UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 2391)	)	CAUSE NO. 3:12-MD-2391
This Document Relates to All Cases	)	

OPINION AND ORDER

Both the Plaintiffs' Executive Committee II and Biomet have moved to exclude portions of experts' opinion testimony under Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). This opinion addresses the motions and witnesses in the following order and at the following pages:

Page 24: Biomet's motion to exclude opinions and testimony of the plaintiffs' expert Mari Truman [Doc. No. 3386];

Page 34: Biomet's motion to exclude opinions and testimony of the plaintiffs' expert George S. Kantor, M.D. [Doc. No. 3399];

I. STANDARD OF REVIEW

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's opinion in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). Krik v. Exxon Mobil Corp., 870 F.3d 669, 673 (7th Cir. 2017). "The proponent of the expert bears the burden of demonstrating that the expert's testimony would satisfy the Daubert standard." Lewis v. CITGO Petroleum Corp., 561 F.3d 698, 705 (7th Cir. 2009) (citing Fed. R. Evid. 702, advisory committee's note (2000 Amends.)).

Rule 702 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.

Fed. R. Evid. 702; Myers v. Illinois Cent. R. Co., 629 F.3d 639, 644 (7th Cir. 2010). A court should consider a proposed expert's full range of practical experience, as well as academic or technical training, when determining whether

that expert is qualified to render an opinion in a given area. Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000).

Daubert requires the trial court to act as a gatekeeper in screening the admissibility of expert testimony by determining whether the proffered testimony is reliable and relevant. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999). The court "must make a preliminary assessment that the testimony's underlying reasoning or methodology is scientifically valid and properly applied to the facts at issue." Krik v. Exxon Mobil Corp., 870 F.3d at 673. The Daubert standard applies to all expert testimony or evidence, whether it relates to areas of traditional scientific competence, engineering principles, or other technical or specialized expertise. Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. at 147.

The Supreme Court "has given courts the following guidance to determine the reliability of a qualified expert's testimony under Daubert, stating that they are to consider, among other things: '(1) whether the proffered theory can be and has been tested; (2) whether the theory has been subjected to peer review; (3) whether the theory has been evaluated in light of potential rates of error; and (4) whether the theory has been accepted in the relevant scientific community.'" Krik v. Exxon Mobil Corp., 870 F.3d at 674 (quoting Baugh v. Cuprum S.A. de C.V., 845 F.3d 838, 844 (7th Cir. 2017)); Bielskis v. Louisville Ladder, Inc., 663 F.3d 887, 894 (7th Cir. 2011). But the reliability inquiry is a flexible one and "the factors identified in [Daubert] may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise,

and the subject of his testimony." Kumho Tire Co. v. Carmichael, 526 U.S. at 150.

"The question of whether the expert is credible or whether his or her theories are correct given the circumstances of a particular case is a factual one that is left for the jury to determine after opposing counsel has been provided the opportunity to cross-examine the expert regarding his conclusions and the facts on which they are based." Smith v. Ford Motor Co., 215 F.3d 713, 719 (7th Cir. 2000). "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 v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596 (1993).

II. DISCUSSION

A. Dr. Schmid's Opinions

Biomet designated Steven R. Schmid, Ph.D., as an expert. Dr. Schmid is a licensed engineer with a Ph.D. in mechanical engineering; a professor of engineering design and tribology (the science of friction, wear, and lubrication) at the University of Notre Dame; and has authored textbooks and peer-reviewed journal articles on those topics. According to his report [Doc. No. 3415-2], he was retained as an expert to opine on the reasonableness of the use of different materials in an orthopedic implant design.

The Executive Committee doesn't argue that Dr. Schmid is unqualified to opine on issues related to engineering design and tribology, but seeks to exclude

his opinions on Food and Drug Administration regulatory affairs and the reasonableness of Biomet's actions with regard to design and safety decision-making.

Biomet acknowledges that Dr. Schmid isn't a regulatory expert and says it doesn't intend to offer any opinions by Dr. Schmid on FDA evaluation, clearance, or approval of hip replacement devices or Biomet's alleged adherence to FDA rules and regulations. Based on those representations, I deny the Executive Committee's motion to the extent it seeks to exclude Dr. Schmid's opinions on regulatory affairs.

The Executive Committee also argues that I should exclude the broad category of Dr. Schmid's opinions on the reasonableness of Biomet's actions with regard to the design and manufacture of the devices because he has an insufficient foundation to apply his scientific principles and methods to the facts of this case. The Executive Committee doesn't dispute that Dr. Schmid is qualified to opine on these topics or point to specific opinions I should exclude, but contends that Dr. Schmid only reviewed the design files, which, according to the Executive Committee, gives him an insufficient basis to opine on the reasonableness of Biomet's actions.

For Dr. Schmid's testimony to be admissible, it must be "based on sufficient facts or data." Stuhlmacher v. Home Depot U.S.A., Inc., 774 F.3d 405, 409 (7th Cir. 2014). *See also* Lantec, Inc. v. Novell, Inc., 306 F.3d 1003, 1026 (10th Cir. 2002) (an expert may not unduly rely on anecdotal data). "Rule 702's reliability elements require the district judge to determine only that the expert is

providing testimony that is based on a correct application of a reliable methodology and that the expert considered sufficient data to employ the methodology." Stollings v. Ryobi Techs., Inc., 725 F.3d 753, 766 (7th Cir. 2013).

Biomet says Dr. Schmid's opinions at issue are based on his review of relevant literature, depositions, and Biomet's design files for the devices at issue in this case. Biomet notes that the design file for the M2a Magnum device contains: (1) the initial and all subsequent design reviews by the design team; (2) the final design; (3) design risk management activities, including the identification and quantification of all risks considered by the design team; (4) all design input considered by the design team; (5) all design-phase testing, including fatigue, pull-out, and simulator testing; (6) instructions for use drafts; (7) FDA regulatory process documents; and (8) post-market review documents.

An expert needn't review voluminous case-specific data before offering an opinion, but can't, for example, base an opinion about average gross sales price on data from a single customer. *See* Stollings v. Ryobi Techs., 725 F.3d at 766 (a court could properly exclude expert testimony based on an insufficient factual basis). Any minor shortcomings with regard to a factual basis that are "within the realm of a lay juror's understanding," should be left to the jury to weigh. Id.

Dr. Schmid's opinions on the reasonableness of Biomet's actions with regard to the design and manufacture of the devices are based on his review of a large design file, which contains draft and final device designs, relevant risk factors, and the results of multiple types of testing. A jury can easily comprehend the documents Dr. Schmid did and didn't review in this case, and those design

files he did consider meet Rule 702's threshold requirement that an opinion be based on sufficient facts or data. Whether he could have considered other documents before opining on the reasonableness of Biomet's actions with regard to the design and manufacture of the devices goes to the weight a jury should assign his opinions, not their admissibility.

Accordingly, I deny the Executive Committee's motion to exclude Dr. Schmid's opinions.

B. Mr. Schroeder's Opinions

Biomet designated David Schroeder as an expert. Mr. Schroeder is a biomaterials engineer and senior research director at Biomet. He has been employed with Biomet for more than twenty years and led the design and development of Biomet's metal-on-metal devices.

The Executive Committee moves to exclude Mr. Schroeder's opinions about Biomet's compliance with codes and regulations, the factors that surgeons use to select Biomet devices, and the reasonableness of Biomet's actions with regard to design and safety decision-making.

1. Mr. Schroeder's Regulatory Compliance Opinion

In his expert report, Mr. Schroeder concluded that: "The M2a-Taper, M2a-38, M2a-Magnum, and ReCap complied with all applicable codes, standards, and regulations applicable to hip implant devices at the time they were designed, manufactured, [and] tested." [Doc. No. 3382-2 at 37]. The Executive Committee

argues that this opinion falls outside of Mr. Schroeder's area of expertise -- the design and development of Biomet devices -- and that he offered no scientific methodology to support his opinion. Biomet acknowledges that Mr. Schroeder isn't a compliance or regulatory expert, but argues that Mr. Schroeder can permissibly rely on views of others for his opinion that Biomet complied with applicable codes, standards, and regulations under Fed. R. Evid. 703.

Rule 703 allows an expert to offer "an opinion on facts or data in the case that the expert has been made aware of or personally observed . . . [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. *See also* Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert"). But Rule 703 doesn't allow a "scientist, however well credentialed he may be, . . . to be the mouthpiece of a scientist in a different specialty." Dura Auto. Sys., 285 F.3d at 614. So while a doctor needn't be a radiology expert to rely on an x-ray for a diagnosis, an architect can't testify to the state of repair of a building because the engineer who reviewed the building's condition explained it to him. Id. at 613.

Biomet asserts that Mr. Schroeder can permissibly offer opinions about the role that regulatory compliance plays in the design and development of medical devices and the role such compliance played in the development of Biomet's devices. I agree. But Mr. Schroeder's unqualified and sweeping opinion

that the devices at issue in this case complied with *every* applicable code, standard, and regulation when they were designed by his team and long after, including when each individual device was manufactured and tested, goes beyond what Rules 702 and 703 allow. Mr. Schroeder also didn't offer a reliable methodology for arriving at that opinion.

Mr. Schroeder may rely on reports of others about regulatory compliance in reaching an opinion based on his own expertise, but his opinions on compliance with codes, standards, and regulations must be confined to the role it plays in device development and the development of the Biomet devices at issue in this case.

2. Mr. Schroeder's Opinion on Factors Surgeons Consider

Mr. Schroeder concludes in his report that:

> Given the significant differences between each device at issue in this proceeding, careful attention must be paid to a multitude of variables including variations in geometry, size, materials, clearance, range of motion, and performance. Moreover, an assessment must also be made of a series of highly idiosyncratic patient, surgeon and health care specific factors concerning matters such as (i) the age, physical condition, health and activity levels of particular patients; (ii) the knowledge base, experience and skill levels of different surgeons; and (iii) a range of factors concerning the treatment provided to particular patients both prior to and following hip replacement or resurfacing surgeries.

[Doc. No. 3382-2 at 38].

The Executive Committee seeks to exclude Mr. Schroeder's opinion about the factors surgeons consider when selecting a hip implant device, arguing that he isn't qualified to offer an opinion on the selection of a device for a particular

patient because he has no medical experience or training, and generalized opinions about the existence of these basic factors doesn't require expert testimony. Biomet notes in its response that it doesn't intend to offer any testimony by Mr. Schroeder about the selection of a device for a particular patient, so my inquiry is limited to whether Rules 702 and 703 allow Mr. Schroeder to opine on the factors surgeons consider when selecting devices generally and how those factors impact the design and development of hip devices.

Mr. Schroeder's report focuses on the design and development of Biomet's metal-on-metal devices. He notes that device designers need to take into account factors such as the age, health, and activity level of particular patients, when designing and developing the devices. I disagree with the Executive Committee's contention that expert testimony on this issue wouldn't be helpful to the trier of fact. For example, Mr. Schroeder opines that to accommodate patients with more active lifestyles, Biomet sought to design a device with a larger femoral head component because it offered greater range of motion. And while Mr. Schroeder might have relied on the opinions of others, including surgeons, about how age, health, and activity level of a patient factors into device selection, Rules 702 and 703 permit that. *See* Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 612 (7th Cir. 2002) (recognizing that an expert witness can rely on the opinions of others when formulating an opinion).

3. Mr. Schroeder's Opinion on Revision Rates and Negative Media Attention

The Executive Committee seeks to exclude Mr. Schroeder's opinion about the impact negative media attention might have had on revision rates. Mr. Schroeder's expert report doesn't address this issue, but he was questioned about it during his deposition. Because Biomet indicated in its response that it doesn't intend to elicit any opinion or testimony on the matter from Mr. Schroeder, on that issue, I deny the Executive Committee's motion to exclude Mr. Schroeder's opinions on revision rates and negative media attention.

C. Dr. Schultz's Opinions

Biomet designated Daniel Schultz, M.D., as an expert. Dr. Schultz is a board-certified surgeon who worked at the FDA from 1994 to 2009, directing the Center for Devices and Radiological Health, which is responsible for oversight of medical devices. He now provides regulatory guidance on pre- and post-market regulatory requirements for medical devices and combination products to healthcare companies.

Dr. Schultz's report describes the FDA's 510(k) clearance process generally and the Biomet devices' 510(k) process specifically. He was asked at his deposition for his opinion on a report that criticized the FDA's 510(k) process. Dr. Schultz said he disagreed with the report's contention that the 510(k) process only evaluates substantial equivalence, not safety and effectiveness. Dr. Schultz didn't dispute that the statutory and regulatory language focuses on substantial equivalence, but noted that in applying the statute and the regulations, the FDA

staff "compar[e] the safety and effectiveness of one device with the safety and effectiveness of another device in order to establish substantial equivalence." [Doc. No. 3383-2 at 29].

The Executive Committee seeks to exclude these opinions, arguing that (1) the Executive Committee doesn't contend Biomet violated the 510(k) process and statutory and regulatory compliance is a question of law that an expert can't resolve; (2) Dr. Schultz's opinion that the 510(k) process considers safety and effectiveness in addition to substantial compliance is contrary to the FDA's statutory and regulatory authority; and (3) testimony that Biomet devices were cleared through the 510(k) process is more prejudicial than probative because it is likely to mislead and confuse the jury while offering little, if any, evidence of the reasonableness of Biomet's actions or that the devices were safe.

The Executive Committee is right that "[t]he meaning of federal regulations is not a question of fact, to be resolved by the jury after a battle of experts . . . [rather] [i]t is a question of law, to be resolved by the court." Bammerlin v. Navistar Int'l Transp. Corp., 30 F.3d 898, 900 (7th Cir. 1994). But not all expert testimony that touches on federal regulations and statutes is impermissible. "Experts are permitted to testify regarding how their government agency applies rules as long as the testimony does not incorrectly state the law or opine on certain ultimate legal issues in the case." United States v. Davis, 471 F.3d 783, 789 (7th Cir. 2006).

Dr. Schultz's opinions describe the way the FDA applies the 510(k) rules, rather than invading the court's province to define the law. His report outlines

the 510(k) process at the FDA and the clearance of the Biomet devices. The Executive Committee focuses on Dr. Schultz's opinion, which was elicited during his deposition, that the 510(k) substantial equivalence process doesn't exclude safety and effectiveness issues. But in his testimony, Dr. Schultz recognized the statutory and regulatory framework and noted that, in applying that framework, FDA staff "compar[e] the safety and effectiveness of one device with the safety and effectiveness of another device in order to establish substantial equivalence." [Doc. No. 3383-2 at 29].

The Executive Committee argues that Dr. Schultz's opinion directly contradicts the law. I disagree. Dr. Schultz couldn't and didn't opine that 510(k) clearance is a formal FDA safety and effectiveness review of a device or indicates that the FDA has determined that the device is safe and effective. That opinion would contradict the law. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (recognizing that the § 510(k) process doesn't include a formal safety or efficacy review); In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913, 921 (4th Cir. 2016) (the FDA's 510(k) clearance of a device rests on a substantial equivalence finding, not a safety or effectiveness determination). But Dr. Schultz's opinion that FDA staff examines safety and effectiveness when making a substantial equivalence determination doesn't contradict the law. The Supreme Court understood that the 510(k) clearance process "is focused on *equivalence*, not safety" but recognized that, as part of the substantial equivalence determination process "the FDA may well examine § 510(k) applications . . . with a concern for the safety and effectiveness of the device."

Medtronic, Inc. v. Lohr, 518 U.S. 470, 493 (1996). The FDA's guidance for staff conducting 510(k) evaluations explains that "the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review." FOOD AND DRUG ADMIN., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)], 6 (2014).

The Executive Committee is on firmer ground when it argues that any probative value of Dr. Schultz's opinions on the 510(k) process is substantially outweighed by the risk of undue delay or misleading or confusing the jury and so should be excluded under Rule 403. "Rule 403 permits the court to exclude otherwise relevant evidence 'if its probative value is substantially outweighed by a danger of ... unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence.'" Thompson v. City of Chicago, 722 F.3d 963, 971 (7th Cir. 2013) (quoting Fed. R. Evid. 403).

Some courts have excluded expert testimony on the 510(k) process, finding that "[w]hile 510(k) clearance might, at least tangentially, say something about the safety of the cleared product, it does not say very much," In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913, 920 (4th Cir. 2016), and any probative value is substantially outweighed by the risk of time-consuming mini-trials on regulatory compliance, battles of experts on the import of the 510(k) process's safety inquiry, and jury confusion about whether "federal regulatory compliance, not state tort liability, was the core issue." Eghnayem v. Boston Sci. Corp., ___ F.3d ___, No. 16-11818, 2017 WL 4681345, at *7 (11th Cir. 2017); Huskey v. Ethicon, Inc., 848 F.3d 151, 160–61 (4th Cir.

2017). *See also* In re Zimmer Nexgen Knee Implant Prod. Liab. Litig., No. 11 C 5468, 2015 WL 5145546, at *14 (N.D. Ill. Aug. 31, 2015) (excluding expert testimony on the 510(k) process because "there is significant risk that jurors may be led to believe that the 510(k) clearance that [the device] received is equivalent to a finding of non-negligent design, which is an incorrect statement of law"); Lewis v. Johnson & Johnson, 991 F. Supp. 2d 748, 754 (S.D.W. Va. 2014) (excluding 510(k) clearance evidence in the Ethicon's mesh products MDL because "[a]dmission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims").

Other courts have admitted expert testimony on the 510(k) process because expert "testimony on FDA guidelines and regulations, and [a manufacturer's] compliance therewith, is helpful to the trier of fact because '[a] lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the [medical device] industry.'" Tillman v. C.R. Bard, Inc., 96 F. Supp. 3d 1307, 1329 (M.D. Fla. 2015) (quoting In re Fosamax Prod. Liab. Litig., 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009)). *See also* In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig., 810 F.3d 913, 920 (4th Cir. 2016) (recognizing that "some courts have found evidence of compliance with the 510(k) equivalence procedure admissible in product liability cases").

It's not possible for me to properly weigh, on a docket-wide basis, the probative value of evidence of compliance with the 510(k) process against the

risk of prejudice, delay, or misleading or confusing the jury because the probative value turns on the nuances of state law. For example, in In re C.R. Bard, the Fourth Circuit recognized that under Georgia law compliance with the 510(k) process is relevant to the issue or punitive damages so a "district court is entitled to put 510(k) evidence before the jury." In re C.R. Bard, 810 F.3d at 922.

Regulatory compliance in a product liability case can also be relevant in other states. *See, e.g.,* Colo. Rev. Stat. § 13-21-403 (creating a rebuttable presumption that a product wasn't defective and a manufacturer wasn't negligent if the product "[c]omplied with . . . any applicable code, standard, or regulation adopted or promulgated by the United States or by this state, or by any agency of the United States"); Ind. Code § 34-20-5-1 (creating a rebuttable presumption that a product wasn't defective and a manufacturer wasn't negligent if the product "complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States"); Kan. Stat. Ann. § 60-3304 (deeming a product not defective if it was in compliance with "administrative regulatory safety standards relating to design or performance"); Mich. Comp. Laws § 600.2946 (creating a rebuttable presumption that a manufacturer isn't liable in a product liability action if the product was "in compliance with regulations or standards"); N.D. Cent. Code § 28-01.3-09 (creating a rebuttable presumption that a product isn't defective if "the plans, designs, warnings, or instructions for the product . . . were in conformity with government standards established for that industry"); Okla. Stat. Ann. tit. 76, §

57.2 (creating a rebuttable presumption that a manufacturer isn't liable in a product liability action if the product complied with "regulations adopted, promulgated, and required by the federal government, or an agency of the federal government"); Tenn. Code Ann. § 29-28-104 (creating a rebuttable presumption that a product isn't unreasonably dangerous if the manufacturer complied with "any federal or state statute or administrative regulation . . . prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions").

I agree with Biomet that a Rule 403 ruling on Dr. Schultz's opinions would be premature. A court should exclude evidence on a motion *in limine* "only if the evidence clearly is not admissible for any purpose." United States v. Jones, No. 1:12-CR-00072-TWP, 2013 WL 2936205, at *1 (S.D. Ind. June 14, 2013). *See also* Thomas v. Sheahan, 514 F. Supp. 2d 1083, 1087 (N.D. Ill. 2007). "Unless evidence meets this exacting standard, evidentiary rulings must be deferred until trial so questions of foundation, relevancy, and prejudice may be resolved in context." United States v. Jones, 2013 WL 2936205, at *1. *See also* Thomas v. Sheahan, 514 F. Supp. 2d at 1087.

Determining that Dr. Schultz's opinions on the 510(k) process aren't admissible for any purpose would require a review of a diverse body of state law on the role of regulatory compliance in product liability actions. As I have previously noted in the course of this MDL, such state law determinations should be reserved to the transferor courts. [*See* Doc. No. 3047 at 5], so the Executive

Committee's motion to exclude Dr. Schultz's opinions on the 510(k) process is denied.

D. Dr. Spitzer's Opinions

Biomet designated Andrew Spitzer, M.D., as an expert. Dr. Spitzer is a board-certified orthopedic surgeon, specializing in knee and hip replacement. He is the director of the joint replacement program at Cedars-Sinai Medical Center and conducts an average of 200 joint replacement surgeries each year, forty percent of which are hip replacements. Biomet offered Dr. Spitzer as an expert to testify on, among other things, the rationale for second generation metal-on-metal devices.

The Executive Committee seeks to exclude Dr. Spitzer's opinions about tribology, arguing he is unqualified to opine on the topic.[1] The Executive Committee doesn't take issue with his qualifications to testify on the other topics addressed in his report or contend that his reasoning or methodology isn't scientifically valid and properly applied to the facts at issue. Biomet and Dr. Spitzer both acknowledge that he isn't an expert in tribology and Biomet notes that Dr. Spitzer isn't being offered as a tribology expert, but it contends that he can permissibly rely on the opinions of others when testifying about the improved

[1] The Executive Committee raised for the first time in its reply brief that Dr. Spitzer hasn't implanted or revised any Biomet M2a metal-on-metal devices, seemingly suggesting that his opinions are therefore unreliable. The Executive Committee doesn't develop an argument related to this point and any such argument would be deemed waived because it was raised for the first time in its reply brief. *See* Nelson v. La Crosse Cty. Dist. Atty. (State of Wisconsin), 301 F.3d 820, 836 (7th Cir. 2002) ("[i]t is well settled that issues raised for the first time in a reply brief are deemed waived").

tribological characteristics of the second generation metal-on-metal implants. Biomet points to four journal articles that Dr. Spitzer relied on for these opinions.

As previously discussed, Rule 703 allows an expert to offer "an opinion on facts or data in the case that the expert has been made aware of or personally observed . . . [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. An orthopedic surgeon can reasonably rely on the opinions of other experts, including tribology experts, when deciding whether a hip implant device is safe and effective for his or her patients, so to the extent Dr. Spitzer's opinions on allegedly improved tribological characteristics of the second generation metal-on-metal implants are the type on which an orthopedic surgeon would commonly rely, they are permissible. *See also* Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert").

But, as the Executive Committee notes, Rule 703 doesn't allow a "scientist, however well credentialed he may be, . . . to be the mouthpiece of a scientist in a different specialty." Dura Auto. Sys., 285 F.3d at 614. So while an orthopedic surgeon like Dr. Spitzer can reasonably rely on the opinions of other experts to testify on tribology incident to his expert opinions on hip devices, he can't take the place of a tribology expert and offer opinions beyond those on which an orthopedic surgeon would commonly rely.

Because the Executive Committee seeks to exclude a broad category of testimony—any of Dr. Spitzer's opinions addressing tribology—and some of those opinions would be permissible under Rule 703, I deny the motion to exclude Dr. Spitzer's opinions addressing tribology to the extent an orthopedic surgeon would reasonably rely on a tribology expert in forming an opinion on the issue and grant it to the extent Dr. Spitzer's is attempting to testify as a tribology expert.

E. Dr. St. John's Opinions

Biomet designated Kenneth St. John, Ph.D., as an expert. Dr. St. John has a Ph.D. in biomedical engineering, is a professor emeritus at the University of Mississippi Medical Center, has published research on hip device wear in peer-reviewed journals, and was the long-time chair of ASTM International's[2] biocompatibility testing methods committee. Biomet offered Dr. St. John as an expert to testify on its testing of its M2a device, particularly its premarket testing.

The Executive Committee doesn't object to Dr. St. John's opinions about Biomet's premarket testing of its devices, but seeks to exclude his opinions on Biomet's application of the results of post-market surveillance of its metal-on-

[2] ASTM International, formerly the American Society for Testing and Materials, is an organization comprised of academic, industry, and regulatory representatives, that develops and promulgates standards for manufacturing and materials testing, including testing standards for hip implants. *What Is ASTM?*, ASTM, https://www.astm.org/ABOUT/factsheet.html; Doc. No. 3385-1 at 2; [Doc. No. 3419 at 2].

metal devices and his opinion that metal-on-metal revision rates may be artificially inflated.

The Executive Committee seeks to exclude two conclusions in Dr. St. John's expert report: (1) "Biomet conducted post-market surveillance of [its] devices and appropriately applied the information gleaned from those studies to re-evaluate the status of their devices" and (2) "Biomet reviewed information and data published in peer-reviewed journals concerning clinical experience with [its] devices and appropriately applied any new knowledge that was acquired in assessing potential long term success of the products and any adverse events that may have been seen." [Doc. No. 3385-1 at 16]. The Executive Committee argues that Dr. St. John isn't qualified to offer these opinions because he lacks specialized training or experience to offer the opinions, such as training or experience with FDA regulatory procedures and, to the extent Dr. St. John's opinion simply seeks to note that Biomet performed post-market surveillance, there is no dispute that Biomet conducted some such surveillance and an expert witness isn't necessary to testify to that fact. The Executive Committee also asserts that these opinions lacks sound methodology.

Dr. St. John's report shows that he reviewed and analyzed data from post-market studies published in peer-reviewed papers and data found in national registries of hip implant surgeries to determine how Biomet devices performed as compared to other metal-on-metal devices and metal-on-polyethylene devices. Based on this analysis, he concluded that the data supported Biomet's design and evaluation of the devices.

It's undisputed that Dr. St. John is an expert in hip device wear testing, which requires him to analyze and apply data. I don't see any reason why his qualifications analyzing data in the testing field wouldn't qualify him to analyze data from post-market studies and reports, including clinical studies, conducted by others, especially given that he has experience with a clinical trial himself.

As for his methodology, his report demonstrates that Dr. St. John's opinions on Biomet's post-market surveillance are based on his review of data Biomet provided to the FDA from its post-market surveillance studies on patients who had received metal-on-metal hips, data from studies published in peer-reviewed papers, and data found in national registries of hip implant surgeries. Dr. St. John's opinions are "reasoned, use[ ] the methods of the discipline, and [are] founded on data" so they are admissible. Lang v. Kohl's Food Stores, Inc., 217 F.3d 919, 924 (7th Cir. 2000).

The Executive Committee's contention that Dr. St. John's opinion about post-market surveillance should be excluded for lack of specialized training or experience with FDA regulatory procedures requires a narrow and strained reading of his report. While Dr. St. John's opinion references the "status" of Biomet's devices, which could be interpreted as encompassing FDA clearance or approval of a device, Dr. St. John noted in his testimony that he wasn't offering an opinion on whether Biomet's post-market surveillance complied with FDA regulations, demonstrating that any confusion about this issue can be dealt with through cross-examination. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S.

579, 596 (1993) (recognizing that cross-examination is the appropriate way to attack admissible expert testimony).

The Executive Committee also seeks to exclude Dr. St. John's opinion that metal-on-metal revision rates might be artificially high due to increased scrutiny of the devices. In his report, he opines that:

> In light of the increased attention that MOM devices have received in recent years, comparing revision rates for MOM devices with those for MOP devices may exaggerate perceived differences. Increased attention being focused on MOM devices may mean that CT, MRI, and serum or urine metal ion testing is being performed for MOM, but not MOP[,] patients. Some surgeons may be performing revisions out of an abundance of caution for clinical observations that would not be identified or be considered reasons for revision in MOP patients not receiving the same level of scrutiny.

[Doc. No. 3385-1 at 13]. The Executive Committee seeks to exclude this opinion as unreliable, and I agree that Biomet hasn't demonstrated that Dr. St. John's methodology is scientifically reliable.

To determine the reliability of an expert's theory, courts consider, among other factors, whether it "has been tested[,] . . . subjected to peer review[,] . . . evaluated in light of potential rates of error[,] and . . . accepted in the relevant scientific community." Krik v. Exxon Mobil Corp., 870 F.3d 669, 674 (7th Cir. 2017). This inquiry is made more difficult because, despite heavy citations throughout his report, Dr. St. John provides no citations to support his opinion that metal-on-metal revision rates may be artificially high.

While Biomet notes that Dr. St. John indicated in his deposition that his opinion was based on three articles and two examples of asymptomatic patients having revision surgery because of the patient's concerns about metal ions, it

appears as though those articles considered asymptomatic revisions generally and didn't offer any opinions on whether metal-on-metal revision rates were artificially inflated. When asked if he was aware of any studies or research that "attempts to scientifically prove this theory that you're advancing about revision rates," Dr. St. John couldn't offer any.

Biomet hasn't offered any indication that Dr. St. John's theory that metal-on-metal revision rates are artificially inflated has been tested, subjected to peer review, evaluated for error rates, accepted within the scientific community, or is supported by any other indicia of reliability. Without such reliability indicators, I can't conclude that Dr. St. John's opinion that metal-on-metal revision rates are artificially inflated is "grounded in the scientific process" rather than "a subjective belief or unsupported conjecture," so it must be excluded. *See* Lewis v. CITGO Petroleum Corp., 561 F.3d 698, 705 (7th Cir. 2009).

F. Ms. Truman's Opinions

The Executive Committee designated Mari Truman as an expert. Ms. Truman is a biomedical engineer with a B.S.E. in biomedical engineering and a master's degree in mechanical engineering. She holds nine patents for orthopedic devices; has experience designing devices and directing, analyzing, and performing testing of devices; worked for DePuy Orthopedics for 11 years, including as manager of hip and knee implant technology and senior product development engineer; and now serves as an associate at Robson Forensic.

Biomet seeks to exclude Ms. Truman's opinions that: (1) all metal-on-metal devices are defectively designed; (2) metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices; (3) Biomet should have conducted additional testing of its metal-on-metal devices; (4) Biomet should have provided additional and more aggressive warnings to surgeons about the risks associated with its metal-on-metal devices; (5) Biomet downplayed the risks of its metal-on-metal devices; and (6) excessive metal ions cause certain clinical effects in patients with metal-on-metal devices.

1. Ms. Truman's Qualifications to Opine on Metal-on-Metal Design Defects

Biomet first argues that Ms. Truman isn't qualified to opine that all metal-on-metal devices are defectively designed because she doesn't have expert qualifications in tribology. Biomet supports this argument in part by pointing to portions of the report of Dr. Schmid, Biomet's tribology expert, that question the soundness of Ms. Truman's conclusions about fluid film lubrication. But whether her conclusions are correct is for a factfinder; my role as gatekeeper, is whether she is qualified to offer it.[3] Smith v. Ford Motor Co., 215 F.3d 713, 719 (7th Cir. 2000).

Ms. Truman is a biomedical engineer with experience designing and testing medical device implants, including hip implants. I agree with Judge

[3] While Biomet also asserts that Ms. Truman's opinions that the use of metal-on-metal articulation was itself a design defect is unreliable, it didn't develop this argument or support it with relevant facts from the record or legal authority, so it is waived. United Cent. Bank v. Davenport Estate LLC, 815 F.3d 315, 318 (7th Cir. 2016).

Kinkeade that an engineer with experience with lubrication and device wear issues through device design and testing can opine on those issues "despite the fact that [her] degrees are in the field of mechanical engineering rather than tribology." In re: DePuy Orthopaedics, Inc., No. 3:11-MD-2244-K, 2016 WL 6271474, at *10 (N.D. Tex. Jan. 5, 2016). To the extent Biomet seeks to exclude Ms. Truman opinion that all metal-on-metal devices are defectively designed because she is not qualified to offer it, the motion is denied.

2. Ms. Truman's Opinion that Metal-on-Polyethylene Devices are a Reasonably Safe Alternative to Metal-on-Metal Devices

Biomet next seeks to exclude Ms. Truman's opinion that metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices, arguing that her opinion is unreliable because she "entirely failed to consider material evidence of advantages of metal-on-metal devices and disadvantages of metal-on-polyethylene devices." Biomet contends that her methodology is flawed because she cherry-picked evidence in support of her opinion and ignored other relevant evidence, citing LeClercq v. The Lockformer Co., No. 00 C 7164, 2005 WL 1162979, at *4 (N.D. Ill. Apr. 28, 2005) (holding that cherry-picking facts to support an opinion can't satisfy the scientific method or Daubert).

Ms. Truman's report discusses metal-on-metal and metal-on-polyethylene devices, including their advantages and disadvantages, extensively. Despite arguing that she "entirely failed to consider material evidence of advantages of metal-on-metal devices and disadvantages of metal-on-polyethylene devices," Biomet subsequently recognizes that Ms. Truman articulated two advantages of

metal-on-metal devices over metal-on-polyethylene devices in her report: reduced osteolysis and reduced risk of dislocation. And while Biomet contends that Ms. Truman didn't consider metal-on-metal devices' "outstanding corrosion resistance," Ms. Truman discussed corrosion at length in her report. [*See* Doc. No. 3387-2 at 56–62].

Ms. Truman might not have considered each piece of evidence that Biomet thinks is relevant, but that can be addressed on cross-examination. I am satisfied that she didn't cherry-pick facts, but rather considered sufficient facts and data in reaching her opinion that metal-on-polyethylene devices are a reasonably safe alternative to metal-on-metal devices, so it is admissible over this objection. *See* Stuhlmacher v. Home Depot U.S.A., Inc., 774 F.3d 405, 409 (7th Cir. 2014).

3. Ms. Truman's Opinion that Biomet should have Conducted Additional Testing of its Metal-on-Metal Devices

Biomet seeks exclusion of Ms. Truman's opinion that Biomet should have conducted additional testing of its metal-on-metal devices, arguing that she isn't qualified to opine on the adequacy of the testing and that she didn't employ a reliable methodology in forming her opinion.

Biomet first contends that Ms. Truman isn't qualified to opine on Biomet's simulator testing for wear because she isn't a tribology expert and doesn't have expertise in designing simulator tests. I am not persuaded that opining on the adequacy of metal-on-metal device testing requires a degree in tribology or expertise in designing, as opposed to evaluating, simulator tests. Biomet cites no

authority to support this argument and other courts have found that engineers are qualified to opinion on the adequacy of joint replacement device testing. *See, e.g.*, In re Zimmer Nexgen Knee Implant Prod. Liab. Litig., No. 11 C 5468, 2015 WL 3669933, at *12 (N.D. Ill. June 12, 2015) (recognizing that an engineer could properly "rely on his expertise and experience to critique the testing that Zimmer itself conducted").

Ms. Truman notes that her experience includes "performing laboratory evaluation of performance characteristics for orthopedic implant . . . systems" and indicates that she is familiar with in vitro testing (laboratory wear, static, and fatigue testing) from her role as the leader of a medical device design team. [Doc. No. 3387-2 at 3–4]. Biomet acknowledges her experience setting performance standards, but argues that an opinion on the adequacy of testing requires experience designing testing. Experience and expertise in testing design could qualify an expert to opine on the adequacy of testing, but I don't see any reason why experience and expertise in setting performance standards for testing wouldn't also qualify an expert to opine on the adequacy of testing. Furthermore, Ms. Truman testified that she has experience in designing testing related to finger joint devices. For these reasons, I have no reason to part with other courts who have found that Ms. Truman is qualified to opine on the adequacy of medical device testing. *See, e.g.*, Moore v. Wright Med. Tech., Inc., No. 1:14-CV-62, 2016 WL 1316716, at *5 (S.D. Ga. Mar. 31, 2016).

I also find that Ms. Truman employed a reliable methodology in forming her opinions on the adequacy of Biomet's testing. As demonstrated in her report,

she examined the testing Biomet conducted and pointed to other testing employed in peer-reviewed studies, [Doc. No. 3387-2 at 41], and compared Biomet's metal-on-metal testing with its metal-on-polyethylene testing. Id. at 45. Biomet argues that Ms. Truman doesn't recognize that Biomet's simulator testing was standards-compliant, but that goes to the weight her opinion should be afforded by a factfinder rather than its admissibility. *See* Stollings v. Ryobi Techs., Inc., 725 F.3d 753, 766 (7th Cir. 2013).

Accordingly, to the extent Biomet seeks to exclude Ms. Truman's opinions on the adequacy of its testing of its metal-on-metal devices, the motion is denied.

4. Ms. Truman's Opinion on the Adequacy of Biomet's Warnings

Biomet moves to exclude Ms. Truman's opinions on the adequacy of its warnings, arguing that she isn't qualified to opine on the issue and that she didn't employ a reliable methodology in forming her opinion. Biomet argues that Ms. Truman isn't qualified to opine on the topic because she isn't "an orthopedic surgeon and thus has no experience or expertise in evaluating . . . warnings." Biomet cites to a case from another circuit to support its argument that a medical degree or medical training is necessary to opine on warning labels. *See* Gebhardt v. Mentor Corp., 15 F. App'x 540, 542 (9th Cir. 2001).

"Whether a witness is qualified as an expert can only be determined by comparing the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness's testimony." Gayton v. McCoy, 593 F.3d 610, 616 (7th Cir. 2010) (quoting Carroll v. Otis

Elevator Co., 896 F.2d 210, 212 (7th Cir.1990)). While Ms. Truman isn't an orthopedic surgeon, she has "been involved in both the creation and review of warnings and precautions provided in package inserts and surgical techniques for well over a dozen [orthopedic] product families for about a dozen different [orthopedic] companies." [Doc. No. 3387-2 at 4]. Ms. Truman's experience developing and reviewing warnings for orthopedic products qualifies her to opine on the adequacy of Biomet's warnings. *See* Diaz-Granados v. Wright Med. Tech., Inc., No. 614CV1953ORL28TBS, 2016 WL 1337264, at *5 (M.D. Fla. Apr. 1, 2016) (holding that "Ms. Truman is qualified to opine on the adequacy of Defendant's warning because she has thirty-five years of experience in biomechanics and orthopedics, which includes experience serving on design and development teams creating and reviewing warnings accompanying several orthopedic medical devices").

Biomet next asserts that Ms. Truman's methodology is unreliable because she doesn't explain whether and how additional warnings would have affected a surgeon's decisions and she didn't test her theory through studies or other mechanisms. Biomet cites no authority to support its contention Ms. Truman needed to explain whether and how additional warnings would impact a surgeon; this argument goes more to the weight the jury should assign her opinion rather than its admissibility. While Ms. Truman acknowledged that she hasn't tested her theory through studies, her "methodology is based on [her] extensive practical experience in this area, rather than novel methodology subject to publication, [so her] failure to publish does not cast doubt on the reliability of

[her] analytical technique." Smith v. Ford Motor Co., 215 F.3d 713, 720 (7th Cir. 2000). Ms. Truman's methodology is evident from her report: she compared Biomet's warnings with relevant research on the alleged risks associated with metal-on-metal devices and opined on what additional warnings were necessary based on the deficiencies she found. This methodology is reliable. *See* In re Zimmer Nexgen Knee Implant Prod. Liab. Litig., No. 11 C 5468, 2015 WL 3669933, at *32 (N.D. Ill. June 12, 2015) (holding that an expert's methodology for opining on the adequacy of warnings was unreliable because he didn't "described what warnings were in fact included in [the product's] package insert or why he believed those warnings were inadequate. Nor did he describe what an adequate warning would have included.").

5. Ms. Truman's Opinion that Biomet Downplayed the Risks of its Metal-on-Metal Devices

Ms. Truman says that Biomet knew about the risks of its metal-on-metal devices and downplayed those risks. Biomet contends these opinions aren't helpful to the jury because no specialized knowledge is needed to evaluate what Biomet knew about any risks associated with its devices or whether it downplayed those risks.

Rule 702 requires that an expert offer "specialized knowledge [that] will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. The threshold question is whether Ms. Truman's opinions are "beyond the ken of the average layperson." Florek v. Vill. of Mundelein, Ill., 649 F.3d 594, 602 (7th Cir. 2011). Biomet argues that her opinions aren't beyond the

grasp of the average layperson because the Executive Committee could just show the jury the relevant documents to demonstrate what Biomet knew and compare that to what their marketing materials included.

I disagree that Ms. Truman's testimony won't help the jury understand the evidence related to Biomet's knowledge of alleged risks of its devices and whether it downplayed those risks. Biomet is correct that the jury can be shown Biomet's design file documents, emails, and post-market surveillance reports Ms. Truman points to as evidence that Biomet was aware of alleged risks associated with its devices and Biomet's marketing materials she claims downplayed those risks. But Ms. Truman's expertise, subject to Biomet's cross-examination, could help the jury understand the import and implications of the information and studies referenced in Biomet's materials and whether its marketing materials adequately captured the alleged risks described in the relevant scientific literature. Accordingly, to the extent Biomet seeks to exclude Ms. Truman's opinion that Biomet knew about the risks of its metal-on-metal devices and downplayed those risks, the motion is denied.

6. Ms. Truman's Opinion on the Clinical Effects of Metal Ions

Biomet moves to exclude Ms. Truman's opinion on the clinical effects of metal ions in the body. Ms. Truman opined that Biomet's metal-on-metal devices can cause "elevated metal ions with immune response complications . . . and tissue necrosis." [Doc. No. 3387-2 at 86]. Biomet argues that she isn't qualified

to offer an opinion on the clinical effects of metal ions in the body because she isn't a pathologist and has no relevant experience.

As previously noted, Rule 703 allows Ms. Truman to offer "an opinion on facts or data in the case that the expert has been made aware of or personally observed . . . [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. But Rule 703 doesn't allow a "scientist, however well credentialed he may be, . . . to be the mouthpiece of a scientist in a different specialty." Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002).

Ms. Truman's report shows that the opinion at issue is offered in support of one of her report's central conclusions: that Biomet's metal-on-metal devices are unreasonably dangerous. To substantiate this opinion, she describes metal-on-metal articulations as unforgiving and prone to edge loading, which generates excessive wear. She notes that this excessive wear produces elevated metal ions, which cause immune response complications and tissue necrosis. She recognized in her deposition testimony that she isn't a surgeon, pathologist, or toxicologist, and will leave the "clinical" opinions to medical professionals, but asserted she reviewed the peer-reviewed literature to familiarize herself with the topic because experts considering the devices' design and their risks should be familiar with that literature. [Doc. No. 3411-1 at 161–164].

Ms. Truman can't testify as an expert on the clinical effects of metal ions, but she can permissibly rely on other experts' opinions that metal ions cause clinical effects to support her opinion that metal-on-metal devices are

unreasonably dangerous. *See* Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002). That's what she did in her report, so her opinion is admissible.

G. Dr. Kantor's Opinions

The Executive Committee designated George Kantor, Ph.D., as an expert. Dr. Kantor is a board-certified orthopedic surgeon, specializing in hip, knee, and shoulder replacement. He completed a post-doctoral fellowship in adult reconstructive and joint replacement surgery and has served as an instructor or consultant to Johnson and Johnson Orthopedics and DePuy Orthopaedics. Over the course of thirty years of practice, Dr. Kantor has performed some 5,000 total hip arthroplasty procedures.

Biomet seeks to exclude Dr. Kantor's opinions that (1) metal-on-metal devices generally, and Biomet's metal-on-metal devices specifically, are defectively designed and their risks outweigh their benefits; (2) Biomet didn't conduct sufficient testing and monitoring of its devices; (3) Biomet's instructions for use were inadequate; and (4) elevated metal ions might cause cancer.

1. Dr. Kantor's Opinions on Metal-on-Metal Devices Generally and Biomet's Devices Specifically

Biomet seeks to exclude Dr. Kantor's opinions that all metal-on-metal devices, regardless of design differences, and including Biomet's devices, have the same design defects and that the risks associated with all metal-on-metal devices, including Biomet's devices, outweigh the benefits. Biomet argues that

these opinions should be excluded because (1) Dr. Kantor isn't a tribology expert, (2) his opinions aren't based on a reliable methodology, and (3) his opinions on Biomet's devices specifically aren't based on adequate facts and data because he didn't conduct any device-specific analysis on Biomet's devices.

I disagree with the proposition the Dr. Kantor isn't qualified to opine on the design of and risks associated with metal-on-metal devices because he isn't a tribology expert. Dr. Kantor opines, for example, that all metal-on-metal devices suffered from a basic design problem: metal-on-metal bearing surfaces and large femoral heads. Biomet contends that such an opinion requires tribology expertise because it presupposes that it isn't possible to design a metal-on-metal hip implant that sufficiently diminishes wear to reduce metal ion level to clinically acceptable levels.[4] I disagree.

In his report, Dr. Kantor indicates that his opinions on the risks associated with metal-on-metal devices are based on his training, research, and experience with metal-on-metal devices, not tribology. For example, he opined that "I have, time and time again, personally seen the negative impact of the significant orthopedic and musculoskeletal damage caused by [metal-on-metal] hip systems implanted in my patients and the patients who have been reported in the medical literature. Specifically, prosthetic-generated metallic wear debris can destroy the

[4] Biomet argues in its reply brief that Dr. Kantor opined that it was "impossible to design a safe and effective hip implant that includes metal-on-metal bearing surfaces and a 'large' femoral head." [Doc. No. 3448 at 4]. But Biomet doesn't cite where in his report or his testimony he offered such an opinion.

soft tissue . . . as well as the bony foundation to the hip joint." [Doc. No. 3446-1 at 15].

While Dr. Kantor discusses issues that arguably fall within the field of tribology, [*see, e.g.,* Doc. No. 3446-1 at 15 (noting that the use of metal-on-metal bearing surfaces causes metal debris)], Rule 703 allows an orthopedic surgeon to reasonably rely on the opinions of other experts. *See* Dura Auto. Sys. of Indiana, Inc. v. CTS Corp., 285 F.3d 609, 614 (7th Cir. 2002) ("it is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert"). Dr. Kantor permissibly relied on his training, research, and experience in forming his opinions on the risks associated with metal-on-metal devices and permissibly relied on the expertise of others rather than attempting to testify as a tribology expert.

Biomet next contends that Dr. Kantor's opinions on the risks associated with metal-on-metal devices are based on unreliable methodology because he didn't address the impact of so-called second-generation metal-on-metal devices on his previously formed opinions about metal-on-metal devices.[5]

[5] Biomet also argues that Dr. Kantor failed to meaningfully engage "the primary clinical evidence available in the 1990s that design advances had solved many of the problems with first-generation metal-on-metal hips." Biomet goes on to describe a Metasul study it claims Dr. Kantor didn't engage as a "glaring example" of his failure to consider relevant studies. Assuming, *arguendo*, that Dr. Kantor's opinion would be rendered unreliable if he ignored the Metasul study despite the body of research he considered, his testimony shows he was familiar with the study but found it unpersuasive. He testified at his deposition that he didn't find the study persuasive because the post-implant period considered in the study was too short to offer meaningful data and the study didn't appropriately consider patient-specific variables.

As his report and his deposition testimony demonstrate, Dr. Kantor considered the key design differences between first and second-generation metal-on-metal devices, addressed the foundation for his opinion that second-generation devices still pose risks, and engaged relevant studies on the issue. Dr. Kantor noted that second-generation metal-on-metal devices differed from first-generation devices in the metal alloys employed, the production and polish techniques, stem designs, head sizes, and the use of cementless components. He testified that while the failure modes of first and second-generation devices are mechanically and histologically similar, the nanoparticulate size of ion debris associated with second generation devices causes increased soft tissue complications.

I am satisfied that Dr. Kantor considered the effect and impact of the second-generation devices in forming the opinions he offered in his report and his testimony. He also demonstrated that those opinions were based on a reliable methodology. First, Dr. Kantor indicated that he tested his opinions against "numerous studies published over the last few years, updated patient safety information from government regulatory agencies, data from international joint registries" and the experience of patients in his and colleagues' practices, [Doc. No. 3446-1 at 13-14], which is a factor demonstrating reliability. *See* Krik v. Exxon Mobil Corp., 870 F.3d 669, 674 (7th Cir. 2017) ("whether the proffered theory can be and has been tested" suggests reliability). More importantly, in his report, Dr. Kantor indicated he has performed approximately 5,000 total hip arthroplasty procedures and has performed revision surgeries and treated

patients with second generation metal-on-metal devices. His experience with metal-on-metal devices in his practice, including second generation devices, demonstrates reliability because "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 156 (1999).

Accordingly, I deny Biomet's motion to the extent it seeks to exclude Dr. Kantor's generic opinions about the design problems and risks associated with metal-on-metal devices generally.

Biomet next argues that Dr. Kantor didn't perform device-specific analysis of its M2a devices and, instead, simply lumped all second-generation devices together, making his opinions on Biomet devices unreliable because they aren't based on sufficient facts or data or reliable principles and methods.

The reliability inquiry requires that I determine whether Dr. Kantor "considered sufficient data to employ [his] methodology." Stollings v. Ryobi Techs., Inc., 725 F.3d 753, 766 (7th Cir. 2013). The Executive Committee asserts that Dr. Kantor met this obligation because he reviewed 130 peer-reviewed journal articles and Biomet's design files and revised one Biomet device and assisted with another revision. But while those journal articles and Biomet's design file were included in the list of materials Dr. Kantor relied on for his report, it is unclear how many, if any, of the journal articles addressed Biomet devices specifically and his testimony suggests the documents he reviewed didn't provide him with a sufficient factual foundation upon which to opine on Biomet's devices. He testified that he "didn't really focus on" Biomet's design file and didn't

know the two to three-year or ten-year revision rates of Biomet's devices. He concedes that there are differences between Biomet's devices and other metal-on-metal devices, but states neither how the Biomet products share the problems of other devices, nor why any differences between the Biomet product and other products he's seen aren't relevant.

The Executive Committee insists that it's unnecessary for Dr. Kantor to perform device-specific analysis regarding Biomet's devices to reach his generic opinions on the risks and flaws associated with metal-on-metal devices generally. I agree and, for the reasons stated previously, Dr. Kantor's generic testimony about metal-on-metal devices is admissible. But Dr. Kantor, in his report and his deposition, offers opinions about Biomet's devices specifically. For those opinions to be admissible, the Executive Committee must demonstrate that Dr. Kantor considered sufficient data in developing his opinion. *See* Stollings v. Ryobi Techs., Inc., 725 F.3d 753, 766 (7th Cir. 2013). Because the record doesn't demonstrate that Dr. Kantor considered sufficient data in developing his opinion on the risks associated with and the design defects of Biomet devices specifically, I will exclude those opinions as unreliable.

2. Dr. Kantor's Opinion that Biomet Didn't Conduct Sufficient Testing and Monitoring of Its Devices

In his report, Dr. Kantor opined "that manufacturers of [metal-on-metal] hip implants, including the Biomet [metal-on-metal] hip implants, conducted an insufficient number of studies of the long-term safety of the [metal-on-metal] hip implants to provide adequate information to orthopedic surgeons and patients

about the risks versus the utility of the [metal-on-metal] hip implant designs." [Doc. No. 3400-1 at 86]. Biomet moves to exclude Dr. Kantor's opinions about the sufficiency of Biomet's testing and clinical studies.

Dr. Kantor's opinion about Biomet's testing suffers from the same flaw as his opinion on risks associated with and the design defects of Biomet devices: he didn't consider the data required to offer a reliable opinion. When asked at his deposition if he reviewed Biomet's preclinical testing, Dr. Kantor conceded that he didn't review all of the relevant testing. [*See* Doc. No. 3446-1 at 66]. For example, Dr. Kantor acknowledged that he only saw "*some* of Biomet's preclinical testing, *some* of [its] bench testing and *some* of [its] wear testing, things like that" and didn't review two articles in the Journal of Arthroplasty on the short and mid-term testing of Biomet's devices. [Doc. No. 3446-1 at 66, 68 (emphasis added)].

An opinion on the sufficiency of Biomet's testing of its devices that is based on a review of only some of the testing conducted rather than a thorough review of that testing isn't based on adequate data and isn't reliable. *See* Stollings v. Ryobi Techs., Inc., 725 F.3d 753, 766 (7th Cir. 2013). Accordingly, I will exclude Dr. Kantor's opinions about the sufficiency of Biomet's testing and clinical studies.

3. Dr. Kantor's Opinions on the Devices' Instructions for Use

In his report, Dr. Kantor opined that "the [i]nstructions for [u]se for the Biomet [metal-on-metal] hip implants, as changed over time, provided

insufficient information to orthopedic surgeons to allow them to fully evaluate the risks versus benefits of the Biomet [metal-on-metal] hip implants and make proper recommendations to their patients." [Doc. No. 3446-1 at 14]. Biomet seeks to exclude this opinion, arguing it isn't based on a reliable methodology.

An expert opinion on a device's instructions for use "does not require the type of scientific methodology outlined in Daubert." Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d 420, 440 (E.D.N.Y. 2011). A "commonly accepted methodology used by experts admitted to testify as to the accuracy of [instructions for use]" is for the experts to reach "their conclusions by comparing facts in evidence with the content shown . . . in the [instructions]." Id. *See also* In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., No. MDL 1203, 2000 WL 876900, at *12 (E.D. Pa. June 20, 2000) ("the court cannot preclude [experts'] opinions comparing facts in evidence with the status of the content shown on the labeling of the diet drugs"). Dr. Kantor did just that here. When he was asked at his deposition what Biomet should have included in its instruction for use, he said:

> they should warn people of the potential generation of metal ion debris in not only the articulating interface, but with the use of a -- with the use of a mixed metal head with a larger head, what the potential effects could be with those -- with those design – with those design choices that were being suggested.

[Doc. No. 3446-1 at 72–73]. *See also* Id. at 74 (opining that the instructions for use should have warned people that the large femoral heads can create increased forces that then generates wear particulate debris that can affect the body locally and systematically). Dr. Kantor's testimony demonstrates

that he reached his conclusions by comparing facts of the case with the content of Biomet's instructions for use so it is admissible. *See* Deutsch v. Novartis Pharm. Corp., 768 F. Supp. 2d at 440.

4. Dr. Kantor's Opinions that Elevated Metal Ions Might Cause Cancer

Biomet seeks to exclude Dr. Kantor's opinion, found in his report, that "systemic consequences . . . can result from the use of [metal-on-metal] bearing surfaces and the metal ion particulate debris they produce in the human body." The Executive Committee indicated in its response that it doesn't intend to elicit any opinion or testimony on whether there was a causal link between Biomet's devices and systemic disease, such as cancer, from Dr. Kantor. Accordingly, to the extent Biomet seeks to exclude Dr. Kantor opinions on the systemic effects of elevated metal ions, I deny the motion.[6]

III. CONCLUSION

For the foregoing reasons:

[6] In its reply brief, Biomet argues that I also must exclude any opinions by Dr. Kantor that devices are defectively designed because the risk of systemic diseases outweighed any benefit of the devices, additional pre-market testing or post-market monitoring of Biomet devices would have supported a causal link between Biomet devices and systemic diseases, and Biomet should have included warnings regarding support for a causal link between Biomet M2a hip implants and systemic diseases. As previously noted, the Executive Committee indicated in its response that it wouldn't elicit testimony from Dr. Kantor regarding whether there was a causal link between Biomet's devices and systemic disease from Dr. Kantor, so this argument is moot.

1. The Executive Committee's motion to exclude opinions and testimony of Biomet's expert Steven R. Schmid, Ph.D. [Doc. No. 3381] is DENIED.
2. The Executive Committee's motion to exclude opinions and testimony of Biomet's expert David Schroeder [Doc. No. 3382] is:
    a. GRANTED to the extent it seeks to exclude Mr. Schroeder's opinion that the devices at issue in this case complied with every applicable code, standard, and regulation when they were designed and when each device was manufactured and tested; and
    b. DENIED to the extent it seeks to exclude Mr. Schroeder's opinions on compliance with codes, standards, and regulations confined to the role such compliance plays in device development and the development of the Biomet devices at issue in this case;
    c. DENIED to the extent it seeks to exclude Mr. Schroeder's opinion about the factors surgeons consider when selecting a hip implant device; and
    d. DENIED to the extent it seeks to exclude Mr. Schroeder's opinions on revision rates and negative media attention.
3. The Executive Committee's motion to exclude opinions and testimony of Biomet's expert Daniel Schultz, M.D. [Doc. No. 3383] is DENIED.

4. The Executive Committee's motion to exclude opinions and testimony of Biomet's expert Andrew I. Spitzer, M.D. [Doc. No. 3384] is:

    a. DENIED to the extent it seeks to exclude Dr. Spitzer's opinions that reasonably rely on tribology as an orthopedic surgeon would in forming an opinion; and

    b. GRANTED to the extent it seeks to exclude opinions that amount to Dr. Spitzer's attempting to testify as a tribology expert.

5. The Executive Committee's motion to exclude opinions and testimony of Biomet's expert Dr. Kenneth St. John [Doc. No. 3385] is:

    a. DENIED to the extent it seeks to exclude Dr. St. John's opinions on Biomet's application of the results of post-market surveillance of its metal-on-metal devices; and

    b. GRANTED to the extent it seeks to exclude Dr. St. John's opinion that metal-on-metal revision rates may be artificially inflated.

6. Biomet's motion to exclude opinions and testimony of the plaintiffs' expert Mari Truman [Doc. No. 3386] is DENIED.

7. Biomet's motion to exclude opinions and testimony of the plaintiffs' expert George S. Kantor, M.D. [Doc. No. 3399] is:

a. GRANTED to the extent it seeks to exclude Dr. Kantor's opinions on the risks associated with and the design defects of Biomet devices specifically;

b. GRANTED to the extent it seeks to exclude Dr. Kantor's opinions about the sufficiency of Biomet's testing and clinical studies;

c. DENIED to the extent it seeks to exclude Dr. Kantor's generic opinions about the design problems and risks associated with metal-on-metal devices generally;

d. DENIED to the extent it seeks to exclude Dr. Kantor's opinions on the Biomet devices' instructions for use; and

e. DENIED to the extent it seeks to exclude Dr. Kantor's opinions on the systemic effects of elevated metal ions.

SO ORDERED.

ENTERED: December 21, 2017

/s/ Robert L. Miller, Jr.
Judge, United States District Court