IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CHARLES CONN, *et al*,	§	
	§	
Plaintiffs,	§	
VS.	§	CIVIL ACTION NO. 4:14-CV-298
	§	
C.R. BARD, INC, *et al*,	§	
	§	
Defendants.	§	

ORDER

Pending before the Court is Plaintiff Charles Conn's ("Conn") Motion to Exclude Certain Opinions of Defense Expert Moni Stein, M.D. (Doc. No. 69). Defendants C.R. Bard, Inc., and Bard Peripheral Vascular, Inc. (collectively, "Bard") responded. (Doc. No. 110). After considering the motion, response, record, and applicable law, the Court GRANTS IN PART and DENIES IN PART the motion.

I. Background

This is a products liability action involving the G2 Filter (the "Filter"), a medical device manufactured and distributed by Bard. Conn was implanted with the Filter on August 24, 2006 and claims it "fractured and a strut migrated to the right ventricle causing [ ] significant injuries." (Doc. No. 1 at 23–24). Conn sued Bard alleging negligence, failure to warn, design defects, manufacturing defect, breach of implied warranty of merchantability, negligent representation, and loss of consortium on behalf of Plaintiff Alyssa Conn, his wife. He also sought punitive damages.

Bard has identified Dr. Moni Stein, an interventional radiologist, as a case specific expert witness "to provide opinions about Bard Inferior Vena Cava Filters (IVCF) and Plaintiff Michael Conn." (Doc. No. 69, Ex. A at 5). Dr. Stein is a board-certified, practicing, interventional

radiologist at Columbus Radiology in Columbus, Ohio. (Doc. No. 110-2). He has placed approximately 640 IVC filters over the past 25 years, half of which have been a Bard variety. (Doc. No. 69-1 at 2). Conn asks the Court to exclude three categories of opinions offered by Dr. Stein: (1) the design of Bard filters; (2) the rate of adverse events associated with Bard filters, including how they compare with other manufactures' filters; and (3) Mr. Conn's prognosis with respect to the fractured filter strut in his heart. (Doc. No. 69 at 1–3). Bard opposes the motion. (Doc. No. 110). The Court will address each category.

II. Legal Standard

Under Rule 702, a qualified expert may testify on the basis of "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence," provided the testimony rests on "sufficient facts or data" and "reliable principles and methods," and "the witness has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)-(d). An expert may be qualified to testify based on his or her "knowledge, skill, experience, training, or education." *Id.*

The proponent of expert testimony must prove by a preponderance of the evidence that the testimony is reliable. *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). The Supreme Court has clarified in *Daubert* and *Kumho Tire* that it is the gatekeeping role of the Court to determine whether an expert's proffered testimony conforms with Rule 702. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). The Court is to "ensure the reliability and relevancy of expert testimony," *Kumho Tire*, 526 U.S. at 152, and is not required to "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Id.* at 157 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

III. Discussion

A. Design and Mechanical Function of the Filter

Dr. Stein offers several opinions regarding the Filter's design. He offers the opinion that the G2 filter does "not have inherent design defects," and "no defect or action or inaction on the part of Bard caused or contributed to Mr. Conn's alleged injuries or damages." (Doc. No. 69-1 at 28). He also opines that the G2 filter had enhanced fracture resistance, better centering, and improved fixation hooks. (*Id.* at 4–5). Finally, he opines that Conn's G2 filter "performed as designed," and was "the best available IVC filter at the time of [Conn's] implantation." (*Id.* at 18, 30). Conn argues that Dr. Stein lacks the qualifications, factual basis, and reliable methodology to offer his opinions regarding IVC filter design.

Under Rule 702, an expert's testimony must be limited to the bounds of his or her qualifications. *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999). Dr. Stein has never made or designed a device for implantation in humans. Dr. Stein is not an engineer of any kind. (Doc. No. 110-4 at 3). He is not a metallurgist or any other kind of specialist in selecting or crafting materials to be used in human implantation. He has never attempted to design an IVC filter, nor has he reviewed the design history for any Bard filter. (Doc. No. 70 at 108, 61). He has similarly not performed any research regarding IVC filters. (Doc. No. 69-3 at 5). As a result, Dr. Stein lacks the specialized knowledge, skill, experience, and training to opine as to whether the filter has "inherent design defects." Since Dr. Stein is not qualified to opine as to an inherent design defect, he similarly cannot opine that there was "no defect" that caused Conn's injuries. In addition to Dr. Stein's lack of qualifications to offer these opinions, such testimony is not reliable under Rule 702 because Bard has not established that he used or relied upon an application of reliable methodology or sufficient facts. *Kumho Tire*, 526 U.S. at 152. While Dr. Stein cannot testify that there was "no

defect" that caused Conn's injuries, Dr. Stein can opine on what, in his medical opinion, did or did not cause Conn's alleged injuries, if any. For example, based upon his training, experience, and review of the medical records, he could opine that Conn has suffered no medical injury, or suffered no injury that he attributes to the filter.

It is also outside the realm of Dr. Stein's qualifications to offer opinions about the enhanced fracture resistance, better centering, and improved fixation hooks from a design or mechanical point of view, because he has no training in mechanical (or any other type of) engineering nor is he a metallurgist or materials specialist. Moreover, having testified that he has not received any information "about internal testing, dynamic testing, and bench-testing that was done to prove to the Bard designers that the G2 and G2X provided better centering" or "fixation," Dr. Stein lacks a factual basis upon which to form an opinion about any mechanical improvement in the G2 filter or its structural design. (Doc. No. 70 at 276).

Dr. Stein can, however, testify as to the medical aspects of centering and fixation from the viewpoint of one who implants the device insofar as they are based upon his own training, clinical experience, and his review of medical studies as outlined in his previous MDL report. (*See* Doc. No. 110-4 at 8–9). For example, in Dr. Stein's deposition, he stated that he relied upon his own experience for his opinion that "Bard filters, due to their design, center better in the cava and are therefore easier to retrieve." (Doc. 110-5 at 11–12). After explaining that the G2 filter has both "arms" and "legs" which help center it during impanation, he testified that "I've noticed over the years based on my experience that – especially the most recent generation of Bard devices with the centering arms, that that's actually a helpful addition." (*Id.* at 12). He is permitted to testify based upon his training and experience with the G2 filter and other models, that compared to other filter models, the G2 filter is easier to use or more reliably stable.

Dr. Stein can also opine as to whether the filter "performed as designed" to the extent that he can state, based on clinical experience and his expert review of the medical records, that it performed the functions for which it was designed. As the Supreme Court has explained, "the relevant reliability concerns may focus upon personal knowledge or experience. *Daubert* makes clear that the factors it mentions do *not* constitute a definitive checklist or test." *Kumho Tire*, 526 U.S. at 150. For example, Dr. Stein may offer his expert opinion as to what the IVC filter is designed to do (which is, according to him, to "prevent PE"), how it is implanted, and how it works, as this is within his area of expertise as an interventional radiologist who regularly implants IVC filters. (*See* Doc. No. 110 at 11). He can then, based upon his review of Conn's medical records, extrapolate from the intended use of the filter as to whether it performed as intended. In the same vein, he can certainly opine that, based upon his clinical experience of implanting and explanting IVC filters, *at that time,* it was his opinion that the G2 Filter was the best available filter. *See Kumho*, 526 U.S. at 150.

B. Rate of Adverse Events

Dr. Stein intends to offer the opinion that Bard filters have "similar rates" of fracture, embolization and perforation compared to other conical filters. (Doc. No. 69 at 8). Conn contends that Dr. Stein lacks qualification, a factual basis, and a reliable methodology to offer his adverse event rate opinions. (*Id.*).

Dr. Stein has not conducted any study of IVC filter complication and/or adverse effect rates, nor has he stated that he has even collected clinical data from his personal cases to compare IVC filter rates. According to his expert report, his opinions are based on his "experience as a CT reader," and in his "experience, Bard filters have similar rates of fracture and embolization compared with other conical filters." (Doc. No. 69-1 at 4). In other words, his opinion concerning

the rate of adverse events is based solely on personal experience implanting, explanting, and monitoring IVC filters: it is, at best, "anecdotal." (Doc. No. 69 at 8). In short, Dr. Stein provides no information from which the Court can conclude that his own experiences or training as a physician provide "sufficient facts and data" to support an opinion on the rate of adverse events in Bard filters, or as compared to other filters. Fed. R. Evid. 702(b). Similarly, he has not identified any "reliable principles and methods" he used in forming opinions from his "experience." *Id.*, 702(c); *see also In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495189, at *2–3 (D. Ariz. Jan. 22, 2018) (hereinafter, the "Hurst Opinion") (excluding expert testimony about higher complication rates of Bard IVC filters based on personal clinical experience in MDL proceeding).

Bard argues that Dr. Stein's opinions on the adverse event rates are supported by his earlier MDL report, in which he reviewed medical studies to "try and establish" comparisons of performance differences between the filters available on the market. (Doc. No. 110 at 16 & Doc. No. 110-4 at 4). Dr. Stein, however, does not refer to these studies in his case specific expert report, where he instead emphasizes only his clinical experience. (Doc. No. 69-1 at 4). In fact, in Dr. Stein's deposition, he confirmed that the basis of his opinions as to Bard's rate of fracture and embolization compared with conical filters was the direct observation of his patients. (Doc. No. 110-5 at 16).

To the extent he may be relying upon the medical literature, Dr. Stein testified that there is *only one* study he would rely upon regarding the G2 filter, and that study "does not compare" rates to other filters. (*Id.* 17). Even if the literature did suggest that the rates of adverse events is similar across all filters, Dr. Stein does not claim to have taken any steps to verify their conclusions.

Merely restating those conclusions does not constitute a reliable basis for rendering an expert opinion under Rule 702. *See Hurst Opinion*, at *3.

In conclusion, Dr. Stein, outside of his personal experience, cannot present an expert opinion concerning the overall adverse event rates of the Bard G2 and comparable filters because that opinion is not based on sufficient facts and data he has identified, to which he has applied reliable principles and methods. Fed. R. Evid. 702(b) & (c). He may testify only to his observations from his personal experience implanting and explanting the Bard G2 filters, but cannot extrapolate from that experience general trends or rates of adverse events since he has not identified or collected any data or applied any principles or methods to such data.

C. Conn's Prognosis

Finally, Dr. Stein offers opinions about Conn's prognosis related to the filter strut in Conn's heart, including: "His metallic heart fragment will remain clinically silent for the remainder of his life" and the filter fragment "is highly unlikely to cause or contribute to any future harm or symptomology, including but not limited to chest pains or tightness." (Doc. No. 69 at 9). Conn contends that Dr. Stein lacks the expertise, a scientific basis, and a reliable methodology to offer his prognosis opinions. (*Id.*).

Dr. Stein is not a cardiologist or cardio-vascular surgeon; nor does he purport to be a heart specialist. He has never treated a patient with a fractured filter strut in his or her heart. During Dr. Stein's deposition, when asked how many of his patients had a fractured component of an IVC filter migrate to the heart, he replied, "Zero. Nobody." (Doc. No. 110-5 at 10). Similarly, when asked if he had ever treated any patient who had a piece of an IVC filter in his or her heart, he replied, "I have not." (*Id.*). Thus, Dr. Stein's opinions about Conn's prognosis related to the

fractured strut in his heart cannot be based on clinical experience, since he has none in this precise area.

According to Dr. Stein's own deposition testimony, his prognosis opinions do not rely on peer-reviewed literature either. (*Id.* at 20). In his deposition, he clarified that he is relying "on common sense" for the proposition that the "fragment is unlikely to cause or contribute to future harm." (*Id.* at 28).

While this Court is always in favor of all witnesses using common sense, it concludes that his opinions as to whether the filter fragment will never cause future harm to Conn are therefore too speculative to pass muster under *Daubert*. *Guillory v. Domtar Indus., Inc.*, 95 F.3d 1320, 1331 (5th Cir. 1996) (upholding trial court decision to exclude expert opinion based on mere speculation).

Dr. Stein can, based upon his expertise and review of Conn's records, opine as to the status of the fragment and its placement in the heart. He can opine, for example, that the fragment has thus far remained "clinically silent," and has "embolized" in a position "without myocardial perforation" and is "stable," because these are observations based upon his training, expertise, and his review of Conn's medical records. (Doc. No. 69-1 at 23). He can also infer from the records that the fragment is unlikely to move because of the way in which it has embolized. He cannot, however, opine as to whether the filter fragment will never cause any future harm. Having no training as a cardiologist, and no data from which to draw such conclusions, Dr. Stein's opinions about future harm are not grounded in his expertise, experience, factual basis, or scientific methodology under Rule 702.

The cases to which Bard cites for the proposition that Dr. Stein can opine as to Conn's prognosis based on his differential diagnosis, despite not having treated a patient with filter

fragment or relying upon a literature review, are inapposite. In *Holt v. St. Luke's Health Sys.,* CV H-16-2898, 2018 WL 706469, at *7 (S.D. Tex. Feb. 5, 2018) the court held that Dr. MacGregor could testify and make an "inference based on the observations and data shown in the record, and on his medical training and experience." There, Dr. MacGregor's testimony, based upon literature reviews, thorough review of the facts, and his own experience as a cardiologist, was offered in a malpractice case to establish the standard of care, breach of that standard, and the causal connection between breach and damages. Here, Dr. Stein is opining as to future events, outside the realm of his expertise, and he is not relying upon literature review, medical records, or even direct clinical experience. Defendant also cites to *McKay v. Novartis Pharm. Corp.*, 984 F. Supp. 2d 647, 655 (W.D. Tex. 2012), wherein the court found that in certain circumstances, differential diagnosis is a reliable method for determining causation. Causation is distinct from trying to predict what types of harm may arise in the future. Employing a differential diagnosis to rule out alternative causes of Conn's chest pain to ascertain causation is plainly different from opining as to whether the embolized strut in Conn's heart will *ever* cause any harm to his heart. The case law cited by Bard is therefore unpersuasive, and Dr. Stein cannot testify as to the long-term prognosis related to the filter strut lodged in Conn's heart, because those opinions are not within his area of expertise and are not based on sufficient facts and data he identified, to which he then applied reliable scientific methods. Fed. R. Evid. 702(b) & (c).

IV. Conclusion

For the foregoing, the Court grants in part and denies in part Conn's Motion to Exclude Certain Opinions of Defense Expert Moni Stein, M.D. (Doc. No. 69).

Signed at Houston, Texas, this 8th day of June 2021.

Andrew S. Hanen
United States District Judge