TH 03-0005-C M/H McMullen v Medtronic, Inc
Judge Larry J. McKinney Signed on 9/16/04

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

JACK MCMULLEN, BARBARA MCMULLEN, Plaintiffs, vs. MEDTRONIC INC., Defendant.	)	NO. 2:03-cv-00005-LJM-WGH

Jeremy A. Klotz
ICE MILLER
jeremy.klotz@icemiller.com

Kevin R. Knight
ICE MILLER
kevin.knight@icemiller.com

Stephen A. Kurowski
LAW OFFICES OF STEVEN A. KUROWSKI
kurowskilaw@aol.com

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
TERRE HAUTE DIVISION

JACK McMULLEN and BARBARA McMULLEN, Husband and Wife, Plaintiffs,	)	
vs.	)	2:03-cv-005-LJM-WGH
MEDTRONIC, INC., Defendant.	)	

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

This matter comes before the Court on Cross Motions for Summary Judgment filed by the Plaintiffs, Jack McMullen ("Mr. McMullen") and Barbara McMullen, husband and wife (collectively "the McMullens"), and Defendant Medtronic, Inc. ("Medtronic").

For the reasons stated herein, the Court **GRANTS** Medtronic's Motion for Summary Judgment, and **DENIES** the McMullens' Motion for Summary Judgment.

I. BACKGROUND

The McMullens filed a complaint against Medtronic on December 5, 2002, in Vermillion County Circuit Court, which Medtronic removed to this Court on January 8, 2003. The two-count complaint sets forth claims for a duty to warn based on Mr. McMullen's experience with the Medtronic Activa Tremor Control System ("the Activa"), and loss of consortium. The Activa is a prescription medical device that was bilaterally implanted in Mr. McMullen to help relieve him of symptoms associated with Parkinson's

disease.[1] The McMullens allege that Medtronic was under a strict and nondelegable duty to warn recipients of the Activa of dangers posed to recipients both before and after the implantation of such devices. Medtronic did not issue warnings to Mr. McMullen of the danger of severe brain damage or death from diathermy/electrocautery treatments until May 2001, when it knew, or should have known, prior to that time that such treatments could result in injury. Comp. ¶¶ 12-15. Having not been warned, Mr. McMullen underwent a dental procedure involving the use of diathermy/electrocautery and suffered severe brain damage with resultant diverse, permanent, and disabling injuries. *Id*. ¶¶ 16-17. Plaintiffs further allege that Barbara McMullen, by Medtronic's wrongful acts and omissions, has been deprived of Mr. McMullen's support, society, companionship, services, and consortium, and will continue to be so deprived. *Id*. ¶ 20. Medtronic moved for summary judgment as to both claims and the McMullens moved for summary judgment as to liability.

A. THE ACTIVA SYSTEM

Medtronic's unilateral Activa was first approved by the FDA in 1997 for the suppression of tremor in the upper extremity of patients diagnosed with essential tremor or Parkinsonian tremor. Def.'s Exh. 3. The unilateral Activa is composed of three distinct implanted products: (1) the implantable pulse generator ("IPG"), which is a power source for the System consisting of a sealed, oval-shaped metal container

[1] As summarized in Medtronic's Motion, "Parkinson's disease is a progressive, degenerative neurological disease arising from a reduced level of dopamine, a neurotransmitter that enables communications between the cells that control movement." Def.'s Br. Supp. at 6. 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*, McMullen had two Activa devices surgically implanted in his body to help alleviate the symptoms of his condition.

housing a special battery and programmable electronics that control the electrical charge the battery generates; (2) an extension, which is a thin insulated conductor connected to the IPG on one end and to the lead on the other end; and (3) the lead, which is a thin insulated wire with a series of tiny electrodes at one end that conveys electrical pulses from the IPG through the extension to the tissues in the brain where it stimulates a portion of the brain to suppress the disease symptoms. Def.'s Exh. 2, ¶ 30.

The Activa works by electrically stimulating the targeted structures in the brain that control movement and muscle function, a process also known as Deep Brain Stimulation ("DBS"). Def.'s Exh. 2, ¶16, Tab D at 3. Continuous stimulation of these areas blocks the signals between the brain and the rest of the body. In patients with tremor, these messages do not work correctly and cause the disabling motor symptoms of Parkinson's disease. Stimulation from these systems may interrupt the messages that result in tremor and help suppress tremor. *Id*. As a result, many patients achieve greater control over their body movements.

On January 14, 2002, the Medtronic Activa Parkinson's Control System ("Activa Parkinson's") was approved by the FDA as a bilateral therapy – with electrodes implanted on both sides of the brain – for reducing additional symptoms of advanced Parkinson's disease. Def.'s Exh. 4. The Activa Parkinson's uses the same devices approved with the Activa. Def's Br. Supp. at 7.

B. THE PRE-MARKET APPROVAL PROCESS

A central issue in this case is whether the McMullens' state claims are preempted by the Medical Device Amendments ("MDA") of 1976 to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 321-394 ("MDA"). Medtronic asserts that the McMullens' failure to warn and loss of

consortium 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 a ruling on the instant motions.

In 1976, Congress enacted the MDA, which modified the FDCA to allow the FDA to regulate medical devices. The MDA divides medical devices into three categories, or classes. The most strict FDA regulation is reserved for Class III devices, defined as those which: (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. *See* 21 U.S.C. § 360c(a)(1)(C)(ii)(I-II). To market a Class III device within the United States, the manufacturer must either submit its product to the FDA for PMA, or qualify for one of two exceptions to this time-intensive regulatory review. The PMA process involves close scrutiny of the device by the FDA, and approval requires that the FDA conclude that it has received "reasonable assurances of [the device's] safety and effectiveness" from the manufacturer. *Id*. § 360c(a)(1)(C). To that end, 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 the proposed labels, and various other information. *See* 21 C.F.R. § 814.20(b). The FDA then reviews such submissions for an average of 1,200 hours before either approving or disapproving the device. *See id*. §§ 812.1-.150; *see also Mitchell v. Collagen Corp*., 126 F.3d 902, 905 (7th Cir.1997).

A manufacturer may also gain regulatory clearance for a Class III device through one of two exemptions from the PMA process. First, the statute permits devices that are "substantially equivalent" to medical devices in existence in 1976 to be marketed and sold without PMA approval, in order not to stifle competition with technology existing at the time of the enactment of the MDA. *See* 21 U.S.C. §

360j(g)(1). This limited form of review is known as "premarket notification" or "the § 510(k) process," and averages only 20 hours of review as opposed to some 1,200 hours in the PMA process. *See Medtronic, Inc., v. Lohr*, 518 U.S. 470, 479 (1996).

Second, devices representing innovative technology may be marketed under an investigational device exemption ("IDE"), 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, a device operating under the IDE exemption need not comply with premarket approval requirements during the trial period. *See* 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812-813.

Should a manufacturer merely propose to modify a Class III device that already has received approval pursuant to the PMA process, the manufacturer may submit a PMA Supplement rather than re-submit the entire device for review. *See* 21 C.F.R. §§ 814.39, 814.80. The procedures applicable to a PMA Supplement are the same as those applicable to an original PMA, although the FDA only requires the manufacturer to provide that information necessary to support the proposed modifications. *See id*. § 814.3(g).

C. MR. McMULLEN'S EXPERIENCE WITH THE ACTIVA

Mr. McMullen has suffered from the symptoms of Parkinson's disease since 1985. Pl.'s Ex. 1. Mr. McMullen underwent a conventional drug therapy to control his symptoms. By 2000, his dosage requirements had risen to a point where his increasing symptoms could be only marginally controlled. Pl.'s

Ex. 2. Mr. McMullen was implanted with two Activa systems, resulting in bilateral stimulation to the subthalamic nucleus area of both the left and right sides of his brain. Pl.'s Exh. 3. As a result of the implementation of this bilateral DBS system, Mr. McMullen experienced an excellent remediation of his Parkinson's symptoms. Pl.'s Exh. 2.

Medtronic became aware in January 2001 that a user of an implanted DBS system had sustained potentially serious injury while undergoing routine diathermy following oral surgery. Pl.'s Exh. 8. On March 13, 2001, Mr. McMullen underwent a dental procedure involving the use of an electrical surgical instrument. Pl.'s Exh. 10. The parties dispute whether the procedure involved diathermy or electrocautery. *See e.g.*, Comp. ¶ 16; Def.'s Br. Supp. 1-3; Pl.'s Resp. at 2-4. The McMullens' complaint asserts that, as a result of the use of the electrical surgical instrument during his dental procedure, Mr. McMullen suffered severe brain damage with resultant diverse, permanent, and disabling injuries. Comp. ¶ 17. On May 18, 2001, Defendant sent a letter to recipients of its deep brain stimulation systems, informing them of the dangers of severe injury or death from exposure to diathermy, approximately two months after Mr. McMullen's dental procedure. Pl.'s Exh. 11.

The parties do not dispute that the Activa Tremor Control System is a Class III medical device and that the Activa Tremor Control System went through the rigorous PMA process and was approved by the FDA on July 31, 1997, before it was marketed by Medtronic. *See* Pl.'s Exh. 4; Def.'s Exh. 3. Further, the parties agree that the Activa Parkinson's Control System was approved by the FDA as a bilateral therapy -- with electrodes implanted on both sides of the brain -- for reducing additional symptom's of Parkinson's disease on January 14, 2002. Def.'s Exh. 4.

D. NATURE OF THE DEVICE IMPLANTED IN MR. McMULLEN

The parties expend great energy disputing the very nature of the DBS device implanted in Mr. McMullen on May 17, 2000. Medtronic correctly asserts it was a bilateral – and off-label – use of two Activas, which had received PMA approval on July 31, 1997. The McMullens claim the device was a single Activa Parkinson's that did not receive PMA approval under a supplemental application until January 14, 2002, barring preemption under § 360k, and is instead, governed by IDE regulations.

The McMullens call attention to an admission by Medtronic to support their claim that the device was an Activa Parkinson's. Pursuant to the Civil Justice Reform Act of 1990, 28 U.S.C. § 471 *et seq.*, Federal Rule of Civil Procedure 16 and 26, Southern District of Indiana Local Rule 16.1, and Order of the Court, the parties tendered a Case Management Plan ("CMP") to govern the proceedings in this case. In Defendant's Case Synopsis, Medtronic states: "On or about May 17, 2000, [Mr.] McMullen was implanted with an Activa® *Parkinson's* Control Therapy device." Case Management Plan ¶ II.B (emphasis added).

However, the medical records of Mr. McMullen and other uncontroverted evidence establish the device implanted in Mr. McMullen on May 17, 2000, was the Activa Tremor Control Therapy System, a Class III medical device approved in July 1997 for marketing by the FDA under the PMA process. Pl.'s Br. Resp., Exh. A, Pl.'s Exh. 2 ¶ 19-24. Further, the record indicates that implantation of the Activa bilaterally was an off-label use of the device.[2] Pl.'s Br. Resp., Exh. B. Whatever semantic difference can

[2] It is well established that the FDA does not prohibit "off-label" use of medical devices. *Minisan v. Danek Medical, Inc*., 79 F. Supp. 790, 798 (N.D. Ind. 1999) *citing Ortho Pharm. Corp. v. Cosprophar, Inc*., 32 F.3d 690 (2d Cir.1994), *aff'd* 179 F.3d 725 (9th Cir.1999); *Weaver v. Reagen*, 886 F.2d 194 (8th Cir.1989). While the FDA controls the marketing and labeling of medical devices, it does not attempt to interfere with the practice of medicine. 21 U.S.C. § 396 ("Nothing in

be found in referencing a medical device under one trade name as opposed to another does not, in reality, change the nature of the device itself. In this particular instance, the Court finds the McMullens' argument unpersuasive. The record indicates that Mr. McMullen received two Activa devices that were approved by the FDA's PMA process. Medtronic, at worst, has made an admission without a distinction that is immaterial to this case.[3]

---

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. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

Another district court has recently reached the conclusion that the PMA process results in preemptive, device-specific requirements in a case involving an off-label use of the device components at issue herein. *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419 (E.D. Pa. 2004).

[3] Additionally, the McMullens argue that Medtronic had applied for, and been granted, an IDE for its Activa Parkinson's, and "[o]perating under an IDE imposes upon the device manufacturer a strict obligation to comply with IDE regulations imposing a strict duty to notify recipients of its device of serious dangers that become known" under various provisions of 21 C.F.R. § 812. Pl.'s Br. Supp. at 12. A complete and thorough search of Medtronic's clinical records verify that Mr. McMullen was never enrolled in any clinical studies of the Activa Parkinson's and further that the enrollment period for Medtronic's tremor control studies was closed before Mr. McMullen's implant surgery on May 17, 2000. Def.'s Br. Resp. at 3-4, Def.'s Exh. C. The McMullens have not presented any evidence to the contrary. Instead, they assert that Medtronic was obligated, having applied for an IDE for its bilateral Activa Parkinson's, to comply with IDE regulations not only with regard to the twenty-nine individuals taking part in the study, but also with regard to individuals, of whom Medtronic was aware had been implanted an equivalent system; a bilateral, off-label implant of two Activas. But under 21 C.F.R. § 812.2(a), IDE regulations apply only, with certain enumerated exceptions inapplicable to this case, to clinical investigations of devices to determine safety and effectiveness of which Mr. McMullen was not a participant.

II. SUMMARY JUDGMENT STANDARD OF REVIEW

Summary judgment is appropriate when 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 a judgment as a matter of law." Fed. R. Civ. P. 56(c). *See also Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This standard of review applies to cross motions for summary judgment. *See Int'l Bhd. of Elect. Workers v. Balmoral Racing Club, Inc.*, 293 F.3d 402, 404 (7th Cir. 2002). We must view the admissible evidence supporting the motion in the light most favorable to the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The nonmovant must show through specific evidence that a triable issue of fact remains on the issues on which he bears the burden of proof at trial. *See Celotex*, 477 U.S. at 324. A genuine issue of material fact exists when the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *See Insolia v. Phillip Morris, Inc.*, 216 F.3d 596, 599 (7th Cir. 2000). It is with these standards in mind that the Court addresses the instant motions.

III. DISCUSSION

The McMullens' two-count complaint sets forth claims for failure to warn and loss of consortium. In the instant motions, Medtronic asserts, and the McMullens' deny, that all of the McMullens' claims are expressly preempted by federal law and must be dismissed. Further, Medtronic argues that the McMullens' claims fail as a matter of law pursuant to applicable Indiana law in the absence of preemption. The McMullens' argue that their claims are not federally preempted because the Defendant was required to track implant recipients so each patient could be located if serious dangers were discovered and, alternatively, because Mr. McMullen was implanted with a device not approved by the FDA until after the injuries complained of. Further, the McMullens move for summary judgment as to liability under Minnesota law. The Court will now address these arguments in light of the applicable summary judgment standard.

A. PREEMPTION

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. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). With express preemption, a federal statute explicitly provides that it overrides state law. *Gracia v. Volvo Europa Truck, N.V.*, 112 F.3d 291, 294 (7th Cir. 1997). "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); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 907 (7th Cir. 1997). 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); *Burlington N. & Santa Fe Ry. C. v. Doyle*, 186 F.3d 760, 790, 795 (7th Cir. 1999).

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

> [N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety 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). Furthermore, the legislative history of the MDA establishes that Congress intended extensive preemption of state law under § 360k. The House committee report for the MDA explains that the preemption provision was intended to be a "general prohibition on non-Federal regulation." H.R. REP. No. 853, 94th Cong., 2d Sess. 45 (1976).

In *Lohr*, the Supreme Court, in a plurality opinion, discussed the preemptive scope of Section

360k. 518 U.S. 470. 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 preexisting device. *Id*. at 484. The Court stated the § 510(k) process for determining "substantial equivalence" "is by no means comparable to the PMA process," as the § 510(k) review "is completed in an average of only 20 hours." *Id*. at 478-79. In *Lohr*, the plaintiff received a pacemaker from a manufacturer. *Id*. at 481. The FDA allowed the pacemaker to be marketed because it was "substantially 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 and required surgery after the pacemaker malfunctioned. *Id*. at 481. Plaintiff filed suit against the manufacturer alleging 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. In deciding the case, the 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*.

In his concurrence with the majority of the Justices, 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). For the 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*.

The Seventh Circuit, in *Mitchell v. Collagen Corp*., 126 F.3d 902 (7th Cir. 1997), followed Justice Breyer's concurrence in *Lohr*, which suggests that § 360k(a) preempts some, but not necessarily all common law claims. *See Lohr*, 518 U.S. at 506 (Breyer, J., concurring). The *Mitchell* court found the *Lohr* disposition must be read "as acknowledging that at least some state-based common law causes of action must be considered 'requirements' as that term is employed in the MDA." *Id*. at 911. Further,

> the PMA process . . . can constitute the sort of specific federal regulation of a product that can have preemptive effect. During the PMA process, the federal government, it can truly be said, has "'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers.'"

Id. (*quoting Papike v. Tambrands, Inc*., 107 F.3d 737, 741 (9th Cir. 1997), *quoting Medtronic*, 518 U.S. at 501). In other words, the *Mitchell* court interpreted *Lohr* to mean that the MDA preempts common law claims to the extent that they interfere or conflict with specific federal requirements. *Mitchell*, 126 F.3d at 913-14.

The *Mitchell* court found most of plaintiffs' claims against the manufacturer of collagen compounds, a Class III medical device, to be preempted. In analyzing the plaintiffs' strict liability claim, premised on allegations that the device was an unreasonably dangerous product and that the manufacturer should have known of such unreasonable danger, the court reasoned that because approval of a product's design,

testing, intended use, manufacturing methods, performance standards and labeling, a state court judgment premised on a contrary determination would constitute a requirement "different from, or in addition to" the standard required by federal authority and is preempted. *Id*. at 913. Likewise, a negligence claim was preempted to the extent that allegations were based on the theory that the manufacturer was negligent despite its adherence to the standards required by the FDA in its PMA process for a specific product. Finally, a mislabeling claim was preempted to the extent that the allegations involve a claim that a manufacturer had incurred liability under state law despite its conformity to the requirements of the PMA.

A "failure to warn" claim was not brought forth in that case and the Seventh Circuit has not directly addressed whether such a claim is preempted under § 360k.[4] However, the majority of circuits that have examined failure to warn claims have found federal preemption with respect to MDA devices. *See Horn v. Thoratec Corp*., 376 F.3d 163, 177 (3rd Cir. 2004); *Brooks v. Howmedica, Inc*., 273 F.3d 785, 796 (8th Cir. 2001); *Martin v. Medtronic, Inc*., 254 F.3d 573, 585 (5th Cir. 2001); *Kemp v. Medtronic, Inc*., 231 F.3d 216, 236 (6th Cir. 2000); *Papike*, 107 F.3d at 742.

However, the Tenth Circuit, in *Oja v. Howmedica, Inc*., 111 F.3d 782 (10th Cir. 1997), in an early post-*Lohr* decision, found that a common law negligent "failure to warn" claim was not preempted by the MDA. The *Oja* court reasoned that generic common law causes of action are not "requirements"developed specifically "with respect to" the medical device, and when stated without application to a particular product, they cannot be said to have been developed "in relation to" the medical

[4] A United States District Court for the Northern District of Indiana, in *Kozma v. Medtronic, Inc*., 925 F. Supp. 602 (1996), like numerous other district courts in pre-*Lohr* decisions (citations omitted), held that a common law failure to warn claim is preempted under the MDA.

device in question and thus are not subject to preemption. *Oja*, 111 F.3d at 789. The Seventh Circuit declined to adopt this approach and instead determined that the MDA preempts general common law claims to the extent that they interfere or conflict with specific federal requirements. *Mitchell*, 126 F.3d at 913-14.

B. PREEMPTION OF THE McMULLENS' CLAIMS

1. Failure to Warn

The Court must examine the tension between the McMullens' state common law "failure to warn" claim and § 360k(a). To the extent that this claim creates requirements that are in addition to, or different from, the federal requirements established by the FDA in approving the Activa, they are necessarily preempted by federally imposed PMA requirements under § 360k(a). *See Horn*, 376 F.3d at 177; *Brooks*, 273 F.3d at 796; *Martin*, 254 F.3d at 585; *Kemp*, 231 F.3d at 236. Put another way, State or local requirements are preempted when the FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements. *See* 21 C.F.R. § 808.1(d). 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." 518 U.S. at 495. As the Seventh Circuit recognized, to the extent that a complaint may be read as alleging the manufacturer failed to adhere to the standards of the FDA in the PMA, the claim would not be preempted." *Mitchell*, 126 F.3d at 913 n. 6. The *Mitchell* court also considered the preemptive scope of the MDA and has held that the PMA process results in

preemptive, device-specific requirements. *Id*. at 911.

The FDA designated the Activa for tracking to the final user or patient so that devices can be located quickly if serious problems occur with those products as is required by regulation. *See* Pl.'s Exh. B; Pl.'s Exh. 5 (*citing* 21 C.F.R. § 821 *et seq*.). Additionally, through the PMA process, the FDA set forth specific warnings to be issued with the Activa. Medtronic provided the following FDA approved warnings to Mr. McMullen's physician in the Medtronic DBS implant manual:

> Electrocautery can cause temporary suppression of pulse generator output and or reprogramming of the pulse generator. If the use of electrocautery is necessary, the current path (ground plate) should be kept as far away from the pulse generator and lead as possible.

Def.'s Exh 2, Tab C at JMD 00021; Exh. 2, Tab G at JMD 00082; Exh. 2, Tab E at JMD 00119. Furthermore, Medtronic, in accordance with the FDA's PMA process, provided the following warning with respect to diathermy in the DBS implant manual:

> The effects of diathermy on patients with an implanted neurostimulation system are unknown. Use of diathermy directly over an implanted lead or pulse generator is not recommended since internal components may be damaged.

Exh. 2, Tab C at JMD 00020; Exh. 2, Tab G at JMD 00083; Exh. 2, Tabe E at JMD 00120.

Medtronic also provided the following information directly to patients, including Mr. McMullen, in the Activa patient manual:

> Diathermy treatments that are sometimes used for muscle relaxation may affect the neurostimulator output and/or damage its electronics.
>
> * * *
>
> Tell your dentist where your IPG is implanted, so he or she can take precautions with dental drills and ultrasonic probes used to clean your teeth. These devices should not be used directly over the implant site.

> Therapeutic ultrasound, electrolysis, radiation therapy, and electrocautery also should not be used directly over the implant site.

Def.'s Exh. 2, Tab D at JMD 00066.

A jury finding of failure to warn would be premised on the fact that the labels, warnings, and documentation provided to both Mr. McMullen and his physician were not written in a particular way, did not contain certain information, or that Medtronic had additional duties, beyond those spelled out in federal regulations pertaining to the Activa. This would be equivalent to a state regulation imposing specific warning requirements. Justice Breyer illustrated this principle in his concurring opinion in *Lohr* when he posited a situation in which an MDA regulation required that a hearing aid contain a 1-inch wire, but a state regulation required a 2-inch wire. That MDA regulation would preempt the state regulation. The same result ought to obtain, reasoned Justice Breyer, if a state tort action were to impose liability on the failure to have a 2-inch wire. Consequently, wrote the Justice, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Lohr*, 518 U.S. at 505 (Breyer, J., concurring).

While the McMullens couch their argument as Medtronic's failure to adhere to warning requirements set forth by the FDA through the PMA process, they, in actuality, argue the warnings required under the FDA were inadequate and seek to impose a standard of care or behavior imposed by a state-law tort action. The McMullens' claim is premised on the theory that Medtronic was under a strict and nondelegable duty to warn DBS devices before and after the implantation. Comp ¶ 12. The Plaintiffs base their claim on the federal requirement imposed by the FDA. Pl.'s Exh. B; Pl.'s Exh. 5 (*citing* 21 C.F.R.

§ 821 *et seq*.). However, there is a logical disconnect between the federal regulation to track recipients of a device, and a duty, not set forth in any federal regulation pertaining to this device, to contact all recipients of that device upon the discovery of an adverse reaction in a recipient that, as it appears to be in this case, was the subject of product warnings approved by the FDA's PMA process. While the purpose of the tracking requirement is to prevent harm to individuals with Class III medical devices, it does not necessarily follow that the manufacturer is under a "strict and nondelagable" duty to inform recipients of all adverse reactions, or further to do so "within hours." The FDA retains continuing oversight over approved Class III devices. It requires manufacturers to report any deaths or serious injuries which result from the use of the product. *See* 21 C.F.R. § 803.1(a). The device at issue was thoroughly tested and otherwise scrutinized by the FDA, which approved Medtronic's application for PMA, thus allowing Medtronic to manufacture, market, and sell its DBS system as a prescription medical device. All aspects of the device were approved, including design, packaging, and warnings – which include warnings regarding diathermy and electrocautery procedures. The failure to warn claim asserted by the McMullens presupposes a duty "in addition to" the specific federal requirements imposed on Medtronic through the Activa's PMA process and approval.

Considering the Seventh Circuit's decision in *Mitchell*, and Justice Breyer's concurrence in *Lohr*, the Court aligns itself with the great weight of authority and finds federal preemption of the McMullens' failure to warn claims under the particular circumstances of this case. Even under these unfortunate circumstances, the McMullens' state common law cause of action for a failure to warn is preempted under

§ 360k(a), and their subsequent arguments are rendered moot.[5]

2. Loss of Consortium Claim

The McMullens' Complaint includes a claim for loss of consortium. Based on the present state of the briefing, the Court will also grant the motion for summary judgment as to the loss of consortium claim that derives from the preempted claim.

V. CONCLUSION

For the foregoing reasons, the Court **GRANTS** defendant's, Medtronic Inc., Motion for Summary Judgment, and **DENIES** plaintiffs', Barbara and Jack McMullen, Motion for Summary Judgment.

IT IS SO ORDERED this 15th day of September, 2004.

_____

LARRY J. McKINNEY, CHIEF JUDGE
United States District Court
Southern District of Indiana

Distribution attached.

[5] Although the McMullens have asserted that Indiana law, under *Reed v. Ford Motor Co*., 679 F. Supp. 873, 879 (S.D. Ind. 1988), requires that a manufacturer or seller's duty to warn does not end at the time it places the product into the stream of commerce. Alternatively, the McMullens assert that under Minnesota law, a post-sale duty to warn also has been recognized, citing *Hodder v. Goodyear*, 426 N.W. 2d 826, 833 (Minn. 1988) (additional citations omitted).

Distributed electronically to:

Jeremy A. Klotz
ICE MILLER
jeremy.klotz@icemiller.com

Kevin R. Knight
ICE MILLER
kevin.knight@icemiller.com

Stephen A. Kurowski
LAW OFFICES OF STEVEN A. KUROWSKI
kurowskilaw@aol.com