UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

TERRY JENNINGS-MOLINE,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC.; DEPUY PRODUCTS, INC.; DEPUY INTERNATIONAL LIMITED; JOHNSON & JOHNSON COMPANY; and JOHNSON & JOHNSON SERVICES, INC.,

Defendants.

Case No. 2:23-cv-00031-AKB

MEMORANDUM DECISION AND ORDER REGARDING DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF NATHANIEL P. YOUNG (Dkt. 30)

I. INTRODUCTION

Pending before the Court is Defendants'[1] Motion to Exclude the Opinions and Testimony of Nathaniel P. Young under Federal Rule of Evidence 702.[2] (Dkt. 30). The Court heard oral argument on October 25, 2023, and took the motion under advisement. For the reasons discussed below, the Court grants the motion in part and denies the motion in part.

[1] The named Defendants in this action are DePuy Orthopaedics, Inc., DePuy Products, Inc., DePuy International Limited, Johnson & Johnson Company, and Johnson & Johnson Services, Inc.

[2] Defendants also filed two other Rule 702 motions, including their Motion to Exclude the Opinions of Certain Plaintiffs' Experts (Dkt. 28); and their Motion to Exclude the Opinions of Albert H. Burstein, Ph.D.[;] J. Marcus Hollis, Ph.D.[;] and Nathan Young, M.S.[;] Regarding the Nature and Medical Cause of Plaintiffs' Alleged Injuries (Dkt. 29). Defendants have withdrawn these motions, however, even though the latter motion related to Jennings-Moline's disclosed expert, Young. (Dkt. 65).

II. BACKGROUND

In January 2016, Terry Jennings-Moline underwent hip surgery, and Dr. Douglas McInnis implanted a Pinnacle hip implant that included an AltrX polyethene acetabular liner (AltrX liner). (Dkt. 4 at ¶ 2.3). In February 2018, Dr. McInnis performed a revision hip surgery on Jennings-Moline. (*Id.* at ¶¶ 2.4, 2.5). Dr. McInnis concluded the AltrX liner had dissociated and replaced the liner within the existing hip implant hardware. (*Id.* at ¶ 2.5).

In April 2019, Jennings-Moline filed this action in state court against Defendants, alleging numerous claims based on the AltrX liner's dissociation and the resulting revision surgery, and Defendants removed the action to federal court. (*See* Dkt. 4). Thereafter, in August 2019, Jennings-Moline underwent a second revision surgery. (Dkt. 33-1 at p. 11). During this surgery, the liner was replaced with a liner manufactured by another company. (*Id.*).

In February 2020, the United States Judicial Panel on Multidistrict Litigation transferred this action under 28 U.S.C. § 1407 to the Northern District of Texas for inclusion in the coordinated or consolidated pretrial proceedings for the Pinnacle hip implant products liability litigation. (Dkt. 15). *See In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-CV-1941-K, 2019 WL 13193930, at *1 (N.D. Tex. Jan. 10, 2019). In January 2023, the Panel remanded the action back to the District of Idaho. (*See* Dkts. 50, 51). Before the remand, Jennings-Moline disclosed Nathan Young, M.S., as an expert witness, and in January 2022, he issued his expert report. (Dkt. 46-1).

Young is a biomedical and mechanical engineer with at least eighteen years of experience and expertise in medical device development, design, and testing. To reach his opinions, Young conducted searches in and reviewed data from the Federal Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database. (*Id.* at p. 13). According to the FDA

website, "[t]he MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers."[3]

> Manufacturers and importers must submit reports when they become aware of information that reasonably suggests that one of their marketed devices may have caused or contributed to a death or serious injury or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[4]

Based on his review of MAUDE data, Young noted 129 liner dissociation events involving the AltrX liner occurred before Jennings-Moline's first hip surgery. (*Id.* at p. 14). Further, Young compared the number of medical device reports among different manufacturers and noted "the data suggests that the liner dissociation problem affects the Depuy AltrX at a significantly higher rate than other products." (*Id.* at p. 15). Further, Young conducted a literature review. For this purpose, he used the Google Scholar search engine, searched for "liner dissociation," located eighteen articles, and reviewed "the full text or abstract for each article." (*Id.*). Based on his review of the MAUDE data and the literature he located, Young opined about what the data shows, the absence of alternative causes, Jennings-Moline's resulting physical issues, Defendants' negligence, and that the data he reviewed suggests a design defect.

On December 16, 2022, Defendants moved to exclude Young's opinions. (Dkt. 30). On December 30, Jennings-Moline responded to this motion. (Dkt. 46). Additionally on that date, she filed Young's declaration and his written response to Defendants' motion, explaining in further

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[3] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm (last updated 9/30/2023) (footnote omitted).

[4] *Id.* at n.1.

detail the MAUDE database, his use of that database, and his literature review.[5] (Dkt. 46-1 at pp. 3, 20-27). On February 9, 2023, Defendants deposed Young (Dkt. 58-1, pp. 2-33), and on March 29, they filed their reply. (Dkt. 58).

IV. LEGAL STANDARD

The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence. Rule 702 limits the admissibility of expert testimony in two ways. First, it only permits witnesses with special "knowledge, skill, experience, training, or education," to testify as experts. Fed. R. Evid. 702(a). Second, it limits a qualified expert's testimony to that which "will help the trier of fact to understand the evidence or to determine a fact in issue," is based on "sufficient facts or data," is "the product of reliable principles and methods," and is "reliably applied" to the facts of the case. Fed. R. Evid. 702(a)-(d).

The Ninth Circuit has summarized the requirements of Rule 702 as follows: "expert testimony must (1) address an issue beyond the common knowledge of the average layman, (2) be presented by a witness having sufficient expertise, and (3) assert a reasonable opinion given the state of the pertinent art or scientific knowledge." *United States v. Vallejo*, 237 F.3d 1008, 1019 (9th Cir. 2001) (citing *United States v. Morales*, 108 F.3d 1031, 1038 (9th Cir. 1997)). District

[5] Defendants did not move to strike either Young's declaration or his December 2022 report. In their reply brief, however, they argue the Court should not consider Young's "untimely supplemental declaration." (Dkt. 58, p. 4 n.1). The Court does not construe Young's post-motion declaration and report as "supplemental," however. Rather, they are intended to address Defendants' arguments in their motion to exclude him. Generally, a defendant discloses an opposing expert witness to challenge the opinions of plaintiff's expert witness, and in turn that expert is provided an opportunity to rebut the challenge. In this case, Defendants' counsel—not an expert—challenge the bases and reliability of Young's opinions. In this circumstance, the Court will allow Young's declaration and responsive report to address those challenges, but it does not construe Young's declaration and December 2022 report as stating new opinions not previously disclosed in his January 2022 report.

courts have broad discretion in applying this test. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999).

The district court's role in applying Rule 702 is to be a gatekeeper. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). In that role, the court considers both the relevance and reliability of the proffered evidence. *Kumho*, 526 U.S. at 141. "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (citation omitted); *accord Elosu v. Middlefork Ranch Inc.*, 26 F.4th 1017, 1024 (9th Cir. 2022). "To carry out its gatekeeping role, a district court must find that an expert's testimony is reliable—an inquiry that focuses not on 'what the experts say,' or their qualifications, 'but what basis they have for saying it.'" *United States v. Holguin*, 51 F.4th 841, 854 (9th Cir. 2022) (quoting *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1316 (9th Cir. 1995)), *cert. denied*, 143 S. Ct. 2509 (2023).

Effective December 1, 2023, Rule 702 will clarify the proponent of expert testimony must meet all of Rule 702's substantive standards for admissibility by a preponderance of evidence.[6] The amendments are intended to correct some courts' prior, inaccurate application of Rule 702. As the Committee Notes to the 2023 Amendment state, "many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a)." Fed. R. Evid. 702 Committee Note (1) (effective Dec. 1, 2023). "The Committee

[6] The Supreme Court approved the proposed amendments, which will become effective on December 1, 2023, unless Congress disapproves of them. At oral argument, the parties agreed this Court should apply the amended version of Rule 702.

concluded that emphasizing the preponderance standard of Rule 702 was made necessary by the courts that have failed to apply correctly the reliability requirements of that rule." *Id.*

"Rule 702(d) has also been amended to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology." Fed. R. Evid. Committee Note (2) (discussing amendment of Rule 702(d) to state "the expert's opinion [must] reflect[] a reliable application of the principles and methods of the facts of the case"). Because Rule 702's amendments are intended to correct prior inaccurate court rulings; Congressional disapproval of the amendments is unlikely; and this case will not be tried until after the amendments' effective date, this Court's analysis relies on amended Rule 702.

III. ANALYSIS

Defendants challenge Young's expert "opinions regarding the purported defect in the AltrX liner" because they are "based on a flawed and unreliable methodology." (Dkt. 30 at p. 5). Specifically, Defendants contend the information in the MAUDE database is unreliable; Young's literature review is incomplete; and he failed to account for the number of products sold making his estimated failure rates meaningless. The Court disagrees that Young's methodology is unreliable for purposes of opining about what the MAUDE data and his literature review shows and that this information suggests a design defect.

A. MAUDE Data

Defendants cite multiple cases for the proposition that "courts routinely exclude expert testimony based on adverse event report data—like data from MAUDE—recognizing it is not a reliable basis to conclude that a product is defective or that it caused an alleged injury." (Dkt. 30 at p. 10). Defendants are correct that several courts have concluded the MAUDE data is an unreliable source of information to prove causation. *See, e.g.*, *McClain v. Metabolife Int'l, Inc.,*

401 F.3d 1233, 1250 (11th Cir. 2005) (holding adverse event reports are "one of the least reliable sources to justify opinions about both general and individual causation"); *Soldo v. Sandoz-Pharmaceuticals Corp.*, 244 F. Supp. 2d 434, 541 (W.D. Pa. 2023) (concluding adverse drug events do not constitute reliable support for experts' causation opinions); *In re Baycol Prods. Litig.,* 532 F. Supp. 2d 1029, 1040 (D. Minn. 2007) (citing cases concluding adverse event reports are unreliable for offering causation opinions); *In re Accutane Prods. Liab.,* 511 F. Supp. 2d 1288, 1298 (M.D. Fla. 2007) (stating adverse event reports are "unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes").[7]

These cases, however, do not stand for the proposition that an expert may not rely on the MAUDE data for purposes other than opining on causation. Indeed, other courts have rejected reliability challenges to experts who relied on the MAUDE data to opine on issues other than causation. For example, in *Tillman v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307, 1331 (M.D. Fla. 2015), the plaintiff's expert relied on MAUDE data to conclude the defendant's medical device was "failing at an alarmingly high'" rate. *Id.* at 1331. The defendant challenged this opinion, arguing the data was unreliable. *Id.* The court noted, however, that the expert acknowledged the weaknesses in the MAUDE data and was not using the data to state a medical causation opinion, but rather was only relying on it to state what the data showed regarding the defendant's device

[7] Defendants also cite *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991 (S.D.W.V. May 6, 2015). Although the court in that case did generally discuss the unreliability of the MAUDE database, its ruling was the expert could not rely on MAUDE data to conclude the defendant "failed to report adverse events" to the MAUDE database. *Id.* at *18. Whether Defendants reported to the database, however, is not at issue in this case so *Mathison is inapposite*.

and other comparable devices. *Id.* at 1332. For this reason, the court did not find persuasive those authorities that conclude the MAUDE data is unreliable for purposes of causation opinions. *Id.* Rather, the *Tillman* court concluded the defendant's arguments concerning the MAUDE data's weaknesses "go to the weight rather than the admissibility of the opinion." *Id.*

The court in *In re Bard IVC Filters Prods. Liability Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 11447701 (D. Ariz. Jan. 22, 2018), reached a similar conclusion. In that case, the plaintiffs' expert witness acknowledged the MAUDE data's limitations but relied on it, in part, to opine generally that "there is a higher risk of adverse events" for the defendant's temporary medical device versus its permanent medical device. *Id.* at *1. The defendant challenged the expert's reliance on MAUDE data. *Id.* at *4. The court noted that "an expert's reliance on adverse events reports [is] unreliable as proof of causation because, in general, the events were not observed in such a way as to rule out coincidence or other potential causes," but the expert did not present a causation opinion. *Id.* at *5. Further, the court cited numerous cases in which "[o]ther courts have noted that adverse event reports, including reports from the MAUDE database, may be used for opinions other than causation." *Id.* (citing cases). Accordingly, the court denied the defendant's motion to exclude the expert's opinion based on MAUDE data. *Id.; cf. Brocato v. DePuy Orthopaedics, Inc.*, No. 14-2607, 2015 WL 854150 at *6 (E.D. La. Feb. 25, 2015) (noting favorably plaintiff's reliance on MAUDE data in denying motion to dismiss complaint).

As in *Tillman* and *In re Bard*, Young readily acknowledges the MAUDE data's weaknesses and limitations. Further, as in those cases, many of Young's opinions state what the data shows. For example, he observes the AltrX liner "has a documented history of liner dissociation"; a liner dissociation "is something that is rarely seen in other products"; "[a] significant number of failures occurred prior to [Jennings-Moline's] surgery"; and the data shows "the failure has occurred over

the entire history of the product." From these observations of the MAUDE data, Young opines, for example, "the [failure] problem is specific to the [AltrX liner]"; Defendants had a "significant amount of time to address the issue"; a "manufacturing defect" is unlikely; and the design of the liner caused its dissociation. Young's methodology in searching the MAUDE database and reaching these and other similar opinions is reliable. Further, based on Young's knowledge, skill, and experience, the Court concludes Young is qualified to testify about a defect in an orthopedic implant's design and how that defect generally may manifest and cause complications. *See Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1124 (9th Cir. 1994) (rejecting argument expert's lack of medical degree precluded expert from being qualified to offer opinion on causal connection because of expert's knowledge, skill, and experience).

Moreover, Defendants challenge Young's consideration of the MAUDE data in its entirety without challenging *how* Young factored it into his opinion. Generally, a challenge to the factual basis for an expert's testimony goes to the weight of the testimony, not to its admissibility. *Elosu*, 26 F.4th at 1024; *In re Bard*, 2018 WL 11447701, at *2; *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *13 (N.D. Tex. July 18, 2014); *Tillman*, 96 F. Supp. 3d at 1331-32. The Court's gatekeeping function requires a determination of whether sufficient factual grounds exist to support the conclusions made, not whether the conclusions are correct or even corroborated by other evidence. *Elosu*, 26 F.4th at 1026. "Challenges that go to the weight of the evidence are within the province of a fact finder, not a trial court judge." *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1044 (9th Cir. 2014).

B. Medical Opinions

Young's medical causation opinions, however, are excludable under Rule 702. Both parties agree Young is not qualified to give medical causation opinions, and Young denies making any such opinions. Regardless, he offers two opinions which are medical in nature: First, he states "[t]he absence of failures with other companies' products strongly suggests that the failure [of the AltrX liner] is not due to physician placement or technique or due to patient movement or mis use [sic]." This opinion seeks to eliminate alternative causes for the liner's failure, is specific to Jennings-Moline's surgeries, and is not reliably based on either Young's review of either the MAUDE data or a literature review.

Second, Young states Jenning-Moline's "additional procedures . . . have resulted in physical issues associated with multiple orthopedic procedures." That Jennings-Moline has suffered "physical issues associated with multiple orthopedic procedures" is a medical opinion which Young is not qualified to make. Accordingly, Young may not testify about either the absence of alternative causes for the AltrX's liner's failure or Jennings-Moline's resulting physical issues.

At oral argument, Defendants characterized as a medical causation opinion Young's statement that "the design of the AltrX liner in the Pinnacle cup has resulted in the disassembly of two of [Jennings-Moline's] hip replacements, necessitating two revision surgeries." That the liners disassembled and resulted in two surgeries, however, are undisputed facts about which Jennings-Moline's surgeon, Dr. McInnis, testified in his deposition. Young may rely on those facts. *See, e.g.*, *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Pracs., & Prod. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) ("[E]xpert opinions may find a basis in part 'on what a different expert believes on the basis of expert knowledge not possessed by the first expert.'")

(quoting *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002)); *accord In re Bard IVC Filters Prods. Liability Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 6554163, at *2 (D. Ariz. Dec. 22, 2017) (citing *In re Toyota*). Because Dr. McInnis testified the liner failed, and as a result Jennings-Moline had surgeries, and Defendants do not dispute these facts, Young's statement about the liner's disassembly and resulting surgeries is not an improper medical causation opinion.

C. Literature Review

In addition to challenging Young's reliance on the MAUDE data, Defendants also challenge Young's literature review as "flawed and unreliable." In support, they criticize the extent of Young's review and his reliance, in part, on abstracts and case reports. The commentary notes to Rule 702, however, state such a challenge goes to the weight and not the admissibility of an expert's opinions. Fed. R. Evid. 702 Committee Note (1) (effective December 1, 2023) ("For example, if the court finds it more likely than not that an expert has a sufficient basis to support an opinion, the fact that the expert has not read every single study that exists may raise a question of weight and not admissibility."); *see also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, No. 3:11-MD-2244-K, 2016 WL 9560113, at *3 (N.D. Tex. Oct. 3, 2016) (noting "whether the expert considered all potentially relevant literature" is not generally the type of "extreme" circumstance underlying a finding that the opinion is unreliable). The Court finds it is more likely than not that Young has a sufficient basis to support his design defect opinion based on his review of the MAUDE data and literature.

D. Number of Liner Sales

Defendants also challenge Young's opinion for failing to account "for the number of liner sales when calculating and comparing 'failure rates.'" As Young correctly notes, however, he

does not have an opinion on failure rates. Indeed, Defendants acknowledge this fact. (Dkt. 30 at p. 13) (stating Young "does not actually calculate a failure rate or a complaint rate"). Because he does not opine on failure rates, Young did not need to consider the number of liner sales and his failure to consider that number does not render his opinions unreliable.

E. Negligence

Finally, Defendants contend Young should be barred from opining that Defendants were negligent. (Dkt. 30 at p. 11). In his expert report, Young states: "As a result of the negligence of DePuy Orthopaedics, their failure to address the defective liner design, Ms. Jennings-Moline suffered through two revision surgeries in less than two years to address liner dissociation." (Dkt. 29-4 at p. 113). Jennings-Moline agrees this statement should be stricken from Young's report and testimony. (Dkt. 46 at p. 16).

In summary, Young may not testify about Defendants' negligence, the absence of alternative causes for the AltrX liner's dissociation in Jennings-Moline's hip replacement, or her "physical issues associated with multiple orthopedic procedures." Young may, however, testify about what the MAUDE data and the literature he reviewed shows and whether that data suggests a design defect.

V. ORDER

IT IS HEREBY ORDERED Defendants' Motion to Exclude the Opinions and Testimony of Nathaniel P. Young (Dkt. 30) is **GRANTED IN PART** and **DENIED IN PART**.

DATED: November 01, 2023

Amanda K. Brailsford
U.S. District Court Judge