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

RICHARD DAVENPORT,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	NO. 00-6105
MEDTRONIC, INC.,	:	
Defendant.	:	

MEMORANDUM

ROBERT F. KELLY, Sr. J. FEBRUARY 3, 2004

Presently pending before this Court is the Motion for Summary Judgment of Defendant Medtronic, Inc. (Medtronic"). For the following reasons, Medtronic's Motion will be granted.

I. BACKGROUND

A. Introduction

Richard Davenport ("Davenport") filed a Complaint against Medtronic on January 16, 2001. The three-Count Complaint sets forth claims for negligence[1] (Count I), breach of implied and express warranties (Count II) and strict product liability (Count III) based on Davenport's experience with the Medtronic Activa Tremor Control System (the "Activa"). The Activa is a prescription medical device that was bilaterally implanted in Davenport to help

[1] In terms of the negligence claim, Davenport alleges that the Activa systems implanted in him were negligently manufactured. (Comp. ¶¶ 24-25). Further, Davenport alleges that Medtronic was negligent in allowing a doctor to perform a bilateral implantation of the Activa when it knew that the FDA had only approved the device for unilateral implantation at the time the Activa systems were surgically implanted in his body. (Id. ¶ 26).

relieve him of symptoms associated with Parkinson's disease.[2] Davenport alleges that the Activa systems implanted in him failed to function properly and caused him substantial damage.[3] In the instant Motion, Medtronic claims that all of Davenport's claims are preempted by federal law and must be dismissed. Further, Medtronic argues that Davenport's claims fail as a matter of law pursuant to applicable Pennsylvania law.

Davenport has suffered from the symptoms of Parkinson's disease since 1976 when he was twenty-nine years old. Prior to having the Activa systems implanted, Davenport used standard medication treatment and tried other medical procedures in an attempt to relieve the symptoms of the disease.[4] These methods of treatment were only temporarily successful and caused numerous side effects. Thus, the failures of these treatment options led Davenport to the surgical implant of the Activa systems.

---

[2] As summarized in Medtronic's Motion, "Parkinson's disease is a progressive, degenerative neurological disease arising from a reduced level of dopmaine, a neurotransmitter that enables communications between the cells that control movement." (Def.'s Mem. Supp. Summ. J. at 3). Symptoms of Parkinson's disease include tremors (trembling), general slowness of movement, difficulty maintaining balance, and rigidity or stiffness in the limbs. (Id.). As will be discussed infra, Davenport had two Activa devices surgically implanted in his body due to his condition.

[3] Specifically, Davenport claims that he has incurred hospital and medical expenses for the diagnosis and treatment of his problems associated with the Activa systems. (Compl. ¶ 20). Moreover, Davenport alleges that he has experienced mental and physical pain and suffering, fear and anxiety, emotional distress, loss of the ability to enjoy life and life's pleasures, loss of opportunity for remission of symptoms, aggravation of symptoms and other general damages stemming from his problems with the Activa systems. (Id.).

[4] For example, in 1996, Davenport underwent bilateral Pallidotomies to treat the disease. This is surgery of the inner brain where tissue is destroyed in an attempt to eradicate the disease's symptoms.

B. The Activa

The Activa consists of three distinct implanted components: (1) the implantable pulse generator (the "IPG"), (2) the extension lead (the "Extension") and (3) the intra-cranial lead (the "Lead"). First, the IPG is the power source for the Activa and it is inserted in the recipients's thorax. The IPG is composed of a sealed, oval-shaped, metal container that houses a special battery and programmable electronics that dictate the electric charge generated by the battery. Second, the Extension is a thin insulated wire that contacts the IPG and the Lead. The Extension transports the electrical pulses from the IPG to the Lead. Finally, the Lead is a thin insulated wire that enters the brain. The Lead has a series of tiny electrodes at one end that convey electrical pulses from the Extension to the tissues in the brain. These pulses are intended to stimulate portions of the brain to suppress the symptoms of Parkinson's disease.

The Activa operates by electronically stimulating the targeted tissues in the brain that control movement and muscle function through a process called Deep Brain Stimulation ("DBS"). The DBS is intended to interrupt the messages to the brain that cause the symptoms of Parkinson's disease (i.e. tremors) and suppress these symptoms. As a result of DBS, patients are theoretically supposed to achieve greater control over their bodily movements. It should be noted that the surgical implantation of the Activa is done in two stages. In stage one, a hole is drilled into the cranium of the patient and the electrodes are introduced into the brain. The second stage of the procedure calls for the implantation of the IPG in the chest area. The IPG is then programmed using an external console and the system is completely activated.

C. The Activa and the Pre-Market Approval Process

A central issue in this case is whether Davenport's state claims are preempted by

the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act**,** 21 U.S.C. §§ 321-394 ("MDA"). Medtronic contends that Davenport's state claims are preempted because the Activa went through a pre-market approval ("PMA") process by the Food and Drug Administration ("FDA"). A brief discussion of the MDA and PMA is necessary for disposition of the instant Motion.

The MDA establishes a comprehensive regulatory framework for controlling the safety and effectiveness of medical devices. The MDA classifies medical devices into three categories (Classes I, II, or III) based on the risk that the devices pose to the public. Class III devices are those that "(1) [are] to be used for supporting or sustaining human life or that [are] of substantial importance in preventing impairment of public health; or (2) present[] a potential unreasonable risk of illness or injury."[5] Horn v. Thermo Cardiosystems, Inc., 229 F. Supp.2d 381, 385 (M.D. Pa. 2002)(citing 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II)). A Class III device is subject to a strict safety evaluation by the FDA. Significantly, "[b]efore a Class III device may be introduced to the market, the manufacturer must provide the [FDA] with a reasonable assurance that the device is safe and effective under the MDA. To provide that assurance, a manufacturer

[5] Class I and II devices are defined as follows:

> Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.' Devices that are potentially more harmful are designated Class II; although they may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as 'special controls.'

Medtronic, Inc., v. Lohr, 518 U.S. 470, 477 (1996)(citing 21 U.S.C. § 360c(a)(1)(A)).

must obtain [PMA] from the FDA."[6] Mitchell v. Collagen Corp., 126 F.3d 902, 905 (7th Cir. 1997). The PMA is a rigorous process in which manufacturers must submit detailed information to have their devices approved.[7]

If the FDA determines that the manufacturer has established a "reasonable assurance that the device is safe and effective under the MDA, the agency then issues an order that allows the manufacturer to market the device as approved." Steele, 2003 WL 22946150, at *2. "It does so after a manufacturer demonstrates that the manufacturing and processing methods and facilities conform to FDA requirements, and that the proposed labeling of the device is not false or misleading." Id. (citing 21 U.S.C. § 360e(d)(2)). Subsequently, the manufacturer may not change the approved labeling, product design or manufacturing process in any manner that would affect the safety or effectiveness of the device. Id.

In the instant case, the parties do not dispute that the Activa is a Class III medical device. Moreover, the parties agree that the Activa went through the rigorous PMA process and

---

[6] There are various exceptions that allow a manufacturer to market a medical device without PMA. First, there is a "grandfathering" provision in the MDA that allows devices on the market prior to 1976 to remain on the market until the FDA initiates and completes the PMA process for such devices. Mitchell, 126 F.3d at 905. Second, there are investigational device exemptions that are available that allow manufacturers to market devices for the purpose of conducting investigations on the devices. Steele v. Depuy Orthopaedics, Inc., No. 02-3783, 2003 WL 22946150, at *3 (D.N.J. Dec. 11, 2003). Finally, medical devices that are "substantially equivalent" to "grandfathered" products are exempt from the PMA process until the FDA initiates and does a PMA of such products. Id. It is important to note that these exceptions to the PMA process are less relevant for purposes of this case since the Activa went through the complete PMA process.

[7] The FDA spends approximately 1200 hours per PMA application. Lohr, 518 U.S. at 477. "Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests." Mitchell, 126 F.3d at 905 (citing 21 C.F.R. § 814.20).

was approved by the FDA before it was marketed by Medtronic.[8] Specifically, on July 31, 1997, "the FDA approved the PMA application for the [Activa] as indicated for unilateral thalamic stimulation for suppression of essential and Parkinsonian tremor." (Def.'s Mem. Supp. Summ. J. at 6). This PMA indicates that all of the FDA's stringent requirements were satisfied in relation to the Activa.

D. Davenport's Experience with the Activa

In 1998, Davenport began researching DBS and learned of the Activa after other methods of treating his Parkinson's disease were unsuccessful. Initially, Davenport discussed the procedure with one of his doctors, Dr. Stephen Gollomp ("Dr. Gollomp"), and Dr. Gollomp recommended that Davenport consider the DBS procedure. However, Dr. Gollomp explained to Davenport that DBS was not yet approved by the FDA for the indication that Davenport needed. Specifically, Davenport's condition necessitated that a bilateral DBS would need to be performed. Thus, while at that point the FDA had approved only unilateral use of the Activa, a bilateral implant of the Activa would involve the implantation of two complete systems (two IPGs, two Extensions and two Leads) to stimulate both sides of the brain.[9] After learning of the FDA's failure to approve bilateral DBS for patients with Parkinson disease, Davenport was prompted to write the FDA regarding why bilateral DBS had not been approved. Davenport

[8] The parties agree that Medtronic's PMA application "detailed information concerning the safety and effectiveness of the [Activa], including bench testing [in vitro studies], animal study data, clinical (human) study data, including patient data forms, device characteristics, performance standards, manufacturing methods and controls, labels. . . . ." (Def.'s Mem. Supp. Summ. J. at 8).

[9] It was not until January 14, 2002 that the FDA gave Medtronic approval for bilateral implantation.

received no response from the FDA.

In October of 1998, Davenport met with Dr. Michael Munz ("Dr. Munz") of Temple University Hospital to discuss bilateral implantation of the Activa as therapy for his symptoms. Dr. Munz informed Davenport that the bilateral implantation would be an "off-label use of the [Activa] for his particular case."[10] (Munz Dep. at 88). Dr. Munz told Davenport that "the FDA ha[d] approved the device that all of the components of the device were approved, but the FDA . . . was working with Medtronic to approve it for this particular . . . indication." (Id.).

On November 9, 1998, Dr. Munz performed a surgical bilateral implant of Activa systems on Davenport. After surgery was completed, the Activa systems were activated and Davenport found that many of the symptoms of his Parkinson's disease became suppressed. Specifically, "he not only had relief from tremors but also obtained relief from dyskinesia (abnormal moving of extremities in a slow fashion). . . . He also noted improvement in his stiffness, equilibrium and balance." (Pl.'s Mem. Opp. Summ J. at 2).

Within a month or two after surgery, Davenport began to experience problems. For example, the IPGs began to turn off and on for no apparent reason. Moreover, Davenport began feeling fluttering sensations in his chest. The problems with the IPGs and the fluttering sensations continued for months. In fact, the sensations in the chest caused Davenport to check himself into Chester County Hospital where he was cleared of any cardiac abnormalities. As a result of these complications, Davenport visited Dr. Munz in March of 1999 for an evaluation. In conjunction with this visit, Medtronic representative Denise Kelly ("Kelly") interrogated Davenport's Activa devices. Kelly was able to identify two possible explanations for

[10] For a description of "off-label" uses, see infra at 30.

Davenport's complaints: (1) the IPGs had been placed too close to each other or (2) bodily fluid had leaked into one IPG. (Kelly Dep. at 37-44).

On April 14, 1999, Dr. Munz removed the IPGs and implanted two new IPGs, keeping the previously implanted extensions. Dr. Munz attempted to place the new IPGs farther apart from one another in attempt to prevent any future complications. In performing the operation, Dr. Munz noticed that a strand of fatty material had grown in one of the explanted IPG connectors, the mechanism that attached the IPG to the Extension. At this time, Dr. Munz hypothesized that the fatty material had created a "fluid short" that was the cause of Davenport's complications.

On October 5, 1999 (approximately six months after his second surgery), Davenport had additional problems with the Activa systems. At the suggestion of Dr. Gollomp, Davenport went to Chester County Hospital. Again, Kelly interrogated the Activa systems on behalf of Medtronic. Kelly found that the IPGs were functioning normally, but found that electricity was not flowing properly to the contacts in the brain. Subsequently, Davenport was transferred to Temple University Hospital, where he was put under the care of Dr. Jack Jallo ("Dr. Jallo"), since Dr. Munz had left the Hospital.

On October 6, 1999, Dr. Jallo performed another surgery on Davenport to evaluate the Activa systems. Initially, Dr. Jallo interrogated the IPGs and found that they were functioning properly. After analysis of the Extension components of the systems revealed no problems, Dr. Jallo hypothesized by a process of elimination (since there are only three separate components to each Activa system) that the Activa systems were not functioning normally because there were fractures in the Leads that extended into the brain. Revision and replacement

of the Leads was discussed at the time, but Davenport was unwilling to commit to the surgery that would be required.[11] The Activa systems were turned off and Davenport was discharged from Temple Hospital on October 9, 1999.

Subsequently, Davenport suffered further medical problems. On October 11, 1999, Davenport was readmitted to Chester County Hospital because he had sustained a right hemothorax as a result of the October 9, 1999 surgery. Davenport underwent two surgical procedures to correct this problem. After he was discharged from the hospital on October 23, 1999, he was readmitted to the same hospital two days later complaining of "chest pains, shortness of breath and swelling, and was found to have acute inflammation with hypoalbuminemia and a urinary tract infection." (Def.'s Mem. Supp. Summ. J. at 15).

E. Procedural History[12]

Davenport originally filed a Writ of Summons against Medtronic on November 3, 2000, in the Philadelphia County Court of Common Pleas. Medtronic removed the case to this Court and Davenport filed his Complaint on January 16, 2001. The three-Count Complaint set forth claims for negligence (Count I), breach of implied and express warranties (Count II) and strict product liability (Count III) based on Davenport's experience with the Activa systems. Medtronic answered the Complaint on February 12, 2001.

On January 28, 2003, the Court entered an Order, agreed to by the parties,

---

[11] In fact, Davenport has consulted several doctors about the possibility of replacing the Leads, but has declined to go forward with the procedure because of the nature of surgery. To this day, the Activa systems (with the new IPGs and Extensions) remain in Davenport's body, but have been de-activated.

[12] In his Response to the instant Motion, Davenport accepts the procedural history as recited by Medtronic in the original Motion. (Pl.'s Mem. Opp. Summ. J. at 7).

regarding testing of the IPGs that were explanted from Davenport on April 14, 1999. On July 23, 2003, Medtronic completed its testing pursuant to the aforementioned Order. As stated by Medtronic and conceded by Davenport, "[b]oth IPGs passed Medtronic's final functional test, confirming that they satisfied the PMA-approved functional and performance requirements." (Def.'s Mem. Supp. Summ. J. at 16). Moreover, as stated by Medtronic and conceded by Davenport, "Medtronic also performed extensive interaction characterization testing of the two IPGs, including a series of tests specifically requested by Plaintiff's's expert, and found no interaction between the IPGs that would explain Plaintiff's complaints of sensations within his chest adjacent to the IPGs." (Id.) Notably, Davenport has not performed any tests on the IPGs as he is permitted to pursuant to the January 28, 2003 Order.

Medtronic filed the instant Motion for Summary Judgment on September 22, 2003. Medtronic claims that all of Davenport's claims are preempted by federal law and must be dismissed. Further, Medtronic argues that Davenport's claims fail as a matter of law pursuant to applicable Pennsylvania law. On October 9, 2003, Davenport filed his Response to the Instant Motion. Additionally, on December 11, 2003, the Court granted Medtronic's Motion for Leave to File a Reply Brief and Medtronic's Reply Brief was deemed filed. The Court held a Hearing regarding the instant Motion on December 19, 2003.

II. SUMMARY JUDGMENT STANDARD OF REVIEW

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is proper "if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). Essentially, the inquiry is "whether the evidence presents a sufficient disagreement to require submission to the jury or

whether it is so one-sided that one party must prevail as a matter of law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-252 (1986). The moving party has the initial burden of informing the court of the basis for the motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). An issue is genuine only if there is a sufficient evidentiary basis on which a reasonable jury could find for the non-moving party. Anderson, 477 U.S. at 249. A factual dispute is material only if it might affect the outcome of the suit under governing law. Id. at 248.

To defeat summary judgment, the non-moving party cannot rest on the pleadings, but rather that party must go beyond the pleadings and present "specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e). Similarly, the non-moving party cannot rely on unsupported assertions, conclusory allegations or mere suspicions in attempting to survive a summary judgment motion. Williams v. Borough of W. Chester, 891 F.2d 458, 460 (3d Cir. 1989)(citing Celotex, 477 U.S. at 325 (1986)). Further, the non-moving party has the burden of producing evidence to establish *prima facie* each element of its claim. Celotex, 477 U.S. at 322-23. If the court, in viewing all reasonable inferences in favor of the non-moving party, determines that there is no genuine issue of material fact, then summary judgment is proper. Id. at 322; Wisniewski v. Johns-Manville Corp., 812 F.2d 81, 83 (3d Cir. 1987).

III. DISCUSSION

As previously noted, Davenport's three-Count Complaint sets forth claims for negligence (Count I), breach of implied and express warranties (Count II) and strict product liability (Count III) based on his experience with the Activa. In the instant Motion, Medtronic claims that all of Davenport's claims are expressly preempted by federal law and must be

dismissed. Further, Medtronic argues that Davenport's claims fail as a matter of law pursuant to applicable Pennsylvania law. The Court will now address each of these arguments in light of the applicable summary judgment standard.

A. Preemption Generally

Article VI of the United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Thus, "any state law that conflicts with federal law is 'without effect.'" Cipollone v. Ligget Group, Inc., 505 U.S. 504, 516 (1992) (citation omitted). Express preemption, where there is a explicit federal statutory command that state law be displaced, is one manner by which federal law may preempt state law.[13] St. Thomas–St. John Hotel & Tourism Ass'n, Inc. v. Gov't of the U.S. Virgin Is., 218 F.3d 232, 238 (3d Cir. 2000). "Whether federal law preempts a state law establishing a cause of action is a question of congressional intent." Hawaiian Airlines, Inc. v. Norris, 512 U.S. 246, 252 (1994). Further, "[i]f the statute contains an express preemption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993). In the instant case, Medtronic moves for summary judgment claiming that all of Davenport's state-law claims are expressly preempted by a provision of the MDA.

[13] Federal law may also preempt state law through "field preemption" when federal law so thoroughly occupies a legislative field that a reasonable inference can be made that Congress was leaving no room for the States to supplement it. St. Thomas–St. John Hotel & Tourism Ass'n, Inc., 218 F.3d at 238. Finally, federal law may preempt state law through "conflict preemption" when a state law makes it impossible to comply with state and federal law, or when state law stands as an obstacle to goals and purposes of Congress. Id.

B. The MDA's Preemption Clause

Section 360k of the MDA expressly preempts specific state-law requirements regarding medical devices. The preemption provision states the following:

> [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 and 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). As one court in the Third Circuit recently emphasized, "although at first glance the language of Section 360k(a) might seem fairly straightforward, that section has spawned a legion of cases attempting to determine its preemptive scope." Steele, 2003 WL 22946150, at *7.

In Medtronic, Inc. v. Lohr, the Supreme Court, in a plurality opinion, discussed the preemptive scope of Section 360k. 518 U.S. 470 (1996). The issue in Lohr was whether state tort claims were preempted because the FDA allowed a Class III pacemaker device to be marketed because it qualified as "substantially equivalent" to a pre-existing device.[14] Id. at 484. In Lohr, the plaintiff received a pacemaker (a Class III medical device) from a manufacturer. Id. at 481. The FDA allowed the pacemaker to be marketed because it was "substantially

[14] As previously noted in supra note 6, a medical device may be exempted from the PMA through this manner. Nevertheless, as the Supreme Court noted in Lohr, the review process pursuant to this "substantially equivalent' analysis is much less rigorous than under PMA review. In fact, substantially equivalent devices have "never been formally reviewed under the MDA for safety and efficacy" and the FDA itself does not consider the process "official FDA approval." Lohr, 518 U.S. at 493.

equivalent" to a preexisting medical device and was therefore exempted from the PMA process. Id. at 492. The plaintiff who received the device developed a serious heart condition that required surgery after the pacemaker malfunctioned. Id. at 481. Plaintiff filed suit against the manufacturer alleging both negligence and strict liability claims for defective design, failure to warn and negligent manufacturing. Id.

The Court concluded that the plaintiff's claims were not preempted based on the fact that the "substantially equivalent" review process was not the type of specific federal requirement that triggered preemption. Id. at 501 (stating that the "substantially equivalent" approval process "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"). In deciding the case, the Lohr Court offered guidance concerning when the MDA mandates that state-law claims are preempted. First, there must be a federal requirement that is specific to the particular device. Id. at 500. Second, there must be a state-law requirement that relates "to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device." Id. Finally, the state requirement must be "different from or in addition to" federal requirements. Id.

The majority of the Justices in Lohr also clarified that state common-law claims could be preempted pursuant to the MDA preemption provision if the aforementioned elements were met. Horn, 229 F. Supp.2d at 389 (M.D. Pa. 2002)(citations omitted). Specifically, in his concurrence, Justice Breyer stated that "the MDA preempts a state requirement embodied in a state statute, rule, regulation, or other administrative action, [as it would] pre-empt a similar

requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." Lohr, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). Significantly, for purposes of the instant case, the Court also emphasized that "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Id. at 495. As stated by Horn, this statement clarifies that "so long as the [plaintiff's] claims [seek] to enforce only the specific regulations that the FDA imposed upon the [medical device], those claims [do] not constitute different or additional requirements and [are] not preempted." Horn, 229 F. Supp.2d at 389.

The Lohr Court left open the question of whether the PMA process itself imposes specific federal requirements on a medical device to trigger preemption pursuant to the MDA. Nevertheless, post-Lohr, a vast majority of federal and state courts have held that the PMA approval process sets specific federal requirements on a medical device that provoke preemption of state-law claims. See, e.g., Brooks v. Howmedica, Inc., 273 F.3d 785, 795-96 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002); Martin v. Medtronic, Inc., 254 F.3d 573, 584 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002); Kemp v. Medtronic, Inc., 231 F.3d 216, 226-27 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001); Mitchell, 126 F.3d at 911 (7th Cir. 1997); Enlow v. St. Jude Med., Inc., 210 F. Supp.2d 853, 858-62 (W.D. Ky. 2001); Easterling v. Cardiac Pacemakers, Inc., 986 F. Supp. 366, 373-75 (E.D. La. 1997); Richman v. W.L. Gore & Assocs. 988 F. Supp. 753, 758 (S.D.N.Y. 1997); Fry v. Allergan Med. Optics, 695 A.2d 511, 516 (R.I. 1997); Green v. Dolsky, 685 A.2d 110, 117-18 (Pa. 1996). Further, prior to Lohr, the Court of Appeals for the Third Circuit ("Third Circuit') held that the PMA imposes federal requirements

that trigger preemption pursuant to the MDA.[15] Michael v. Shiley, Inc., 46 F.3d 1316, 1324 (3d Cir. 1995). Courts within this Circuit have recently agreed with the position of this strong majority concerning the preemptive impact of the PMA and have found that this position is consistent with Shiley. Steele, 2003 WL 22946150, at *11, Horn, 229 F. Supp.2d at 390.

This Court follows the position of Shiley and the strong majority and finds that the Activa's PMA process imposes specific federal requirements that trigger preemption pursuant to the MDA's preemption clause and the first prong of the Lohr Court's guidance. This Court agrees that the "PMA of a product's design, testing, intended use, manufacturing methods, performance standards and labeling, is 'specific to the product,' and therefore preempts state-law claims that would impose requirements 'different from, or in addition to' the agency's determination on those matters." Steele, 2003 WL 22946150, at *11 (citing Mitchell, 126 F.3d at 913). As Horn emphasized,

> many courts have distinguished the PMA process from the ['substantially equivalent'] process, holding PMA to be a specific requirement, even after Lohr's holding that [the 'substantially equivalent' process] does not trigger preemption. They point to the fact that while the ['substantially equivalent' review] 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.

229 F. Supp.2d at 390. We agree with this reasoning and find that the device-specific and thorough nature of the PMA process imposes specific federal requirements that trigger preemption.

---

[15] The Third Circuit has not ruled on this issue since the Supreme Court's decision in Lohr.

C. Preemption of Davenport's Claims

The fact that this Court follows the majority view and Shiley, and finds that PMA of the Activa triggers preemption because it qualifies as a specific federal requirement, does not end the inquiry. We must still determine whether the specific claims set forth by Davenport are preempted based on the other Lohr preemption factors and Section 360k of the MDA. In this case, this Court finds that a majority of Davenport's claims are not preempted based on the nature of his allegations.

1. Strict Product Liability and Negligence Claims

Davenport's strict product liability claim is premised on the theory that the Activa systems had manufacturing defects when they left the control of Medtronic. (Comp. ¶ 34). In terms of the negligence claim, Davenport's allegations are two-pronged. Davenport alleges that the Activa systems implanted in him were negligently manufactured. (Id. ¶¶ 24-25). Moreover, Davenport alleges that Medtronic was negligent in allowing bilateral implantation of the Activa when it knew that the FDA had only approved the device for unilateral implantation at the time of his initial surgery. (Id. ¶ 26). Based on the nature of these strict product liability and negligence claims, it is clear from Lohr and subsequent case-law that these claims are not preempted pursuant to the MDA.

As previously noted, the Lohr Court emphasized that "nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Lohr, 518 U.S. at 495. As the Court of Appeals for the Fifth Circuit ("Fifth Circuit") recognized, "[t]his language tells us that tort suits based on a manufacturer's failure to follow the FDA's regulations and procedures are not

preempted. . . . In the context of the PMA process, . . . state tort suits that allege, as the basis of their claim, that the approved FDA requirements have not been met are not preempted." Martin, 254 F.3d at 583; see also Mitchell, 126 F.3d at 913 n.6 ("To the extent that the [Plaintiff's] complaint may be read as alleging that [the manufacturer] was negligent in adherence to standards of the FDA in the PMA, the negligence claim would not be preempted."); Horn, 229 F. Supp.2d at 389 (emphasizing that the Lohr 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").

In the present case, Davenport's strict product liability and negligent manufacturing claims are based on the theory that the Activa systems implanted in him did not satisfy PMA/FDA standards. These claims do not impose requirements "different from or in addition to" PMA/FDA requirements, which is a requirement for preemption under Lohr and Section 360k of the MDA. As such, the strict product liability and negligent manufacture claims are not preempted pursuant to the MDA. Further, Davenport's claim that Medtronic was negligent in allowing a bilateral implantation of the Activa, when the FDA had only approved the device for unilateral implantation, is also not preempted as this claim concerning Medtronic's conduct does not fall within the realm of the MDA's preemption clause.

2. Express Warranty Claim

The foundation for Davenport's express warranty claim is not clear from the face of the Complaint or his Response to this Motion.[16] However, at the Hearing on the instant

[16] The Complaint states the following:

Defendant Medtronic both expressly and impliedly, warranted that

Motion, Davenport clarified that the express warranty he bases his claim upon is an express Limited Warranty that applied to the Leads in the Activa systems (the "Limited Warranty").[17] In terms of preemption, in light of caselaw within and outside the Third Circuit, it is clear that the MDA does not preempt express warranty claims.

As Steele recognized, "because express warranties 'arise from representations of the parties,' and therefore 'do not result from the independent operation of state law,' the MDA does not preempt state law claims of breach of express warranty." 2003 WL 22946150, at *14 (quoting Shiley, 46 F.3d at 1325); see also Mitchell, 126 F.3d at 915 ("[Express] warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted."). The MDA preemption clause does not preempt an express warranty claim based on a warranty that is a product of the parties' bargain because any "requirements" imposed by the warranty are created by the warrantor and not imposed by state law as required for MDA preemption. Steele, 2003 WL 22946150, at *14 (citing Cippollone, 505 U.S. at 526). In the instant case, based on the aforementioned authority, it is clear that

---

> the [Activa] was safe and effective for its intended use. The [Activa] Systems which were implanted into Plaintiff on November 9, 1998 were not safe nor effective nor fit for their intended use, because such said systems contained defects which rendered them adulterated medical devices and which caused them to malfunction. . . .

(Compl. ¶¶ 29-30).

[17] For a further discussion of the scope of the express warranty language, see infra at 33.

Davenport's express warranty claim is not preempted pursuant to the MDA, as the Limited Warranty arose from representations of Medtronic and not from the independent operation of state law.

3. Implied Warranty Claim

The basis for Davenport's implied warranty claim is not clear from the face of Davenport's Complaint.[18] In fact, Davenport's only stated basis for his implied warranty claim is the same as for his express warranty claim.[19] Nevertheless, at the Hearing on the instant Motion, Davenport clarified that his claim was based on the implied warranty of merchantability. (Summ. J. Hr'g Tr. at 25). In relation to preemption, in light of case-law within and outside this Circuit, it is clear that the MDA does preempt Davenport's implied warranty claim.

The implied warranty of merchantability, as described in the Uniform Commercial Code ("U.C.C.") and adopted by Pennsylvania, is "a warranty that the goods will pass without objection in the trade and are fit for the ordinary purposes for which such goods are used." Borden, Inc. v. Advent Ink Co., 701 A.2d 255, 258 (Pa. Super. 1997)(quoting Moscatiello v. Pittsburgh Contractors Equip. Co., 595 A.2d 1190, 1193 (Pa. Super. 1992)). The warranty "serves to protect buyers from loss where the goods purchased are below commercial standards." Hornberger v. Gen. Motors Corp., 929 F. Supp. 884, 888 (E.D. Pa. 1996). An implied warranty claim is centered around the accepted standards of design and manufacture of products in the state of Pennsylvania. Shiley, 46 F.3d at 1324-25.

---

[18] Specifically, in the Complaint, Davenport does not specify which implied warranty he is moving under.

[19] For a discussion of the foundation for the warranty claims, see supra note 16.

In light of the factors described in Lohr, this implied warranty claim is preempted by Section 360k of the MDA. First, as previously established in Section III. B. of this Memorandum, the PMA imposed specific federal requirements relating to the Activa. Second, this U.C.C. cause of action meets the second Lohr prong in that it imposes state requirements that relate to the safety and effectiveness of the Activa. Finally, a judgment for breach of implied warranty would rest on allegations relating to standards "different from or in addition to" federal requirements set forth in the PMA. Specifically, the accepted standards of design and manufacture for products in the state of Pennsylvania would be "different from or in addition to" the requirements set through the PMA process. Thus, "a state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it." Mitchell, 126 F.3d at 915. This determination is in accord with cases within and outside this Circuit that have found that implied warranty of merchantability claims are preempted by the MDA's preemption clause. Id.; Shiley, 46 F.3d at 1325; Enlow, 210 F. Supp.2d at 862; In re Orthopedic Bone Screw Prods. Liab. Litig., No. MDL 1014, 1996 WL 221784, at *8 (E.D. Pa. Apr. 8, 1996).

In summary, Davenport's strict product liability, negligence and breach of express warranty claims survive federal preemption pursuant to the MDA. However, Davenport's implied warranty of merchantability claim is preempted in light of Lohr and other relevant case-law. We must now examine whether Davenport's non-preempted claims should reach the trial stage in light of the summary judgment standard and Medtronic's state-law arguments.

D. Failure to Meet Summary Judgment Standard

The fact that the majority of Davenport's claims survive preemption does not

automatically protect his claims from summary judgment. This Court must decide whether Davenport has met his burden as the non-moving party at the summary judgment stage. In this case, we find that Davenport has failed to meet his burden on the remaining claims. Thus, we find that Davenport's strict product liability, negligence and breach of express warranty claims are not entitled to go to a jury.

1. Brief Summary of Burdens at Summary Judgment Stage[20]

As previously noted, pursuant to Rule 56(c), summary judgment is proper "if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). The court must determine whether there is a genuine issue of triable fact. Anderson, 477 U.S. at 249. It is clear that "when the non-moving party bears the burden at trial and the movant meets its burden of directing the court to items demonstrating the absence of a genuine issue of material fact, the non-moving party must produce evidence sufficient to create a genuine issue." Kozma v. Medtronic, Inc., 925 F. Supp. 602, 609 (N.D. Ind. 1996)(citing Celotex Corp., 477 U.S. at 324). Significantly, the non-moving party cannot sustain this burden through unsupported assertions, conclusory allegations or mere suspicions in attempting to survive a summary judgment motion. Williams, 891 F.2d 458, 460 (3d Cir. 1989)(citing Celotex Corp., 477 U.S. at 325 (1986)). "If the non-moving party fails to meet this evidentiary burden, the court should, in most circumstances, grant summary judgment in favor of the movant." Kozma, 925 F. Supp. at 609 (citing Celotex Corp., 477 U.S. at 322). In the instant case, Davenport has failed to meet his evidentiary burden for all of his non-preempted claims.

[20] For further discussion of the Court's standard of review on the instant Motion, see Part II. of this Memorandum.

2. Strict Liability and Negligence Claims

As previously established, Davenport's strict product liability and negligent manufacture claims are not preempted because they are based on Medtronic's purported non-compliance with FDA/PMA standards. Nevertheless, Medtronic challenges these allegations by presenting evidence that Davenport's Activa systems were in fact FDA/PMA compliant. Medtronic has provided the Court with substantial evidence through traceability records and testing that indicate that Davenport's Activa systems met all FDA/PMA requirements. We find that Medtronic has proven that there is no genuine issue of material fact concerning this compliance issue. Davenport has not provided the Court with sufficient evidence to allow a jury to infer that Medtronic did not meet all FDA/PMA standards in relation to his Activa systems.

Davenport claims that two significant problems with his Activa systems demonstrate that the devices did not satisfy all FDA/PMA requirements. First, Davenport asserts that the fact that fatty material was found in one of the IPG connector mechanisms explanted from his body indicates that the Activa systems were not FDA/PMA compliant. (Pl.'s Mem. Opp. Summ. J. at 12). Specifically, Davenport claims that the entire IPG component (including the IPG connector) should be water-tight pursuant to FDA/PMA standards.[21] (Id.). Second, Davenport contends that the fact that the Leads malfunctioned (and possibly fractured) after his second surgery indicates that certain FDA/PMA requirements were not met. (Id.). Davenport has presented the Court with two expert reports from Mr. Ted Milo ("Milo"), his electrical

[21] At the Hearing on the instant Motion, Davenport's counsel began to use the term "hermetically sealed" interchangeably with the term "water-tight." (Summ. J. Hr'g Tr. at 14, 32-33). For consistency purposes, the Court uses the term "water-tight" throughout this Memorandum.

engineer, in support of these allegations relating to the Activa systems variance from FDA/PMA requirements. (Pl.'s App., Ex. A; Pl.'s Suppl. App., Ex. B).

In fulfilling its burden at this summary judgment stage, Medtronic has directed the Court to concrete and substantial evidence that Davenport's Activa systems met all FDA/PMA standards. For example, Medtronic submitted to the Court traceability records that indicate that all components of the specific Activa systems at issue were manufactured and tested in accordance with FDA/PMA requirements. (Def.'s App., Tab 27). Further, in accordance with this Court's January 28, 2003 Order, Medtronic tested the IPGs that were explanted from Davenport on April 14, 1999. As stated by Medtronic and specifically conceded by Davenport in his Response to the instant Motion, "[b]oth IPGs passed Medtronic's final functional test, confirming that they satisfied the PMA-approved functional and performance requirements." (Def.'s Mem. Supp. Summ. J. at 16). Moreover, as stated by Medtronic and conceded by Davenport, "Medtronic also performed extensive interaction characterization testing of the two IPGs, including a series of tests specifically requested by [Davenport's] expert, and found no interaction between the IPGs that would explain Plaintiff's complaints of sensations within his chest adjacent to the IPGs." (Id.) Significantly, Davenport has not performed any tests on the IPGs as he is permitted to pursuant to the January 28, 2003 Order that would refute these findings.

In similar cases, courts have examined the parties' burdens at this summary judgment stage. For example, in Kozma, the court had to consider whether plaintiffs' claim for adulteration/negligent manufacturing of a pacemaker could withstand the defendant manufacturer's summary judgment motion. 925 F. Supp at 603 (N.D. Ind. 1996). As an initial

matter, the court found that the adulteration/negligent manufacturing claim was not preempted because the plaintiffs' claim was based on the premise that the manufacturer failed to comply with FDA regulations with respect to the specific pacemaker at issue. Id. at 609. In terms of the parties' burdens at the summary judgment stage, the court stated the following:

> Here, the Defendant has offered considerable proof that it complied with FDA regulations in every aspect of the design, manufacture and labeling of its pulse generator and leads. This evidence is sufficient to shift the burden to the Plaintiffs to produce evidence that the Defendant had not complied with FDA regulations in manufacturing the specific pacemaker involved in this case. The Plaintiffs have not done so.

Id. (emphasis added). In Kozma, despite the plaintiff's's failure to meet their burden, the court denied the defendant's motion for summary judgment on the adulteration/negligent manufacturing claim because "the Plaintiff had not had the opportunity to inspect the allegedly defective pacemaker." Id. at 610. The court found that summary judgment would be "premature" because the manufacturer had always had control of the pacemaker and that discovery was needed concerning the device. Id.

In addition, in Brooks v. Howmedica, Inc., the Court of Appeals for the Eighth Circuit ("Eighth Circuit") considered whether the district court properly dismissed the plaintiff's claim that the defendant manufacturer failed to comply with FDA regulations regarding product instructions. 273 F.3d at 798. Initially, the Eighth Circuit agreed with the lower court's conclusion that the failure to comply claim was not preempted by the MDA. Id. at 799. The Eighth Circuit then went on to affirm the lower court's decision that the claim should be dismissed at summary judgment because the plaintiff had not presented sufficient evidence of the manufacturer's failure to comply with federal law. Id. Specifically, the Court stated that

"[plaintiff] has presented no evidence that [the manufacturer] violated federal regulations or refused to add warnings drafted by the FDA, changed FDA-approved labels, failed to meet regular reporting requirements, failed to report a known hazard to the FDA, or failed to comply with federal law in any other respect." Id.

In the instant case, Davenport has pointed to the fact that tissue was found in the IPG connector in an attempt to show the IPGs were not manufactured in accordance with FDA/PMA requirements. Davenport states that "the presence of fatty material where the FDA requirement mandates that there be no such material constitutes failure of this product to meet FDA standards. . . ." (Pl.'s Mem. Opp. Summ J. at 12). Davenport's assertion is based on his claim that Milo stated in his expert reports that these devices should be sealed and water-tight pursuant to the FDA. (Id.) However, after a thorough examination of Milo's expert reports, we find no reference in the reports to any FDA/PMA requirements that were allegedly breached if the IPG connector was not completely water-tight.[22] While Milo's report mentions the impact of "failed insulation" within his reports, he does not point to any FDA/PMA requirements in relation to the sealed nature of the IPGs. Instead, Milo's report makes broad conclusory statements such as the "IPGs implanted in November of 1998 should not malfunction as it did in Mr. Davenport unless these devices were defective." (Pl.'s Supp. App., Ex. B., at 26). Moreover, Davenport himself does not point to any specific FDA/PMA requirement in terms of the sealed nature of the IPG. Further, this case is unlike Kozma in that Davenport and his expert had the opportunity to test the explanted IPG to refute Medtronic's evidence of FDA/PMA

[22] In one of his expert reports, Milo states that he read through relevant portions of the 59,177 page PMA. (Pl.'s Suppl. App., Ex. B at 23).

compliance. Even accepting every inference for Davenport at this stage in the litigation (i.e. that a "fluid short" in the IPG caused Davenport's complications), Davenport and his expert have simply not produced sufficient evidence to support the claim that Medtronic failed to comply with FDA/PMA requirements in the manufacturing of the IPGs at issue.

Davenport also directs the Court to the fact that the Leads malfunctioned after Davenport's second surgery in an attempt to show that the Leads did not meet FDA/PMA standards. In his Response to the instant Motion, Davenport alleges that "Milo has stated his opinion that the leads should not have malfunctioned as they did, if these leads had been in compliance with FDA standards." (Pl.'s Mem. Opp. Summ. J. at 13). Again, after a thorough examination of Milo's expert reports, the Court finds no reference in the reports to any FDA/PMA requirement that was not met even if these leads became fractured or frayed while in Davenport's body. Even at this stage, Davenport and his expert cannot simply point to the malfunction itself to prove that the Leads were not manufactured in accordance with FDA/PMA specifications. Accepting every inference for Davenport at this stage in the litigation (i.e. that frayed or fractured Leads caused Davenport's complications), Davenport and his expert have not produced sufficient evidence to support the claim that Medtronic failed to comply with FDA/PMA requirements in the manufacturing of the Leads.

We find that Davenport has failed to show that there is a triable issue of fact concerning whether the Activa systems met FDA/PMA standards. Notably, at the Hearing on the instant Motion, the Court gave Davenport an additional opportunity to direct the Court to evidence that FDA/PMA standards were not met. In fact, a week prior to the Hearing, the Court

provided both parties with detailed questions that the Court directed the parties to address.[23] In

[23] The questions the Court provided to the parties prior to the Hearing were as follows:

I. **Count I** (Negligence Claims)

1. What specific FDA regulations or [PMA] standards did Medtronic not comply with? (*Question also applicable to strict product liability claim*)

A. For example, what FDA/PMA requirement mandates that IPGs must be water-tight? (Question also applicable to strict product liability claim)

B. For example, what FDA/PMA requirement was violated when the [Leads] allegedly malfunctioned? (Question also applicable to strict product liability claim)

2. How does [Davenport] respond to fact that the IPGs explanted from [Davenport] were tested by Medtronic and were found to pass all testing requirements? Doesn't this indicate (as Medtronic alleges) that all PMA approved functional and performance requirements were met?

3. What is the basis for Plaintiff's claim that Medtronic was negligent in allowing bilateral implantation of the devices when they were only approved for unilateral implantation? Don't the courts and the FDA specifically allow for a doctor to use prescription medical devices in an off-label manner? What is the basis for holding Medtronic (as the manufacturer) liable for Dr. Munz's decision to perform a bilateral implant?

II. **Count II** (Strict Product Liability Claim)

1. What is [Davenport's] response to the argument that Comment K of 402A operates to preclude application of strict product liability theory to prescription medical devices because they are unavoidably unsafe products? ([Davenport] did not respond to this argument in his Brief)

III. **Count III** (Breach of Warranty Claims: Implied and Express Warranty Claims)

1. What implied warranty is Davenport making a claim under? (i.e. implied warranty of merchantability?)

2. Where is the language of the express warranty that Davenport claims was breached?

this document, the Court specifically asked the following: (1) "what FDA/PMA requirement mandates that the IPGs must be water tight?" and (2) "what FDA/PMA requirement was violated when the leads allegedly malfunctioned?" See supra note 20.

At the Hearing, after a lengthy dialogue between the Court and Davenport's counsel, the Court was never directed to any specific FDA/PMA requirements that were not met in relation to the IPGs or the Leads. (Hr'g Tr. at 13-22). Instead, Davenport's counsel could only make the conclusory assertion that some FDA/PMA requirement must not have been met since tissue was found in the IPGs, the Leads malfunctioned and Davenport experienced problems. (Id.). This argument ignores the fact that there may have been other causes for Davenport's issues with the Activa systems, notwithstanding that the devices were manufactured within FDA/PMA standards.[24] At the Hearing, just as in the Response to the instant Motion, Davenport has failed to direct the Court to any FDA/PMA requirement Medtronic did not meet. For example, Davenport has not pointed to any manufacturing process, component requirement, or testing standard that Medtronic did not satisfy in relation to the Activa systems at issue. Davenport has failed to support his argument that his Activa systems were not manufactured in accordance with FDA/PMA standards.

Davenport's strict product liability and negligent manufacturing claims only

[24] Notably, some of Medtronic's Activa literature warned both doctors and patients of some of the complications that Davenport experienced. For example, the Lead Implant Manual warned that "Leads may fail to function for a variety of causes, including but not limited to, medical complications, body rejection phenomena, or failure by breakage or by breach of their insulation covering." (Def's App., Ex. G at 51). Further, the Medtronic Physician and Hospital Manual warned that "IPGs are used with extensions, which are implanted in the extremely hostile environment of the human body. IPGs may fail to function for a variety of causes, including but not limited to, medical complications, body rejection phenomena, or component failure." (Def.'s App., Ex. C. at 71).

survive preemption because they are based on the premise that the Activa systems at issue were not in compliance with FDA/PMA standards. Medtronic has presented substantial evidence that Davenport's Activa devices were manufactured within FDA/PMA standards. In response, Davenport has made only conclusory allegations and has not presented this Court with sufficient evidence to create a triable issue of fact on this issue. Therefore, summary judgment in Medtronic's favor is appropriate for the strict product liability and negligence manufacture claims.

Finally, the Court finds no basis for Davenport's secondary negligence claim that Medtronic was negligent in "allowing bilateral implantation of [the Activa systems] when [it] knew that the FDA had allowed only unilateral implantation of the device." (Comp. ¶ 26). In Pennsylvania, the elements of a negligence claim are: (1) a duty or obligation recognized by the law, requiring the actor to conform to a certain standard of conduct; (2) a failure to conform to that standard; (3) a casual connection between the conduct and the resulting injury; and (4) actual loss or damage resulting to the interests of another. Morena v. S. Hills Health Sys. Co., 462 A.2d 680, 684 n.5 (Pa. 1983). This aspect of the negligence claim also fails because Davenport has failed to produce any evidence or authority that shows that Medtronic was *prima facie* negligent in allowing Dr. Munz to perform a bilateral implant of the Activa.

Neither party disputes that the bilateral implant of the Activa qualified as an "off-label" usage (i.e. use of a device for a purpose that has not been approved by the FDA) of the Activa systems. As Medtronic notes, it is well established that the FDA does not prohibit "off-label" use of medical devices. Southard v. Temple Univ. Hosp., 781 A.2d 101, 104 (Pa. 2001). While the FDA controls the marketing and labeling of medical devices, it does not attempt to

interfere with the practice of medicine. Id.; 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). The Supreme Court has emphasized that off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350 (2001).

Courts have dismissed similar claims at summary judgment that were based on a manufacturer allowing a physician to use a medical device in an "off-label" manner. Little v. Depuy Motech, Inc., No. 96-0393, 2000 WL 1519962, at *9 (S.D. Cal. June 13, 2000)("Dr. McKinley's decision to use [the manufacturer's] device in an 'off-label' manner does not subject the manufacturer to liability, even if it knows of the off-label use. Accordingly, [the manufacturer] cannot be held liable for Dr. McKinley's decision to implant the [manufacturer's] device in an off-label manner."); Cox v. Depuy Motech, Inc., No. 95-3848, 2000 WL 1160486, at *8-9 (S.D. Cal. Mar. 29, 2000)("A physician may use any device legally on the market in any way the physician deems appropriate which may be consistent with the seller's labeling or 'off-label,' as in this case. A seller is not liable even if it knows of the off-label use."). Based on the foregoing authority, and the fact that Davenport has presented no evidence to support this aspect of the negligence claim, the Court finds that summary judgment in Medtronic's favor is appropriate on this aspect of the negligence claim.

3. Express Warranty Claim

As previously established, Davenport's express warranty claim is not preempted

because any express warranty would have arose from the representations of the parties and not from the independent operation of state law. Nevertheless, Medtronic has presented evidence that Davenport's express warranty is baseless and should therefore be dismissed at the summary judgment stage, notwithstanding that the claim survives preemption. Davenport has failed to produce any evidence supporting this claim to create a triable issue of fact. Thus, the court agrees with Medtronic that summary judgment in favor of Medtronic is appropriate regarding the express warranty claim.

Pennsylvania law specifically defines how express warranties are formed. As set forth by the U.C.C. and Pennsylvania statute, an express warranty can be formed in the following ways:

> 1) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise;
>
> 2) Any description of the good which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description; and
>
> 3) Any sample or model which is part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

13 Pa.C.S. § 2313. "Express warranties arise from the representations of the parties which are made the basis of the bargain." Shiley, 46 F.3d at 1325.

In the present case, in his Complaint and Response to the instant Motion, Davenport does not clarify the language of the express warranty upon which he bases his claim. However, at the Hearing, Davenport clarified that he was moving pursuant to language in the

Limited Warranty relating to the Leads. The Limited Warranty states:

> Should the Lead fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the date of implantation of the Lead, Medtronic will, at its option: (a) issue a credit to the purchaser of the replacement Lead equal to the Purchase Price . . . against the purchase of any Medtronic Lead required as its replacement, or (b) provide a functionally comparable Lead at no charge.

(Def.'s App., Ex. H). The undisputed facts of this case show that Medtronic has not breached this warranty. Conversely, the facts display that Davenport himself has decided not to avail himself of the express warranty because he refuses to have the surgical procedure necessary to have the Leads replaced. We find that this express warranty claim should be dismissed at summary judgment because Davenport has presented no evidence that Medtronic has breached any express warranty.[25]

In summary, the Court finds that Davenport's strict product liability, negligence and express warranty claims should be dismissed at the summary judgment stage even though the claims survive preemption pursuant to the MDA. Davenport has failed to produce sufficient evidence on these claims to proceed to a jury. The Court finds there are no triable issues of fact surrounding these remaining claims and that Medtronic is entitled to judgment as a matter of law.

E. Failure of Claims Pursuant to Pennsylvania Law

A portion of Davenport's claims also fail under Pennsylvania law. Comment k of Section 402A precludes the application of a strict product liability theory in this case. Further,

[25] Davenport's counsel all but conceded this claim at the Hearing. Specifically, he stated that "I don't have any express warranty language other than what [Defendant's counsel] presented to you here today, and I understand that's limited and I don't see that I'm going to win on that point. (Summ. J. Hr'g Tr. at 25).

the caselaw is clear that Davenport's implied warranty claim fails as well because of the nature of prescription medical devices. Thus, the Court finds that Medtronic is entitled to summary judgment on Davenport's claims for these alternative reasons.[26]

1. Strict Product Liability Claim

Pennsylvania has adopted Section 402A of the Restatement (Second) of Torts, which places liability on manufacturers of products sold "in a defective condition unreasonably dangerous to the user or consumer." Mazur v. Merck & Co., 964 F.2d 1348, 1353 (3d Cir. 1992). Comment k of Section 402A, however, entitled "Unavoidably Unsafe Products," alters the strict liability rule on certain products. Comment k "denies application of strict liability to products such as prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." Hahn v. Richter, 673 A.2d 888, 889-90 (Pa. 1996). In Hahn, the Supreme Court of Pennsylvania made clear that 402A is inapplicable to prescription drugs. Id. at 891. "The Supreme Court of Pennsylvania recognizes that prescription drugs present a unique set of risks and benefits in that what may be harmful to one patient may be beneficial to another." Taylor v. Danek Medical, Inc., No. 95-7232, 1998 WL 962062, at *7 (E.D. Pa. Dec.29, 1998).

Subsequent to Hahn, the Supreme Court of Pennsylvania has never specifically addressed whether prescription medical devices, as opposed to just prescription drugs, should fall within the realm of Comment k and qualify as "unavoidably unsafe products." Nevertheless, numerous courts in the Eastern District of Pennsylvania have predicted that the Pennsylvania

[26] Notably, in his Response to the instant Motion, Davenport did not respond to Medtronic's argument relating to Comment k of Section 402A. In fact, Davenport only responded to the Medtronic's preemption arguments in his Response.

Supreme Court will follow its reasoning in Hahn and hold that prescription medical devices are not covered by Section 402A. Murray v. Synthes (U.S.A.) Inc., No. 95-7796, 1999 WL 672937, at *7 (E.D. Pa. Aug. 23, 1999); Burton v. Danek Med., Inc., No. 95-5565, 1999 WL 118020, at *7 (E.D. Pa. Mar. 1, 1999); Taylor, 1998 WL 962062, at *7. This Court agrees with the reasoning in these cases and finds that Comment k precludes application of Section 402A to prescription medical devices. Thus, Davenport's strict product liability claim relating to the Activa prescription medical device must fail since it is not covered by Section 402A.

2. Implied Warranty of Merchantability Claim

Similar to the reasoning in Hahn relating to application of Section 402A, "Pennsylvania courts have held that the nature of prescription drugs also precludes claims for breach of the implied warranty of merchantability." Burton, 1999 WL 118020, at *7 (citing Makripodis v. Merrell-Dow Pharms., Inc., 523 A.2d 374, 376-77 (Pa. Super. 1987)); see also Murray, 1999 WL 672937, at *7. As noted by other courts, "this reasoning would also preclude implied warranty claims for prescription medical devices." Murray, 1999 WL 672937, at *7. Thus, Davenport is unable to maintain his claim for breach of the implied warranty of merchantability since it relates to a prescription medical device.

IV. CONCLUSION

In summary, only Davenport's implied warranty of merchantability claim is preempted pursuant to the MDA. Nevertheless, Davenport's remaining claims (strict product liability, negligence and express warranty claims) are not entitled to reach a jury because Davenport has failed to meet his summary judgment burden regarding these claims. Finally, Davenport's strict product liability and implied warranty of merchantability claims simply fail as

a matter of Pennsylvania law.

For the reasons that are set forth above, the Court finds summary judgment in Medtronic's favor is appropriate in this matter. There are no genuine issues of fact surrounding any of Davenport's claims and Medtronic is entitled to judgment as a matter of law. Accordingly, Medtronic's Motion for Summary Judgment will be granted.

An appropriate Order follows.

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

RICHARD DAVENPORT,	:	CIVIL ACTION
Plaintiff,	:	
v.	:	NO. 00-6105
MEDTRONIC, INC.,	:	
Defendant.	:	

ORDER

AND NOW, this 3rd day of February, 2004, upon consideration of Defendant's Motion for Summary Judgment (Doc. No. 27), and the Response and Reply thereto, it is hereby **ORDERED** that Defendant's Motion is **GRANTED**.

BY THE COURT

Robert F. Kelly, Sr. J.

.