

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

SUPRIYA GOYAL, M.D.,

Plaintiff,

v.

THERMAGE, INC.,

Defendant.

CIVIL NO.: WDQ-08-0020

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MEMORANDUM OPINION

Dr. Supriya Goyal Bellew¹ sued Thermage, Inc. for negligence, strict products liability, and breach of implied warranties. For the following reasons, Bellew’s motion to exclude the expert report and testimony of Larry Fennigkoh, PhD, will be denied.

I. Background

Beginning in September 2004, Bellew was employed as a cosmetic dermatology research fellow at the Maryland Laser, Skin, and Vein Institute. Bellew Dep. 90:17-91:3. Bellew treated patients using a ThermoCool device developed by Thermage to reduce the signs of aging in skin. *Id.* 124:3-16. The ThermoCool device has a handpiece, which the operator holds to a patient’s skin while pressing a button or foot pedal to deliver

¹ The Plaintiff will be referred to by her legal surname, “Bellew.” Supriya Goyal Bellew Dep. 6:7-19, March 12, 2009. Goyal is the Plaintiff’s middle name. *Id.* 6:18-19.

radio frequency pulses. *Id.* 111:8-112:5, 135:4-7. Bellew was taught to use the device by Drs. Robert and Margaret Weiss. *Id.* 130:9-10.

In October or November 2004, Bellew developed soreness and pain in her hand, arm, shoulder, and neck, which she associated with use of the ThermaCool device. *Id.* 208:13-20. On January 4, 2005, Bellew delivered two ThermaCool treatments and developed severe pain. *Id.* 170:6-8, 209:3-7, 213:18-214:4. On January 18, 2005, Bellew was diagnosed with "irritation [of her] right ulnar nerve secondary to repetitive motion," which "appear[ed] directly related to her use of the Thermage machine." ECF No. 64, Ex. 8. Bellew has since experienced chronic pain. Bellew Dep. 209:15-16.

On January 2, 2008, Bellew sued Thermage for negligence, strict products liability, and breach of warranty. ECF No. 1.² Thermage retained Fennigkoh, a biomedical and electrical engineer and professor at the Milwaukee School of Engineering, to evaluate the handpiece's ergonomic design. Pl.'s Mot., Ex. 3 at 1. Fennigkoh (1) identified risk factors of ulnar nerve injury, (2) took measurements, (3) compared the handpiece to other dermatological hand-held devices, and (3) observed clinicians give ThermaCool treatments. *Id.* at 3-10. He

² On July 1, 2010, this Court granted summary judgment to Thermage on Bellew's breach of warranty claims. ECF No. 80.

concluded that the handpiece was "not intrinsically dangerous [or] defective" and that it had not caused her ulnar neuropathy. *Id.* at 11. On March 22, 2010, Bellew moved to exclude Fennigkoh's report and related testimony. ECF No. 70.³

II. Analysis

Bellew has moved to exclude Fennigkoh's report under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

A. Rule 702 and *Daubert*

Under Rule 702, expert testimony is admissible if it will assist the trier of fact and is (1) "based upon sufficient facts or data," (2) "the product of reliable principles and methods," and (3) "the principles and methods [have been applied] reliably to the facts of the case." Fed. R. Evid. 702. As the *Daubert* Court has explained, evidence is admissible under Rule 702 if "it rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597; see also *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999) (extending *Daubert* to "the testimony of engineers and other experts who are not scientists"). The proponent of the expert testimony must prove its admissibility by a preponderance of the evidence. *Id.* at 590.

³ Because these matters are well-briefed and supported, no hearing is necessary. See *United States v. Davis*, 602 F. Supp. 2d 658, 663 (D. Md. 2009).

Several factors may be relevant to the determination of reliability, including: (1) whether a theory or technique has been tested, (2) whether it has been subjected to peer review and publication, (3) the known or potential rate of error, and (4) whether the theory or technique is generally accepted within a relevant scientific community. *Copper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001). The factors are "neither definitive nor exhaustive, and some may be more pertinent than others depending on the nature of the issue, the expert's particular expertise and the subject of his testimony." *Newman v. Motorola, Inc.*, 218 F. Supp. 2d 769, 733 (D. Md. 2002).

B. Fennigkoh's Report

Bellew contends that Fennigkoh's report is "incomplete" and "riddled with methodological errors." Pl.'s Mem. Supp. 24. She argues that the report should be excluded because Fennigkoh did not: (1) include measurements of the device's "b-b section" in his analysis, (2) weigh the device's cord in determining its weight and balance, (3) review the manufacturer's design documents, and (4) observe a live demonstration of the device Bellew used. *Id.* 9-23.

Thermage argues that Bellew's objections are proper subjects of cross-examination, not a basis for exclusion. Thermage contends that because it is unknown how Bellew held the

handpiece,⁴ Fennigkoh properly limited his analysis to the "a-a" section, where users are most likely to grip the device. Def.'s Opp'n 13.⁵ Similarly, Fennigkoh did not include measurements of the cord because there is no evidence of how the cord affected Bellew's use of the device, and the cord shifts throughout treatment, affecting the device's weight and balance in different ways. *Id.* 19. Fennigkoh did review some design documents and watched the video demonstration relied on by Bellew's expert. Fennigkoh Dep. 278:6-11, 279:20-280:4, 290:20-291:8, Oct. 16, 2009. Fennigkoh also attended a live demonstration of a Thermage handpiece to assess the degree of elbow flexion involved in administering a ThermaCool treatment. *Id.* 58:20-59:18.

To be admissible, the expert testimony need not be "irrefutable or certainly correct." *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006). The court's task is not to

⁴ At her March 12, 2009 deposition, Bellew testified "I can't tell you exactly how I held that device five years ago right after I was trained by Robert Weiss on how to do the procedures. It's been five years since I've done or seen that handpiece." Bellew Dep. 242:19-243:1, 250:1-5.

⁵ Fennigkoh has testified that the handpiece is "self-selecting" meaning that its user, although "[g]iven the opportunity to use it in a variety of ways, . . . will often self-select a position that is most comfortable." Larry Fennigkoh Dep. 75:2-8, Oct. 16, 2009. His report incorporated the different ways the device could be held, but his analysis focused on the "a-a" level. Pl.'s Mot., Ex. 3 at 6.

decide the correctness of the opinion, and “[a]s with all other admissible evidence, expert testimony is subject to testing by vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.” *Id.* (internal quotation marks and citation omitted).

But, an expert’s “conclusions regarding causation must have a basis in established fact and cannot be premised on mere suppositions.” *McLean v. 988011 Ontario, Ltd.*, 244 F.3d 797, 801 (6th Cir. 2000). If an expert’s report is based on assumed facts those facts “must find some support . . . in the record.” *Id.*; see also *Daubert*, 509 U.S. at 592 (“an expert is permitted wide latitude to offer opinions, including those that are not based on first-hand knowledge or observation.”).

Thermage has shown by a preponderance of the evidence that Fennigkoh’s opinion satisfies *Daubert* and Rule 702. Fennigkoh’s conclusions are based on the available evidence and are not so speculative as to be unreliable.⁶ His deposition testimony demonstrates that his process and techniques are defensible and

⁶ See *Boss v. Nissan N. Am., Inc.*, 228 Fed. Appx. 331, 337-38 (4th Cir. 2007)(expert testimony that particle jam caused steering malfunction was properly excluded when no evidence supported that theory, “the probability of a particle causing a jam [was] never established,” and “[t]he risk of a steering malfunction caused by particle jamming is not generally accepted in the engineering community”); *FedEx Ground Package Sys., Inc. v. Applications Int’l Corp.*, 695 F. Supp. 2d 216, 224-25 (W.D. Pa. 2010)(excluding expert report based on assumed facts the expert “could have and should have independently verified”).

his opinion is the product of reliable principles and methods.⁷ His testimony will assist the jury in deciding whether Bellew's injuries were caused by the handpiece's design.

The asserted flaws in Fennigkoh's report are the proper subject of cross-examination.⁸ The issues Bellew raises are straightforward, and, with the aid of cross-examination and Bellew's expert witness, a jury can determine whether the asserted deficiencies undermine Fennigkoh's opinion. Bellew's motion will be denied.

III. Conclusion

For the reasons stated above, Bellew's motion to exclude Fennigkoh's report and testimony will be denied.

February 17, 2011
Date

_____/s/_____
William D. Quarles, Jr.
United States District Judge

⁷ Fennigkoh's methodology and conclusions are based on several published studies, measurements of Bellew's hand and the device, Bellew's testimony, and ThermaCool procedure demonstrations. See Pl.'s Mot., Ex. 3 at 6-12.

⁸ "The district court must exclude expert testimony if it is so fundamentally unreliable that it can offer no assistance to the jury, otherwise, the factual basis of the testimony goes to the weight of the evidence." *Meterlogic Inc. v. KLT, Inc.*, 368 F.3d 1017, 1019 (8th Cir. 2004).