SIGNED: 03/25/04

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

JEAN M. WHITSON and	**:**	**No. 3:03cv746**
RANDY S. WHITSON,	**:**	
Plaintiffs	**:**	**(Judge Munley)**
	:	
v.	**:**	
SAFESKIN CORPORATION, INC.,	**:**	
SURGIKOS, INC.,	**:**	
JOHNSON & JOHNSON, and	**:**	
JOHNSON & JOHNSON	**:**	
MEDICAL, INC.,	**:**	
Defendants	**:**	

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MEMORANDUM

Before the court for disposition is the defendants' motion for summary judgment. The motion has been fully briefed and argued and is ripe for disposition. For the following reasons, we will grant the defendants' motion.

Background[1]

Plaintiff Jean Whitson was employed as a registered nurse at Hanover General Hospital in Hanover, Pennsylvania, from April 21, 1990 to June 25, 1997. As a nurse, she used and was exposed to natural rubber latex gloves. As a consequence of her exposure to latex gloves, Ms. Whitson has suffered a permanent hypersensitivity to products containing the natural latex protein. Ms. Whitson alleges that she was exposed and sensitized to natural rubber latex in gloves that were predominantly manufactured and/or distributed by Safeskin

[1] The background facts, which are not in dispute, are taken from the complaint and the parties' briefs.

Corporation, Inc. and Johnson & Johnson Medical ("defendants").

Plaintiffs commenced this action on December 29, 1997, by filing a complaint that asserts counts in Negligence, Strict Products Liability, Failure to Warn, Breach of Express and Implied Warranties, Fraudulent Concealment, and Loss of Consortium. On March 9, 2001, the Honorable Edmund V. Ludwig of the Eastern District of Pennsylvania entered an Order granting in part Defendants' Motion for Summary Judgment, finding that plaintiffs' tort claims were time-barred under Pennsylvania's two-year statute of limitations, and that plaintiffs' express and implied warranty claims were similarly time-barred with respect to glove sales prior to December 27, 1993, based on Pennsylvania's four-year statute of limitations governing warranty actions.[2] Upon plaintiffs' motion for reconsideration, the Eastern District Court vacated its March 9, 2001 Order with respect to plaintiffs' loss of consortium claim only.

The claims remaining in this matter are for breach of an implied warranty for the Safeskin and Johnson & Johnson gloves sold to Hanover Hospital between December 27, 1993 and December 27, 1997, and loss of consortium. Defendants have filed a motion for summary judgment on these remaining claims, bringing the case to its present posture.

Jurisdiction

The Court has jurisdiction over this dispute pursuant to the diversity jurisdiction statute, 28 U.S.C. § 1332. Because the Court is sitting in diversity, the substantive law of

[2] Judge Ludwig's opinion also indicates that the plaintiffs agreed to withdraw the breach of express warranty claim.

Pennsylvania shall apply. Chamberlain v. Giampapa, 210 F.3d 154, 158 (3d Cir. 2000) (citing Erie R.R. v. Tompkins, 304 U.S. 64, 78 (1938)).

Standard of Review

The granting of 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 judgment as a matter of law." See Knabe v. Boury, 114 F.3d 407, 410 n.4 (3d Cir. 1997) (citing FED. R. CIV. P. 56(c)). "[T]his standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original).

In considering a motion for summary judgment, the court must examine the facts in the light most favorable to the party opposing the motion. International Raw Materials, Ltd. v. Stauffer Chemical Co., 898 F.2d 946, 949 (3d Cir. 1990). The burden is on the moving party to demonstrate that the evidence is such that a reasonable jury could not return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is material when it might affect the outcome of the suit under the governing law. Id. Where the non-moving party will bear the burden of proof at trial, the party moving for summary judgment may meet its burden by showing that the evidentiary materials of record, if reduced to admissible evidence, would be insufficient to carry the non-movant's burden of proof at

trial. Celotex v. Catrett, 477 U.S. 317, 322 (1986). Once the moving party satisfies its burden, the burden shifts to the nonmoving party, who must go beyond its pleadings, and designate specific facts by the use of affidavits, depositions, admissions, or answers to interrogatories showing that there is a genuine issue for trial. Id. at 324.

Discussion

Plaintiffs contend that the defendants have breached their implied warranties of fitness and merchantability under the Uniform Commercial Code (UCC). The UCC , as adopted in Pennsylvania, provides that:

> a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind . . . . Goods to be merchantable must be at least such as:
> (1) pass without objection in the trade under the contract description;
> (2) in the case of fungible goods, are of fair average quality within the description;
> (3) are fit for the ordinary purposes for which such goods are used;
> (4) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved;
> (5) are adequately contained, packaged, and labeled as the agreement may require; and
> (6) conform to the promises or affirmations of fact made on the container or label if any.

See 13 Pa. C. S. § 2314(a); (b).

Defendants do not dispute that they are "merchants," and that the latex gloves are "products," which are subject to the UCC. Defendants, however, put forth several arguments in support of their motion for summary judgment. First, defendants argue that plaintiffs' implied warranty claim is preempted by the Medical Device Amendments (MDA) to the

Food, Drug and Cosmetic Act. 21 U.S.C. §§ 360c - 360k. Second, defendants argue that the implied warranty theory is not applicable to the facts of the present case. Finally, defendants argue that plaintiffs' loss of consortium claim is based on tort theory, and therefore must be dismissed as untimely. We will discuss each of defendants' arguments *seriatim*.

Preemption

Medical devices, including latex gloves, are regulated by the federal Food and Drug Administration (FDA) through the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act. See 21 U.S.C. §§ 360c - 360k. Under the MDA, disposable latex patient examination gloves, such as those used by Plaintiff Jean Whitson, are classified as Class I medical devices. 21 C.F.R. §880.6250. "Class I devices are those devices which pose little or no threat to public health." Burgstahler v. AcroMed Corp., 670 A.2d 658, 661 (Pa. Super. Ct. 1995). The MDA contains an express preemption provision, which states that:

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

21 U.S.C.360k(a).

Under FDA regulations, state law is preempted "only when the FDA has established specific counterpart regulations or . . . other specific requirements applicable to a particular device." Medtronic v. Lohr, 518 U.S. 470, 498 (1996) (citing 21 CFR § 808.1(d)(1995)).

The FDA has established specific labeling requirements for latex gloves in a manual, "Regulatory Requirements for Medical Gloves: A Workshop Manual" (hereafter "Glove Manual"), which was published by the FDA in May 1993. See Glove Manual, Defendants' Exhibit "E." In this Manual, the FDA sets forth requirements for the labeling on patient examination gloves. See Glove Manual, pp. 3-2 to 3-9. These requirements deal with specific issues, such as identification of the glove manufacturer or distributor, quantity statements, latex identification, and significant labeling changes that would require the submission of a new 510(k),[3] such as the inclusion of hypoallergenicity claims or the addition of antimicrobials. See Glove Manual, Exhibit "E," at pp. 3-2 to 3-9.[4]

Defendants argue that, according to the MDA, the plaintiffs' claims for implied warranties are preempted by the FDA's requirements related to glove labeling, since they seek a determination that the gloves should have contained labeling that was different from, or additional to, the FDA's mandated language. After careful review, we agree.

In Medtronic, the Supreme Court considered the MDA's preemptive effect on

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[3] One of the methods by which a medical device can enter the market is through the 510(k) process, which requires a manufacturer to submit a "premarket notification" to the FDA showing that it is substantially equivalent to a device that is already on the market. See Medtronic, 518 U.S. at 478.

[4] Andrew Lowery, a former FDA official, testified about the labeling requirements for latex gloves, including the Glove Manual, its preparation and formal clearance by the FDA. See Lowery testimony, Exhibit "D," at 47, 51. Mr. Lowery, who had worked for the FDA for twenty years assisting medical device manufacturers in their compliance with FDA regulations, directed FDA employees to prepare the Glove Manual. See id. at 26-27; 29-30; 51. According to Lowery, the Manual made it clear that the FDA did not want any warning language on the glove labels that went beyond what was contained in the Manual. Id. at 210. Additionally, the FDA sent the manufacturers a letter with their copy of the Glove Manual making it clear that the requirements in the Manual must be followed in order for a manufacturer's 510(k) to be cleared. Id. at 211. Mr. Lowery explained that the FDA had considerable power over the glove manufacturers and that manufacturers complied with the FDA's labeling requirements. Id. at 45-46.

common law negligence and strict liability claims relating to a Class III medical device which entered the marketplace via the 510(k) process. See Medtronic, 518 U.S. 470. Although the claims brought against the medical device manufacturer in Medtronic did not include UCC breach of warranty claims, as in the present case, the Supreme Court nonetheless delineated factors that must be present for preemption to occur with respect to devices like latex patient examination gloves.[5] Id. The Supreme Court explained that preemption occurs:

> only where a particular state requirement threatens to interfere with a specific federal interest. State requirements must be 'with respect to' medical devices and 'different from, or in addition to,' federal requirements. State requirements must also relate 'to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device,' and the regulations provide that state requirements of 'general applicability' are not pre-empted except where they have 'the effect of establishing a substantive requirement for a specific device.' Moreover, federal requirements must be 'applicable to the device' in question, and, according to the regulations, pre-empt state law only if they are 'specific counter-part regulations' or 'specific' to a 'particular device.' The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended preemptive scope of the statute and regulations.

Id. at 500.

Thus, according to Medtronic, the first factor that must be established is that the claims must "be with respect to" medical devices and seek to impose requirements that are "different from, or in addition to" the applicable federal requirements for that device. Id.

[5] As with the medical device in Medtronic, it is undisputed that the gloves at issue in the present case entered the marketplace through the the 510(k) process.

Here, plaintiffs argue that "[d]efendants breached the implied warranty which they made by manufacturing, distributing and selling gloves with high latex protein content without providing adequate warnings on the dangers posed by these gloves . . .." See Plaintiffs' Second Amended Responses to Defendants' Interrogatories Concerning Plaintiffs' Alternative Theories of Liability, at p. 41, Defendant's Exhibit "H" (emphasis added). Since plaintiffs' claims concern labeling that is different from, or in addition to, the labeling that the FDA requires, the first Medtronic factor is established.

The second factor that must be established is that the claims must relate to the safety of the medical device. See Medtronic, 518 U.S. at 500. Here, plaintiffs argue that "[d]efendants breached their express and implied warranties of fitness and merchantability, insofar as the latex gloves were placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to plaintiff." Plantiffs' Complaint, Defendant's Exhibit "A," at ¶ 51 (emphasis added). Since plaintiffs' claims relate to the safety of defendants' latex gloves, the second Medtronic factor is established.

The third factor is that the allegedly-preemptive federal regulations at issue must be "specific" to a "particular device." See Medtronic, 518 U.S. at 500. As discussed above, the FDA has established specific labeling requirements for latex gloves in the Glove Manual. Therefore, the final Medtronic factor is established. Accordingly, plaintiffs' implied warranty claims are preempted.

Plaintiffs nevertheless argue that general requirements, such as warranty of fitness

claims brought under the Uniform Commercial Code, are exempt from federal preemption claims. Plaintiffs assert that the MDA does not preempt state or local requirements of general applicability where the purpose relates to other products in addition to devices. For this proposition, plaintiffs cite Mulligan v. Pfizer, Inc., 850 F. Supp. 633, 635 (S.D. Ohio 1994) (citing 21 C.F.R. § 801.1(d)(1)) ("[The MDA] does not preempt State or Local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code (warranty of fitness).").

Plaintiffs thus contend that their claims should not be preempted because warranty claims under the UCC are not limited to latex gloves or even to medical devices. Plaintiffs further argue that if preemption is permitted, "what would have occurred is the effective repeal of part of Pennsylvania (sic) implied warranty law (i.e. to the extent it dealt with medical devices)." Plaintiff's Opp. Brief, at p. 6. After careful review, we disagree.

Part of Pennsylvania's implied warranty law will not be repealed. It is, however, preempted to the extent that it would require the defendants to label their latex patient examination gloves in a different manner than that required by the FDA's Glove Manual. This is, in fact, the only effect of our finding of preemption in the present case.[6] Our decision here is consistent with Pennsylvania Supreme Court jurisprudence. See Green v.

[6] As discussed below, even though we find that the MDA preempts plaintiffs' intended claims, we nevertheless also conclude that plaintiffs have failed to put forth a cognizable implied warranty claim. Accordingly, plaintiffs' claims will be dismissed as a matter of law.

Dolsky, 685 A.3d 100 (Pa. 1996). In Green, the Pennsylvania Supreme Court held that an implied warranty claim based on a failure to warn is preempted under the MDA in the context of a Class III medical device that was cleared under the PMA process. See id. at 118. In Green, the device at issue was a Zyderm Collagen Implant that allegedly caused the plaintiff to develop an auto-immune disorder. Id. at 113. The plaintiffs there contended that the manufacturer had breached an implied warranty that the collagen implant was "safe, fit and proper for cosmetic use for injection into the body." Id. at 118. The court held that "the claim must fail for the FDA has restricted the labeling to be used in the sale of this product." Id.[7] Similarly, here, plaintiffs' implied warranty claims must fail because the FDA has restricted the labeling to be used in the sale of latex patient examination gloves.

Even if we had not found that plaintiffs' implied warranty claims are preempted by the MDA, we nevertheless also find that the plaintiffs have failed to set forth a valid implied warranty claim. An implied warranty of merchantability arises by operation of law and warrants that the goods are of reasonable quality and are fit for the ordinary purpose for which they are sold. See Hornberger v. Gen. Motors Corp., 929 F. Supp. 884, 887-88 (E.D. Pa. 1996). "[T]he law in Pennsylvania is well settled that a seller cannot be liable for breach

[7] Prior to Medtronic and Green, the Court of Common Pleas for Dauphin County considered the preemptive effect of the MDA on implied warranty claims in the specific context of latex surgical gloves. See Bateman v. Gen. Med. Corp., 1996 Pa.D. & C.4th 1 (Pa. Comm. Pl. Ct. 1996). In Bateman, the Court found that because the FDA specifically regulates the labeling of latex gloves, claims against glove sellers for failure to warn or inadequate labeling, whether brought under theories of negligence, strict liability, or breach of implied warranty, are preempted by the MDA. Id. at 12-13. The Court held that "plaintiffs' claim for breach of the implied warranty of merchantability and fitness for a particular purpose is preempted . . . since a verdict against defendant on this claim would create a requirement upon the device in addition to the labeling requirements imposed by the FDA upon surgical gloves." Id. Similarly, here, plaintiffs' claims would require labels on latex gloves that are different from, or in addition to, the labeling requirements imposed by the FDA. Accordingly, plaintiffs' implied warranty claims are preempted.

of an implied warranty merely because of a harmful effect due to an individual idiosyncrasy on the part of the buyer."[8] Morris v. Pathmark Corp., 592 A.2d 331, 334 (1991); see also Shouey v. Duck Head Apparel Co., 49 F. Supp.2d 413, 429 (M.D. Pa. 1999) (holding that the defendant cigarette lighter manufacturer had not breached its implied warranty, since there was no evidence that the lighter did anything other than serve its ordinary purpose, i.e., produce a flame).

Here, there is no factual dispute that the "ordinary purpose" of defendants' gloves is to protect the wearer from transmitting, or gaining exposure to, blood-borne pathogens that cause serious illnesses. Plaintiffs do not contend that Ms. Whitson was exposed to a blood-borne illness but instead that the use of defendants' gloves caused her latex allergy. The harm that Ms. Whitson complains of is not a harm that she can recover for under a theory of breach of an implied warranty. Accordingly, because plaintiffs have failed to state a valid claim for breach of an implied warranty, defendants' motion for summary judgment will be granted.[9]

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[8] In Morris, the court explained that "in Barrett v. S.S. Kresge Co., 144 Pa. Super. 516, 19 A.2d 502 (1941), the court held that where dermatitis suffered after a buyer had worn a new dress was attributable to an individual allergic reaction, and there was no evidence that the same would have harmed a normal person, the seller of the dress was held not liable for breach of an implied warranty of fitness for a particular purpose. In the instant case, appellant suffered an allergic reaction to appellee's product but offered no evidence to show that a normal consumer would have been similarly afflicted by use of the product." Morris, 592 A.2d at 334. Similarly, here, the plaintiffs have not directed the court's attention to any evidence that a typical consumer would have been similarly afflicted by the use of the latex gloves. Accordingly, plaintiffs have failed to establish a claim for breach of an implied warranty.

[9] Plaintiffs failed to address in their opposition brief defendants' arguments on the inapplicability of warranty theory to the facts of this case. The court, on its own initiative, has also been unable to locate any authority that would indicate that warranty theory is applicable to the facts of this case. At oral argument on defendants' summary judgment motion, plaintiffs' counsel did not discuss the issue of the applicability of warranty theory. The court therefore asked plaintiffs' counsel to submit a supplemental brief solely addressing their warranty claim. Plaintiffs' supplemental brief,

Since the loss of consortium claim is derivative of plaintiffs' other claims, summary judgment will also be granted on the loss of consortium claim. See, e.g., Boarts v. McCord, 511 A.2d 204, 209 (Pa. Super. Ct. 1986).

Conclusion

For the foregoing reasons, defendants' motion for summary judgment will be granted. An appropriate order follows.

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however, fails to cite any authority that would indicate that they are capable of setting forth a valid warranty theory. Plaintiffs mistakenly cite to a previous decision by Judge Ludwig in this case for the proposition that he "has already ruled on the issue of a free standing breach of implied warranty claim." Plaintiffs' Supp. Brief, at p. 1. The defendants' previous motion for summary judgment was based solely on the statute of limitations and Judge Ludwig only decided the question of whether or not some or all of plaintiffs' claims were subject to dismissal "based on time bar." See Judge Ludwig's Memorandum, March 9, 2001, Plaintiff's Exhibit 'A'. Accordingly, plaintiffs are incorrect in asserting that Judge Ludwig has previously ruled on the warranty claims.

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Plaintiffs	**:**	**(Judge Munley)**
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SAFESKIN CORPORATION, INC.,	**:**	
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JOHNSON & JOHNSON	**:**	
MEDICAL, INC.,	**:**	
Defendants	**:**	

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ORDER

AND NOW, to wit, this _____ day of March 2004, defendants' motion for summary judgment (Doc. 10) is **GRANTED**. The clerk of court is directed to close this case.

BY THE COURT:

_____
JUDGE JAMES M. MUNLEY
United States District Court

FILED: 03/25/04