

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
LOUISVILLE DIVISION
CIVIL ACTION NO. 3:11-CV-00450-TBR

BRIAN SADLER and MICHELLE SADLER,
Individually and on behalf of their Minor Child, B.S.

Plaintiffs

v.

ADVANCED BIONICS, LLC

Defendant

MEMORANDUM OPINION AND ORDER

This matter is before the Court upon Defendant Advanced Bionics, LLC's Motion to Limit the Testimony of Plaintiffs' Expert Tom Green. (ECF No. 117.) Plaintiffs Brian and Michelle Sadler, individually and on behalf of their minor child B.S., have responded, (ECF No. 137), and Defendant has replied, (ECF No. 160). This matter is now ripe for adjudication. For the reasons that follow, Defendant's Motion will be sustained in part and denied in part.

I.

The admissibility of expert testimony is governed by Fed. R. Evid. 702, which provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and

- (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharm., Inc.*, “the Supreme Court established a general gatekeeping obligation for trial courts to exclude from trial expert testimony that is unreliable and irrelevant.” *Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 792 (6th Cir. 2002) (alteration and internal quotation marks omitted) (quoting *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001) (applying *Daubert*, 509 U.S. 579, 597 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48 (1999))). The Court must determine whether evidence proffered under Fed. R. Evid. 702 “both rests on a reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597. A key consideration is “whether the reasoning or methodology underlying the testimony is sufficiently valid.” *Id.* at 592-93. The Supreme Court advises that the inquiry is “a flexible one,” and that “[t]he focus . . . must be solely on principles and methodology, not on the conclusions they generate.” *Id.* at 594-95. A testifying expert must “employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152.

Despite that there is no “definitive checklist or test” for meeting the standard of Fed. R. Evid. 702, *Daubert* laid out a number of factors that typically “bear on the inquiry,” including: whether the theory or method in question “can be (and has been) tested,” whether it “has been subjected to peer review and publication,” whether it has a “known or potential rate of error,” and whether the theory or technique enjoys “general acceptance” in the “relevant scientific community.” *Daubert*, 509 U.S. at 593-94. Although *Daubert* addressed scientific evidence, the Supreme Court in *Kumho Tire Co. v. Carmichael* held that a trial court may consider the *Daubert* factors for all types of expert

evidence. *Kumho Tire*, 526 U.S. at 150. Thus, the *Daubert* factors are nonexhaustive and may not be pertinent in cases where “the relevant reliability concerns . . . focus upon personal knowledge or experience.” *Id.*; see also *First Tenn. Bank Nat’l Ass’n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001).

The Court need not necessarily hold a *Daubert* hearing to determine the admissibility of expert testimony but, nonetheless, must ensure that the disputed testimony is both relevant and reliable. See *Clay v. Ford Motor Co.*, 215 F.3d 663, 667 (6th Cir. 2000). Generally, “a trial judge . . . ha[s] considerable leeway in deciding whether particular expert testimony is reliable,” *Kumho Tire*, 526 U.S. at 152; accord *Conwood*, 290 F.3d at 792; *Jahn v. Equine Servs., PSC*, 233 F.3d 382, 388 (6th Cir. 2000), and his decision whether to admit expert testimony is reviewed for abuse of discretion, see *Kumho Tire*, 526 U.S. at 142; *Newell Rubbermaid*, 676 F.3d at 527; *Hardyman*, 243 F.3d at 258; see also *Tamraz v. Lincoln Electric Co.*, 620 F.3d 665, 672 (6th Cir. 2010) (“Rule 702, we recognize, does not require anything approaching absolute certainty. And where one person sees speculation, we acknowledge, another may see knowledge, which is why the district court enjoys broad discretion over where to draw the line.” (internal citations omitted)).

II.

Plaintiffs’ expert Tom Green holds a bachelor of science in metallurgy and materials engineering, as well as a master’s degree in engineering administration. His field of expertise is hermeticity, in which he has over thirty-years’ experience. (See ECF No. 118 at 53-58.) Green also professes substantial experience in hermeticity testing and failure analysis in the context of microelectronic packing. Green submitted a more than

page expert report detailing his opinions in this matter. (*See* ECF No. 118.) He has been deposed previously in other cases but has never testified at trial.

Defendant moves to exclude Green's testimony on four grounds: (1) Green opines on regulatory matters beyond his expertise; (2) Green offers inadmissible personal opinions characterizing Defendant's conduct as "negligent" and "reckless," and Green improperly offers legal conclusions; (3) Green discusses irrelevant matters that are both unrelated to the Astro Seal feedthru at issue here and unsupported by scientific evidence; and (4) Green seeks to impose requirements different from, or in addition to, FDA requirements, which are preempted and, therefore, irrelevant. (ECF No. 117, at 1.) The Court will address each in turn.

A.

Defendant first argues that Green should be precluded from testifying about Defendant's compliance with FDA regulations because such testimony would be beyond the scope of Green's expertise, would not be helpful to the jury, would not be relevant, and would be unfairly prejudicial. (ECF No. 117-1, at 3.) In his expert report, Green opines that Defendant's hermeticity testing is flawed for several reasons. (*See* ECF No. 118, at 5-6.) He states that the universally accepted test designed to determine the effectiveness or hermeticity of a seal is "Mil-STD 883, Test Method 1014." (ECF No. 118, at 5.) He concludes that Defendant represented to the FDA that it was in full compliance with this standard when, in fact, Defendant did not comply with this standard and thus could not detect for hermeticity failure during production. His report goes on to detail at some length how and why Defendant's testing is inconsistent with FDA requirements and industry standards. (*See* ECF No. 118, at 10-15.)

In support of its position, Defendant points to Green's deposition testimony in which Green testified that he does not consider himself an expert on FDA regulations. (See ECF No. 118-1, at 2-5.) Because Green admittedly has never worked for the FDA, never taken courses or training on FDA regulations, and, essentially, has had no involvement with FDA regulations prior to this litigation, Defendant insists that Green's proposed testimony in this regard must be excluded under Fed. R. Evid. 702 because Green lacks the knowledge, skill, experience, training, or education to opine on Defendant's compliance with FDA regulations. (ECF No. 117-1, at 5.) Additionally, Defendant maintains that Green should be precluded from basing his opinions about Defendant's compliance with FDA regulations on a summary or paraphrasing of FDA documents, arguing that such testimony would not assist the trier of fact as required by Fed. R. Evid. 702. (ECF No. 117-1, at 5.)

The Court is not persuaded that Green lacks sufficient knowledge and expertise to render his proposed expert opinion relative to FDA regulations. For one, the Court reads Green's expert report as focusing on Defendant's testing procedures—namely, whether those procedures deviated from the industry standard and whether Defendant misrepresented its testing procedures to the FDA. (See ECF No. 118, at 10-11.) The Court agrees with Plaintiffs that, based on Green's extensive experience in this field, he is qualified to testify relative to FDA regulations in the limited manner in which he proposes to. Green's references to FDA regulations relate to deviations from the industry standard and other engineering aspects of FDA regulations. He does not propose to testify that Defendant committed FDA violations *per se*, but rather to “give the limited FDA regulatory context needed to understand his opinions on engineering.” (ECF No. 137, at

8.) To the extent Green's ultimate opinion focuses on whether Defendant followed industry testing standards and protocols (as opposed to an ultimate opinion that Defendant committed FDA violations), the Court finds Green is amply qualified by his education and professional knowledge and experience to render such an opinion.

Furthermore, the Court finds Defendant's objection to Green's reliance on FDA documentation without merit. Green's expert report makes clear that his opinions are based on his technical assessments and go well beyond simple reliance on FDA regulations or documentation. Green proposes to opine that Defendant failed to conduct testing as it said it would, that Defendant poorly designed and implemented their manufacturing process flow, that Defendant conducted untimely and substandard failure analysis testing, and that Defendant improperly relied on a theorized cause of moisture in devices that should have been readily disproven. Thus, these opinions appear to be based not upon FDA regulations or documentation, but rather upon Green's experience, education, training, and professional knowledge. Furthermore, the Court is persuaded that Green's proposed testimony would assist the trier of fact so as to warrant inclusion under Fed. R. Evid. 702.

Therefore, having considered Green's expert report, *curriculum vitae*, deposition testimony, and proposed expert opinions, the Court finds Defendant's first argument without merit. These issues, at best, go more appropriately to the weight of Green's testimony and are proper matters for cross-examination; they do not render Green unqualified or his proposed testimony unreliable.

B.

Defendant next argues that Green's characterizations of Defendant's conduct as "negligent," "reckless," "irresponsible," and the like should be excluded as inadmissible personal opinions that are not the proper subject of expert testimony, and also because an expert may not express a legal conclusion. (ECF No. 117-1, at 6.) Plaintiffs recognize that experts may not offer purely legal opinions, but assert that there is nothing improper about Green using the factual term "defective." (ECF No. 137, at 10.) To this end, Plaintiffs cite the Sixth Circuit's recent decision in *United States v. Lay*, in which the court held that a witness may testify using terms that have a legal meaning so long as that testimony "does not involve terms with a separate, distinct and specialized meaning in the law different from that present in the vernacular." 612 F.3d 440, 448 (6th Cir. 2010) (quoting *United States v. Sheffey*, 57 F.3d 1419, 1426 (6th Cir.1995)). Because "[t]he word 'defective' in law does not have a meaning separate and distinct from its common usage," Plaintiffs insist that under *Lay* the Court should not exclude use of that term. (ECF No. 137, at 10-11.)

The Court finds that the terms "defect" and "defective" can have a distinct and specialized legal meaning in the context of products liability. To the extent Green proposes to opine that the product in question was "defective," the Court finds that such an opinion is tantamount to an ultimate legal conclusion and should be excluded as such. The Court is not, however, prepared to grant Defendant a blanket exclusion of the words "defect" or "defective" in any context. While products liability frequently speaks of "defects" and "defective products," these terms are seldom used in jury instructions. Further, because "defect" and "defective" also have a common and universal meaning, the Court does not

believe an expert referring to a product as being defective means the expert's opinion necessarily will be prejudicial or will confuse the jury. Therefore, Green may use those terms generally in expressing his opinion. Consistent with the foregoing, any objection to the use of those terms may be appropriately raised and addressed at trial, if necessary.

The Court further finds that any testimony by Green that Defendant was “reckless” or “negligent,” or acted “recklessly” or “negligently,” to the extent that testimony expresses a purely legal conclusion, is likewise inadmissible. Additionally, because the term “reckless” carries a distinct legal meaning and also connotes an inadmissible personal opinion beyond the proper scope of an expert's testimony, Green is precluded from using the characterizations “reckless” or “recklessly” at trial. *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (finding that an expert “may not infuse his personal views as to whether [the defendant] acted . . . recklessly”). Further, these phrases carry some personal opinion of intent, to which the expert cannot opine. *See Johnson v. Baker*, 2009 WL 3486000, at *5 (W.D. Ky. Oct. 23, 2009) (Russell, C.J.) (citing *Woodhull v. Cnty. of Kent*, 2006 WL 2228986, at *6 (W.D. Mich. Aug. 3, 2006); *United States v. Libby*, 461 F. Supp. 2d 3, 7 (D.D.C. 2006)) (“A party's state of mind . . . is not within the knowledge of any expert.”).¹ Plaintiff avers that Green will not be asked whether Defendant was “negligent,” so Defendant's contention with that term may be moot. (*See*

¹ Furthermore, as this Court has previously recognized, “Various courts have excluded expert testimony on issues relating to state of mind in civil cases.” *Id.* (citing *Halcomb v. Washington Metro. Area Transit Auth.*, 526 F. Supp. 2d 24 (D.D.C. 2007); *Woodhull*, 2006 WL 2228986, at *6; *Meals v. City of Memphis*, 2005 WL 5988642, at *2 (W.D. Tenn. Feb. 10, 2005)); *accord CMI-Trading, Inc. v. Quantum Air, Inc.*, 98 F.3d 887, 890 (6th Cir. 1996) (“[An expert's] opinion regarding whether the parties *intended* to enter a [contractual] relationship was not admissible. The intent of the parties is an issue within the competence of the jury and expert opinion testimony will not assist the jury, within the meaning of Federal Rule of Evidence 701 . . .”), *abrogated on other grounds by Morales v. Am. Honda Motor Co.*, 151 F.3d 500 (6th Cir. 1998).

ECF No. 137, at 11.) To the extent it need be addressed here, the Court similarly finds that the term “negligent” has a distinct legal meaning, and whether Defendant acted “negligently” sounds of the sort of subjective personal opinion not befitting expert testimony. As such, Green is precluded from using the characterizations “negligent” or “negligently” at trial.

Finally, the Court agrees with Plaintiffs that, as an expert in hermeticity and the Mil-STD standard, Green is properly qualified to opine as to whether Defendant complied with that standard. However, testimony characterizing Defendant as “irresponsible” appears to be the sort of personal opinion testimony that would exceed the proper bounds of Green’s expert opinion. *See In re Baycol Prods. Litig.*, 532 F. Supp. 2d at 1054 (finding that an expert “may not infuse his personal views as to whether [the defendant] acted . . . irresponsibly”). To the extent Green proposes to testify at trial that Defendant’s actions were “irresponsible” or something similar, such testimony will be excluded. Any further objection thereto may be properly raised and addressed, if necessary, at trial.

C.

Third, Defendant moves to exclude Green’s testimony as it pertains to several topics that Defendant asserts are not relevant, will not assist the trier of fact, and/or are opinions based solely on *ipse dixit*. (ECF No. 117-1, at 7.) Specifically, Defendant argues that Green’s expert report includes discussion of four issues that are not relevant to the issues in this case: (1) a recall of certain HiRes 90K magnets; (2) hermeticity failures in the older generation C1.2 device that were caused by a different interface of the circuit to the feedthrus; (3) a table of purported other hermeticity problems identified in earlier devices or in other HiRes 90Ks; and (4) speculation about possible fluid exchange in and out of the

device and whether the device contains elements that are potentially harmful to the body. (ECF No. 117-1, at 7.) Plaintiffs disclaim that Green will testify as to numbers (1) and (4); therefore, the Court need not address those issues further and instead will focus on Defendant's challenges to numbers (2) and (3).²

In regard to number (2), hermeticity failures in older generation C1.2 devices, Plaintiffs insist that because this topic deals with prior leaking issues, it is clearly relevant because it goes to the issue of notice. (ECF No. 137, at 12.) Plaintiffs reason that if prior models were leaking at the location of the feedthru, Green will explain why it would be important to disprove leaking at that location under actual or simulated conditions, because the feedthru would be the most logical place for water to enter the device. (ECF No. 137, at 12.) Defendant argues that because Plaintiff B.S.'s device was manufactured five years after the last C1.2 was made, and further because the C1.2 had a different case design, different case material, and involved complications different than the Astro Seal issue, Green's opinion regarding prior devices is not relevant and must be excluded. (ECF NO. 160, at 5-6.)

Defendant's position is well-taken, and the Court has reservations whether, even to the limited extent Green intends to testify in regard to number (2) for the purpose of showing notice, this evidence would be admissible. If, during the course of trial, Plaintiff feels that Defendant opens the door to the introduction of this evidence or that this evidence otherwise becomes admissible, Plaintiff shall approach the Court and seek leave to introduce it.

² Defendant also challenges each of the four numbered topics as based on nothing more than the *ipse dixit* of the expert. (See ECF No. 117-1, at 8-9.) Defendant does not renew this challenge in its Reply. (See ECF No. 160.) Based on the Court's review of Green's expert report, the Court finds this argument unpersuasive and, as such, need not address it further here.

In regard to number (3), Plaintiffs argue that Green should be permitted to testify regarding a table of other hermeticity issues identified in earlier devices and in other HiRes 90Ks, even if those issues are different from that of B.S.'s device. (ECF No. 137, at 12.) In essence, Plaintiffs aim to refute any impression Defendant might give to the jury that Defendant makes "a good, reliable product" by showing these other, albeit unrelated, leaking and moisture problems. (*See* ECF No. 137, at 12.) For purposes of proving liability, the Court finds that this proposed testimony should be excluded on grounds of relevancy under Fed. R. Evid. 402. Moreover, even if this testimony were relevant, the Court finds that exclusion is proper under Fed. R. Evid. 403 because its probative value would be substantially outweighed by the risk of unfair prejudice, confusion of the issues, and misleading the jury. However, should Plaintiff feel that this proposed testimony becomes admissible at trial, Plaintiff shall approach the Court and seek leave to introduce it.

D.

Lastly, Defendant moves to exclude Green's opinion that Defendant should have used manufacturing processes different from, or in addition to, those approved by the FDA on grounds of preemption. (ECF No. 117-1, at 9.) The Court addressed the issue of preemption more fully in its Memorandum Opinion and Order entered March 8, 2013. (ECF No. 162.) In light of that Opinion, the Court finds no reason at this time to exclude Green's proposed expert testimony insofar as it goes to nonpreempted issues and Plaintiffs' two viable parallel claims. (*See* ECF No. 162.) Any other objections to Green's testimony in this regard appropriately may be raised and addressed at trial.

III.

Being otherwise sufficiently advised,

IT IS HEREBY ORDERED that Defendant's Motion to Limit the Testimony of Plaintiffs' Expert Tom Green, (ECF No. 117), is SUSTAINED IN PART and DENIED IN PART consistent with the foregoing Opinion.

The image shows a handwritten signature in black ink that reads "Thomas B. Russell". The signature is written in a cursive style. In the background, there is a faint circular seal of the United States District Court, which features an eagle with wings spread, perched on a shield, surrounded by the words "UNITED STATES DISTRICT COURT".

**Thomas B. Russell, Senior Judge
United States District Court**

April 1, 2013