Howmedica*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002);

Solicitor General recently has noted, to depart from that position now. *See* Opp'n App. 34a-35a (Brief for the United States as Amicus Curiae at 2-3, *Riegel v. Medtronic, Inc.*, No. 06-179 (S. Ct. May 2007)).

In sum, the petition presents a unique fact-bound issue that is, in essence, nothing more than a dispute with the probate court's correct evidentiary ruling. Even if one gets beyond the discrete nature of the dispute, the controlling preemption principles are well settled, and there is no material conflict in the law. The asserted bases for this Court's review are not present and the petition should be denied.

STATEMENT OF THE CASE

The Regulatory Bases For Federal Preemption As Applied To Class III Medical Devices

This case involves a question of federal preemption as applied to a Class III medical device. These devices are the most highly regulated and invoke express preemption principles by virtue of the controlling federal regulatory scheme.

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, which vastly expanded the authority of the FDA to regulate medical devices. At the same time it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That

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Kemp v. Medtronic, Inc., 534 U.S. 818 (2001); *Worthy v. Collagen Corp.*, 524 U.S. 954 (1998).

general prohibition, which also safeguards the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable ... to the device" under federal law. 21 U.S.C. § 360k(a).

To obtain premarket approval, manufacturers must provide the FDA with research results and other data supporting the intended use of the device, a sample of the device, and other information, including the proposed device composition and proposed product labeling. Clerk's Record (CR) 3055-56; *see also* 21 U.S.C. § 360c(a)(1)(C); 21 C.F.R. § 814.20(b)). Among other information, a PMA application must include:

- all known reports pertaining to the device's safety and efficacy, § 360e(c)(1)(A);
- a full statement of the components, ingredients, and properties and of the principle or principles of operation of such device, § 360e(c)(1)(B);
- a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device, § 360e(c)(1)(C);
- samples of the device when practical, § 360e(c)(1)(E); and
- specimens of the labeling proposed to be used for the device, § 360e(c)(1)(F).

CR 3055-56.

Device innovations also receive this same scrutiny. Thus, if a PMA medical device is subsequently modified, the manufacturer must seek approval for the modification through the "PMA supplement" process. CR 3056; *see also* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39. All the procedures and actions applicable to a PMA application apply to a PMA

supplement. CR 2791-92 (citing *Worthy*, 967 S.W.2d at 364-65 (describing the PMA supplement process) and *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (same)). In a PMA supplement, the manufacturer must provide the same information required by a PMA application to support approval of the proposed modifications. CR 3056-57; *see also* 21 C.F.R. § 814.39(c).

PMA and PMA supplement submissions are voluminous, and the FDA's experts evaluate them fully. On average, the FDA spends 1200 hours reviewing a PMA. CR 3056; *see generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344-45 (2001) (describing the PMA process); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (same). When the medical device at issue is a heart valve, the FDA employs a staff of experts in that specific area, and uses standards contained in an FDA document entitled "Replacement Heart Valve Guidance" (Guidance Document).[2] CR 3059.

The medical device at issue in this case was reviewed through these processes. In December 1982, following two years of regulatory review, the FDA approved St. Jude Medical's initial PMA application for a mechanical heart valve, called the "Bi-Leaflet Center Opening Pyrolytic Carbon Cardiac Valve." CR 3161-62. In the years following approval, St. Jude Medical provided the FDA with a tremendous amount of additional data regarding the safety and efficacy of the valves, in a series of PMA supplements. *Id.*

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[2] The Guidance Document sets forth the type of testing that must be conducted, and the test data that must be submitted, to adequately demonstrate heart valve safety and efficacy in any PMA or PMA supplement application for that type of device. *See* CR 3059. If the manufacturer deviates from the recommended tests and other recommendations, it must demonstrate the equivalency or superiority of its choice of alternative to the satisfaction of the FDA or the FDA will refuse approval. *Id.*

This standard mechanical heart valve achieved wide acceptance. As medical research continued to evolve, however, St. Jude Medical developed innovative new technologies for physicians and their patients, including modifying its heart valve to incorporate a rotating sewing cuff that eliminated the need for surgeons to position the valve prior to suturing. CR 3162. The PMA supplement for this modification, known as the Masters Series valve, was supported by extensive documentation, including proposed labels, design specifications, and manufacturing standards, and the FDA approved it. CR 3162-63.

Over time, it became clear that an additional new technology was needed to address a well-known risk associated with artificial heart valves: endocarditis. CR 3156. Even with aggressive treatment, endocarditis can be life-threatening, causing death in 25% to 60% of cases. *Id.*

Silver, in various forms, has been used as an antimicrobial agent for many years, including as an infection-resistant coating for other medical devices. CR 3157, 3222, 3237. Spire Corporation had developed a patented technology to coat biomaterials with a silver coating several microns thick, subjected the coating to numerous safety and efficacy in vitro (laboratory) and in vivo (patient or animal) tests, and successfully used it on several medical devices. CR 3285-86. Thus, in December 1995, St. Jude Medical preliminarily notified the FDA of its plan to modify its Masters Series valve to incorporate Spire's infection-resistant, sterile silver coating on the sewing cuff. CR 3148, 3163-64, 3285.

The FDA advised St. Jude Medical that its proposed plan required numerous modifications—based in part on the heart valve Guidance Document—including performance of specific tests and submission of additional data and information. CR 3164-65. Almost a year and a half later, in May 1997, after it had compiled the data the FDA specified, St. Jude Medical formally submitted its PMA supplement to add the

silver coating (under the name Silzone®) to the sewing cuff on its Masters Series mechanical heart valve. CR 3165-67.[3]

The FDA's review of the formal PMA supplement took more than 10 months to complete, in addition to the many months the FDA already had spent reviewing St. Jude Medical's preliminary proposal. CR 3167. During this review process, the FDA demanded further testing and data, label changes, and manufacturing changes. CR 3167-70.

In March 1998, the FDA finally approved the PMA supplement, concluding there was sufficient evidence that the Masters Series heart valve with a Silzone®-coated sewing ring was reasonably safe and effective for its intended use. CR 3170-72. Through its approval, the FDA required St. Jude Medical to use the exact design, labeling, and manufacturing process it had approved. *Id.* The FDA also prohibited St. Jude Medical from making claims regarding efficacy of the Silzone® coating in preventing endocarditis pending the completion of further testing. *Id.*

St. Jude Medical thereafter manufactured and marketed the Silzone® valve in conformity with the established requirements. CR 3152, 3173. Petitioners have never adduced any evidence that the specific valve at issue in this case deviated from the FDA-required design, label, or manufacturing process.

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[3] This application provided important safety and efficacy data regarding the proposed silver coating material, design specifications, a sample package label for the new valve, and details regarding the manufacturing process that would be employed. *See* CR 3165-67. It also included a peer-reviewed report on a human clinical trial of the Silzone® valve. CR 3173-74, 3236. In addition, Spire had submitted to the FDA its own Master File in support of its patented silver coating with additional information on the coating process, quality control procedures, and the results of its own tests, and St. Jude Medical's PMA supplement relied on these materials as well. CR 3166, 3286.

Concomitantly with the marketing of the valve, St. Jude Medical continued to study its efficacy. The largest and most comprehensive of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). CR 3176. An independent data safety and monitoring board (DSMB) periodically reviewed data generated by the AVERT. CR 3176. On January 21, 2000, the DSMB concluded the preliminary data from AVERT indicated that a very small percentage of the patients with the Silzone® valve had an equally small, but statistically significant, increased incidence of explant due to paravalvular leak. CR 3177-78. That same day, St. Jude Medical began a voluntary world-wide recall of all unimplanted Silzone® products.[4] *Id.*

Following St. Jude Medical's voluntary recall, the FDA audited the company but never recommended any change to the company's voluntary recall plan or took formal regulatory action. CR 535-40 ("Current inspection was prompted by a voluntary recall of all unimplanted heart valves with silver ion (silzone) impregnated sewing cuffs . . . . No FDA 483 was issued to this firm. It appears that St. Jude responded quickly to the outcomes of the [redacted] study"); CR 3178. The FDA also never took any of the steps needed to formally revoke approval for the Silzone® valve described in 21 C.F.R. § 814.46. Two FDA officials wrote statements, referred to in this case as the "Dee letter" and "Fitzgerald memo," indicating the company's action met "the formal definition of a 'Recall'" and was in lieu of FDA "legal action to remove the defective products from the market." Pet. App. 38a; *see also* Pet. App. 5a-6a. At the same time, the FDA's position on

[4] In connection with this voluntary recall effort, St. Jude Medical alerted the FDA and also sent overnight alert letters to those cardiac surgeons and other physicians known to use its products. CR 3177-78; *see also* CR 1334-43. Those letters asked the recipients to stop using the Silzone® valve and to return any unimplanted Silzone® products. CR 3177-78; *see also* CR 1334-43.

already-implanted valves was that normal monitoring was sufficient to detect the relatively low-risk occurrence reported in the AVERT study. CR 604, 619-23.

Petitioners Keith Baker and Ian Baker filed a lawsuit in Probate Court Number One of Harris County, Texas claiming that their mother's death resulted from negligent care provided by her physicians. CR 925. They also alleged several common law product liability theories and a statutory deceptive trade practices claim (Tex. Bus. & Com. Code Ann. § 17.01 *et seq.* (Vernon 2002 & Supp. 2006)) against St. Jude Medical. CR 946-48. Each of petitioners' claims alleged the heart valve is "an unreasonably dangerous and defective" medical device that should have been manufactured and marketed with a design and label different from the one the FDA approved and required St. Jude Medical to use. *See* CR 947.

St. Jude Medical moved for summary judgment arguing that both express and implied preemption barred the common law and statutory claims. CR 2788-2812. Because the record established the requisite PMA and PMA supplement approval of the Silzone®-coated sewing cuff (CR 1019-1048), the probate court granted summary judgment (Pet. App. 21a). It also upheld several of St. Jude Medical's evidentiary objections and excluded the salient portions of the Dee letter (Pet. App. 37a-41a), and the Fitzgerald memo (Pet. App. 33a-36a). Opp'n App. 1a-2a, 8a. The probate court later denied petitioners' new trial motion and renewed evidentiary arguments. CR 4362.

Afterward, St. Jude Medical also successfully moved for summary judgment on the claims of an additional 69 plaintiffs in a coordinated state court proceeding in Harris County, Texas involving the same Silzone® heart valve. *See* Opp'n App. 9a, 21a-24a (*In re Heart Valve Litigation*, 2005 WL 1541059 (Tex. App. June 30, 2005)).

Petitioners in this case then appealed (CR 4363), and the 69 plaintiffs in the coordinated Texas proceeding filed a companion appeal. The court of appeals affirmed summary judgment both in this case and in the companion appeal, and published its decision in this case. Pet. App. 1a-20a; Opp'n App. 9a-24a. It did not disturb the probate court's exclusion of the Dee letter (Pet. App. 37a-41a), or the Fitzgerald memo (Pet. App. 33a-36a) excerpts. *See* Pet. App. 5a-6a & n.4. It also affirmed on both express and implied preemption grounds. *See id.* at 16a-17a (affirming judgment for St. Jude Medical on negligence, product liability and Texas Deceptive Trade Practices Act claims on express preemption grounds); *id.* at 17a-20a (affirming judgment for St. Jude Medical on fraud claim on implied preemption grounds).

In affirming, the court of appeals expressly recognized that, pursuant to 21 C.F.R. § 814.46, the FDA must follow a formal process to withdraw premarket approval, and that it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. at 6a.

The court of appeals denied petitioners' motion for rehearing on February 8, 2006. Opp'n App. 25a-26a. Petitioners here then sought discretionary review by the Texas Supreme Court, although the 69 plaintiffs in *In re Heart Valve Litigation* did not. After the parties filed merits briefs, the Texas Supreme Court denied review in this case on December 15, 2006. Pet. App. 22a.[5]

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[5] In one place, the petition states that "[t]hese issues were appealed directly by the petitioners to the Texas Supreme Court." Pet. 5. But in fact the Texas Supreme Court denied petitioners' discretionary petition for review after full merits briefing on issues such as whether the court of appeals' opinion in this case was a faithful application of the Texas Supreme Court's precedent, *Worthy*, 967 S.W.2d 360. *See* Pet. App. 22a, 110a-112a.

REASONS FOR DENYING THE PETITION

A. The Petition Incorrectly Represents The Record Regarding The Status Of FDA Approval For The Medical Device In Question

The federal regulations provide one avenue by which the FDA may withdraw premarket approval: it must issue formal notice to the medical device manufacturer, hold a hearing, and offer an appeal process. *See* 21 C.F.R. § 814.46. The Texas court of appeals recognized no such steps were taken for the Silzone® device, and thus it was undisputed "that the FDA never formally withdrew its PMA approval of the valve, and the valve had FDA approval on the date it was implanted in Baker." Pet. App. 6a; *cf.* Opp'n App. 44a (Solicitor General's amicus brief in *Riegel*, describing statutory requirements for FDA to withdraw premarket approval and stating "[w]here the FDA has not taken such action, its approval of the PMA – and the 'requirements' that result from that approval – remain in effect.").

At best, the petition mischaracterizes the appellate court's statement that it was undisputed the FDA never formally withdrew approval. It represents in one place that the Texas court of appeals merely "implied that the Silzone-coated valves must still be FDA-approved" and suggests it was "clearly . . . incorrect" in reaching that conclusion. Pet. 10.

More often, however, the petition represents this case as unequivocally involving the opposite circumstance – that the Silzone® valve undisputedly lost approval – without any acknowledgement of the probate court's contrary evidentiary finding. *See* Pet. 1 ("suppose a particular device is no longer FDA-approved?"); 12 ("Preemption When the Product is No Longer FDA-Approved" and "this product is no longer approved by the FDA"); 13 ("the product no longer has FDA approval").

To make these assertions, petitioners construct an argument based upon the Dee letter and Fitzgerald memo (Pet. 9-11), yet never once acknowledge that those documents were excluded by the probate court, or that their exclusion was left undisturbed by the Texas court of appeals (Pet. App. 5a-6a & n.4, 11a n.5). This omission is not a minor one, given that half the petition is premised on the Dee letter and Fitzgerald memo and results in petitioners' argument that certiorari is warranted because the lower courts upheld preemption for a device that was not FDA-approved.

There is no reason for this Court to grant certiorari to address a putative legal issue not supported by the record in this case. *See* S. Ct. R. 14.4 ("The failure of a petitioner to present with accuracy, brevity, and clarity whatever is essential to ready and adequate understanding of the points requiring consideration is sufficient reason for the Court to deny a petition."). There also is no reason for this Court to grant certiorari to address the propriety of the probate court's evidentiary ruling. *See* S. Ct. R. 10 ("A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings.").

B. There Is No Split Of Authority Regarding Preemption Involving Medical Devices That Allegedly Lost FDA Approval After Implantation

Even without petitioners' fundamental record problem, the grounds for denying certiorari are ample. According to petitioners, the "opinion of the Texas Court of Appeals is the only published appellate opinion in this country in which a court has directly addressed" the issue of whether preemption applies when a "product is no longer approved by the FDA." Pet. 12. On its face, this question presents no split in authority that can traditionally provide a "compelling reason" under Rule 10 for review.

The vast majority of courts—and *all* recent appellate decisions—have found that premarket approval and the resultant bar on changes to an FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. *See, e.g.*, Pet. App. 11a-16a; *Riegel v. Medtronic Corp.*, 451 F.3d 104 (2d Cir. 2006); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 487–88 (7th Cir. 2005); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn v. Thoratec Corp.*, 376 F.3d 163, 171–73 (3d Cir. 2004); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226–27 (6th Cir.); *Mitchell*, 126 F.3d at 911 (7th Cir.); *Worthy*, 967 S.W.2d at 376 (Tex.); *Fry v. Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to these decisions, petitioners identify (at Pet. 1) – but never discuss – an outdated federal court of appeals decision that did not find premarket approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). The decision in *Goodlin*, which arises on facts different from those presented here, is not reflective of the current state of law and is no threat to the stability of the prevailing authority in the Texas state courts or elsewhere.[6]

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[6] Petitioners also identify one unpublished interlocutory district court order that involved the same medical device as this case and did not find the PMA and PMA supplement process preemptive, *In re St. Jude Medical, Inc., Silzone Heart Valves Prods. Liab. Lit.*, 2004 U.S. Dist. LEXIS 148 (D. Minn. Jan. 5, 2004) (MDL No. 01-1396). (Pet. App. 42a, 77a). But they do not contend that this order is of any significance in terms of a split of authority (Pet. 7-10), nor could they given the order's interlocutory nature and the fact it is only a trial court order that has not yet received appellate review. *See* S. Ct. R. 10 (identifying other compelling circumstances where review is warranted).

In the eight years since *Goodlin* was decided, no other court of appeals and no other state supreme court has joined the Eleventh Circuit. Given the legal and administrative developments in the meantime, there is reason to believe that the Eleventh Circuit will correct itself. *See* Opp'n App. 51a-52a.

The appellate court's decision in this case also does not conflict with this Court's precedent *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). Petitioners argue that "it is not entirely clear" after *Bates* "when requirements might be deemed imposed by state court suits so as to run afoul of preemption provisions." Pet. 25. But once again, the vast majority of lower courts, and *all* courts to have considered the issue recently, have held that, under the MDA, state tort claims can be preempted. *See, e.g.*, Pet. App. 7a-11a; *McMullen*, 421 F.3d at 487; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–77; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–14; *Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–77; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–18.

Similarly, petitioners contend that "*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." Pet. 25. But in *Bates*, this Court held that the term "requirements" in the identically-worded Federal Insecticide, Fungicide, and Rodenticide Act includes common law claims. *Bates*, 544 U.S. at 443. This issue thus is also well settled.[7] *See* Opp'n App. 44a-45a (Solicitor

[7] As the FDA explained through the Solicitor General, during the PMA process it conducts "a thorough review of a substantial scientific record" (Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *16 (3d Cir. May 14, 2007) (No. 02-4597)) and performs a "careful balancing" of the benefits and risks associated with a particular

General acknowledging that this Court has consistently held state common law actions can create state "requirements").

Whatever petitioners' confusion about the state requirement side of the preemption analysis, it is not reflected in any recent circuit or state high court decision. There also is no conflict between the appellate court's position and this Court's *Bates* decision. The result reached below likewise comports with the prevailing administrative construction of the pertinent regulatory scheme. Finally, as the FDA has emphasized, "very strong public policy considerations" support application of preemption principles to state common law claims involving Class III medical devices. Brief for the United States as Amicus Curiae, *Horn v. Thoratec*, 2004 WL 1143720, at *25 (3d Cir. May 14, 2007) (No. 02-4597). According to the FDA—the agency charged with implementing the MDA—"the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application." Opp'n App. 45a.

CONCLUSION

The petition at bottom asks this Court to revive and resolve a state law evidentiary dispute that does not present a reason to grant certiorari and was not preserved for appeal. Beyond that, it asks this Court to set a Texas court on its proper course without any showing that the preemption principles applied are in need of correction. Even as to the result reached, an examination of the recent and controlling case

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device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.

law reveals no material conflict in the application of established preemption principles to this unique set of facts. For each of these reasons, the petition should be denied.

Respectfully submitted,

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