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. 3:11-MD-2244-K
This Order Relates To: *Aoki* – 3:13-cv-1071-K *Christopher* – 3:14-cv-1994-K *Greer* – 3:12-cv-1672-K *Klusmann* – 3:11-cv-2800-K *Peterson* – 3:11-cv-1941-K	§	

ORDER DENYING 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 Partially Exclude the Opinions and Testimony of Nicholas P. Jewell, Ph.D. [*Aoki* (3:13-cv-1071) Doc. 26, *Christopher* (3:14-cv-1994) Doc. 20, *Greer* (3:12-cv-1672) Doc. 23, *Klusmann* (3:11-cv-2800) Doc. 36, and *Peterson* (3:11-cv-1941) Doc. 37];

2. Defendants' Motion to Exclude, in Part, the Expert Opinions and Testimony of Minette E. Drumwright [*Aoki* Doc. 27, *Christopher* Doc. 21, *Greer* Doc. 24, *Klusmann* Doc. 37, and *Peterson* Doc. 38];

3. Defendants' Motion to Partially Exclude the Opinions and Testimony of George S. Kantor, M.D. and William R. Evans, M.D., P.A. [*Aoki* Doc. 34, *Christopher* Doc. 27, *Greer* Doc. 31, *Klusmann* Doc. 44, and *Peterson* Doc. 45];

4. Defendants' Motion to Exclude Dr. David Egilman's Opinions and Testimony [*Aoki* Doc. 35, *Christopher* Doc. 28, *Greer* Doc. 32, *Klusmann* Doc. 45, and *Peterson* Doc. 46];

5. Defendants' Motion to Exclude Dr. Greg Hallman's Opinions and Testimony [*Aoki* Doc. 36, *Christopher* Doc. 29, *Greer* Doc. 33, *Klusmann* Doc. 46, and *Peterson* Doc. 47];

6. Defendants' Motion to Partially Exclude the Opinions and Testimony of Michael Phillips, M.D. [*Aoki* Doc. 38, *Christopher* Doc. 31, *Greer* Doc. 35, *Klusmann* Doc. 49, and *Peterson* Doc. 49];

7. Defendants' Motion to Partially Exclude the Opinions and Testimony of Albert H. Burstein, Ph.D. [*Aoki* Doc, 39, *Christopher* Doc. 32, *Greer* Doc. 36, *Klusmann* Doc. 50, and *Peterson* Doc. 50]; and

8. Defendants' Motion to Partially Exclude the Opinions of Dan Bagwell and David Altman [*Klusmann* Doc. 47].

For the reasons set forth herein, the motions are DENIED.

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.

Pursuant to an Order of this Court dated August 26, 2015, the *Aoki*, *Christopher*, *Greer*, *Klusmann*, and *Peterson* matters were selected as bellwether matters to be prepared for trial. Defendants' Motions address the qualifications of many of Plaintiffs' designated trial expert witnesses and the reliability and relevance of the opinions to be proffered and seek to exclude, in whole or in part, the testimony of Nicholas P. Jewell, Minette E. Drumwright, George S. Kantor, William R. Evans, David Egilman, Greg Hallman, Michael Phillips, Albert H. Burstein, Dan Bagwell, and David Altman.

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 to 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 Chemical 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 F. 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. The Qualification Requirement

The first key to the admission of expert testimony is an expert who is qualified to testify on the subject at issue. 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), *cert. denied*, 510 U.S. 859 (1993). A formal education, however, is not required; practical experience may suffice. *United States v. Hernandez-Palacios*, 838 F.2d 1346, 1350 (5th Cir. 1988).

B. The Reliability Requirement

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. *See 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 Products Liab. Litigation*, No. 05-4046, 2006 WL 6624015, at *4 (E.D. La. Feb. 3, 2006) ("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)).

C. The Relevance Requirement

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. In *Daubert*, the Court provides this example of relevance:

> The study of the phases of the moon, for example, may provide valid scientific "knowledge" about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact. However (absent credible grounds supporting such a link), evidence that the moon was full on a certain night will not assist the trier of fact in determining whether an individual was unusually likely to have behaved irrationally on that night.

Id. at 591.

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) (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 Chemical 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. Nicholas P. Jewell, Ph.D.

Plaintiffs have 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% 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% at 15 years post primary surgery. Specifically, Defendants contend that these opinions are speculative and unreliable and should be excluded.

Defendants' basis for their motion to exclude these opinions of Dr. Jewell is the contention 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. Indeed, 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. Rather than contest Dr. Jewell's methods, Defendants essentially contest the accuracy of the analysis performed by Dr. Jewell in reaching his conclusions regarding the Pinnacle Device's future revision rate. However, 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). Accordingly, Defendants' Motion to Partially Exclude the Opinions and Testimony of Nicholas P. Jewell, Ph.D. [*Aoki* Doc. 26, *Christopher* Doc. 20, *Greer* Doc. 23, *Klusmann* Doc. 36, and *Peterson* Doc. 37] is DENIED.

B. Minette E. Drumwright, Ph.D.

Plaintiffs have 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 5794942, at *4 (E.D. La. Nov. 6, 2014); *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); *see also Daubert v. Merrell Dow Pharma.,* 509 U.S. 579, 592 (1993) ("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 v. Gayden*, 571 F.3d 442, 452-56 (5th Cir. 2009). 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). The Court finds that a similar analysis holds true 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) Marketing, Sales Practices & Products Liab. Litig.*, No. 09-02100, 2011 WL 6302287, at *8 (E.D. Ill. Dec. 16, 2011)).

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 Solutions 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. Continental Oil Co.,* 568 F.2d 378, 381-383 (5th Cir. 1978).

Defendants rely on *In re Rezulin Products 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 Andrade,* 996 F. Supp. at 626; *see also See FFE Transp. Servs. Inc. v. Fulgham,* 154 S.W.3d 84, 90-91 (Tex. 2004); *Ethicon Endo-Surgery Inc. v. Gillies,* 343 S.W.3d 205, 212 (Tex. App.—Dallas 2011, pet. denied). 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.

Accordingly, Defendants' Motion to Exclude, in Part, the Expert Opinions and Testimony of Minette E. Drumwright [*Aoki* Doc. 27, *Christopher* Doc. 21, *Greer* Doc. 24, *Klusmann* Doc. 37, and *Peterson* Doc. 38] is DENIED.

C. George S. Kantor, M.D., and William R. Evans, M.D., P.A.

Plaintiffs have identified Dr. Kantor and Dr. Evans as experts in the fields of medicine and orthopedic surgery to give "fact and/or opinion testimony regarding the concept, development, design and performance of metal-on-metal bearing surfaces" including those manufactured by Defendants. Defendants move to exclude the opinion of Drs. Kantor and Evans concerning the alleged risks of systemic illness due to cobalt and chromium in hip implant debris, as Defendants contend that Drs. Kantor and Evans are not qualified to opine on such systemic risks and that their opinions are neither reliable nor relevant.

Dr. Kantor is a board certified orthopedic surgeon specializing exclusively in joint replacement of the hip, knee, and shoulder. In his private practice, Dr. Kantor has performed approximately 12,000 Total Joint procedures, and approximately 25-30% of his practice has involved complex revision procedures. In his expert report, Dr. Kantor identifies his designated areas of testimony as "the concept, development, design and performance of the metal on metal bearing surfaces including those manufactured by Johnson & Johnson (J&J)/DePuy," including specific opinions regarding Plaintiff Thibodeau's injuries. Plaintiff Thibodeau was originally designated as a bellwether Plaintiff, but the Court has since Ordered that his case will not be tried in the upcoming, January 6, 2016, trial. Accordingly, any objections to testimony related specifically to Thibodeau is moot.

Dr. Evans is a board certified orthopedic surgeon who routinely performs total hip replacements as well as selected operations on hip joints that have previously been replaced. In his expert report, Dr. Evans identifies his designated areas of testimony as opinions regarding Plaintiffs Aoki, Christopher, Greer, Klusmann, and Peterson, specifically issues with their implants, index hip replacement surgery, revision surgery, the current status of the plaintiff's hip and future prognosis for plaintiff. Defendants do not contest that Drs. Kantor and Evans each have expertise in the areas of orthopedic surgery, including revision surgery. Drs. Kantor and Evans each also have expertise in the secondary complications resulting from metal on metal

hip implants, and the accompanying patient monitoring and care, due to their areas of practice.

In their Response, Plaintiffs stated that they will not elicit testimony from Dr. Kantor or Dr. Evans that patients with the Pinnacle Device are at an increased risk of developing a systemic illness due to cobalt and chromium metal wear debris; nor will they elicit testimony or opinions from Dr. Kantor regarding warnings accompanying or pertaining to the Pinnacle Ultamet. To the extent Plaintiffs seek to elicit testimony from Dr. Evans regarding long term patient monitoring as an aspect of patient care associated with metal on metal hip implants, such testimony falls outside of Defendants' motion and, moreover, presents a disagreement as to the accuracy of Dr. Evans' conclusions, which is an issue of the weight of the testimony at trial rather than its admissibility. *See Daubert*, 509 U.S. at 595.

Defendants' Motion to Partially Exclude the Opinions and Testimony of George S. Kantor, M.D. and William R. Evans, M.D., P.A. [*Aoki* Doc. 34, *Christopher* Doc. 27, *Greer* Doc. 31, *Klusmann* Doc. 44, and *Peterson* Doc. 45] is DENIED as moot.

D. David Egilman, M.D.

Plaintiffs have identified Dr. Egilman as an expert in the fields of public health, epidemiology, warnings, clinical practice and medicine to testify regarding corporate duties and responsibilities with respect to the safe testing and sale of products as well as corporate awareness, compliance and communication of public health and safety

issues related to their products. Defendants contend that Dr. Egilman's opinions should be excluded in their entirety as he is not qualified to opine on orthopedic and other specialized medicine and scientific matters, and that his opinions are unreliable as based on subjective personal opinion and as improper legal conclusions. Here, Dr. Egilman's expert testimony concerns regulatory, post-marketing surveillance, and marketing opinions.

Dr. Egilman received his medical doctorate from Brown University and subsequently received a master's degree in public health from Harvard University, where he studied epidemiology, statistics, occupational medicine, industrial hygiene, warnings, and occupational and environmental law. Dr. Egilman has had numerous academic and hospital appointments, and currently serves as a Clinical Professor in the Department of Family Medicine at Brown University. Dr. Egilman's publications in peer-reviewed journals include over forty articles over the last twenty years on a number of subjects, in addition to non-peer reviewed articles, book chapters, and speaking engagements.

Dr. Egilman's publications have covered "medical epistemology," the study of cause-and-effect determinations in medicine, medical ethics, and corporate responsibilities to test products and warn of health hazards, along with peer-reviewed papers on the topics of the proper conduct of medical research, including study design and informed consent, corporate responsibility to test products and publish study results, conflicting interests in the context of public health, techniques used to

manipulate scientific studies, post-market safety surveillance, "guest authorship" and "ghost-writing" in the pharmaceutical industry, seeding trials, post-market safety surveillance and pharmaceutical marketing, including FDA-mandated warnings and FDA regulation of drugs and devices. Dr. Egilman has also published papers and co-authored two textbook chapters on medical warnings, and teaches about medical warnings in his course at Brown University's medical school and to residents in clinical settings.

Rule 702 requires that an expert be qualified by virtue of his "knowledge, skill, experience, training, or education." Fed. R. Evid. 702; *see also Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881 (5th Cir. 2013); *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999). Thus, the rule expressly provides that a witness's expertise is not limited to subjects in which he or she has received formal education or training, but includes subjects in which the expert has knowledge, skill, or experience. *See also Hernandez-Palacios*, 838 F.2d at 1350 (formal education not required; practical experience may suffice). Dr. Egilman's formal training is not in orthopedics, tribology, or toxicology; however, he has significant experience in research design and interpretation, regulatory requirements, and marketing of medical information, including medical warnings. Based on Dr. Egilman's background, he is sufficiently qualified to offer his opinion on these subjects, including his review and comparison of Defendants' actions, documents, studies, and marketing materials with available scientific literature and regulatory and other applicable standards.

Defendants further contend that Dr. Egilman's opinions are unreliable or do not constitute proper expert testimony, as they are based on a subjective personal belief, not scientific methodology, and improperly consist of factual narratives, opinions on state of mind, and legal conclusions. However, the Court finds that, in his review of litigation documents, relevant scientific literature, and applicable industry and agency standards to form a basis for his expert opinion, Dr. Egilman's opinions are not properly categorized as "subjective personal belief" but rather constitute a sufficiently reliable methodology accepted in peer-reviewed scientific work. Similarly, it is Dr. Egilman's review, analysis, and opinions of the contents of Defendants' documents which are reflected in the alleged "state of mind" testimony, not impermissible mental state speculation, and it is his admissible expert opinion on applicable regulations and standards which is reflected in the purportedly improper legal conclusions. To the extent Defendants contend that Dr. Egilman has a bias against corporations, Defendants, corporate defendants, or the products at issue, it implicates the weight, not admissibility of the testimony. *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1335 (11th Cir. 2014).

As to Defendants' contentions regarding the narrative nature of Dr. Egilman's testimony, the Court observes that expert narrative testimony is entirely permissible where—as is the case here—the documents and other information the expert is reviewing are complicated, voluminous, or involve scientific or technical data and such narrative summary would assist the trier of fact in understanding the

documents. Fed. R. Evid. 1006; *United States v. Osum*, 943 F.2d 1394, 1405 (5th Cir. 1991); *United States v. Pree*, 408 F.3d 855, 869-70 (7th Cir. 2005); *In re Welding Fume Prod. Liab. Litig.*, No. 03-17000, 2005 WL 1868046, at *17 (N.D. Ohio Aug. 8, 2005). The admission of this alleged speculation and narrative testimony, however, is not properly the subject of this Court's gatekeeping function under *Daubert*. It implicates this Court's discretion over the presentation of evidence at trial and should be taken up there.

Defendants' Motion to Exclude Dr. David Egilman's Opinions and Testimony [*Aoki* Doc. 35, *Christopher* Doc. 28, *Greer* Doc. 32, *Klusmann* Doc. 45, and *Peterson* Doc. 46] is DENIED.

E. Greg Hallman, Ph.D., M.B.A.

Plaintiffs have identified Dr. Hallman as an expert in the field of corporate finance, valuation, and investments. Defendants move to exclude Dr. Hallman's opinions regarding (1) the metal-on-metal hip implant product as "a compelling financial opportunity for DePuy"; (2) the revenue earned by DePuy from nationwide sales of Pinnacle metal-on-metal implants from 2001-2013; (3) DePuy's marketing strategies; and (4) the amount of money Defendant Johnson & Johnson could pay as punitive damages "without affecting their ability to run their day-to-day business." Defendants contend, respectively, that (1) Dr. Hallman is not qualified to opine regarding the financial opportunity presented by the Pinnacle Device, and his opinion on the same is an improper factual narrative; (2) Dr. Hallman's opinion is overbroad

and irrelevant; (3) Dr. Hallman's opinion does not "fit the facts" of the case and is a narrative summary of Defendants' documents; and (4) Dr. Hallman is not qualified to opine regarding punitive damage, such an opinion would invade the province of the jury, and such an opinion is unreliable.

Dr. Hallman holds a Ph.D. in finance from the University of Texas and is currently a member of the faculty at the McCombs School of Business, where he teaches graduate courses in valuation, real estate finance, and investment theory, and Director of the McCombs Master of Science in Finance Program and Director of the McCombs MBA REIT Fund. Dr. Hallman's work focuses on analyzing a firm's competitive position in a market, revenues and costs of potential new projects, and how this information is used by firms in deciding to pursue new projects, business opportunities or investments.

Defendants contend that Dr. Hallman is not qualified to opine on financial opportunities from metal-on-metal devices, as he has no experience with such devices, and he is similarly unqualified to opine on punitive damages because he has not done so before. As this Court has previously observed, however, 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 v. Gayden*, 571 F.3d 442, 452-56 (5th Cir. 2009). Dr. Hallman has significant experience in business valuation, including the assessment of new corporate projects, and in the analysis of a company's competitive position in a market. Accordingly, he has sufficient expertise to testify

on the financial opportunities to Defendants from metal-on-metal devices and the amount of money Defendant Johnson & Johnson could pay without affecting their ability to run their business.

Dr. Hallman's expertise likewise informs the scientific methodology relied upon in Dr. Hallman's opinions. First, as to Defendants' contentions that Dr. Hallman's opinions are improper factual narratives or otherwise serve to summarize Defendants' documents, this argument is unpersuasive. As the Court has noted, expert narrative testimony is permissible where documents and other information the expert is reviewing are complicated, voluminous, or involve scientific or technical data and such narrative summary would assist the trier of fact in understanding the documents. Fed. R. Evid. 1006. Any contest to the admission of narrative testimony implicates this Court's discretion over the presentation of evidence at trial and should be taken up there.

Next, Defendants contend that Dr. Hallman's opinions are overbroad, irrelevant, and do not fit the facts of this case. However, Dr. Hallman's opinions on the metal-on-metal business opportunity and the valuation thereof are based upon an analysis of the hip implant market, including specifically Defendants' place in that market, whether Defendants could improve their position in that market with a metal-on-metal hip implant through, for example, expanding the market or increasing their market share, and Defendants' efforts to pursue the Pinnacle opportunity through, for example, its efforts to be first in the market on a new product and its

efforts to make the Pinnacle Device a profitable investment. Such opinions on the valuation of the Pinnacle opportunity, including Dr. Hallman's clarification and summary of Defendants' business plans, are relevant and would be helpful to a jury.

To the extent Dr. Hallman's opinions include testimony regarding Pinnacle metal implant sales revenues Defendants received after the bellwether plaintiffs were implanted and from states where the plaintiffs do not reside, this does not render Dr. Hallman's testimony overbroad and inadmissible. Texas courts permit the introduction of evidence occurring, for example, post-accident in assessing punitive damages and for other purposes, *see Mathon, Inc. v. Gries*, 288 S.W.3d 471, 487 (Tex. App.—Eastland 2009, no pet.), and while out-of-state conduct is not permitted for use in the calculation of punitive damages, it may be admitted for other purposes, such as the determination of whether a defendant acted reprehensibly. *State Farm Mutual Automobile Co. v. Campbell* 538 U.S. 408, 421-423 (2003).

Defendants' opinions on punitive damages with respect to Johnson & Johnson's ability to run its business are based upon Dr. Hallman's calculations of Johnson & Johnson's market capitalization, median change in market value, and a generally accepted value of what constitutes a significant change in market value to conclude that a change in market value of less than $4.4 billion is not statistically significant, and a review of Johnson & Johnson's cash flow, dividend payments, share repurchases, cash on hand, and borrowing capabilities, to assess the figure of excess funds not needed to fund projects or pay day-to-day operating costs. In making these

assessments, Dr. Hallman uses his education and experience in finance and business valuation and relies upon academic studies supporting these methodologies, which can be can be subjected to testing, verification, and cross-examination.

Finally, Dr. Hallman's opinions as to the calculations of figures which would not affect Johnson & Johnson's day-to-day operations do not impermissibly invade the province of the jury in determining appropriate punitive damages. Rather than provide any purportedly expert opinion on what amount of punitive damages would be appropriate given an assessment of the conduct at issue, Dr. Hallman instead provides helpful information to the jury regarding a defendants' financial circumstances and ability to pay, which are proper to address to a jury prior to their ultimate determination of punitive damages. *See, e.g.*, *Haryanto v. Saeed*, 860 S.W.2d 913, 921 (Tex. App.—Houston [14th Dist.] 1993, writ denied).

Defendants' Motion to Exclude Dr. Greg Hallman's Opinions and Testimony [*Aoki* Doc. 36, *Christopher* Doc. 29, *Greer* Doc. 33, *Klusmann* Doc. 46, and *Peterson* Doc. 47] is DENIED.

F. Michael Phillips, M.D.

Plaintiffs have identified Dr. Phillips as an expert in the fields of immunology, medicine, human reactions to prosthetics, foreign body granulomas, and T-cell mediated immunopathology. Defendants seek to exclude Dr. Phillips' opinions regarding the revision rate of Plaintiffs' hip implants as based on incorrect factual

bases. In their response, Plaintiffs state that they will not offer any opinion testimony from Dr. Phillips at trial regarding revision rates of the Plaintiffs' implants. Accordingly, Defendants' Motion to Partially Exclude the Opinions and Testimony of Michael Phillips, M.D. [*Aoki* Doc. 38, *Christopher* Doc. 31, *Greer* Doc. 35, *Klusmann* Doc. 49, and *Peterson* Doc. 49] is DENIED as moot.

G. 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. 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 also 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 also 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 and subject to repetition and cross examination, and based upon reliable

data. Likewise, Dr. Burstein's failure analysis of Plaintiffs' retrieved implants followed the procedure he developed and which was adopted by the National Standards Bureau; his analysis of the cause of Plaintiffs' injuries is based on a reliable method accepted in the industry capable of repetition. Additionally, 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, and published research studies and Dr. Burstein's own research while at Cornell University, and as such are based upon 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. *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999).

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. Rule 26 requires an expert to make a complete statement of his or her opinions and the reasons for them; however, Dr. Burstein's report includes his opinion regarding full fluid film lubrication. *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 design 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 directly 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 Defendants' marketing claims.

Defendants' Motion to Partially Exclude the Opinions and Testimony of Albert H. Burstein, Ph.D. [*Christopher* Doc. 32, *Greer* Doc. 36, *Klusmann* Doc. 50, and *Peterson* Doc. 50] is DENIED.

H. Dan Bagwell, BSN, RN, CLCP, CCM, CDMS, and David Altman, M.D.

Plaintiffs have identified Mr. Bagwell and Dr. Altman as experts in the field of life care planning and medical and medically related goods and services. Defendants contend that the opinions of Mr. Bagwell and Dr. Altman that Plaintiff Richard

Klusmann will require ongoing surveillance for complications related to "metallosis" should be excluded as speculative and not supported by the facts in the case.

Mr. Bagwell is a registered nurse and certified life care planner who holds a Bachelor of Science in Nursing from the University of Mississippi and completed his post-graduate studies in life care planning for advanced catastrophic case management at the University of Florida. Dr. Altman obtained his medical doctorate from Brandeis University and is a board certified neurologist and life care planner with experience in clinical care, neurorehabilitation, life care planning, and clinical research. While neither Mr. Bagwell nor Dr. Altman contend to be experts in cobalt exposure, their respective experiences qualify them each as experts in the area of life care planning.

Mr. Bagwell and Dr. Altman opine that Plaintiff Klusmann will require long-term monitoring for metal exposure as a result of his implantation with the Pinnacle Device. Defendants contend that such opinions are speculative and not based on the facts of the case. Specifically, because Mr. Bagwell and Dr. Altman have testified that the long-term biological effects of chromium and cobalt exposure are unknown, Defendants contend that the recommendation for continued monitoring lacks a reliable basis. However, the opinion that Plaintiff Klusmann will require the monitoring at issue is based upon Mr. Bagwell's and Dr. Altman's application of their expertise in life care planning to their reviews of scientific literature regarding chromium and cobalt exposure, as well as their familiarity with prudent medical care.

As such, the opinion is not based upon speculation. In essence, Defendants disagree with the conclusions drawn by Mr. Bagwell and Dr. Altman as contrary to Defendants' own positions on the literature and the available data. This disagreement is an issue of the weight of the testimony at trial rather than its admissibility and is more properly made the subject of cross-examination.

Defendants' Motion to Partially Exclude the Opinions of Dan Bagwell and David Altman [*Klusmann* Doc. 47] is DENIED.

SO ORDERED.

Signed January 5th, 2016.

Ed Kinkeade

ED KINKEADE
UNITED STATES DISTRICT JUDGE