IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

GERALD R. SMITH,	*	
	*	
Plaintiff,	*	
	*	
v.	*	Civil Action No. AW-07-3196
	*	
CENTRAL ADMIXTURE PHARMACY SERVICES, INC.,	*	
	*	
	*	
Defendant.	*	
	*	

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MEMORANDUM OPINION

Plaintiff filed this action against Defendant on November 28, 2007. Currently pending before the Court is Defendant's Motion to Exclude Testimony of David P. Suchard, M.D. (Doc. No. 52) and Defendant's Motion for Summary Judgment (Doc. No. 51). The Court has reviewed the entire record, as well as the pleadings, with respect to the instant motion. The issues have been fully briefed, and the Court held a hearing on these motions on January 20, 2010. *See* Local Rule 105.6 (D. Md. 2008). For the reasons stated more fully below and described at the hearing, the Court will DENY Defendant's Motion to Exclude Testimony of David P. Suchard, M.D., and GRANT IN PART and DENY IN PART Defendant's Motion for Summary Judgment.

I. FACTUAL AND PROCEDURAL BACKGROUND

On December 8, 2004, Gerald R. Smith ("Smith") underwent open-heart cardiac bypass surgery at Mary Washington Hospital in Fredericksburg, Virginia. The doctors infused cardioplegia solution, the medicated solution used to stop and restart the heart during cardiac bypass surgery, manufactured by Defendant Central Admixture Pharmacy Services, Inc.

("CAPS"), into Smith's body during the surgery. After the surgery, Smith allegedly developed systemic inflammatory response syndrome (SIRS), which caused him multi-organ failure, including renal failure. Consequently, he had a "complicated, painful, frightening extended hospital stay" and continued dialysis as an out-patient for several months afterwards. (Compl. ¶ 13.)

Dr. John Marshall Armitage was Smith's cardiac surgeon and never diagnosed Smith with SIRS. But, Plaintiff's expert, Dr. Herr, later stated that his condition was attributable to SIRS. (Doc. No. 56, Ex. 19 at 33.)

In September 2005, the Mary Washington Hospital closed its cardiac unit after one patient died after cardiac surgery and two others became seriously ill after undergoing surgery involving infusion of the CAPS-manufactured cardioplegia solution. On September 12, 2005, the Maryland Board of Pharmacy received a complaint, and the U.S. Food and Drug Administration's ("FDA's") Baltimore District Office began an investigation concerning patients at the Mary Washington Hospital who had developed SIRS after receiving CAPS cardioplegia while undergoing open-heart surgery. On September 16, 2005, CAPS recalled its cardioplegia solution, at the request of the Maryland State Board of Pharmacy. On January 10, 2006, the Maryland State Board of Pharmacy entered a consent order finding that CAPS "was not operating within the standards required of an aseptic facility suitable for the compounding of patient specific and anticipatory IV drug products." (Doc. 56, Ex. 1 at 7, ¶ 16.)

Smith brought this Complaint against CAPS on November 28, 2007, alleging negligence (Count I), strict products liability (Count II), breach of implied warranty (Count III), and breach of express warranty (Count IV), and seeking compensatory damages and punitive damages.

CAPS denies any liability for this incident. On May 14, 2009, CAPS moved for summary judgment on all counts, and moved to strike the testimony of Plaintiff's expert, David. P. Suchard.

II. MOTION TO EXCLUDE TESTIMONY OF DAVID P. SUCHARD

1. Standard of Review

Rule 702 of the Federal Rules of Evidence provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Federal Rules of Evidence Rule 702. "A trial judge, faced with a proffer of expert scientific testimony, must conduct 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.' The proponent of the testimony must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199-200 (4th Cir. 2001) (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993)).

"Unless he is to testify only to general [] principles that any [person in the profession] would know, the [proffered expert] must possess 'some special skill, knowledge or experience,' concerning the particular issue before the court." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 393 (D. Md. 2001) (quoting *Ancho v. Pentek Corp.*, 157 F.3d 512, 517 (7th Cir. 1998)). Additionally, "while the fit between an expert's specialized knowledge and experience and the issues before the court need not be exact . . . an expert's opinion is helpful to the trier of fact, and

therefore relevant under Rule 702, 'only to the extent the expert draws on some special skill, knowledge or experience to formulate that opinion.'" *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 392-393 (D. Md. 2001) (quoting *Ancho*, 157 F.3d at 518 (internal quotations omitted)).

In assessing reliability of an expert's testimony, a judge can consider, among other factors, "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199-200 (4th Cir. Md. 2001) (citing *Daubert*, 509 U.S. at 592-94; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150, 143 L. Ed. 2d 238, 119 S. Ct. 1167 (1999)).

2. Analysis

The qualifications of Plaintiff's expert, David P. Suchard, M.D. ("Dr. Suchard"), and the reliability of his methodology are at issue in this case. The Court believes the question of whether Dr. Suchard's testimony is admissible is a very close question. Making all inferences in favor of the non-movant, the Court finds that Dr. Suchard's testimony should not be stricken.

a. Qualifications

Dr. Suchard is Plaintiff's expert witness on the standard of care applicable to a pharmaceutical compounding manufacturer. Dr. Suchard has a B.S. in Chemistry, a B.A. in Biophysics, a Master's degrees in Epidemiology and Toxicology, and a medical degree. Moreover, he is a practicing toxicologist, and has observed the compounding of sterile preparations, reviewed compounding procedures, and has much experience in laboratory

techniques. To prepare his report for this case, he reviewed internal CAPS documents from 2004 produced by Defendant, including Defendant's TPN/CP/CRRT Validation report, CQAIP Quarterly Summary Reports, Employee gloved fingertip Bioburden Monitoring Logs, Air Bioburden Monitoring Log, Touch Plate Monitoring Logs and maintenance logs from 2004. (Doc. No. 57 at 3.) Dr. Suchard provided a short report, based on his examination of internal CAPS documents and the FDA report. He concluded that it is reasonably probable that CAPS cardioplegia solution was the source of the bacteria infection that caused Smith's organ failure. (Doc. No. 57 at 4).

Plaintiff offers this expert not as a specialist in cardioplegia production, but as a scientist generally knowledgeable about lab conditions. The Court agrees with Plaintiff that Dr. Suchard is qualified to testify as an expert in the area of aseptic sterile techniques, because that is an area that "any chemist, epidemiologist, physician, and/or toxicologist has sufficient scientific, technical, or other specialized knowledge above and beyond that of a laymen to assist the jury." (Doc. No. 57 at 14.) Dr. Suchard is offering his opinion on what the lab reports indicate about cleanliness at the CAPS lab, and does not need to be an expert in cardioplegia production to do so. The Court disagrees with Defendant's contention that a general scientist cannot testify as to the conclusions to be drawn from the internal CAPS documents, and that only someone with special knowledge about cardioplegia, or at least about pharmaceutics compounding could do so. Seeing as Dr. Suchard's testimony is limited to describing CAPS' procedures in relation to general laboratory techniques, it is admissible.

The Court agrees with Defendant that Dr. Suchard would not be qualified to testify as an expert on cardioplegia production. It is well established that "general expertise is not sufficient

to qualify [an expert] to testify on a matter that requires particularized knowledge, training, education, or experience." *Fitzgerald v. Smith & Nephew Richards, Inc.*, 1999 U.S. Dist. LEXIS 22709, 22709 (1999). Clearly, Dr. Suchard's experience in toxicology lab work is not closely enough fitted to pharmaceutical lab work or cardioplegia compounding to qualify him as an expert in this specific area. Defendant is correct that Suchard is not qualified to testify to any issues unique to pharmaceutical compounding of cardioplegia solution because he lacks the knowledge, skill, and experiences to do so. As Defendant notes, "prior to this case [Dr. Suchard] had never reviewed regulations pertaining to cardioplegia" and "never produced, manufactured or used cardioplegia," and thus cannot qualify as an expert on that issue. (Doc. No. 52). The Court also finds merit in Defendant's contention that because only a licensed pharmacist can oversee the process of cardioplegia production, and Dr. Suchard is not a licensed pharmacist, but rather an occupational and environmental physician, and has never been to a manufacturing facility where cardioplegia is produced, he cannot testify to any issues *unique* to the design, manufacture, operation, distribution or safety of the preparation or transporting of cardioplegia. This lack of experience with cardioplegia production does not negate his overall experience with labs as a toxicologist and M.D., however, and does not compel the Court to strike his testimony.

The stricken testimony in *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378 (D. Md. 2001), which Defendant argues is similar to Dr. Suchard's testimony, is distinguishable because Defendant is not offering Dr. Suchard as an expert on the safe design and manufacturing of cardioplegia solution, but rather on the "general issues of laboratory conditions and the probability of contamination," which are within the general area of knowledge of "anyone who is a chemist, epidemiologist, physician and/or toxicologist." (Doc. No. 57 at 11.) The Court in

Shreve v. Sears, Roebuck & Co. found the expert unqualified to testify as an expert on snow thrower manufacture because he had "no professional experience with respect to the design, manufacture, operation, or safety of outdoor power equipment, including snow throwers. [He] did not conduct a review of the literature on snow throwers. He has never been involved with any industry or government body charged with the responsibility of developing of overseeing safety standards for snow throwers or any similar device." 166 F. Supp. 2d 378 (D. Md. 2001). In this case, however, it appears that the expert has reviewed literature on the potential for contamination during drug compounding, has been involved in laboratory work, and has spent a significant amount of time reviewing relevant information to prepare his opinion. (Doc. No. 57 at 12.)

In any case, any possible defects in Dr. Suchard's testimony are clear on the face of the report itself, and will be readily apparent to the jury.

b. Reliability

Defendant has not convinced the Court at this stage that Dr. Suchard's testimony is unreliable. The Court will not exercise its discretion to exclude this testimony based solely on Defendant's assertion that Dr. Suchard's testimony is not reliable because there is too great of an analytical gap between the data and Suchard's opinion. (Doc. No. 52 at 9.) Defendant argues that Dr. Suchard's conclusion is based on "a random selection of internal documents" and that this reliance itself shows "his lack of understanding of the pharmaceutical compounding processes." (Doc. No. 52 at 9.) But the Court believes that the relationship between the data and opinion is not so far-fetched that the opinion must be stricken. Instead, the Court will allow the jury to assess the credibility of this evidence.

III. MOTION FOR SUMMARY JUDGMENT

1. Standard of Review

Summary judgment is only appropriate if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-25 (1986). The court must draw all justifiable inferences in favor of the nonmoving party, including questions of credibility and of the weight to be accorded to particular evidence. *Masson v. New Yorker Magazine, Inc.*, 501 U.S. 496, 520 (1991) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)). To defeat a motion for summary judgment, the nonmoving party must come forward with affidavits or other similar evidence to show that a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). While the evidence of the nonmoving party is to be believed and all justifiable inferences drawn in his or her favor, a party cannot create a genuine dispute of material fact through mere speculation or compilation of inferences. S*ee Deans v. CSX Transp., Inc.*, 152 F.3d 326, 330-31 (4th Cir. 1998). Additionally, hearsay statements or conclusory statements with no evidentiary basis cannot support or defeat a motion for summary judgment. *See Greensboro Prof'l Fire Fighters Ass'n, Local 3157 v. City of Greensboro*, 64 F.3d 962, 967 (4th Cir. 1995).

2. Analysis

a. Strict liability, negligence, and implied warranty of merchantability

In order to prevail on a products liability claim a plaintiff must show: (1) the existence of a defect; (2) the attribution of the defect to the seller; and (3) a causal relation between the defect

and the injury. *See Watson v. Sunbeam Corp.*, 816 F. Supp. 384, 387 (D. Md. 1993). "The elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence . . . or breach of warranty." *Watson v. Sunbeam Corp.*, 816 F. Supp. 384, 387 n.3 (D. Md. 1993) (internal citations omitted). "A negligence claim has a more onerous evidentiary burden than strict liability in torts, and a breach of implied warranty places more procedural requirements and limitations." *Murphy v. Playtex Family Prods. Corp.*, 176 F. Supp. 2d 473, 494-495 (D. Md. 2001). "A warranty of merchantability is implied in the contract of sale when the seller of goods is a merchant with respect to goods of that kind.'" *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 421-422 (D. Md. 2001).

"The Maryland cases reflect that proof of a product defect may be adduced by one or more of three legitimate paradigms: (1) direct proof based on the nature of the accident in the context of the particular product involved; (2) circumstantial proof based on an inference of a defect from a weighing of several factors; and (3) direct affirmative proof through opinion testimony by an expert witness." *Id*.

Plaintiff uses the circumstantial method of proof of product liability, as he has no direct evidence that the particular bag of cardioplegia, as produced by CAPS and used in Plaintiff, was contaminated. (Doc. No. 51 at 9.)

Courts in Maryland weigh five factors laid out in *Harrison v. Bill Cairns Pontiac of Marlow Heights, Inc.*, 77 Md. App. 41, 549 A.2d 385 (Md. Ct. Spec. App. 1988), to "determin[e] whether a product defect may be inferred from circumstantial evidence: (1) expert testimony as to possible causes; (2) the occurrence of the accident a short time after the sale; (3) same accidents in similar products; (4) the elimination of other causes of the accident; (5) the type of

accident that does not happen without a defect." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 410 (D. Md. 2001); *see also Gross v. DaimlerChrysler Corp.*, 2003 U.S. Dist. LEXIS 24673 (D. Md. Sept. 29, 2003) (granting summary judgment on a circumstantial manufacturing defect claim because, "[i]n the final analysis, only one of the *Harrison* factors weighs in favor of Gross"); *Watson v. Sunbeam Corp.*, 816 F. Supp. 384, 388 (D.Md. 1993) (denying summary judgment because deposition testimony "directly contradicted" the other two causes the defendant identified, leaving three for the plaintiff, one neutral, and one for the defendant).

The Court finds that the balance of these *Harrison* factors weighs in favor of Plaintiff.

i. Expert testimony as to possible causes

Plaintiff contends that Dr. Suchard's testimony tends to support the possibility that Defendant's cardioplegia solution was defectively manufactured. Indeed, Dr. Suchard stated that, "it is more probable than not that the cardioplegia solution utilized during Mr. Smith's cardiac bypass surgery was contaminated . . ." (Doc. 56, Ex. 14 at 69.) Defendant argues that Dr. Suchard is unqualified to testify as to the manufacture, production, or distribution of cardioplegia, and thus his testimony cannot establish that cardioplegia was the cause of Plaintiff's SIRS. Additionally, Defendant notes that its expert, Dr. Lloyd Allen, has indicated that at the time of manufacture, CAPS was in compliance with all industry standards. As the Court has declined to exclude Dr. Suchard's testimony, this factor weighs in favor of Plaintiff.

ii. Occurrence of the accident a short time after the sale

Because Plaintiff began showing signs of the infection two days after the December 8, 2004 surgery, this factor weighs in favor of Plaintiff.

iii. Same accidents in similar products

There is no dispute that patients who received other batches of CAPS cardioplegia suffered similar injuries. Plaintiff notes that Defendant's expert Donald Poretz, M.D., confirmed that cases of SIRS related to contaminated batches of Defendant's cardioplegia solution arose in March 2004, about ten months before Plaintiff's case, and the summer of 2005, six or seven months after Plaintiff's case. (Doc. No. 56, Ex. 21 at 34:3-8.) This factor thus weighs in favor of Plaintiff.

iv. Elimination of other causes of the accident

Plaintiff's expert Dr. Herr opined that the CAPS cardioplegia solution was the sole cause of Smith's development of SIRS. (Doc. No. 56, Ex. 19 at 9:8-10:9, 13:19-15:9, 20:21-21:2.) Indeed, in response to the question of "what's the basis of your opinion that the cardioplegia solution in this case was, in fact, the cause of the SIRS," Dr. Herr responded "I cannot find anything else in the medical record that would associate his SIRS event with any other disease process." (Doc. No. 56, Ex. 19 at 20:21-21:2.) Defendant claims that Plaintiff developed SIRS as a result of a pre-existing inflammatory condition. Defendant argues that Plaintiff's own treating cardiac surgeon, John Marshall Armitage, M.D., testified that due in large part to the extensive underlying inflammatory aortic pathology that Mr. Smith brought with him to the hospital, he specifically excluded Mr. Smith's case as one of the cases he believed were affected by allegedly contaminated cardioplegia. (Doc. No. 51 at 10.) But, Dr. Herr disagrees with this analysis. (Doc. No. 56, Ex. 19 at 33). Given that the parties have presented conflicting expert testimony on this issue, this factor is neutral.

v. Type of accident that does not happen without a defect

"The final factor of Harrison's five-factor test is whether the accident is 'of the type . . . that does not happen without a defect.' It is not entirely clear what this factor comprehends." *Watson v. Sunbeam Corp.*, 816 F. Supp. 384 (D. Md. 1993) (quoting *Harrison*, 77 Md. App. at 51, 549 A.2d at 390). Because Defendant has identified the pre-existing inflammatory condition as an alternative cause, the Court cannot say this is the sort of accident that does not happen without a defect. Thus this factor weighs in favor of the Defendant.

Thus, in sum, three factors weigh in Plaintiff's favor: Plaintiff has presented expert testimony that contaminated CAPS cardioplegia solution caused Plaintiff's case of SIRS, the infection began only two days after Plaintiff was infused with CAPS cardioplegia solution, and there have been similar accidents caused by the product both before and after Plaintiff's case. Plaintiff's expert, Dr. Herr, reviewed Plaintiff's medical records and opined that there was no possible cause of Plaintiff's development of SIRS other than contaminated cardioplegia solution, (Doc. No. 56, Ex. 19 at 9-10, 13-15, 20-21), but Defendant has neutralized this testimony with other testimony that Plaintiff could have developed SIRS as a result of a pre-existing inflammatory condition. Additionally, because there are other possible causes of the SIRS, such as pre-existing inflammatory condition, it cannot be deemed the type of accident that would not happen absent a defect, thus this factor weighs in favor of Defendant. Because the Plaintiff has shown that the balance of these factors weighs in his favor, the Court will deny Defendant's motion for summary judgment.

b. Breach of Express Warranty of Merchantability

At the January 20, 2010, hearing, Plaintiff conceded that he did not have sufficient evidence

to proceed with the claim for breach of express warranty of merchantability (Count IV) and conceded to its dismissal. Thus, the Court will dismiss this claim.

IV. CONCLUSION

The Court will DENY Defendant's Motion to Exclude Testimony of David P. Suchard, M.D., and GRANT IN PART and DENY IN PART Defendant's Motion for Summary Judgment. A separate Order will follow.

March 18, 2010
Date

/s/
Alexander Williams, Jr.
United States District Judge