IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION	§	MDL Docket No.
This Order Relates To:	§	
Andrews – 3:15-cv-03484-K	§	
Davis – 3:15-cv-01767-K	§	3:11-MD-2244-K
Metzler – 3:12-cv-02066-K	§	
Rodriguez – 3:13-cv-3938-K	§	
Standerfer – 3:14-cv-01730-K	§	
Weiser – 3:13-cv-03631-K	§	

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO EXCLUDE EXPERT TESTIMONY

Before the Court are the following motions to exclude, in whole or in part, the opinions and testimony of expert witnesses identified by Plaintiffs:

1. Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Experts Regarding the Purported Risks of Systemic Illness Associated with Metal-on-Metal Hip Implants [*Andrews*, Doc. 79; *Davis*, Doc. 76; *Metzler*, Doc. 72; *Rodriguez*, Doc. 71; *Standerfer*, Doc. 75; and *Weiser*, Doc. 77];

2. Defendants' Motion to Partially Exclude the Opinions and Testimony of Albert H. Burstein, Ph.D. [*Andrews*, Doc. 74; *Davis*, Doc. 75; *Metzler*, Doc. 71; *Rodriguez*, Doc. 70; *Standerfer*, Doc. 74; and *Weiser*, Doc. 76];

3. Defendants' Motion to Exclude, in Part, the Expert Opinions and Testimony of Minette E. Drumwright [*Andrews*, Doc. 75; *Davis*, Doc. 77; *Metzler*, Doc. 73; *Rodriguez*, Doc. 72; *Standerfer*, Doc. 76; and *Weiser*, Doc. 78];

4. Defendants' Motion to Partially Exclude the Opinions and Testimony of Nicholas P. Jewell, Ph.D. [*Andrews*, Doc. 71; *Davis*, Doc. 78; *Metzler*, Doc. 74; *Rodriguez*, Doc. 73; *Standerfer*, Doc. 77; and *Weiser*, Doc. 79];

5. Defendants' Motion to Exclude the Testimony of Antoni Nargol [*Andrews*, Doc. 78; *Davis*, Doc. 79; *Metzler*, Doc. 75; *Rodriguez*, Doc. 74; *Standerfer*, Doc. 78; and *Weiser*, Doc. 80];

6. Defendants' Motion to Bar Bernard Morrey, M.D., from Testifying at Trial [*Andrews*, Doc. 72; *Davis*, Doc. 81; *Metzler*, Doc. 77; *Rodriguez*, Doc. 76; *Standerfer*, Doc. 80; and *Weiser*, Doc. 82];

7. Defendants' Motion to Exclude Undisclosed Opinions and Testimony of Dr. Nicholas Athanasou [*Andrews*, Doc. 64; *Davis*, Doc. 82; *Metzler*, Doc. 78; *Rodriguez*, Doc. 77; *Standerfer*, Doc. 81; and *Weiser*, Doc. 83.]; and

8. Defendants' Motion to Limit the Testimony of Matthew Morrey, M.D., to Opinions Disclosed in His Expert Report [*Andrews*, Doc. 63; *Davis*, Doc. 83; *Metzler*, Doc. 79; *Rodriguez*, Doc. 78; *Standerfer*, Doc. 83; and *Weiser*, Doc. 84].

For the reasons set forth herein, the first four motions—concerning "systemic illness," Burstein, Drumwright, and Jewell—are DENIED. Motions five through eight—concerning Nargol, Bernard Morrey, Athanasou, and Matthew Morrey—are GRANTED IN PART pursuant to the conditions explained below.

I. Factual and Procedural Background

Pursuant to 28 U.S.C.§1407, the United States Judicial Panel on Multidistrict Litigation ordered coordinated or consolidated pretrial proceedings in this Court of all actions involving the Pinnacle Acetabular Cup System hip implants ("Pinnacle Device") manufactured by Defendant DePuy Orthopaedics, Inc. The DePuy Pinnacle multidistrict litigation ("MDL") involves the design, development, manufacture, and distribution of the Pinnacle Device. The Pinnacle Device is used to replace diseased hip joints and was intended to remedy conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, or fracture, and to provide patients with pain-free natural

motion over a longer period of time than other hip replacement devices. Presently there are over eight thousand cases in this MDL involving Pinnacle Devices made with sockets lined with metal, ceramic, or polyethylene. The Plaintiffs in the MDL act through a large group of Plaintiffs' lawyers that form the Plaintiffs' Steering Committee, which in turn is headed by the Plaintiffs' Executive Committee, a small group from the Plaintiffs' Steering Committee appointed by this Court to conduct discovery and other pretrial proceedings and identify common issues in the MDL.

On July 15, 2016, the Court entered a Scheduling Order providing that six cases involving California Plaintiffs Andrews, Davis, Metzler, Rodriguez, Standerfer, and Weiser be set for a third bellwether trial. Defendants' Motions address the qualifications of many of Plaintiffs' designated trial expert witnesses and the reliability and relevance of the opinions and seek to exclude, in whole or in part, the testimony of four experts on alleged "systemic injuries" as well as Plaintiffs' experts Albert H. Burstein, Ph.D., Minette E. Drumwright, Nicholas P. Jewell, Ph.D., Antoni Nargol, Bernard Morrey, M.D., Dr. Nicholas Athanasou, and Matthew Morrey, M.D. from this third bellwether trial.

II. Burden of Proof for Exclusion of Expert Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides that: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may

testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. The Supreme Court affirmed that Rule 702 is the standard for admission of expert testimony and stated that the dual standards of "relevance" and "reliability" would determine the admissibility of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). Rule 702 was amended in 2000 and now provides more guidance, instructing that the Court should assist the trier of fact by admitting expert evidence "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

Faced with a proffer of expert scientific testimony, this Court must determine at the outset admissibility under Rule 702 by following the directions provided in Rule 104(a) of the Federal Rules of Evidence. Under Rule 104(a), this Court is to conduct preliminary fact finding and make a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and whether that reasoning or methodology properly can be applied to the facts of the case. Fed. R. Evid. 104(a); *Daubert*, 509 U.S. at 592-93. This Court, however, is not bound by the rules of evidence in determining preliminary questions concerning qualification of witnesses and admissibility of evidence. Fed. R. Evid. 104(a); *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). The party offering expert testimony has the burden to prove by a preponderance of the evidence that the testimony satisfies rule 702. *Mathis v. Exxon Corp.*, 302 F.3d 448, 459-60 (5th Cir. 2002). This Court has

broad discretion in determining the admissibility of expert evidence under *Daubert*. *Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 351 (5th Cir. 2007). Once it is determined that an expert is qualified to testify, the proponent need only demonstrate that the expert's findings and conclusions are more likely than not reliable. *Moore*, 151 F.3d at 276.

The expert's opinions do not have to be either infallible or uncontradicted to be admissible; the question of whether the expert's opinions are correct is reserved for the fact finder. *Wattle v. Barko Hydraulics LLC*, 107 Fed. App'x 396, 398 (5th Cir. 2004). *Daubert* makes clear that the appropriate means of attacking admissible, albeit shaky, evidence is through vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof. *Daubert*, 509 U.S. at 596; *see also Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004) ("It is the role of the adversarial system, not the court, to highlight weak evidence . . .").

A witness testifying under rule 702 must be qualified as an expert by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. The witness's qualification as an expert may be by way of education, even in the absence of practical, hands-on experience. *Lavespere v. Niagara Machine & Tool Works, Inc.*, 910 F.2d 167, 176-77 (5th Cir. 1990). A formal education, however, is not required; practical experience may suffice. *United States v. Hernandez-Palacios*, 838 F.2d 1346, 1350 (5th Cir. 1988).

In *Daubert*, the Supreme Court provided a list of four non-exhaustive factors that a court may use in making its gatekeeping determination of reliability: (1) "whether a theory or technique . . . can be (and has been) tested;" (2) "whether the theory or technique has been subjected to peer review and publications;" (3) whether, "in the case of a particular scientific technique," there is a high "known potential rate of error" and there are "standards controlling the technique's operation;" and (4) whether the theory or technique enjoys "general acceptance" within a "relevant scientific community." *Daubert*, 509 U.S. at 593-94. The *Daubert* factors, however, are not definitive or exhaustive. *Broussard v. State Farm Fire & Casualty Co.*, 523 F.3d 618, 631 (5th Cir. 2008) (data from space center and eyewitnesses relied upon to form opinion was sufficiently reliable and expert opinion admissible despite the fact "his work had not been peer reviewed and he did not know of others who had used his methods"); *see also In re Vioxx Prods. Liab. Litig.*, No. 05-4046, 2006 WL 6624015, at *4 (E.D. La. Feb. 3, 2006) (Fallon, J.) ("Whether some or all of [the *Daubert*] factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony.") (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 138 (1999)).

In addition to determining whether the proffered expert testimony is reliable, the Federal Rules of Evidence and the Supreme Court require that this Court determine whether the evidence will assist the trier of fact—the relevance requirement. Rule 402 provides that all relevant evidence is admissible unless

otherwise provided. Fed. R. Evid. 402. Relevant evidence is defined as that which has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence. Fed. R. Evid. 401; *Daubert*, 509 U.S. at 587.

III. Analysis

Daubert and Rule 702 are not intended to provide an automatic challenge to the testimony of every expert; rather, the rejection of expert testimony is the exception not the rule. Fed. R. Evid. 702 advisory committee note (2000). A review of cases within the Fifth Circuit in which expert opinions have been deemed unreliable and inadmissible reveals extreme circumstances of unreliability that were well beyond, for example, whether the expert considered all potentially relevant literature. *See Burleson v. Glass*, 268 F. Supp. 2d 699, 704-05 (W.D. Tex. 2003) (not one epidemiological study supported expert's theory, no published peer reviewed literature, and expert testified to "significant level of uncertainty" related to potential error in theory); *Frischhertz v. SmithKline Beecham Corp.*, No. 10-2125, 2012 WL 6697124, at *3-4 (E.D. La. Dec. 21, 2012) (Berrigan, J.) (general and specific causation opinions excluded as "pure speculation;" expert admitted that "he knew of no evidence in humans or animals that demonstrates that [drug] was . . . [a] teratogen, and that he does not know if it is . . ."); *Viterbo v. Dow Chem. Co.*, 826 F.2d. 420, 423-24 (5th Cir. 1987) (excluding expert after determining that the medical history that expert relied upon was incomplete in multiple respects).

A. "Systemic Illness"

In advance of the third bellwether trial, Defendants move to exclude the opinions and testimony of four experts designated by Plaintiffs "who seek to opine or suggest that patients with Pinnacle Ultamet implants are at an increased risk of developing cancer (or some other systemic illness) due to the cobalt and chromium in metal wear debris." Mot. at 1. Specifically, Defendants request that the Court exclude testimony on opinions and suggestions touching the "systemic illness" question offered by Dr. Bernard Morrey, Dr. Matthew Morrey, Dr. David A. Kessler, and Dr. Albert H. Burstein. For purposes of the Motion, Defendants define systemic illness as one affecting the body generally rather than a single organ or part—"medical problems in parts of the body other than the hip itself." *Id.* at 1 n.1.

Defendants contend that Dr. Burstein, a biomechanical engineer, is inherently unqualified to testify on systemic illness because he is not a medical doctor. Drs. Morrey, Morrey, and Kessler, Defendants assert, "do not have any expertise in oncology, toxicology, or epidemiology that would allow them to opine on whether exposure to metal ions from the wear of metal-on-metal hip implants causes any sort of cancer or other systemic illness." *Id.* at 10. Additionally, Defendants contend that such expert testimony would be speculative and "impermissible guesswork and pure conjecture" as well as irrelevant to the Plaintiff-specific claims at issue in the third bellwether trial. *Id.* at 15, 18.

"A doctor does not qualify as an expert in all medicine just because the doctor qualifies as an expert in one medical field." *Kallassy v. Cirrus Design Corp.*, No. 3:04-cv-0727-N, 2006 WL 1489248, at *7 (N.D. Tex. May 30, 2006) (Godbey, J.), *aff'd*, 265 F. App'x 165 (5th Cir. 2008). Rather, for a physician to qualify as an expert in a specific field, that physician must demonstrate "sufficient specialized knowledge" regarding the specific field of inquiry. *Tanner v. Westbrook*, 174 F.3d 542, 548 (5th Cir. 1999), superseded by rule on other grounds, Fed. R. Evid. 103(a). The question of sufficient specialized knowledge is a fact-specific inquiry. *See Huss v. Gayden*, 571 F.3d 442, 455 (5th Cir. 2009). In *Huss*, the court distinguished its opinion in *Tanner* and explained that support in the literature, an expert's examination of the party, and an expert's professional experience are all factors considered in determining whether an expert may testify. *See id.*

Reliable expert testimony is that which is "derived by the scientific method," or the result of "more than subjective belief or unsupported speculation." *Moore*, 151 F.3d at 275 (citing *Daubert*, 509 U.S. at 589-90). "It would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty." *Daubert*, 509 U.S. at 590. Support in the literature though, is a factor in favor of reliability. *See Moore*, 151 F.3d at 273-74. "Expert testimony which does not relate to any issue in the case is not relevant." *Daubert*, 509 U.S. at 591. In other words, "there must be a connection between the expert's opinion and the fact testimony." *El Aguila Food Prods. Inc. v. Gruma Corp.*, 301 F. Supp. 2d 612, 619 (S.D. Tex. 2003).

Having conducted two bellwether trials, the Court is generally familiar with these expert witnesses, their qualifications, and their opinions. All four have previously been qualified to testify by this Court in varying areas of expertise. For example, after hearing extensive questioning on his qualifications and experience in the second bellwether trial, the Court recognized Dr. Burstein as an expert in design defect and its implications and the development, design, and effects of certain prostheses in addition to biomechanical engineering.

At trial, Dr. Burstein expressly disclaimed expertise in certain areas such as pathology, the neurological consequences of cobalt toxicity, and cytotoxicity, but testified as an expert in the areas for which he was qualified. Notably, Defendants' complaints about Dr. Burstein's testimony in the second bellwether trial come exclusively from their cross-examination of him rather than from his direct testimony elicited by Plaintiffs' counsel. *See* Mot. at 7 (citing Tr. 204:17–24, 206:2–13, 207:16–19). Dr. Burstein answered the questions of Defendants' counsel, who did not then object to his answers as nonresponsive, speculative, or irrelevant. The transcript of the second bellwether trial reveals that Defendants made objections and received rulings on the record to specific testimony offered by these expert witnesses and were able to thoroughly cross-examine them on their opinions. The third bellwether trial will be conducted in the same manner.

Having heard the previous testimony and weighed the qualifications of these expert witnesses, the Court will not issue a blanket order excluding their opinions on

all "medical problems in parts of the body other than the hip itself" as Defendants request—particularly when it is Defendants' counsel asking the questions that prompt the alleged conjecture. Instead, Defendants should make individualized objections to specific testimony adduced at trial to the extent they believe it exceeds the purposes for which the witnesses have been qualified to testify as experts or pursuant to any other rule of evidence. Consequently, Defendants' Motion to Exclude the Opinions and Testimony of Plaintiffs' Experts Regarding the Purported Risks of Systemic Illness Associated with Metal-on-Metal Hip Implants [*Andrews*, Doc. 79; *Davis*, Doc. 76; *Metzler*, Doc. 72; *Rodriguez*, Doc. 71; *Standerfer*, Doc. 75; and *Weiser*, Doc. 77] is DENIED.

B. Albert H. Burstein, Ph.D.

Plaintiffs have identified Dr. Burstein as an expert in the field of biomechanical engineering to provide opinions regarding anatomy and biomechanics, implant design, the Pinnacle hip implant system and other hip implants, and causation. In addition to the "systemic illness" motion, Defendants move to exclude Dr. Burstein's testimony regarding (1) a particle threshold for osteolysis; (2) the nature and medical cause of Plaintiffs' injuries; (3) the extent of full fluid film lubrication in metal-on-metal hips; (4) taper wear and taper corrosion; and (5) Dr. Burstein's marketing opinions. Defendants contend with regards to opinions (1), (2), and (3) that Dr. Burstein is not qualified to testify on these subjects and that his opinions on the same are unreliable. With respect to (3), Defendants also contend that Dr. Burstein's

opinions on full fluid film lubrication should be excluded because Dr. Burstein did not disclose the same in his expert report. Defendants further contend that, with respect to (4) and (5), Dr. Burstein's opinions should be excluded as irrelevant, and that Dr. Burstein's opinions regarding the truthfulness of DePuy's marketing, item (5), should be excluded because Dr. Burstein is not qualified to opine on marketing.

Dr. Burstein holds a Ph.D. in Applied Mechanics from New York University and, for more than forty years, has designed orthopedic implants. Over the course of his career, Dr. Burstein has held teaching positions at Case Western Reserve University, the Sibley School of Mechanical and Aerospace Engineering, Cornell University, and the Hospital for Special Surgery (1976-present), and has authored or co-authored over 100 peer-reviewed articles, textbooks, and book chapters in the areas of biomechanics, skeletal mechanics and joint replacement, along with serving as a peer-reviewer and editor for the Journal of Bone and Joint Surgery. Dr. Burstein started an implant retrieval analysis program at the Hospital for Special Surgery where he examined over 5,000 retrieved implanted devices, including first-generation metal-on-metal devices. Dr. Burstein also developed The Dana Center, an orthopedic implant design and manufacturing facility, where he designed and oversaw the manufacture of approximately 1,000 custom joints for patients at the Hospital for Special Surgery. Dr. Burstein holds 30 patents for orthopedic implants and total joint replacements.

Defendants contend that Dr. Burstein is not qualified to testify regarding a particle threshold for osteolysis, the nature and medical cause of Plaintiffs' injuries, the extent of full fluid film lubrication in metal-on-metal hips, or the truthfulness of Defendants' marketing. However, Dr. Burstein's lengthy experience as an engineer and designer of orthopedic implants has informed his familiarity and expertise with the materials used in such implants, including the results of decades of research on the effect of the wear debris particles caused by materials used in such implants. As a result, Dr. Burstein is qualified to offer opinions on the effects of debris particles, including osteolysis. Dr. Burstein's applicable experience in conducting a failure analysis on over 5,000 retrieved devices, and subsequently authoring a book chapter detailing that procedure, qualifies Dr. Burstein to perform a failure analysis on the Plaintiffs' retrieved implants and opine as to the nature and cause of Plaintiffs' injuries. Likewise, Dr. Burstein's analysis of lubrication issues in his implant design and failure analysis work qualify him to opine on the same despite the fact that his degrees are in the field of mechanical engineering rather than tribology, and Dr. Burstein, while not a marketing expert, is sufficiently qualified to compare Defendants' marketing messages with the underlying research.

Defendants also contend that Dr. Burstein's testimony regarding a particle threshold for osteolysis, the nature and medical cause of Plaintiffs' injuries, and the extent of full fluid film lubrication in metal-on-metal hips, should be excluded as unreliable. However, in making his assessments regarding the particle threshold for

osteolysis, Dr. Burstein relies on Defendants' documents, published literature, and testimony from Defendants' experts, as well as mathematical calculations of the particles required to produce osteolysis and other cell necrosis with both polyethylene particles and cobalt-chromium particles. Dr. Burstein's methodology underlying his evaluation of the implants regarding their associated particle thresholds is objectively verifiable, subject to repetition and cross examination, and based upon reliable data.

Dr. Burstein's failure analysis of Plaintiffs' retrieved implants followed the procedure he developed and was adopted by the National Standards Bureau. Thus, his analysis of the cause of Plaintiffs' injuries is also based on a reliable method accepted in the industry capable of repetition. Dr. Burstein's testimony regarding extent of full fluid film lubrication in metal-on-metal hip replacements is based upon Defendants' simulator tests, Dr. Burstein's observations of the Plaintiffs' retrieved implants, published research studies and Dr. Burstein's own research while at Cornell University; all of which is accepted, reliable methodology. To the extent Defendants contend that Dr. Burstein's testimony does not accurately rely on or misstates the scientific literature available on these topics, such a contention is more appropriately addressed through cross-examination. *Kumho*, 526 U.S. at 153.

Defendants contend that Dr. Burstein's opinions on full fluid film lubrication should also be excluded because Dr. Burstein did not disclose the same in his expert report. However, Dr. Burstein's report includes his opinion regarding full fluid film lubrication. Rule 26 requires an expert to make a complete statement of his or her

opinions and the reasons for them. *See* Fed. R. Civ. P. 26(a)(2)(B). Should the parties believe that an expert's testimony may exceed his or her expert report, they should address it to the Court at that time for a context-specific inquiry. *See, e.g.*, *CP Interests, Inc. v. Cal. Pools Inc.*, 238 F.3d 690, 698-99 (5th Cir. 2001) (finding no abuse of discretion in admission of expert testimony on subjects mentioned in the report or which were raised on cross examination).

Finally, Defendants contend that Dr. Burstein's testimony as to taper wear and taper corrosion and the truthfulness of Defendants' marketing should be excluded as irrelevant. However, Dr. Burstein's testimony that the design of the taper connection—where the femoral head connects to the neck of the femoral stem—contributed to the excessive number of wear particles necessitating revision surgery, is relevant to the claims at issue and would assist the jury in this matter. Likewise, Dr. Burstein's testimony regarding the truthfulness of Defendants' marketing will be helpful to a fact finder in interpreting complex scientific data to assess the truth of the marketing claims. Accordingly, Defendants' Motion to Partially Exclude the Opinions and Testimony of Albert H. Burstein, Ph.D. [*Andrews*, Doc. 74; *Davis*, Doc. 75; *Metzler*, Doc. 71; *Rodriguez*, Doc. 70; *Standerfer*, Doc. 74; and *Weiser*, Doc. 76] is DENIED.

C. Minette E. Drumwright, Ph.D.

As with Dr. Burstein, Defendants re-urge the Court to exclude certain testimony by Dr. Drumwright despite its ruling applicable to the second bellwether

trial. Plaintiffs identified Dr. Drumwright as an expert in the fields of advertising, marketing, and corporate responsibility to testify generally about advertising and marketing strategies that businesses and other entities employ and specifically about the advertising and marketing strategies of Defendants with respect to metal-on-metal hip implants and Defendants' corporate responsibility. Defendants challenge Dr. Drumwright's opinions regarding (1) whether the marketing of the Pinnacle Device was misleading, inaccurate, or unsupported by science, including opinions on product warning and testing issues; (2) DePuy's compliance with ethical standards in testing, marketing, and selling the Pinnacle Device; (3) DePuy's marketing effect as to orthopedic surgeons and consumers; (4) DePuy's knowledge and intent; and (5) DePuy's relationships with consultants and alleged incentives offered to physicians. Defendants contend that Dr. Drumwright's opinions should be excluded because, respectively, (1) Dr. Drumwright is unqualified to opine on scientific accuracy and her testimony would be unhelpful; (2) compliance with ethical standards are irrelevant; (3) Dr. Drumwright is unqualified to testify about the information that orthopedic surgeons consider when deciding to use a product or the effect of marketing on surgeons, and her testimony is speculative and unreliable; (4) Dr. Drumwright's opinions on DePuy's state of mind are not proper expert testimony and are speculative and unhelpful; and (5) Dr. Drumwright's opinions on DePuy's relationship with its consultants are unhelpful and speculative.

Dr. Drumwright is an Associate Professor at the University of Texas at Austin's Stan Richards School of Advertising & Public Relations, Moody College of Communication, and Department of Business, Government & Society, McCombs School of Business. Dr. Drumwright, who holds a Ph.D. in Business Administration from the University of North Carolina at Chapel Hill, has also taught at Harvard University, the University of North Carolina at Chapel Hill, and Baylor University, and has taught, researched, and consulted in the areas of marketing and corporate responsibility including teaching and advising on responsible marketing in medical and healthcare fields.

Defendants contend that Dr. Drumwright is unqualified to testify regarding scientific accuracy or what surgeons consider when deciding to use a product. However, an expert witness may properly rely on the reports and opinions of other experts as a basis for her expert opinion. *Nat'l Union Fire Ins. Co. v. Smith Tank & Steel Inc.,* No. 3:11-CV-00830, 2014 WL 5794952, at *4 (M.D. La. Nov. 6, 2014) (DeGravelles, J.); *In re Actos (Pioglitazone) Prods. Liab. Litig.*, MDL 6:11-MD-2299, No. 12-cv-00064, 2014 WL 108923, at *8 (W.D. La. Jan. 8, 2014) (Doherty, J.); *see also Daubert,* 509 U.S. at 592 ("Unlike an ordinary witness, *see* Rule 701, an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation."). Moreover, an expert need not have experience in the specific specialty at issue as long as she has sufficient expertise that her opinion is reliable and relevant. *See Huss*, 571 F.3d at 452-56. Here, the Court finds that Dr.

Drumwright has sufficient expertise based upon her education and experience to qualify as an expert, and that her opinions about marketing of the Pinnacle Device are within her areas of expertise.

Defendants also contend that Dr. Drumwright's conclusions regarding the alleged deceptive marketing at issue is just a subjective interpretation of the documents without the application of special skills or a foundation in any scientific, technical, or other specialized knowledge. However, Dr. Drumwright has applied her specialized knowledge in the discipline of marketing, including the areas of marketing codes, regulations, and guidelines, to analyze the voluminous specific marketing representations made by Defendants, and this testimony is helpful to the factfinder. Dr. Drumwright offers opinions from the application of her expertise to documents and their contents, not speculation as to DePuy's state of mind. As Defendants note, this Court has previously rejected Defendants' argument concerning the admission of alleged speculation and narrative testimony concerning a different expert in a prior trial within this MDL. *See In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, MDL No. 3:11-MD-2244-K (N.D. Tex. July 18, 2014). A similar analysis applies here; any alleged speculation within Dr. Drumwright's report is not properly the subject of this *Daubert* analysis and should be addressed to the Court in the context of the presentation of evidence at trial. *See id.* (citing *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, No. 09-02100, 2011 WL 6302287, at *8 (E.D. Ill. Dec. 16, 2011) (Herndon, C.J.)).

Defendants also contend that any opinion Dr. Drumwright may offer regarding Defendants' compliance with "ethical standards," including Johnson & Johnson's corporate credo and company ethics policies, are irrelevant, as they have no bearing on Defendants' compliance with the legal standards at issue in this case. The Court observes that opinions on ethical standards may be helpful to a jury when ethical obligations are of consequence to the issues to be decided by the jury, such as an attorney's ethical obligations in a breach of fiduciary duty claim or a physician's standard of care in claims of negligence. *See, e.g.*, *Client Funding Sols. Corp. v. Crim*, 943 F. Supp. 2d 849, 863-64 (N.D. Ill. 2013) (attorney); *Andrade v. Columbia Med. Ctr.*, 996 F. Supp. 617, 626 (E.D. Tex. 1998) (health care providers). The ethical standards at issue here include published industry standards, which are a valid source when looking to the applicable standard of care. *See Frazier v. Cont'l Oil Co.,* 568 F.2d 378, 381-383 (5th Cir. 1978).

Defendants rely on *In re Rezulin Prods. Liability Litigation* for the premise that ethics opinions are irrelevant and accordingly unhelpful in matters of product liability and marketing claims. *Rezulin*, 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004) (precluding opinions on ethical standards of pharmaceutical companies in suit concerning manufacturing, labeling, and marketing of product). However, expert testimony regarding applicable ethical standards may be helpful in cases where, as here, one party's duties to another are in question through for example, negligence claims, or if the standard of care of alleged negligence is not within the ordinary

experience of lay persons. *See Carlin v. Superior Court*, 920 P.2d 1347, 1351 (Cal. 1996); *Wright v. Stang Mfg. Co.*, 54 Cal. App. 4th 1218, 1230-31, 63 Cal. Rptr. 2d 422 (Cal. Ct. App. 1997); *cf. Johnson v. Superior Court*, 143 Cal. App. 4th 297, 305, 49 Cal.Rptr.3d 52 (Cal. Ct. App. 2006). Dr. Drumwright's testimony on compliance with industry standards and Defendants' own internal policies, therefore, is sufficiently relevant and helpful to the jury to be admitted.

Finally, Defendants question the marketing conclusions drawn by Dr. Drumwright, including conclusions as to the allegedly misleading nature of the marketing in light of testimony regarding several implanting surgeons' own perceptions of whether or not they relied on Defendants' marketing material, and her conclusions on the effect of the marketing. However, Dr. Drumwright's conclusions are supported by citations to peer-reviewed articles demonstrating the effect of marketing claims on physicians. Any contention by Defendants as to the accuracy of Dr. Drumwright's conclusions is more appropriately an attack made on the weight of the testimony at trial rather than its admissibility. *See Daubert*, 509 U.S. at 595.

As Defendants' instant Motion tracks its previous motion regarding Dr. Drumwright, so does the Court's analysis. Defendants' Motion to Exclude, in Part, the Expert Opinions and Testimony of Minette E. Drumwright [*Andrews*, Doc. 75; *Davis*, Doc. 77; *Metzler*, Doc. 73; *Rodriguez*, Doc. 72; *Standerfer*, Doc. 76; and *Weiser*, Doc. 78] is DENIED.

D. Nicholas P. Jewell, Ph.D.

As with Dr. Burstein and Dr. Drumwright, Defendants again move to exclude opinions of Dr. Jewell. Plaintiffs identified Dr. Jewell as an expert in the fields of statistics and biostatistics to offer opinions regarding the relative performance of artificial hip implants with different bearing surfaces. Defendants move to exclude Dr. Jewell's opinions that (1) data from the National Joint Registry for England, Wales and Northern Ireland suggest a Pinnacle metal-on-metal revision rate of 41 percent at 15 years post primary surgery; and (2) combined data from an internal DePuy registry and its clinical studies suggest a Pinnacle metal-on-metal revision rate of 64 percent at 15 years post primary surgery. Specifically, Defendants contend that these opinions are speculative and unreliable and should be excluded.

Defendants' contend that Dr. Jewell's contested opinions are unreliable, as they are based on statistical extrapolations of existing data into future years versus an analysis of the actual revision rate at 15 years post primary surgery, for which no data is available. As a preliminary matter, there is no question from the parties as to Dr. Jewell's qualifications as an expert in statistics and biostatistics. Defendants argue that the Court's previous review of this issue misunderstood Defendants to contest the accuracy of Dr. Jewell's analysis, rather than the methodology. To the contrary, this Court found in the previous bellwether, and affirms here, that Dr. Jewell's statistical methodology, the application of a fitted quadratic model to observed hazard rate data, is a common and well-accepted statistical method that can be

subjected to testing, verification, and cross-examination. Defendants' position is more appropriately an attack made on the weight of the testimony at trial rather than its admissibility. *See Daubert*, 509 U.S. at 595 (district court's focus must be on the principles and methodology, not the conclusions they generate). Defendants' Motion to Partially Exclude the Opinions and Testimony of Nicholas P. Jewell, Ph.D. [*Andrews*, Doc. 71; *Davis*, Doc. 78; *Metzler*, Doc. 74; *Rodriguez*, Doc. 73; *Standerfer*, Doc. 77; and *Weiser*, Doc. 79] is DENIED.

E. Antoni Nargol

Plaintiffs have designated Antoni Nargol, an orthopedic surgeon practicing in England, as a "non-retained expert in the fields of medicine and orthopaedic surgery" for the third bellwether trial. Pls.' Expert Disclosure at 4 (dated Aug. 12, 2016) (attached to Defendants' Motion as Exhibit 2). According to Plaintiffs, "Mr. Nargol has not been retained or specially employed to provide expert testimony in this litigation." *Id.* Plaintiffs designate Nargol to offer expert testimony on experience with DePuy metal-on-metal hips, interactions with DePuy "with respect to the failure of DePuy metal-on-metal hips," and other topics discussed in his deposition. *Id.* at 4-5. Plaintiffs further disclose 18 bullet-pointed "facts and opinions" to which Nargol may testify. *Id.* at 5-6.

Defendants contend they recently learned that Nargol is "a retained, well-paid expert" and, pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), must produce an expert report. Mot. at 2. Instead, Defendants assert, Nargol has only provided

the less extensive summary disclosure required for non-retained experts. *Id.* at 3. For this reason, Defendants request the Court exclude Nargol's testimony in its entirety for failure to produce an expert report or, in the alternative, provide an expert report that complies with Rule 26(a)(2)(B). Plaintiffs contend that most if not all of Mr. Nargol's testimony is lay testimony for which no expert report is required.

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony. Witnesses who are "retained or specially employed to provide expert testimony in the case" must provide a written report containing "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B). In contrast, a party offering a non-retained expert must only provide a disclosure stating the subject matter on which the witness is expected to present evidence and a summary of the facts and opinions to which the witness is expected to testify. *Id.* 26(a)(2)(C). If a party fails to comply with these requirements, the Court may exclude the testimony of the expert witness at trial "unless the failure was substantially justified or is harmless." *Id.* 37(c).

The Court is familiar with Nargol, as his testimony was offered in the first two bellwether trials. Because Nargol has testified in the two previous bellwether trials and has given deposition testimony at the request of Plaintiffs and Defendants, the parties are familiar with Nargol's opinions and bases for those opinions. The Court holds that Plaintiffs may offer Mr. Nargol's testimony at trial by way of live testimony—whether in court or pursuant to a Court order, via contemporaneous

transmission—or by deposition. However, because there has been some remuneration of Nargol related to the Pinnacle MDL, out of an abundance of caution, the Court orders Plaintiffs to produce an expert report on any expert testimony that may be offered at least three (3) days prior to any trial testimony pursuant to Rule 26(a)(2)(B).

Defendants' Motion to Exclude the Testimony of Antoni Nargol [*Andrews*, Doc. 78; *Davis*, Doc. 79; *Metzler*, Doc. 75; *Rodriguez*, Doc. 74; *Standerfer*, Doc. 78; and *Weiser*, Doc. 80] is thus GRANTED IN PART and may be re-urged in its entirety if Plaintiffs do not provide a written report pursuant to Rule 26(a)(2)(B) at least three days prior to any trial testimony by Mr. Nargol.

F. Bernard Morrey, M.D.

Defendants' assert that Dr. Bernard Morrey should not be allowed to testify because he has not produced an expert report in accordance with Federal Rule of Civil Procedure 26(a)(2)(B). Plaintiffs do not list Dr. Bernard Morrey as one of their "witnesses who are not required to provide a written report." Mot. at 2 (citing Pls.' Expert Disclosure at 7-8). Defendants assert that they recently learned he was paid by Plaintiffs for his services after the last bellwether trial.

The same analysis applies as with Mr. Nargol. There is evidence that Dr. Bernard Morrey has received remuneration in the Pinnacle MDL, even if he has not been retained in these bellwether actions. However, the parties are generally familiar with his opinions and bases for those opinions despite the absence to date of the

required report. Dr. Bernard Morrey's testimony has been presented and Defendants cross-examined him at earlier trials and depositions, and he provided a report during the second bellwether trial. As a result, the Court will not exclude Dr. Bernard Morrey's expert testimony if Plaintiffs provide a written report to Defendants three days prior to offering his testimony at trial.

Defendants' Motion to Bar Bernard Morrey, M.D., from Testifying at Trial [*Andrews*, Doc. 72; *Davis*, Doc. 81; *Metzler*, Doc. 77; *Rodriguez*, Doc. 76; *Standerfer*, Doc. 80; and *Weiser*, Doc. 82] is thus GRANTED IN PART and may be re-urged in its entirety if Plaintiffs do not provide a written report pursuant to Rule 26(a)(2)(B) no later than three (3) days prior to any trial testimony by Dr. Bernard Morrey.

G. Dr. Nicholas Athanasou

Defendants contend that a certain opinion by Dr. Nicholas Athanasou should be excluded from trial because he failed to disclose it in his expert report and did not reveal the opinion at issue until his deposition testimony on September 14, 2016. Specifically, Defendants seek to exclude Dr. Athanasou's opinion that Plaintiff Judith Rodriguez's implant caused or contributed to an infection and necessitated her revision. Athanasou Depo. 267:20–270:2. Further, Defendants argue, Dr. Athanasou has disclaimed any qualification to definitively conclude from inspection of Ms. Rodriguez's tissue that the tissue reaction necessitated a revision surgery or that it caused her pain. Plaintiffs assert that Dr. Athanasou's opinions were

adequately disclosed, and even if they were not, any violation of Rule 26 would be harmless.

It does appear that Dr. Athanasou offered new expert testimony on the day of his deposition, potentially leaving Defendants unprepared to cross-examine him on this "new" opinion. The use of this specific deposition testimony by Plaintiffs at trial may prejudice Defendants. Consequently, the Court will exclude that portion of the deposition, specifically pages 267:20–270:2, from trial. Should Plaintiffs wish to introduce this updated opinion concerning Ms. Rodriguez at trial, they must supplement Dr. Athanasou's written report and provide it to Defendants at least three (3) days before he would testify in the third bellwether trial. Defendants then would be able to prepare for cross-examination, and further examination of Ms. Rodriguez's record could well provide more reliable evidence for the trier-of-fact.

Defendants' argument that Dr. Athanasou has disclaimed his qualifications to testify on the matter is unavailing. A review of the testimony shows that Dr. Athanasou acknowledged that no pathologist could determine that "some kind of tissue reaction was the reason for the revision." Athanasou Depo. 288:13–289:3. This is far from stating that neither he, nor any other pathologist, could testify as to the cause of a tissue reaction. Dr. Athanasou's opinions are based on his "knowledge, skill, experience, training, [and] education" and are "more than subjective belief or unsupported speculation." *See* Fed. R. Evid. 702; *Moore*, 151 F.3d at 275.

Defendants' Motion to Exclude Undisclosed Opinions and Testimony of Dr. Nicholas Athanasou [*Andrews*, Doc. 64; *Davis*, Doc. 82; *Metzler*, Doc. 78; *Rodriguez*, Doc. 77; *Standerfer*, Doc. 81; and *Weiser*, Doc. 8.] is thus GRANTED IN PART to exclude deposition pages 267:20–270:2 and may be re-urged concerning his previously undisclosed opinion regarding Ms. Rodriguez if Plaintiffs do not provide a supplemental written report pursuant to Rule 26(a)(2)(B) no later than three (3) days prior to any trial testimony by Dr. Athanasou.

H. Matthew Morrey, M.D.

Defendants move to limit the testimony of Dr. Matthew Morrey, seeking to exclude opinions not included in his expert report regarding Plaintiff Michael Weiser. Defendants assert that in Dr. Matthew Morrey's deposition on September 14, 2016, he offered a number of previously undisclosed opinions relating to, among other things, the position in which the implanting surgeon placed Mr. Weiser's cup, the reason for Mr. Weiser's revision, Mr. Weiser's metal ion levels, the absence of an infection, the absence of co-morbidities, and the likelihood that Mr. Weiser would have had a revision if he had received a metal-on-polyethylene implant. Matthew Morrey Depo. 376:1–379:3. None of these opinions were offered in Dr. Matthew Morrey's expert report provided to Defendants prior to his deposition, and, according to Defendants, were formulated when Dr. Matthew Morrey reviewed Mr. Weiser's records just hours before his deposition. Plaintiffs assert that Dr. Matthew Morrey's

opinions were adequately disclosed, and even if they were not, any violation of Rule 26 would be harmless.

However, because he did not disclose these opinions to Defendants until the day of his deposition, Defendants were potentially unable to prepare to cross-examine Dr. Matthew Morrey regarding these "new" opinions. The use of this deposition testimony by Plaintiffs at trial may prejudice Defendants. Consequently, the Court will exclude that portion of the deposition, specifically pages 376:1–379:3, from trial. Should Plaintiffs wish to introduce these updated opinions concerning Mr. Weiser at trial, they must supplement Dr. Matthew Morrey's written report and provide it to Defendants at least three (3) days before he would testify to them in the third bellwether trial. Defendants then would be able to prepare for cross-examination, and further examination of Mr. Weiser's record could well provide more reliable evidence for the trier-of-fact.

Thus, Defendants' Motion to Limit the Testimony of Matthew Morrey, M.D., to Opinions Disclosed in His Expert Report [*Andrews*, Doc. 63; *Davis*, Doc. 83; *Metzler*, Doc. 79; *Rodriguez*, Doc. 78; *Standerfer*, Doc. 83; and *Weiser*, Doc. 84] is GRANTED IN PART to exclude deposition pages 376:1–379:3 and may be re-urged in its entirety if Plaintiffs do not provide an updated written report pursuant to Rule 26(a)(2)(B) no later than three (3) days prior to any trial testimony by Dr. Matthew Morrey.

SO ORDERED.

Signed October 3rd, 2016.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE