

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Robert E. Blackburn**

Civil Action No. 14-cv-02667-REB-NYW

ALFONSO A. ALARID,

Plaintiff,

v.

BIOMET, INC.,
BIOMET ORTHOPEDICS, LLC,
BIOMET MANUFACTURING, LLC,

Defendants.

**ORDER GRANTING DEFENDANTS' MOTION TO EXCLUDE
TESTIMONY AND EVIDENCE OF DAVID SCHNEIDER, M.D.**

Blackburn, J.

The matter before me is **Defendants' Motion To Exclude Testimony and Evidence of David Schneider, M.D. [#63]**,¹ filed September 21, 2015. I grant the motion.

I. JURISDICTION

I have jurisdiction over this case pursuant to 28 U.S.C. § 1331 (diversity of citizenship).

II. STANDARD OF REVIEW

Rule 702 of the Federal Rules of Evidence, which governs the admissibility of expert witness testimony, provides that

¹ “[#63]” is an example of the convention I use to identify the docket number assigned to a specific paper by the court’s case management and electronic case filing system (CM/ECF). I use this convention throughout this order.

[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.

FED. R. EVID. 702. As interpreted by the Supreme Court, Rule 702 requires that an expert's testimony be both reliable, in that the witness is qualified to testify regarding the subject, and relevant, in that it will assist the trier in determining a fact in issue.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 589-92, 113 S.Ct. 2786, 2795-96, 125 L.Ed.2d 469 (1993); ***Truck Insurance Exchange v. MagneTek, Inc.***, 360 F.3d 1206, 1210 (10th Cir. 2004). An expert may be qualified by "knowledge, skill, experience, training, or education" to offer an opinion on an issue relevant to the case.

FED. R. EVID. 702(a). ***See also 103 Investors I, L.P. v. Square D Co.***, 470 F.3d 985, 990 (10th Cir. 2006). An expert opinion is reliable when it is based on sufficient facts or data, employs a methodology generally deemed reliable in the expert's field, and properly applies such methods to the facts of the case. ***See FED. R. EVID. 702(b), (c), & (d); United States v. Crabbe***, 556 F.Supp.2d 1217, 1222-23 (D. Colo. 2008).

Guided by these principles, the trial court has broad discretion in determining whether expert testimony is sufficiently reliable and relevant to be admissible. ***Truck Insurance Exchange***, 360 F.3d at 1210; ***Smith v. Ingersoll-Rand Co.***, 214 F.3d 1235, 1243 (10th Cir. 2000). The overarching purpose of the court's inquiry is "to make certain that the expert . . . employs in the courtroom the same level of intellectual rigor that

characterizes the practice of an expert in the relevant field.” *Goebel v. Denver and Rio Grand Western Railroad Co.*, 346 F.3d 987, 992 (10th Cir. 2003) (quoting *Kumho Tire*, 119 S.Ct. at 1176). Generally, “rejection of expert testimony is the exception rather than the rule.” *United States v. Nacchio*, 519 F.3d 1140, 1154 (10th Cir. 2008), *vacated in part on rehearing en banc*, 555 F.3d 1234 (10th Cir. 2009). **See also** FED. R. EVID. 702 (2000 Advisory Comm. Notes). “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” *Daubert*, 113 S.Ct. at 2798.

III. ANALYSIS

Plaintiff in this case alleges strict products liability and negligence claims related to alleged design and manufacturing defects in the Comprehensive Reverse Shoulder, a prosthetic device designed, manufactured, marketed, and sold by defendants. Plaintiff underwent two reverse total shoulder arthroplasties² in 2009³ and 2010⁴ in connection with which Comprehensive Reverse Shoulder devices were implanted in both shoulders. Both devices failed within about three years of the original surgeries,

² According to plaintiff, “[r]everse shoulder replacement, or RTSA, is a surgical procedure that reverses the anatomy of the shoulder. It is designed so that the ball is attached to the shoulder blade (scapula) and the socket is placed on top of the upper-arm bone (humerus). By reversing the normal anatomy, the deltoid muscle, one of the stronger shoulder muscles and the only abducting muscle remaining in the shoulder, is given control to raise the arm.” (**First Am. Compl.** ¶ 24 at 4.)

³ This surgery was required to repair a “massive” rotator cuff tear in plaintiff’s left shoulder. (**See First Am. Compl.** ¶ 21 at 3 [#5], filed September 26, 2014.)

⁴ This surgery was intended to correct “severe glenohumeral joint arthritis with labral tearing and irregularity with a large paralabral cyst along the posterior glenoid” in plaintiff’s right shoulder. (**See First Am. Comp.** ¶ 36 at 5.)

fracturing at the joint between the baseplate and the trunnion. As a result, plaintiff experienced pain and loss of function and was required to undergo revision surgeries to remove and replace both devices. This lawsuit followed.

By this motion, defendants seek to limit the testimony of Dr. David Schneider, the orthopedic surgeon who performed both plaintiff's original and revision surgeries.

Plaintiff designated Dr. Schneider as a non-retained expert to testify regarding his treatment of plaintiff, and thus produced no expert report. **See FED. R. CIV. P.**

26(a)(2)(B). However, in his Rule 26 disclosures, plaintiff suggested that, in addition to describing his treatment of plaintiff, Dr. Schneider also would testify that the failure of the Comprehensive Reverse Shoulder devices was attributable to "bad engineering," that defendants had "used [the] wrong material and wrong thickness," and that the "reason for the failure is the design of the humeral tray – material too thin to withstand pressures." (**Plf. Resp. App.**, Exh. A at 6, Exh C at 1 [#79-1], filed October 15, 2015.)

In addition, plaintiff suggests that Dr. Schneider "will testify to his knowledge of medical device development, general safety procedures which should be followed in the development of medical devices, impedance matching and impact techniques and requirements for devices that connect with tapers." (**Id.**, Exh. B at 3.)

Defendants maintain that Dr. Schneider is unqualified to testify as to these matters because they exceed the scope of his acknowledged expertise as an orthopedic surgeon. It is undisputed that Dr. Schneider is not an engineer. He personally does not consider himself an expert in biophysics, biomechanics, metallurgy, or biomaterials. (**Def. Reply App.**, Exh A at 31-32 [#89], filed October 29, 2015.)

Although he has consulted with defendant in the past regarding the design of shoulder prosthetics, his role in that capacity was as an orthopedic surgeon; other members of the design team focused on engineering, biomechanics, and materials selection. (*Id.* at 256-257.)

In this circuit, it is clear that “merely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue.” ***Ralston v. Smith & Nephew Richards, Inc.***, 275 F.3d 965, 970 (10th Cir. 2001). **See also *Hauck v. Michelin North America, Inc.***, 343 F.Supp.2d 976, 983 (D. Colo. 2004) (“[T]o be qualified in one area of a discipline or science does not necessarily demonstrate that the tendered expert is qualified in other areas of the discipline.”); ***Alexander v. Smith & Nephew, P.L.C.***, 98 F.Supp.2d 1310, 1315 (N.D. Okla. 2000) (“A blanket qualification for all physicians to testify as to anything medically-related would contravene the Court’s gate-keeping responsibilities.”) (footnotes omitted). Although a lack of specialization does not automatically disqualify an expert from testifying regarding a particular subject matter, he nevertheless must stay “within the reasonable confines of his subject area.” ***Ralston***, 275 F.3d at 970 (quoting ***Compton v. Subaru of America, Inc.***, 82 F.3d 1513, 1519-20 (10th Cir.), ***cert. denied***, 117 S.Ct. 611 (1996)) (citation and internal quotation marks omitted). The court does not abuse its discretion by excluding the opinions of a putative expert who possesses only “marginal familiarity with general concepts in the relevant field.” *Id.*

Such clearly is the nature of Dr. Schneider’s opinions regarding the design of the Comprehensive Reverse Shoulder device in general and the potential causes of its

failure in particular. Plaintiff suggests, without substantiation, that “[o]rthopedic surgeons are trained to assess the quality and capabilities of orthopedic devices in making treatment recommendations, as well as when confronted with device failures and having to carry out revision procedures.” (**Plif. Resp.** at 8.) He makes no showing that Dr. Schneider himself has any such expertise, however, and indeed, Dr.

Schneider’s deposition testimony suggests that such is not in fact the case:

Well, of course there's not a single surgeon out there who's presented with all this biomechanical failure data when they're getting ready to contemplate any kind of component that's placed. We're just assured, "The testing on this is really good. The FDA has approved it. We think it will be great for your patients."

Now, in this case, after failure, I was curious to know what some of the biomechanical testing numbers actually were. And of course I've glanced in a cursory fashion at some of the testing from this engineering consultant.

(**Def. Reply App.**, Exh. A at 167.) It thus appears that Dr. Schneider himself relied on the manufacturer in choosing a prosthetic device, and his “cursory” review of failure testing data hardly qualifies him to offer an expert opinion regarding any alleged defects in the Comprehensive Reverse Shoulder device.

Moreover, to the extent plaintiff argues it was “incumbent on Dr. Schneider to determine the reason for the failure” of the original prosthetic so that revision surgery might produce a better outcome (**Plif. Resp.** at 8), it is plain that Dr. Schneider’s opinions as to why the device failed are wholly conclusory. Asked why he believed the materials used in the original device were inadequate, he stated merely that the fact of their ultimate failure “speaks for itself.” (**Def. Reply App.**, Exh. A at 165.) When asked

to suggest what materials should have been used instead, he responded “[w]hatever material is stronger. I would assume that Biomet has done all the testing on that . . .” (*Id.*, Exh. A at 166.) There is no evidence suggesting that these opinions are based on adequate facts and data, and even if they were, “[n]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” ***General Electric Co. v. Joiner***, 522 U.S. 136, 146, 118 S.Ct. 512, 519, 139 L.Ed.2d 508 (1997). It thus appears to this court that any opinions Dr. Schneider may have on the design and manufacture of the Comprehensive Reverse Shoulder device are both unreliable and outside his realm of expertise.

Plaintiff attempts to elide the requirement of qualifying Dr. Schneider as an expert on these topics by suggesting that he instead may testify about them as a lay witness. Federal Rule of Evidence 701 provides that a lay witness cannot testify in the form of an opinion, *inter alia*, if his testimony is “based on scientific, technical, or other specialized knowledge within the scope of Rule 702.” **FED. R. EVID.** 701. Thus, while “Rule 701 allows lay witnesses to offer observations [that] are common enough and require . . . a limited amount of expertise, if any,”⁵ a witness may not, under the mantle of Rule 701, “express an opinion as to matters which are beyond the realm of common experience and which require the special skill and knowledge of an expert witness.” ***James River Insurance Co. v. Rapid Funding, LLC***, 658 F.3d 1207, 1214 (10th Cir. 2011) (citations

⁵ “The prototypical example of the type of evidence contemplated by the adoption of Rule 701 relates to the appearance of persons or things, identity, the manner of conduct, competency of a person, degrees of light or darkness, sound, size, weight, distance, and an endless number of items that cannot be described factually in words apart from inferences.” ***James River Insurance Co. v. Rapid Funding, LLC***, 658 F.3d 1207, 1214 (10th Cir. 2011) (citation and internal quotation marks omitted).

and internal quotation marks omitted).⁶

While plaintiff cites this requirement of the rule, he utterly fails to address it, perhaps because any such argument would be specious. There is no credible argument to be made that the design and manufacture of prosthetic shoulder devices are matters of common experience or otherwise within the ken of an ordinary layperson. Although Dr. Schneider putatively may testify as a percipient witness as to what he observed when he explanted the fractured devices, he may not offer an opinion concerning the causes for the failures or the changes in the design, or otherwise opine regarding matters relating to the design and manufacture of such devices.

IV ORDERS

THEREFORE, IT IS ORDERED as follows:

⁶ The *James River Insurance Company* court illustrated the difference between Rule 701 lay opinion testimony and Rule 702 expert testimony by comparing two prior decisions:

In *Bryant v. Farmers Insurance Exchange*, 432 F.3d 1114 (10th Cir. 2005), we held that a witness should have been permitted under Rule 701 to testify to elementary mathematical operations:

Taking a simple average of 103 numbers, though technically a statistical determination, is not so complex a task that litigants need to hire experts in order to deem the evidence trustworthy. A mathematical calculation well within the ability of anyone with a grade-school education is, in our opinion, more aptly characterized as a lay opinion under Fed. R. Evid. 701.

Id. at 1124.

In *LifeWise Master Funding v. Telebank*, 374 F.3d 917 (10th Cir. 2004), we found inadmissible under Rule 701 a CEO's testimony about his business's lost profits because his results were based on more sophisticated economic models. "The model concerned moving averages, compounded growth rates, and S-curves. [The witness] could not testify about these technical, specialized subjects under Rule 701." *Id.* at 929. We explained that "a person may testify as a lay witness only if his opinions or inferences do not require any specialized knowledge and could be reached by any ordinary person." *Id.* (quotation omitted).

James River Insurance Co., 658 F.3d at 1214.

1. That **Defendants' Motion To Exclude Testimony and Evidence of David Schneider, M.D.** [#63], filed September 21, 2015, is granted;

2. That the expert testimony of Dr. David Schneider shall be limited to those matters relating to his treatment of plaintiff; and

3. That Dr. David Schneider shall not be permitted to testify in the form of an opinion or otherwise as to issues that are beyond his perceptions as plaintiff's treating physician relating to the design or manufacture of the Comprehensive Reverse Shoulder device.

Dated February 1, 2016, at Denver, Colorado.

BY THE COURT:



Robert E. Blackburn
United States District Judge