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

DIANE KORDEK	:	CIVIL ACTION
	:	
v.	:	
	:	
	:	
BECTON, DICKINSON AND CO.	:	NO. 10-7040

MEMORANDUM

McLaughlin, J. February 1, 2013

This case arises out of injuries sustained by a surgical technician while removing a shield from the blade of a scalpel manufactured and sold by the defendant. The plaintiff claims that the scalpel, specifically the scalpel shield, was defectively designed. She brings her suit under both strict products liability and negligence causes of action. The defendant has moved for summary judgment on both counts. First, the defendant argues that the plaintiff's sole expert witness should be excluded under Fed. R. Evid. 702. In the alternative, the defendant argues that even including the expert witness's opinion, the plaintiff's claims fail because she has not demonstrated the existence of a reasonable alternative design. The Court grants the defendant's motion.

I. Factual History[1]

A. The Plaintiff's Injury

Plaintiff Diane Kordek was formerly employed as a surgical technician by Albert Einstein Medical Center in Philadelphia. As a surgical technician, Ms. Kordek was responsible for setting up and preparing the operating rooms in the Labor and Delivery unit of the hospital. This included gathering surgical instruments that were needed for child delivery procedures. Transcript of Deposition of Diane Kordek ("Kordek Dep.") 115:12-20, 143:23-144:6.

On the evening of September 11, 2008, Ms. Kordek prepared a room for an urgent Cesarean section delivery. One of the surgical instruments she handled was a disposable scalpel with a fully removable shield covering the blade. Id. 124:22-128:9, 252:1-7; 274:12-15; 161:7-21.

The scalpel's shield was difficult to remove, and Ms. Kordek wrapped all of her fingers around the shield and pulled. Ms. Kordek pulled on it several times before it came loose. Id. 315:8-17; 310:15-311:10.

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[1] The facts presented here are undisputed unless otherwise noted. Disputed facts are read in the light most favorable to the nonmoving party, the plaintiff. Sheridan v. NGK Metals Corp., 609 F.3d 239, 251 n.12 (3d Cir. 2010).

In the course of removing the shield, Ms. Kordek lacerated her hand and arm. She has testified that as a result of the scalpel injury, she now suffers from reflex sympathetic dystrophy (RSD) and complex regional pain syndrome (CRPS), such that she is permanently disabled. Compl. ¶ 29.

B. Defendant's Involvement

The scalpel that injured Ms. Kordek was manufactured and sold by defendant, Becton, Dickinson and Company (BD).[2] At the time of the incident, BD manufactured a range of scalpel products, which included the conventional disposable scalpel and the protected disposable scalpel. Compl. ¶ 23; Tr. Dep. Carl Chrisbacher ("Chrisbacher Dep.") 25:1-24.

1. Conventional Disposable Scalpel

A conventional disposable scalpel (also called a conventional scalpel or a disposable scalpel with a fully removable shield) is a single-use product in which the blade is heat-staked into a plastic handle. BD's conventional scalpel blades are protected by a flexible, tube-like vinyl shield,

[2] Specifically, Ms. Kordek has testified that "BD" was written on the packaging containing the scalpel. Kordek Dep. 170:10-14.

which is fully removed from the scalpel before use. To remove the shield, the individual holds the scalpel with one hand and uses the fingers of the other hand to pinch the tip of the shield and pull it away from the blade. Thus, a person must use two hands to remove the scalpel shield from a conventional disposable scalpel. This is the type of scalpel that Ms. Kordek handled on the night of the incident. Chrisbacher Dep. 130:3-7; 25:23-26:10, 45:10-46:13, 47:4-8; Kordek Dep. 267:6-16; 161:7-21.

Aside from Ms. Kordek, Mr. Chrisbacher has not heard any complaints from users encountering difficulty in removing the shield from the conventional scalpel. In addition, in 2008-09, BD did not receive any reports of complaints of injuries from a conventional scalpel and received only one complaint about an "unknown" scalpel. Chrisbacher Dep. 180:21-181:2; Def. Mot. Exh. 8, pp. 4, 6.

2. Protected Disposable Scalpel

Beginning in 2000, BD began developing and implementing a new line of safety-engineered reusable blade systems disposable scalpels, which included the protected disposable scalpel. Chrisbacher Dep. 20:23-21:4.

The protected disposable scalpel (also called a retractable shield scalpel) is a single-use product and consists of a plastic handle, blade, and shield. Unlike the conventional disposable scalpel, which has a fully removable vinyl shield, the protected disposable scalpel has a shield that can be retracted for use then pushed back over to protect the blade. Chrisbacher Dep. 24:4-12. This protected disposable scalpel was eventually made available in Albert Einstein Medical Center facilities. Tr. Dep. Karen Horner ("Horner Dep.") 86:1-87:4.

As a result of the retraction device, a person can "remove" the shield using only one hand. Carl Chrisbacher, BD's manufacturing integrator manager, testified that the ability of the protected disposable scalpel to retract its shield with one hand improved the safety of the scalpel. Chrisbacher Dep. 10:3-10; 36:16-24, 37:21-24, 39:6-20, 41:23-42:1.

BD designed these scalpels to minimize the risk of surgical blade injuries. In subsequent advertising literature regarding the retractable shield products, BD described these products as "[a]llowing clinicians to retract the protective shield easily and safely with one hand." It also stated that the scalpels were "virtually the same size and weight" as conventional scalpels. Id. 37:21-24; Pl. Opp. Exh. K.

BD initially thought that if demand for its scalpels with the retraction capacity was sufficient, it might opt to carry only that line of scalpels and discontinue the manufacture of the products incapable of retraction. However, BD did not choose to do so. Chrisbacher Dep. 35:1-36:9.

3. Reaction to Retractable Shield Scalpels

The reaction to BD's retractable shield scalpel products has been mixed. According to Mr. Chrisbacher, some of BD's customers continued to demand the conventional scalpel due to the different "feel" of the retractable shield products. Physicians reported to BD that the added step of retracting the shield, and the shield itself, gave a bulkier feel to the scalpel in the hand, and, in some instances, obscured their line of vision. Id. 61:2-20. Several academic studies have expressed similar sentiments. For example, one study reported that 84% of doctors surveyed stated that they did not like the feel of safety-engineered scalpels and that more than 68% were concerned with their line of sight. Def. Mot. for Summ. J. ("Def. Mot.") Exh. 7.

On the other hand, Karen Horner, the nurse manager of the plaintiff's unit at the Albert Einstein Medical Center, has

testified that the staff "really liked" the retractable shield scalpels. Horner Dep. 88:17-19.

In 2007, the American College of Surgeons issued a statement which reflected the mixed reaction to the retractable shield products. The statement encouraged the use of safety-engineered sharp instruments but also stated that this endorsement did not extend to "situations where [the use of safety instruments] may compromise the safe conduct of the operation or safety of the patient." Def. Mot. Exh. 7(f), at 3.

Statements from the Occupational Safety and Health Administration (OSHA) also make reference to concerns regarding the "feel" of the instruments. In 2000, in response to Congress's enactment of the Needlestick Safety and Prevention Act, a BD product manager submitted an inquiry to OSHA regarding whether healthcare facilities would now be required to use safety-engineered blades and scalpels if such options were commercially available.[3] Def. Mot. Exh. 12. In his reply, Richard Fairfax, OSHA's Director of Enforcement Programs, stated that "a healthcare facility would be required to evaluate them

[3] The Needlestick Safety and Prevention Act, Pub. L. 106-430, 114 Stat. 1901 (2000), requires employers to detail their plans to minimize risks related to potentially infectious materials.

for appropriateness and effectiveness." However, he acknowledged that "[i]n some surgical procedures . . . the 'feel' of a device in the hands of the surgeon may be crucial to properly executing the surgical technique. The importance of the 'feel' of a device could be a critical factor which may affect the outcome of the procedure, and, ultimately, the safety of the patient." In those situations, "[i]f a safer medical device compromises patient safety, worker safety or the medical integrity, its use would not be required." Def. Mot. Exh. 13.

II. Analysis

The defendant has moved for summary judgment under Fed. R. Civ. P. 56(a).[4] Its argument is in three parts. First, it seeks to preclude the plaintiff's sole expert witness, Dr. Brian Benda, as unreliable. Second, and in the alternative, it argues that the plaintiff cannot sustain her strict products liability

[4] The defendant is entitled to summary judgment if there "is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the initial burden of demonstrating an absence of genuine issues of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). An issue is genuine if there is a sufficient evidentiary basis for a reasonable jury to find for the non-moving party; it is material if it may affect the outcome of the suit under governing law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

cause of action because she has not proven the existence of a reasonable alternative design. Third, it argues that the plaintiff cannot sustain her negligence claim. The Court proceeds in this order.

A. Motion to Exclude Dr. Benda's Testimony

The defendant seeks to exclude the opinion of the plaintiff's sole expert witness, Dr. Brian Benda, under the requirements of Fed. R. Evid. 702 and the Supreme Court's holding in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). District courts in the Third Circuit examine three factors in determining whether to preclude an expert opinion: 1) the expert's qualifications, 2) the reliability of the expert's methodology, and 3) the "fit" of the proposed testimony to the issues in the case. In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741-43 (3d Cir. 1994). The defendant does not dispute Dr. Benda's qualifications at this time.[5] Instead, it argues that Dr. Benda's opinion is unreliable and does not fit the issues in this case.

[5] Dr. Benda is a biomechanical engineer at ARCCA Incorporated in Penns Park, PA. He holds a Ph.D. in Medical Engineering and Medical Physics from MIT and Harvard Medical School.

An expert opinion is reliable if it is based on "methods of procedures of science" rather than on "subjective belief or unsupported speculation." Daubert, 509 U.S. at 590. This test is flexible; a district court may consider whether a method was subject to peer review, whether it is generally accepted, the qualifications of the expert witness testifying based on the methodology, and the existence of standards controlling the technique's operation, among other factors. See, e.g., Oddi v. Ford Motor Co., 234 F.3d 136, 144-45 (3d Cir. 2000). If the Court finds by a preponderance of the evidence that the opinion is reliable, then it can admit the testimony. In re Paoli, 35 F.3d at 744.

Based on the record in front of the Court of Dr. Benda's testimony and reports,[6] Dr. Benda's expert opinion can be categorized into three types of conclusions: 1) Ms. Kordek's physiological reactions when the accident occurred; 2) an engineering-based assessment of the conventional scalpel design;

[6] In the instant case, Dr. Benda has submitted two expert reports and was deposed in August 2012. His first expert report is dated March 1, 2012. Expert Report, Dr. Brian Benda, Mar. 1, 2012 ("Benda Report I") (Def. Mot. Exh. 15). His second report is dated July 31, 2012. Supplemental Report, Dr. Brian Benda, July 31, 2012 ("Benda Report II") (Def. Mot. Exh. 16). His deposition was held on August 1, 2012. Tr. Dep. Brian Benda ("Benda Dep.") (excerpts in Def. Mot. Exh. 18).

and 3) the availability of a reasonable alternative design — that is, the retractable shield scalpel.

The Court finds that the first two "conclusions" are sufficiently reliable to pass Daubert muster. First, Dr. Benda has described the neurological reactions that "kicked in" when Ms. Kordek attempted to remove the shield as a "pull away/pull back" effect which resulted in a puncture of her medial right wrist. Benda Report I at 8. Because Dr. Benda has performed peer-reviewed research on how the body responds when acted upon by forces, and because in the instant case he has reviewed the exhibits related to Ms. Kordek's injury and her testimony regarding the incident, the Court holds that Dr. Benda's testimony is reliable in this aspect. Id. at 2-4.

Next, Dr. Benda analyzed the design of the conventional scalpel that injured Ms. Kordek. He used a two-step "product design" analysis: he first conducted a hazard identification and assessment analysis, in which he identified and examined the manners in which a consumer may be injured through foreseeable uses of the product; then, he engaged in a hazard mitigation analysis, in which he outlined the steps that could be taken to mitigate the risks identified earlier. Id. at 10.

In terms of hazard identification, Dr. Benda stated that contact with a sharp blade is a hazard associated with a foreseeable use of the scalpel. He also identified five steps in which the sharp blade could potentially injure a user. Id. at 11-12. In terms of hazard mitigation, Dr. Benda stated that it was appropriate for the defendant to opt to provide a guard to mitigate the hazard. However, Dr. Benda determined that the design of the guard itself was inadequate, first because the act of removing the guard required the fingers to be in "close proximity" to the exposed blade, and second because the blade was exposed for periods of time in which it was unnecessary to be exposed. Id. at 12-13. Dr. Benda concluded that the scalpel shield's design was inadequate. Id. at 17.

The Court holds that Dr. Benda's analysis of the conventional scalpel through the two-part methodology described above is also sufficiently reliable. Dr. Benda cited to several standard operating manuals from the Department of Defense and the National Safety Council that adopt similar methodologies.[7] Id. at 46. He also based his conclusions on personal

[7] Indeed, the defendant's reply concedes that Dr. Benda's hazard risk assessment and mitigation analysis may be "supported by broad engineering principles." Def. Rep. at 4.

observations of the conventional scalpel's design. Finally, his discussion of the conventional scalpel's design within the context of standard engineering methodologies may be helpful to the jury, even if, as the defendant contends, his final conclusion is intuitive.

Third, Dr. Benda concluded that the retractable shield scalpel is a "reasonable alternative" to the conventional scalpel. He reached this conclusion by comparing the retractable shield scalpel to the conventional one used by Ms. Kordek and determining that the retractable shield scalpel provided two advantages: "first, the blade can be exposed using a single hand; second, the action required to expose the blade moves the involved hand away from the sharp edge." Id. at 13. If Ms. Kordek had used a retractable shield scalpel, "the mechanism that caused her injuries would have been eliminated." Id. at 16. From these observations, Dr. Benda concluded that an "alternative design was available at the time of the subject incident." Id. at 18.

Unlike Dr. Benda's analysis regarding the scalpel that injured Ms. Kordek, his analysis regarding a reasonable alternative was not tied to any hazard identification and mitigation analysis. It is thus unclear whether this method of

analysis has been tested, was subject to peer review or publication, has an identifiable rate of error, or is generally accepted. See generally Oddi, 234 F.3d at 144-45.

Moreover, in concluding that the retractable shield scalpel is a reasonable alternative to the conventional one, Dr. Benda's definition of "reasonable alternative" is narrow. Dr. Benda admitted that he compared the scalpels only as to a single risk: inadvertent exposure to the blade in the manner experienced by Ms. Kordek. He did not consider other risks that may be associated with the retractable scalpel. He did not factor into his opinion the number of reported injuries sustained as a result of this exposure. He did not rely on medical literature to determine the efficacy of the retractable shield scalpel in reducing percutaneous injuries. He did not consider the opinions of government regulators.[8] Most crucially, he did not speak with any physicians about whether the two

[8] In fact, at deposition, Dr. Benda stated that he had no reason to disagree with OSHA's statement that the safety of patients may sometimes be better served by the use of a non-safety-engineered medical device. Benda Dep. 275:18-277:9.

scalpels are comparable in feel and utility.[9] Benda Dep. 258:9-24; 252:14-253:20; 315:6-18; 320:22-321:19; 266:20-24.

Thus, Dr. Benda's definition of "reasonable alternative" is confined to the issue of whether the retractable shield product would have protected Ms. Kordek from the injuries she sustained by using the conventional product. Dr. Benda's answer in the affirmative to this limited question is of little help to the Court. Not only is his definition of "reasonable alternative" far narrower than the one the Court must utilize, his conclusion as to that question is fairly obvious, as well.

However, the Court holds that Dr. Benda's opinion regarding the existence of a reasonable alternative, in the context of his narrow reasoning as described above, should not be precluded. As the Third Circuit has stated, "The grounds for the expert's opinion merely have to be good, they do not have to be perfect. The judge might think that there are good grounds for an expert's conclusion . . . even if the judge thinks that a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different

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[9] Although Dr. Benda did incorporate the deposition testimony of Ms. Horner, the plaintiff's supervisor and nurse manager, Ms. Horner does not perform surgical operations herself.

result." In re Paoli, 35 F.3d at 744. Under this standard, the Court finds that Dr. Benda's narrow "reasonable alternative" analysis is sufficiently reliable. The Court thus denies the defendant's motion to preclude Dr. Benda's opinion and proceeds to a substantive analysis of the facts.

B. Strict Liability

The defendant asserts that even if Dr. Benda's opinion is admitted, Ms. Kordek's strict liability state law claim fails because she has not established sufficient facts for a reasonable jury to conclude that a reasonable alternative design exists. The presence of a reasonable alternative design is a central issue for determining whether a design is defective under either the Restatement (Third) or Restatement (Second) of Torts. The Court will grant the defendant's motion for summary judgment as to the plaintiff's strict liability cause of action.

1. Second or Third Restatement of Torts

First, the Court will briefly address whether it applies the Restatement (Third) or Restatement (Second) of Torts.[10] The

[10] In her original complaint in state court, which was removed to federal court, the plaintiff's strict liability action was

federal courts apply Pennsylvania state law when considering a strict products liability cause of action. As of the date of this opinion, the Pennsylvania Supreme Court has not expressly ruled on whether its strict liability law should be governed by the Restatement (Third) or Restatement (Second) of Torts.

In June 2011, the Third Circuit directed federal district courts to apply the Restatement (Third) to design defect claims arising under Pennsylvania law. Covell v. Bell Sports, Inc., 651 F.3d 357, 360 (3d Cir. 2011). District courts are bound by such instructions by the Third Circuit "unless the state supreme court issues a contrary decision or it appears from a subsequent decision of the appellate courts that the court of appeals erred." Largoza v. Gen. Elec. Co., 538 F. Supp. 1164, 1166 (E.D. Pa. 1982). Thus, absent a change in Pennsylvania law in the interim between Covell and the instant decision, this Court must apply the Restatement (Third).

Since Covell, the Pennsylvania Supreme Court has neither affirmed nor rejected the Third Circuit's application of the

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asserted under the Restatement (Second) of Torts. Compl. ¶ 36. However, at this stage, both parties have briefed the issues under both Restatements.

Restatement (Third).[11] It was given an opportunity to make such a decision in Beard v. Johnson & Johnson, Inc., in which the appellee invited the Supreme Court to adopt the Restatement (Third), but it did not take the invitation. See 41 A.3d 823, 836 (Pa. 2012) (acknowledging the "continuing state of disrepair" in this arena but declining to decide on the appropriate Restatement "pending remediation of the foundational deficiencies"). Because Beard did not "affirmatively disavow the premise of the Covell decision," this Court is still bound by Covell. Cf. Sansom v. Crown Equip. Corp., No. 10-958, 2012 WL 3027989, at *4-6 (W.D. Pa. July 24, 2012). The Court will therefore apply the Restatement (Third) of Torts to its subsequent analysis.[12] The Court notes, however, that it does

[11] A comprehensive summary of the state of Pennsylvania products liability law can be found in Sansom v. Crown Equip. Corp., a Western District of Pennsylvania decision from July 2012. No. 10-958, 2012 WL 3027989, at *4-6 (W.D. Pa. July 24, 2012).

[12] Indeed, the majority of cases deciding this issue post-Beard have decided to apply the Restatement (Third) of Torts, as well. See, e.g., Vaskas v. Kenworth Truck Co., No. 10-1024, 2013 WL 101612, at *6 (M.D. Pa. Jan. 8, 2013); Lynn v. Yamaha Golf-Car Co., No. 10-1059, 2012 WL 3544774, at *12 (W.D. Pa. Aug. 16, 2012); Sansom v. Crown Equip. Corp., No. 10-958, 2012 WL 3027989, at *4-6 (W.D. Pa. July 24, 2012); Giehl v. Terex Util., No. 12-83, 2012 WL 1183719, at *9 (M.D. Pa. Apr. 9, 2012); but see Sikkelee v. Precision Airmotive Corp., 876 F.Supp.2d 479, 490 (M.D. Pa. 2012); Carpenter v. Shu-Bee's, Inc., No. 10-0734, 2012 WL 2740896 (E.D. Pa. July 9, 2012).

not believe that its decision to apply the Restatement (Third) will change the outcome of its decision.[13]

2. Reasonable Alternative Design

Section 2(b) of the Restatement (Third) of Torts, which governs design defect strict liability, explicitly requires an inquiry into the existence of a reasonable alternative design. It states that a product "is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller . . . and the omission of the alternative design renders the product not reasonably safe." Restatement

[13] To the contrary, because the presence of a reasonable alternative design is also a central issue in the balancing test found in the Restatement (Second), the Court likely would grant the defendant's motion under that Restatement, as well. See Surace v. Caterpillar, Inc., 111 F.3d 1039, 1046 (3d Cir. 1997) (listing as one of seven factors "the availability of a substitute product which would meet the same need and not be as unsafe."). Although the Court has not fully explored the remaining six factors, the Court notes that the conventional scalpel is a useful product to the public as a whole (factor 1), there have been minimal injuries reported in removing the guard (factor 2), and the danger of injury is obvious and the user should be aware of it (factor 6). There is no evidence in front of the Court comparing the expense of the two products as required for factor 4. Whether the user could have exercised care to avoid the danger (factor 5) and whether the manufacturer can spread the loss (factor 7) are issues of dispute between the parties.

(Third) of Torts, § 2(b). Thus, a threshold issue for determining whether a design is defective under the Restatement (Third) is whether there exists a reasonable alternative.

The court may consider a variety of factors in determining whether an alternative design is reasonable and whether the omission of this design renders the product unreasonably safe. Such factors include "the magnitude and probability of the foreseeable risks of harm, the instructions and warnings accompanying the product, and the nature and strength of consumer expectations regarding the product . . . [and the] relative advantages and disadvantages of the product as designed and as it alternatively could have been designed." Id. at cmt. f. The plaintiff bears the burden of proving that a reasonable alternative design was available at the time of the product's sale or distribution. Id. at cmt. d.

The plaintiff has asserted that the retractable shield scalpel is a reasonable alternative design to the one used by Ms. Kordek. She argued that the retractable shield has the same utility to the user and addresses and improves upon the same safety hazards. The Court disagrees. The Court is persuaded that the retractable shield products are not reasonable

alternatives because they create additional hazards which do not occur with the use of the conventional scalpel.

As the commentary of the Restatement (Third) states, "When evaluating the reasonableness of a design alternative, the overall safety of the product must be considered. It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product other dangers of equal or greater magnitude." Id. at cmt. f. Thus, the Court's determination of whether a product is a reasonable alternative design must be conducted comprehensively. The Court must not limit its analysis to the particular injury sustained by the plaintiff. See, e.g., Lynn v. Yamaha Golf-Car Co., No. 10-1059, 2012 WL 3544774, at *15 (W.D. Pa. Aug. 16, 2012) ("The overall safety of the alternative design must be considered, for the omission of an alternative design that would have prevented or reduced the harm in one instance but gives rise to other, more serious risks in another would not render the initial product unreasonably dangerous."); Riley v. Becton Dickinson Vascular Access, Inc., 913 F. Supp. 879, 886 (E.D. Pa. 1995) (concluding that a substitute may not be "safer overall when other aspects of the alternative design are considered"); Beard v. Johnson &

Johnson, 41 A.3d at 835, n.14 (2012) ("[A]lternative designs must be safer to the relevant set of users overall, not just the plaintiff, and . . . an argument to the contrary [is] an absurd position.") (internal citations omitted).

This comprehensive analysis reveals that retractable shield scalpel products are not reasonable alternatives to conventional scalpels. First, the defendant's expert, Dr. Robert Solomon, an emergency room physician, has testified that the retractable shield scalpel products are bulkier. That bulkiness "may negatively affect precision handling of the instrument, which is especially important when a procedure requires a meticulous approach." Report, Dr. Robert Solomon at 2. There is evidence in healthcare publications that Dr. Solomon's experience is not unique. According to one study, 68% of doctors surveyed were concerned with their line of sight when using such products. See Def. Mot. Exh. 7A-E (detailing the results of studies that have found, for example, that doctors find that the scalpels "have cumbersome handling parts or pieces.").

Second, government regulatory bodies do not ban conventional scalpel products and instead allow their use where they are medically necessary. In response to an inquiry from

the defendant, OSHA noted that the "feel" of a device by the surgeon may affect the outcome of the procedure and the safety of the patient. Thus, it concluded, "[i]f a safer medical device compromises patient safety, worker safety, or the medical integrity, its use would not be required." Def. Mot. Exh. 13. OSHA's position is also supported by similar statements from the American College of Surgeons. Def. Mot. Exh. 7F.

Third, there is no statistical evidence indicating that the conventional scalpel has a dangerously high rate of injury. The defendant asserts that the known rate of injury from removing the guard from a conventional scalpel is minimal, and may be as low as one. See Def. Mot. Exh. 7(b); Def. Mot. Exh. 8. The low risk of injury associated with the conventional scalpel is relevant to the analysis in the Restatement (Third) regarding whether the "omission of the alternative design renders the product not reasonably safe," as it appears that the conventional product is reasonably safe without the alternative design. Restatement (Third) of Torts §2(b).

Another Eastern District of Pennsylvania case, Riley v. Becton Dickinson Vascular Access, Inc., is very persuasive to the Court. The facts of Riley are similar to the facts in the

instant case:[14] a nurse who contracted HIV when stuck with an intravenous catheter needle brought a products liability action against the defendant-manufacturer. 913 F. Supp. 879, 880 (E.D. Pa. 1995). The plaintiff argued that a reasonable alternative was available in the form of a catheter with a retractable needle that was at that time manufactured and marketed by the defendant. Id. at 886. The district court disagreed. It pointed to evidence, both from the hospital at issue and in healthcare publications, that suggested that the retractable needle had safety and pragmatic problems. Id. It concluded that the substitute may not be "safer overall when other aspects of the alternative design are considered." Id.

The plaintiff argues that she has established genuine issues of material fact sufficient to defeat a motion for summary judgment. She points to testimony from Ms. Kordek's supervisor, Ms. Horner; the defendant's corporate designee, Mr. Chrisbacher; and advertising literature from the defendant. Ms.

[14] The Court is not persuaded by the factual distinctions identified by the plaintiff between Riley and the instant case. See Pl. Opp. at 34-44. For example, the plaintiff has not offered evidence that the risk of injury when removing the guard from a scalpel is much higher than the risk of HIV exposure when using a catheter. Moreover, the fact that this case involves advertising materials, and the Riley case had no such advertisements, is insufficient to distinguish the two.

Horner, a nurse manager at the Albert Einstein Medical Center, testified that the staff "really liked" the retractable shield scalpels, and the plaintiff contends that this testimony suggests a conflict in whether medical professionals prefer the conventional or retractable shield scalpel. Mr. Chrisbacher testified that the ability of the protected disposable scalpel to retract its shield with the action of one hand improved the safety of the scalpel, which the plaintiff argues supports her position that the retractable shield scalpel is safer overall. BD had also developed a series of advertisements that touted the retractable shield products as "virtually the same size and weight" as conventional scalpels; according to the plaintiff, these products should be considered reasonable alternatives. Pl. Opp. at 42. See also Tr., Oral Argument 1/9/13, 32:19-33:3.

The Court is not persuaded that these pieces of evidence and testimony cause a genuine issue of material fact regarding whether medical professionals experience difficulty utilizing the retractable shield scalpel. Ms. Horner does not perform operations and does not speak to the bulkiness of the products when operating. When she stated that the "staff really liked" the retractable shield scalpel, it is not clear whether she was referring to staff who prepared the rooms for operations or

staff who actually performed these operations. Horner Dep. 88:17-19. In a similar vein, Mr. Chrisbacher's testimony about the mechanics of the retractable shield scalpel also does not express an opinion on the experiences of medical professionals who must handle the instruments during operations. Chrisbacher Dep. 41:23-42:1. The BD advertisements' expression that the products are "virtually" the same in size and shape is of limited relevancy to the actual experience of medical professionals. Taken together, they are not a sufficient basis for a reasonable jury to find in favor of the plaintiff.

Finally, there is the narrow expert opinion of Dr. Benda. Dr. Benda's testimony, although admissible, is of little persuasion to the Court. As discussed earlier, Dr. Benda's opinion is admittedly narrow on the "reasonable alternative" issue. Dr. Benda's conclusion does not consider the opinions of medical professionals. He did not consider whether the retractable shield scalpel posed any risks that are not posed by the conventional scalpel. He did not consider the cost of retractable shield scalpels as compared to the conventional ones. He was not familiar with the statements from OSHA, and when questioned at deposition, he stated that he had no reason to disagree with OSHA's position that the safety of patients may

sometimes be better served by the use of a non-safety-engineered medical device. Benda Dep. 275:18-277:9. Dr. Benda may have concluded that the retractable shield scalpel is a "reasonable alternative" as he defined it, but the scope of his analysis is far narrower than that which must be conducted by the Court.

Because of the reasons stated above, the Court holds that no reasonable jury could find that the retractable shield scalpel is a reasonable alternative design. Without the establishment of such an alternative, the plaintiff cannot prove her strict liability cause of action. The Court grants the defendant's motion for summary judgment as to this claim.

C. Negligence

Finally, the defendant contends that the plaintiff has not put forth sufficient evidence to sustain a negligence claim. Under Pennsylvania law, a plaintiff's negligence claim must demonstrate each of the following factors: 1) a duty or obligation recognized by the law, requiring the actor to conform to a certain standard of conduct; 2) a failure to conform to the standard required; 3) a causal connection between the conduct and the resulting injury, and 4) actual loss or damage resulting

to the interests of another. Morena v. S. Hills Health Sys., 501 Pa. 634, 642 n.5 (1983).

With regard to the duty of care analysis, Ms. Kordek's relationship to BD is that of a foreseeable consumer of its product, which would likely be sufficient to establish a duty of care. In addition, the defendant concedes in its reply that BD owes a duty of care to Ms. Kordek. Def. Rep. at 51. However, because the Court finds that the plaintiff has not established a breach of this duty, it need not analyze the Althaus factors.[15]

Instead, the Court finds that no reasonable jury could find that the defendant has breached its duty here by manufacturing the conventional scalpel that injured Ms. Kordek. As stated earlier, BD's conventional scalpels are not defective under the Restatement (Third); the defendant's manufacture of such scalpels cannot be perceived as a breach of any duty of care owed to Ms. Kordek. The plaintiff cannot prove that the defendant breached a duty or failed to conform to the standard

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[15] In Pennsylvania, a duty of care inquiry concerns the Althaus factors: the relationship between the parties; the social utility of defendant's conduct; the nature of the risk imposed and foreseeability of the harm incurred; the consequences of imposing a duty upon the defendant; and the overall public interest in the proposed solution. Althaus v. Cohen, 562 Pa. 547, 553 (2000).

required, and its negligence cause of action fails as a matter of law. The Court grants the defendant's motion for summary judgment as to this claim.

Thus, the Court denies the defendant's motion to preclude the expert opinion of Dr. Brian Benda. However, the Court grants the defendant's motion for summary judgment as to the plaintiff's strict liability and negligence causes of action. Judgment is hereby entered in favor of the defendant on all counts.

An appropriate order shall issue separately.