LEXSEE

KEITH BAKER, INDIVIDUALLY, AND IAN BAKER, INDIVIDUALLY AND AS INDEPENDENT EXECUTOR OF THE ESTATE OF JEAN BAKER, DECEASED, Appellants v. ST. JUDE MEDICAL, S.C., INC. AND ST. JUDE MEDICAL, INC., Appellees

NO. 01-02-00802-CV

COURT OF APPEALS OF TEXAS, FIRST DISTRICT, HOUSTON

178 S.W.3d 127; 2005 Tex. App. LEXIS 5135

June 30, 2005, Filed

SUBSEQUENT HISTORY: [1]** Petition for review filed by, 03/20/2006

PRIOR HISTORY: On Appeal from the Probate Court Number One. Harris County, Texas. Trial Court Cause No. 312,543-402-A. Trial Judge: Hon. Russell Austin.

COUNSEL: FOR APPELLANT: James V. Pianelli, Mcgehee & Pianelli, L.l.p., Houston, TX; Timothy D. Riley, Riley Law Firm, Houston, TX.

FOR APPELLEE: David M. Gunn, Beck, Joe W. Redden, Jr., Redden & Secrest, L.L.P., Houston, TX.

JUDGES: Panel consists of Chief Justice Radack and Justices Jennings and Higley.

OPINIONBY: Sherry Radack Chief Justice

OPINION:

[*130] This appeal involves the issue of federal preemption of state law causes of action arising out of the implantation of an allegedly defective heart valve in the deceased, Jean Baker. Specifically, we must decide whether state common-law causes of action asserted by Baker's heirs against the valve manufacturer are preempted by the manufacturer's compliance with the Food and Drug Administration's premarket approval procedures for certain medical devices. Because we hold that state product-liability claims are preempted by federal law in this case, we affirm the summary judgment granted in the manufacturer's **[**2]** favor.

BACKGROUND

Legislative Background of Medical Devices Act

In 1976, in response to mounting consumer concern over, among other things, defective intrauterine devices, Congress passed the Medical Device Amendments (MDA) to allow the Food and Drug Administration (FDA) to regulate medical devices. The MDA creates three categories of medical devices. The most stringent FDA control is over Class III devices, which are devices that either "present a potential or unreasonable risk of illness or injury," or which 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." *See 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II)*. It is undisputed that a heart valve is a Class III medical device.

Obtaining FDA Approval to Market Class III Devices

1. Full PMA Approval

Before marketing a Class III device, the manufacturer must either submit its product to the FDA for premarket approval (PMA) or qualify for one of two exceptions to the premarket approval process. To obtain PMA approval, the manufacturer must provide **[**3]** the FDA with "reasonable assurance" that the device is safe and effective. **[*131]** *See 21 U.S.C. § 360e(d)(2)*. To do so, manufacturers submit detailed information regarding their device, which the FDA then reviews for an average of 1200 hours before approving or disapproving the device. *Medtronic, Inc. v. Lohr, 518 U.S. 470, 477, 116 S. Ct. 2240, 2247, 135 L. Ed. 2d 700 (1996)*.

2. § 510(k) Exemption to PMA approval

In addition to the "rigorous" PMA process, there are two exemptions by which a manufacturer may gain the FDA's permission to market a device. *Id. at 477-78, 116 S. Ct. at 2247*. One of these exemptions permits devices that are "substantially equivalent" to devices existing in n1 to be marketed and sold without full PMA approval. *See 21 U.S.C. § 360j(g)(1)*. This review is known as a section 510(k) review (after the number of the section in the original act) and is "by no means comparable to the PMA process." *Lohr, 518 U.S. at 479, 116 S. Ct. at 2247*. As opposed to the PMA's average review time of 1200

hours, a § 510(k) review takes an average of only 20 hours to **[**4]** complete." *Lohr, 518 U.S. at 478, 116 S. Ct. at 2247*. ***3. PMA Supplementation for Modifications to PMA-Approved Devices***

n1 The MDA includes a "grandfathering" clause, which allows pre-1976 devices to remain on the market until such time as the FDA initiates and completes PMA approval. *See 21 U.S.C. § 360e(b)(1)(A)*. The MDA also contains an investigational device exemption (IDE), which permits unapproved devices to be used in human trials. *See 21 C.F.R. § 812.1*. Neither the grandfathering clause or the IDE exemption is relevant to this case.

If a manufacturer wants to modify a Class III device that already has PMA approval, the manufacturer may submit a PMA supplement, rather than obtain an entirely new PMA approval. *See U.S. v. Prigmore, 243 F.3d 1, 5 (1st Cir. 2001)* (describing PMA supplement process). The PMA supplement "must contain scientific information that provides a basis for approval of the modified **[**5]** device." *Id.* (quoting *21 C.F.R. § 814.39(c)*). The procedures for a PMA supplement are the same as those for an original PMA, although the FDA requires only that the manufacturer provide materials supporting the proposed modification. *Worthy v. Collagen Corp., 967 S.W.2d 360, 364-65, 41 Tex. Sup. Ct. J. 424 (Tex. 1998)*; *Kemp v. Medtronic., Inc., 231 F.3d 216, 222 (6th Cir. 2000)*.

Factual Background

In 1982, the FDA approved St. Jude's initial PMA application for a mechanical heart valve. During the following years, St. Jude made several improvements to the valve, which were approved through a series of PMA supplements. One of these improvements incorporated a rotating sewing cuff, which eliminated the need for surgery to position the valve before sewing it in place.

In an effort to combat endocarditis, a life-threatening infection of the heart muscle, n2 St. Jude notified the FDA that it planned to develop a mechanical heart valve with an infection-resistant, sterile, silver coating on the sewing cuff. In May 1997, after an FDA-required animal test was completed, St. Jude submitted a PMA supplement to add the Silzone n3 coating **[**6]** to its already approved heart valve.

n2 The record shows that the decedent, Baker, was suffering from endocarditis before her valve replacement surgery. Endocarditis is fatal in 25% to 60% of those suffering from it.

n3 Silzone (R) is the trademark name for the sterile, silver coating that St. Jude added to the sewing cuff of its heart valve.

In March 1998, the FDA approved St. Jude's PMA supplement. As part of its approval, the FDA imposed several post-approval **[*132]** requirements, including how the valve could be marketed. Specifically, the FDA prohibited St. Jude from making any claims about the efficacy of the Silzone coating in preventing endocarditis. St. Jude began marketing the Silzone valve accordingly.

St. Jude, however, continued to participate in studies to determine the efficacy of the Silzone coating in preventing endocarditis. One of these studies was the Artificial Valve Endocarditis Reduction Trial (AVERT). On January 21, 2000, approximately one month before Baker's death, an independent board **[**7]** reviewing the AVERT data concluded that patients with the Silzone valve were more likely to experience a post-operative complication known as a paravalvular leak. Approximately 2% of the patients with the Silzone valve experienced such leaks, as opposed to .25% of patients with conventional valves.

The same day that it became aware of the conclusions of the AVERT monitoring board, St. Jude began a voluntary recall of all non-implanted Silzone valves, and so informed the FDA. In response, the FDA, in a letter from Edwin Dee to St. Jude, stated, "We agree with your firm's decision to recall [the Silzone valve] . . . We have reviewed your action and conclude that it meets the formal definition of a 'Recall.'" This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove the defective products from the market." n4 It is undisputed, however, that the FDA never formally withdrew its PMA approval of the valve, and that the valve had FDA approval on the date it was implanted in Baker.

n4 Appellants contend that the trial court erred in granting St. Jude's objection to the Dee letter and to another FDA memo, in which an FDA official referred to the Silzone valve as "misbranded" or "adulterated." We do not find the admissibility of this evidence to be a deciding factor in this case (*see* fn. 5).

[8]**

The decedent in this case, Jean Baker, a 66-year-old woman, had undergone open heart valve-replacement surgery in November 1999. A Silzone-coated heart valve, manufactured by St. Jude, was implanted in Baker to replace her own deteriorating mitral heart valve. In

February 2000, approximately one month after St. Jude issued its voluntary recall of the valves, Baker died.

Baker's two sons, Ian Baker and Keith Baker, filed this wrongful death suit against St. Jude based on theories of negligence, product liability, breach of warrant under the *Deceptive Trade Practices Act*, malice, and fraud. St. Jude filed a motion for summary judgment, contending that the appellee's state court claims were preempted by the FDA's federal regulation over the valves at issue. The trial court agreed, and granted St. Jude's motion for summary judgment.

ANALYSIS

Standard of Review for Summary Judgments

We will uphold a summary judgment only if the record establishes that there is no genuine issue of material fact, and that the movant is entitled to judgment as a matter of law on a ground set forth in the motion. *See TEX. R. CIV. P. 166a(c)*; *Cathey v. Booth, 900 S.W.2d 339, 341, 38 Tex. Sup. Ct. J. 927 (Tex.1995).* **[**9]** In reviewing the summary judgment, we indulge every reasonable inference in favor of the non-movant, resolve any doubts in its favor, and take as true all evidence favorable to it. *Pace v. Jordan, 999 S.W.2d 615, 619 (Tex. App.--Houston [1st Dist.] 1999, pet. denied).*

Preemptive Effect of PMA Approval

1. Can a State-Court Action be a Prohibited State "Requirement"?

[*133] State laws that conflict with federal laws are preempted under the Supremacy Clause of the Constitution. *U.S. CONST. Art. VI, cl. 2*. Congressional intent to preempt state law can either be expressly stated in statutory language or implied in the structure and purpose of federal law. *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, 112 S. Ct. 2608, 2617, 120 L. Ed. 2d 407 (1992)*. The MDA contains an express preemption provision, which provides as follows:

> *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-*
>
> (1) *which is different from, or in addition to*, any *requirements applicable under this [Act]* to the device, and
>
> (2) **[**10]** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this [Act].

21 U.S.C. § 360k (emphasis added). The initial issue, thus, is whether a state tort lawsuit can ever be a state "requirement," prohibited by *§ 360k*.

The Supreme Court considered this issue in *Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)*. In *Lohr*, the Supreme Court held that state-tort claims were not preempted if a medical device received FDA approval through the § 510(k) notification process. The majority noted that, under § 510(k) approval process, the FDA makes no endorsement as to a product's safety, but concludes only that it is "substantially equivalent" to a device already on the market. The Court concluded that because a § 510(k) approval by the FDA did not impose any federal requirements, any requirement imposed by the states was not prohibited. *518 U.S. at 493-94, 116 S. Ct. at 2254-55*.

The *Lohr* court, however, could not agree on whether a state-court action could ever be considered a state "requirement." **[**11]** Four justices of the majority (Stevens, Kennedy, Souter, and Ginsburg) could not accept "Medtronic's argument that by using the term 'requirement,' Congress clearly signaled its intent to deprive States of any role in protecting consumers from the dangers inherent in many medical devices." *518 U.S. at 489, 116 S. Ct. at 2252*.

This portion of the *Lohr* opinion, however, was not supported by a majority of the members of the Court. The dissenting justices (O'Connor, Rehnquist, Scalia, and Thomas) concluded that "a fair reading of *§ 360k* indicates that state common-law claims are preempted, as the statute itself states, to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device." *518 U.S. at 512, 116 S. Ct. at 2263* (O'Connor, J., dissenting).

Justice Breyer also refused to join the portion of the opinion holding that *§ 360k* did not prohibit state-court actions because he was "not convinced that future incidents of MDA preemption of common law claims will be 'few' or 'rare'." *518 U.S. at 508, 116 S. Ct. at 2261-62* (Breyer, J., concurring). Justice Breyer concluded **[**12]** that, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *518 U.S. at 504-05, 116 S. Ct. at 2260*.

As we read *Lohr*, a majority of the justices of the

Supreme Court would hold that a state-court tort claim can be expressly preempted by *§ 360k* of the MDA. **[*134]** Since *Lohr*, a majority of the federal courts considering the issue have agreed. *See Horn v. Thoratec Corp., 376 F.3d 163, 176 (3rd Cir. 2004)* (holding that state common law claims and duties were preempted because they were "in severe tension with" requirements established by FDA in approving device); *Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001)* (holding that "a medical device manufacturer's compliance with the FDA's PMA process will preempt state tort law claims with respect to that approved device and relating to safety, effectiveness or other MDA requirements when the substantive requirements imposed by those claims potentially conflict with PMA approval. **[**13]** "); *Kemp v. Medtronic, Inc., 231 F.3d 216, 230 (6th Cir. 2000)*; *Mitchell v. Collagen Corp., 126 F.3d 902, 913-14 (7th Cir.1997)*; *Brooks v. Howmedica, Inc., 273 F.3d 785, 796 (8th Cir. 2001); Papike v. Tambrands, Inc., 107 F.3d 737, 742 (9th Cir.1997)*; *but see Oja v. Howmedica, Inc., 111 F.3d 782, 789 (10th Cir. 1997)* (common-law failure to warn claim is not subject to preemption under the MDA)*; Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999)* (holding that simple approval of a PMA application imposes no federal "requirements"); *In re St. Jude Medical, Inc., 2004 U.S. Dist. LEXIS 148, 2004 WL 45503, *10 (D. Minn. Jan. 5, 2004)* (same).

Importantly, the Texas Supreme Court has held that "a federal requirement concerning a device *can preempt* a suit in which the claim is that the device should have been made or marketed differently provided . . . the federal requirement is sufficiently specific." *Worthy v. Collagen Corp., 967 S.W.2d 360, 371, 41 Tex. Sup. Ct. J. 424 (Tex. 1998)* (emphasis added).

The Supreme Court has recently reaffirmed that a "requirement" can reach beyond positive enactments, **[**14]** such as statutes and regulations, to embrace common-law duties. *Bates v. Dow Agrosciences, L.L.C., 544 U.S. 431, 161 L. Ed. 2d 687, 125 S. Ct. 1788, 1798 (2005)*. "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." *Id. at 1799*. Like the preemption clause in *Bates*, *§ 360k* prohibits requirements that are *different from, or in addition to* those provided in the federal act. A state-law requirement is not preempted if it is equivalent to, and fully consistent with, the federal act. *See id. at 1800*.

Based on the authorities cited above, we conclude that state-tort claims can impose prohibited state "requirements" under *§ 360k of the MDA* if a jury award on the cause of action would conflict with or add to a specific requirement set by the FDA for the device at issue. That is, if a jury award on the asserted cause of action could potentially set a standard of care different from that specifically set by the FDA, the state law cause of action would constitute a prohibited state-law "requirement." Accordingly, we disagree with appellants' assertion that their lawsuit merely **[**15]** seeks "remedies," but does not impose any additional state "requirements." n5

n5 We likewise disagree with appellants' assertion that preemption, if applicable, evaporates if the FDA later determines that the PMA approval was wrongly granted. Appellants cite no authority for this position. The issue is whether, at the time the device was implanted, it was covered by PMA approval. Whether St. Jude was in compliance with federal requirements setting the standard of care at the time the alleged tort was committed is appropriate issue. *See Carey v. Shiley, 32 F. Supp. 2d 1093, 1095 (S.D. Iowa 1998)* (preemption appropriate in suit involving PMA-approved device although product was later withdrawn from market). It is undisputed that, in this case, the Silzone valve, at the time it was implanted in Baker, had been approved by the FDA through both a PMA and a PMA supplement.

[*135] ***2. Does the PMA/PMA Supplement Process Impose Federal Requirements?***

The issue of whether a state law cause of action **[**16]** imposes a state requirement is irrelevant if there is no federal requirement to preempt the state requirement. In *Lohr*, the Supreme Court held that, under the less rigorous § 510(k) approval process there was no federal requirement imposed because the FDA makes no endorsement as to a product's safety, but concludes only that it is "substantially equivalent" to a device already on the market. Thus, the Court concluded that a § 510(k) approval by the FDA did not impose any federal requirements. *518 U.S. at 493-94, 116 S. Ct. at 2254-55*. There being no federal requirement, no issue of preemption was raised.

Appellants argue that, like the 510(k) process evaluated in *Lohr*, the PMA supplement process is too "abbreviated" to have imposed any "federal requirements." In support, appellants argue that the PMA Supplement took only 10 months to obtain and the entire file for the supplement is only 2 inches thick.

We disagree with appellants' characterization of the PMA supplement process as "abbreviated." In *Kemp v. Medtronic*, the Sixth Circuit considered an argument that the PMA supplement process was less rigorous than the initial PMA approval process. *231 F.3d at 227*. **[**17]** The court noted that

> this distinction [between the rigors of an initial PMA and a PMA Supplement] is readily understandable because a PMA requires review of a previously unapproved device that does not qualify for exemption either as substantially equivalent to devices extant in 1976 or as in IDE. By contrast, a PMA Supplement proposes changes to a device that has already received rigorous review and approval during the original PMA process. Hence, because the FDA has already made a determination as to the safety and effectiveness of the underlying device in the original PMA, it can evaluate only the proposed modifications presented in the PMA Supplement while relying on its earlier approval of the original device.

Id. Similarly, a federal district court in Texas has adopted the reasoning of *Kemp* and held that "for purposes of a preemption analysis . . . there is no difference between the PMA process and the PMA Supplement process." *In re Medtronic Polyurethane Insulated Pacing Lead Prod. Liability Litigation, 96 F. Supp. 2d 568, 570 (E.D. Tex. 1999)*. In fact, the federal regulations applicable to PMA supplements provide that "all procedures **[**18]** and actions that apply to an application under [an initial PMA] also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." *21 C.F.R. § 814.39(c)*.

There is no categorical distinction between a device approved solely on a PMA application and a device that has been approved through a PMA application coupled with a subsequent PMA supplement. If we were to accept appellants' argument that the PMA supplement must itself be as exhaustive as the initial PMA, there would be no need for PMA supplements. Rather, an entire new PMA application would be required for each product innovation. Therefore, in analyzing whether the PMA approval process is sufficient to support a finding that federal regulations were imposed, we believe that we must look at the initial PMA and the PMA Supplement together. Thus, the **[*136]** proper inquiry is to consider the initial PMA application and the PMA supplement, as a whole, in determining whether federal requirements have been imposed.

In concluding that PMA approval imposed federal requirements, the *Worthy* court considered the specificity of the manufacturer's presentation **[**19]** to the FDA, the amount of time required to obtain approval, the recurrence of the investigation a decade later, the prohibition against deviation from the conditions of approval, and the FDA's specific finding that the product was "safe and effective." *967 S.W.2d at 376*.

We find many of these same factors present in this case. St. Jude's submissions to the FDA in connection with the initial PMA included detailed information about its intended use, manufacturing methods, design, testing, labeling, etc. The FDA imposed specific conditions, including the required labeling for the valve. The FDA imposed precise manufacturing standards. The initial PMA application took nearly two years to complete.

The PMA Supplement process, which addressed only the addition of the silver coating to the sewing cuff, was equally as exacting and took an additional 10 months. The FDA required that St. Jude conduct certain animal tests, which St. Jude conducted before ever submitting its PMA Supplement application. St. Jude's PMA supplement application included detailed information regarding how the silver coating would be manufactured. Specifically, a coating of silver 0.4 microns thick would **[**20]** be applied to the rotating cuff by using an ion beam to assist the deposition process. The application further stated that the manufacturing process for the Master Series mechanical heart valve with and without Silzone was identical, with the exception of the silver coating. In four amendments to its PMA Supplement application, St. Jude, at the request of the FDA, provided further substantiation regarding the benefits of the silver cuff, labeling changes regarding the effectiveness of reducing endocarditis in humans, revisions to a proposed clinical study, and information regarding corrosion issues that had been raised by an FDA expert. St. Jude's final amendment to its PMA Supplement application included a detailed explanation of the sewing cuff attachment mechanism, a discussion of the manufacturing and assembly process, and a discussion regarding corrosion issues.

Finally, some 10 months after St. Jude filed the PMA Supplement application and over two years after initially proposing the silver cuff to the FDA, the FDA approved the PMA Supplement for the Masters Series valve with the Silzone coating. The FDA's approval was conditioned on certain labeling, including a requirement **[**21]** that, when the term "Silzone" was used, that it be followed by an asterisk that directed the reader to a prominently placed footnote explaining that no clinical studies were performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis.

Like the *Worthy* court, we conclude that the FDA's approval of the PMA supplement device constituted a finding that the device, as modified, was "safe and effective," *see* 21 U.S.C. at *§ 360e(d)(2)*, although the FDA did not allow St. Jude to make any claims about its effectiveness in preventing endocarditis. n6 This conclusion is supported by the FDA's own words in its letter approving the PMA Supplement, wherein the FDA

notes that further PMA Supplements are required whenever a "device is to be modified and the modified **[*137]** device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device *remains* safe and effective." (Emphasis added).

n6 Ms. Baker's death was allegedly caused by a paravalvular leak, not endocarditis.

[22]**

Accordingly, we hold that the PMA approval process that St. Jude went through in obtaining FDA approval, including both the initial application process and the PMA Supplement process for the Silzone-coated cuff, was sufficiently specific to impose federal requirements on St. Jude regarding the manufacture and labeling of the heart valve.

2. Are Appellants' State-Court Causes of Action Prohibited "Requirements"?

Having decided that state-tort claims can be prohibited state "requirements" under *§ 360k*, and that the PMA and PMA Supplement process imposed federal requirements in this case, we must now decide whether appellants' state-law claims impose requirements that potentially conflict with or add to the FDA's requirements. To do so, we examine the allegations made under each cause of action.

A. Negligence/Products Liability/DTPA

In their petition, appellants contend that St. Jude was negligent in the design, manufacture, and marketing of the Silzone valve. Under their products-liability claims, the appellants contend that the Silzone valve was unreasonably dangerous and defective and was defectively manufactured. Under their DTPA claim, appellants allege **[**23]** that St. Jude made promises and express warranties that the product was safe and that there were implied warranties of merchantability and fitness in connection with the product. In sum, the appellants' claims all require them to prove that the Silzone valve was not safe.

In *Worthy*, the Texas Supreme Court considered whether preemption applied to a product that had been approved by the FDA through a PMA application and following PMA supplement. *967 S.W.2d at 364-65, 376-77*. The plaintiff in that case brought DTPA claims, asserting that the product, Zyderm, was unsafe for her use. Such a finding, the court noted, would "contradict not only the FDA's specific finding to the contrary but also the manufacturing, distribution, and labeling protocols approved by the FDA." *Id. at 376*. The court also noted that there was "no difference in substance" between the plaintiff's claims under the DTPA or "common law claims for negligence, breach of warranty, and products liability." *Id.*

Based on *Worthy*, we conclude that appellants' claims for negligence, products liability, and DTPA violations are preempted because they would require a finding that the **[**24]** Silzone valve was unsafe, a direct contradiction to the PMA approval and PMA supplemental approval granted by the FDA. In other words, 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. The FDA had set specific manufacturing and labeling requirements that cannot be altered by a jury's potential finding that another manufacturing process would have been safer or another label clearer. Thus, we hold that appellants' negligence, products liability, and DTPA claims are expressly preempted under *§ 360k*.

B. Fraud/Malice

The appellants also allege that St. Jude committed fraud and acted with malice because it did not report certain adverse events involving Silzone valves before issuing its voluntary recall, even though the FDA had mandated that it do so. n7 Appellants argue that, because these **[*138]** claims rely on the enforcement of a federal requirement, they are not "additional" state requirements.

n7 In March 1998, when the FDA approved the PMA Supplement to add the Silzone coating to the sewing cuff of the valve, it did so on the condition that St. Jude: (1) not market the product with any claim or implication that the Silzone coasting was effective in the prevention of endo carditis; (2) submit post-approval reports to the FDA at intervals of one a year; (3) carefully track, to the final user or patient, each device so that they could be located quickly is serious problems were determined to be occurring with the product; (4) submit a new PMA Supplement when any unanticipated adverse effect, increase in the incidence of adverse effect, or device failure, was encountered; (5) submit, within 10 days of having knowledge, any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that was attributable to the device; and (6) report any time [appellees] received or otherwise became aware of any information from any source, that suggested that the device may have caused or contributed to a serious death or injury, or had malfunctioned such that it could be likely to cause or contribute to a death or serious injury if the malfunction were to recur, within 30 days of becoming aware of a reportable death, injury, or malfunction, or within 5 days of becoming

> aware that a reportable event required remedial action to prevent an unreasonable risk of substantial harm to the public.

[25]**

We agree that claims based on a manufacturer's failure to follow the FDA's regulations and procedures in manufacturing and marketing a device are not preempted. *Martin, 254 F.3d at 583*. "Nothing in *§ 360k* denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Lohr, 518 U.S. 470, 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700*. Appellants contend that St. Jude knew of adverse effects at the time of Baker's implant, but did not report them to the FDA until the AVERT study was completed. Appellants argue that St. Jude's failure to make these reports, as required by the FDA, gave rise to a common-law cause of action for fraud and also shows malice.

St. Jude, however, contends that this is essentially a "fraud-on-the-FDA" claim, which the Supreme Court has held is preempted. In *Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012, 1015, 148 L. Ed. 2d 854 (2001)*, the plaintiffs contended that the defendant made misrepresentations to the FDA to secure PMA approval for the product at issue, and that, but for those misrepresentations, **[**26]** FDA would not have approved the product and the plaintiffs would not have been injured. *531 U.S. at 343, 121 S. Ct. at 1015*. The Supreme Court concluded that "policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" and held that the plaintiffs' claims arising out of misrepresentations made to the FDA were "impliedly preempted." *531 U.S. at 347, 348, 121 S. Ct. 1017*. Such claims, the court held, "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administrations judgment and objectives." *531 U.S. at 350, 121 S. Ct. at 1018*. The Supreme Court noted that "although [*Lohr*] can be read to allow certain state-law causes of action 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." *531 U.S. at 353, 121 S. Ct. at 1020*.

We also note that the FDA has the tools necessary to police and punish those who conceal or fail to report information. As the Court detailed in *Buckman*,

> The FDA is empowered to investigate suspected fraud, *see* **[**27]** *21 U.S.C. § 372*; 21 CFR § 5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, *§ 10.30*. In addition to the general criminal proscription on making false statements to the Federal Government, *18 U.S.C. § 1001 (1994 ed., Supp. V)*, **[*139]** the FDA may respond to fraud by seeking injunctive relief, *21 U.S.C. § 332*, and civil penalties, *21 U.S.C. § 333(f)(1)(A)*; seizing the device, *§ 334(a)(2)(D)*; and pursuing criminal prosecutions, *§ 333(a)*. The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration.

531 U.S. at 349, 121 S. Ct. at 1017-18 (footnote omitted).

In this case, appellants' fraud claim is not based on a "parallel federal safety requirement." Rather, appellants are essentially alleging that St. Jude withheld, or unreasonably delayed, in providing the FDA with information that it had regarding adverse effects associated with the Silzone valve. As such, we hold that appellants' fraud claim is really a "fraud-on-the-FDA claim," and is, therefore, **[**28]** impliedly preempted.

CONCLUSION

Because we have held that all of appellants' claims are preempted by federal law, we affirm.

Sherry Radack

Chief Justice