

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

JOHN HERZOG and)
MARY E. HERZOG,)
)
Plaintiffs)
)
v.)
) CIVIL No. 02-76-P-C
ARTHROCARE CORPORATION and)
SURGI-CARE, INC.,)
)
Defendants)

PUBLIC VERSION
**RECOMMENDED DECISION ON DEFENDANTS’
MOTIONS FOR SUMMARY JUDGMENT and
PLAINTIFFS’ MOTION FOR PARTIAL SUMMARY JUDGMENT**

Plaintiffs John Herzog, D.O., and Mary Herzog filed suit against ArthroCare Corporation, the manufacturer of a surgical implement called the AthroWand, and Surgi-Care, a regional marketer and distributor of the ArthroWand, for injuries Dr. Herzog allegedly sustained from a surgeon’s use of an ArthroWand to debride or “sculpt” articular cartilage located on his right knee joint and for Mary Herzog’s loss of consortium. The following dispositive motions are now pending, in order of filing date: (1) Surgi-Care’s Motion for Summary Judgment; (2) Dr. and Mary Herzog’s Motion for Partial Summary Judgment; and (3) ArthroCare’s Amended Motion for Summary Judgment. I now recommend that the Court **GRANT** Defendants’ Motions on all of the Plaintiffs’ claims **EXCEPT** for those portions of Counts I, II, VI, IX, X and XIV, which rely on the theory of a defective product design or unfit product condition. I further recommend that the Court **DENY** Plaintiffs’ Motion.

Facts

Plaintiffs John Herzog and Mary Herzog live in Grand Blanc, Michigan, but at all times relevant to the events underlying this lawsuit were residents of Maine. Defendant ArthroCare Corporation (“ArthroCare”) is a corporation with its principal place of business in Sunnyvale, California. ArthroCare is in the business of manufacturing medical devices, including the device that is the subject of this litigation, a certain 3.0 millimeter 60° Bevel ArthroWand (“the Wand”). (Docket No. 35, ¶ 1.)¹ Defendant Surgi-Care, Inc. is an independent distributor of various medical devices for various manufacturers, including ArthroCare, and has its principal place of business in Waltham, Massachusetts. (*Id.*, ¶¶ 3, 4; see also Surgi-Care’s “Answer to Plaintiffs’ First Amended Complaint,” ¶ 7.)²

¹ Because this is a recommended decision, I cite to the parties’ filings to assist the Court with its review. Because the parties are unlikely to be familiar with the docket numbers assigned to their filings, I provide the following citation key for their convenience.

Docket No. 34—“Defendant Surgi-Care, Inc.’s Motion for Summary Judgment and Incorporated Memorandum of Law”;
Docket No. 35—“Defendant Surgi-Care, Inc.’s Statement of Material Facts”;
Docket No. 43—“Defendant ArthroCare’s Amended Motion for Summary Judgment and Supporting Memorandum of Law”;
Docket No. 44—“Defendant ArthroCare’s Amended Statement of Undisputed Material Facts”;
Docket No. 63—“Plaintiffs’ Opposition to Defendant Surgi-Care, Inc.’s Motion for Summary Judgment and Incorporated Memorandum of Law”;
Docket No. 64—“Plaintiffs John Herzog and Mary Herzog’s Opposition to Defendant Surgi-Care, Inc.’s Statement of Material Facts”;
Docket No. 65—“Plaintiffs John Herzog and Mary Herzog’s Supplemental Statement of Material Facts”;
Docket No. 68—“Plaintiffs’ Opposition to Defendant ArthroCare’s Amended Motion for Summary Judgment”;
Docket No. 69—“Plaintiffs’ Opposition to Defendant ArthroCare’s Amended Statement of Undisputed Material Facts”;
Docket No. 70—“Plaintiffs’ Statement of Additional Undisputed Material Facts, Submitted in Opposition to Defendant ArthroCare’s Motion for Summary Judgment”;
Docket No. 72—“Defendant Surgi-Care, Inc.’s Reply Statement of Material Facts”;
Docket No. 81—“Sealed Defendant ArthroCare Corporation’s Response to Plaintiffs’ Statement of Additional Undisputed Material Facts”;
Docket No. 84—“Defendant ArthroCare Corporation’s Reply Memorandum in Support of Its Motion for Summary Judgment.”

² The parties do not endeavor to explain in their statements of material fact exactly what the Wand is or how it works. The following description is provided from non-record sources. It is provided solely for the Court’s general information and to provide context. Simply put, an ArthroCare ArthroWand is a medical device used for, among other things, removing tissue. ArthroCare’s website describes its Wands as:

Dr. Herzog alleges in this suit that the Wand used on him during a December 29, 1998 knee surgery, contrary to representations made by the Defendants in their marketing materials and product indications, produced sufficient heat to damage collateral tissue in his knee, causing “serious and permanent injury to his body, including past and future pain, suffering, mental and emotional stress, . . . loss of enjoyment of life[,] . . . significant medical and rehabilitative expenses[,] . . . and . . . future lost income and an impairment to his earning capacity.” (First Amended Complaint, Docket No. 12, ¶¶ 1, 31-33.) His theories of liability sound mostly in tort—strict product liability, negligence, misrepresentation—but also include breach of the implied warranty of merchantability and unfair trade practices. Dr. Herzog’s wife, Mary Herzog, pursues a tort claim for loss of consortium.

In March 1995, Dr. Herzog was involved in a skiing accident and injured his right knee. (Docket Nos. 44 & 69, ¶ 6.) As a result of this injury, Dr. Herzog underwent reconstructive surgery to his anterior cruciate ligament (“ACL”) on May 10, 1995. (*Id.*, ¶ 8.) After the operation, Dr. Herzog experienced pain and instability in his knee during exercise, but was still able to tolerate physical activities such as running, snow skiing, windsurfing and waterskiing. (*Id.*, ¶ 9.) Dr. Herzog underwent a second ACL reconstructive surgery on December 15, 1995.

the most comprehensive range of radiofrequency (RF) surgical tools for tissue removal, dissection and coagulation. Combining innovative electrode design and patented Coblation® technology, ArthroWands provide surgeons with precise and versatile tools able to remove tissue layers as fine as 120 microns, with only minimal damage to surrounding tissue.

The “patented Coblation technology” is billed as a unique technology that enables the Wand to cut away targeted tissue without generating high temperatures that could cause thermal injury to collateral tissue. According to ArthroCare:

The Coblation process . . . is a controlled, non-heat driven process. With Coblation technology, radiofrequency energy [(RFE)] is applied to a conductive medium (usually saline), causing a highly focused plasma field to form around the energized electrodes. The plasma field is comprised of highly ionized particles. These ionized particles have sufficient energy to break organic molecular bonds within tissue. The by-products of this non-heat driven process are elementary molecules and low molecular weight inert gases. Instead of exploding tissue, Coblation causes a low temperature molecular disintegration. The result is volumetric removal of target tissue with minimal damage to surrounding tissue.

(Id., ¶ 10.) This surgery did not succeed in removing the pain and instability, but Dr. Herzog continued to be able to engage in the same physical activities as before. (Id., ¶ 11.) In July 1998, Dr. Herzog “re-injured” his knee while water skiing. (Id., ¶ 13.) Following that incident, Dr. Herzog stopped engaging in a number of physical activities he previously enjoyed, including windsurfing, rollerblading and waterskiing, but continued others, including running. (Docket No. 69, ¶ 22; Docket No. 70, ¶ 21.)³

In December 1998, Dr. Herzog underwent an arthroscopic procedure, described by the parties as his third knee surgery. (Id., ¶ 14.) This procedure was performed by Dr. Douglas Brown, an orthopedic surgeon at Orthopedic Associates in Portland, who intended to do a thorough evaluation of the “apparently failed” ACL surgery and to “do what I could short of a redo reconstruction to sort of clean things up and make his knee feel better.” (Id., ¶ 19; Brown Depo. at 51-52.) At the time, Dr. Herzog was also employed with Orthopedic Associates as an orthopedic surgeon. From Dr. Herzog’s perspective, the procedure was intended to “help increase peak performance in sports.” (Docket No. 70, ¶ 18.) During the surgery, Dr. Brown observed significant preexisting osteoarthritis within the articular cartilage of Dr. Herzog’s knee, which he identified as degenerative joint disease. (Docket No. 69, ¶ 20.) Dr. Brown classified the degree of cartilage degeneration as “Grade III” on a four-grade scale, where Grade I reflects minimal damage and Grade IV total or near-total destruction of the articular cartilage down to the bone. Grade III signifies “significant” damage. (Docket No. 44, ¶¶ 20, 44.) Specifically, Dr. Brown found, among other areas of damage, “modest sized” areas of degeneration in the medial

³ In their Statement of Additional Undisputed Material Facts, Submitted in Opposition to Defendant ArthroCare’s Motion for Summary Judgment, the Herzogs assert that it was during the December 29, 1998 surgery that Dr. Brown used the Wand on Dr. Herzog’s knee in a way that caused injury. (Docket No. 70, ¶ 4.) But they also assert that it was during the June 3, 1999 surgery that Dr. Brown “shaved,” debrided or otherwise sculpted Dr. Herzog’s articular knee cartilage with the Wand. (Docket No. 69, ¶¶ 25-30.) Evidently, the Wand was applied to the surface of his knee on both dates, but the prior occasion did not result in disabling pain and the manner in which it was used on that date is not made clear in the summary judgment record.

femoral condyle and “a relatively mild grade III, middle of the road III” on the patella. (Brown Depo. at 131.) During this procedure, Dr. Brown utilized the Wand in some manner not specified by the parties in their summary judgment filings, presumably “to clean things up” in some manner. (Docket No. 35, ¶ 10.) The relative degree of Dr. Herzog’s pain and activity level following this procedure is not established by the parties’ filings; to the extent they are suggested, the record citations are unresponsive.⁴

On June 3, 1999, Dr. Brown performed another surgery on Dr. Herzog’s knee during which he repaired Dr. Herzog’s ACL and also debrided articular cartilage located in certain areas of Dr. Herzog’s knee with the aid of the Wand. (Docket No. 44, ¶¶ 25, 29, 30, 49.) Dr. Brown videotaped portions of this surgery and also documented the surgery with notes and photographs. (Id., ¶¶ 26-28.) At his June 2002 deposition, Dr. Brown could not recall all of the areas of Dr. Herzog’s knee on which he had used the Wand, but he was confident that he had used it on the medial femoral condyle, or MFC. In an operative record, Dr. Brown indicated that there was “shaving of articular cartilage—patella and MFC.” (Docket No. 69, ¶ 29) However, Dr. Brown could not recall with certainty whether the debridement (shaving) he did on Dr. Herzog’s patella was accomplished with the Wand or with a mechanical shaver. (Brown Depo. at 65-67.)

The Wand that Dr. Brown used on Dr. Herzog’s knee was supplied to Orthopedic Associates by Surgi-Care. (Docket No. 35, ¶ 7.) When supplying the Wand to Orthopedic Associates, Surgi-Care also provided with the Wand the product inserts and statements authored

⁴ According to ArthroCare, Dr. Herzog resumed athletic activity following this surgery, although its citation to the record is not supportive. (Docket No. 44, ¶ 22.) For his part, Dr. Herzog admits “only that [he] engaged in unicycling in 1999.” (Docket No. 69, ¶ 22.) In another statement of fact, Dr. Herzog states that he “was forced to abandon all his previous activities” following “Dr. Brown’s surgery.” (Docket No. 70, ¶ 21.) It appears that this reference to “Dr. Brown’s surgery” is to the later, June 1999 procedure during which the Wand was employed to “sculpt” the articular cartilage of Dr. Herzog’s knee. It also appears that some of the confusion in the record stems from a mistaken supposition during Dr. Herzog’s deposition that the Wand was used in this fashion during the 1998 procedure rather than the 1999 procedure.

and supplied by ArthroCare, including a videotape that ArthroCare created and disseminated to clinicians entitled “Procedures of the Knee, Articular Cartilage Sculpting.” (*Id.*, ¶¶ 8, 12.) The record supports the finding that Dr. Brown viewed this video prior to using the Wand on Dr. Herzog’s knee. (Docket No. 69, ¶ 35.) According to Dr. Brown, he applied the Wand in a manner generally consistent with ArthroCare’s product indications, except that he attempted to use an even “lighter touch” than the “direct” touch suggested in ArthroCare’s indications. (Docket No. 64, ¶¶ 27, 36; Brown Depo. at 104-105, 113-114; Docket No. 69, ¶ 35.)

The primary factual dispute involves the degree of Dr. Brown’s knowledge concerning the risk of using the Wand to debride the surface of articular cartilage on the knee. The parties’ relevant statements of fact⁵ refer the Court to Dr. Brown’s deposition testimony at pages 13, 24-30, 36-37 and 95-102. It is easier to review this testimony directly than to contend with the parties’ sometimes attenuated paraphrasings. What it reveals, when taken in the light most favorable to Dr. Herzog, is that Dr. Brown “gave a paper” in 1991 on the topic of laser usage during arthroscopy. (Brown Depo. at 13.) This fact does not support a finding that Dr. Brown had “specialized knowledge” of radio frequency ablaters such as the Wand. Dr. Brown’s testimony also revealed that Dr. Brown is a member of the Herodicus Society and attended its 1997 summer meeting in Sun Valley. (Brown Depo. at 24.) At the meeting, Dr. Brown attended an oral presentation on the use of radio frequency devices for chondroplasty, which he described as a “clinical applicability study” that was “in no means meant to be a scientific appraisal.” (*Id.* at 25-26.) As Dr. Brown recollected, the substance of the presentation was that radio frequency devices “appear[] to make the articular surface look better when . . . trying to smooth it than when you use a mechanical device. And it does not appear to cause any excessive damage to the

⁵ See paragraphs 31-40 of Docket Numbers 44 and 69; paragraphs 7-15 of Docket Numbers 70 and 81; and paragraphs 13-37 of Docket Numbers 35 and 64.

articular surface much beyond what one sees visually” (Id. at 27.) Following the presentation, those in attendance discussed “how deep does the damage go,” and how the goal in using such a device is to “do better than a mechanical device” would. (Id. at 28.) Dr. Brown specifically recalled “several people whom I considered to be conservative voices in orthopedics saying I wouldn’t use it because I don’t think we know enough about it,” and others saying “well, I don’t think there is any real evidence that it’s harmful either.” (Id. at 28-29.) Dr. Brown further testified that over the next year or so, “it was just my general impression from talking to colleagues nationally and in my practice that there was a growing acceptance” of the use of the Wand to debride articular cartilage of the knee. “Not a unanimous acceptance, but a growing acceptance that this may be a good application for radio frequency.” (Id. at 30.) Dr. Brown also read a peer reviewed article on the topic prior to the June 1999 operation, the findings of which he did not relate during his deposition. (Id. at 30.) Dr. Brown understood that, at lower settings, the Wand could be used without causing fluid at the surface of the articular cartilage to boil (reach 100° Celsius), but that at higher settings the Wand could cause surface temperatures capable of damaging collateral tissue. (Id. at 37.)⁶ He also understood that application of the Wand to articular cartilage required a light touch, that it was “better to hold it a little adjacent to the tissue rather than directly on it.” (Id. at 96.) Although Dr. Brown was willing to admit that use of the Wand to debride articular cartilage was an “off-label” and innovative approach, his understanding was that “one could use [the Wand] . . . without causing injury to adjacent or collateral tissue.” (Id. at 101-102.) Indeed, this understanding was reached, in part, based on ArthroCare’s video, “Procedures of the Knee, Articular Cartilage Sculpting,” which not only depicts the Wand being applied to articular cartilage, but affirmatively indicates that the Wand is

⁶ The Wand is utilized by clinicians for various procedures, including cauterization, which requires a higher setting.

suitable for “sculpting” the articular cartilage of the knee. (Id. at 31, 102, 113-114; see also Gambarella Depo. Ex. 11.)

According to Dr. Herzog, he experienced significantly increased amounts of pain in his knee after this procedure, which he had not previously experienced and which included pain when standing. (Docket No. 70, ¶¶ 21, 22.) This statement is supported by Dr. Herzog’s own deposition testimony. Dr. Herzog also asserts that during the surgery⁷ the Wand “caused additional injury or aggravated his existing diseased articular cartilage, thereby rapidly accelerating and causing complete loss of articular cartilage resulting in his current disabling injury.” (Id., ¶ 4.) However, the claim of “complete loss of articular cartilage” blows the underlying testimony out of proportion. The expert testimony the Herzogs cite for this proposition would, if admitted, support only a finding that Dr. Brown’s application of the Wand to Dr. Herzog’s knee resulted in a burn injury. (Minas Depo. at 75; Mayor Depo. at 182.) Dr. Herzog returned to work as an orthopedic surgeon following the June 1999 surgery and continued in that work until the summer of 2000. However, his productivity was notably reduced due to his inability to stand for any appreciable length of time. (Id., ¶ 48.) As a consequence, Dr. Herzog has since decided to stop working as a full-time orthopedic surgeon. (Id., ¶¶ 5-6.)

Subsequent to the June 1999 procedure in which Dr. Brown employed the Wand, four additional procedures have been performed on Dr. Herzog’s right knee. On February 7, 2000, Dr. Thomas Gill performed a microfracture procedure, which involved drilling holes in the cartilage of Dr. Herzog’s knee and was intended to increase the supply of blood to stimulate the

⁷ Dr. Herzog’s statement points to the December 1998 surgery, but it seems from the record that he is, once again, confusing the December 1998 and the June 1999 procedures.

growth of new cartilage. (Docket No. 44, ¶¶ 51, 52.) On September 27, 2000, Dr. Thomas Minas performed an arthroscopic knee surgery, during which he harvested some articular cartilage in order to grow additional cartilage in the lab for a subsequent transplant procedure. (Id., ¶¶ 53, 59.) On December 4, 2000, Dr. Minas performed a further surgery to implant this cartilage. (Id., ¶ 59.) On May 2, 2001, Dr. Minas performed his third procedure, a minimally invasive, evaluative arthroscopy, to evaluate Dr. Herzog’s recovery from the transplant surgery. (Id., ¶ 64.)

During the December 2000 surgery, Dr. Minas observed “tissue that was tan-colored on the back of the patellar lateral facet as well as on th[e] medial femoral condyle,” the two areas on which Dr. Brown had “shaved” articular cartilage in June 1999. (Docket No. 70, ¶ 23.) Dr. Minas described this tissue as firm and as appearing the way articular cartilage looks when it is burned. (Id., ¶ 24.) Based on his partial review of a video of Dr. Brown’s surgery, Dr. Minas “felt that the area of burnt tissue was compatible with the application of the radio frequency wand to that area.” (Id., ¶ 25.) Based on his observation of burned tissue in these locations, coupled with Dr. Herzog’s complaints of “much worse symptoms after the wand was applied to his medial side,”⁸ Dr. Minas is prepared to opine that Dr. Herzog’s knee was worsened as a result of thermal injury arising from application of the Wand. (Id., ¶ 26.)⁹ In addition to Dr. Minas, Dr. Herzog’s summary judgment statements of fact rely on Dr. Andrew E. Rosenberg and Dr. Michael Brook Mayor. Their anticipated testimony is addressed in the discussion portion of this Recommended Decision, below.

⁸ According to Dr. Minas, Dr. Herzog’s pain symptoms were located on the “medial side” of his right knee. (Docket No. 70, ¶ 26 (citing Minas Depo. at 79-80).)

⁹ ArthroCare does not challenge Dr. Minas’s testimony with a Daubert motion. Instead, it contends that Dr. Minas did not actually offer an opinion on the issue of causation. My assessment is that Dr. Minas’s deposition testimony does indicate that he considers the Wand to have caused thermal damage to Dr. Herzog’s articular cartilage and that such damage significantly increased Dr. Herzog’s pain and discomfort.

Discussion

There are two preliminary comments I would like to make before embarking on a point-by-point discussion of the issues raised in the parties' memoranda. The first concerns how much of a showing a summary judgment movant must make to place a particular legal claim in jeopardy. The second concerns the relationship the parties' numerous Daubert motions have to the disposition of the summary judgment motions.

The parties' summary judgment filings raise a significant concern about the nature of summary judgment practice in this District. Surgi-Care asserts in the opening paragraph of its Motion for Summary Judgment that "[t]here is no genuine issue of material fact with respect to any of [the Herzogs'] counts, and Surgi-Care is entitled to judgment as a matter of law on all of the claims that have been asserted against it." (Docket No. 34 at 1.) From there, Surgi-Care proceeds to brief the legal and factual issues as though the Herzogs' action concerns only the adequacy or inadequacy of ArthroCare's product inserts and marketing materials, without even attempting to articulate how its various arguments might relate to the particular elements of a defective design claim. Similarly, ArthroCare begins its principal memorandum with a slightly more emphatic statement that the Herzogs' products liability action is exclusively a failure to warn case. (Docket No. 43 at 1.) It then proceeds to brief the matter as though only a failure to warn theory is being pressed. Like Surgi-Care, ArthroCare never attempts to articulate how any of its arguments might relate to the elements of a defective design claim. For their part, the Herzogs respond simply that they "have made abundantly clear that the ArthroWand used upon [Dr. Herzog] was defective from the standpoint of its design as well." (Docket No. 68 at 1.) They do not attempt to put forward the facts or articulate in their memoranda how the facts come

together to support a claim for defective design.¹⁰ Thus, if the Court should accept my recommendation that the failure to warn, misrepresentation and trade practices claims are not maintainable, it is left to hypothesize what, exactly, remains of Counts I, II, VI, IX, X and XIV. For obvious reasons, I have refrained from attempting to portray these claims in the absence of input from the parties.

Pursuant to the Supreme Court's holding in Celotex Corp. v. Catrett, 477 U.S. 317 (1986), the Court might be within its discretion to enter summary judgment against Counts I, II, VI, IX, X and XIV, in toto. In Celotex, the Supreme Court held that a plaintiff often must produce the evidence supporting a claim despite the defendant's failure to introduce evidence negating the claim. Id. at 323-24. Indeed, the Supreme Court has indicated that defendants, in order to have a motion for summary judgment considered, need not introduce claim-negating evidence at all, so long as they "point[] out . . . that there is an absence of evidence to support the nonmoving party's case." Id. at 325; see also id. at 326 ("[D]istrict courts are widely acknowledged to possess the power to enter summary judgments sua sponte, so long as the losing party was on notice that she had to come forward with all of her evidence."). In my view, the Defendants' Motions were sufficient to place the Herzogs on "notice" that the factual basis for a defective design claim was challenged. Nevertheless, from an equitable perspective, it would seem to me that the Defendants' utter failure to brief one or more of the elements of this claim should stay the Court's hand at this stage. After all, ArthroCare's summary judgment motion is so targeted at the failure to warn claim and the proximate cause element of that claim

¹⁰ The Herzogs do introduce one solitary fact relating to a design defect in opposition to Surgi-Care's Motion for Summary Judgment, but they never allude to it in the body of their memoranda: "According to Dr. Mayor, there is no benefit to using the ArthroCare Wand in debridement of articular cartilage surfaces." (Docket No. 65, ¶ 18.) How this singular fact might generate a trial-worthy issue of whether a design defect proximately caused Dr. Herzog's injury is not discussed. Nor do the Herzogs actually introduce this fact in the context of ArthroCare's independent Motion.

that it fails ever to even mention, for example, Count VI (breach of implied warranty of merchantability) or even to tie its proximate cause arguments to specific Counts in the First Amended Complaint.

The other issue of concern involves the pending Daubert motions. There are some 27 filings on the docket concerning 15 expert witnesses. When ruling on a Daubert motion, the Court is not bound by the summary judgment standard that evidence must be viewed in the light most favorable to the non-moving party. Thus, in circumstances where a non-movant's opposition to summary judgment depends on expert opinion, it is sometimes appropriate to conduct Daubert hearings prior to or in the context of disposing of a summary judgment motion. After all, summary judgment facts must be of evidentiary quality and summary judgment should not be denied based on inadmissible evidence. But, because the determination of the pending summary judgment motions does not hinge primarily on the admissibility of any expert witness's testimony, I have not endeavored to dispose of the Daubert motions prior to, or in conjunction with, this Recommended Decision. In particular, in discussing the punitive damage claim I have assumed, arguendo, that all of the relevant expert testimony would be admissible and I have construed that evidence in the light most favorable to the Herzogs because, in my view, this evidence would still be insufficient to support an award of punitive damages. Furthermore, to the extent that the alternative recommendation referenced in footnote 11 hinges upon the admissibility of Dr. Markel's testimony, the Defendants' motion to exclude Dr. Markel is DENIED for purposes of resolving the summary judgment motions. I think the better course of action in this case would be to defer a final ruling on the Daubert motions until the dust finally settles on the various claims and defenses discussed herein. At that point in time the parties can

renew any of the Daubert motions that remain relevant and only to the extent that they remain relevant.

I. ARTHRO CARE'S MOTION FOR SUMMARY JUDGMENT

Dr. Herzog asserts the following causes of action against ArthroCare, ordered by count number: (I) strict liability for a defective and unreasonably dangerous product and for failure to provide an adequate warning; (II) negligence for defective design, insufficient warning and misleading marketing; (III) fraudulent misrepresentation for indicating that the Wand was safe and effective for use on articular cartilage in the knee and that the Wand does not employ a thermal process; (IV) negligent misrepresentation based on the same allegations; (V) violation of the Restatement (Second) of Torts § 402B based on the same allegations; (VI) breach of the implied warranty of merchantability (fitness for intended use); and (VII) violation of the Maine Unfair Trade Practices Act. In addition, Mary Herzog asserts a loss of consortium claim in Count VIII.

In addition to challenging the existence of a defective design theory, ArthroCare argues that the Herzogs cannot support their failure to warn theory because the facts reveal that the alleged failure to warn did not proximately cause the Herzogs' alleged injuries and because the facts do not support a finding that the Wand actually burned Dr. Herzog's articular cartilage sufficiently to cause his alleged injury. Finally, ArthroCare makes individualized challenges to the Herzogs' misrepresentation claims, unfair and deceptive trade practices claim, punitive damage demand and lost future wage claim. I address these several arguments in the order in which they are presented by ArthroCare.

A. The Herzogs Fail to Generate a Triable Issue on Whether the Alleged Failure to Warn Proximately Caused Their Injuries.

This case illustrates well the role proximate cause plays in the law of torts. Even when a defendant's conduct might best be described as patently reckless, such conduct is not actionable unless it proximately causes an injury. Thus, even though I would ultimately conclude that the Herzogs have generated sufficient evidence to permit a jury to conclude (1) that ArthroCare knew the Wand had the capacity to thermally injure articular cartilage if not employed carefully and (2) that ArthroCare breached a duty of care by marketing the Wand for use on articular cartilage without including in their product and/or marketing materials an adequate warning of the risk of thermal injury, both relatively serious findings, I nevertheless recommend that summary judgment enter based on the absence of proximate causation.

Relying on Cuthbertson v. Clark Equip. Co., 448 A.2d 315 (1982), ArthroCare contends that Dr. Brown's personal knowledge of the risk of thermal injury was sufficiently extensive that receipt of a warning would not have prevented him from conducting the chondroplasty with the Wand or from using the Wand in the manner he did. (Docket No. 43 at 3.) Dr. Herzog characterizes this argument as an invocation of the "knowledgeable user" rule and argues that it does not apply because "a significant factual dispute exists as to whether Dr. Brown was 'fully apprised of all of the attendant risks associated with' using the ArthroWand on articular cartilage." (Docket No. 68 at 3 (citing Anderson v. Sandoz Pharm. Corp., 77 F. Supp. 2d 804, 808 (S.D. Tex. 1999).) What was missing, according to Dr. Herzog, was a warning that "applying the Wand's tip directly on the tissue [will] cause significant thermal damage" or that there is a "dangerously high risk of thermal damage when the Wand's tip is held in a particular location for too long." (Docket No. 68 at 4.)

In Cuthbertson, plaintiff-appellant argued that the trial court had committed reversible error in not instructing the jury that a distributor has a duty to inform customers and prospective users of the dangers posed by a product it distributes, including the existence of devices or methods for minimizing the dangers. Id. at 319. The plaintiff's theory was that her husband's death would not have occurred had the defendant-distributor of a front-end loader notified the decedent's employer of the machine's tendency to roll over and of the availability of a certain "roll-over protective system." Id. at 316. The Law Court assumed for purposes of argument that the distributor had a duty to warn purchasers of new protective devices, but concluded that "there could be no causal connection between a failure to warn and the injury which ensued" because the employer already knew of the risk at issue. Id. at 319-20.

Application of Cuthbertson to the facts of this case is not a straightforward matter. Each of the three supportive authorities cited by the Law Court in Cuthbertson has been overruled. Skyhook Corp. v. Jasper, 560 P.2d 934, 939 (N.M. 1977), overruled by Klopp v. Wackenhut Corp., 824 P.2d 293 (N.M. 1992); Halvorson v. American Hoist & Derrick Co., 240 N.W.2d 303, 308 (Minn. 1976), overruled by Holm v. Sponco Mfg., 324 N.W.2d 207 (Minn. 1982); Jackson v. New Jersey Mfg. Co., 400 A.2d 81, 89 (N.J. App. Div. 1979), cert. denied, 407 A.2d 1204 (N.J. 1979), overruled by Feldman v. Lederle Labs., 479 A.2d 374, 388-89 (N.J. 1984) ("[S]ubsequently acquired knowledge, both actual and constructive, also may obligate the manufacturer to take reasonable steps to notify purchasers and consumers of the newly-discovered danger."). Even if Cuthbertson were correctly decided with respect to the duty of the distributor in that case, there is no general statement of Maine law that can be readily extracted from it to assist the Court with respect to the duties of a product manufacturer.

ArthroCare's argument is really a straight-forward proximate cause argument. In Maine:

The general rule is that the supplier of a product is liable to expected users for harm that results from foreseeable uses of the product if the supplier has reason to know that the product is dangerous and fails to exercise reasonable care to so inform the user. A products liability action for failure to warn requires a three-part analysis: (1) whether the defendant held a duty to warn the plaintiff; (2) whether the actual warning on the product, if any, was inadequate; and (3) whether the inadequate warning proximately caused the plaintiff's injury.

Pottle v. Up-Right, Inc., 628 A.2d 672, 675 (Me. 1993) (internal citations and quotation marks omitted). “Proximate cause is ‘that cause which, in natural and continuous sequence, unbroken by an efficient intervening cause, produces the injury, and without which the result would not have occurred.’” Merriam v. Wanger, 2000 ME 159, ¶ 8, 757 A.2d 778, 780 (quoting Searles v. Trustees of St. Joseph’s College, 1997 ME 128, ¶ 8, 695 A.2d 1206, 1209). “The mere possibility of such causation is not enough, and when the matter remains one of pure speculation or conjecture, or even if the probabilities are evenly balanced, a defendant is entitled to a judgment.” Id. at 781. In failure to warn cases involving medical devices and pharmaceutical products, it is generally recognized that a manufacturer discharges its duty to warn consumers by providing an adequate warning to the learned intermediary (e.g., the prescribing physician) who will utilize or prescribe the medical device or pharmaceutical product at issue. Violette v. Smith & Nephew Dyonics, 62 F.3d 8, 13 (1st Cir. 1995) (involving appeal from the District of Maine); see also Ellis v. C. R. Bard, Inc., 311 F.3d 1272, 1280 (11th Cir. 2002) (applying Georgia law and citing cases from numerous other jurisdictions involving application of the learned intermediary rule where medical devices are concerned). However, even if the manufacturer breaches its duty by failing to warn the learned intermediary, the injured patient must be able to demonstrate that the failure to warn the intermediary proximately caused his or her injury. Pottle, 628 A.2d at 675. ArthroCare contends that the alleged failure to warn

could not have been the cause of Dr. Herzog's injury because Dr. Brown was already aware of the dangers of direct contact and static application of the Wand.

Dr. Herzog's effort to generate a genuine issue on proximate causation falls short. First, Dr. Brown's testimony indicates that he knew the Wand required a deft touch, that it should be held adjacent to—or very lightly against—the tissue rather than pressed against it, and that thermal damage could result to collateral tissue if the Wand were too vigorously applied. The warning that the Herzogs insist is missing (no direct or static contact) is, essentially, duplicative of information Dr. Brown was already considering. What is more, Dr. Brown's deposition testimony reveals that his use of the Wand would have comported with these warnings. (Docket No. 64, ¶ 36, citing Brown Depo. at 104-105.) Not only does he state that he tried to use as light a touch as possible, but also there is no indication that he applied the Wand in a static manner. And while the Herzogs do offer Dr. Brown's testimony that he would not have used the Wand if it generated temperatures in the range created by lasers ("several hundred degrees Centigrade"), Dr. Brown testified that the Wand would not reach such temperatures when used on low settings and that he used a "lower" setting. (Docket No. 64, ¶ 21; Docket No. 69, ¶ 37; Brown Depo. at 36-39 & 96-97.) The testimony the Herzogs rely on simply does not support a finding that Dr. Brown would not have used the Wand or that he would have used the Wand in a different fashion had he received a warning from ArthroCare not to press the Wand directly into the tissue and not to hold it static in one location. Without such facts, any determination that the absence of a warning proximately caused Dr. Herzog's injury would necessarily be based on speculation. For that reason, I recommend that summary judgment enter against Count I and II to the extent the Herzogs allege an injury based on a defective product warning. Even if ArthroCare had a

duty to supply a warning of the kind suggested, the Herzogs have not generated an issue as to whether the absence of such a warning actually caused Dr. Herzog's injury.¹¹

B. The Herzogs Fail to Generate a Triable Issue on Whether They Justifiably and Detrimentially Relied on a Misrepresentation of Fact.

In Counts III, IV and V, the Herzogs press claims for fraudulent misrepresentation, negligent misrepresentation and violation of Section 402B of the Restatement (Second) of Torts, respectively. ArthroCare moves for entry of summary judgment based on insufficient evidence of reliance, a key element of all three theories. (Docket No. 43 at 12.) See Harkness v. Fitzgerald, 1997 ME 207, ¶ 7, 701 A.2d 370, 372 (outlining elements of fraud); Perry v. H.O. Perry & Son Co., 1998 ME 131, ¶ 8, 711 A.2d 1303, 1305-06 (“[A] showing of detrimental reliance is essential to an action for negligent misrepresentation.”); Restatement (Second) Torts § 402B (requiring detrimental reliance for tort of “misrepresentation by seller of chattels to consumer”). In their First Amended Complaint, the Herzogs allege that Dr. Herzog and Dr. Brown justifiably relied on representations “that the ArthroWand was safe and effective for use

¹¹ In the event that the Court should reject my proximate cause recommendation, I address ArthroCare's “specific causation” argument here, albeit in a cursory fashion. In my view, the testimony of Dr. Herzog's experts, if admitted, would generate a genuine issue whether Dr. Brown caused a burn injury with the Wand. Dr. Minas's observation of darkened tissue consistent with a radio frequency would be supportive of this finding as would the opinion of the pathologist, Dr. Rosenberg, that a post-operative slide of this tissue reflected cellular necrosis from a burn injury. In addition to these two experts, Dr. Mark Markel, D.V.M., opines that the caramelization and bubbling on the surface of Dr. Herzog's medial femoral condyle, which is apparently depicted on the videotape of the June 1999 procedure, are indicative of a surface temperature in excess of 100° Celsius, which would result in extensive chondrocyte (cell) death, “often progressing to the subchondral bone.” (Docket No. 70, ¶¶ 39-41.) Dr. Markel testified during his deposition that thermal damage to nerve endings beneath the cartilage, on the surface of the bone would cause significant pain. (Docket No. 44, ¶ 47; Docket No. 70, ¶ 43.) This evidentiary presentation relies upon more than just temporal coincidence to establish proximate causation. Although I agree with ArthroCare that the evidence Dr. Herzog has presented at the summary judgment stage is insufficient to support the allegation that the Wand caused total cartilage loss so that the bones of his knee joint were coming into direct contact, or that, but for the Wand, he would not have required a total knee replacement, a jury could conclude from these several evidentiary sources, based on more than mere conjecture or speculation, that the thermal properties of the Wand caused disabling post-operative subchondral pain in Dr. Herzog's medial femoral condyle. Still, such evidence would not establish that a failure to warn proximately caused a burn injury. I note that the expert opinions of Drs. Markel and Rosenberg, but not Dr. Minas, are challenged in ArthroCare's Daubert filings. I by no means intend to suggest the likely outcome of those motions in this footnote.

on articular cartilage in the knee, did not employ a thermal process in its performance, and would not cause unintended damage to tissue.” (Docket No. 12, ¶¶ 44, 47, 50, 52.)

The Herzogs misrepresentation claims are unique. Surgical tools like the Wand are simply not marketed to the general public. Instead, manufacturers and sellers of surgical products make their representations directly to surgeons and other medical personnel. Thus, the standard patient would not be able to show that he or she had received false statements of fact, let alone that he or she had relied on such statements when deciding to undergo a surgical procedure. Indeed, but for Dr. Herzog’s unique position as an orthopedic surgeon, the misrepresentation claims would not deserve much comment at all. As is it, Dr. Herzog claims that by virtue of his orthopedic practice he was privy to ArthroCare’s product representations and that, but for these representations, he would have affirmatively instructed Dr. Brown not to use the Wand during either arthroscopic procedure. The Herzogs’ relevant statements of fact assert that, prior to the June 1999 procedure, an ArthroCare salesman informed Dr. Herzog of a “revolution of articular cartilage surgery” and provided him with articles, studies and basic information on the Wand. (Docket No. 70, ¶ 50.) Yet, despite this information, Dr. Herzog testified during his deposition that he never used the Wand to debride osteoarthritic cartilage on the knees of his own patients. (Id., ¶ 49; Herzog Depo. at 30.)¹² The Herzogs also indicate that

¹² When discussing his own usage of the Wand, Dr. Herzog basically testified at his deposition that he did not consider it safe to use the Wand to debride articular cartilage surfaces.

- Q. Have you ever or did you ever perform arthroscopic surgery using an ArthroCare Wand?
A. Yes.
Q. And did you ever use an ArthroCare Wand on articular cartilage surfaces?
A. I don’t recall any exact case, but if a piece of tissue would be hanging down separated from the joint surface by, let’s say, half an inch, you could touch that safely and remove it, but it was not a practice to do any arthritic debridement type things, but I did numerous lateral releases and soft tissue resections and even attempted to do menisectomies with it.
Q. With an ArthroCare Wand?
A. Yes.
Q. When you said it is not a practice to do debridement, . . . not whose practice?
A. It wouldn’t be my preference to burn the tissue on the end of a bone.

Dr. Herzog “did not talk to Dr. Brown prior to his surgery about what device [Dr. Brown] was going to use.” (Docket No. 70, ¶ 51.) Based on these statements of fact, the Herzogs make the following argument in their memorandum:¹³

It is . . . reasonable that Dr. Herzog would have relied on [ArthroCare’s] misrepresentations and omissions in deciding that he need not request that Dr. Brown not use the ArthroWand on his knee. . . . Had he known, through conversations with ArthroCare representatives, the truth about the dangers associated with the Wand, it is safe to assume that he would have raised that issue with Dr. Brown. His direct contact with ArthroCare representatives and their marketing materials, in which he was assured that the ArthroWand was safe and effective, implicitly persuaded him to refrain from objecting to the Wand’s use on his knee. In light of its extensive, direct sales pitches to Dr. Herzog regarding the safety and efficacy of the Wand, any claim by ArthroCare now that Dr. Herzog could not have relied on its misrepresentations/omissions belies the record, and should be dismissed by this Court.

(Docket No. 68 at 15-16.) If there is one thing that is certain about summary judgment practice, it is that a plaintiff cannot meet his or her burden based on assumptions. It is hard to understand why those things the Herzogs want the Court to assume could not have been set forth affirmatively by way of affidavit. As it is, the only facts the Herzogs introduce are that Dr. Herzog was told of a “revolution” in articular surgery and that he “did not talk to Dr. Brown prior to his surgery about what device he was going to use.” (Docket No. 70, ¶¶ 50, 51.) On this limited showing, I do not think the Court should infer that Dr. Herzog relied to his detriment on any “misrepresentations” or “omissions.” Nor do I agree with the Herzogs suggestion that a misrepresentation to a surgeon about a surgical tool would support a misrepresentation claim by

Q. Did you ever talk to Dr. Brown prior to his surgery on your knee about what device he was going to use to do debridement?
A. No.

(Herzog Depo. at 30-31.) See also Docket No. 50, ¶ 16 concerning Dr. Herzog’s “gut instinct” about the Wand.

¹³ The first argument the Herzogs make is that the Court should ignore this challenge based on ArthroCare’s failure to produce evidence supporting the challenge. (Docket No. 68 at 14.) This turns the summary judgment process on its head. It is the Herzogs who must demonstrate that facts exist to support their claims. Celotex 477 U.S. at 323.

the patient.¹⁴ Nor do I think the summary judgment record permits a finding that ArthroCare materially mislead Dr. Brown, who acknowledged that he understood the thermal properties of the Wand and the attendant risks of direct application on articular cartilage. My impression is that the summary judgment record no more supports a finding of reliance by Dr. Brown on a misrepresentation than it does a finding that Dr. Herzog's injury was proximately caused by a failure to warn Dr. Brown. For this reason, I recommend that the Court grant ArthroCare summary judgment against Count III, IV and V.

C. Summary Judgment Should Enter Against Count VII Because the Unfair Trade Practice Act Does Not Extend to the Facts of This Case.

In Count VII, Dr. Herzog asserts a claim for violation of Maine's Unfair Trade Practices Act, asserting, "ArthroCare's conduct in its design, research, development, and sale of the ArthroWand constitutes an unfair or deceptive act or practice in the conduct of trade or commerce." (Docket No. 12, ¶ 63.) That Act permits private suits by those who purchase or lease "goods, services or property . . . primarily for personal, family or household purposes," under certain circumstances. 5 M.R.S.A. § 213. ArthroCare moves for summary judgment against this claim on the ground that Dr. Herzog was not the purchaser of the Wand that was used on his knee. (Docket No. 43 at 13.) In opposition, Dr. Herzog has established that he paid Orthopedics Associates' invoice for the price of two ArthroCare Wands. (Docket No. 70, ¶ 52.) Whether or not Dr. Herzog paid for his surgeon's acquisition of the Wand or Wands used during his surgery, it is apparent that he did not purchase the Wand for his personal use. I agree with

¹⁴ Comment j of the Restatement (Second) Torts § 402B states that "reliance need not necessarily be that of the consumer who is injured [but] may be that of the ultimate purchaser of the chattel, who because of such reliance passes it on to the consumer who is in fact injured, but is ignorant of the misrepresentation." In my view, this caveat is addressed to situations in which the plaintiff was the actual "user" of the product, but not the one to whom a product misrepresentation was made. *See id.*, cmt. i ("Consumer' is to be understood in the broad sense of one who makes use of the chattel in the manner which a purchaser may be expected to use it. Thus an employee of the ultimate purchaser to whom the chattel is turned over, and who is directed to make use of it in his work, is a consumer, and so is the wife of the purchaser of an automobile who is permitted by him to drive it.").

ArthroCare that the Act does not extend protection to individuals who pay the bill for a medical service provider's acquisition of a medical device, even though that device is "used" on them for "personal purposes." Such purchasers do not themselves use the good at issue; nor do they ever possess the good; nor is the good at issue properly understood to be a "consumer good."

D. The Viability of Mary Herzog's Loss of Consortium Claim Depends on the Viability of the Defective Design Claim.

Because there remains a question regarding the existence of facts supporting the defective design claim against ArthroCare, I recommend that summary judgment not enter at this time against Mary Herzog's derivative loss of consortium claim, Count VIII.

E. Summary Judgment Should Enter Against Plaintiffs' Demand for Punitive Damages.

Under Maine law, punitive damages are available only where the defendant's conduct was motivated by actual malice directed against the plaintiff or where the defendant's conduct was "so outrageous that malice toward a person injured as a result of that conduct can be implied." Tuttle v. Raymond, 494 A.2d 1353, 1361 (Me. 1985). Neither recklessness nor gross negligence will suffice under this standard. Id. The burden of proof of actual or implied malice is by clear and convincing evidence. Id. at 1363. In Tuttle, the Law Court reserved for later consideration how the punitive damages regime might apply in products liability cases. Id. at 1360 n.20 ("[A]lthough our opinion today provides a careful evaluation of a longstanding doctrine, many issues concerning the availability of punitive damages . . . remain for future consideration and resolution. These issues include, *inter alia*, . . . the application of punitive damages in products liability . . . litigation."). Thus, it is at least conceivable that the standard may be lowered in some way to account for the strict liability regime.

According to the Herzogs, ArthroCare actively concealed information revealing a serious risk of harm that the Wand could cause significant cellular necrosis when applied directly to, or held “even momentarily” in a stationary position over, articular cartilage. (Docket No. 68 at 18.) The Herzogs contend that such concealment is outrageous given that the device is “a medical product intended for insertion within the human body with an electrical capacity to burn and injure valuable and necessary tissue within the body.” (Id. at 20.) In addition to challenging the evidentiary basis for Plaintiffs’ contention, Defendant relies on Davies v. Datapoint Corp., 1995 U.S. Dist. LEXIS 21739, *42 (D. Me. Oct. 31, 1995), to argue that even knowing concealment would fall short of the requirements of Tuttle.

In their Statement of Additional Undisputed Material Facts (in opposition to ArthroCare’s Motion), the Herzogs offer evidence of three sources of information available to ArthroCare prior to Dr. Herzog’s operation. The first source involves two documents that were discussed during the deposition of Phillip Eggers, one of the designers/inventors of the Wand. Without divulging in their relevant Statement of Additional Undisputed Material Facts, Docket No. 70, what any of the contents of the documents were, the Herzogs complain that none of the contents were incorporated into ArthroCare’s marketing materials. In order to find out what these contents were, one must look to the Herzogs’ “Supplemental Statement of Material Facts,” Docket No. 65, submitted in opposition to Defendant Surgi-Care’s Motion

REDACTED

Additionally, ArthroCare’s president inquired of Mr. Eggers, “What happens when I am firmly

against the tissue and the vapor layer is not allowed to form?"

REDACTED

REDACTED

REDACTED

Tuttle, 494 A.2d at 1362;

DiPietro v. Boynton, 628 A.2d 1019, 1024 (Me. 1993).

F. ArthroCare’s Challenge to the Herzogs’ Lost Wage Claim Should be Disregarded at this Juncture.

ArthroCare asks that Dr. Herzog’s lost future wage claim be stricken. (Docket No. 43 at 16.) This request apparently arises from Dr. Herzog’s allegation that, “[a]s a result of ArthroCare’s and Surgi-Care’s wrongful conduct, Dr. Herzog can no longer earn his livelihood as an orthopedic surgeon” and that “[h]e is physically incapable of performing the tasks necessary to maintain his practice.” (Amended Complaint, Docket No. 12, ¶ 33.) ArthroCare complains that the Herzogs have not designated a vocational expert and that Dr. Herzog’s knee injury does not prevent him from working as an orthopedic surgeon. (Docket No. 43 at 17.) According to ArthroCare, “there is absolutely no basis for [Dr. Herzog’s] future lost wage claim.” (Id. at 18.) The Herzogs argue that this challenge is inappropriate in the context of a summary judgment motion and should be raised in an in limine motion. (Docket No. 68 at 21.) They also explain that the future lost wage claim is based on a significant reduction in Dr. Herzog’s productivity, which bears directly on his earning potential and that the facts to support this element of damages can be presented without the assistance of a “vocational expert.” (Id. at 22.) This aspect of ArthroCare’s Motion does not warrant extended discussion and should be denied.

II. SURGI-CARE'S MOTION FOR SUMMARY JUDGMENT.

Dr. Herzog asserts the following causes of action against Surgi-Care, ordered by count number: (IX) strict liability for placing a defective and unreasonably dangerous product in the stream of commerce and for failure to warn of the same; (X) negligence for marketing, selling and placing a defective product in the stream of commerce, for failing to warn and for failing to independently investigate and research the safety and efficacy of the Wand; (XI) fraudulent misrepresentation; (XII) negligent misrepresentation; (XIII) violation of the Restatement (Second) of Torts § 402B; (XIV) breach of implied warranty; (XV) violation of the Maine Unfair Trade Practices Act; and (XVI) violation of the Massachusetts Consumer Protection Act. In addition, Mary Herzog pursues a loss of consortium claim in Count XVII and the Herzogs make their demand for punitive damages in "Count XVIII." Surgi-Care's Motion for Summary Judgment is similar to ArthroCare's, but somewhat more nuanced. Like ArthroCare, they essentially proceed as though the only product liability issue is the adequacy of ArthroCare's warnings.

A. The Herzogs Fail to Generate a Triable Issue on Whether the Alleged Failure to Warn Proximately Caused Their Injuries.

Surgi-Care argues that, even if an inadequate warning was provided with the Wand, Dr. Herzog's alleged injury could not have been caused by a failure to warn because Dr. Brown testified he would not have heeded such a warning. (Docket No. 34 at 4-5.) Although Surgi-Care mischaracterizes Dr. Brown's testimony, Surgi-Care is nevertheless entitled to summary judgment against the failure to warn theory asserted in Counts IX and X for the same reasons I indicated in regard to ArthroCare in Section I.A., supra.

B. The Herzogs Fail to Generate a Triable Issue on Whether They Justifiably and Detrimentially Relied on a Misrepresentation of Fact.

In addition to submitting its own Motion for Summary Judgment, Surgi-Care has also “joined” in ArthroCare’s Motion for Summary Judgment. (Defendant Surgi-Care, Inc.’s Joinder in Defendant ArthroCare Corporation’s Motions, Docket No. 56.) For the reasons stated in Section I.B., I recommend that summary judgment enter against Counts XI, XII and XIII.

C. The Learned Intermediary Rule Would Not Entitle Surgi-Care to Summary Judgment.

I address this argument in the event that the Court should reject my recommendation in Section II.A. Surgi-Care argues that the Herzogs’ claims are barred by the learned intermediary doctrine. (Docket No. 34 at 2.) According to Surgi-Care, it satisfied its duty to the Herzogs by providing Dr. Brown “with information and a videotape regarding the proper uses of the ArthroWand.” (Id.)

“It is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient.” Knowlton v. Deseret Med., Inc., 930 F.2d 116, 120 n. 2 (1st Cir. 1991). Thus, when an adequate warning is provided to the “learned intermediary,” it is up to the intermediary to pass along the warning to the patient. See, e.g., Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992) (“Under this doctrine, the manufacturer’s duty is fulfilled once it adequately warns the physician.”). But when an inadequate warning or no warning is provided to the learned intermediary, the manufacturer or seller has not satisfied its duty to the consumers. In the opinion of Dr. Tucker, ArthroCare’s warning was inadequate in that it was non-existent. (Docket No. 64, ¶ 2.)

D. The Rule Articulated in Section 6 of the Restatement (Third) of Torts: Product Liability is Not Applicable to the Facts of This Case.

I address this argument in the event that the Court should reject my recommendation in Section II.A. With respect to Counts IX (strict liability), X (negligence), and XIV (breach of implied warranty), Surgi-Care argues that it fulfilled its duties to the Herzogs as a matter of law because it passed along all of ArthroCare's print and video materials concerning the Wand. (Docket No. 34 at 7-9.) Although Maine's product liability statute clearly imposes liability on sellers and suppliers in addition to manufacturers, 14 M.R.S.A. § 221, Surgi-Care contends that it is against public policy to impose liability on a distributor of medical devices on a failure to warn theory because all that can fairly be expected of the distributor is that it pass along the manufacturer's warning. (Id. at 8.)

Surgi-Care's reliance on Section 6 of the Third Restatement of Products Liability is misplaced. Surgi-Care is attempting to make an analogy between its situation as a seller of surgical tools and the situation of pharmacists, who are sometimes sued for failing to supplement a drug manufacturer's inadequate warnings or failing to catch a physicians' inappropriate prescriptions. One problem with this analogy is that the case law generally immunizes pharmacists from strict liability because they are not the kind of "retailers" that strict liability regimes are designed to target. Jones v. Irvin, 602 F. Supp. 399, 400 (D. C. Ill. 1985) (citing cases). Pharmacists are equally, if not more significantly, service providers. See, e.g., Murphy v. E.R. Squibb & Sons, Inc., 710 P.2d 247, 252 (Cal. 1985) (construing California statute to support the conclusion that "even though a pharmacist is paid for the medication he dispenses, his conduct in filling a prescription is to be deemed a service . . . immune from strict liability.") This rationale has also been used to exempt hospitals from strict liability for obtaining medical devices and products that are used by physicians in medical procedures. See, e.g., Parker v. St.

Vincent Hosp., 919 P.2d 1104, 1106-07 (N.M. App. 1996) (“According to the weight of authority, a hospital is not a distributor of medical supplies, even though it may bill separately for the item and charge the patient a markup over the hospital’s cost. The courts have generally held that the essence of the hospital’s role is the provision of services, regardless of whether a product is involved.”) (citing cases). This rationale does not apply to a distributor of medical devices like Surgi-Care, which is nothing if not a retailer.¹⁵ Another distinction between pharmacists and retailers is that pharmacists are not intermediaries between manufacturers and physicians the way that distributors of medical devices are. Thus, for instance, a pharmacist is not involved in providing a manufacturer’s warnings to a prescribing physician. This fact further highlights that the rule of no liability for pharmacists is not really based on the “learned intermediary” doctrine at all, but on special policy considerations that do not translate to the circumstance of a distributor of medical devices.

The authors of the Restatement (Third) of Torts have attempted to restate the foregoing precedent with language suggesting that the rule of strict liability does not extend to a “retail seller or other distributor of a . . . medical device” in a failure to warn case. Restatement (Third) of Torts: Products Liability § 6(e) & cmt. h (1998). However, other than one case involving a hospital, St. Vincent Hosp., supra, every case cited by the Restatement authors involved injury from ingestion of pharmaceutical drugs. See id., cmt. h. My assessment of this Restatement provision is that the authors intended the expansive language of § 6(e) to be confined by the definitional provision in § 6(a): “A prescription drug or medical device is one that may be

¹⁵ Surgi-Care’s policy argument also overlooks the economic impetus behind strict product liability regimes. See St. Germain v. Husqvarna Corp., 544 A.2d 1283, 1287 n.3 (Me. 1988) (“Among the policy reasons that led the American Law Institute to adopt section 402A [was] . . . that the cost of damaging events due to defectively dangerous products can best be borne by the manufacturers and sellers of those products . . .”).

legally sold or otherwise distributed only pursuant to a health-care provider's prescription." Id., § 6(a) (emphasis added).

In addition to relying on the foregoing Restatement provision, Surgi-Care relies on Jones v. Irvin, supra, and In re Rezulin Prods. Litig., 133 F. Supp. 2d 272, 288 (S.D.N.Y. 2001). However, "[t]he precise issue" in Jones v. Irvin was "whether a pharmacist, who correctly fills a prescription, is negligent for failing to warn the customer or notify the physician that the drug is being prescribed in dangerous amounts . . . or that the various drugs in their prescribed quantities could cause adverse reactions to the customer." Id. (emphasis added). The Court held that Illinois law would not impose an independent duty on the pharmacist to second-guess the prescribing physician or to identify and warn of possible adverse effects in a pharmaceutical drug that have never been identified by the manufacturer. Id. at 402-403. Similarly, in Rezulin, the court ruled that claims for injuries arising from the use of a pharmaceutical drug could not proceed against various pharmacy defendants because imposition of an independent duty to investigate and warn would cause "risk averse" pharmacists "to dispense [warnings] that [might] be uninformed, inapplicable to or misunderstood by the patient." 133 F. Supp. 2d at 288. These two cases simply illustrate the special rule described in the Restatement, which is designed for the unique circumstances inherent in the dispensation of prescription drugs and devices.

E. Summary Judgment Should Enter Against the Fraudulent and Negligent Misrepresentation Claims Based on Surgi-Care's Lack of Knowledge of Any Misrepresentation.

I address this argument in the event that the Court should reject my recommendation in Section II.B. Surgi-Care argues that summary judgment should enter against Counts XI (fraudulent misrepresentation), XII (negligent misrepresentation) and XIII (violation of the Restatement (Second) of Torts § 402B) based on the assertion that it had no knowledge of a

product design defect or of any inadequacy in ArthroCare's marketing materials.¹⁶ According to Surgi-Care, even if the marketing materials contained false or misleading statements, it was merely passing along ArthroCare's statements, without independent knowledge of their falsity, and without owing an independent duty to assure against false statements by the manufacturer. (Docket No. 34 at 10.) The Herzogs respond only that agents who commit torts on behalf of their principals are equally liable for such torts. (Docket No. 63 at 12.) In my view, even if the Court rejects my recommendation in Section I.B. that the misrepresentation claims fail for lack of detrimental reliance, Surgi-Care would still be entitled to summary judgment against Counts XI and XII, but not against XIII.

In order to prevail on a claim of fraud a plaintiff must show, inter alia, that the defendant either knew the statement at issue was false or that the defendant made the statement in reckless disregard of its truth or falsity. McCarthy v. U.S.I. Corp., 687 A.2d 48, 53 (Me. 1996). The Herzogs fail to articulate in their memorandum the factual basis for a finding that Surgi-Care knew ArthroCare's statements were false.¹⁷ Thus, Surgi-Care would be entitled to summary judgment on Count XI even if the Herzogs could show detrimental reliance. See, e.g., Emerson v. Ham, 411 A.2d 687, 689-90 (Me. 1980) (affirming directed verdict for real estate broker on fraud claim where the evidence could not support a finding that the broker knew the seller's statement was false). The elements of the negligent misrepresentation claim are similar, but less burdensome on the issue of "knowledge":

¹⁶ The claims premised on the Maine and Massachusetts consumer protection statutes are also targeted in this portion of Surgi-Care's Motion. However, rather than attempting to articulate exactly how a lack of knowledge might relate to the specific elements of these claims, which Surgi-Care does not even endeavor to do, I address them in Section II.F.

¹⁷ In another portion of their opposition memorandum, the Herzogs discuss statements allegedly made by Dr. Parker to a Surgi-Care representative. These statements, which are discussed in Section II.H., below, are simply too vague and indefinite to support the requisite finding that Surgi-Care knew or acted in reckless disregard of whether ArthroCare's product representations were false.

One who, in the course of his business, profession or employment or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary losses caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating information.

Id. In my view, the Herzogs' presentation would fail to meet even this standard of proof and, thus, I would recommend that summary judgment enter against Count XII even if the Herzogs could show detrimental reliance.

Count XIII, which relies on the Restatement (Second) of Torts, § 402B, does not require any showing that the defendant knew or should have known of the falsity of a statement.

Pursuant to Section 402B:

One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though:

(a) it is not made fraudulently or negligently

Thus, unlike the fraud and negligent misrepresentation claims, a "strict liability" product misrepresentation claim such as the one articulated in Section 402B of the Restatement would not require proof of either actual or constructive knowledge, though it would still require proof of reliance.¹⁸ Section 402B would impose liability for even "innocent" misrepresentations.

Thus, to the extent that Surgi-Care moves for summary judgment based solely on a lack of knowledge, it could not succeed against Count XIII.¹⁹

¹⁸ The Law Court has yet to recognize such a tort, though it typically recognizes tort principles set forth in the Restatements. It also appears that this Court has yet to consider the viability of a "strict liability misrepresentation claim."

¹⁹ Surgi-Care argues that comment j of Section 402B draws an exception applicable to this case. Pursuant to comment j:

j. Justifiable reliance. The rule here stated applies only where there is justifiable reliance upon the misrepresentation of the seller, and physical harm results because of such reliance, and because

F. Summary Judgment Should Enter Against Counts XV and XVI.

Like ArthroCare, Surgi-Care argues that the UTPA is inapplicable because the Wand is not a consumer product. For the reasons stated in Section I.D, supra, I agree. In my view, summary judgment should enter against Count XV. Furthermore, the Herzogs concede that the claim under the Massachusetts consumer protection statute is not actionable. Therefore, summary judgment should enter against Count XVI.

G. Summary Judgment Should Not Enter Against Count XVII.

Surgi-Care moves for summary judgment against Mary Herzog's loss of consortium claim in the event that summary judgment should enter against all of Dr. Herzog's claims. Because there remains a question regarding the existence of facts supporting the defective design claim, I recommend that summary judgment not enter at this time against Mary Herzog's derivative loss of consortium claim, Count XVII.

H. Summary Judgment Should Enter Against "Count XVIII" Because There is Insufficient Evidence of Implied Malice on the Part of Surgi-Care.

There is no evidence in this case that Surgi-Care harbored ill will toward Dr. Herzog. Instead, the Herzogs argue that Surgi-Care behaved outrageously because it had in its possession "critical and important information about the use and effectiveness of the ArthroWand that it chose to conceal." (Docket No. 63 at 17.)

The facts on which the Herzogs base their claim that Surgi-Care engaged in outrageous concealment involve an alleged oral exchange, of a very casual nature, between a Surgi-Care representative and an orthopedic surgeon in late 1997 or early 1998. According to H. Gary

of the fact which is misrepresented. It does not apply where the misrepresentation is not known, or there is indifference to it, and it does not influence the purchase or subsequent conduct.

Surgi-Care takes comment j out of context. It clearly relates to situations in which the plaintiff either had no knowledge of the misrepresentation or was indifferent to it and, therefore, could not have relied. The comment is not addressed to situations in which the seller did not know of the misrepresentation. Surgi-Care's argument that its lack of knowledge would preclude liability on this claim is false.

Parker, M.D., he stopped using the ArthroCare Wand for articular cartilage procedures in 1997 after three of his patients experienced rapid osteoarthritis following the use of an ArthroCare Wand on their articular knee cartilage. (Docket No. 65, ¶¶ 4, 5.) Dr. Parker would testify that in late 1997 or early 1998, he mentioned his findings and decision not to use the Wand on knee cartilage to a Surgi-Care representative “several times.” (*Id.*, ¶¶ 7, 8.) In addition to denying that any such conversations took place, Surgi-Care points out that even Dr. Parker describes his alleged oral reports as “casual” and “offhand.” (Docket No. 72, ¶ 7.) Perhaps most telling is the following deposition exchange:

Q. When you had the conversations with Mark Brountas, were they formal conversations or casual? How would you describe it?

A. They were casual.

Q. You never gave any sort of formal report or written complaint of anything?

A. No. I just said in my hand it doesn't seem to be working.

Q. Did you ever give him the names of patients?

A. No.

Q. Did you give him any—specifically link it not being good in your hands to patient care saying I have three patients or anything as specific as that?

A. No.

(Dr. Parker Deposition at 41-42.) According to the Herzogs, Surgi-Care was duty bound to report this exchange with Dr. Parker to all of its sales representatives, to ArthroCare and to all potential purchasers of the Wand. Even assuming that Surgi-Care was negligent in failing to do so, given the casual and indefinite nature of Dr. Parker's oral comments, no reasonable jury could conclude from this evidence that Surgi-Care's decision not to amount to “outrageous

concealment.” I recommend that summary judgment enter against the punitive damages plea recited as “Count XVIII.”

III. PLAINTIFFS’ MOTION FOR PARTIAL SUMMARY JUDGMENT

I address the Herzogs’ Motion for Partial Summary Judgment, in the event that the Court should reject my recommendation to grant the Defendants’ summary judgment motions. The Herzogs move for limited summary judgment against ArthroCare’s and Surgi-Care’s assertions of the affirmative defenses of assumption of the risk and comparative negligence. (Docket No. 39 at 1.) There is no reason to belabor the discussion of this motion. “The theory that a plaintiff’s negligence claim could be barred because he or she voluntarily assumed the risk was abolished in Maine with the adoption of comparative negligence principles.” Harvey v. Mid-Coast Hosp., 36 F. Supp. 2d 32, 34 (D. Me. 1999). See also Merrill v. Sugarloaf Mt. Corp., 2000 ME 16, ¶ 9, 745 A.2d 378, 383 & n.3. Whatever arguments the Defendants wish to pursue under the heading “assumption of the risk” may now be pursued under the heading of “comparative negligence.” But in no case will a simple finding that Dr. Herzog “assumed the risk” automatically bar his claim. Any evidence that Dr. Herzog “voluntarily and unreasonably proceed[ed] to encounter a danger known to him” must be compared to the Defendants’ fault under 14 M.R.S.A. § 221, if any, or under the other tort theories of liability. Austin v. Raybestos-Manhattan, Inc., 471 A.2d 280, 287-88 (Me. 1984). However, the Section 221 product liability claim is special in the following regard: the only comparative fault argument that can be offered against this claim is that Dr. Herzog “voluntarily and unreasonably proceed[ed] to encounter a danger known to him.” Id. The factual statements offered in connection with this Motion reveal that Dr. Herzog did not know that Dr. Brown would use the Wand on his knee, but that Dr. Herzog knew the Wand was present in the office and that some

people in the office used it for unspecified procedures. (Docket No. 50, ¶ 4; Docket No. 53, ¶¶ 3, 4.) Dr. Herzog did not himself use the Wand for the sculpting procedure that Dr. Brown performed on him, but Dr. Herzog had previously used the Wand on a knee where “a piece of tissue would be hanging down separated from the joint surface by, let’s say, half an inch.” (Id.; Herzog Depo. at 30.) Dr. Herzog also testified at his deposition that, before the date of the June 1999 procedure, he considered it inadvisable to use the Wand on articular cartilage located on a weight bearing surface because of the risk of thermal injury. (Docket No. 50, ¶ 16.) Viewing this testimony in the light most favorable to the Defendants, a jury might conclude that Dr. Herzog should have known that Dr. Brown might use the Wand on his articular knee cartilage and that, therefore, he unreasonably proceeded to encounter a danger that was known to him. I therefore recommend that the Court deny Plaintiffs’ Motion for Partial Summary Judgment.

Conclusion

For the reasons stated herein, I **RECOMMEND** that the Court **GRANT** Defendants’ summary judgment motions in their entirety **EXCEPT** against those portions of Counts I, II, IX and X that assert claims premised on defective design **AND EXCEPT** against Counts VI and XIV, which assert claims for breach of the implied warranty of merchantability. I further **RECOMMEND** that the Court **DENY** Plaintiffs’ partial summary judgment motion.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum, within ten (10) days of being served with a copy thereof. A responsive memorandum shall be filed within ten (10) days after the filing of the objection. Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

Dated: March 21, 2003

Margaret J. Kravchuk

TRIALLIST, MAGRECUSED, BANGOR, STANDARD

United States Magistrate Judge

**U.S. District Court
District of Maine (Portland)
CIVIL DOCKET FOR CASE #: 2:02-cv-00076-GC
Internal Use Only**

HERZOG, et al v. ARTHROCARE CORPORATI, et al

Assigned to: JUDGE GENE CARTER

Referred to:

Demand: \$0

Lead Docket: None

Related Cases: None

Case in other court: None

Cause: 28:1391 Personal Injury

Date Filed: 04/08/02

Jury Demand: Both

Nature of Suit: 365 Personal Inj. Prod.

Liability

Jurisdiction: Diversity

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