

No. 06-0223

---

**In the Supreme Court of Texas**

---

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

***PETITIONERS,***

***VS.***

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

***RESPONDENTS.***

---

**PETITIONERS' BRIEF ON THE MERITS**

---

**On Appeal from No. 01-02-00802-CV  
Court of Appeals for the First District of Texas**

---

**RILEY LAW FIRM**

Tim Riley  
State Bar No. 16931300  
The Civil Justice Center  
112 E. 4<sup>th</sup> St.  
Houston, Texas 77007-2502  
(713) 646-1000 Telephone  
(800) 637-1955 Telecopier  
E-mail: [tdr@txtrial.com](mailto:tdr@txtrial.com)

**PIANELLI LAW FIRM**

James V. Pianelli  
State Bar No. 15966740  
The Civil Justice Center  
112 E. 4<sup>th</sup> St.  
Houston, Texas 77007-2502  
(713) 864-3333 Telephone  
(800) 637-1955 Telecopier  
E-mail: [jvp1000@aol.com](mailto:jvp1000@aol.com)

***Attorneys for Petitioners***

No. 06-0223

**In the Supreme Court of Texas**

---

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

***PETITIONERS,***

***VS.***

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

***RESPONDENTS.***

---

**IDENTITY OF PARTIES AND COUNSEL**

***Petitioners:***

Keith Baker, Individually

Ian Baker, Independently and as Executor of the Estate of Jean Baker, deceased

***Petitioners' Counsel:***

Tim Riley (Trial and Appellate Counsel)

RILEY LAW FIRM

The Civil Justice Center

112 E. 4<sup>th</sup> St.

Houston, TX 77007-2502

James V. Pianelli (Trial and Appellate Counsel)

PIANELLI LAW FIRM

The Civil Justice Center

112 E. 4<sup>th</sup> St.

Houston, TX 77007-2502

Jack E. McGehee (Trial Counsel only)  
MCGEHEE & WACHSMAN  
1225 N. Loop W., Ste. 810  
Houston, TX 77008

***Respondents:***

St. Jude Medical, S.C., Inc.

St. Jude Medical, Inc.

***Respondents' Counsel:***

Mr. Joe W. Redden, Jr. (Trial and Appellate Counsel)  
BECK, REDDEN & SECREST  
1221 McKinney, Suite 4500  
Houston, Texas 77010-2010

Mr. David Gunn (Appellate Counsel only)  
BECK, REDDEN & SECREST  
1221 McKinney, Suite 4500  
Houston, Texas 77010-2010

Steven M. Kohn (Appellate Counsel only)  
James C. Martin  
Lisa M. Baird  
CROSBY, HEAFEY, ROACH & MAY  
355 South Grand Ave., Ste. 2900  
Los Angeles, California 90071

No. 06-0223

In the Supreme Court of Texas

---

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

*PETITIONERS,*

*VS.*

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

*RESPONDENTS.*

---

TABLE OF CONTENTS

Identity of Parties and Counsel .....	i
Table of Contents .....	iii
Index of Authorities .....	vi
Statement of the Case .....	xi
Statement of Jurisdiction .....	xii
Issues Presented .....	xii
Statement of Facts .....	1
Summary of the Argument .....	11
Argument .....	13
Argument and Authorities Under Issue 1 .....	13

Issue 1: Should claims involving Silzone-coated valves by Texas citizens filing suit in Texas state courts be deemed preempted by federal law when identical claims under the laws of all states have been deemed not preempted in the federal courts?

Argument and Authorities Under Issues 2-6 ..... 19

Issue 2: If the FDA has determined that a product is “defective,” “adulterated,” “misbranded,” and appropriate for an FDA seizure action, are state court civil lawsuits alleging the product is defective somehow nonetheless preempted?

Issue 3: In determining whether FDA approval preempts civil lawsuits, should the courts look at whether the product was FDA-approved when it left the hands of the manufacturer or at the time of judgment in the state court suit?

Issue 4: Does the recent United States Supreme Court opinion in *Bates v. Dow Agrosciences, LLC*, preclude preemption of civil tort suits under the MDA?

Issue 5: Are all medical devices that have ever been PMA- or PMA Supplement-approved by the FDA automatically and forever exempt from all civil liability merely because the FDA approval implied a (now null and void) finding that the device was “safe,” without the necessity of the reviewing court going through the specific approval/allegation analysis mandated by the United States Supreme Court in *Medtronic, Inc. v. Lohr*, and by this Court in *Worthy v. Collagen Corp.*?

Issue 6: Was the now null and void FDA approval of the medical device in dispute, under an abbreviated PMA Supplement application, sufficiently rigorous and specific in its requirements under *Worthy* so as to preempt all civil lawsuits arising from the use of the admittedly defective product?

A.	The “Once-Upon-a -Time” Defense .....	20
B.	The Medical Device Amendments .....	22
1.	Legislative Background .....	22
2.	Device Classification .....	23
3.	State Regulatory Efforts and Preemption under the MDA .....	26
C.	Preemption .....	26
1.	Types of Preemption .....	26
2.	Inapplicability of Implied Field Preemption .....	29
3.	<i>Bates v. Dow Agrosciences, LLC</i> , and the Necessity of Conflicting Federal Regulation under Express and Implied Conflict Preemption Doctrines .....	32
4.	<i>Medtronic, Inc. v. Lohr</i> .....	36
5.	<i>Worthy v. Collagen Corporation</i> .....	40
6.	<i>Worthy Applied</i> .....	41
D.	Impact of Current <i>Baker</i> Opinion .....	42
	Argument and Authorities Under Issue 7 .....	47
	Issue 7: Can a manufacturing defect claim be dismissed on summary judgment under a claim of federal preemption and without being raised in the summary judgment motion?	
	Prayer .....	48
	Signature .....	49
	Certificate of Service .....	49
	Appendices:	
	<i>In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation</i> , MDL No. 01-1396. 2004 U.S. Dist. LEXIS 148, at * 2 (D. Minn. January 5, 2004) .....	A

In the Supreme Court of Texas

---

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

*PETITIONERS,*

*VS.*

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

*RESPONDENTS.*

---

INDEX OF AUTHORITIES

---

**Constitutions:**

Article VI, Clause 2, UNITED STATES CONSTITUTION . . . . . 26

**Statutes:**

7 U.S.C. § 136 . . . . . 34

21 U.S.C. § 331(a) . . . . . 9

21 U.S.C. § 351(e) . . . . . 7

21 U.S.C. § 352(j) . . . . . 7

21 U.S.C. § 355(d) . . . . . 45

21 U.S.C. § 360c . . . . . 23

21 U.S.C. § 360c(a)(1)(A) . . . . . 23

21 U.S.C. § 360c(a)(1)(B) . . . . . 23

21 U.S.C. § 360c(a)(1)(C) .....	23
21 U.S.C. § 360e(d)(2) .....	25, 43
21 U.S.C. § 360e(e)(1) .....	8
21 U.S.C. § 360k(a) .....	14, 20, 28, 31, 33, 37, 47
21 U.S.C. § 393(b)(2)(B) .....	45
42 U.S.C. § 300aa-1 .....	28
42 U.S.C. § 2210 .....	28
49 U.S.C. § 40101 .....	28
28 U.S.C. § 1407 .....	13
Tex. Gov't Code § 22.001(a)(6) .....	x

**Cases:**

<i>Baker v. St. Jude Medical, S.C., Inc.</i> , 178 S.W.3d 127 (Tex.App.-Houston [1 <sup>st</sup> Dist.] 2005, pet. filed) .....	x, <i>passim</i>
<i>Bates v. Dow Agrosciences, LLC</i> , 544 U.S. 431 (2005) .....	12, <i>passim</i>
<i>Brooks v. Howmedica, Inc.</i> , 273 F.3d 785 (8th Cir. 2001) .....	37, 39
<i>Buckman v. Plaintiffs' Legal Committee</i> , 531 U.S. 341 (2001) .....	14, 15, 16, 17, 21, 22, 30, 31, 32
<i>Camps Newfound/Owatonna, Inc. v. Town of Harrison</i> , 520 U.S. 564 (1997) .....	29
<i>Cartwright v. Pfizer, Inc.</i> , 369 F.Supp. 876 (E.D. Tex. 2005) .....	45
<i>Celadon Trucking Servs. v. Titan Textile Co.</i> , 130 S.W.3d 301 (Tex.App.-Houston [14 <sup>th</sup> Dist.] 2004, pet. denied) .....	19
<i>Cipollone v. Liggett Group, Inc.</i> , 505 U.S. 504 (1992) .....	27, 30, 33, 35
<i>Comeau v. Heller</i> , 945 F.Supp. 7 (D. Mass. 1996) .....	40
<i>Crosby v. Nat'l Foreign Trade Council</i> , 530 U.S. 363 (2000) .....	27

<i>Dow Agrosciences, LLC v. Bates</i> , 332 F.3d 323 (5 <sup>th</sup> Cir. 2003), <i>rev'd</i> , 544 U.S. 431 (2005) .....	34
<i>English v. General Elec. Co.</i> , 496 U.S. 72 (1990) .....	26, 27, 29
<i>Ex Parte Garcia</i> , 560 S.W.2d 948 (Tex. Crim. App. 1978) .....	18
<i>Fidelity Federal Sav. And Loan Ass'n. v. de la Cuesta</i> , 458 U.S. 141 (1982) .....	27
<i>Gade v. National Solid Wastes Mgmt. Ass'n</i> , 505 U.S. 88 (1992) .....	26, 27, 29, 46
<i>Goodlin v. Medtronic, Inc.</i> , 167 F.3d 1367 (11th Cir. 1999) .....	39, 40
<i>Haase v. Glazner</i> , 62 S.W.3d 795 (Tex. 2001) .....	48
<i>Haidak v. Collagen Corp.</i> , 67 F.Supp.2d 21 (D. Mass. 1999) .....	40
<i>Hawkins v. Leslie's Pool Mart, Inc.</i> , 184 F.3d 244 (3d Cir. 1999) .....	26
<i>Hill v. Searle Labs.</i> , 884 F.2d 1064 (8 <sup>th</sup> Cir. 1989) .....	45
<i>Hillsborough Co., Fl. v. Automated Med. Labs, Inc.</i> , 471 U.S. 707 (1985) .....	27
<i>Horn v. Thoratec</i> , 376 F.3d 163 (3d Cir. 2004) .....	24, 33
<i>In re Grand Jury Subpoena</i> , 220 F.R.D. 130 (D. Mass. 2004) .....	9
<i>In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation</i> , No. 1396, 2001 U.S. Dist. LEXIS 5226 (J.P.M.L. April 18, 2001) .....	13
<i>In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation</i> , MDL No. 01-1396. 2004 U.S. Dist. LEXIS 148 (D. Minn. January 5, 2004) .....	4, <i>passim</i>
<i>Jones v. Rath Packing Co.</i> , 430 U.S. 519 (1977) .....	27
<i>Kemp v. Medtronic, Inc.</i> , 231 F.3d 216 (6 <sup>th</sup> Cir. 2000) .....	27
<i>Lakie v. SmithKline Beecham</i> , 965 F.Supp. 49 (D. D.C. 1997) .....	40
<i>Little v. Texas Dep't of Criminal Justice</i> , 148 S.W.3d 374 (Tex. 2004) .....	18
<i>Malone v. White Motor Corp.</i> , 435 U.S. 497 (1978) .....	46
<i>McConnell v. Southside Ind. School Dist.</i> , 858 S.W.2d 337 (Tex. 1993) .....	48

<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996) .....	3, <i>passim</i>
<i>Nixon v. Mr. Property Mgmt. Co.</i> , 690 S.W.2d 546 (Tex. 1985) .....	1
<i>Quillin v. American Hosp. Supply Co.</i> , No. 94-C-1020-BU, 1997 U.S. Dist. LEXIS 6974, 1997 WL 382095 (N.D. Ok., March 31, 1997) .....	40
<i>Public Util. Comm'n v. Cofer</i> , 754 S.W.2d 121 (Tex. 1988) .....	47
<i>Retail Clerks v. Schermerhorn</i> , 375 U.S. 96 (1963) .....	46
<i>Rice v. Norman Williams Co.</i> , 458 U.S. 654 (1982) .....	20
<i>Rice v. Santa Fe Elevator Corp.</i> , 331 U.S. 218 (1947) .....	27
<i>Riegel v. Medtronic Corp.</i> , 451 F.3d 104 (2d Cir. 2006) .....	29, 33
<i>Silkwood v. Kerr-McGee Corp.</i> , 464 U.S. 238 (1984) .....	15, 29
<i>Sowell v. Bausch &amp; Lomb, Inc.</i> , 230 A.D.2d 77, 656 N.Y.S.2d 16, 21 (N.Y. App. Div. 1997) .....	40
<i>Sprietsma v. Mercury Marine</i> , 537 U.S. 51 (2002) .....	29
<i>United States v. Superharm Corp.</i> , 530 F.Supp. 408 (E.D. NY. 1981) .....	7, 9
<i>Webster v. Pacesetter, Inc.</i> , 171 F.Supp.2d 1 (D.D.C. 2001) .....	40
<i>Weiland v. Telectronics Pacing Sys., Inc.</i> , 721 N.E.2d 1149 (Ill. 1999) .....	40
<i>Woods v. Gliatech, Inc.</i> , 218 F. Supp.2d 802 (W.D. Va. 2002) .....	40
<i>Worthy v. Collagen Corp.</i> , 967 S.W.2d 360 (Tex. 1998) .....	11, <i>passim</i>

**Rules:**

21 C.F.R. § 7.40(a) .....	7, 9
21 C.F.R. § 7.41(a) .....	7
21 C.F.R. §§ 7.45(a) .....	7, 8, 9
21 C.F.R. § 7.46(a) .....	8

21 C.F.R. § 314.105(c) . . . . .	45
21 C.F.R. § 803.10(c)(1) . . . . .	4, 7
21 C.F.R. § 808.1(d) . . . . .	16
21 C.F.R. § 814.3(g) . . . . .	25
21 C.F.R. § 814.47(2) . . . . .	7
21 C.F.R. § 814.82(a)(9) . . . . .	4
21 C.F.R. § 870.3925 . . . . .	23
21 C.F.R. § 895.1 . . . . .	7
Tex. R. App. Proc. 55.2(g) . . . . .	1

**Secondary Authorities:**

<i>Current Developments, MDL No. 01-1396,</i> <a href="http://www.mnd.U.S.C.courts.gov/Tunheim_Mdl/current_developments.htm">www.mnd.U.S.C.courts.gov/Tunheim Mdl/current_developments.htm</a> . . . . .	18
FDA, <i>Device Evaluation Information, What We Do</i> (2002), <a href="http://www.fda.gov/cdrh/ode/whatwedo.html">www.fda.gov/cdrh/ode/whatwedo.html</a> . . . . .	26
FDA, <i>Panel Review for Premarket Approval Applications, May 3, 1996, (P91-2),</i> <a href="http://www.fda.gov/cdrh/p91-2.html">http://www.fda.gov/cdrh/p91-2.html</a> . . . . .	24
Fischell, R.E., <i>Regulatory Concerns and Issues: Have the Bureaucrats Won?</i> , 13 J. INVASIVE CARDIOL. 139-40 (2001) . . . . .	25
<i>Manual for Complex Litigation</i> § 31.133 (3d ed. 1995) . . . . .	19
<i>MedicineNet.com Medical Dictionary,</i> <a href="http://www.medterms.com/script/main/art.asp?articlekey=11065">http://www.medterms.com/script/main/art.asp?articlekey=11065</a> . . . . .	2
Vladeck, D., <i>Symposium: Federal Preemptions of State Tort Law: The Problem of Medical Drugs and Devices: Preemption and Regulatory Failure</i> , 33 Pepp. L. Rev. 95 (2005) . . . . .	46
Yustein, A., <i>The FDA's Process of Regulatory Premarket Review for New Medical Devices,</i> <a href="http://www.gastro.org/user-assets/Documents/08_Publications/06_GIHep_Annual_Review/Articles/Yustein.pdf#search=%22does%20pma%20approval%20usually%20require%20human%20clinical%20trials%22">http://www.gastro.org/user-assets/Documents/08_Publications/06_GIHep_Annual_Review/Articles/Yustein.pdf#search=%22does%20pma%20approval%20usually%20require%20human%20clinical%20trials%22</a> . . . . .	24

**No. 06-0223**

**In the Supreme Court of Texas**

---

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

***PETITIONERS,***

***VS.***

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

***RESPONDENTS.***

---

**STATEMENT OF THE CASE**

This is a suit for monetary damages, arising under theories of negligence, products liability, breach of warranty, and violations of the Texas DTPA. The petitioners, plaintiffs below, are Keith Baker, individually, and Ian Baker, individually and on behalf of the estate of Keith and Ian's deceased mother, Jean Baker. The respondents, defendants below, are two closely-related Minnesota manufacturers, St. Jude Medical, S.C., Inc., and St. Jude Medical, Inc. (hereinafter collectively "SJM"). On April 25, 2002, Hon. Russell Austin, Probate Court Number One of Harris County, Texas, entered summary judgment in favor of SJM in Cause No. 312,543-402 (later severed into Cause No. 312,543-402-A). The plaintiffs appealed.

On June 30, 2006, the First Court of Appeals issued its opinion and judgment in Cause No. 01-02-00802-CV, affirming the summary judgment decision of the trial court in favor of SJM.

*Baker v. St. Jude Medical, S.C., Inc.*, 178 S.W.3d 127 (Tex.App.-Houston [1<sup>st</sup> Dist.] 2005, pet. filed).

The participating justices were Chief Justice Radack and Justices Jennings and Higley.

### STATEMENT OF JURISDICTION

The Supreme Court has jurisdiction over this appeal because the court of appeals has committed an error of law of such importance to the state's jurisprudence that it should be corrected.

Tex. Gov't Code § 22.001(a)(6).

### ISSUES PRESENTED

- Issue 1: Should claims involving Silzone-coated valves by Texas citizens filing suit in Texas state courts be deemed preempted by federal law when identical claims under the laws of all states have been deemed not preempted in the federal courts?
- Issue 2: If the FDA has determined that a product is “defective,” “adulterated,” “misbranded,” and appropriate for an FDA seizure action, are state court civil lawsuits alleging the product is defective somehow nonetheless preempted?
- Issue 3: In determining whether FDA approval preempts civil lawsuits, should the courts look at whether the product was FDA-approved when it left the hands of the manufacturer or at the time of judgment in the state court suit?
- Issue 4: Does the recent United States Supreme Court opinion in *Bates v. Dow Agrosciences, LLC*, preclude preemption of civil tort suits under the MDA?
- Issue 5: Are all medical devices that have ever been PMA- or PMA Supplement-approved by the FDA automatically and forever exempt from all civil liability merely because the FDA approval implied a (now null and void) finding that the device was “safe,” without the necessity of the reviewing court going through the specific approval/allegation analysis mandated by the United States Supreme Court in *Medtronic, Inc. v. Lohr*, and by this Court in *Worthy v. Collagen Corp.*?
- Issue 6: Was the now null and void FDA approval of the medical device in dispute, under an abbreviated PMA Supplement application, sufficiently rigorous and specific in its requirements under *Worthy* so as to preempt all civil lawsuits arising from the use of the admittedly defective product?
- Issue 7: Can a manufacturing defect claim be dismissed on summary judgment under a claim of federal preemption and without being raised in the summary judgment motion?

## STATEMENT OF FACTS

For the most part, the court of appeals correctly stated the nature of the case. However, the court made some errors with regard to the nature of the claims asserted. The court also omitted numerous material facts relied on by the petitioners. Accordingly, pursuant to Tex. R. App. Proc. 55.2(g), the petitioners respectfully present the following particularized facts to correct and supplement the factual summary by the court below.<sup>1</sup>

In 1999 in Houston, Texas, Jean Baker, the 65 year old mother of Ian and Keith Baker, was suffering from symptoms of advanced congestive heart failure. She sought medical care from her cardiologist, Dr. Salah El Hafi. Dr. El Hafi determined that Ms. Baker had a severely leaking cardiac mitral valve, which was causing her problems.<sup>2</sup> CR 928-29.

Fortunately, prosthetic mitral valves are readily available on the market to correct this malady. Because this requires open heart surgery, Dr. El Hafi referred Ms. Baker to a cardiovascular surgeon, Dr. Jim Garza. Dr. Garza concurred with Dr. El Hafi's diagnosis and, in November 1999, Dr. Garza performed valve replacement surgery on Ms. Baker. CR 929.

---

<sup>1</sup> Some of these facts are contested, of course, by SJM. However, for the purposes of this summary judgment review, a reviewing court is obligated to presume the truth of the allegations in the plaintiffs' petition and indulge in all reasonable inferences from the summary judgment evidence in favor of the non-movants. *Nixon v. Mr. Property Mgmt. Co.*, 690 S.W.2d 546, 548-49 (Tex. 1985).

<sup>2</sup> By way of contextual background only, the mitral valve, a one-way valve, allows blood to pass from the heart's left atrium to its left ventricle. During the heart's resting stage the valve naturally closes. However, if the valve does not completely close (usually due to congenital problems, disease, degeneration, or infection), blood regurgitates through the partially open valve, back into the left atrium. This causes cardiac congestion, making it harder for the heart to pump and thus reducing cardiac output, known as congestive heart failure (CHF). The symptoms of CHF include severe fatigue (due to reduced cardiac output), shortness of breath, lower extremity swelling, and jugular venous distention. If untreated or inadequately treated, patients with valve disease are reduced to a sedentary lifestyle and often an eventual cardiac insufficiency death. *See, generally*, CR 54, 1186.

For the procedure Dr. Garza selected a market-leading SJM prosthetic mitral valve. CR 2834-35. This particular valve was made of pyrolytic carbon, with an attached fabric sewing cuff. CR 2832-33. The sewing cuff is sutured to the wall of the heart after the diseased native valve has been removed surgically. CR 2819 n.3. Once sewed in place the prosthetic valve acts virtually identically to the one-way operation of a non-leaking native valve, and thus is designed to eliminate or significantly reduce CHF and its symptoms. CR 2823-25.

After the implant Ms. Baker initially improved sufficiently to be discharged from the hospital. Tragically, though, thereafter Ms. Baker's CHF symptoms did not continue to improve. In fact, Ms. Baker deteriorated to a cachectic state.<sup>3</sup> In her drawn and wasted condition, Jean Baker finally died three months later, in February 2000.

Before she died, neither Ms Baker nor her sons knew why she continued to waste away after her successful valve replacement surgery. CR 930-32. However, a post-mortem examination was performed. Examination of Ms. Baker's heart revealed that she died as a result of the resumption and progression of her CHF, exactly what the valve was designed to correct. This occurred because Ms. Baker developed a large hole in her heart, a "paravalvular leak," immediately adjacent to where the SJM valve sewing cuff was sutured to her heart muscle wall. CR 930-32, 1415-27.

Unbeknownst to Dr. Garza was that the SJM valve he implanted into Ms. Baker was very different from those he had used successfully for several years. Dr. Garza learned after Ms. Baker's death that Ms. Baker had received an SJM valve with a significant modification made in 1998. The

---

<sup>3</sup> "Cachexia: Physical wasting with loss of weight and muscle mass caused by disease. Patients with advanced cancer, AIDS, and some other major chronic progressive diseases may appear cachectic. Cachexia is a wasting syndrome that causes weakness and a loss of weight, fat, and muscle." *See, MedicineNet.com Medical Dictionary*, <http://www.medterms.com/script/main/art.asp?articlekey=11065>.

modification was the addition of a thin silver coating to the sewing cuff. CR 1401-03.

The original SJM prosthetic mitral valve went through the full and rigorous PMA process to obtain FDA approval for sale in 1982. CR 2833. The “Masters Series” of the valve added the fabric sewing cuff, and it was approved in 1995. CR 2818, 2833.

The development of endocarditis, a cardiac infection, was (and remains), 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 the Masters Series valve with what SJM called a “Silzone” coating. CR 1096-1104.

The procedures employed by the FDA in considering a PMA Supplement application are significantly less rigorous than when a full PMA is considered. In fact, the PMA Supplement approval process in general is much closer to the “grandfather” 510k process than the full PMA approval process.<sup>4</sup> CR 1098-1103.

The Silzone-coated valve was allowed to proceed under a more abbreviated process than was normally allowed 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. No human

---

<sup>4</sup> A medical device can be approved for sale merely by showing that the proposed product is “substantially equivalent” to a device already on the market prior to 1976, the date the federal government began regulating medical devices. This “grandfather process” is known as a “510k application,” named after a section in the original act. It is well-settled that a 510k approval cannot give rise to a preemption claim under any circumstance. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-78, 494 (1996). Refer to pages 22-26, *infra*.

studies were considered or required by the FDA. CR 1086, 1104.

With regard to animal studies, the FDA stipulates in published guidelines applicable to prosthetic heart valves that at least 6 of the subject animals must be allowed to survive at least 20 weeks, to ensure no late reactions. CR 1089-90, 1099, 1104. The FDA initially required compliance from SJM with this guideline. However, SJM asked to be allowed to cut short the required animal studies, and the FDA acquiesced. CR 66-67. Thus, for the Silzone PMA Supplement a shortcut animal study, which sacrificed the subject animals only 10 weeks after implant (70 days), was followed. CR 1088-90, 1099, 1104.

*In short, despite SJM's vociferous protestations to the contrary in this proceeding, there is a blatant admission – directly from SJM in the FDA public filings – that: “the St. Jude Medical Master Series Silzone-coated heart valve was approved on a Pre-Market Application (PMA) Supplement, without extensive clinical testing.”* CR 1197 (emphasis added).

The FDA approved the PMA Supplement for the addition of the silver coating to the SJM Masters Series prosthetic mitral valve on March 30, 1998. CR 1062. However, because SJM was not able to demonstrate that the silver coating had any efficacy whatsoever in reducing endocarditis, the FDA prohibited SJM from marketing the product with any such claims.<sup>5</sup> CR 1091.

---

<sup>5</sup> Other continuing conditions on approval also were imposed. Specifically, there was an express condition that SJM closely track the recipients and very timely report any adverse events to the FDA. CR 1061-79, 1081, 2907-08. Indeed, any adverse reaction, side effect, or injury attributable to the device was required, as a continuing condition of approval, to be reported to the FDA within 10 days. 21 C.F.R. § 814.82(a)(9); CR 2910. Moreover, SJM was required to report within 30 days any injury or death in which the newly-approved valve *may* have been a causative or contributing factor. 21 C.F.R. § 803.10(c); CR 2911. Contrary to those conditions, on November 22, 1999, around the same time as Ms. Baker's implant, the Silzone-coated valves were placed under a "Medical Advisory" in the United Kingdom (the equivalent of a recall in the United States), for problems associated with excess

However, because the company still wanted to market the product as reducing endocarditis, SJM sponsored a multi-center, post-approval, human study to attempt to determine efficacy. This trial was known as the Artificial Valve Endocarditis Reduction Trial, or "AVERT." CR 1074, 2847. This was the first human study on the product designed to determine product safety, and it was not started until *after* the product was released on the market by SJM.<sup>6</sup>

Since it is required by federal law for such human clinical studies, the patients in the AVERT were required to be informed that the Silzone-coated devices they were to receive were only experimental with regard to any alleged benefit over their predecessors. They were also required to be informed that they were among the first humans to receive and test the product. CR 1101.

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

---

clotting. CR 1098. There is no record that SJM ever timely reported this significant British recall event to the FDA in accordance with the conditions for continuing approval. CR 1098, 1105-1395.

<sup>6</sup> This suit arises because the defective Silzone coating caused Ms. Baker's lethal paravalvular leak. CR 1415-27. There was one very small European clinical trial prior to the release of Silzone. But this limited study was designed only to determine whether there was any detectable leached silver in the patients' blood. CR 1203. Of the 38 study patients who received the Silzone valves, 5 died. No autopsies were performed to determine if any had sustained a paravalvular leak. CR 2918-19. In living patients, paravalvular leaks are confirmed and followed by serial echocardiograms. CR 1125, 1127, 1174, 2918-19. The study report indicated "no complications were observed clinically" (other than the alarming 13% mortality rate). However, the report did not indicate that a single enrolled patient had even one post-implant echocardiogram. Moreover, at the time of approval of the Silzone-coated implants by the FDA, the results of this study had not yet been published. CR 2845. This perhaps explains why the results apparently were not presented to or considered by the FDA. CR 1086.

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.<sup>7</sup> *In re St. Jude Medical, Inc., Silzone Heart Valves Products Liability Litigation*, MDL No. 01-1396. 2004 U.S. Dist. LEXIS 148, at \* 2 (D. Minn. January 5, 2004) (hereinafter “*SJM MDL*”) (Appendix A).

In addition to the patients in the AVERT, Silzone-coated valves were implanted in 36,000 other patients worldwide, including Jean Baker. CR 1140. Because none of these patients was involved in a human clinical study they would not have received the same type of close follow-up that disclosed the paravalvular leaks in patients enrolled in the AVERT. CR 1186. Nor would these patients have known that their valves had never been subjected to a controlled human trial to evaluate safety, had never been reviewed by any FDA expert panel, had been approved with a shortcut animal study, and had absolutely no demonstrated benefit over their predecessors.

Eventually the evidence from AVERT of Silzone causing paravalvular leaks became overwhelming. SJM once again was obligated at that point to notify the FDA immediately of these

---

<sup>7</sup> This eight-fold increase is a comparison by the MDL Court 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 (8/398 compared to 1/394). CR 1186. Subsequent follow-up revealed that, by November 30, 2000, only 8 months later, 14 of the 403 AVERT patients with Silzone valves, or 3.5%, had to be explanted due to paravalvular leaks. CR 81.

It also is quite significant that the average time for onset of paravalvular leaks in the Silzone-valve patients in the AVERT was 170 days, with the low end of the range 77 days. CR 1172. Recall that the animals studied to obtain the PMA Supplement approval were sacrificed, at SJM’s request, at only 70 days. This was in lieu of the 140 days usually required under the FDA’s published protocols for heart valves to watch for late complications. Thus, the animals that received Silzone valves as the basis for PMA Supplement approval were killed and their hearts examined by SJM one week short of when the paravalvular leaks first started appearing in the human AVERT patients. CR 1088-90, 1099, 1104.

results, as the persistent observed development of paravalvular leaks after implant unquestionably involved a significant threat to the lives of implant recipients.<sup>8</sup> *See*, 21 C.F.R. § 803.10(c)(1).

A 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), 814.47(2), and 895.1, *et seq.* *See also*, *United States v. Superharm Corp.*, 530 F.Supp. 408, 409-10 (E.D. NY. 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, which in this case was chaired by FDA employee Mary Ann Fitzgerald. 21 C.F.R. § 7.41(a). Less than 60 days later after notification, on March 20, 2000, the conclusion of the FDA committee was formalized into a memorandum known as the “Fitzgerald Memo.” The Fitzgerald Memo noted that the 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.”<sup>9</sup> CR 1183-85 (emphasis added). These determinations were based on

---

<sup>8</sup> Like the British recall, there is no record of these adverse events being reported to the FDA on a timely basis in accordance with the conditions of approval, other than the formal recall notice of January 21, 2000, see below. CR 1105-1395 (finding no adverse event reports submitted by SJM to the FDA).

<sup>9</sup> 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).

unanimous factual findings by the FDA committee.<sup>10</sup> CR 1186-88.

On March 22, 2000, these determinations were conveyed to SJM by FDA Acting Regional Director Edwin S. Dee (the “Dee Letter”). SJM was formally notified in the Dee Letter that the FDA found the circumstances and actions of SJM met the formal definition for a “recall.” The FDA found that significant because, under that definition, the FDA was formally finding that the “voluntary recall” was in fact “*an alternative to an FDA legal action to remove the defective products from the market.*” CR 1151-53 (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 be seizing these defective and no longer approved products, but for the fact that the manufacturer recognized the products as defective and voluntarily withdrew them from the market. *Id.*

The court of appeals implied that the Silzone-coated valves were still FDA-approved because the PMA Supplement approval was never formally withdrawn. But this clearly is a non-sequitur.

It is true 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).

---

<sup>10</sup> The products also failed miserably in reducing endocarditis. Indeed, after reports from this initial test, the FDA found the Silzone-coated valves had: “a significantly *higher* rate of explant due to endocarditis.” CR 1151 (emphasis added).

However, by the terms of the 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 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).

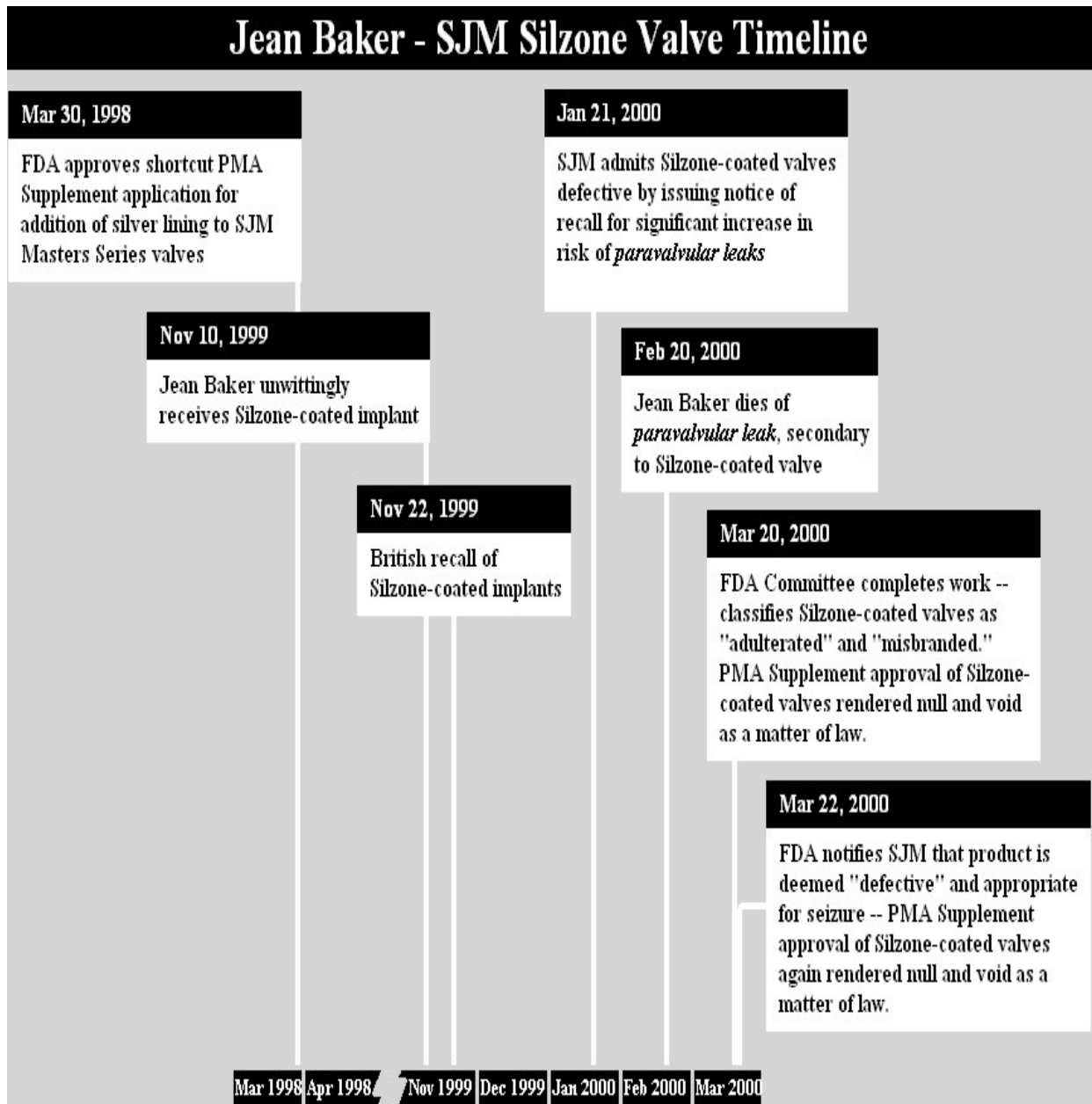
This is true because it is a criminal act for any person or entity to introduce into interstate commerce a product that the FDA has found to be either misbranded or adulterated. 21 U.S.C. § 331(a); *In re Grand Jury Subpoena*, 220 F.R.D. 130, 154 (D. Mass. 2004). Moreover, product seizure (or the alternative 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.

It is undenied by SJM – and indeed undeniable – that the SJM Silzone-coated valves no longer are approved by the FDA for manufacture or sale in any form anywhere within the United States of America. It is equally undenied and undeniable that the Silzone-coated valves would have to undergo an entirely new PMA submission for approval to be sold in this country. CR 1098. Therefore, it is beyond dispute that the formal classification of SJM's notification as a "recall" by the FDA was *the* means of withdrawal of the PMA Supplement approval of the product under these circumstances. *See*, 21 U.S.C § 331(a), *and SJM MDL* at \*13.

As part of this U.S. recall of these admittedly defective products, SJM expressly represented to the FDA that it would notify all cardiac surgeons (and therefore the patients indirectly), so that the condition of the patients could be monitored closely and the valves timely replaced if a patient should develop recurrent CHF symptoms as the result of a developing paravalvular leak. CR 1120,

1161. Yet, Ms. Baker's surgeon, Dr. Garza, was never notified by SJM. CR 1403. Consequently, Ms. Baker never knew of the recall. CR 1401. The post-mortem examination revealed that Ms. Baker died of the same fatal paravalvular leak that had necessitated the recall. CR 1415-27.

The following timeline graphically illustrates the most relevant dates:



The original SJM Masters Series valve without the Silzone coating presumably remains an FDA-approved product. There were no allegations in the petitioners' suit that the Masters Series valve without Silzone was in any manner defective. The only allegations related to the defective Silzone coating on the valve, which of course no longer has FDA approval and thankfully can no longer be sold to innocent patients like the late Jean Baker.

#### **SUMMARY OF THE ARGUMENT**

This is a case of national significance. But it is not the only case in which this specific preemption issue with regard to these products has been addressed. There were numerous identical federal suits filed against SJM in a number of states over this same product defect. In 2001, all these federal suits were transferred to a Multidistrict Litigation proceeding in Minnesota.

Prior to the issuance of the opinion on appeal here, the federal MDL Court considering the same issue of federal preemption heard the identical arguments raised by SJM in this proceeding. In a very well-reasoned opinion, the MDL Court determined that none of the numerous state court claims against SJM is preempted by federal law. Thus, the incongruous impact of the opinion in this case is that SJM Silzone suits brought by Texas citizens in Texas state courts are preempted by federal law, while identical suits brought in federal court are not preempted by federal law, regardless of where they are filed or which state's substantive law applies.

Second, according to the majority opinion of the United States Supreme Court in *Medtronic*, 518 U.S. at 470, and this Court in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998), the basis of the express preemption doctrine under the MDA is the conflict between a requirement implicit in a state court judgment and the requirements imposed by ongoing FDA approval. But, because this product no longer has FDA approval there can be no conflict whatsoever between the allegations of

the petitioners that the Silzone-coated product is defectively dangerous and the FDA's finding that the product is "defective," "adulterated," "misbranded," and appropriate for seizure.

Third, the recent opinion of the United States Supreme Court in *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005), compels reversal. *Bates* holds unequivocally that the mere fact that a state court judgment might induce a manufacturer to change product specifications does not equate to a "requirement" that might invoke preemption under statutes like the MDA.

Fourth, the unprecedented holding of the court of appeals is that, if a medical device was ever PMA- or PMA Supplement-approved by the FDA, the manufacturer is exempt from all civil liability for every class of claim arising in any way from the use of that device. This exemption, according to the court of appeals, applies forever, even if the approval is withdrawn, and even if it should later be proven conclusively that the approval was secured through fraud.

But that is exactly the type of "blanket preemption" expressly rejected by the United States Supreme Court in *Medtronic*, and also by this Court in *Worthy*, even before *Bates*. Both *Medtronic* and *Worthy* demanded that the inferior courts make a critical analysis of the specific claims raised in the suit against the specifics of the approval of the challenged product. Here, though, the court of appeals refused to look at the specificity of the approval of the only challenged product, or to compare the specific approval against the allegations in this suit.

Moreover, to approve the sale of any drug, the FDA also must find the drug is "safe" as designed and marketed. Accordingly, the perpetual and unconditioned blanket preemption holding of the court of appeals in this case also would apply to every drug ever approved by the FDA, under the implied conflict preemption doctrine. Again, this would be true even if the approval were later withdrawn or if the approval was fraudulently secured.

The question of whether any claim is preempted must be governed by congressional intent. There is nothing in the statutes or legislative history that would support a conclusion that Congress intended to exempt forever all medical device or drug manufacturers from all civil liability for every product ever approved by the FDA. The United States Supreme Court has held that any argument favoring “blanket” preemption for any FDA-approved product is inherently “implausible.”

Finally, the court of appeals held that even the manufacturing defect claim is preempted by federal law. But the manufacturing defect claim was not expressly addressed in the summary judgment motion, and manufacturing claims can never be preempted under these circumstances.

## ARGUMENT

### *ARGUMENT AND AUTHORITIES UNDER ISSUE 1*

Issue 1: Should claims involving Silzone-coated valves by Texas citizens filing suit in Texas state courts be deemed preempted by federal law when identical claims under the laws of all states have been deemed not preempted in the federal courts?

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, pursuant to 28 U.S.C. § 1407, to a federal MDL court in the Minnesota District, Hon. John 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). In addition, all such cases thereafter filed in any federal court were or will be transferred automatically to the MDL Court as “tag-along” cases. *Id.* at n.1 (expressly including at least one known Texas case).

In 2003, SJM filed a motion for summary judgment in the MDL. SJM contended, there and here, that all state court claims filed against SJM are preempted because once-upon-a-time the

Silzone-coated valves had been FDA-approved. *SJM MDL*, 2004 U.S. Dist LEXIS at \*1. SJM claimed, there and here, that the following language in the MDA mandates preemption for all civil tort suits if a medical device has ever gone through any PMA or PMA Supplement approval process: “...no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement ... which is different from, or in addition to, any requirement applicable under this chapter to the device....” 21 U.S.C. § 360k(a). *SJM MDL* at \* 5.

The MDL Court received extensive briefs and heard lengthy argument from national counsel for SJM on the matter. At the conclusion, the MDL Court determined that no state court claims were preempted by federal law, and issued a lengthy and well-reasoned supportive opinion. *Id.*

The MDL Court first examined closely the arguments raised by SJM under the “implied preemption” theory. In that case, as here, SJM contended that the United States Supreme Court in *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001), had applied the doctrine of implied preemption to a claim arising from an FDA-approved medical device. *SJM MDL* at \*7-8.

However, the MDL Court found that SJM’s reliance on *Buckman* was completely misplaced. *Buckman* involved a pure “fraud-on-the-FDA” claim by the plaintiffs. The defendant in *Buckman* was not in the stream of commerce to the plaintiffs, and was not in any way involved in designing, manufacturing, or marketing the device in issue. In fact, the defendant’s duties in that case arose *solely* under the MDA, and ran *solely* to the FDA. By contrast, the claims raised in these suits arise from state-based common law duties to the plaintiffs, which long-preceded the MDA.<sup>11</sup>

---

<sup>11</sup> A more complete analysis of the inapplicability of the doctrine of implied preemption and *Buckman* to this case can be found at pages 29-32, *infra*.

The *Buckman* Court itself expressly distinguished a case relied on by the plaintiffs in the SJM MDL proceeding and the petitioners here, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), because the claims in *Silkwood* were brought under “traditional state tort law principles of the duty of care....” *Buckman*, 531 U.S. at 351-52. As the MDL Court logically found, the same is true here. The plaintiffs in these proceedings are not suing for “fraud-on-the-FDA,” contending that they were harmed as a result of the submission, by an entity not in the plaintiffs’ decedent’s stream of commerce, of fraudulent data to secure FDA approval. Rather, in these cases the plaintiffs are suing under principles of Texas common law. Accordingly, *Buckman* and the implied preemption doctrine have no applicability to the case at hand. *SJM MDL* at \*7-8.

In contrast, in the case at bar the court of appeals confusingly held that most of the petitioners’ claims against SJM – the product’s designer, manufacturer, and marketer – were essentially the same as “fraud-on-the-FDA claims,” and thus impliedly preempted by *Buckman*. *Baker*, 178 S.W.3d at 138-39. The court of appeals declined to address the distinctions raised between *Buckman* and this case. The court also wholly failed to note the distinction placed by the *Buckman* Court itself with respect to state common-law claims, based on a common law duty flowing from a device manufacturer to the plaintiffs, compared to a federal claim against a consultant whose only duties flowed to the FDA.

With respect to the petitioners’ implied and express warranty claims, and the claims arising under the Texas Deceptive Trade Practices-Consumer Protection Act, the MDL Court correctly recognized that federal regulations themselves expressly hold that such claims are *not* preempted under the MDA. *SJM MDL* at \*10-11:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. *There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:*

(1) *... unfair trade practices in which the requirements are not limited to devices.*

(2) *... requirements that are equal to, or substantially identical to, requirements imposed by or under the act.*

\* \* \*

(6)(ii) *requirement[s] prohibiting the manufacture of adulterated or misbranded devices.*

21 C.F.R. § 808.1(d) (emphasis added).

In the case at bar, however, the court of appeals held that the petitioners' warranty and DTPA claims were "in substance" identical to the product and negligence claims and therefore preempted. *Baker*, 178 S.W.3d at 137. The court made no effort to harmonize this holding with the above-quoted federal regulation, which clearly and unambiguously compels the opposite result.

The MDL Court also recognized the serious issues raised by the plaintiffs with regard to: (a) the impact of the nullification of the FDA's approval of the product; and (b) whether the PMA Supplement approval was closer to a 510k rather than a full PMA approval. *SJM MDL* at \*12-13. However, because the MDL Court held none of the plaintiffs' claims were preempted, the court found it unnecessary to attempt to resolve either issue. By contrast, both issues were squarely raised

in the case at bar, and required appropriate resolution in light of the (erroneous) preemption holding.

With regard to the question of the impact of the nullification of the PMA Supplement approval, the court of appeals simply dismissed the issue with a non-explanatory footnote. *Id.* at 134 n.5. The court did not attempt to explain how preemption could possibly exist since there is no longer any FDA approval with which a state court jury finding could possibly conflict. This is a critical issue because the MDA preemption statute only applies to conflicting *requirements* imposed by state law. The only argument for extending preemption under the MDA to monetary judgments is that facing the possibility of a monetary judgment over a design or marketing decision arguably can impose requirements on a manufacturer that would conflict with the requirements imposed on the manufacturer for that product under its PMA approval.<sup>12</sup> Even assuming that argument were still viable, it nonetheless still would be axiomatic that if there is no existing PMA approval a state court judgment cannot possibly create a conflicting requirement as a matter of law.<sup>13</sup>

On the question of whether the PMA Supplement was closer to a 510k or a full PMA approval, the court of appeals dodged the issue by improperly considering the full PMA approval of the valve without the silver coating. *Baker*, 178 S.W.3d at 135-36.<sup>14</sup>

---

<sup>12</sup> But note that this argument was pointedly rejected last year by the United States Supreme Court. *Bates*, 544 U.S. at 445. Refer to pages 32-36, *infra*.

<sup>13</sup> Not to be critical of the thoughtful analysis provided by the MDL Court to this case, but it seems patently obvious, as clearly explained by Justices Stevens and Thomas in *Buckman*, that an argument that the MDA somehow preempts civil lawsuits because of conflicting “requirements” becomes nonsensical when the product is no longer approved by the FDA. *Buckman*, 531 U.S. at 354 (Stevens, J., concurring). This critical point is addressed in detail at pages 19-23, *infra*.

<sup>14</sup> This approach directly deviates from both *Medtronic* and *Worthy*, discussed in more depth at pages 36-42, *infra*.

The holding of the federal MDL Court on the preemption issue – with regard to this specific product and these identical claims – is important authority which could not be more directly on point. However, the only passing nod to the MDL ruling in *Baker* was a dismissive “*but see*” reference, in *obiter dictum*, to this important precedential opinion. *Baker*, 178 S.W.3d at 134.

This leaves an extremely incongruous result. The issue is whether application of federal law preempts state law claims. The federal court charged with making this decision determined that preemption should not apply to claims against the Silzone-coated products filed in federal court under the laws of any state. However, the opinion of the court of appeals in this case, if allowed to stand, would mean that all Texas citizens who file such claims in Texas state courts are preempted by application of federal law.

Granted that the Texas appellate courts are not bound by the decision of the federal MDL Court. However, this is an issue of federal, not state law. The MDL Court was expressly entrusted by the MDL Panel to make this almost certainly final determination for the federal courts.<sup>15</sup>

Texas courts generally should be guided closely by the decisions of the federal courts in determining issues of federal law. *See, e.g., Little v. Texas Dep’t of Criminal Justice*, 148 S.W.3d 374, 382 (Tex. 2004). When the federal courts rule on a federal issue, comity, logic, judicial economy, uniformity, fairness, and predictability all dictate that the various state courts should follow suit, absent some compelling case-specific distinction. *See, e.g., Ex Parte Garcia*, 560 S.W.2d 948, 952 (Tex. Crim. App. 1978). This principle is well established in Texas law. *See,*

---

<sup>15</sup> The MDL Court’s order has resulted in actual settlement (or settlement negotiations), in all of those cases except those in which SJM contends no injury occurred. This makes it extremely unlikely that the cases will ever be remanded or appealed for further consideration of this issue. *See, Current Developments, MDL No. 01-1396, [www.mnd.U.S.C.courts.gov/Tunheim Mdl/current\\_developments.htm](http://www.mnd.U.S.C.courts.gov/Tunheim_Mdl/current_developments.htm).*

*Celadon Trucking Servs. v. Titan Textile Co.*, 130 S.W.3d 301, 305 n.4 (Tex.App.-Houston [14<sup>th</sup> Dist.] 2004, pet. denied) (and numerous cases cited therein).

But the opposite occurred here. Inexplicably, the court of appeals all but completely ignored the most on-point federal opinion on this federal issue. The result, that Texas citizens who choose to file their cases in Texas state courts are singularly preempted by federal law, while the federal courts themselves have determined no federal preemption barrier exists *even when Texas law applies*, is absurd and unfair. This amply illustrates why the federal courts strongly discourage the type of disruptive rogue route followed by the court of appeals in this case.<sup>16</sup>

#### ***ARGUMENT AND AUTHORITIES UNDER ISSUES 2-6***

- Issue 2: If the FDA has determined that a product is “defective,” “adulterated,” “misbranded,” and appropriate for an FDA seizure action, are state court civil lawsuits alleging the product is defective somehow nonetheless preempted?
- Issue 3: In determining whether FDA approval preempts civil lawsuits, should the courts look at whether the product was FDA-approved when it left the hands of the manufacturer or at the time of judgment in the state court suit?
- Issue 4: Does the recent United States Supreme Court opinion in *Bates v. Dow Agrosciences, LLC*, preclude preemption of civil tort suits under the MDA?
- Issue 5: Are all medical devices that have ever been PMA- or PMA Supplement-approved by the FDA automatically and forever exempt from all civil liability merely because the FDA approval implied a (now null and void) finding that the device was “safe,” without the necessity of the reviewing court going through the specific approval/allegation analysis mandated by the United States Supreme Court in *Medtronic, Inc. v. Lohr*, and by this Court in *Worthy v. Collagen Corp.*?

---

<sup>16</sup> See, e.g., *Manual for Complex Litigation* § 31.133 (3d ed. 1995) (“Although the transferor court has the power to vacate or modify rulings made by the [MDL] transferee court, subject to comity and ‘law of the case’ considerations, doing so in the absence of a significant change of circumstances would frustrate the purposes of centralized pretrial proceedings.”).

Issue 6: Was the now null and void FDA approval of the medical device in dispute, under an abbreviated PMA Supplement application, sufficiently rigorous and specific in its requirements under *Worthy* so as to preempt all civil lawsuits arising from the use of the admittedly defective product?

**A. The “Once-Upon-a-Time” Defense**

The preemption defense asserted by SJM in this case can be characterized accurately as the “Once-Upon-a-Time” defense. In other words, SJM contends (and the court of appeals agreed), 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. This is true, SJM contends, *even if the PMA approval were to be voided, or if it should later be determined that the approval was secured through fraud*. This contention is as outlandish as it sounds, particularly when considered in the context of the very limited reference to *any* preemption in the MDA.

As discussed below, the application of preemption under the MDA has had a curious and confusing history. As it has evolved, however, it has been decided that, if there is ongoing FDA approval for a product with a particular and mandatory design specification and a state later should pass a regulation mandating a different design, enforcement of the latter would be precluded by application of § 360k(a). *Bates*, 544 U.S. at 443. 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.

The 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 United States Supreme Court decision in *Bates*, discussed in more detail below. However,

there is one aspect of the doctrine which 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. *Bates*, 544 U.S. at 443-44.

This analysis subsumes that there is some ongoing FDA regulation or finding with which the jury’s finding might arguably conflict. Accordingly, it is an absolute absurdity to suggest that a state court judgment is preempted by the MDA when the product no longer has PMA approval and therefore there is no existing FDA requirement with which the judgment might conflict. Thus, the fact that the Silzone-coated valves are no longer approved by the FDA should end this debate.

It is important to keep in mind that only an actual, irreconcilable conflict can give rise to preemption. To quote the Supreme Court:

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 by the federal antitrust laws simply because in a hypothetical situation a private party’s compliance with the statute might cause him to violate the antitrust laws.

*Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982).

**Indeed, the very situation which faces this Court today – whether preemption should apply when FDA approval no longer exists – was foreshadowed and analyzed cogently in a concurrence in *Buckman*:**

*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*, 531 U.S. at 354 (Stevens, J., concurring) (emphasis added).

What *requirements* does the FDA currently impose on SJM with regard to Silzone-coated valves? Just two. First, the FDA has made it a criminal act for SJM to market these valves because the FDA has determined that the products are misbranded, adulterated, defective, and appropriate for seizure. Second, the FDA has required that SJM notify all physicians who may be following patients with Silzone-coated valves so that the patients can be observed for valve-related complications. Even if a jury verdict in this case could somehow be construed as imposing some type of *requirement*, it is difficult to see how a jury verdict agreeing with the FDA that the product is unsafe could possibly conflict with any FDA requirement currently imposed on this product. *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.

## **B. 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.*) (the “MDA”). 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. Device Classification**

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 same in connection with some devices, specifically 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. *See also*, Yustein, A., *The FDA's Process of Regulatory Premarket Review for New Medical Devices* (“Nearly all PMA submissions require clinical data [human tests] in addition to bench and possibly animal data in support of their application.”).<sup>17</sup>

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.”).<sup>18</sup> *See also*, *Worthy*, 967 S.W.2d at 363.

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); *Worthy*, 967

---

<sup>17</sup> “Clinical data” refers to human clinical tests. CR 1082. Dr. Yustein is the Deputy Director, Office of Device Evaluation, Center for Devices and Radiologic Health, FDA. The quoted article in its entirety can be found at: [http://www.gastro.org/user-assets/Documents/08\\_Publications/06\\_GIHep\\_Annual\\_Review/Articles/Yustein.pdf#search=%22does%20pma%20approval%20usually%20require%20human%20clinical%20trials%22](http://www.gastro.org/user-assets/Documents/08_Publications/06_GIHep_Annual_Review/Articles/Yustein.pdf#search=%22does%20pma%20approval%20usually%20require%20human%20clinical%20trials%22)

<sup>18</sup> This FDA publication can be located at <http://www.fda.gov/cdrh/p91-2.html>.

S.W.2d at 363, 376. *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). To quote the FDA directly on the oft-limited scope of PMA Supplement application reviews:

After a PMA is approved, the PMA holder may request FDA approval of changes to be made. For example, it may request changes to the device, its labeling or packaging,... FDA's review of a PMA supplement may be easy or difficult depending on the type of device, the significance of the change, and the complexity of the technology. Some PMA supplements can be as complex as the original

application. Although the statutory timeframe is 180 days for PMA Supplements, FDA is committed to reviewing these in shorter timeframes....

FDA, *Device Evaluation Information, What We Do* (2002).<sup>19</sup>

### **3. State Regulatory Efforts and Preemption under the MDA**

During the MDA enactment process, Congress was informed of various states, most notably California, 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.*

## **C. Preemption**

### **1. Types of 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); *Hawkins v. Leslie’s Pool Mart, Inc.*, 184 F.3d 244, 247 (3d Cir. 1999).

---

<sup>19</sup> This FDA document can be located at [www.fda.gov/cdrh/ode/whatwedo.html](http://www.fda.gov/cdrh/ode/whatwedo.html).

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.<sup>20</sup> *Id.* at 517; *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6<sup>th</sup> Cir. 2000).

The last category, implied conflict preemption, is recognized because a manufacturer cannot be obligated to comply with a federal regulation that would subject it to liability under state law.<sup>21</sup> *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 (1977) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

---

<sup>20</sup> This is not always the case. However, implied field preemption clearly cannot apply here. *See* pages 29-32, *infra*.

<sup>21</sup> 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. This subcategory, however, has been recognized as indistinguishable from implied field preemption, and essentially is referred to separately by the Supreme Court only to maintain the historical context of the older opinions in which implied field preemption was analyzed under this nomenclature. *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. Accordingly, the analysis of this subcategory of implied conflict preemption would be identical to the analysis of implied field preemption and need not be repeated in this brief.

In this arena, the courts are required to engage in a strong presumption against preemption. *Bates*, 544 U.S. at 449. 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 perhaps 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 a cogent argument to be made that preemption was not intended. *Bates*, 544 U.S. at 449.

The presumption against preemption is also compelling here because the Congress provided no federal remedy under the MDA. In instances where Congress intended to preempt civil liability completely, not only has Congress generally stated so clearly, but it also has provided an alternative federal remedy. *See, e.g.*, 49 U.S.C. § 40101 (Air Transportation Safety and System Stabilization Act of 2001); 42 U.S.C. § 2210 (Price-Anderson Act); *and* 42 U.S.C. §§ 300aa-1, *et seq.* (National Childhood Vaccine Injury Act of 1986). *See also, Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 142 (1990) (holding existence of ERISA cause of action clear indication of congressional intent to preempt state causes of action).

This point was succinctly addressed by one jurist as follows:

‘This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct.’ It is hard to believe that Congress, while enacting the FDA to protect consumers, intended to preempt all state tort claims, when that result will have such negative consequences for those same consumers.... If the FDA or the manufacturer negligently fails to consider a

potential danger posed by a medical device, it is the injured consumer alone who will pay the price. Worse still, because the Supreme Court has found that fraud on the FDA claims are impliedly preempted, see *Buckman...*, even if PMA was obtained through intentional misrepresentation on the part of the manufacturer, by, for example, failing to report studies indicating substantial risks, the injured consumer cannot recover any compensation for her injury. ‘If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.’

*Riegel v. Medtronic Corp.*, 451 F.3d 104, 129 (2d Cir. 2006) (Pooler, J., concurring in part and dissenting in part) (quoting *Bates*, 544 U.S. at 449, and *Silkwood*, 464 U.S. at 251).

## **2. Inapplicability of Implied Field Preemption**

It is accurate that 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.

The Supreme 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 reluctance 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. 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). To quote the Court in *Buckman*:

We must also reject respondent's attempt to characterize both the claims at issue in *Medtronic* (common-law negligence action against the manufacturer of an allegedly defective pacemaker lead) and the fraud claims here as "claims arising from violations of FDCA requirements." Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim. In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.

*Buckman*, 531 U.S. at 352.

Moreover, this Court unequivocally rejected implied field preemption with respect to the scope of § 360k(a) of the MDA in *Worthy*. 967 S.W.2d at 369. As this Court recognized, if Congress had intended for the MDA to occupy the entire medical device regulatory field, including proscribing all liability, there would have been absolutely no purpose in the United States Supreme Court analyzing whether section 360k(a) expressly preempted the claims in *Medtronic*. *Id.*

Nor does the result in *Buckman* assist SJM here. In *Buckman*, the claims were not against a product designer, manufacturer, or marketer. Rather, the plaintiffs' claims were against a consultant that helped the product manufacturer obtain 510k approval for its product from the FDA.

Because the defendant was not involved in designing, manufacturing, or marketing the product, the defendant had no duty to the plaintiffs. Accordingly, the plaintiffs' *sole* allegations were that the defendant made misrepresentations to the FDA in securing approval for the product in issue, that but for those misrepresentations the product would not have entered the market, and therefore the plaintiffs would not have been injured. *Id.* at 343.

According to the Court, the defendant's duty in this regard ran solely to the FDA, not to the plaintiffs. Therefore, in the absence of any duty flowing from the defendant to the plaintiff, the plaintiffs in effect were suing the defendant for defrauding the FDA. But the Court logically held that policing fraud on the FDA was a function reserved to the FDA itself. *Id.* at 347-48, 351-52. There was no state common law claim in existence prior to the passage of the MDA that would have given the plaintiffs such a cause of action against the defendants, and the MDA certainly did not create a private cause of action in favor of the plaintiffs. Accordingly, the claim was barred under the implied field preemption doctrine.

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*, *Silkwood*, and *Worthy*. Thus, the doctrine of implied field preemption is inapplicable. *Buckman*, 531 U.S. at 352; *Worthy*, 967 S.W.2d at 368.

**3. *Bates v. Dow Agrosciences, LLC*, and the Necessity of Conflicting Federal Regulation under Express and Implied Conflict Preemption Doctrines**

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 while doing so would subject the manufacturer to liability under state law. *Id.* This Court fully concurs:

In essence, *Worthy* claims that *Zyderm* was not safe for her use. She does not contend that *Zyderm* was manufactured, marketed, or injected in her in any way other than that approved by the FDA. To prevail, therefore, *Worthy* must prove that *Zyderm* as approved by the FDA is not safe. This contradicts not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA. *Collagen cannot both market Zyderm in compliance with FDA requirements and not market Zyderm because it is unsafe.*

*Worthy*, 967 S.W.2d at 376 (emphasis added).

Even the courts which have erroneously found preemption with a PMA-approved product have reasoned similarly. For example, the Third Circuit Court of Appeals recently explained:

... Horn's Complaint alleges that the HeartMate was negligently designed.... This claim unquestionably would require TCI to alter the HeartMate's design.... Yet the HeartMate's design as approved by the FDA would remain approved by the FDA for national distribution and sale, and any changes to the design would require further FDA review and approval.... [Thus, TCI] would be left in the untenable and unenviable position of having to comply with conflicting state

and federal requirements, precisely the conflict the § 360k(a) [MDA] preemption provision is meant to avoid.

*Horn*, 376 F.3d at 176. *Accord*, *Riegel*, 451 F.3d at 122 (identical analysis).

Not only is this analysis very firmly supported by *Medtronic*, *Horn*, *Riegel*, and *Worthy*, but the analysis also makes perfect and irrefutable logical sense. The MDA is completely silent with respect to whether Congress intended to preempt civil lawsuits in any respect. To quote the Court:

There is, to the best of our knowledge, nothing in the hearings, the Committee Reports, or the debates suggesting that any proponent of the legislation intended a sweeping pre-emption of traditional common-law remedies against manufacturers and distributors of defective devices. If Congress intended such a result, its failure even to hint at it is spectacularly odd, particularly since Members of both Houses were acutely aware of ongoing product liability litigation.

*Medtronic*, 518 U.S. at 491.

The *only* reference in the MDA that has been raised to support the preemption argument in fact is section 360k(a), which prohibits states from imposing or continuing *requirements* that differ from *requirements* imposed on the product by the FDA. 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 the United States Supreme Court in *Cipollone*, 505 U.S. at 507, and recently reaffirmed in *Bates*, 544 U.S. at 443-44.

However, according to the Supreme 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 (5<sup>th</sup> 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 the United States Supreme 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. The proper inquiry calls for an examination of the elements of the common-law duty at issue, it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

*Bates*, 544 U.S. at 445.

The Court in *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 was 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.*

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 in the case at bar.

#### **4. *Medtronic, Inc. v. Lohr***

Even if analyzed under frankly facetious arguments that: (a) there is some remaining federal approval of the product in issue; and (b) *Bates* did not relegate to only historical significance SJM's "conflicting requirements arising from liability exposure" argument; the result still would be the same under clear law before *Bates*.

Until *Bates*, the dispositive case on this issue was the 1996 opinion of the United States Supreme Court in *Medtronic*. But *Bates* did not overrule the holding of *Medtronic*. In fact, the *Bates* Court indicated that its unanimous conclusion 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.*

The Supreme Court summarily rejected the claim of express and implied “blanket” preemption regardless of route of approval.<sup>22</sup> *Id.* at 486-87. Rather, to determine whether the MDA expressed Congressional intent to preempt any state court remedies, the Court recognized that 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 to a state court judgment.<sup>23</sup> *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, the Supreme 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. The Court concluded that the manufacturer's blanket preemption argument: “is not only unpersuasive, it is implausible.” *Id.* at 487. According to the

---

<sup>22</sup> As this Court also later did in *Worthy*, 918 S.W.2d at 369-70. Refer to pages 40-42, *infra*.

<sup>23</sup> Five Justices including Justice Breyer explained: “The statute and regulations ... require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.” *Medtronic*, 518 U.S. at 500. The Eighth Circuit correctly explained that substantial consideration should be given to Justice Breyer's role as the swing vote in *Medtronic*. *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 794 (8th Cir. 2001). This Court similarly focused on Justice Breyer's opinion in *Worthy*. 918 S.W.2d at 369.

Court, such a construction of Section 360k:

would have the *perverse* effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation.... [I]t would take language much plainer than the text of § 360k to convince us that Congress intended that result.

*Medtronic*, 518 U.S. at 487 (emphasis added).

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 expressly 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.

As the MDL Court sagely observed:

Defendant's argument [for blanket preemption] would allow medical device manufacturers to wrongfully withhold data from the FDA, gain PMA or PMA Supplement approval, and then be completely immune from liability based on that approval. This cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated.

*SJM MDL* at 9 (citing *Medtronic*, 518 U.S. at 487).

Another important aspect of *Medtronic* was in the opinion authored by Justice O'Connor, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In also rejecting the manufacturer's blanket preemption claims, these four justices concluded that, where a state cause

of action seeks merely to enforce a requirement that is consistent with the current FDA requirements, that claim cannot possibly be "different from, or in addition to" requirements applicable under federal law. *Id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

Justice Breyer illustrated how a state might set such conflicting standards. According to Justice Breyer, preemption might be raised, for example, when a federal requirement obligated manufacture of a medical device with a two inch wire, but a state agency regulation was enacted mandating that the manufacturer use only a one inch wire. The federal law, embodied in the two inch requirement, would preempt the conflicting state agency regulation.<sup>24</sup> *Id.* at 504.

Unfortunately, *Medtronic* left for another day the question of whether a product that enjoys FDA approval under a PMA should be exempt in any way from state court liability. *Worthy*, 918 S.W.2d at 367. Since *Medtronic*, that question has been addressed by a number of courts, with some holding that any product with current PMA approval is exempt from liability, and others holding that PMA approval provides no liability exemption. *Compare, e.g., Brooks v. Howmedica*, 273 F.3d at 785; *with Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1380 (11th Cir. 1999). Other courts, including this Court, have read *Medtronic* to require a more complex analysis, comparing the specifics of the approval and the process against the allegations in the suit. *See, e.g., Worthy*, 918 S.W.2d at 376.

*Bates* clearly demonstrated that *Medtronic* was in no way intended to apply only to products approved under the MDA via the 510k process. Even before *Bates*, though, the holding of this Court in *Worthy* still would compel the same result reached in both *Medtronic* and *Bates*.

---

<sup>24</sup> Notably, Justice Breyer's example necessarily envisions a conflict arising from a FDA-mandated manufacturing duty going forward from the date of a state law that might require a different future manufacturing standard. Refer to pages 20-22, *supra*.

## 5. *Worthy v. Collagen Corporation*

Texas jurisprudence regarding the preemption of medical device tort claims is found in *Worthy*, 967 S.W.2d at 360. In *Worthy*, this Court expressly *rejected* the contention advanced by the court of appeals in this case, that the mere fact that the device had gone through a PMA approval process is sufficient to invoke the express preemption provisions of the MDA. *Worthy*, 967 S.W.2d at 376. *Accord*, *SJM MDL* at \*6. Both this Court and the MDL Court concluded that recognizing the PMA process as sufficient to invoke preemption would conflict with the dictates of the United States Supreme Court in *Medtronic*. *Worthy*, 967 S.W.2d at 375-76; *SJM MDL* at \*6.

Despite the argument asserted by SJM, in *Bates* the Court clearly reaffirmed that a federal agency's action in approving a product certainly does not implicitly signify that the agency has established a specific federal requirement that supplants a state common law duty. *Bates*, 544 U.S. at 443. Beyond *Bates*, *Medtronic*, *Worthy*, and the *SJM MDL*, numerous other courts have analyzed *Medtronic* to require the conclusion that the PMA approval process alone is not a specific requirement that can be compared to, and thus preempt, state common law claims.<sup>25</sup>

Rather than blindly asserting preemption because a medical device had at one time gone through a PMA approval process, this Court in *Worthy* outlined several factors that the trial court

---

<sup>25</sup> See, e.g., *Goodlin*, 167 F.3d at 1375-76; *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459-60 (9th Cir. 1995); *Woods v. Gliatech, Inc.*, 218 F.Supp.2d 802 (W.D. Va. 2002); *Webster v. Pacesetter, Inc.*, 171 F.Supp.2d 1, 9 (D.D.C. 2001); *Haidak v. Collagen Corp.*, 67 F.Supp.2d 21, 23 (D. Mass. 1999); *Lakie v. SmithKline Beecham*, 965 F.Supp. 49, 54 (D. D.C. 1997); *Comeau v. Heller*, 945 F.Supp. 7, 12 (D. Mass. 1996); *Quillin v. American Hosp. Supply Co.*, No. 94-C-1020-BU, 1997 U.S. Dist. LEXIS 6974, 1997 WL 382095 (N.D. Ok., March 31, 1997); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1153 (Ill. 1999); *Sowell v. Bausch & Lomb, Inc.*, 230 A.D.2d 77, 656 N.Y.S.2d 16, 21 (N.Y. App. Div. 1997).

should examine to determine whether preemption should apply:

1. the specificity of presentations to the FDA concerning the device;
2. the specificity of the FDA's conditions in granting approval;
3. the amount of time required to obtain the approval;
4. the recurrence of investigations by the FDA;
5. the prohibitions against deviations from the conditions of approval; and
6. whether there would be, at the time of judgment, a specific conflicting finding by the FDA that the device is "safe and effective."

*Worthy*, 967 S.W.2d at 376.

#### **6. *Worthy* Applied**

In *Worthy*, this Court was quite clear that the following facts gave rise to the preemption determination of Zyderm under the compelling facts presented there:

- Breadth of submission and consideration: The submission to the FDA in the initial full PMA application constituted 8 full volumes of data. The application stated in detail how Zyderm was manufactured, what its typical immunogenic effect was, what data had resulted from clinical and serological tests, what instructions were given to physicians for using the product, and what instructions were given to patients.
- Human Tests: The submission included data from human clinical tests – *with over 5,000 patients* – as well as in vitro data, animal studies, and numerous published articles establishing the safety of the product.
- FDA Expert Advisory Panel review: The 8 full volumes of material were reviewed and approved by an FDA panel of experts appointed to evaluate the safety of the product.
- Continuing evaluation: The product was examined by the FDA again ten years later and still found to be “safe and effective,” still approved for sale and distribution as of the time of trial.

*Id.*

To attempt to reach a decision on the Silzone-coating consistent with the analysis required by *Worthy*, the court of appeals improperly considered: “the initial PMA application and the PMA

supplement, *as a whole*, in determining whether the federal requirements have been imposed.” *See, Baker*, 178 S.W.3d at 136 (emphasis added). But that analysis ignored the petitioners’ allegations, which were limited to the Silzone coating. This reasoning clearly thwarts the directives of both *Medtronic* and *Worthy*, and reaches the wrong result.

Looking at only the approval of the challenged product, as demanded by *Worthy*, there is a marked contrast to the approval facts considered for Zyderm. With regard to the Silzone-coated valves, the following facts are uncontested:

- Breadth of submission and consideration? Shortcut. Instead of the voluminous submission usually involved with a PMA, for the Silzone coating PMA Supplement approval the entire submission package was only about two inches thick. CR 1087-89, CR 1103-04.
- FDA Expert Advisory Panel review? None. CR 1086, 1103.
- Human studies? None. CR 1104.
- Animal studies? Shortcut from established and published protocols for heart valves. CR 1089-90, 1099, 1104.
- Continuing evaluation? None. In fact, the FDA determined post-approval that the Silzone-coated valves are adulterated, misbranded, defective, and appropriate for an FDA seizure action, making the further sale of Silzone-coated implants clearly illegal in the United States. CR 1098.

In short, the factors considered by this Court in *Worthy* to support preemption clearly militate against preemption in the case at bar. The Silzone valves pale in comparison to the specific preemptive factors spelled out for Zyderm in *Worthy*. Thus, in addition to *Bates* and *Medtronic*, *Worthy* also compels reversal of the opinion of the court of appeals in this case.

#### **D. Impact of Current *Baker* Opinion**

The devastating impact of the opinion of the court of appeals on the rights of Texas citizens should not be underappreciated. Moreover, this is a case of national significance. The opinion

creates a broad, sweeping, unsupported, and unprecedented presumption *in favor of* preemption as to all medical device claims. This is directly contrary to the presumption *against* preemption commanded by the United States Supreme Court, so recently and emphatically reaffirmed in *Bates*. 544 U.S. at 449.

As noted above, there have been conflicting views among the federal circuits on preemption under the MDA as applied to various PMA-approved devices. In Texas, this question was addressed with regard to one product, Zyderm, in *Worthy*. However, this Court was quite clear in *Worthy* that the application of preemption should be narrow and tailored, as directed in *Medtronic*.

The court of appeals in *Baker* failed to follow *either* the presumption against preemption, as mandated by the United States Supreme Court in *Bates* and *Medtronic*, *or* the claim-specific analysis demanded by this Court in *Worthy*. Accordingly, the analytic model of *Baker* is flawed, both legally and logically.

The upshot of the opinion of the court of appeals is that a judgment, based on a jury finding that the Silzone-coated valve is “unsafe,” would be contrary to the now-reversed FDA finding that the product was “safe and effective.” *Baker*, 178 S.W.3d at 137. But the “finding” by the FDA that the Silzone coating was “safe and effective” came only by way of implication, *i.e.*, by virtue of the statutory requirement that a product be found “safe and effective” before receiving PMA Supplement approval. *See*, 21 U.S.C. § 360e(d)(2), and *Baker*, 178 S.W.3d at 136. There was no *requirement* imposed by the FDA that SJM manufacture the Masters Series valve with a silver lining on the sewing cuff. Nor would a verdict holding SJM responsible for its defective product require SJM to discontinue selling the silver-coated valves. *Bates*, 544 U.S. at 443. Nor would a jury verdict be inconsistent with the requirements now imposed by the FDA on the product. Accordingly, under

*Bates, Medtronic, and Worthy*, a comparison of the two standards compels no preemption.

But, following the rationale of the court of appeals in this case, it is completely unnecessary to go through a *Medtronic/Worthy* analysis of the specifics of the PMA or PMA Supplement approval against the suit allegations, *in this or any other case*. Rather, because *every* PMA- and PMA Supplement-approved medical device has impliedly been found “safe and effective” by virtue of receiving approval, *any* claim that *any* approved product was “unsafe,” whether brought under a theory of negligence, strict liability, breach of warranty, DTPA, or fraud, would be preempted. *Baker*, 178 S.W.3d at 137. No court would ever need to analyze whether the FDA imposed a requirement on the defendant, or analyze whether a judgment would create a conflicting requirement. This unquestionably conflicts with *Bates, Medtronic, and Worthy*.

The opinion of the court of appeals is, in very real terms, an application of blanket preemption from civil liability for any product that has undergone any form of PMA or PMA Supplement approval at any time. This approach is completely unprecedented under Texas law.

The United States Supreme Court dismissed, in almost ridiculing fashion, materially identical blanket preemption claims with respect to 510k-approved medical devices. None of the three U.S. Supreme Court opinions in *Medtronic* accepted the defendant’s absurd argument that blanket preemption should apply to any product that had gone through any FDA approval process. *See Medtronic*, 518 U.S. at 486-91, 504-07, 512-14. In rejecting the argument, the United States Supreme Court observed:

Medtronic’s sweeping interpretation of the statute would require far greater interference with state legal remedies... while simultaneously wiping out the possibility of remedy.... [We reject] Medtronic’s extreme position.

*Medtronic*, 518 U.S. at 487-88, 490.

Following *Medtronic*, this Court also expressly rejected blanket preemption with respect to PMA-approved medical devices:

...[I]t seems clear both from the statute and the *Medtronic* opinions that Congress did not intend FDA approval of a device to insulate the manufacturer from all liability for injuries resulting from its use....

*Worthy*, 967 S.W.2d at 369.

It also is important to keep in mind that the construction by the court of appeals would not stop with medical devices. Every drug approved by the FDA also has received an implicit certification that the drug is "safe." Like the MDA, the Food, Drug, and Cosmetic Act requires FDA approval of all prescription drugs as "safe" before they can be authorized for sale in the United States. 21 U.S.C. §§ 355(d), 393(b)(2)(B). Similar to the PMA process, to obtain FDA approval the drug manufacturer submits a "New Drug Application" ("NDA") to the FDA. *Id.* § 355(a), (b), (d). The FDA can approve an NDA *only if* the agency "determines that the drug meets the statutory standards for safety... and labeling..." 21 C.F.R. § 314.105(c). Thus, if the court of appeals is correct in its analysis, implied conflict preemption would apply to preclude liability for every drug ever approved by the FDA. But this type of implausible argument about the intended scope of preemption under the FDCA has been repeatedly rejected by the courts. *See, e.g., Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8<sup>th</sup> Cir. 1989); and *Cartwright v. Pfizer, Inc.*, 369 F.Supp. 876, 882-83 (E.D. Tex. 2005).

Congress certainly could have written the Medical Device Amendments to the effect that a manufacturer whose products have been approved by the FDA should never have to face liability in any state civil court suit on any claim arising from the use of that product. But it did not do so, nor

does the legislative history behind the MDA in any way indicate any such intent.<sup>26</sup> Instead, Congress chose a narrowly worded provision that clearly was designed to prevent states from passing competing regulations concerning device design or marketing that would conflict with new and ongoing federal requirements imposed by the FDA. *Id.*

No court has the right or ability to hold as a matter of policy that the passage of a federal regulatory scheme should have included the preemption of all state court claims arising from a regulated product. Rather, the scope of preemption, express or implied, can only be determined only by reference to congressional intent, as congressional intent is the “ultimate touchstone” in *all* preemption cases. *Gade*, 505 U.S. at 92 (Kennedy, J., concurring) (quoting *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978), and *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). And in determining a congressional intent to preempt state common law tort suits the threshold for overcoming the presumption against preemption appropriately remains very high. *Id.*

In interpreting federal law, it is fundamental that the courts are not free to modify the words selected by Congress, or to ignore part of the preempting language. For example, in *Bates*, the Court noted that the broad preemption interpretation advocated by the defendant would give no meaning to the words “in addition to or different from” the preemption language in FIFRA (virtually identical to the language in the MDA). *Bates*, 544 U.S. at 448. The Court noted that Dow’s proposed interpretation would in effect have the Court improperly rewrite the preemption clause to read those

---

<sup>26</sup> *See, Medtronic*, 518 U.S. at 491. *See also*, Vladeck, D., *Symposium: Federal Preemptions of State Tort Law: The Problem of Medical Drugs and Devices: Preemption and Regulatory Failure*, 33 *Pepp. L. Rev.* 95, 103 (2005) (“There is not a hint in the legislative history of the MDA that Congress intended that the amendments would restrict the right of injured persons to bring state law damage actions for compensation.”).

words out of the statute. *Id.*

Texas law is fully in accord. The Texas appellate courts are prohibited, under the guise of “statutory interpretation,” from rewriting a statute to have effects the court may deem desirable. *Public Util. Comm’n v. Cofer*, 754 S.W.2d 121, 124 (Tex. 1988).

But that is exactly what occurred here. In this case, the court of appeals has not only engaged in the fiction that there is a still-existing federal requirement with which the state court judgment might conflict, but also by judicial fiat effectively rewrote § 360k(a) of the Medical Device Amendments to have broad, sweeping, and automatic preemptive effect that is in no way supported by the language of the statute or its legislative history.

The result of this opinion, if it is allowed to stand, would be that all Texas citizens who are hereafter injured or killed by defective medical devices will forever be precluded from recovery for their injuries, *even if: (a) the original FDA approval was secured through blatant fraud; (b) there are no requirements – specific to the product in issue – imposed by the FDA with which the judgment could conflict; and (c) the product is no longer approved at all.* This cannot possibly be what Congress intended.

The opinion of the court of appeals is harmful to Texas citizens and Texas jurisprudence, and it should not be allowed to stand.

#### **ARGUMENT AND AUTHORITIES UNDER ISSUE 7**

Issue 7: Can a manufacturing defect claim be dismissed on summary judgment under a claim of federal preemption and without even being addressed in the summary judgment motion?

As the court of appeals duly noted, the petitioners also brought a claim of a manufacturing defect against SJM. *Baker*, 178 S.W.3d at 137. Without analyzing the manufacturing defect claim,

the court concluded that all of the petitioners' claims were preempted under federal law. *Id.*

But the manufacturing defect allegations were not raised in SJM's summary judgment motion. CR 2788-2813. Thus, it was error for the court of appeals to uphold the summary judgment with respect to the petitioners' manufacturing defect claims. *Haase v. Glazner*, 62 S.W.3d 795, 800 (Tex. 2001); *McConnell v. Southside Ind. School Dist.*, 858 S.W.2d 337, 341 (Tex. 1993).

There also is no authority whatsoever that a claim of manufacturing defect is preempted under the MDA. Indeed, the authority is all to the contrary. *Medtronic*, 518 U.S. at 513 (Breyer, J., concurring). *Accord, Worthy*, 967 S.W.2d at 376.

### ***Prayer***

The opinion of the court of appeals ignores the requirements set out by this Court in *Worthy*. Moreover, the opinion is at loggerheads with the definitive ruling on the same issue in the federal courts with regard to this important question concerning federal law. In addition, the decision of the court of appeals that these claims are preempted flies in the face of the reasoning behind preemption, because there is no conflicting FDA approval. Finally, the opinion of the court of appeals in this case has inconsistent, far-reaching, completely unjustified, and unfair effects that exceed any arguable intent of the United States Congress.

This is an important case that should merit the attention of this State's highest civil appellate court. Accordingly, the petitioners respectfully request this Court grant this petition, reverse the summary judgment, and remand for trial.

Respectfully submitted,

**RILEY LAW FIRM**

//s//

---

Tim Riley  
State Bar No. 16931300  
The Civil Justice Center  
112 E. 4<sup>th</sup> St.  
Houston, Texas 77007-2502  
(713) 646-1000 Telephone  
(800) 637-1955 Telecopier  
E-mail: [tdr@txtrial.com](mailto:tdr@txtrial.com)

**PIANELLI LAW FIRM**

//s//

---

James V. Pianelli  
State Bar No. 15966740  
The Civil Justice Center  
112 E. 4<sup>th</sup> St.  
Houston, Texas 77007-2502  
(713) 864-3333 Telephone  
(800) 637-1955 Telecopier  
E-mail: [jvp1000@aol.com](mailto:jvp1000@aol.com)

ATTORNEYS FOR PETITIONERS

***Certificate of Service***

This is to certify that a true and correct copy of the foregoing was served on counsel for the respondents, in accordance with the requirements of the Texas Rules of Appellate Procedure.

//s//

---

Tim Riley