UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

VICKIE THORNBURG,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	CAUSE NO. 1:05-cv-1378-RLY-TAB
	)	
STRYKER CORPORATION, et al.	)	
	)	
Defendants.	)	

REPORT AND RECOMMENDATION
ON HOWMEDICA OSTEONICS CORP.'S MOTION FOR SUMMARY JUDGMENT

I. Introduction.

Plaintiff Vickie Thornburg underwent hip replacement surgery in 2003 and subsequently filed a product liability and medical malpractice lawsuit related to that procedure. [Docket No. 1, Ex. 1.] Thornburg alleges that Defendant Howmedica Osteonics Corp. d/b/a/ Stryker Orthopaedics ("HOC") "designed, promoted, marketed, manufactured, assembled and sold" the hip replacement system and components at issue in her hip replacement.[1] [Pl. Compl. ¶ 5.] She seeks damages under various theories of product and strict liability. HOC contends that federal law preempts Thornburg's state law claims and moves for summary judgment. [Docket No. 71.] For the reasons set forth below, the Magistrate Judge recommends that HOC's motion be GRANTED.

[1] Thornburg made the same allegations against Defendant Stryker Corporation, which earlier in this litigation successfully moved for summary judgment on other grounds. [Docket No. 69.]

II. Standard.

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Illinois Central Railroad Co. v. South Tec Development Warehouse, Inc.*, 337 F.3d 813, 816 (7th Cir. 2003).

III. Background.[2]

Thornburg alleges that HOC is liable for damages associated with a hip replacement surgery because HOC "designed, promoted, marketed, manufactured, assembled and sold" the product at issue in this litigation. [Docket No. 1 at p. 2.] Under a theory of product liability, Thornburg contends that: (1) the product was negligently designed; (2) HOC "failed to warn of the system's propensity for failure"; and (3) HOC's "negligence and carelessness in the manufacture, design, and failure to warn" caused her injury. [*Id*. at p. 3.] Thornburg asserts that HOC is strictly liable to her because it "placed the hip prosthesis, and its component parts, into the stream of commerce, in a defective and unreasonably dangerous state . . . ." [*Id*. at p. 4.]

HOC designs, manufactures, sells, and distributes the Trident, a class III medical device under the Food, Drug, and Cosmedic Act's ("FDCA") Medical Device Amendments ("MDA"), which was used in Thornburg's hip replacement. [William Cymbaluk Aff. at ¶¶ 3, 5.] HOC applied for FDA approval under the MDA to manufacture and sell Trident on March 2, 2000 via the FDA's § 360(e) pre-market approval ("PMA") application. [*Id*. at 9.] As a part of HOC's

[2] These facts are largely as presented by HOC and uncontroverted by Thornburg. [Docket No. 86 at p. 2.]

PMA application process, HOC provided the FDA with supporting data regarding the Trident. The FDA approved HOC's application for the Trident on February 3, 2003. The FDA's approval of the Trident permitted HOC to sell the Trident commercially in the United States under the FDA-imposed conditions. HOC has not altered the FDA approved design, manufacturing processes, or labeling for the Trident without the FDA's approval. HOC's design, label, and manufacture of the Trident implanted in Plaintiff conformed with FDA-approved specifications. [*Id*. at ¶¶ 13-15; Denis Long, Aff., Ex. B at ¶¶ 4, 5.]

III. Discussion.

HOC's chief basis for summary judgment is that the MDA preempts any of Thornburg's state law claims. [Docket No. 72 at pp. 3-12.] Thornburg argues to the contrary, relying heavily on the United States Supreme Court's decision in *Medtronic v. Lohr*, 518 U.S. 470 (1996). [Docket No. 86 at pp. 2-4.] Overwhelming authority weighs against Thornburg's position.

The Supremacy Clause of the United States Constitution has long been understood to allow preemption of state laws that conflict with federal laws or regulations. *Malone v. White Motor Corp.*, 435 U.S. 497, 504 (1978). Generally speaking, "federal law preempts state law in three situations: (1) when the federal statute explicitly provides for preemption; (2) when Congress intended to occupy the field completely; and (3) where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *JCW Investments, Inc. v. Novelty, Inc*. 482 F.3d 910, 918 (7th Cir. 2007) (*internal citation and quotation omitted*). In this instance, the MDA contains an express provision for preemption:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

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

21 U.S.C. § 360k(a). As interpreted by the Seventh Circuit, this means that before preemption can be found there must be: (1) a requirement that a state establish[es] or continue[s] in effect, with respect to a device intended for human use; (2) a relevant federal requirement under the FDCA applicable to the device at issue; and (3) a state requirement that is different from or in addition to the federal requirement. *McMullen v. Medtronic, Inc*. 421 F.3d 482, 487 (7th Cir. 2005) (*internal citation and quotation omitted*).

The only prong implicated by this matter is the third. The Indiana Product Liability Act ("IPLA") satisfies *McMullen's* first prong because it "governs all actions that are: (1) brought by a user or consumer; (2) against a manufacturer or seller; . . . for physical harm caused by a product." *See* Ind. Code § 34-20-1-1. The MDA satisfies the second prong. Under the third prong, if a state law parallels a federal law requirement then federal law cannot preempt such state law. *McMullen*, 421 F.3d at 488. "In order for a state requirement to be parallel to a federal requirement . . .[Thornburg] must show that the requirements are genuinely equivalent. State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law" *Id*. (*internal citation and quotation omitted*). Thornburg's claims can only survive HOC's preemption-based summary judgment motion if she successfully raises a triable issue of fact concerning the state law requirements' genuine equivalence to the federal requirement. Thornburg's efforts fall short in this respect.

In fact, Thornburg makes no meaningful attempt to address this third prong. Instead, she argues generally that preemption is not appropriate "under a strong presumption against preemption" and relies primarily on *Lohr*. [Docket No. 86 at pp. 4-7.] Thornburg's invocation of *Lohr* is ineffective because the Supreme Court in *Lohr* assessed preemption against the backdrop of a § 510(k) PMA review, which contemplates a significantly shorter review process. Significantly, § 510(k) is only available to medical devices substantially equivalent to devices currently on the market. The PMA review process involved in this instance -- § 360(e) -- concerns a substantially more rigorous process, which is used for devices not shown to be substantially equivalent to those currently on the market. Thus, *Lohr* does not insulate Thornburg from a preemption-based summary judgment.

In fact, the prevailing majority view among courts which have assessed preemption involving a § 360(e) review of medical devices is that federal law preempts state claims similar to Thornburg's. *See In re Sulzer Hip Prothesis and Knee Prothesis Liability Litigation*, 455 F. Supp. 2d 709, 716-17 (N.D. Ohio 2006) (collecting cases holding that the MDA's § 360k(a) provision preempts nearly all state law claims that seek to hold a defendant liable for a § 360(e) PMA-approved medical device). Thornburg does not assert the only type of state law claim -- that HOC negligently failed to "conform with the FDA requirements prescribed by the PMA" -- that would not ordinarily be preempted by federal law. *Id.* Moreover, she admits that HOC did not alter the FDA approved design, manufacturing processes, or labeling for the Trident without the FDA's approval. She further concedes that HOC's design, label, and manufacture of the Trident implanted in Plaintiff conformed with FDA-approved specifications. [See Docket Nos. 72, 86.] Thus, Thornburg's state law claims, consistent with a majority view embraced by the

Seventh Circuit, are preempted and cannot survive HOC's summary judgment motion.

V. Conclusion.

The uncontroverted facts in this record demonstrate that there are no disputed material facts and HOC is entitled to judgment as a matter of law because the MDA's 360k(a) provision preempts all of Thornburg's state law claims. Consequently, the Magistrate Judge finds that Defendant HOC is entitled to judgment in its favor as a matter of law and recommends that its motion for summary judgment [Docket No. 71] be GRANTED.

Any objections to the Magistrate Judge's Report and Recommendation shall be filed with the Clerk in accordance with 28 U.S.C. § 636(b)(1), and failure to file timely objections within the ten days after service shall constitute a waiver of subsequent review absent a showing of good cause for such failure.

Dated: 06/12/2007

Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

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