**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

IN RE: ZIMMER DUROM HIP CUP PRODUCTS LIABILITY LITIGATION

2:09-cv-04414-SDW-MCA

MDL-2158

# ZIMMER'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE/LIMIT TESTIMONY OF JAMES GRIMES (COMMON ISSUES)

MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Telephone: (973) 622-4444
Facsimile: (973) 624-7070

FAEGRE BAKER DANIELS LLP
300 North Meridian Street, Suite 2700
Indianapolis, Indiana 46202
Telephone: (317) 237-0300
Facsimile: (317) 237-1000

# TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Page(s)**

**FEDERAL CASES**

**STATE CASES**



**RULES**



**OTHER AUTHORITIES**

**DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE/LIMIT TESTIMONY OF JAMES GRIMES (COMMON ISSUES)**

Defendants Zimmer Holdings, Inc., and Zimmer, Inc. (collectively, "Zimmer"), moves this Court for an Order excluding James Grimes, M.D. ("Dr. Grimes"), from testifying and in support of this motion states:

## I. INTRODUCTION

Expert evidence is admissible under Federal Rule of Evidence 702 only if the witness "is qualified as an expert by knowledge, skill, experience, training, or education" and if

(a) the expert's scientific technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Third Circuit has explained, Rule 702 embodies a "trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003).

To the extent that Dr. Grimes is being offered for opinions beyond the ken of an orthopedic surgeon, he fails all three restrictions. Dr. Grimes is a practicing orthopedic surgeon. He has no other formal training and no other substantial expertise. Yet he purports to offer design defect opinions grounded in subjects such as bioengineering and toxicology. He is reaching far beyond his substantive background and is not qualified to offer the opinions he has proffered. Furthermore, he draws these opinions from experiments that are not reliable and are

subject to exclusion under *Daubert*. Finally, there is not a good "fit" as required by Rule 702 because Dr. Grimes's experiments lack a valid scientific connection to the issues in the case. They are based on nothing more than "junk science" that will not assist the jury.

## II. OVERVIEW OF GRIMES'S PROPOSED TESTIMONY

Dr. Grimes purports to offer opinions regarding surgical technique for and design features of the Durom Cup. His opinions derive from four sources:

1. His experimentation implanting Durom Cups and other manufacturers' cups in foam board for purposes of measuring metal deformation post-impaction. For purposes of these tests, Dr. Grimes used Durom Cups that had previously been implanted and removed from patients after a period of use.

2. His implantation of two Durom Cups into cadaver acetabulae. For purposes of the cadaver testing, Dr. Grimes used new Durom Cups and implanted them into half cadavers (pelvis to toes). Before and after implanting and removing the cups, Dr. Grimes had certain "form factor" measurements taken of the Durom Cups. He also conducted "dye testing," in which he coated a femoral head with blue machinist dye and rotated it by hand in the Durom Cups to evaluate dye transfer and striation, which he equated to contact of the femoral head with the Durom Cup.

3. His clinical observations from implanting Durom devices in 38 total hip arthroplasties ("THAs") in undisclosed patients.

4. His review of selected literature.

On these bases, Dr. Grimes proposes to testify specifically to:

- elastic deformation of the acetabular component *in vivo* (Grimes Report, Conclusions 1-3, 7, 9-10, 11, at 41-42 (attached as Exhibit A));

- postoperative wear debris production (Grimes Report, Conclusions 6-7, at 41);
- increased cobalt and chrome ion levels (Grimes Report, Summary, at 44);
- alleged design flaws including the "rim fin" and "excessive press fit," subhemispherical design, thin walls, inadequate instrumentation, and inadequate surgical technique (Grimes Report, Conclusion 13, 14, Summary, at 43-44); and
- a medley of various other unsupported opinions (Grimes Report, at 41-44).

For the reasons discussed below, Dr. Grimes's opinions should be excluded.

## III. DR. GRIMES IS NOT QUALIFIED TO OFFER OPINIONS BEYOND THE REALM OF AN ORTHOPEDIC SURGEON

This Court must determine the preliminary question of whether Dr. Grimes is qualified to testify. *See* Fed. R. Evid. 104(a) (court decides preliminary questions of witness qualification); *see also Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 n.10 (1993) (citing Rule 104(a)). The competency of a proffered expert is committed to the discretion of the trial court. *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir. 1987).

### A. Dr. Grimes's Expertise Is Limited to That of a Practicing Orthopedic Surgeon.

Dr. Grimes testified that *he is not an expert on any topic other than orthopedic surgery.* (Grimes Dep. Volume I 127:23-25, Aug. 1, 2014 (hereinafter "Grimes I Dep.") ("Q. Dr. Grimes, besides orthopedic surgery, on what topics do you consider yourself to be an expert? A. None.") (attached as Exhibit B)). He is board certified only in orthopedics. (*Id.* at 69:19-23). The "vast majority" of what he does is orthopedic surgery. (*Id.* at 108:19-20). Research is "not [his] main thing." (*Id.* at 108:20-25).

Specifically, Dr. Grimes admits that he is not an expert in the design of medical devices. (*Id.* at 128:5-9). He has had no formal training in the testing of medical devices. (*Id.* at

128:21-129:2). He has had no specific training in toxicology. (*Id.* at 128:18-20). He does not have any specific training or expertise in metallurgy. (*Id.* at 129:3-7). He has no training or expertise in tribology, and would not consider himself an expert in it. (*Id.* at 129:8-11). He has never performed a finite element analysis ("FEA") and admits that he has no expertise in FEA. (*Id.* at 129:20-130:1). In sum, Dr. Grimes acknowledges that his only formal training is as an orthopedic surgeon. (*Id.* at 69:19-23). He has no other specialty certifications. (*Id.* at 69:22-23). These admissions establish that Dr. Grimes is qualified only as an orthopedic surgeon.

**B. Dr. Grimes Should Not be Permitted To Testify to Engineering and Toxicological Opinions, Which Concern Complex and Specialized Matters in Which He Lacks Experience and Training.**

Though Dr. Grimes is qualified only as an orthopedic surgeon, Plaintiffs are offering product defect opinions from Dr. Grimes that fall within the ken of a toxicologist or someone with biomedical, mechanical, or metallurgical engineering experience. For instance, Dr. Grimes proposes to testify to opinions about metal deformation and the release of metal ions in the body, yet he has no training or experience in the science of these matters. He has never published on metal deformation, metal ion issues, or metal-related pathology. (*Id.* at 91:17-25). In fact, he has never even submitted his work on deformation for peer review (*id.* at 90:21-24), and he acknowledges that his report is not "scholarly" enough for publication. (*Id.* at 155:6-25 ("In its current form, it's not publishable.")). The matters to which he proposes to testify are highly specialized areas outside the realm of his medical training. "[M]erely possessing a medical degree does not qualify its holder as an expert in all medical related fields." *Higgins v. Koch Dev. Corp.*, 997 F. Supp. 2d 924, 930 (S.D. Ind. 2014) (internal quotation and citation omitted). Because Dr. Grimes has no formal training or expertise in engineering and toxicology, he is not competent to offer any opinions regarding these subjects.

Dr. Grimes's lack of qualification is not even a close question. Federal courts across the United States have routinely excluded physicians attempting to testify to purported medical device defects because those physicians lacked relevant background qualifications.[1] Like these excluded surgeons, Dr. Grimes also lacks relevant background experience. While he claims some experiences in product development,[2] he admits that he is not a design expert but rather a "student trying to learn things" (Grimes I Dep. 128:5-9), and that he has no formal training in the testing of medical devices or experience designing pre-market testing (*id.* at 128:21-129:2; 124:22-24).

In sum, Dr. Grimes is an orthopedic surgeon. He has never been qualified or even offered as an expert witness in a product liability case. (*Id.* at 130:5-131:13). He is not qualified to offer design defect opinions that fall outside of his training and qualifications in this case. For that reason, all Dr. Grimes's opinions relating to metal deformation, postoperative wear debris production, increased cobalt ion levels, and product design flaws, including but not limited to "rim fin" and "excessive press fit," subhemispherical design, and thin walls, should be excluded.

[1] *See Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 187–88 (E.D.N.Y. 2013) (plaintiff's orthopedic surgeon lacked training or expertise in biotechnology, manufacturing processes, or materials science and was not qualified to offer opinion regarding the source of wear of polyethylene tibial insert in a knee prosthesis; plaintiff offered "no explanation" as to why the surgeon's clinical experience and personal knowledge provided competence to opine on an alleged manufacturing defect); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1310, 1316 n. 3 (N.D. Okla. 2000) (excluding testimony of physician upon finding he "lacks the qualifications necessary to render opinions regarding the mechanical behavior" of the implanted device, noting that doctor "has demonstrated absolutely no training, education, or experience in biomechanics or any related field"); *see also Harris v. Spine*, No. 3:12CV874TSL-JMR, 2014 WL 4179915, at *4 (S.D. Miss. June 23, 2014) (noting without deciding that neurosurgeon's use and familiarity with products "likely do not qualify him" to testify as to manufacturing defect; resting exclusion instead on lack of relevance and reliability of opinions).

[2] Back in the 1990s, Grimes was involved with Biomet in designing a specialized modular reconstruction system, involving a "low use" "complex expensive system [that] would not be used in routine cases" which is no longer sold. (Grimes I Dep. 114:5-118:19). Grimes also testified to a current design effort involving a femoral head product that has been in development for 10-15 years and is not currently being sold. (*Id.* at 85:17-86:14). Neither device is analogous to the Durom Cup, which is a monoblock acetabular cup with a metal bearing surface.

## IV. DR. GRIMES'S EXPERIMENTS AND CONCLUSIONS ARE NOT BASED ON RELIABLE SCIENTIFIC METHODOLOGY AND FAIL TO MEET *DAUBERT* STANDARDS.

The Court can resolve Zimmer's motion to exclude based solely on Grimes's lack of qualifications. However, Zimmer also challenges the science underlying Grimes's opinions. In *Daubert*, the Supreme Court charged trial judges with the responsibility to act as "gatekeepers" to exclude unreliable expert testimony. 509 U.S. at 597. This Court should exercise that responsibility to exclude opinions from Grimes that are not based on sound scientific principles.

The hallmark of admissibility under *Daubert* and its progeny is that the expert employs a reliable methodology. *Daubert*, 509 U.S. at 592-93; *In re Paoli R.R. Yard P.C.B. Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (*Paoli II*). *Daubert* established four factors to aid courts in determining whether scientific expert testimony is reliable. These reliability factors include:

(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 publication;

(3) the known or potential rate of error; and

(4) whether the theory or technique enjoys general acceptance within the relevant scientific community.

*Daubert*, 509 U.S. at 593-94; *Calhoun v. Yamaha Motor Corp.*, U.S.A., 350 F.3d 316, 321 (3rd Cir. 2003). The Third Circuit has elaborated on the requirements of *Daubert* by considering four additional factors:

(5) "the existence and maintenance of standards controlling the technique's operation";

(6) "the relationship of the technique to methods which have been established to be reliable";

(7) "the qualifications of the expert witness testifying based on the methodology"; and

(8) "the non-judicial uses to which the method has been put."

*Calhoun*, 350 F.3d at 321 (quoting *Paoli II*, 35 F.3d at 742 n.8). The district court must 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 in issue." *Daubert*, 509 U.S. at 592-93. The Third Circuit further requires that "the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Paoli II*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 589-90).

For a host of reasons detailed below, Dr. Grimes's opinions are not reliable when measured against these factors.

**A. Testimony and Opinions Regarding Dr. Grimes's Foam Testing Should Be Excluded for Multiple Reasons.**

Dr. Grimes conducted "foam testing," impacting acetabular components in high-density polyurethane foam that is designed to replicate bone characteristics. He purports to model this testing on an experiment by Jin and other authors. (Grimes I Dep. 105:15-106:6). Specifically, in his first study, Dr. Grimes impacted used Durom Cups and pristine cups from a different manufacturer, Smith & Nephew, into 30 and 40 pcf foam. (Grimes I Dep. Ex. 9). In his second study, Dr. Grimes impacted used Durom Cups and used cups from yet another manufacturer, DePuy, and pristine Smith & Nephew, Biomet, and Cornet cups into 40 pcf foam blocks. (Grimes I Dep. Ex. 11). He then measured clearance and attempted to illustrate contact by applying dye and manually oscillating the heads in the cups. (Grimes I Dep. Exs. 9 & 11).

Dr. Grimes is relying on the conclusion he drew in these studies as one of the bases for his opinions in this case. (Grimes Report, at 13-14 (referencing work cited at footnotes 9 and 10)).

**1. Dr. Grimes and Plaintiffs have failed to disclose the underlying facts and data for Dr. Grimes's foam testing opinions.**

As a threshold matter, this testing should be excluded not only because of reliability problems but also because Dr. Grimes cannot produce the underlying data that provides the basis for his opinions. The raw data underlying these tests was stored on a laptop that he lost and no longer possesses. (Grimes I Dep. 43:3-44:12; 66:12-67:2). Zimmer has access only to the reported results, but none of the underlying documentation or data. This is akin to a physician testifying to a medical opinion without producing the underlying patient medical records.[3] Dr. Grimes's inability to provide Zimmer with the backup data should alone preclude Dr. Grimes from testifying to these results and from relying on the foam testing in support of his opinions. *See* Fed. R. Civ. P. 26(a)(2)(B)(ii) (expert report must disclose "facts or data considered by the witness in forming" the opinions); Fed. R. of Civ. P. 37(c)(1) ("If a party fails to provide information . . . required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.").[4] Plaintiffs' failure to produce the underlying data restricts Zimmer's ability to evaluate Dr. Grimes's purported results and hampers Zimmer's ability to cross-examine Dr. Grimes regarding this testing.

[3] Incidentally, Dr. Grimes tries to do this as well. *See infra* Section VI.

[4] In evaluating a request to exclude evidence as a discovery sanction, the Third Circuit has instructed district courts to consider "(1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted; (2) the ability of the party to cure that prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or willfulness in failing to comply with a court order or discovery obligation." *Nichols v. Pennsylvania State Univ.*, 227 F.3d 133, 148 (3d Cir. 2000). Zimmer appreciates that the data is lost, not merely withheld, but the problem of prejudice remains as Zimmer is unable to fully evaluate the experiment and cross-examine Dr. Grimes without the underlying data.

**2. Dr. Grimes's foam testing is not reliable under the eight factors this Court must consider.**

**a. The foam testing fails factors 1 through 4 as it has not been tested, it has not been peer reviewed or published, there is a high potential error rate, and there is no evidence of general acceptance.**

Dr. Grimes's foam tests have not been tested. Nor have they ever been peer-reviewed or published. (Grimes I Dep. 113:1-4). They were merely the subject of two poster presentations in 2010 and 2011. (*Id.* at 92:1-7; 95:22-96:19).

The error rate for Dr. Grimes's experiment is unknown, but potentially quite high. As noted, Dr. Grimes used explanted Durom Cups (meaning cups that had been implanted in patients and then removed after some undisclosed period of time) in his foam testing trials. (*Id.* at 64:5-15; Grimes Dep. Volume II 463:24-464:1, Sept. 26, 2014 (hereinafter "Grimes II Dep.") (attached as Exhibit C)). He performed no pre-implant (before patient use) analysis on the explanted cups. (Grimes II Dep. 482:6-12). Only the used Durom and DePuy cups showed deformation. (*See* Grimes I Dep. 102:17-20 & Exs. 9 & 11). The pristine cups did not. The use of worn Durom Cups, which have been previously impacted into a patient, used *in vivo* for an undisclosed period of time, and then explanted from the patient only to be re-implanted into foam, renders this test scientifically invalid. Not only do those cups have potential *in vivo* wear and material loss, there are also circumstances related to the prior *in vivo* positioning of the cup as identified by Zimmer's biomedical engineering expert, Kevin Ong, Ph.D. (Ong Report, at 83 (attached as Exhibit E); Ong Dep. 215:2-19, 216:7-15 (attached as Exhibit O)). No generally accepted scientific methodology or correct scientific procedure would sanction using previously worn, explanted acetabular components for the kind of testing Dr. Grimes is purporting to conduct. And of course, Dr. Grimes's tests also do not account at all for *in vivo* wear, reduction

of the hip, and viscoelastic reaction (stress relaxation) as would occur in a live patient. (Ong Dep. 216:16-217:9).

Dr. Grimes's foam-testing technique does not enjoy general acceptance in the scientific community. While he cites to the Jin study as the model on which he based his work, Dr. Grimes admits that the use of explanted cups was not part of the model used by Jin (Grimes II Dep. 464:2-7), and so his work is essentially unprecedented.

**b. The foam testing fails factors 5 through 8 as it does not follow recognized standards, Dr. Grimes uses unreliable methods, he is not qualified to conduct or testify to the experiment, and there is little non-judicial use of this experiment.**

Additionally, beyond the use of explanted cups—which undeniably invalidates his conclusions—Dr. Grimes failed to use proper standards to control the experiment. In particular, Plaintiffs cannot establish that the measurements on which Dr. Grimes relies for clearance and asphericity are reliable. (*See* Ong Dep. 209:22-211:6 (testifying that Dr. Grimes was essentially "double-counting the effects of asphericity" and "artificially inflating the amount of reduction of clearance")).

Dr. Grimes's methods are also unreliable, particularly his choice of foam. While a prior study found good correlation of 30 pcf foam blocks to bone, Grimes used 40 pcf foam blocks, which correlate with harder bone. (Day Report, at 27 (attached as Exhibit D); Ong Dep. 211:7-213:22 ("he's disregarded something that is more representative of the patients in which these devices are implanted in and selectively picked a stiffer foam block for his experiments")). Dr. Grimes also did not make choices consistent with Zimmer's surgical technique for hard, sclerotic bone in his testing in the 40 pcf blocks. (Day Report, at 27; Ong Dep. 213:12-21 (noting that surgical technique recommends reducing the press-fit for sclerotic bone); *see also* Ong Dep. 214:12-23 (noting that Dr. Grimes deviated from Jin model by using harder foam)).

The flaws in Dr. Grimes's experimentation correlate with his lack of qualification and lack of experience testing medical devices. As noted above, Dr. Grimes concedes that he is not an expert in the design of medical devices. (Grimes Dep. I at 128:5-9). He has had no formal training in the testing of medical devices or experience designing pre-market testing. (*Id.* at 128:21-129:2; 124:22-24). Rather, he is a "student trying to learn things." (Grimes I Dep. 128:5-9).

Finally, Dr. Grimes's foam-testing experiment has been put to very little non-judicial use. Although it was the subject of two poster presentations at orthopedic conferences, he stated in his own affidavit that his foam tests "are not as scientifically rigorous as I would like for them to be" because of the use of explanted cups. (Grimes Aff. ¶ 3 (attached as Exhibit F)). Given this fatal flaw alone, not to mention the other concerns, there have not been and there is little chance they would be accepted for any scholarly purpose.

In sum, both because (1) the underlying data is lost and (2) the tests are unreliable under *Daubert*, Dr. Grimes's testimony about and opinions based on these foam tests should be excluded.

**B. Dr. Grimes's Cadaver Testing Is Not Reliable, and Testimony and Opinions Regarding It Should Be Excluded.**

Dr. Grimes's cadaver testing is an extension of his foam testing in an attempt to make his work more "scientifically rigorous," which he described as "necessary." (Grimes Aff. ¶¶ 3, 6). Assessing Dr. Grimes's cadaver experiment against the eight relevant *Daubert* factors, it is clear that his methodology is not more scientifically rigorous and that Plaintiffs cannot demonstrate reliability.

**1. Dr. Grimes methodology has not been tested.**

Because of the vast differences between implantation in a cadaver and implantation in a living patient, Plaintiffs cannot show that Dr. Grimes's cadaver study has been "tested." Dr. Grimes did testify that he adapted his test from one prior study, the Jin study. (Grimes Dep. 105:15-106:6). But in the Jin study, a few cadavers with donor ages of 40-60 years old were used "mainly to develop a laboratory sawbones [foam] model." Jin et al, Deformation of press-fitted metallic resurfacing cups. Part 1: experimental simulation., *J. Engineering in Medicine*, Vol. 220.; 299, 301-302 (2006). Dr. Grimes's work departs in significant respects from the Jin study, as discussed below, such that it is essentially unprecedented.

**2. Dr. Grimes's methodology has not been peer reviewed or published.**

Dr. Grimes has not subjected his testing to peer review. (Grimes II Dep. 381:14-382:4). It has not been published. In fact, Dr. Grimes recognizes that his work is not "scholarly" enough for publication, readily admitting that "[i]n its current form, it's not publishable." (Grimes I Dep. 155:6-25). Another of Plaintiffs' experts, Kurt Kitziger, M.D., testified that he did not think that Dr. Grimes's study "really adds to what is already in the literature," (Kitziger Dep. 69:16-17 (attached as Exhibit K)), implying that the work is neither publishable nor helpful.

**3. Dr. Grimes's experiment has a high potential error rate.**

Because Dr. Grimes's experiment is unprecedented, the "error rate" is unknown. However, because of multiple problems in Dr. Grimes's unreliable methodology and the lack of standards surrounding his testing, a high potential error rate is certain. Dr. Kitziger regards the data for *half* of Dr. Grimes's experiment as "compromised." (*Id.* at 69:8-13).

**4. Plaintiffs cannot show that Dr. Grimes's methodology is generally accepted in the scientific community.**

Dr. Grimes's methodology in conducting the cadaveric tests is novel with no indication that it is generally accepted in the relevant scientific community. Plaintiffs bear the burden of establishing the reliability of the methodology, but Dr. Grimes admitted he cannot meet that burden. Dr. Grimes testified that "general acceptance that would be hard to answer," that he is "not sure" whether his method is generally accepted, and that "generally accepted is probably a little bit of an overstatement." (Grimes II Dep. 382:5-19; 383:3-8).

While it is common for cadavers to be used for training purposes to develop or practice certain aspects of surgery, for example, surgical approach (*see* Grimes I Dep. 152:10-153:8; Schmidt Dep. 194:4-14 (attached as Exhibit G)), it is not common for cadaver bone to be used to evaluate fixation of an implant or to validate a design. Defendants' orthopedic expert James W. Pritchett, M.D., testified that he had a number of concerns with the scientific validity of Dr. Grimes's work, specifically, the absence of a research question, Dr. Grimes's methodology, conflicts, and bias. (Pritchett Dep. 127:22-128:8, attached as Exhibit N). As another orthopedic expert for Defendants, Robert Schmidt, M.D., explained, Dr. Grimes's experiment is not related to "real life" because "assessing fixation probability in cadaveric bone is a model which [he] wouldn't accept." (Schmidt Dep. 194:4-195:14). To implant a device in a cadaver "and use that as some type of equivalency to real life," is nothing more than "magical thinking." (*Id.* at 195:4-14) (describing recognized scientific use of cadavers in the field of orthopedics)).

Dr. Grimes's experiment does not reflect "real life" because of at least two mammoth differences between testing implantation of an acetabular implant in a cadaver and implantation in a live patient. The first is the life of the bone. Living bone has a healing response that dead bone does not. The healing response includes viscoelasticity—a process by which bone relaxes

to accept the implant—which affects the forces on the cup. (Grimes I Dep. 167:12-168:4, Ong Report, at 84). The second is the load-bearing aspect of activities of daily living. Live patients will get up and walk around, putting forces on the intersection between the femoral head and the acetabular component, which likewise affects the acetabular forces on the cup. (Grimes I Dep. 169:1-6; Ong Report, at 84; Day Report, at 57). This is why Plaintiffs' own expert, George Samaras, Ph.D., testified unequivocally that cadaveric implantation cannot be used to validate a design. (Samaras Dep. 268:23-269:7 (attached as Exhibit H)). Dr. Grimes's experiment does not account for or even *acknowledge* these factors, and Plaintiffs cannot show that his work is generally accepted in the scientific community. "[A] court may well cast a jaundiced eye upon a technique which is not supported by any evidence of general acceptance absent other indicia of reliable methodology." *In re TMI Litig.*, 193 F.3d 613, 669 (3d Cir. 1999), *amended by*, 199 F.3d 158 (3d Cir. 2000).

**5. Dr. Grimes's methodology lacks standards.**

The manner in which Dr. Grimes conducted his experiment shows a virtual lack of appropriate standards and controls.

**a. Dr. Grimes failed to use appropriate cadaver specimens.**

Neither cadaver would have been a good candidate for a cementless Durom Cup implantation as a live patient. Cadaver 1 was described as having a cachectic body type, which refers to physical wasting with loss of weight and muscle mass due to disease. (Grimes Report (Figures), at 3). Dr. Grimes described the quality of the bone as "osteoporotic." (Grimes Report, at 2). Osteoporotic bone is normally contraindicated for placement of a Durom Cup. (Schmidt Report, at 5 (attached as Exhibit J); Ong Dep. 182:22-183:22 (noting that Dr. Grimes was "essentially putting the cup into a cadaver that was contraindicated for this procedure to begin

with"). Cadaver 2 was 84 years old. At that age, poor bone quality can be expected and that would also not be a good fit for placement of a Durom Cup. (Schmidt Report, at 6).

Additionally, Dr. Grimes's choice to use a size 54/48N in Cadaver 1 was not reasonable nor does it reflect generally accepted methodology in the orthopedic community. Dr. Grimes himself reported that Cadaver 1 was more ideally suited to a 52/46L Zimmer Durom cup. Nonetheless, Cadaver 1 was "reamed an additional 2 mm to fit a size 54/48N Zimmer Durom acetabular component." (Grimes Report, at 10). After this over-reaming, "the amount of cancellous bone exposed was somewhat more than normal." (Grimes Report, at 10). For this reason, Plaintiffs' expert Dr. Kitziger testified that as a result of the sizing issues, he thought that the "data was probably compromised" as to Cadaver 1. (Kitziger Dep. 69:8-13).

**b. Dr. Grimes's lack of controls as to cadaver characteristics and surgical technique undermine his findings.**

A number of cadaver-specific and surgeon-specific characteristics affect the study that Dr. Grimes performed:

| Cadaver/Donor | Surgeon |
|---|---|
| Bone Properties<br>• Density/Quality<br>• Morphology/shape of socket<br>• Inhomogeneous/spatial variations<br>• Degree of subchondral sclerosis | Reaming<br>• Position<br>• Angle<br>• Depth<br>• Degree of under/over-reaming<br>• Sphericity |
| Post-Operative Changes<br>• Joint Load Magnitude<br>• Joint Load Direction<br>• Joint Load Number of cycles<br>• Bone Remodeling/Gap Bridging<br>• Viscoelasticity (Stress Relaxation) | Cup Impaction<br>• Number of Hits<br>• Applied Force<br>• Angle of Hits<br>• Variation between hits |
| Patient Demographics<br>• Age | Cup Position<br>• Inclination angle |

| Cadaver/Donor | Surgeon |
|---|---|
| • Gender | • Version angle<br>• Depth of cup seating |

(*See* Ong Report, at 72-73 (listing these factors); *see also* Ong Dep. 182:10-185:1 (discussing certain uncontrolled patient factors); Ong Dep. 186:13-188:17 (discussing certain uncontrolled reaming factors)). Dr. Grimes placed no controls on these issues (except for attempting to measure impaction forces, which measurements are likely not valid). (Grimes I Dep. 169:16-170:12; Grimes II Dep. 478:17-480:15; Ong Dep. 186:1-12); *see also* Ong Dep. 181:2-18 (noting Dr. Grimes's failure to control for confounding effects)). He does not even attempt to quantify or account for variations in these characteristics in his opinions. Such an uncontrolled experiment does not reflect correct scientific procedure. "Key aspects of the scientific method include the ability to test or verify a scientific experiment by a parallel experiment or other standard of comparison (control) and to replicate the experiment to expose or reduce error." *Trach v. Fellin*, 817 A.2d 1102, 1113 (Pa. Super. Ct. 2003); *see also Caraker v. Sandoz Pharm. Corp.*, 188 F. Supp. 2d 1026, 1030 (S.D. Ill. 2001) (describing scientific method as requiring "the generation of testable hypotheses that are then subjected to the real world crucible of experimentation, falsification/validation, and replication").

**c. Dr. Grimes's opinions based on the fracture in Cadaver 2 are merely speculative.**

Dr. Grimes attributes a fracture in the Cadaver 2 acetabulum to excessive press-fit of the Durom Cup. However, it is impossible for Dr. Grimes to draw this conclusion because he cannot say to a scientific degree of certainty when the fracture occurred. Dr. Grimes first noticed the fracture in reviewing his fluoroscopic video of the procedure. (Grimes I Dep. 209:2-17). He then assumed that the fracture occurred after impaction. Other experts have noted, however, that

"[t]he crack in the acetabular rim appears to occur adjacent to the placement of a retractor before the cup was impacted, which may have damaged the bone," (Schmidt Report, at 6), that "the fracture noted by Dr. Grimes was consistent with the location of a fracture induced during dislocation of the femoral head," (Day Report, at 60), and that "those cracks or those fractures were already present before he even implanted the cup" (Ong Dep. 195:3-18). For those reasons, "[i]t is likely that the forceful dislocation and/or use of the retractors prior to impaction of the cup contributed to each of these fractures." (Day Report, at 60). Dr. Grimes's conclusion that excessive press-fit was the culprit also fails to account for the qualitative differences of cadaver bone. (Schmidt Report, at 6 ("Cadaver bone is brittle and has been frozen, making it more susceptible to fracture. As such, one cannot rule out excessive force exerted during impaction as a possible cause of acetabular fracture in this cadaver.")).

In sum, Dr. Grimes fails to follow any accepted scientific standards with respect to identifying and isolating the cause of the fracture. His opinion attributing it to excessive press-fit is nothing more than speculation and must be excluded. *See, e.g.*, *In re TMI Litig.*, 193 F.3d at 670 (expert's assumption of possible plume movements was merely speculative and properly excluded under *Daubert*).[5]

**6. Dr. Grimes used unreliable methods in his experimental technique.**

**a. Dr. Grimes's force measurements are not reliable.**

Dr. Grimes had a local machine shop construct the mallet that he used to measure impaction forces. (Grimes I Dep. 16:9-17:13). He cannot say whether this method of measurement is recognized and accepted by the scientific community. (*Id.* at 20:25-21:11). It is unclear whether his load cell was working properly or whether he used the fabricated tool

[5] To the extent further testing is being done on the pelvises, the fracture has an impact on the validity of any such testing. (Ong Dep. 195:19-196:16).

correctly. As Dr. Ong testified: "the way he was impacting the inserter with that sensor could have contributed to invalid results." (Ong Dep. 185:2-14 (discussing "issues with how he measured the impaction force"); *see also* Ong Report, at 92). The tool was not validated in any scientific way. (Grimes I Dep. 20:10-24). Plaintiffs cannot establish that use of such a "homemade," un-validated measuring tool reflects correct scientific procedure.

**b. Dr. Grimes failed to position properly the Durom Cups in his experiment.**

Review of the arthroscopic images suggests that Dr. Grimes's cup positioning was inappropriate. (Ong Report, at 73-75; Ong Dep. 189:3-191:6 (describing how cups did not appear to be placed with sufficient anteversion)). Dr. Grimes even admitted that his placement of the cup in Cadaver 1 was not optimal. (Grimes II Dep. 438:6-8; *see also* Ong Dep. 188:18-189:2). Dr. Grimes's positioning was inconsistent with Zimmer's surgical technique. (Ong. Dep. 191:7-17 (noting that Zimmer's Tips and Pearls "described the importance of engaging the fins in the anterior and posterior walls")). His failure to achieve proper placement of the cups does not reflect valid scientific procedures and invalidates his results and conclusions.

Incidentally, while Dr. Grimes swore in his affidavit that he intended to test the surgical technique (Affidavit ¶ 6 ("[t]he proposed cadaver study is intended to . . . show the presence or absence of total contact between the bone and implant with the recommended surgical technique")), he ultimately did not follow it in his testing, and so he cannot opine as to the surgical technique based on his cadaveric experiment. Moreover, the conclusion he attempts to draw that "[i]f implanted exactly as specified by the manufacturer," then biologic attachment will not result (Grimes Report, at 44), is an entirely invalid conclusion from his testing in *dead* bone.

**c. Dr. Grimes's form factor measurements are not reliable.**

Dr. Grimes sent the Durom Cups off for measurement before and after implantation in the cadavers to two different companies. He did not supervise their measurements. (Grimes I Dep. 185:12-186:4). The intervals tested were not scientific but based only on lab availability. (*Id.* at 191:11-192:19). Dr. Grimes does not even know what algorithms or standards were used to calculate the form factor. (*Id.* at 198:4-199:4). Nor does he state how the pelvic specimens were stored post-impaction. (Ong Report, at 86).

Nonetheless, Dr. Grimes relies on the measurements taken post-impaction as evidence of deformation, particularly as to the 56/50 Durom Cup in Cadaver 2. By Dr. Grimes's own measurements, Cadaver 1 showed only "mild cup impaction deformation" while Cadaver 2 demonstrated "severe impaction deformation." (Grimes Report (Figures), at 51). The numbers for Cadaver 1 are nonsensical, as they *increase* over time. (*See* Grimes Report (Figures), at 51). It makes no sense for alleged deformation to increase over a period of days after impaction. Among other issues, Dr. Grimes's use of multiple vendors, his lack of knowledge of the algorithms used by either vendor, his lack of information on the storage conditions of the cadaver pelvises, and the nonsensical data for Cadaver 1 together fail to establish that the methodology he employed in developing these measurements followed correct scientific procedures. (*See* Ong Dep. 202:22-208:18 (discussing problems with storage of pelvises, multiple vendors, problems with the form factor, failure to acknowledge the designed clearance, and fact that femoral head was not placed in cup); *see also* Day Report, at 57 ("Dr. Grimes is not following any of the recognized consensus standards for the measurement of hip components.")).

Finally, Dr. Grimes's form factor measurements in cadaver bone do not account for the real-life conditions that would be expected in a live patient, specifically, joint loading and

viscoelasticity (stress relaxation), which are known to reduce cup deformation. (Day Report, at 57). At his deposition, Dr. Grimes admitted that "[t]here's no healing response" in cadaver bone. (Grimes Dep. 167:23-168:4). Dr. Ong also testified to these issues, noting that the cadaveric experiment cannot model femoral head reduction, "which would reverse any potential effects from cup deformation," or "bone remodeling," "for example, when the patient starts walking around." (Ong Dep. 193:4-25). He noted that Dr. Grimes could have but did not attempt to analyze joint loading. (Ong Dep. 194:1-8).

**7. Dr. Grimes lacks qualifications to conduct and testify to this experiment.**

Dr. Grimes is not qualified to conduct the cadaveric experiments he adapted from the Jin study. Again, he is a practicing orthopedic surgeon, not a design expert (Grimes I Dep. 128:5-9), and he has had no formal training in the testing of medical devices or experience designing pre-market testing. (*Id.* at 128:21-129:2; 124:22-24). The lack of scientific rigor in his experiment, discussed above, underscores his inexperience and lack of qualification. As an orthopedic surgeon, Dr. Grimes does not fit the bill for the testing he purported to conduct.

**8. Dr. Grimes's experiment has no non-judicial use.**

Dr. Grimes performed his cadaver experimentation exclusively for this and the related litigation. As noted above, he has no intent to publish it in its present condition for academic or medical purposes. (Grimes I Dep. 155:6-25).

In conclusion, it is unlikely that Dr. Grimes's cadaver testing meets any of the eight standards for reliability considered by the Third Circuit, and any testimony regarding that testing or conclusions drawn from it should be excluded. *See, e.g.*, *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 162-63 (3d Cir. 1999) (concluding that district court did not abuse discretion in excluding expert testimony about formula based on "speculation and estimation that was subject

to gross error" because of doubt that the "methodology would meet even one of the eight suggested factors from *Daubert* and *Paoli*").

### C. Dr. Grimes's Dye Testing Is Also Not Reliable and Testimony Regarding It Should Be Excluded.

Likewise, Dr. Grimes cannot establish that his dye testing passes muster under *Daubert*. While this was part of both his foam experiment and his cadaver experiment, it is an independent component with its own flaws. To assess contact between the femoral head and the Durom Cup, Dr. Grimes put an unquantified amount of dye on the femoral head and rotated it in a Durom Cup using unquantified amounts of pressure and direction. With respect to the cadaver testing, Dr. Grimes conducted this experiment pre- and post-impaction on the 54/48N Durom Cup (used with Cadaver 1), but only conducted the experiment post-impaction on the 56/50P Durom Cup (used with Cadaver 2).

Plaintiffs cannot show that Dr. Grimes's dye testing reflects reliable methodology. Indeed, Dr. Ong "wouldn't even consider it an experiment." (Ong. Dep. 200:13-14.) There is little precedent for using dye to evaluate cup deformation as Dr. Grimes is attempting to do. Although Dr. Grimes suggested that he adapted his methodology from the Jin study, he does not testify that the methodology is generally accepted. (*See* Grimes I Dep. 105:15-22). There were no controls on Dr. Grimes's oscillation process, and it was not filmed. Zimmer's experts have attempted to replicate Dr. Grimes's dye testing and have shown that it is highly subject to manipulation. They too swiveled dye-covered femoral heads in Durom Cups and were able to achieve a variety of contact patterns before compression:

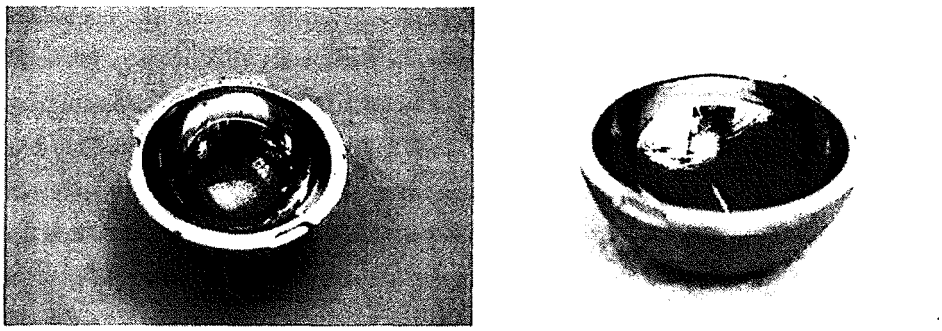

Figure 12. Dye contact testing of an acetabular cup could produce either a polar or linear transfer patch in an undeformed cup depending on the method used to oscillate the head.

(Day Report, at 58). And after compression and deformation:

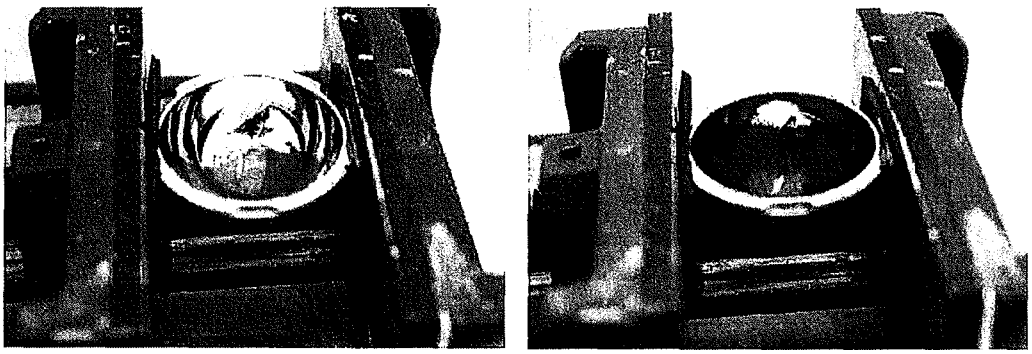

Figure 13. Dye contact testing after application of force to the cup.

(Day Report, at 58). These tests show that the dye testing results were "highly sensitive" to the method used to oscillate the head. (Day Report, at 58). In other words, one swiveling the head could manipulate the test and obtain patterns indicative of deformation in a cup that was known and confirmed to be pristine. Consequently, Dr. Grimes's dye testing "cannot be relied upon with any reasonable degree of scientific or engineering certainty to indicate the location of contact between the head and cup, or as an indication of cup deformation." (Ong Report, at 81). As Dr. Ong testified at his deposition, there are numerous problems with the subjectivity of the dye testing, and for those reasons, the dye test is a "scientifically invalid test" that "doesn't demonstrate anything." (Ong Dep. 197:17-200:14).

**D. Dr. Grimes Has Refused To Provide the Basis for His Ion Opinions, and They Are Not Grounded in Any Recognized Methodology.**

On the basis of testing joint fluid levels in one or two of his patients, Dr. Grimes purports to offer opinions related to release of cobalt and chromium metal ions from the Durom Cup and resulting cell toxicity. (Grimes I Dep. 107:13-18). Even if one or two samples constituted a scientifically acceptable sample size, Plaintiffs have failed or refused to provide data or records related to the patients on whose clinical presentation he relies in conflict with this Court's order. (Grimes II Dep. 399:9-15). On that basis alone, the opinions should be excluded. *See* Fed. R. Civ. P. 26(a)(2)(B)(ii) (expert report must disclose "facts or data considered by the witness in forming" the opinions).

Further, toxicologist Joyce Tsuji, Ph.D., explains that Dr. Grimes's opinions on the release of metal ions are "overly simplistic, toxicologically inaccurate, and inconsistent with the body of scientific literature on the toxicology of these metals." (Tsuji Report, at 7 (attached as Exhibit L)). Dr. Grimes is not following any generally acceptable methodology in rendering opinions on the release of metal ions. (Grimes II Dep. 365:10-18). His opinions that metal ions are released and cause bone cells to "just sit there and do nothing," (Grimes Report, at 36), is entirely speculative and therefore inadmissible. *See, e.g.*, *Oddi v. Ford Motor Co.*, 234 F.3d 136, 156-58 (3d Cir. 2000) (affirming exclusion of design defect opinion testimony who used "little if any methodology beyond his own intuition"); *Fedor v. Freightliner, Inc.*, 193 F. Supp. 2d 820, 830 (E.D. Pa. 2002) (excluding expert because expert's conclusions were not based on a discernable methodology). Those opinions also contradict Plaintiffs' coating expert Roy Bloebaum, Ph.D., who testified that he does not think metal ions have anything to do with the alleged coating issues. (Bloebaum Dep. 325:14-18, attached as Exhibit M).

**E. Dr. Grimes Purports To State Multiple Other Opinions That Are Not Grounded in Any Methodology and Should Be Excluded as Speculative.**

Dr. Grimes offers a medley of opinions that have no basis in any methodology at all. For instance, he speculates that

- Zimmer's hip simulator tests did not simulate the effect of impaction and deformation and underestimate initial wear rates;
- the coating could flake off due to impaction forces;
- micromotion causes taper corrosion at modular junctions;
- the subhemispheric shape of the Durom Cup is problematic;
- the 3 mm rim fin causes excessive press fit and fracture; and
- the cup wall thickness is inadequate.

As discussed at the outset, Dr. Grimes is not qualified to render such opinions because he has no expertise in metallurgy or tribology. He did not review any documents that were specific to the design of the device, such as the design history file. (Grimes I Dep. 140:17-22). Further, by his own admission, Dr. Grimes has performed no investigation or testing with respect to these issues. (Grimes I Dep. 61:16-20 (no wear simulator testing); *id.* at 227:7-229:4 (no testing or investigations regarding taper corrosion at modular junctions); *id.* at 106:19-23; 108:10-12 (no personal ion testing related to the Durom Cup); *id.* at 162:6-11 (no testing or investigation into the coating on the Durom Cup); Grimes II Dep. 361:15-362:1 (no testing comparing how likely it is for an acetabular fracture to occur with the Durom Cup compared to other similar devices). Accordingly, his unqualified and untested opinions are rank speculation and should be excluded. *Paoli II*, 35 F.3d at 742 ("expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation;' the expert must have 'good grounds' for his or her belief" (quoting *Daubert*, 509 U.S. at 589-90)). When an expert's

testimony "relies in part on his own *ipse dixit*, rather than on something more readily verifiable ... it is open to attack." *In re TMI Litig.*, 193 F.3d at 687. Likewise, "something doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315-16 (9th Cir. 1995)); *see also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 527 (W.D. Pa. 2003). Because Dr. Grimes's opinions are based on nothing more than speculation, they cannot possibly assist the jury in finding the truth and must be excluded.

## V. DR. GRIMES'S OPINIONS WILL NOT BE HELPFUL TO THE JURY BECAUSE THEY DO NOT "FIT" THE ISSUES IN THE CASE

Under Federal Rule of Evidence 702, expert testimony must "fit" the issues in the case. "In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *see also Daubert*, 509 U.S. at 591-92 ("Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.").

By and large, Dr. Grimes's opinions do not "fit" this case. Both his foam testing and his cadaver testing evaluate impaction in inanimate substances. But he relies on his findings from these flawed experiments to extrapolate and opine on the process and effects of impacting the Durom Cup in *live* patients. For the reasons previously discussed, implantation of the device in live patients is qualitatively different, and Dr. Grimes makes no effort to take those qualitative differences into account. The differences invalidate any conclusions that Dr. Grimes attempts to draw with respect to implanting the device in a *living* patient. *See Glick v. White Motor Co.*, 458 F.2d 1287, 1294 (3d Cir. 1972) (experimental evidence is admissible if it is relevant and probative; it is probative "if the conditions of the experiment are identical with or similar to the

conditions of the transactions in litigation"); *see also In re TMI Litig.*, 193 F.3d at 670 (water model and plume model lacked "scientific reliability and are inadmissible because of their speculative character" but were "more appropriately inadmissible because they lack fit").

## VI. AS A GENERAL MATTER, DR. GRIMES'S OPINIONS BASED ON UNDISCLOSED PATIENT FILES MUST BE EXCLUDED

Dr. Grimes testified that his clinical experience informs his opinion and that the high revision rate in his 38 Durom Cup THAs prompted him to investigate this matter. (Grimes I Dep. 38:1-39:20). Yet despite specific request and although the files likely exist, Plaintiffs have not produced them. (*Id.* at 36:24-37:3; Grimes II Dep. 399:9-15). Testimony based on Dr. Grimes's clinical experiences must be excluded due to failure to produce these underlying records. It is not fair for Dr. Grimes to rely on these experiences without giving Zimmer an opportunity to investigate the underlying records. *See* Fed. R. Civ. P. 26(a)(2)(B)(ii) (expert report must disclose "facts or data considered by the witness in forming" the opinions); Fed. R. of Civ. P. 37(c)(1) ("If a party fails to provide information . . . required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.").

## VII. CONCLUSION

For the foregoing reasons, Dr. Grimes's opinions should be excluded, and Dr. Grimes should be precluded from testifying at trial.

*s/ Edward J. Fanning, Jr.*
Edward J. Fanning
Zane C. Riester
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102
Telephone: (973) 622-4444
Facsimile: (973) 624-7070
efanning@mccarter.com
zriester@mccarter.com

J. Joseph Tanner
Andrew L. Campbell
Stacy L. Prall
John T. Schlafer
300 North Meridian Street, Suite 2700
Indianapolis, Indiana 46202
Telephone: (317) 237-0300
Facsimile: (317) 237-1000
joe.tanner@faegrebd.com
andrew.campbell@faegrebd.com
stacy.prall@faegrebd.com
john.schlafer@faegrebd.com

Attorneys for Zimmer, Inc. and Zimmer Holdings, Inc.