IP 01-0752-C Y/K Theofanis v Boston Scientific
Judge Richard L. Young Signed on 3/16/05

NOT INTENDED FOR PUBLICATION IN PRINT

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THEOFANIS, KATHERINE PERSONAL RESPRESENTATIVE OF THE ESTATE OF CHRIS C THEOFANIS DECEASED,	)	
Plaintiff,	)	
vs.	)	
BOSTON SCIENTIFIC CORPORATION, BOSTON SCIENTIFIC SCIMED INC,	)	CAUSE NO. IP01-0752-C-Y/K
Defendants.	)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

KATHERINE THEOFANIS, Personal Representative of the Estate of CHRIS C. THEOFANIS, deceased, Plaintiff,	)	
vs.	)	IP 01-752-C-Y/K
BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC., Defendants.	)	

ENTRY ON DEFENDANTS' MOTION TO EXCLUDE PROPOSED TESTIMONY BY DR. BRUCE BARKALOW

This matter now comes before the court on Defendants' Motion to Exclude Proposed Testimony of Dr. Bruce Barkalow ("Dr. Barkalow"), Plaintiff's expert on causation. For the reasons explained below, the court **DENIES** Defendants' motion.

I. Background

The Rotablator System consists of a rotating diamond-coated burr that is maneuvered by a physician over a stainless steel guide wire through a flexible catheter to the diseased portion of the patient's artery. It is a Class III medical device regulated by the FDA. Before receiving its final FDA approval, the Rotoblator System underwent an extensive investigation period with the FDA known as Pre-Market Approval ("PMA") to establish the safety and effectiveness of the device for its intended use. The design and manufacturing process associated with the Rotablator System was ultimately approved by the FDA subject to certain "conditions of approval" and Federal regulations. Specifically, the "conditions of approval" and Federal regulations prohibited the Defendants from making any changes to the design or component

parts of the Rotablator System which could potentially affect the safety and effectiveness of the device without first notifying the FDA and obtaining approval of the changes.

The brake component of the Rotablator System holds the guide wire stationary in a person's artery during the procedure. The Rotoblator System's original brake component consisted of a one-piece device known as a collet. After the Rotoblator System was approved by the FDA, the design of the brake component was changed to a two-piece collet. Boston Scientific did not submit this change for FDA approval. The unapproved brake design ultimately proved less effective in securing the guide wire as intended and as a result, Boston Scientific recalled the less effective brake design in August 1999 (one month after Mr. Theophanis died) and returned to the original design approved by the FDA.

II. Discussion

A. Standard of Review

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Civil Procedure and the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 579 (1993). Federal Rule of Evidence 702 ("Rule 702"), 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.

FED. R. EVID. 702.

Before admitting expert testimony, *Daubert* requires that the district court function as a gatekeeper to ensure that expert testimony is both relevant and reliable. *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). "In other words, as a threshold matter 'a district court is

required to determine (1) whether the expert would testify to valid scientific knowledge, and (2) whether that testimony would assist the trier of fact with a fact at issue.'" *Id.* (quoting *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 590 (7th Cir. 2000)).

In ascertaining whether an expert's opinion pertains to scientific knowledge, the court must consider whether the methodology employed by the expert in reaching his or her conclusion is sufficiently grounded in the "methods and procedures of science." *Daubert*, 509 U.S. at 590. This inquiry ensures that the expert's testimony is based upon more than just "subjective belief or unsupported speculation." *Id*. The court's role as gatekeeper is strictly limited to an examination of the expert's methodology. *Smith*, 215 F.3d at 718. "The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Id.* (citing *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.")).

B. Dr. Barkalow's Qualifications

Dr. Barkalow's testimony is introduced by Plaintiff in an effort to show the likely cause of the guide wire fracture.[1] Dr. Barkalow holds a Ph.D. in biomedical engineering and an M.S. in physics. He is both an engineer and a registered safety engineer pertaining to medical instrumentation, and has acted as a consultant to the FDA in the context of medical device applications, recalls, labeling, and corporate compliance. Defendants concede Dr. Barkalow is qualified to give an expert opinion in this case.

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[1] The issue of causation is complicated by the fact that following Mr. Theofanis' death, the hospital kept only his heart and the broken piece of guide wire. The rest of the guide wire and the Rotablator machine are no longer in existence.

C. Argument

At issue is Dr. Barkalow's opinion as to the cause of the guide wire's facture:

> (23) In my opinion, based on the evidence reviewed in this matter, during the 8 passes of the burr in Mr. Theofanis's coronary artery, the unappreciated movement of the guide wire allowed by insufficient braking effect from the Rotablator® Advancer permitted the guide wire to kink or form a loop such that the diamond coated portion of the burr cut through the guide wire.

Barkalow Report at 7. Defendants advance four reasons in support of their motion. The court will discuss each below.

First, Defendants argue that Dr. Barkalow's methodology is flawed by claiming that it was improper for him to assume that Dr. Fry used the Rotablator correctly.

> (15) *In the absence of any evidence to the contrary*, I assume the subject Rotablator was used by Dr. Fry on July 1, 1999, correctly and according to Boston Scientific instructions, guidelines, precautions, and warnings.

Barkalow Report at 5 (emphasis added).

There is no evidence in the record that Dr. Fry did anything improper during the procedure. Dr. Barkalow's Report reflects that in forming his opinion, he reviewed numerous documents, including the medical and autopsy reports for Mr. Theofanis, the instructions pertaining to use of the device, and VHS tape of the procedure. Barkalow Report at 2-3. Thus, it is clear that in forming his opinion, Dr. Barkalow saw no evidence of any improper use of the equipment. Moreover, Defendants conceded this point. *See* Boston Scientific's Memorandum in Support of Motion to Exclude at 2-3 ("Boston Scientific is *not* contending that Dr. Fry did anything wrong during the Rotoblator procedure. . ." (emphasis in original)). Dr. Barkalow's assumption is therefore consistent with Defendants' position. The court therefore finds that Dr. Barkalow's assumption was a reasonable conclusion based upon his review of the relevant documents related to the procedure.

Second, Defendants argue that Dr. Barkalow failed to consider and rule out the potential ways for the burr to come into contact with the wire as identified by Dr. Marvin McKimpson ("Dr. McKimpson"), a metallurgist. Dr. McKimpson stated in his Report, "Perhaps the tapered section of the guide wire became looped or kinked in the front of the rapidly-rotating burr and came in contact with this burr as the burr was being moved forward." McKimpson Report at 2. Dr. Barkalow did not ignore this potential cause of the guide wire fracture; in fact, he actually concludes that looping or kinking occurred in this case. Barkalow Report at 5.

Dr. Barkalow also addresses and rules out the alternative scenario suggested by Dr. McKimpson that contact between the wire and the inside of the rotating burr could have been a cause. In reaching this conclusion, he was able to rule out manufacturing defects, as well as torsion, tension or fatigue failures. Barkalow Report at 5 ("Review of Dr. McKimpson's observations and findings related to the SEM analysis indicate the guide wire fracture was inconsistent with failure by torsion, tension or fatigue failures."). These other causes were likewise ruled out by Defendants' own expert, Clint Finger. Finger Report at 4. Dr. Barkalow then notes that the inside of the burr is made of brass and that the wire is made of steel. Since brass is softer than steel, it would not likely cause the guide wire to fracture. Barkalow Report at 5. Before issuing his report, Dr. Barkalow also consulted the FDA Manufacturer and User Facility Device Experience Reports, or "MAUDE" reports, which described similar instances where the burr had contacted the wire causing a failure. Barkalow Report at 5. The court therefore finds that Dr. Barkalow did consider the potential causes of the guide wire fracture suggested by Dr. McKimpson, and concluded that the most probable cause of the guide wire fracture was a problem with the braking system, which allowed the unappreciated portion of the guide wire to kink or loop, thereby allowing the diamond coated portion of the burr to cut

through the guide wire.

Third, Defendants take issue with the fact that Dr. Barkalow did not perform additional testing suggested by Dr. McKimpson. *See* McKimpson Report at 2. Dr. McKimpson's Report stated that additional testing would be "desirable" to "support this analysis of the ruptured guide wire." McKimpson Report at 2. Testing, therefore, was offered as a means to further substantiate his theory as to the possible causes of the guide wire fracture. It was not a necessary prerequisite for the acceptance of this opinion. Accordingly, Dr. Barkalow's decision not to conduct further testing, as suggested by Dr. McKimpson, goes to the weight of his testimony, not its admissibility.

The fourth and final claim made by Defendants is that Dr. Barkalow offers no evidence to prove that insufficient braking will form a kink or loop in the wire. However, Defendants own product literature makes it clear that uncontrolled movement of the wire leads to kinking, looping and possible wire fracture. In the absence of any evidence of the misuse of the product by Dr. Fry during the insertion of the wire and operation of the burr, the evidence is clear that the only way for looping or kinking of the wire to occur is from unanticipated movement of the wire. Since the evidence demonstrates that the burr cut the wire, and since the evidence reflects that Dr. Fry used the clip-on wire torquer to secure one end of the guide wire, one can reasonably conclude that the logical area of the guide wire instability was the brake.

Finally, Defendants assert that Dr. Barkalow's testimony is irrelevant because he fails to address how Defendants negligently failed to comply with FDA regulations. As noted in the court's Entry on Defendants' Motion for Summary Judgment, dated June 24, 2003, Defendants own Regulatory Affairs Vice President, Michael Kallok and Defendants' Senior Manufacturing Engineering Manager, Lori Melkerson, both provided sufficient evidence to create genuine

issues of fact with respect to whether Defendants negligently failed to comply with the FDA regulations. Therefore, further evidence on this issue is not necessary. Dr. Barkalow's testimony relates to the cause of the guide wire fracture. Thus, his testimony is highly relevant to Plaintiff's negligence claim.

For the reasons explained above, and in light of all the evidence submitted by the parties, the court finds that Dr. Barkalow's opinion is based upon sufficient facts and data. The court further finds that Dr. Barkalow's methodology of ruling out the least likely causes of the guide wire fracture is a reliable methodology, given the number of documents he reviewed prior to forming his opinion, Barkalow Report at 4-5, and his professional experience dealing with forensic investigations of medical device failures. The court further finds that Dr. Barkalow has applied his methodology reliably to the facts of this case. Accordingly, Defendants' Motion to Exclude Proposed Testimony by Dr. Bruce Barkalow is **DENIED**.

III. Conclusion

For the reasons explained above, the court **DENIES** Defendants' Motion to Exclude Proposed Expert Testimony by Dr. Bruce Barkalow.

SO ORDERED this 16th day of March 2005.

RICHARD L. YOUNG, JUDGE
United States District Court

Southern District of Indiana

Copies to:

W. Scott Montross
Townsend & Montross
230 East Ohio Street
Indianapolis, IN 46204-2149

Kevin R. Knight
Ice Miller
One American Sq
P O Box 82001
Indianapolis, IN 46282-0002

John Tate
Stites & Harbison
1800 Aegon Center
400 W. Market St
Louisville, KY 40202-3352