IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BARBARA E. HORN, Executrix of the Estate of Daniel Ray Horn, Deceased,	:	
Plaintiff	:	4:CV-00-779
	:	(Judge McClure)
v.	:	
THERMO CARDIOSYSTEMS, INC.,	:	
Defendant	:	

M E M O R A N D U M

November 7, 2002

BACKGROUND:

The issue in this case is whether the Medical Device Amendments to the Food, Drug, and Cosmetic Act (the MDA) preempts a plaintiff's common law tort claims.

Barbara E. Horn, as Executrix of the estate of her late husband, Daniel Ray Horn (Horn), is suing Thermo Cardiosystems, Inc. (TCI) for negligence, strict liability, and breach of warranty. The lawsuit focuses on the condition of a heart pump, which had been implanted inside Horn.

TCI asserts that plaintiff's common-law claims are preempted by the MDA's express preemption clause. Before being approved for sale, the heart

pump underwent a rigorous safety review process known as premarket approval. TCI asserts that because the premarket approval represents a specific federal safety requirement with which plaintiff's state claims conflict, the state claims are preempted. The overwhelming weight of authority supports TCI's argument; as a result, we find that plaintiff's claims are expressly preempted.

DISCUSSION:

I. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate if the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

The moving party bears the initial responsibility of stating the basis for its motions and identifying those portions of the record which demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "It can discharge that burden by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Id. at 325.

Once the moving party points to evidence demonstrating that no issue of

material fact exists, the non-moving party has the duty to set forth specific facts showing that a genuine issue of material fact exists and that a reasonable factfinder could rule in its favor. Ridgewood Bd. of Educ. v. N.E., 172 F.3d 238, 252 (3d Cir. 1999) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). "Speculation and conclusory allegations do not satisfy this duty." Ridgewood, 172 F.3d at 252 (citing Groman v. Township of Manalapan, 47 F.3d 628, 637 (3d Cir. 1995)).

II. FACTS

The Product

The HeartMate LVAD (HeartMate) is a pump that assists blood flow to and from the heart in patients with cardiac conditions. The HeartMate contains a "pump body" and two conduit assemblies. The tube-shaped conduit on one side of the pump is surgically attached to the heart; it is designated the "inlet side" because blood flows through it from the ventricle into the pump body. The conduit on the other side of the pump is surgically attached to the aorta; it is designated the "outlet side" because blood flows out to the aorta where it is dispersed into the body. Both conduits are attached to a circle-shaped pump housing, which contains a pump and related equipment. A tube attached to the

pump housing exits the body and connects to a console containing an air compressor. The air compressor forces air through the tube into a pump, which assists the heart's natural pumping of blood from the ventricle to the aorta.

Plaintiff's claims focus on the connection between the pump housing and a certain part of the outlet, known as the "elbow." The elbow is a small tube that is located between the outlet conduit and the pump housing. The elbow is inserted into an adapter conduit, which in turn is screwed into the open port of the pump housing. A screw ring is tightened over the elbow to ensure that the elbow does not become disconnected 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. The HeartMate is manufactured with the adapter conduit, outlet elbow, screw ring and suture in place; thus, when the surgeon implants the HeartMate in a patient, he need not manipulate the screw ring or tie the suture.

The Complaint

On January 17, 1998, Mr. Horn was admitted to the Williamsport Hospital while suffering from an acute myocardial infarction. He was transferred to Hershey Medical Center, where doctors determined that a heart transplant was necessary. On January 22, 1998, Horn's condition deteriorated, and he was

surgically implanted with the HeartMate to provide temporary circulatory support while a transplant donor was being sought. Horn was then transferred to an assisted-living facility.

On May 3, 1998, Horn began to bleed from the site where the tube exits the body. He was taken to Hershey Medical Center, where he underwent exploratory surgery. During the surgery, Dr. Benjamin Sun discovered two problems with the HeartMate: (1) the screw ring that connects the outlet elbow to the pump housing had become disconnected; and (2) the suture had worn through as a result of rubbing against the sternum, allowing the screw ring to disconnect. Sun reconnected the screw ring with metal wire, but he was not in time: the disconnection had allowed an air embolus to go to Horn's brain, and he suffered a brain hemorrhage.

Plaintiff brings claims for negligence, strict liability, and breach of warranty. The crux of her claim is that the outlet elbow was deficiently designed. The complaint 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 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.

(Complaint, Rec. Doc. No. 1, at ¶ 16.)

In addition to its principal focus on the design of the outlet elbow, the complaint contains other allegations relating to negligence, strict liability, and breach-of-warranty. The claims of negligence include: (1) failure to test and study adequately the HeartMate; (2) failure to provide adequate warnings regarding the possibility that the screw ring may disconnect; (3) failure to provide adequate instructions to physicians; and (4) failure to use proper suture material. The claims of strict liability include (1) failure to use "good manufacturing practices"; and (2) failure to provide adequate warnings. Finally, the complaint contains claims that TCI breached the implied warranties of merchantability and fitness.

The MDA

The issue in this case is whether plaintiff's state claims are preempted by the MDA. An explanation of the MDA is thus in order.

In 1976, Congress enacted the Medical Device Amendments, 21 U.S.C. §§ 360c et seq., which modified the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §§ 301 et seq., to allow the Food and Drug Administration (FDA) to regulate medical devices. The MDA assigns each medical device into one of three

"classes," and the class of the device determines the process by which the device is regulated. The HeartMate is considered to be a "Class III" device. A Class III device is defined as one that (1) is to be used for supporting or sustaining human life or that is of substantial importance in preventing impairment of public health; or (2) presents a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). Class III devices undergo the most rigorous safety evaluation. To market a Class III device within the United States, the manufacturer must, in most cases, submit its product to the FDA for a process called premarket approval (PMA). Under the PMA process, the FDA closely scrutinizes the device, and in order for a device to be approved, the FDA must conclude that it has received from the manufacturer "reasonable assurances of [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). Accordingly, manufacturers must provide the FDA with samples of the device, an outline of the device's components, a description of the manufacturing process, copies of proposed labels, and certain other items. See 21 C.F.R. § 814.20(b). After receiving these submissions, the FDA reviews them for an average of 1200 hours before either approving or disapproving the device. 21 C.F.R. §§ 812.1-.150.

Under certain circumstances, a Class III device may be eligible for an exception to the PMA requirement. This exception may arise in one of two ways.

First, devices that are "substantially equivalent" to medical devices that were in existence in 1976 may be marketed and sold without PMA approval. See 21 U.S.C. § 360j(g)(1). This review mechanism is known as "premarket notification" or "the § 510(k) process." The § 510(k) process consists of only 20 hours of review, as opposed to PMA, which consists of approximately 1200 hours.

Second, devices representing innovative technology may be marketed under an investigational device exemption (IDE), which is an experimental regimen that allows for unapproved devices to be utilized in human trials. An IDE permits a manufacturer to market "a device that otherwise would be required to comply with a performance standard or to have premarket approval for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1. Accordingly, during the testing period, the PMA requirements are inapplicable to a device operating under the IDE exemption. 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812-813.

The HeartMate underwent and survived the PMA process. The following description of the HeartMate's PMA process is essentially adopted from TCI's brief, as plaintiff states that she does not dispute the facts regarding the HeartMate's PMA. (Brief, Rec. Doc. No. 40, at 4.)

The basic design of the HeartMate was completed in 1975. During the next ten years, a variety of animal and human cadaver studies were performed with the

device. More than 70 investigations were conducted on goats and calves, and the HeartMate was used successfully in animals for periods of up to 393 days. TCI performed 32 human cadaver studies to determine the optimum pump configuration. In August 1985, the FDA granted TCI's application for an IDE, and TCI began clinical trials of the HeartMate at the Texas Heart Institute.

Over the next nine years, the clinical trials were conducted at several dozen FDA-approved hospitals throughout the country. During this period, TCI submitted more than 90 supplements to its IDE application, and the FDA advanced a large number of inquiries about the device and the conduct of the trials.

In August 1988, TCI reported to the FDA the occurrence of an event during a study in which a leak developed in the connection between the pump housing and the outflow conduit. At the time of this incident, TCI suspended the clinical trial and did engineering studies to determine how to prevent the screw ring from loosening. TCI decided on the addition of a bonding agent and a locking suture, which it proposed to the FDA. In response, the 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. TCI submitted detailed responses to all of the FDA's questions; these responses

included "a suture sample and a sketch of its application to the screw ring." TCI indicated as well that the suture that it proposed to use was known as "Deknatal white braided polyester non absorbable suture size 5." Based on a review of this data, the FDA approved TCI's proposed design changes, including the use of the suture.

On March 30, 1992, on the basis of the trials and all of its previous studies, TCI submitted its 41-volume, 6,886-page PMA application. Throughout the next 2.5 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, materials, and labeling. One of these amendments, which responded to a series of detailed followup questions, consisted of 82 volumes and 15,951 pages. Another amendment, also submitted in response to FDA questions, consisted of five volumes. In late 1993, an expert FDA advisory panel on circulatory devices recommended approval of the device. The FDA also conducted an inspection of TCI's manufacturing facility and approved the facility for manufacturing the HeartMate.

The design of the outlet elbow – and the use of a screw ring and adapter conduit to attach it to the pump housing – were part of the original design of the HeartMate. 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 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 the FDA's requirement that TCI include in its PMA application a full statement of the components, ingredients, and properties and of the principle or principles of operation of the device, 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. It was known that TCI intended to use a screw ring, a bonding agent, and a suture to secure the outlet elbow to the pump housing. Also, the FDA knew of the precise positioning of the suture on the screw ring and the intended location of the pump in the chest cavity after implant.

The documents submitted to the FDA contain an exhaustive description of the screw ring and the fastening of the elbow to the pump housing.

In a section of the PMA application in which TCI was required to explain its choice of the various materials used in the HeartMate, TCI stated that it selected the Tevdek suture as a result of the 1988 incident involving the loosened screw ring: "In order to prevent this from reoccurring, the connector was modified so that it could be suture-locked at the time of the implant. TEVDEK suture

material was selected because it is nonabsorbable and will lock the connectors in place following implantation."

In the "Directions for Use" submitted with the original PMA application, TCI described the positioning of the pump within the body. In a February 7, 1994 letter, the FDA asked for more detailed information on the orientation of the device. 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.

In an effort to help the FDA understand the safety of the design, TCI provided information on the HeartMate's performance in the clinical trials. In its initial submission, TCI gave the FDA an "Event Report and Malfunction Summary" that reported on all problems with the device observed during the clinical trials. TCI reported that the 1988 bleeding incident was the only time in which a screw ring loosened. There were no incidents of broken sutures at the outlet elbow.

At no time during the PMA process did the 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. In fact, as noted above, the FDA had

specifically approved the addition of the suture in 1988, while TCI was still performing clinical trials under its IDE. After the initial PMA submission, the FDA responded with detailed and specific questions about other aspects of the design and materials used, but the FDA never had any questions about the elbow connection or the use of a suture to secure the screw ring.

Finally, TCI submitted directions for use and warnings. Once again, the FDA had a variety of specific questions about the labeling and warnings, but the agency never suggested that there was an insufficient warning with respect to the outlet's elbow screw ring.

On September 30, 1994, after 2.5 years of review of the PMA application, the FDA approved the HeartMate for commercial sale. The 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. In accordance with the FDA's mandate, if TCI wanted to make any change that affected the safety or effectiveness of the device, it was required to obtain further regulatory approval.

III. ANALYSIS

In support of its motion for summary judgment, TCI argues that plaintiff's claims are preempted by the MDA's express preemption clause. Federal law may

preempt state law in one of three ways: (1) "express preemption," which arises when there is an explicit federal statutory command that state law be displaced; (2) "field preemption," which results when federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the states to supplement it; and (3) "conflict preemption," which arises when a state law makes it impossible to comply with both state and federal law or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. The St. Thomas-St. John Hotel & Tourism Assoc., Inc, v. Government of the U.S. Virgin Islands, 218 F.3d 232, 238 (3d Cir. 2000). While the concept of preemption is often expressed in terms of conflicting statutory provisions, "[s]tate common law rules may be preempted in the same ways as state statutes or regulations." Abdullah v. American Airlines, Inc., 181 F.3d 363, 367 n.4 (3d Cir. 1999) (citations omitted).

The MDA has a clause that provides expressly for the preemption of state law claims. The preemption clause states that certain state "requirements" inconsistent with the MDA will be preempted:

> [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).

In Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), the Supreme Court, in a plurality opinion, addressed the scope of the MDA's preemption.

In Lohr, the plaintiff received a Model 4011 pacemaker, a Class III medical device. The pacemaker had received FDA approval as a device "substantially equivalent" to a preexisting medical device, and thus it was exempted from premarket approval. The pacemaker malfunctioned, resulting in a heart condition that required emergency surgery.

The plaintiff and her husband filed a civil action for damages in a Florida state court, relying upon state law theories of negligence and strict liability. After the case was removed to federal court, the defendant moved for summary judgment, arguing that the MDA preempted the plaintiff's claims. That motion was granted, and later the Eleventh Circuit reversed and remanded the case to the district court. The Supreme Court then granted Medtronic's petition for certiorari.

In a plurality decision, the Supreme Court held that none of the plaintiffs' common law tort claims was preempted. Justice Stevens's plurality opinion was joined by Justices Kennedy, Souter, and Ginsburg. Justice O'Connor concurred in

part and dissented in part, and her opinion was joined by the Chief Justice and Justices Scalia and Thomas. Justice Breyer concurred in part and in the judgment, and he joined five of the seven parts of Justice Stevens's opinion. Accordingly, the five sections of Justice Stevens's opinion in which Justice Breyer concurred (Sections I, II, III, V and VII) form the opinion of the Court.

After discussing the history of the MDA and its three classifications of medical devices, a majority of the justices determined that while certain state common-law claims may be preempted under § 360k(a), preemption is appropriate "only where a particular state requirement threatens to interfere with a specific federal interest." Id. at 500. Throughout different parts of the decision, the Court commented on the character of both the federal interest and the state requirement.

In discussing the nature of the federal interest that must be present to lead to preemption, the Court stated that the federal requirements must be specific to the device in question: "federal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if they are 'specific counterpart regulations' or 'specific' to a 'particular device.'" Id.

The Court went on to conclude that the approval process that features the "substantially equivalent" standard is not the type of specific federal requirement that leads to preemption. The §510k process, stated the Court, "reflects important

but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." Id. at 501. Referring specifically to the pacemaker, the Court noted that the § 510k process "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before 1976, to be marketed without running the gauntlet of the PMA process." Id. at 493-94.

The Court also considered under what circumstances a state-law claim may be preempted. It concluded that when a state-law claim diverges from the specific federal requirement, preemption is triggered. The majority of the Court – Justices Breyer, O'Connor, Scalia and Thomas and Chief Justice Rehnquist, – agreed that "a fair reading of § 360k indicates that state common-law claims are pre-empted, as the statute itself states, to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to [a] device." Id. at 510 (O'Connor, J., concurring in part and dissenting in part); id. at 503-504 (Breyer, J., concurring in part and concurring in the judgment and agreeing with Justice O'Connor on this point).

Along the same lines, the Court stated that as long as the plaintiffs' claims

sought to enforce only the specific regulations that the FDA imposed upon the pacemaker, those claims did not constitute different or additional requirements and were not preempted: "Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Id. at 495.

Consistent with the above discussion, courts of appeals have adopted generally accepted guidelines on when the MDA preempts state claims. A state claim that focuses on the safety of a device is preempted only 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. Kemp v. Medtronic, Inc., 231 F.3d 216, 224-225 (6th Cir. 2000) (citing, *inter alia*, Mitchell v. Collagen Corp., 126 F.3d 902, 910 (7th Cir. 1997); Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1371 (11th Cir. 1999)). The key, then, is to focus first on the specificity and applicability of the federal requirement and second, if necessary, on whether the state claim is different from or in addition to the federal requirement.

Our first task is to determine whether the PMA process is a specific federal requirement applicable to the HeartMate. We believe that it is. The HeartMate's PMA process was a determination by the FDA that the HeartMate – and

specifically the HeartMate – was safe and effective. TCI submitted a voluminous amount of material related to the design, manufacturing, and labeling of the specific product. The FDA gave its approval to the marketing of the HeartMate, and TCI needed permission to alter any of the HeartMate's specific design or safety features. Consequently, the PMA process represents a federal "requirement" that is specific to the HeartMate.

The vast majority of federal and state appellate courts that have addressed the issue have held that the PMA process is an example of a federal requirement that may trigger § 360k(a) preemption. See, e.g., Brooks v. Howmedica, Inc., 273 F.3d 785, 795-796 (8th Cir. 2001); Kemp, 231 F.3d at 226-27; Mitchell, 126 F.3d at 911-913; Martin v. Medtronic, Inc., 254 F.3d 573, 584 (5th Cir. 2001); Worthy v. Collagen Corp, 967 S.W.2d 360, 376 (Tex. 1998); Fry v. Allergan Medical Optics, 695 A.2d 511, 516 (R.I. 1997); Green v. Dolsky, 685 A.2d 110, 117 (Pa. 1996). In addition, many courts have distinguished the PMA process from the § 510(k) process, holding PMA to be a specific requirement, even after Lohr's holding that § 510(k) does not trigger preemption. They point to the fact that while the § 510(k) process focuses only on "equivalence" to an already-existing product, the PMA process is much more rigorous and focuses on the safety of a new, specific product. See, e.g, Martin, 254 F.3d at 584; Fry, 695 A.2d 516-17.

We agree with these courts, and we find that the HeartMate's PMA process is a specific federal interest defined in the MDA's preemption clause. This conclusion is consistent with pre-Lohr Third Circuit law, which decrees that the PMA is a federal requirement that triggers MDA preemption. See Michael v. Shiley, 46 F.3d 1316, 1324 (3d Cir. 1995).

Now that we have decided that the PMA process may preempt certain claims, we must determine whether plaintiff's specific common-law claims impose requirements that are different from or in addition to the PMA process. We think they do. Plaintiff brings claims for negligence, strict liability, and breach of warranty. Each claim is based on the premise that the HeartMate was defectively designed or manufactured or contained inadequate labeling. Most of her claims focus on the design and effectiveness of the screw ring, which the FDA analyzed. According to plaintiff, then, 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. Any 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. Many courts have used this logic in finding preemption.

See, e.g., Mitchell, 126 F.3d at 913-14; Green, 685 A.2d at 118-19. Accordingly, the MDA expressly preempts each of plaintiff's claims.

TCI argues in the alternative that because plaintiff's claims conflict with the MDA, they are barred under the doctrine of conflict preemption. Because we find that plaintiff's claims are expressly preempted, we need not reach this issue.

CONCLUSION:

The PMA process applicable to the HeartMate represents the type of federal requirement that preempts under the MDA. Accordingly, each of plaintiff's claims is preempted, and summary judgment is proper. An appropriate order follows.

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James F. McClure, Jr.
United States District Judge

Filed 11/07/2002

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BARBARA E. HORN, Executrix of the Estate of Daniel Ray Horn, Deceased,	:	
Plaintiff	:	4:CV-00-779
	:	(Judge McClure)
v.	:	
THERMO CARDIOSYSTEMS, INC.,	:	
Defendant	:	

O R D E R

November 7, 2002

For the reasons set forth in the accompanying memorandum,

IT IS ORDERED THAT:

1. TCI's motion for summary judgment (Rec. Doc. No. 29) is granted.

2. TCI's motion for protective order (Rec. Doc. No. 22) is denied as moot.

3. The clerk is directed to enter judgment in favor of defendant and against plaintiff.

4. The clerk is directed to close the case file.

James F. McClure, Jr.
United States District Judge

Filed 11/07/2002