No. 02-4597

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

BARBARA HORN,

Plaintiff-Appellant,

v.

THORATEC CORPORATION,

Defendant-Appellee.

On Appeal from the United States District Court
for the Middle District of Pennsylvania

BRIEF FOR APPELLEE THORATEC CORPORATION

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Circuit Rule 26.1 and Fed. R. App. P. 26.1, Defendant-Appellee Thoratec Corporation states that it has no parent company and the only publicly traded company that owns 10% or more of its stock is Thermo Electron Corporation.

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COUNTERSTATEMENT OF JURISDICTION

Defendant agrees with plaintiff's statement of jurisdiction.

COUNTERSTATEMENT OF THE ISSUES

1. Whether the district court correctly concluded, consistent with the vast majority of courts to resolve the issue before and after *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), that 21 U.S.C. § 360k(a) expressly preempts design, manufacturing, labeling, and other safety-related requirements that a plaintiff seeks to impose under state tort law on a medical device that has received premarket approval by the Food and Drug Administration ("FDA").

2. Whether the district court's decision can be upheld on the alternative ground that plaintiff's claims are impliedly preempted.

COUNTERSTATEMENT OF THE CASE

Defendant agrees with plaintiff's statement of the case (the carryover paragraph on pages 1 and 2 of her opening brief).

COUNTERSTATEMENT OF FACTS

This lawsuit arises out of the tragic death in 1998 of Daniel Horn, who was awaiting a heart transplant when he received a surgical implant of the HeartMate Left Ventricular Assist Device ("HeartMate"). Manufactured by Thermo Cardiosystems

Inc. ("TCI"),[1] the HeartMate is powered by an air compressor located outside the body. It is designed to serve as a bridge measure to keep a terminally ill patient alive until a heart donor can be identified and a transplant attempted.

As explained below, FDA in 1994 had granted "premarket approval" to the HeartMate, a complex "Class III" medical device. FDA's premarket approval decision followed years of regulatory scrutiny, including a review of almost twenty years' worth of scientific data from animal studies and clinical trials involving the device. In granting premarket approval, FDA approved every aspect of the device's design, manufacturing process, and labeling.

According to the complaint, however, Mr. Horn's death (more than three months after the HeartMate was implanted in him) occurred because, among other things, the device was unreasonably dangerous in its design, negligently manufactured, and unaccompanied by adequate warnings and instructions. The crux of plaintiff's tort claims is that a particular design feature of the HeartMate – which was developed during the investigational stage, arose directly out of the experiences of the clinical trials, and was specifically reviewed and approved by FDA – was

[1] On February 14, 2001, TCI merged with Thoratec Corporation. For simplicity's sake, we refer to TCI.

inadequate and unsafe, even though FDA cleared the HeartMate for marketing with that design feature in place.

Consistent with the great weight of authority, the district court on summary judgment held that plaintiff's state-law claims are preempted. See App. A-9-29.

A. The Statutory and Regulatory Framework

1. The Medical Device Amendments of 1976

The MDA classifies medical devices into three categories. See *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). The HeartMate is a Class III device. App. A-62 (¶ 7). Because such devices pose the greatest risks, they "must undergo an indisputably thorough, rigorous, and costly premarket review * * * by the FDA." *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 576 (5th Cir. 2001).

All new Class III devices must receive FDA clearance before they may be marketed. Premarket clearance can occur in either of two ways. *First*, FDA evaluates some Class III devices, such as the HeartMate, under the premarket approval ("PMA") process. Characterized by the Supreme Court as "exhaustive" (*Buckman*, 531 U.S. at 349) and "running the gauntlet" (*Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 494 (1996)), the PMA process involves the FDA's most stringent form of regulatory review. It "involves a time-consuming inquiry into the risks and efficacy of each device." *Buckman*, 531 U.S. at 348; App. A-15. Fewer than 20% of new Class III

devices go through the PMA process. See *Lohr*, 518 U.S. at 479-80. The manufacturer must demonstrate that the device satisfies the statutory standard: reasonable assurance of safety and effectiveness. See 21 U.S.C. §§ 360c(a)(1)(C), 360e(c), (d); 21 C.F.R. Part 814. FDA devotes many hours to reviewing a PMA application. *Buckman*, 531 U.S. at 344-45.

The *second* method of obtaining FDA clearance to market new Class III devices is through the so-called "510(k) process." Aimed at fostering competition, the 510(k) process allows a device to bypass the PMA requirements if it is "substantially equivalent" to a "grandfathered" device on the market before 1976. See 21 U.S.C. § 360c(i); *Lohr*, 518 U.S. at 494. The 510(k) process "lacks the PMA review's rigor" (*Buckman*, 531 U.S. at 348) and focuses on "*equivalence*, not safety." *Lohr*, 518 U.S. at 493 (internal quotations omitted). FDA regulations provide that 510(k) clearance "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Lohr*, 518 U.S. at 479.

2. Overview of the PMA Process

The HeartMate received regulatory clearance under the stringent PMA process. The PMA application must include labeling samples, a full description of the device

and the manufacturing methods used in its production, and data from animal studies and clinical investigations relating to the device. 21 C.F.R. § 814.20(b)(6)(i). The PMA application must also contain the results of clinical investigations involving human subjects. *Id*. § 814.20(b)(6)(ii). FDA regulates the clinical trials that produce the data.[2]

In addition to being subjected to FDA review, "[a] PMA application is ordinarily referred to a panel of [outside] experts for study." *Worthy* v. *Collagen Corp*., 967 S.W.2d 360, 363 (Tex. 1998); see 21 U.S.C. §§ 360e(c)(2), 360c(b)(2). The panel recommends whether premarket approval is justified. 21 U.S.C. § 360e(c)(2). A final order is issued if the manufacturer has demonstrated that the device's safety and effectiveness is reasonably assured. *Id*. § 360e(d)(1)(A)(i). The FDA approval order authorizes marketing the device with the particular labeling (including product warnings) and according to the design and manufacturing processes submitted to FDA. The order prohibits changes to the approved labeling, product design, manufacturing process, or construction of the device that would affect

[2] To obtain FDA approval to conduct clinical trials, a manufacturer must apply for an "Investigational Device Exemption" (or "IDE"). The IDE application must include a written protocol, an analysis of the patient risks arising from the investigation, a detailed description of the device, all labeling for the device, and other information. 21 C.F.R. §§ 812.20, 812.25.

its safety or effectiveness without FDA approval. 21 C.F.R. §§ 814.39, 814.80; see *Worthy*, 967 S.W.2d at 364.

3. The MDA's Preemption Clause and FDA's Interpretive Regulation

When Congress created this regulatory regime and conferred on FDA comprehensive new regulatory authority over medical devices, it also took steps to "prevent state requirements from unduly burdening interstate commerce." *Mendes* v. *Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994). Congress sought to preserve the uniformity of the federal regulatory scheme and to protect innovations in device technology from being "stifled by unnecessary restrictions" by including a "general prohibition on non-Federal regulation." H.R. Rep. No. 94-853, at 12, 45 (1976). That express preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement –
>
> > (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
> >
> > (2) 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 chapter.

21 U.S.C. § 360k(a) (emphasis added).

FDA has issued a regulation interpreting the MDA's preemption provision, 21 C.F.R. § 808.1(d), which expresses the view that "[s]tate or local requirements are

preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." The agency also opines that Section 360k(a) "does not preempt State or local requirements of general applicability." *Id*. § 808.1(d)(1).

4. *Medtronic* v. *Lohr*

The Supreme Court interpreted the MDA's preemption clause and FDA's regulation in *Medtronic, Inc.* v. *Lohr*, *supra*. Three separate opinions combine to resolve the issues before the Court: (1) Justice Stevens's opinion, joined by Justices Kennedy, Souter, and Ginsburg; (2) Justice O'Connor's partial concurrence and dissent, joined by Chief Justice Rehnquist and Justices Scalia and Thomas; and (3) Justice Breyer's separate opinion concurring in part and concurring in the judgment, which joined Justice Stevens's opinion in part but also partially agreed with the reasoning of Justice O'Connor's opinion. The Court unanimously concluded that claims embodying state requirements that are *identical* to applicable federal requirements are not preempted by the MDA; and a 5-4 majority held that the Lohrs' manufacturing and warning claims also were not preempted. Justice Breyer cast the deciding vote with respect to the manufacturing and warning claims.

The case involved a medical device that had been cleared through the 510(k) process, which involves a very "limited form of review" by FDA. 518 U.S. at 478.

The Court took pains to contrast the 510(k) process with the far more "rigorous" PMA process. 518 U.S. at 477-78; see also *id*. at 479, 494. The Court concluded that because the 510(k) process does not impose *any* federal design "requirements," it does not preempt state design claims. 518 U.S. at 492-94; *id*. at 513 (opinion of O'Connor, J.).

The Court's 5-4 holding that the manufacturing and warnings claims were not preempted turned on the *general applicability* of the federal regulations imposing manufacturing and labeling requirements – regulations that apply not just to a single medical device or class of devices but to virtually all devices. In this connection, both Justice Stevens's opinion and Justice Breyer's concurrence cited FDA's regulation interpreting Section 360k(a) as preempting "[s]tate or local requirements * * * only when the [FDA] has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device." 21 C.F.R. § 808.1(d) (emphasis added). The focus of Justice Breyer's tie-breaking concurring opinion was on the pertinent *federal* (as opposed to the *state*) requirements. See 518 U.S. at 507 (Breyer, J.) ("Insofar as there are any applicable *FDA requirements* here, those requirements, even if numerous, *are not 'specific' in any relevant sense.*") (emphasis added); *ibid.* ("[N]o law forces the FDA to make *its requirements* pre-emptive if it does not think it appropriate.") (emphasis added).

B. The Factual and Procedural Background

1. The HeartMate

The HeartMate consists of a circular-shaped pump housing and two attached, cylindrical-shaped conduit assemblies. (A diagram and a photograph of the unit can be found at App. A-70, 71.). The conduit attached to the right side of the pump body is surgically connected to the ventricle of the heart. This is referred to as the "inlet side" because blood flows from the heart into the pump body. The conduit attached to the left side of the pump body is surgically connected to the aorta. This is referred to as the "outlet side" because blood flows out from the pump to the aorta. The pump housing contains an internal pump and related equipment. A tube attached to the pump housing exits the body and connects to an air compressor, which forces air through the tube into the pump. The system is designed to assist the heart's natural pumping of blood from the ventricle to the aorta.

Plaintiff's claims relate to the connection between the outlet "elbow" and the pump housing. The outlet elbow (a small, angled tube) is indicated at the top of the drawing on App. A-73. The elbow is inserted into an adaptor conduit, which in turn is screwed into the open port of the pump housing.[3] A screw ring or "retaining nut"

[3] The adaptor conduit cannot be seen from the outside of the pump, and thus cannot be seen in the rendition at App. A-73.

is tightened over the elbow to ensure that the elbow does not disconnect from the pump. To provide added assurance that the screw ring will not rotate, a suture is tied over it and secured to the adaptor conduit, as indicated on App. A-73. TCI manufactures the pump at the factory with the adaptor conduit, outlet elbow, screw ring, and suture in place. When a surgeon implants the HeartMate in a patient, there is no need to manipulate the screw ring or tie the suture. App. A-64 (¶ 12).

2. The Allegations of the Amended Complaint

Barbara Horn, Daniel Horn's wife and executrix, alleges in her amended complaint that Mr. Horn was admitted to the Williamsport Hospital on January 17, 1998, suffering from an acute myocardial infarction. App. A-33 (¶ 4). He was transferred to Hershey Medical Center ("Hershey"), where it was determined that a heart transplant was necessary. *Id*. ¶¶ 5-6. On January 22, Mr. Horn's condition deteriorated and he was surgically implanted with the HeartMate. App. A-34 (¶¶ 7-8).

On May 3, after transfer to an assisted-living facility, Mr. Horn experienced bleeding where the percutaneous tube exits the body. He was taken to Hershey, where surgery was performed to determine the cause. App. A-34-35 (¶¶ 9-11). Plaintiff alleges that, during the surgery, Dr. Benjamin Sun discovered that the screw ring that connects the outlet elbow to the pump housing had become disconnected.

Plaintiff further alleges that the suture had worn through as a result of rubbing against the sternum, allowing the screw ring to disconnect. App. A-35 (¶ 12). Plaintiff claims that Dr. Sun reconnected the screw ring with metal wire, but that an air embolus went to Mr. Horn's brain while the screw ring was disconnected, resulting in a massive hemorrhage. *Id*. ¶ 13. Mr. Horn died on May 7, 1998. *Id*. ¶ 14.

Plaintiff brings claims based on theories of negligence, strict liability, and breach of warranty. The principal focus of her complaint is on the allegedly defective design of the outlet elbow connection. She alleges:

> Had the screw ring been of an appropriate and feasible design which would not permit the screw ring to become unscrewed as a result of pump movement, or had something more durable than a suture been used to secure the tightened screw ring, or had the threaded sleeve with the eyelet[4] been placed in such a way that the retaining suture did not run across the interior portion of the screw ring directly beneath the underside of the sternum, the disconnection which ultimately caused Mr. Horn's death would never have occurred.

App. A-36 (¶ 16). Plaintiff claims both that the device was negligently designed and that TCI is subject to strict liability for manufacturing an unreasonably dangerous product. App. A-37 (¶ 19(a), (b)); App. A-49 (¶ 23).

Plaintiff also alleges that TCI committed other acts of negligence, such as failing to test and study the HeartMate adequately, provide adequate warnings about

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[4] The "threaded sleeve" presumably refers to the adaptor conduit, which is screwed into the end of the pump housing and contains the eyelet to which the suture is secured. See App. A-65 (¶ 16), App. A-73 (showing attachment of the suture).

the possibility of screw ring disconnection, provide adequate instructions to physicians, and use suitable suture material. App. A-37-39 (¶ 19). In addition to the strict liability design defect theory, she alleges that TCI is strictly liable for failing to use proper manufacturing practices and for failing to include adequate warnings. App. A-40 (¶ 23). Finally, plaintiff alleges that TCI breached warranties of merchantability and fitness. App. A-42 (¶¶ 26-29).

As we explain next, the design of the outlet elbow connection, the manufacturing process, and the warnings for the HeartMate were all addressed in detail in TCI's PMA application and approved by FDA. In addition, the use of a suture to anchor the screw ring and a bonding agent – the central design features attacked by plaintiff's complaint – were both added by TCI during the clinical trials with FDA's approval.

3. The Investigational and PMA Processes for the HeartMate

For a decade after the basic design of the HeartMate was completed in 1975, a variety of animal and human cadaver studies were performed with the device. More than 70 investigations were conducted on goats and calves. TCI also performed 32 human cadaver studies to determine the optimal pump configuration. App. A-63 (¶ 9). In 1985, FDA granted TCI's application for an investigational device exemption, and TCI began clinical trials. App. A-63 (¶ 10), A-75-76.

a. *The Clinical Trials.* Over the next nine years, clinical trials were conducted at several dozen FDA-approved hospitals. TCI submitted more than 90 supplements to its IDE application, and FDA propounded a large number of questions about the device and the conduct of the trials. App. A-63 (¶ 10).

In August 1988, TCI reported to FDA an adverse event involving a leak. App. A-63 (¶ 11). TCI suspended the clinical trial and did engineering studies to determine how to prevent the screw ring from loosening. TCI settled on the addition of a bonding agent and a locking suture. *Ibid.* In response, FDA directed TCI to address a variety of issues and to provide, among other things, more information on the bonding agent, "a diagram of how the retention suture is attached," and a description of how the suture "will prevent the connection from becoming loose." App. A-78-80. TCI submitted detailed responses to all of FDA's questions, as well as "a suture sample and a sketch of its application to the screw ring." App. A-81-88. TCI indicated as well the specific suture it proposed to use. App. A-83. Based on its review of this information, FDA specifically approved TCI's proposed design changes aimed at "secur[ing] the connection between the pump housing and the outflow conduit," including the use of the suture. App. A-90-91.

b. *The PMA Process.* On the basis of the trials and all of its previous studies, TCI submitted its 41-volume, 6,886-page PMA application to FDA on March 30,

1992. App. A-64, A-93. Over the next 2½ years, in response to numerous FDA requests, TCI submitted a substantial volume of additional information about the clinical trials and the HeartMate's design, manufacturing process, materials, and labeling. One of these amendments, which responded to a long list of detailed questions posed by FDA (App. A-149-163), consisted of 82 volumes and 15,951 pages. App. A-66 (¶ 22), A-165. Another amendment, also submitted in response to specific FDA questions (App. A-167-176), consisted of five volumes of data. App. A-66 (¶ 24). On other occasions, FDA requested additional information about the manufacturing process. App. A-67 (¶ 26); App. A-204-211. In late 1993, an expert FDA advisory panel on circulatory devices recommended approval of the device. App. A-67 (¶ 27). FDA also inspected TCI's manufacturing facility and approved it for manufacturing the HeartMate. *Ibid.* (¶ 28).

The design of the outlet elbow, and the use of a screw ring and adaptor conduit to attach it to the pump housing, were part of the original design of the HeartMate. App. A-63 (¶ 11). As noted above, the bonding agent and suture were added in 1988 in response to an incident in which a screw ring loosened while the HeartMate was implanted in a patient. Thus, all three elements that are the focus of plaintiff's claims were part of the design of the HeartMate when TCI submitted its original PMA application.

In accordance with FDA's requirement of "a full statement of the components, ingredients, and properties and of the principle or principles of operation, of [the] device" (21 U.S.C. § 360e(c)(1)(B)), TCI provided a detailed description of the system's design, copies of engineering drawings for the critical parts of the HeartMate, and an explanation of manufacturing and inspection procedures. There was no mystery that TCI intended to use a screw ring, a bonding agent, and a suture to secure the outlet elbow to the pump housing. Nor was there any mystery about the precise positioning of the suture on the screw ring or the intended location of the pump in the chest cavity after implant. See App. A-64 (¶ 14), A-65 (¶¶ 15, 18), A-106, A-108-109, A-132, A-139. The inspection procedures specify that the inspector must reject the elbow assembly if the suture is tied improperly or if the screw ring is capable of rotating. To ensure that the screw ring is properly secured, the inspector must attempt to loosen it. App. A-141. The travelers (documents that record in detail every step in the process of assembling the device) also indicate the specific brand of suture material to be used and the approved suppliers. App. A-65 (¶ 19), A-146-147. TCI stated that it selected the Tevdek suture as a result of the 1988 incident involving the loosened screw ring and "because it is nonabsorbable, and will lock the connectors in place following implantation." App. A-65 (¶ 19), A-143.

TCI described the positioning of the pump within the body in the "Directions for Use" submitted with the original PMA application. FDA asked for more detailed information on the orientation of the device. App. A-173 (Question 30). TCI responded by providing an updated version of the "Directions for Use," which included a diagram showing the location of the HeartMate in the body and a detailed description of the implant procedure. App. A-66 (¶ 20), A-194-195.

TCI also provided information on the HeartMate's performance in the clinical trials in an effort to help FDA understand the safety of the design. TCI reported that the 1988 bleeding incident was the only time a screw ring loosened. There were no incidents of broken sutures at the outlet elbow. App. A-66 (¶ 21). In response to a request from FDA, see App. A-150 (Question 1(c)), TCI provided more detailed information on device malfunctions, but again there were no broken sutures at the outlet elbow to report. App. A-66 (¶ 23).

At no time during the PMA process did FDA raise any concern about the design of the outlet elbow connection in general, the use of a bonding agent and screw ring to connect the elbow to the pump, the use of a suture to secure the screw ring, or the positioning of the suture. FDA did ask detailed and specific questions

about *other* aspects of the design and the materials used. See, *e.g.*, App. A-149-163 (Question 27).[5]

Finally, TCI submitted detailed directions for use and warnings. App. A-178-202. Again, FDA had a variety of specific questions, and directed TCI to make many specific revisions to the labeling. App. A-161-162 (Question 36); App. A-172-174 (Questions 29-35). But the agency never suggested that there was an insufficient warning with respect to the outlet elbow screw ring.

In 1994, FDA approved the HeartMate for commercial sale. App. A-67 (¶ 29), A-213-215. FDA stated that TCI was required to comply with a series of conditions, including selling the device only in the form in which it had been approved. If TCI wanted to make any change that affected the safety or effectiveness of the device, it was required to obtain further regulatory approval. App. A-216.

4. The District Court's Decision

The district court granted summary judgment in favor of TCI because all of plaintiff's claims were preempted by Section 360k(a) of the MDA. The court reviewed the extensive regulatory history of the HeartMate; noted that the proposed

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[5] FDA's only questions about the suture related to the procedures used in testing such qualities of the suture as cytotoxicity, mutagenicity, and carcinogenicity. App. A-158 (Question 27(a)(viii)). FDA did not express any concern about the use of a suture as an additional method of restraining the screw ring.

"addition of the bonding agent and the locking suture" arose as a direct consequence of an incident that occurred during the clinical trials and that FDA had specifically reviewed these proposed design changes; and concluded that FDA had specifically "approved TCI's proposed design changes, including the use of the suture." App. A-18; see also App. A-20 (FDA "specifically approved the addition of the suture in 1988"). "[A]ll three elements that are the focus of plaintiff's claims," the district court reasoned, "were part of the design of the HeartMate when TCI submitted its original PMA application." App. A-19.

The district court explained that *Medtronic* v. *Lohr* requires a two-part inquiry into whether "(1) the FDA has established specific counterpart regulations or other specific federal requirements that are applicable to the particular device; and (2) the state claim is different from, or in addition to, the specific FDA requirements." App. A-26. Applying that "generally accepted" test, the district court concluded that both prongs were satisfied. In approving the HeartMate for commercial sale, FDA had indicated that "TCI was *required* to comply with a series of conditions, including selling the device *only in the form in which it had been approved*." *Ibid.* (emphasis added). Under this FDA "mandate," TCI was "required to obtain further regulatory approval" if it "wanted to make any change" to the HeartMate that "affected the safety or effectiveness of the device." *Ibid.* And these requirements were both

"applicable" to the HeartMate and "specific" in nature: "The HeartMate's PMA process was a determination by the FDA that the HeartMate – and specifically the HeartMate – was safe and effective." App. A-26-27. "The vast majority of federal and state appellate courts that have addressed the issue," the court added, including this Court before *Lohr*, "have held that the PMA process is an example of a federal requirement that may trigger § 360k(a) preemption." App. A-27 (citing *Michael* v. *Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995)).

The district court also concluded that plaintiff's "specific common-law claims" for compensatory and punitive damages would impose requirements "that are different from or in addition to the PMA process." App. A-28. First, it noted that a majority in *Lohr* had ruled that Section 360k(a) covers "state common-law claims." App. A-25. Next, the court explained that plaintiff's claims were "based on the premise that the HeartMate was defectively designed or manufactured or contained inadequate labeling" and "[m]ost of her claims focus on the design and effectiveness of the screw ring, which the FDA analyzed." *Ibid.* "According to plaintiff," the court explained, "the HeartMate was unsafe in spite of the fact that the FDA, after approving the product's design (including the use of the screw ring and the accompanying suture), testing, intended use, manufacturing methods, performance standards, and labeling, designated the product as safe." *Ibid.* Thus, "[a]ny

judgment that the HeartMate was unsafe or otherwise substandard would be in direct conflict – *i.e.*, different from – the FDA's determination that the product was suitable for use." *Ibid.* The district court did not reach TCI's alternative argument based on implied preemption. App. A-28-29.

STATEMENT OF RELATED CASES AND PROCEEDINGS

There are no related cases or proceedings.

SUMMARY OF ARGUMENT

"[A]ny" state "requirement" that is "different from, or in addition to" a counterpart federal requirement that applies to a medical device is expressly preempted, so long as the state requirements (a) "relate[]" either "to the safety or effectiveness of the device or to any other matter included in" a federal requirement, and (b) have not been specifically exempted from preemption by FDA. 21 U.S.C. § 360k(a). In *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), a majority held that judgments in state tort suits qualify as state "requirements" covered by Section 360k(a). Relying on 21 C.F.R. § 808.1(d), a different majority in *Lohr* also concluded that, for federal requirements to trigger preemption under Section 360k(a), they must be "specific" to a device or class of devices.

As the district court recognized, the great majority of federal and state courts to have addressed the question – before and after *Lohr* – have concluded that the

premarket-approval process imposes "specific" federal requirements on devices. Most courts have also concluded that federal requirements imposed in the PMA process preempt state-law tort claims like those asserted by the plaintiff in this case, which seek to impose *different* requirements relating to the design, manufacture, and labeling of a medical device. This Court reached that very conclusion in *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (1995). Because *Lohr* did not involve a PMA device, but rather a device subject to far less stringent regulatory scrutiny, *Lohr* does not alter the holding of *Michael*, which is controlling and – in light of certain points that plaintiff is not disputing in this appeal – dispositive here.

The district court faithfully applied the analytical framework set forth in *Lohr*. Moreover, its conclusion that the PMA process imposes requirements that expressly preempt different counterpart requirements imposed under state tort law finds substantial support in the text and legislative history of the MDA and in FDA's exemption practices. In attempting to persuade this Court to join the tiny minority of jurisdictions that have rejected preemption in this setting, plaintiff relies on a misreading of *Lohr*, an incomplete account of the available evidence of Congress's preemptive intent, an *amicus* brief filed by FDA that defended a proposed "interpretive rule" the *agency subsequently withdrew*, and an inaccurate description of how FDA has interpreted the MDA's express preemption clause. She also relies

on several general background principles – such as the "presumption against preemption" and the need to take into account FDA's interpretation – that either lend no support to her position or are already factored into the *Lohr* framework. Finally, plaintiff relies on another provision of the MDA (21 U.S.C. § 360h(d)) that the Supreme Court in *Lohr* ignored as irrelevant and, as she candidly admitted below, "does not directly limit the pre-emption clause of Section 360k." Plaintiff's Br. in Opp. to Motion for Summary Judgment ("SJ Opp.") 14. None of these arguments provides any basis for reversing the district court's judgment.

Last but not least, even if plaintiff's claims are not expressly preempted by Section 360(a), they are *impliedly* preempted. If allowed to proceed, her claims would conflict with and frustrate the federal purposes underlying the MDA by inviting lay jurors to second-guess the expert judgments of FDA, rendered in the PMA process, concerning the safety and effectiveness of the HeartMate's design, method of manufacture, and labeling.

STATEMENT OF STANDARD OF REVIEW

Defendant agrees that this Court reviews the grant of summary judgment *de novo*.

ARGUMENT

"[S]tate law that conflicts with federal law is 'without effect.'" *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Congress's purpose "is the ultimate touchstone of pre-emption analysis." *Ibid.* (internal quotations and citations omitted). When Congress includes an express preemption provision in a statute, its intent to preempt state law is obvious. Even in the absence of an express preemption clause, federal law may *impliedly* preempt state law. *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

The district court properly concluded that all of plaintiff's claims are expressly preempted by Section 360k(a). This is an especially strong case for preemption because of the lengthy and exhaustive regulatory oversight exercised by FDA during the investigational and PMA phases and because plaintiff's claims challenge design features that FDA specifically reviewed and approved.

I. THE DISTRICT COURT CORRECTLY CONCLUDED THAT PLAINTIFF'S CLAIMS ARE EXPRESSLY PREEMPTED

The district court ruled that plaintiff's state-law claims are expressly preempted because they would impose "requirements" on the design, manufacture, and labeling of the HeartMate that are "different from, or in addition to" the extensive requirements imposed on that heavily regulated device by federal law. 21 U.S.C.

§ 360k(a). Under the broad terms of Section 360k(a), which is quoted above (at 6), this case presents a straightforward example of express preemption. The MDA's express preemption nullifies "any" state "requirement" that satisfies three conditions. First, the state requirement must affect "a device intended for human use" — *i.e.*, a medical device. Second, the state requirement must be "different from, or in addition to, any requirement applicable" to the device under the MDA. Third, the state requirement must "relate to" — a deliberately broad phrase — either "the safety or effectiveness of the device," or "any other matter included in a requirement applicable to the device under [the MDA]" (another deliberately broad phrase not limited to safety and efficacy matters). 21 U.S.C. § 360k(a). States are precluded from imposing "any requirement" that meets these conditions, unless FDA grants them an exemption from preemption under 21 U.S.C. § 360k(b).

Plaintiff's design and other claims fall squarely within the language of Section 360k(a). In *Lohr*, a majority made clear that state tort duties imposed through the common law constitute "requirements" within the meaning of Section 360k(a). See 518 U.S. at 509-11 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part); *id.* at 504-05 (opinion of Breyer, J.). Justice Breyer even gave as an example of a claim that would be preempted by the MDA "a state law tort action that premises liability upon the

defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id*. at 504. Plaintiff's claims in this case all would impose "requirements" under state law that "relate[] to the safety or effectiveness" of the HeartMate. 21 U.S.C. § 360k(a). Finally, plaintiff has never disputed that her claims would impose requirements that are "different from, or in addition to," the applicable federal design, manufacturing, and labeling requirements. Cf. note 8, *infra*.

Of course, the Supreme Court in *Lohr* adopted a limiting construction of the broad language of the MDA's express preemption clause. See 518 U.S. at 496-97. In so doing, the Court relied on a narrow interpretation of Section 360k(a) adopted by FDA in setting forth the agency's procedures for considering exemptions from preemption. See 21 C.F.R. § 808.1(d). In particular, the majority in *Lohr* appeared to agree with FDA that Section 360k(a)'s broad reference to "any" federal requirement should be limited to requirements that are "specific" in their applicability. See 518 U.S. at 500, 506-07.[6] Consistent with that interpretation, the

[6] We say "appeared" because the same majority that seemed to endorse the "specificity" gloss in *Lohr* elsewhere declared: "[W]e do not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted." 518 U.S. at 500. That statement, of course, reflects a *rejection* of the idea that requirements under Section 360k(a) are preempted or preemptive only if they are "specific."

district court held that this case satisfies a two-part test that most courts have used since *Lohr*: "(1) the FDA has established specific counterpart regulations or other specific federal requirements that are applicable to the particular device; and (2) the state claim is different from, or in addition to, the specific FDA requirements." App. A-26.[7]

Plaintiff suggests that the language of Section 360k(a) is not satisfied here because PMA approval imposes no "requirements" *at all* on a medical device. She also argues that the district court failed to recognize an additional precondition to express preemption: the state requirement must be "specific" to the device. And she argues that neither the federal nor the state requirements involved in this case satisfy FDA's "specificity" gloss on Section 360k(a). Finally, she invokes a hodgepodge of other arguments to try to escape the broad language of Section 360k(a).

Even so, there are several key points that plaintiff does *not* dispute. Taken together, these undisputed points go far – if not all the way – toward providing an independent basis for affirming the judgment below without any need to examine the various arguments advanced by plaintiff for reversal.

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[7] As is clear from these limitations contained in Section 360k(a) – and from the limiting construction added in *Lohr* – no one is even remotely suggesting that the MDA confers a "sweeping immunity from state-law damages actions." Pl. Br. 16, 20. That is a straw man of plaintiff's making.

A. The Decision Below Can And Should Be Affirmed Largely On Narrow Grounds That Plaintiff Does Not Dispute

Three points are not disputed in this appeal. ***First***, plaintiff acknowledges that in *Michael* v. *Shiley, Inc.*, 46 F.3d 1316 (1995), this Court squarely held that the PMA process imposes "requirements" on devices; those requirements trigger express preemption under Section 360k(a); state requirements imposed in tort actions are covered by Section 360k(a); and the federal requirements imposed through the PMA process expressly preempt different requirements imposed under state tort law. Plaintiff notes in passing that *Shiley* "is not binding on this Court *to the extent that* it is inconsistent with *Medtronic*" (Br. 16 (emphasis added)), but she cannot bring herself to say that *Shiley is in fact* inconsistent with *Lohr*.

To be sure, plaintiff *does* insist (Br. 14) that *Lohr* involved "a context almost identical to that presented here." But *Lohr* involved the Section 510(k) clearance process, which is far less rigorous than the PMA process involved here. See pages 3-4, 7-8, *supra*. Nothing in *Lohr* calls this Court's *Shiley* decision into question. The Court's decision in *Lohr* with respect to the non-preemption of the Lohrs' labeling and manufacturing claims hinged on the general applicability of the federal labeling and manufacturing regulations, which apply to virtually *all* medical devices

(and thus are more general in their applicability than are requirements imposed by the PMA process and by the FDA's approval of the HeartMate for marketing).

Moreover, this Court in *Shiley* considered FDA's "specificity" gloss on the statute and concluded, among other things, that the PMA process (and even the requirement that a device obtain PMA approval in the first place) qualified as "specific requirements applicable to a particular device under the act" (21 C.F.R. § 808.1(d)). 46 F.3d at 1324. Thus, nothing in *Lohr* alters this Court's conclusion that, under FDA's regulation, the PMA process imposes "requirements" and those requirements "constitute proper bases for pre-emption under § 360k." 46 F.3d at 1324; see also *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 906-07, 911 (7th Cir. 1997) (reaffirming, after remand by Supreme Court following *Lohr*, that PMA process imposes "specific" federal requirements); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 580-84 (5th Cir. 2001) (same). And, as explained above, *Lohr confirms* the holding of *Shiley* that state tort law imposes "requirements" within the meaning of Section 360k(a).

Second, many of plaintiff's arguments about the nature of the *federal* requirements involved in this case focus on the broader question whether, *as a general matter*, premarket approval of a medical device gives rise to preemptive federal requirements. But the lower court's decision turned not *just* on the fact that

HeartMate had received premarket approval. It also turned on FDA's specific review and regulation of the particular design features underlying plaintiff's claims. App. A-18; see also App. A-20 (FDA "specifically approved the addition of the suture in 1988"). Plaintiff does not seriously challenge the "specificity" arising from these circumstances.

Third, plaintiff does not argue that her claims escape preemption because they impose requirements that are not "different from, or in addition to" (21 U.S.C.§ 360k(a)) the counterpart federal design, manufacturing, or labeling requirements.[8] She also failed in the lower court to identify any respect in which the state requirements underlying her claims were identical to the applicable federal requirements. Accordingly, it is a given that the state requirements involved in this case are "different from, or in addition to" (*ibid*.) to the counterpart federal requirements.[9]

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[8] The only apparent exception to this is plaintiff's newly minted argument that her warning claims are not different insofar as TCI is permitted to make certain labeling changes immediately while a request for approval to make the change is pending before the FDA. Br. 38. That argument was never raised below and therefore is waived. In the lower court, plaintiff acknowledged that, "strictly speaking," her failure-to-warn claim "might be said to impose an 'additional' requirement" on the HeartMate. SJ Opp. 24.

[9] In the lower court, plaintiff did argue that under *Lohr* express preemption is limited to situations where a specific federal requirement *conflicts with* its counterpart state requirement (and, she said, that was not true here). But she has evidently abandoned

These three undisputed propositions effectively resolve the express preemption issue raised in this appeal, at least under the two-part analysis applied by the district court. According to that court, Section 360k(a) preempts state law if "(1) the FDA has established specific counterpart regulations or other specific federal requirements that are applicable to the particular device[,] and (2) the state claim is different from, or in addition to, the specific FDA requirements." App. A-26. Taken together, the three undisputed propositions satisfy this test. In any event, as we next explain, plaintiff's remaining arguments should be rejected.

B. The PMA Process Imposes "Requirements" On Approved Devices

Plaintiff's only serious effort to avoid the text of Section 360k(a) is her far-reaching contention (Br. 31, 33, 35) that the rigorous PMA process does not impose any "requirements" at all on the approved device. According to plaintiff, this is true because a PMA device's design, manufacturing process, and labeling all *originate* in

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that argument on appeal, and with good reason. The lower court specifically ruled that the applicable state and federal requirements in this case are "in direct conflict" (App. A-28), and plaintiff does not seriously challenge that holding. In any event, the argument lacks support either in the language of the preemption clause itself, which is plainly broader, see 21 U.S.C. § 360k(a) ("different from, or in addition to"), or in FDA's regulation, see 21 C.F.R. § 808.1(d) ("substantially identical"). See also 21 U.S.C. § 360k(b) (language of exemption provision confirms that non-conflicting state requirements may be exempted from, and therefore are covered by, Section 360k(a)). Nor is it sensible to read the sweeping language of Section 360(k) as an effort by Congress to narrow the ordinary operation of implied preemption principles (which already nullify conflicting state requirements).

choices made by the manufacturer. In addition to being squarely foreclosed by *Shiley*, this argument fails for at least four reasons. *First*, it is refuted by the many provisions of the MDA that refer to "requirements" imposed by FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See, *e.g.*, 21 U.S.C. § 331(e) (prohibiting, among other things, the "failure to establish or maintain" records "required under" Section 360e(f)); *id*. § 351(f)(1)(A)(i), (B)(i), (C) (in sections relating to adulterated devices, referring to "require[ment]" of having premarket approval); *id*. §§ 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 382(a)(2)(A).

Second, it ignores practical realities. As plaintiff admitted below (SJ Opp. 22), under federal law a device that is approved for marketing through the PMA process may not be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id*. § 814.39. *Compliance, in other words, is not optional.* That FDA can change these requirements following the submission and approval of a PMA supplement does not make these requirements anything less than mandatory.[10]

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[10] Changes to the design of a PMA device trigger a supplemental FDA review process, and the change cannot be implemented until approved by FDA. See 21 C.F.R. § 814.39. Therefore, plaintiff's suggestion below (SJ Opp. 7-8) that post-1994

Third, it conflates the genesis of an obligation with whether the obligation is binding. Private parties may petition FDA to make rules and regulations. See 21 C.F.R. §§ 10.25(a), 10.30, 10.40(a)(2). Requirements eventually imposed by the agency are in no way optional just because they originated in the proposal of a private party. And the MDA's express preemption provision states that "*any* requirement applicable * * * to the device" under the MDA preempts different or additional state requirements. 21 U.S.C. § 360k(a) (emphasis added). It does not say "any requirement that originates in the FDA rather than the manufacturer."

Fourth, as the district court recognized, plaintiffs' argument is contrary to the substantial weight of authority. Before and since *Lohr*, courts have ruled that the PMA process imposes preemptive federal requirements. Indeed, if plaintiff's theory were correct, then the federal requirements imposed on *investigational* devices through the IDE process would also fail to trigger express preemption (since manufacturers also make choices in that context about design and other matters). Yet numerous courts have reached the opposite conclusion. See, *e.g.*, *Chambers* v. *Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997); *Martin* v. *Telectronics Pacing*

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design changes to the HeartMate somehow eliminate the federal "requirement" is inconsistent with the regulatory scheme.

Systems, Inc., 105 F.3d 1090, 1098-1101 (6th Cir. 1997). Under plaintiff's view, Section 360k(a) would be a virtual nullity.

C. The PMA Process Imposes Requirements That Are "Specific"

The Court pointed out in *Lohr* that, for federal requirements to have preemptive force, they "must be 'applicable to the device' in question, and, according to the [FDA] regulations, pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d)). The federal design, labeling, and manufacturing requirements applicable to the HeartMate easily satisfy that test. Although plaintiff acknowledged below the "specificity and considerable rigor of the PMA process" (SJ Opp. 21), she now contends that the district court erred in concluding that the premarket approval process resulted in any "specific" federal requirements that would trigger preemption under Section 360k(a). Even if this argument were not foreclosed by *Shiley*, it should be rejected.

1. By its nature, PMA approval is a *specific* determination by FDA that a *particular* device is reasonably safe and effective, based on FDA's review of data relating exclusively to that device. See *Buckman*, 531 U.S. at 348 (PMA process "involves a time-consuming inquiry into the risks and efficacy of *each* device") (emphasis added). In contrast, the 510(k) process involved in *Lohr* is a means of

bypassing the stringent PMA process, and it focuses on equivalence rather than safety.[11]

Moreover, as explained above, FDA's 2½-year review of the HeartMate was especially thorough and time-consuming. Even before the PMA application was submitted, FDA oversaw years of investigational trials, during which FDA specifically approved the design feature at the center of plaintiff's claims: the use of a suture and bonding agent as additional methods of securing the screw ring on the outlet elbow. It is difficult to see how the design and other requirements involved in this case could be described as anything other than "specific" to the HeartMate. See, *e.g.*, *Worthy*, 967 S.W.2d at 376 ("We believe the details of the FDA's premarketing approval of Zyderm – as opposed to the PMA process in general – are sufficiently specific to have preemptive effect."); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 225-28 (6th Cir. 2000). Unlike the federal manufacturing and labeling requirements found not to be preemptive in *Lohr*, this is plainly

> a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved * * *, and implemented that conclusion via a specific mandate on [the] manufacturer[ ].

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[11] Because the Court held in *Lohr* that the 510(k) process imposes no design requirements at all, it had no occasion to consider whether such requirements would qualify as "specific."

Lohr, 518 U.S. at 501. Accord *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997) (stating that PMA process fits this description).

In *Lohr*, the Court held that certain federal labeling and good manufacturing practices (GMP) requirements, which applied generally to *all* medical devices, were not sufficiently "specific" to trigger preemption. Those regulations are also distinguishable from the regulations governing the PMA process because the former apply, "with a few limited exceptions," to "every medical device." 518 U.S. at 497. In contrast, FDA's requirements relating to the PMA process – even viewed in the abstract, apart from their specific application to the HeartMate – are limited to a *single regulatory class* of medical devices: devices for which premarket approval is sought. The FDA has acknowledged that "specific FDA requirements applicable to a particular device *or class of devices*" trigger express preemption under the MDA. 43 Fed. Reg. 18661, 18662 (1978) (emphasis added). And in several regulatory notices, FDA has indicated that the requirement of premarket approval triggers federal preemption. See pages 37-41, *infra*.

The "vast majority of federal and state appellate courts that have addressed the issue" (App. A-27) since *Lohr* have recognized that PMA "[a]pproval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" and is "specific to the product."

Mitchell, 126 F.3d at 913.[12] In concluding that the PMA process imposes preemptive federal requirements, these courts have routinely distinguished the vastly different 510(k) pre-market clearance process at issue in *Lohr*, which the Supreme Court held does not impose any "requirements" on the design of the device. This was also the lopsided majority approach before *Lohr*. See *Worthy*, 967 S.W.2d at 373 (collecting pre-*Lohr* cases).

2. The proposition that the PMA process imposes requirements that trigger express preemption also finds substantial support in the text and legislative history of the MDA and in FDA's exemption practice. As noted above (at 31), many provisions of the MDA refer to "requirements" imposed by the PMA process. Beyond that, the legislative history strongly confirms Congress's understanding that premarket approval by FDA would trigger preemption. The House Report stated:

> In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation * * * is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law *requires premarket approval* of all new medical devices * * * . * * *

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[12] Accord *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 584 (5th Cir. 2001); *Kemp*, 231 F.3d at 226-27; *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996); *Fry* v. *Allergan Medical Optics*, 695 A.2d 511, 516 (R.I. 1997); *Worthy*, 967 S.W.2d at 376 (collecting cases). But see *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1375-76 (11th Cir. 1999) (holding that, although PMA approval "is clearly specific to the device under review," it imposes no "requirements" at all on the device).

> In the Committee's view, *requirements imposed under the California statute serve as an example of requirements that the Secretary should authorize to be continued* (provided any application submitted by a State meets the requirements [for exemption] * * *).

H.R. Rep. No. 94-853, at 45-46 (1976) (emphasis added). The Committee plainly believed that requirements imposed pursuant to a state premarket approval process – including requirements relating to device design and labeling – would be subject to preemption unless exempted. What would have triggered such preemption? The answer is self-evident: The counterpart requirements imposed through the federal PMA process.

Nor is this all. The conference committee that chose the final language of the MDA opted for the preemption clause in the House bill (H.R. 11124, 94th Cong., 2d Sess. (1976)) instead of the narrower version in the Senate bill (S. 510, 94th Cong., 1st Sess. (1975)). See H.R. Conf. Rep. 94-1090, at 40 (1976). The Senate bill provided:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or *scientific review pursuant to section 514 under this Act is in effect*, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same device unless such requirements are identical to the requirements of the Federal requirements.

S. Rep. No. 94-33, at 72-73 (1975) (emphasis added). The reference to "Section 514" was to the process for premarket scientific review set forth in the Senate bill. Thus, the Senate bill plainly envisioned that federal PMA requirements would have preemptive effect. There is no reason to think that Congress, in choosing the *broader* language of the House bill, intended a *narrower* form of preemption that would not be triggered by PMA requirements.

Finally, similar evidence appears in the regulatory history of the statute. In a 1978 notice, FDA, in response to several commentors who stated that it was "unclear" in FDA's proposed regulation concerning exemptions from preemption "whether or when State and local premarket approval requirements are preempted," provided the following clarification:

> Like all other medical device requirements, different or additional *State and local premarket approval requirements are preempted* when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act. For a device classified in Class III * * * *the counterpart FDA requirement — the requirement that the product have premarket approval — was established by operation of the act immediately upon enactment of the Amendments on May 28, 1976. * * * Once these FDA requirements are established, different or additional State requirements are preempted*.

43 Fed. Reg. 18661, 18664 (1978) (emphasis added). FDA subsequently reaffirmed that the federal requirement of premarket approval triggers express preemption. 45 Fed. Reg. 67321, 67322-23 (1980); 44 Fed. Reg. 19438, 19439 (1979).

FDA's exemption practice – before and after *Lohr* – further confirms that the PMA process imposes requirements that trigger preemption. As plaintiff points out (Br. 25), "[t]he decision whether to exempt a [state] law from preemption requires the agency first to determine whether the law would be preempted in the first place" – which requires a judgment about whether the federal and state requirements at issue are of the kind encompassed by Section 360k(a). Shortly after the MDA was enacted, FDA considered – and denied – a request by California seeking an exemption from preemption from the federal GMP regulations, which California had adopted as its own, insofar as California wished to interpret them in a way different from FDA. See 45 Fed. Reg. 67321, 67322 (1980) ("if California interprets or applies the GMP regulations in such a way as to make them different from or in addition to the Federal regulations, then the California requirements *will be preempted* to that extent") (emphasis added). That action, of course, presupposes that the federal GMPs, despite their general applicability to virtually all medical devices, have preemptive effect under Section 360k(a).[13] To be sure, the Supreme Court in *Lohr* reached the opposite conclusion about the preemptive effect of the GMP requirements, but that does not

[13] Consistent with FDA's early exemption practice, the United States *expressly conceded* in its *amicus* brief in *Lohr* that the requirements imposed in the GMP regulations give rise to preemption of state requirements. See Nos. 95-754, 95-886 U.S. Br., 1996 WL 118035, at *24 n.19 ("We do not dispute that the GMPs impose 'requirement[s]' within the meaning of Section [360k(a)].").

change FDA's prior exemption practice, nor does it alter the position taken by FDA in *Lohr* itself (see note 13, *supra*).[14]

The FDA's exemption practice since *Lohr* provides further support for the conclusion that requirements imposed through the PMA process trigger express preemption. For example, in a December 18, 1996, advisory opinion issued following *Lohr*, FDA opined that certain requirements imposed in the PMA approval process on an over-the-counter HIV-test kit preempted divergent requirements imposed under state law. (See Addendum 1a-4a.) Moreover, in other exemption settings FDA has made clear that the "specificity" gloss adopted in *Lohr* on preemptive federal requirements is not restricted to requirements that apply to a single device. For example, several of the exemptions considered by FDA during the period it regulated cigarettes as a medical device involved FDA regulations relating to both cigarettes

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[14] Notably, the United States in *Lohr* did *not* urge the Supreme Court to adopt, or even to defer to, the "specificity" concept expressed in 21 C.F.R. § 808.1(d). On the contrary, the federal government *expressly rejected* that gloss in its brief. See, *e.g.*, note 13, *supra*; see also Nos. 95-754, 95-886 U.S. Br., 1996 WL 118035, at *17-18 (criticizing as "strained as a grammatical matter" the Lohrs' argument that "the 'with respect to' phrase [in Section 360k(a)] limits the scope of the provision to *state* requirements that *specifically refer or relate to medical devices*, and therefore excludes general common-law duties"; and suggesting that the "with respect to" language instead "suggests that such a [state] 'requirement' *may be one of general applicability*") (emphasis added); *id*. at *10 (acknowledging that "a substantive obligation created by state tort law, such as the duty to use due care, may constitute a 'requirement' within the meaning of [Section 360k(a)]").

and smokeless tobacco. See 21 C.F.R. § 897.1 *et seq.* (1998); 62 Fed. Reg. 7390 (1997); 62 Fed. Reg. 63721 (1997).[15] In sum, the MDA's text as well as its legislative history and FDA's exemption practice remove any doubt about whether the PMA process imposes preemptive federal requirements.

Finally, there is an independent reason why the PMA requirements here are sufficiently specific *in applicability* to trigger preemption under 21 C.F.R. § 808.1(d): they have been *specifically applied* to the *particular* medical device at issue in this case. The FDA's regulation requires nothing more before Section 360k(a) is triggered. The same is true of the *state* requirements involved in this case, as we next explain.

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[15] In its *amicus* brief in *Buckman*, the United States gave various examples of federal requirements that qualify as applicable "to a specific device or set of devices" and thus trigger express preemption. 98-1768 U.S. Br., 2000 WL 1364441, at *12. Those examples include federal requirements that apply to all medical devices that contain natural rubber (21 C.F.R. § 801.437). The "natural rubber" regulation applies to *43 different categories* of medical devices, including catheters, latex gloves, tracheal tubes, condoms, enema kits, and ophthalmic eyeshields. 63 Fed. Reg. 50660, 50673-50676 (1998). FDA has estimated that these 43 categories comprise "approximately 17,600" different models of medical devices. *Id.* at 50676.

D. Plaintiff's Claims Would Impose State "Requirements" Within The Meaning Of Section 360k(a) That Are Also "Specific" Within The Meaning Of FDA's Regulation

Following the lead of "[m]any" other courts (App. A-28), the district court correctly ruled that the *state* requirements plaintiff sought to have imposed in this tort action are all preempted by Section 360k(a). "Any judgment that the HeartMate was unsafe or otherwise substandard," the district court reasoned, "would be in direct conflict – *i.e.*, different from – the FDA's determination that the product was suitable for use." App. A-28. That holding is correct.

1. Plaintiff faults the district court (Br. 27) for failing to consider whether the state requirements involved in this case are sufficiently "specific" within the meaning of FDA's regulation. In plaintiff's view, "an essential step in the analysis" required by *Lohr* is an inquiry into whether "Ms. Horn's damages claims were general or device-specific." Br. 27.[16] That argument, however, is based on a misreading of

[16] The concept of "specificity" is ambiguous. A requirement can be "specific" in *content* (as in Justice Breyer's example of a 2-inch wire requirement, which is specific when compared to a more generalized duty to use reasonable care in the design of a product). Alternatively, a requirement can be "specific" in *applicability* (as where it applies to a single device or class of devices). FDA's regulation makes clear, however, that it is the *latter* gloss that the agency intends for the state "requirements" covered by Section 360k(a). See 21 C.F.R. § 808.1(d)(1) (Section 360k(a) "does not preempt State or local requirements of general *applicability*") (emphasis added). At the same time, *Lohr* makes clear that common law duties that apply generally even to products other than devices may become "specific" where, as here, they are applied to a particular medical device in the course of litigation.

Lohr. As we explained above (at 8), Justice Breyer's opinion turned on the character of the *federal* requirements at issue. For that reason, he simply had no occasion to decide whether the *state* requirements must also be "specific" within the meaning of FDA's regulation.

To be sure, Justice Breyer did join (and thus provide a fifth vote for) a portion of Justice Stevens's opinion in which the Court indicated not only that "[t]he 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 pre-emptive scope of the statute and regulations" but also that "the general common-law requirements in this suit * * * escape preemption" because "their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." 518 U.S. at 500, 502. At the same time, however, this very same portion of Justice Stevens's opinion included statements suggesting that Section 360k(a) was *not* limited to "specific" requirements. See note 6, *supra*. And beyond

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Accord Addendum 3a (post-*Lohr* FDA advisory opinion). Much of plaintiff's brief rests on the unstated assumption – which she elsewhere contradicts (Br. 25) – that "specificity" under FDA's regulation means only "content-specificity." If that were true (and it is not), the threshold legal defense of preemption would be available only on post-trial motions or after substantial litigation has forced a plaintiff (perhaps in the jury instructions mentioned by plaintiffs, see Br. 29) finally to specify her particular theory of liability or alternative design.

that, Justice Breyer *expressly joined* the O'Connor bloc in agreeing (for a majority of the Court) that state tort duties imposed through the common law – which by their nature apply to a wide array of products – constitute "requirements" within the meaning of Section 360k(a). See pages 24-25, *supra*. Justice Breyer even gave as an example of a claim that would be preempted by the MDA "a state law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id.* at 504. That statement is impossible to square with plaintiff's characterization of what the majority (including Justice Breyer) "held" in *Lohr*.

Other courts have read *Lohr* exactly this way. See, *e.g.*, *Harris* v. *Ford Motor Co.*, 110 F.3d 1410, 1414 n.8 (9th Cir. 1997) ("We do not believe that [*Lohr*] precludes express pre-emption when a state law of general applicability * * * is involved."); *Papike* v. *Tambrands*, 107 F.3d 737, 742 (9th Cir. 1997) ("Although Justice Breyer joined in Section V [of Justice Stevens's opinion], * * * it is clear enough that the Court found no preemption of common-law claims largely because the pacemaker was not subject to any device-specific *FDA regulations*.") (emphasis added); *Easterling* v. *Cardiac Pacemakers, Inc.*, 986 F. Supp. 366, 372-73 (E.D. La. 1997). The district court was therefore correct to adopt the "generally accepted" two-

part test, under which there is no need to examine the specificity of the state requirements. App. A-18.

2. In any event, the state requirements involved in this case satisfy FDA's "specificity" gloss on the statutory text. Plaintiff's claims are no less "specific" than Justice Breyer's example of a claim based on the manufacturer's failure to use a 1-inch wire. In each of her claims, plaintiff is applying state-law duties that apply to a wide array of products with specificity to the HeartMate. Her design defect claims, for example, would require TCI either to use an entirely different design than the screw ring to connect the outlet elbow to the pump, or to use different materials instead of the suture, or to place the eyelet in a different position. Similarly, her failure-to-warn claims would require TCI to provide different warnings and instructions from those approved by FDA. In each of these examples, a lay jury would be called upon at trial to apply a generalized common law duty with specificity to the HeartMate. Because the state common law duties underlying plaintiff's claims would be applied with specificity in this case to the HeartMate, they satisfy the "specificity" concept expressed in FDA's regulation. 21 C.F.R. § 808.1(d)(1).

Before and after *Lohr*, the majority of appellate courts have concluded that state-law tort claims of the kind involved in this case are preempted by federally imposed PMA requirements under Section 360k. *E.g.*, *Kemp*, 231 F.3d at 228-37;

Mitchell, 126 F.3d at 911-15; *Papike*, 107 F.3d at 741-42; *Worthy*, 967 S.W.2d at 376-77. This Court should reject plaintiff's invitation to join the ranks of a tiny minority of courts that have concluded otherwise.

3. FDA's exemption practice further refutes plaintiff's submission that a state requirement must apply to a single device to qualify as "specific" within the meaning of FDA's regulation. FDA has acted on at least a dozen requests for preemption exemptions for state provisions that apply not only to medical devices but to other products as well. See 21 C.F.R. §§ 808.51 (exempting Alabama statute "[t]o the extent that" it applies to medical devices), 808.52 (same for Alaska statute), 808.55(b)(1), (2) (denying exemptions for nine separate provisions of California statute "to the extent that they apply to devices"), 808.94 (exempting Utah statute "[t]o the extent" it applies to medical devices).[17] And FDA has made clear that even "general [state] requirements not applicable to specific devices" are covered by Section 360k(a) once they are "applied to a specific device in such a way as to establish requirements." 45 Fed. Reg. 67321, 67322 (1980).

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[17] Thus, the Supreme Court's statement in *Lohr* that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability" (518 U.S. at 499-500) reflects a mistaken understanding of FDA's exemption practice. Of course, the point was not developed in the *Lohr* briefing because the United States did not urge deference to the FDA's "specificity" gloss and indeed expressly repudiated that gloss. See notes 13-14, *supra*.

FDA's exemption practice since *Lohr* has continued to reflect this understanding. Thus, in evaluating exemption requests for state and local requirements relating to cigarettes and smokeless tobacco, the agency considered several state statutes even though they applied to products other than what the agency then regarded as medical devices. See 62 Fed. Reg. 7390, 7392 (1997); 62 Fed. Reg. 63271, 63272 (1997). For example, the agency considered whether to exempt an Alabama statute that applied to "cigarettes, cigarette tobacco or *cigarette paper*, or *any substitute for either of them*." 62 Fed. Reg. at 7391 (quoting Alabama Code § 13A-12-3) (emphasis added); see also Addendum 3a (post-*Lohr* FDA advisory opinion).

4. Finally, plaintiff's suggestion that a state requirement is "specific" only if it applies to a single device should be rejected because it would create an "utterly irrational loophole." *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992). There is no reason why Congress would have meant to allow States to circumvent Section 360k(a) through the simple expedient of passing laws that apply to more than a single device. Nor is there any reason why FDA would have intended "specificity" to have a different and narrower meaning with respect to the *state* "requirements" covered by Section 360k(a) than it does with respect to the *federal*

"requirements." See 43 Fed. Reg. 18661, 18662 (1978) (federal requirements trigger preemption if they apply to "a class of devices").

In sum, the state and federal requirements at issue in this case are "specific" in every relevant sense. They arise from the particularized application of state and federal laws to a single device (and no others); they impose obligations to use specific designs, manufacturing processes, and labeling for the HeartMate; and they are the product, on the federal side, of active and particularized review by FDA.

E. The Relevant Federal And State Requirements Are "Different"

As explained above (at page 29 & n.8), plaintiff does not contend that the state and federal requirements involved here are identical. At bottom, plaintiff's design, manufacturing, and labeling claims are all premised on the notion that what FDA approved in the PMA process was insufficient to ensure the safety and effectiveness of the HeartMate.[18]

[18] Plaintiff's negligence claims fault TCI for failing to test and study the HeartMate adequately. Cplt. ¶ 19. In that regard, plaintiff is seeking to impose under state law a specific testing requirement that is different from, and fundamentally inconsistent with, the federal testing requirements imposed on the HeartMate in the FDA-supervised clinical trials. Numerous courts have held since *Lohr* that the IDE process preempts tort actions seeking to impose divergent state-law requirements on *investigational* devices. See pages 32-33, *supra*.

F. Plaintiffs' Remaining Efforts To Avoid Express Preemption Are Unavailing

In an effort to avoid the principles set forth above, plaintiff advances a series of additional arguments. *First*, she argues that this Court should rely on statements made in a government *amicus* brief that was filed in 1997 in conjunction with an "interpretive rule" that FDA proposed but subsequently withdrew. *Second*, she urges this Court to rely heavily on the so-called "presumption against preemption." *Third*, she attaches significance to 21 U.S.C. § 360h(d). *Fourth*, she advances a variety of arguments aimed at sparing her failure-to-warn claims from preemption. These arguments should all be rejected.

1. Deference To FDA's 1997 *Amicus* Brief And Withdrawn "Interpretive Rule"

Plaintiff points to statements made in an *amicus* brief filed in December 1997 contemporaneously with the government's publication of a *proposed* regulation (62 Fed. Reg. 65384 (1997)) in which FDA purported to "interpret" the MDA's express preemption clause and thereby resolve certain conflicts in the federal courts. See Br. 26-27, 29-35. Notably, plaintiff never informs this Court of the existence of the proposed regulation, or of the fact that it was later withdrawn, or of the very close connection between these two documents (much of the *amicus* brief is devoted to

describing the content of the regulation and defending its "interpretation"). Plaintiff's reliance on this *amicus* brief is misplaced.

As plaintiff is aware, the proposed regulation itself is of no moment because FDA withdrew it after receiving a flurry of critical comments. Because the proposed regulation was withdrawn, numerous courts have correctly indicated that it is "entitled to no weight." *Dunlap* v. *Medtronic*, Inc., 47 F. Supp. 2d 888, 897 (N. D. Ohio 1999); accord *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1375 n.15 (11th Cir. 1999); see also *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 375 (Tex. 1998).[19]

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[19] In the court below, plaintiff suggested that FDA's proposed rule was withdrawn "because of concerns regarding its timing with respect to amendments to the MDA enacted in late 1997." SJ Opp. 16 n.1. That explanation, however, is incomplete. See 63 Fed Reg. 39789, 39789 (1998). In fact, the proposal was withdrawn after an industry trade group complained that FDA had secretly and selectively shared a preliminary draft with the Public Citizen Litigation Group – plaintiff's lawyers in this appeal – and apparently elicited Public Citizen's input before the proposal was published in the Federal Register. See 4/9/98 Letter of S. Northrup (Addendum 5a-6a). Noting that federal regulations make it illegal for FDA to do that (see 21 C.F.R. § 10.80(b)(2)), the trade group called for a "thorough investigation." See Addendum 5a. FDA later indicated that it was "tak[ing] [these] concerns seriously and [was] initiating an investigation." See 5/1/98 Letter of M. Friedman (Addendum 9a). FDA eventually withdrew the proposed regulation in part because it determined that "an early draft * * * was shared during the spring of 1997" – many months before the December 12, 1997, publication date – with "attorneys for Public Citizen," and the agency had concerns that this secret lobbying effort might have undermined public "confidence that the agency is addressing [commentators'] concerns in an impartial manner." 63 Fed. Reg. at 39789.

There is no earthly reason why the views expressed in the withdrawn notice warrant this Court's deference simply because they were echoed in a contemporaneous *amicus* brief. Nor do the views expressed in the brief (and in the withdrawn rule) reflect the agency's "long and consistently held view" about the scope of preemption under Section 360k(a). Br. 27. As the discussion above makes clear, the views floated by FDA in the 1997 brief are *patently inconsistent* with the agency's other regulatory pronouncements, exemption practices, and *amicus* filings. For example, the government's *amicus* brief in *Lohr* did not ask the Supreme Court to defer to the "specificity" concept expressed in FDA's regulations and indeed repudiated that concept as inconsistent with the broad text of Section 360k(a). See notes 13-14, *supra*. Nor is plaintiff correct to suggest that FDA has always taken the view that PMA approval does not give rise to preemptive requirements under Section 360k(a). On the contrary, as explained above (at 38-41), FDA's exemption practice has proceeded on the assumption that state and federal PMA requirements *are* covered by Section 360k(a). Equally mistaken is plaintiff's suggestion that the 1997 notice and accompanying *amicus* brief reflects the government's longstanding views about the nature of the *state* requirements covered by Section 360k(a).[20]

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[20] For example, FDA's proposed regulation involved differential treatment of state requirements that were based in the "common law." See 62 Fed. Reg. 65384, 65388 (1997) (quoting proposed 21 C.F.R. § 808.1(d)(11)(i)). Putting aside the obvious

As the Supreme Court explained in *United States* v. *Mead Corp.*, 533 U.S. 218, 228 (2001), an important factor in determining the appropriate level of deference is the agency's "'consistency with earlier and later pronouncements.'" Accordingly, and because "[a]n interpretation advanced in a litigation brief" receives deference at the lowest end of the spectrum of judicial responses, "near indifference" (*ibid.*), this Court should disregard the views expressed in the 1997 *amicus* brief.

If this Court nevertheless believes that FDA's views on the scope of express preemption are important to the proper resolution of this appeal, then it should ask the agency to file a brief in this case. In our view, however, this case is easily resolved by reference to the undisputed propositions discussed in Section I.A above, the plain statutory language, FDA's longstanding exemption practice, and the overwhelming

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anomalies caused by the fact that many states have codified their common law of torts or products liability, this formulation was hardly consistent with FDA's views about the scope of preemption under Section 360k(a). Indeed, in its *Lohr* brief filed in 1996 FDA explained that it had "*not* heretofore taken a formal position specifically on whether the term 'requirement' in Section [360k(a)] encompasses obligations established by a State's common law of torts" – and went on to say that Section 360k(a) *does* encompass common law obligations. Nos. 95-754, 95-886 U.S. Br., 1996 WL 118035, at *10, *15-17 & n.12. Nor is there any basis in FDA's prior practice for treating requirements imposed under state *tort* law in a special way. Indeed, FDA refused to exempt from preemption (and thus found preempted) a California law forbidding fraudulent and other representations in advertising with respect to medical devices. See 21 C.F.R. § 808.55(b)(2) (hearing aids). That statute essentially embodied a tort duty under California law.

weight of the case law before and after *Lohr* (including this Court's still-binding decision in *Michael v. Shiley*, *supra*).

2. The "Presumption Against Preemption"

Plaintiff also relies heavily on the general "presumption against preemption." Br. 16-21. But the framework adopted in *Lohr already* takes that presumption into account. Furthermore, it is difficult to see why, when Congress has enacted an express preemption provision, courts should entertain the (obviously mistaken) assumption that Congress did not intend to disturb state regulatory authority. And the "presumption against preemption" has been either avoided or criticized by the Supreme Court in many cases since *Lohr*, and has been subjected to harsh criticism by recent scholarship. See, *e.g.*, *Sprietsma* v. *Mercury Marine*, 123 S. Ct. 518, 526 (2002) (relying on "natural[] read[ing]" of express preemption clause without mention of presumption);[21] *Buckman*, 531 U.S. at 347 (declining to apply the presumption); *Crosby* v. *National Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) (same); *United States* v. *Locke*, 529 U.S. 89, 107-08 (2000) (criticizing the presumption as

[21] Plaintiff is wrong to suggest that *Sprietsma* has implicitly overruled the majority's holding in *Lohr* that Section 360k(a) covers requirements imposed through the common law. Br. 40, 43. *Sprietsma* turned on the quite different language of the Boat Safety Act's preemption clause, which (unlike the MDA) refers to "*a* law or *regulation*" and includes a general savings clause exempting "liability at common law." See 123 S. Ct. at 527 (emphasis added).

"artificial" and declining to apply it).[22] See also Dinh, *Regulatory Compliance as a Defense to Products Liability: Reassessing the Law of Preemption,* 88 GEO. L.J. 2085, 2096-97 (2000) (constitutional structure of federalism does not admit of a general presumption against federal preemption of state law); Nelson, *Preemption*, 86 VA. L. REV. 225, 235-64, 292-93 (2000) (arguing on the basis of extensive historical analysis that a presumption against preemption is inconsistent with the text of the Supremacy Clause). Accordingly, it is far from clear that the "presumption" retains any continuing validity.

3. Section 360h(d)

Plaintiff also invokes 21 U.S.C. § 360h(d), which she suggests has "vast significance" to this case. Br. 43-44. In fact, however, plaintiff relies on the provision only to prove an undisputed point: that the MDA "contemplated" that "'at least some common law remedies would remain in conjunction with FDA regulation." Br. 44-45 (quoting *Michael*, 46 F.3d at 1326). So much is already apparent from Section 360k(a) itself. See pages 23-26 & n.7, *supra*.

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[22] In *Locke*, the Product Liability Advisory Committee (PLAC) filed a brief demonstrating that the presumption is of only recent vintage, has been applied by the Supreme Court in an inconsistent and haphazard fashion (and frequently ignored), suffers from a number of internal logical inconsistencies, and is fundamentally at odds with the central principle of preemption law: that Congress's *intent* determines the scope of preemption. See Nos. 98-1701, 98-1706 Br. of PLAC, 1999 WL 966527, at *4-12.

In any event, as plaintiff conceded below, Section 360h(d) "does not directly limit the pre-emption clause of Section 360k." SJ Opp. 14. It is thus not a "savings clause" at all. Section 360h(d) is part of a provision that governs FDA orders directing manufacturers to notify health professionals and others of certain risks, to recall or replace devices, or to refund the purchase price of devices. See 21 U.S.C. § 360h(d). By its plain terms, Section 360h(d) is limited to describing the effect of compliance with one of the various but limited FDA orders that could issue under Section 360h. There is no such order in this case. Not surprisingly, the Supreme Court in *Lohr* ignored Section 360h(d), even though the Lohrs argued that it was relevant to the preemption inquiry. See Nos. 95-754, 95-886 Br. for Cross-Petitioners Lohrs, 1996 WL 88460, at *27-28.

4. Other Arguments Relating to the Failure-To-Warn Claims

Trying to salvage specific claims from express preemption, plaintiff advances several arguments limited to her failure-to-warn claims. Br. 37-40. First, she contends that the labeling requirements applicable to the HeartMate are derived from 21 C.F.R. § 801.109, which is "the same regulation found too general to warrant preemption in" *Lohr*. Br. 37. That argument was never made in the lower court, however, and is therefore waived. In any event, the argument overlooks the fact – admitted by plaintiff below – that the HeartMate's "warning label and package inserts

have been reviewed and approved by the FDA" as part of the PMA process and "regulations required the manufacturer to include the approved information on the label." SJ Opp. 24; see also App. A-214, A-216 (PMA approval letter referring to the "approved labeling"). In contrast, in *Lohr* labeling requirements had not been specifically applied to a particular device through the PMA process. Moreover, the labeling requirements imposed in the PMA process extend far beyond those contained in 21 C.F.R. § 801.109, as a comparison of that regulation and the HeartMate's approved labeling makes clear. See A-178-202.

Second, she argues (Br. 38-39) that her failure-to-warn claims are not preempted to the extent they seek to require additional warnings communicated *outside* of the product labeling. That argument was also never raised below and thus has been waived. Indeed, the complaint nowhere even alleges that TCI should have provided warnings through means outside of the labeling (the traditional means of communicating warnings to the learned-intermediary physician). In any event, even in cases involving express preemption provisions that are (unlike the MDA) limited to state "labeling" requirements, the federal courts have repeatedly rejected this argument. See, *e.g.*, *Papas* v. *Upjohn Co.*, 985 F.2d 516, 519 (11th Cir. 1993) (such claims "necessarily challenge the adequacy of the warnings provided on the product's

labeling or packaging"); *Taylor AG Indus.* v. *Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *Worm* v. *American Cyanamid Co.*, 5 F.3d 744, 748 (4th Cir. 1993).

II. PLAINTIFF'S CLAIMS ARE ALSO IMPLIEDLY PREEMPTED

Even when a federal statute does not expressly preempt state law, it may preempt state law by implication. *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287-89 (1995). Implied "conflict" preemption occurs where, as here, state law conflicts with federal law or "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941).

In *Lohr*, the Court suggested that even those common law claims that are not expressly preempted by the MDA can still be "pre-empted under conflict pre-emption analysis." 518 U.S. at 503; see also *id*. at 507-08 (Breyer, J.). And in *Buckman*, the Court unanimously held that state-law "fraud on the agency" claims relating to medical devices are impliedly preempted because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman*, 531 U.S. at 350. Thus, "ordinary experience-proved principles of conflict pre-emption" apply with full force in this context. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874-75 (2000); accord *Buckman*, 513 U.S. at 352.

The district court in this case correctly ruled that the relevant state and federal requirements concerning the HeartMate are "in direct conflict." App. A-28. Put simply, plaintiff's claims are impliedly preempted because they conflict with and frustrate the federal purposes underlying the MDA and the PMA process and invite lay jurors to second-guess the considered, expert judgment of FDA concerning the safety and effectiveness of the HeartMate LVAD's design, its method of manufacture, and its labeling. As the Texas Supreme Court explained in a case involving a PMA device:

> In essence, [plaintiff] 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 as approved by the FDA. To prevail, therefore, [she] 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. Indeed, the conflict is even greater in the present setting than it was in *Buckman*, because by granting PMA approval FDA has necessarily reached a judgment about the safety and efficacy of the device, whereas FDA may not have decided whether it has been defrauded by an applicant in the 510(k) process.

Finally, as FDA has made clear in several recent *amicus* briefs filed in product liability cases involving prescription drugs, in "areas of FDA oversight" such as drug

labeling, "federal law preempts additional requirements imposed under state law that are in conflict with specific FDA determinations based on scientific evidence and evaluation of the pertinent public health issues." Troy, *FDA Involvement in Product Liability Lawsuits*, FDA UPDATE, Jan./Feb. 2003, at 7 (authored by FDA Chief Counsel) (Addendum 13a). Thus, federal law impliedly preempts plaintiff's efforts to reopen and second-guess scientific judgments concerning the design, manufacture, and labeling of the HeartMate made by expert regulators at FDA during the PMA process.

CONCLUSION

The judgment should be affirmed.

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CERTIFICATION OF BAR MEMBERSHIP

I hereby certify that I am a member of the bar of this Court.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 13,955 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using the WordPerfect 10 word processing program in 14 point Times New Roman.

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CERTIFICATE OF SERVICE

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