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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

2:09-cv-04414-SDW-MCA

IN RE: ZIMMER DUROM HIP CUP PRODUCTS LIABILITY LITIGATION

MDL-2158

This Document Relates To All Waters & Kraus Cases

PLAINTIFFS' RESPONSE TO PLAINTIFFS' CO-LIAISON MOTION FOR RECONSIDERATION OF JUNE 7, 2018 ORDER GRANTING MOTION FOR DISBURSEMENT OF FEES AND EXPENSES FROM COMMON BENEFIT FUND AND EXPENSES FOR A STAY OF THAT ORDER [DOC. 986]

COMES NOW Waters & Kraus, LLP, through undersigned counsel, and respectfully moves this Court to deny Plaintiffs' Co-Liaison Counsel's Motion for Reconsideration of June 7, 2018 Order Granting Motion for Disbursement of Fees and Expenses form Common Benefit Fund and Expenses for a Stay of that Order [Doc. 986].

DATED: June 28, 2018.

Respectfully submitted,

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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 This Document Relates To All Waters & Kraus Cases

PLAINTIFFS' BRIEF IN SUPPORT OF THEIR RESPONSE TO PLAINTIFFS' CO-LIAISON NOTICE FOR RECONSIDERATION OF JUNE 7, 2018 ORDER GRANTING MOTION FOR DISBURSEMENT OF FEES AND EXPENSES FROM COMMON BENEFIT FUND AND EXPENSES FOR A STAY OF THAT ORDER [DOC. 986]

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COMES NOW Waters & Kraus, LLP ("Waters & Kraus"), through undersigned counsel, and files this response to the Motion of Plaintiffs' Co-Liaison Counsel for Reconsideration and Stay of Court Order Allocating and Disbursing Fees and Expenses from Common Benefit Fund ("Motion to Reconsider"), and will show as follows:

I. PRELIMINARY STATMENT

Leaving aside for a moment the many gaps and inconsistencies in the narrative constructed by Messrs. Cecchi and Seeger, all of which are addressed *infra*, it is important to note at the outset that the sole issue before the Court is whether they have provided a proper basis for reconsidering the Court's Order Granting Plaintiffs' Motion Seeking Disbursement from Common Benefit Fund [Doc. 983], which was entered on June 7, 2018 ("June 7th Order"). It is well-established throughout the Third Circuit that "motions for reconsideration are an inappropriate avenue for relitigating matters which could have been adequately presented the first time."[1] Here, as the Court will recall, Messrs. Cecchi and Seeger did not even file a formal response to the Plaintiffs' Motion Seeking Disbursements from Common Benefit Fund [Doc. 972] ("Motion to Disburse"). Instead, they sent two letters to the Court: (1) one on April 20, 2018 ("Mr. Seeger's April 20th Letter"), telling the Court it needed to establish "an orderly application and distribution process . . . regarding the

[1] *NL Indus., Inc. v. Commercial Union Ins. Co.*, 935 F. Supp. 513, 516 (D.N.J. 1996).

distribution of common benefit fees";[2] and (2) a second on May 30, 2018 ("Mr. Cecchi's May 30th Letter"), advising the Court that it needed "to establish a process with clear guidelines and instructions for all counsel who wish to seek common benefit funds."[3] Curiously, neither letter even acknowledged Case Management Order No. 3 [Doc. 33] ("CMO No. 3"), or offered any explanation why the disbursement process and guidelines contained therein were not "orderly" or "clear," respectively. Nor did Messrs. Cecchi and Seeger remind the Court in these letters that they had requested *pursuant to CMO No. 3* and been granted common benefit funds on two previous occasions in this litigation.

All that said, "[t]o be successful on a motion for reconsideration, a petitioner must present '**something new** or **something overlooked** by the court in rendering the earlier decision.'"[4] Even if Mr. Seeger's April 20th Letter and Mr. Cecchi's May 30th letter are considered "responses," those letters did not provide the Court any fact or law that it had "overlooked" in making its decision to enter the June 7th Order.[5] Indeed, those letters were completely devoid of both fact and law. Thus, to

[2] Letter from C. Seeger to Judge S. Wigenton, dated Apr. 20, 2018 [Doc. 973].
[3] *NL Indus., Inc.*, 935 F. Supp. at 516 ("Accordingly, such motions will be granted only where (1) an intervening change in the law has occurred, (2) new evidence not previously available has emerged, or (3) the need to correct a clear error of law or prevent a manifest injustice arises.") (citing *North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995)).
[4] *Chiniewicz v. Henderson*, 202 F. Supp. 2d 332, 334 (D.N.J. 2002) (quoting *Hernandez v. Beeler*, 129 F. Supp.2d 698, 701 (D.N.J. 2001)) (emphasis added).
[5] Notably, "[a]n argument is not deemed overlooked because it is not specifically addressed in a court's opinion. An argument may be regarded as having been considered if it is presented to the court in written submissions and in oral argument." *Byrne v. Calastro*, No. CIVA 05-CV-68 DMC,

be successful, Messrs. Cecchi and Seeger's Motion to Reconsider must identify "an intervening change of law" or "new evidence not previously available."[6] Their motion fails to do either. Instead, the Motion to Reconsider essentially asks the Court to rethink its June 7th Order based on case law and "evidence" that was available long before June 7th. In so doing, Messrs. Cecchi and Seeger ignored this Court's recent admonition that a "motion for reconsideration is 'an extremely limited procedural vehicle[,]"[7] and that "[a]sking this Court to 'rethink' its holding is not an appropriate basis upon which to seek reconsideration."[8]

Even if the arguments contained within the Motion to Reconsider were procedurally appropriate, a denial would still be required. Simply put, the members of the Plaintiffs' Liaison Counsel who filed the Motion to Disburse followed the guidelines and procedures of CMO No. 3 and the Court properly performed its oversight role under CMO No. 3 in entering the June 7th Order. For all of these reasons, discussed in greater detail *infra*, the Motion to Reconsider should be denied.

2006 WL 2506722, at *2 (D.N.J. Aug. 28, 2006) (citing *Eichorn v. AT & T Corp.*, No. Civ. A. 96–3587(MLC), 1999 WL 33471890 (D.N.J. Aug. 23, 1999)).

[6] *NL Indus., Inc.*, 935 F. Supp. at 516 ("Accordingly, such motions will be granted only where (1) an intervening change in the law has occurred, (2) new evidence not previously available has emerged, or (3) the need to correct a clear error of law or prevent a manifest injustice arises.") (*North River*, 52 F.3d at 1218).

[7] *Mid-American Salt, LLC v. Morris Cty. Coop. Pricing Council*, Civil Action No. 17-4262, 2018 WL 1801178, at *1 (D.N.J. Apr. 16, 2018) (quoting *A.K. Stamping Co., Inc. v. Instrument Specialties Co.*, 106 F. Supp. 2d 627, 662 (D.N.J. 2000)).

[8] *Id.* (citing *Oritani Sav. & Loan Ass'n v. Fid. & Deposit Co. of Md.*, 744 F. Supp. 1311, 1314 (D.N.J. 1990)).

II. BACKGROUND

A. The Origin of CMO No. 3

Case Management Order No. 1 [Doc. 17], entered on September 23, 2010, established Plaintiffs' Liaison Counsel in this litigation. Plaintiffs' Liaison Counsel initially consisted of Mr. Cecchi of Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C., Mr. Seeger of Seeger Weiss LLP and Wendy Fleishmann of Lieff Cabraser.[9]

On January 21, 2011, the Court entered CMO No. 3 with the stated purpose of:

> [P]rovid[ing] for the fair and equitable sharing among plaintiffs of the cost of **services performed** and **expenses incurred** by Plaintiffs' Liaison Counsel and other attorneys acting for and providing a common benefit [for] all plaintiffs in this complex litigation[.][10]

Waters & Kraus first entered an appearance in this MDL on March 21, 2012.[11] George Tankard and Gibbs Henderson of Waters & Kraus, as well as Derek Braslow of Pogust Braslow & Millrood, were subsequently added to Plaintiffs' Liaison Counsel.[12]

[9] *See* Case Management Order No. 1, dated Sept. 23, 2010 [Doc. 17], at ¶ 20;
[10] Case Management Order No. 3 [Doc. 33] (hereinafter, "CMO No. 3") at 1 (emphasis added).
[11] Notice of Appearance by George Tankard of Waters & Kraus, dated Mar. 21, 2012 [Doc. 113].
[12] *See* Agreed Case Management Order Supplementing Plaintiffs' Liaison Counsel, June 13, 2013 [Doc. 184]; and Order Granting Plaintiffs' Motion to Substitute Counsel, dated June 26, 2015 [Doc. 730].

B. Previous Requests for Disbursement Pursuant to CMO No. 3

All members of Plaintiffs' Liaison Counsel have, at some point in this litigation, sought and obtained money from the Common Benefit Fund ("CBF") pursuant to CMO No. 3. These requests have all been similar in nature, as discussed below.

1. Mr. Cecchi's March 2, 2012 Request

The first such request was made by Mr. Cecchi on behalf of his firm, Mr. Seeger's firm and Lieff Cabreser on March 2, 2012 ("March 2nd CBF Request").[13] The only evidence attached to the March 2nd CBF Request was a declaration by Mr. Cecchi representing that: "Liaison Counsel expended 956.1 hours, for a lodestar of $538,410.00 . . . [and t]he total amount of expenses for liaison counsel is $41,399.33."[14] Three days later, on March 5, 2012, the Court entered an order "in accordance with [CMO No. 3]" that disbursed all money in the CBF at the time, $506,140, to Mr. Cecchi's firm.[15]

2. Mr. Cecchi's December 12, 2012 Request

On December 12, 2012, Mr. Cecchi submitted a request "in accordance with CMO-3" requesting all monies in the CBF.[16] Unlike his previous request, Mr.

[13] Letter from J. Cecchi to Mag. Judge M. Arleo, dated Mar. 2, 2012 [Doc. 111].
[14] Declaration of James Cecchi, dated Mar. 2, 2012 [Doc. 111-1] at 2.
[15] Order, dated Mar. 5, 2012 [Doc. 112]
[16] Letter to Mag. Judge M. Arleo from J. Cecchi, dated Dec. 12, 2012 [Doc. 143].

Cecchi did not attach a declaration specifying the common benefit hours and costs he was seeking to recover; he merely attached a proposed Order [Doc. 143-1] explaining that "Liaison Counsel shall pay such monies to themselves in accordance with the agreement among Liaison Counsel . . . ." Pursuant to that request, the Court entered an order on December 18, 2018, disbursing $248,933.69 to Mr. Cecchi's firm.[17]

3. Waters & Kraus and Lieff Cabraser's March 11, 2015 Request

Waters & Kraus and Lieff Cabraser submitted a request to the Court for reimbursement of common benefit expenses on March 11, 2015.[18] Included within that request was a sworn declaration documenting expenses of $290,324.64 for Waters & Kraus and $36,973.04 for Lieff Cabraser.[19] Pursuant to that request, the Court entered an order on March 24, 2015 permitting payment to Waters & Kraus and Lieff Cabraser out of the CBF in the requested amounts.[20]

C. Events Leading Up to the June 7th Order

Back on June 14, 2016, Waters & Kraus disclosed to all members of Plaintiffs' Liaison Counsel its total billable "common benefit" hours in 2013 and 2014 for this litigation (3,906.25 hours) and an approximation of its "common benefit" expenses

[17] Order, dated Dec. 18, 2012 [Doc. 146].
[18] Letter from K. Cole to Mag. Judge S. Mannion, dated Mar. 11, 2015 [Doc. 680].
[19] *Id*. at Decl. of Kyla G. Cole [Doc. 680-1].
[20] Order, dated Mar. 25, 2015 [Doc. 694].

to date ($900,000).[21] In that same letter, Waters & Kraus invited the other members of Plaintiffs' Liaison Counsel to submit their "common benefit" hours and expenses as "a first step" in dividing up the monies in the CBF.[22] Messrs. Cecchi and Seeger did not provide hours and expenses in response to that request.

On February 2, 2018, Waters & Kraus sent a letter to its fellow members of Plaintiffs' Liaison Counsel – including Messrs. Cecchi and Seeger – inviting each firm to submit its recorded expenses and hours for the purpose of a joint submission seeking the division and disbursement of the CBF.[23] That letter also noted that, as of December 12, 2017, there was $3,288,170.40 in the common benefit fund.[24] Waters & Kraus promptly received a submission in response to this request from Pogust Braslow & Millrood. Meanwhile, Lieff Cabraser, through Wendy Fleishman, asked on February 21, 2018, that it be included in the contemplated motion to disburse and informed Waters & Kraus that it would be providing an accounting of its "common benefit" hours and expenses.[25]

[21] *See* **Exhibit G**, Letter from G. Henderson to Co-Liaison Counsel, dated June 15, 2016. After considerable review, these numbers were altered slightly before being presented as part of the Motion to Disburse.
[22] *See id*.
[23] *See* **Exhibit A**, Letter from G. Henderson to Co-Liaison Counsel, dated Feb. 2, 2018.
[24] *See id*. at 2.
[25] *See* **Exhibit H**, Email from W. Fleishman to G. Henderson, dated Feb. 21, 2018. Ms. Fleishman was sent a draft of the motion to reconsider for her review on March 20, 2018, and acknowledged receipt on the following day. *See* **Exhibit I**, Email from W. Fleishman to E. Wood, dated Mar. 21, 2018.

On April 18, 2018, Waters & Kraus, Lieff Cabraser, and Pogust Braslow & Millrood – constituting three-fifths of Plaintiffs' Liaison Counsel (hereinafter, the "PLC Majority") – filed a Motion Seeking Disbursements from Common Benefit Fund [Doc. 972] ("Motion to Disburse"), which recommended that they be reimbursed for their documented common benefit expenses and hours in the following amounts:

- Waters & Kraus: $788,709.25 in expenses and $1,578,418.50 in fees;
- Pogust Braslow & Milrood: $0 in expenses and $23,154.80 in fees;[26] and
- Lieff Cabraser: $100,349.43 in expenses and $739,505.84 in fees.[27]

In support of the Motion to Disburse, the PLC Majority attached: (a) a list of the common benefit depositions taken by Waters & Kraus;[28] (b) a summary of Waters & Kraus's common benefit document review efforts;[29] (c) an itemized list of Waters & Kraus's common benefit expenses;[30] (d) an itemized list of Waters & Kraus's common benefit hours coded consistent with CMO No. 3;[31] and (e) an

[26] *See* Mot. to Disburse at 11.
[27] Leiff Cabraser's common benefit expenses and hours were supplemented on May 4, 2018. Pls.' Supp. Br. in Support of Mot. Seeking Disbursements from Common Benefit Fund [Doc. 977] at 2.
[28] *See* Mot. to Disburse at Ex. A, "Common Benefit Depositions Lead [sic] by Plaintiff's Liaison Counsel" [Doc. 972-3].
[29] *See* Mot. to Disburse at Ex. B, Declaration of George G. Tankard III [Doc. 972-4] at 1.
[30] *See* Mot. to Disburse at Ex. D, Waters & Kraus Common Benefit Expense Spreadsheet [Doc. 972-6].
[31] *See* Mot. to Disburse at Ex. E, Waters & Krause Common Benefit Hours Spreadsheet [Doc. 972-7].

itemized list of Pogust Braslow & Milrood's common benefit hours, including detailed descriptions for each entry.[32] The PLC Majority subsequently supplemented its Motion to Disburse with sworn summaries detailing Lieff Cabreser's: (a) common benefit hours and fees;[33] and (b) common benefit expenses.[34]

As discussed above, the PLC Majority's Motion to Disburse was granted on June 7, 2018, and Zimmer was ordered to pay the requested amounts out of the CBF. Following the filing of Messrs. Cecchi and Seeger's Motion to Reconsider, Zimmer informed the Court that it would await the resolution of that motion before complying with the Court's June 7th Order.[35]

III. ARGUMENTS & AUTHORITIES

A. The Entry of CMO No. 3 at the Outset of this Litigation was Appropriate, and Served to Clarify the Expectations of the Parties.

"In a consolidated national mass litigation . . . it is standard practice for the courts to compensate attorneys who work for the common benefit of all plaintiffs by setting aside a fixed percentage of settlement proceeds."[36] According to the

[32] *See* Mot. to Disburse at Ex. F, Pogust Braslow & Milrood's Common Benefit Hours Spreadsheet [Doc. 972-8].
[33] *See* Pls.' Supplemental Br. in Supp. of Mot. Seeking Disbursements from Common Benefit Fund [Doc. 977] at Ex. A, Lieff Cabraser Common Benefit Hours Spreadsheet [Doc. 977-2].
[34] *See* Pls.' Supplemental Br. in Supp. of Mot. Seeking Disbursements from Common Benefit Fund [Doc. 977] at Ex. B, Lieff Cabraser Common Benefit Expenses Spreadsheet [Doc. 977-3].
[35] Letter from A. Campbell to Judge S. Wigenton, dated June 25, 2018 [Doc. 988].
[36] *In re Zyprexa Prods. Liab. Litig.*, 467 F. Supp. 2d 256, 265 (E.D.N.Y. 2006).

MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.927, the role of this so-called liaison counsel or steering committee, broadly speaking, is "to litigate common issues and prepare the case[s] for trial or settlement."[37]

The rationale for this practice, which deviates from the default "American rule" of making each party bear its own costs, is simple. As the First Circuit explained in 1992:

> [W]hen a court consolidates a large number of cases, stony adherence to the American rule invites a serious free-rider problem. If a court hews woodenly to the American rule under such circumstances, each attorney, rather than toiling for the common good and bearing the cost alone, will have an incentive to rely on others to do the needed work, letting those others bear all the costs of attaining the parties' congruent goals.[38]

To avoid the "free-rider" problem discussed by the First Circuit, *supra*, "the U.S. Supreme Court over 125 years ago approved the common benefit doctrine . . . ."[39] "In accordance with the common benefit doctrine, it has been a common practice in federal courts to impose set-asides in the **early stages of complex litigation** in order to preserve common-benefit funds for later distribution."[40] Consistent with the emphasized language, the MANUAL FOR COMPLEX LITIGATION (FOURTH) advises that the percentage and procedures pertaining to the common benefit fund should be

[37] MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.927.
[38] *In re Nineteen Appeals Arising Out of San Juan Dupont Plaza Hotel Fire Litig.*, 982 F.2d 603, 606 (1st Cir. 1992) (citation omitted).
[39] *Turner v. Murphy Oil USA, Inc.*, 422 F. Supp. 2d 676, 680 (E.D. La. 2006) (citations omitted).
[40] *Id*. (citations omitted) (emphasis added).

established at the outset of the litigation.[41] Establishing "guidelines and procedures" applicable to the common benefit fund early in the litigation will, the authors write, "lighten the burdens on the participants, **clarify expectations**, and reduce the opportunities for disputes."[42]

In the instant litigation, this Court faithfully followed the guidance of the above-cited authorities by entering CMO No. 3 at the outset of this litigation. CMO No. 3 also clarified the expectations of all parties, including Plaintiffs' Liaison Counsel, by establishing: (a) a set common benefit assessment for all settlements and verdicts of four percent;[43] and (b) standards and procedures for counsel seeking fee and expense reimbursement from the common benefit fund.[44] As to the latter, CMO No. 3 provided detailed guidelines for both "time reporting" and "expense reporting."[45] Among other things, those guidelines specified that any counsel "seeking fees from the Common Fund is required to maintain contemporaneous and detailed time and expense records."[46] CMO No. 3 also explicitly authorized

[41] MANUAL FOR COMPLEX LITIGATION (FOURTH) § 14.211 (May 2017 Update) ("Judges should consider advising the parties at the outset of the litigation about the method to be used for calculating fees and, if using the percentage method, about the likely range of percentages.").
[42] *Id.* (emphasis added).
[43] *See* CMO No. 3 at ¶ 3.
[44] *See id.* at ¶ 9.
[45] *Id.*
[46] *Id.* at ¶ 9.c.

members of Plaintiffs' Liaison Counsel to be reimbursed for "services provided and expenses incurred in preparation and trial of the bellwether cases."[47]

CMO No. 3 also expressly identified who would be eligible to seek fees and expense reimbursement from the CBF. Specifically, paragraph 10 stated that the only parties eligible to receive monies from the CBF were "limited to Plaintiffs' Liaison Counsel, and other attorneys performing responsibilities approved by Plaintiffs' Liaison Counsel in MDL-2158."[48]

With those guidelines in place, CMO No. 3 states, "The Court shall receive and consider recommendations from Plaintiffs' Liaison Counsel concerning distribution of the Common Benefit Fund."[49] All disbursements pursuant to those recommendations, in turn, must be approved by the Court.[50]

As discussed in more depth below, CMO No. 3's method for calculating fees is entirely consistent with Third Circuit precedent, and the PLC Majority faithfully adhered to the guidelines and procedures CMO No. 3 established.

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[47] *See* CMO No. 3 at ¶ 10 (emphasis added).
[48] *Id*. at ¶ 10.
[49] *See id*. at ¶ 9.
[50] *See id*. at ¶ 13.

B. Messrs. Cecchi and Seeger Have Not Provided an Appropriate Basis for Reconsidering the Court's June 7th Order.

1. Motions to reconsider are a limited procedural vehicle.

"Local Rule 7.1(i) governs motions for reconsideration filed in New Jersey."[51] "The comments to that Rule make clear that 'reconsideration is an extraordinary remedy that is granted 'very sparingly.'"[52] "As such, a party seeking reconsideration must satisfy a high burden . . . ."[53]

District courts in New Jersey have repeatedly emphasized the limited nature of motions to reconsider over the years.[54] As one court put it, these motions "should not provide the parties with an opportunity for a second bite at the apple."[55] In the words of another, motions to reconsider "may not be used to expand the record before the court."[56] These motions are not intended as procedure vehicles for a party

[51] *Champion Labs., Inc. v. Metex Corp.*, 677 F. Supp. 2d 748, 750 (D.N.J. 2010) (citation and internal quotations omitted). Notably, such motions are "not expressly authorized by the Federal Rules of Civil Procedure, [but] are [considered] proper pursuant to this District's Local Civil Rule 7.1(i)."

[52] *Rich v. State*, 294 F. Supp. 3d 266, 272 (D.N.J. 2018) (quoting L. Civ. R. 7.1(i) cmt. 6(d)).

[53] *Leja v. Schmidt Mfg., Inc.*, 743 F. Supp. 2d 444, 456 (D.N.J. 2010). *See generally U.S. ex rel. Haskins v. Omega Inst., Inc.*, 25 F. Supp. 2d 510, 513 (D.N.J. 1998) "Because New Jersey district courts have used the terms 'reargument' and 'reconsideration' interchangeably, Loc. Civ. R. 7.1(g) has been found to govern both motions for reargument and motions for reconsideration."

[54] *See, e.g.*, *Leja*, 743 F. Supp. 2d at 456 (quoting *Resorts Int'l v. Greate Bay Hotel & Casino*, 830 F. Supp. 826, 831 (D.N.J.1992) (alteration in original) ("[I]t is well-established in this district that a motion for reconsideration is an extremely limited procedural vehicle.").

[55] *Tischio v. Bontex, Inc.*, 16 F. Supp. 2d 511, 532 (D.N.J. 1998) (quoting *In re Christie*, 222 B.R. 64, 66 (Bankr. D.N.J.1998)) (alteration in original).

[56] *In re Consol. Parlodel Litig.*, 22 F. Supp. 2d 320, 329 (D.N.J. 1998) (quoting *Resorts Int'l, Inc.*, 830 F. Supp. at 831).

to express "mere disagreement" with a decision,[57] or "'to ask the Court to rethink what [it] had already thought through—rightly or wrongly.'"[58] The rationale for these limitations is both obvious and compelling: "Each step of the litigation should build upon the last and, in the absence of newly discovered, non-cumulative evidence, the parties should not be permitted to reargue previous rulings made in the case."[59]

According to Third Circuit, courts may only grant a motion to reconsider "if the moving party shows one of the following: (1) an **intervening change in the controlling law**; (2) the availability of **new evidence that was not available** when the court issued its order; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice."[60] As the emphasized language illustrates, "[m]otions for reconsideration 'are not an opportunity to argue what could have been, but was not, argued in the original set of moving and responsive papers.'"[61] Indeed, District of New Jersey courts have consistently held that, "[m]atters may not be introduced for the first time on a reconsideration motion, and absent unusual circumstances, a

[57] *Assisted Living Assocs. of Moorestown, L.L.C. v. Moorestown Twp.*, 996 F. Supp. 409, 442 (D.N.J. 1998) (citations omitted) ("Mere disagreement with a decision of the district court . . . is inappropriate on a motion for reargument [under Local Rule 7.1].").
[58] *Oritani Sav. & Loan Ass'n*, 744 F. Supp. at 1314 (quoting *Above the Belt v. Mel Bohannan Roofing, Inc.*, 99 F.R.D. 99, 101 (E.D. Va. 1983)).
[59] *Id.* (citing *Johnson v. Tp. of Bensalem*, 609 F. Supp. 1340, 1342 n. 1 (E.D. Pa. 1985)).
[60] *Johnson v. Diamond State Port Corp.*, 50 F. App'x 554, 560 (3d Cir. 2002) (citing *Max's Seafood Café v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)) (emphasis added).
[61] *D'Argenzio v. Bank of Am. Corp.*, 877 F. Supp. 2d 202, 210 (D.N.J. 2012) (quoting *Bowers v. NCAA*, 130 F. Supp. 2d 610, 613 (D.N.J. 2001)).

court should reject new evidence which was not presented when the court made the contested decision."[62]

2. There has been no "intervening change of law."

In the instant matter, Messrs. Cecchi and Seeger fail to identify *any* "intervening change in controlling law" that occurred between the Court's June 7th Order and the filing of their Motion to Reconsider – much less a holding that would warrant a different outcome. Indeed, the most recent decision cited in their brief on the issue of common benefit fees dates back to 2014.[63] As explained in *Leja*, *supra*, "a motion for reconsideration may not be premised on legal theories that could have been adjudicated . . . but [were] not presented prior to the earlier ruling."[64]

3. The Motion to Reconsider does not identify any evidence that was unavailable to Messrs. Cecchi and Seeger prior to June 7.

Messrs. Cecchi and Seeger's Motion to Reconsider also fails to identify any newly discovered evidence as a basis for voiding the Court's June 7th Order. The Motion to Reconsider's lengthy "Statement of Facts" contains nothing more than Messrs. Cecchi and Seeger's revisionist slant on this litigation's well-documented procedural history, which the Court was obviously aware of at the time of the June 7th Order. While Messrs. Cecchi and Seeger's second-guessing of the Waters &

[62] *Fellenz v. Lombard Inv. Corp.*, 400 F. Supp. 2d 681, 683 (D.N.J. 2005) (citing *Yureko v. Pt. Authority Trans-Hudson Corp.*, 279 F. Supp. 2d 606, 609 (D.N.J. 2003)).
[63] Mot. to Reconsider at 16 (citing *In re Vioxx Prod. Liab. Litig.*, 2014 WL 31645, at *5-6 (E.D. La. Jan. 3, 2014)).
[64] *Leja*, 743 F. Supp. 2d at 456.

Kraus's legal strategy is "new," so to speak, it does not constitute "evidence," nor is it an argument that was unavailable to them when responses to the PLC Majority's Motion to Disburse were due on May 7, 2018.

Meanwhile, the only "evidence" attached to the Motion to Reconsider is the self-serving declaration of Mr. Seeger, which contains a mixture of his recollections and "beliefs." Presumably these recollections and beliefs were available to Mr. Seeger prior to June 7th and, as such, they do not represent newly discovered evidence and should not be considered by the Court.[65]

4. There were "no dispositive facts" or "controlling law" for the Court to "overlook."

Since the Motion to Reconsider does not identify any "intervening change in controlling law" or "evidence that was not available" back on June 7th, Messrs. Cecchi and Seeger are presumably[66] seeking reconsideration on the basis of the third prong of the Third Circuit's standard: "(3) the need to correct a clear error of law or fact or to prevent manifest injustice."[67] As this Court explained just two months ago:

[65] *See Oritani Sav. & Loan Ass'n*, 744 F. Supp. at 1314–15 ("Likewise, Fidelity has pointed to no other 'matter' which it claims the court has overlooked. The only matter to which Fidelity refers is an affidavit by Ray Britt, an employee of Fidelity from October, 1949 to April, 1987. Mr. Britt states that he participated in drafting the standard form of the blanket bond which is the subject of these proceedings. However, **this Court did not and could not have 'overlooked' this affidavit, as it was not submitted in connection with the previous motion**, although Fidelity certainly could have submitted it. This is not newly discovered evidence such as would warrant reconsideration.") (emphasis added).

[66] The Motion to Reconsider does not identify the specific prong under which it seeks relief.

[67] *Johnson*, 50 F. App'x at 560.

> [in the absence of] any intervening change in the relevant law or new evidence that was unavailable at the time this Court entered its decision, [**a motion to reconsider] rests solely on the contention** that this Court's decision **contains an error of fact or law that, if left uncorrected, would result in manifest injustice**.[68]

In practice, this means that "[t]o prevail under the third prong, the movant must show that 'dispositive factual matters or controlling decisions of law **were brought to the court's attention [prior to the original ruling] but not considered**.'"[69] In conducting this third prong analysis, "[t]he word 'overlooked' is the operative term" – as in, did the court overlook or fail to notice "facts and legal arguments that might reasonably have resulted in a different conclusion had they been considered."[70] Here, the Court could not have "overlooked" any such facts or legal arguments in deciding its June 7th Order because Messrs. Cecchi and Seeger did not bother to file a response to the PLC Majority's Motion to Disburse. Even if the Court generously considered Messrs. Cecchi and Seeger's April 20th Letter and May 30 Letter as "responses" – which they most certainly are *not* under Local Rules 7.1 and 7.2 – the analysis would be the same because those two letters are completely

[68] *Mid-Am. Salt, LLC*, 2018 WL 1801178, at *1.
[69] *Mitchell v. Twp. of Willingboro Municipality Gov't*, 913 F. Supp. 2d 62, 77–78 (D.N.J. 2012) (quoting *P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 353 (D.N.J. 2001)) (emphasis added). *See also Damiano v. Sony Music Entm't, Inc.*, 975 F. Supp. 623, 634 (D.N.J. 1996) (quoting *Pelham v. United States*, 661 F. Supp. 1063, 1065 (D.N.J.1987)) ("Rather, motions for reargument succeed only where a "dispositive factual matter or controlling decision of law" was presented to the Court but not considered.").
[70] *Summerfield v. Equifax Info. Servs. LLC*, 264 F.R.D. 133, 145 (D.N.J. 2009) (citing *United States v. DeLaurentis*, 83 F. Supp. 2d 455, 474 n. 2. (D.N.J. 2000)).

lacking in fact and law. Indeed, those letters consist solely of requests by Messrs. Cecchi and Seeger for the Court to abandon CMO No. 3 and to appoint *themselves* "to develop and administer a common benefit application process for all plaintiffs' counsel."[71]

C. Even if the Court Allowed New Arguments, Those Put Forward by Messrs. Cecchi and Seeger Fail.

As discussed above, the Third Circuit's position on the purpose and appropriate scope of a motion to reconsider is not ambiguous:

> The purpose of a motion for reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence. Motions for reargument or reconsideration **may not be used as a means to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided**.[72]

Based on this well-established policy, the various arguments presented by Messrs. Cecchi and Seeger in their Motion to Reconsider are not properly before the Court.[73] Even assuming, *arguendo*, that they were, the new "issues" raised by

[71] Letter from C. Seeger to Judge S. Wigenton, dated Apr. 20, 2018 [Doc. 973]. *See also* Letter from J. Cecchi and C. Seeger to Judge S. Wigenton, dated May 30, 2018 [Doc. 979] (recommending their "appointment to develop and administer a uniform and coherent common benefit application process . . .").

[72] *Johnson*, 50 F. App'x at 559–60 (citations and internal quotations omitted) (emphasis added).

[73] *See Munich Reinsurance Am., Inc. v. Am. Nat. Ins. Co.*, 936 F. Supp. 2d 475, 483 (D.N.J. 2013), *aff'd*, 601 F. App'x 122 (3d Cir. 2015) ("As Local Rule 7.1 case law makes clear, reconsideration may not be used to raise arguments or present evidence that could have been raised prior to the entry of judgment. On this basis alone, ANICO's motion could be denied.") (citing *NL Indus.*, 935 F. Supp. at 516).

Messrs. Cecchi and Seeger do not provide an appropriate basis for reconsidering the June 7th Order.

Although not entirely clear, Messrs. Cecchi and Seeger's asserted bases for vacating the Court's June 7th Order appear to consist of two arguments: (1) that the process and guidelines established by CMO No. 3 were in some way flawed;[74] and/or (2) that the PLC Majority did not follow CMO No. 3, and, as a result, Messrs. Cecchi and Seeger were deprived of "their constitutionally protected property interest without due process of law."[75] In addition to being procedurally improper at this point, *supra*, these arguments also fail on their own merits.

1. The process set out by CMO No. 3 was appropriate and consistent with Third Circuit precedent.

As discussed above, Mr. Seeger's April 20th Letter and Mr. Cecchi's May 30th Letter asked the Court to (surprise) *appoint themselves* "to develop and administer a uniform and coherent common benefit application process to compensate for costs borne and work performed for the common benefit of all plaintiffs and their counsel."[76] Implicit in those requests was the suggestion that CMO No. 3 did *not* provide "a uniform and coherent common benefit application

[74] This appears to be the main thrust of the April 20th Letter and May 30th Letter, which did not address CMO No. 3 and which sought the appointment of Messrs. Cecchi and Seeger to establish new guidelines and procedures for distributing the money in the CBF.
[75] Mot. to Reconsider at 14.
[76] Letter to Judge S. Wigenton from J. Cecchi, dated May 30, 2018 [Doc. 979], at 1.

process."[77] If that was, indeed, Messrs. Cecchi and Seeger's position at the time those letters were drafted, it would run contrary to their prior actions in this litigation. As set out in Section II, *supra*, Messrs. Cecchi and Seeger have *twice* requested and obtained CBF disbursements totaling almost $800,000 by invoking the process laid out by CMO No. 3.

Even if Messrs. Cecchi and Seeger had not already tacitly endorsed the process and guidelines set out by CMO No. 3, they would not have any basis for challenging the methods that order prescribed. "In cases where a common benefit exists, courts have awarded fees based on the lodestar method developed by the Third Circuit in *Lindy I* and *Lindy II*."[78] CMO No. 3 utilizes this lodestar formula, under which the "initial estimate of a reasonable attorneys' fees requires the court to first inquire into the hours spent by the attorneys on their services and then multiply those by a reasonable hourly rate."[79] Messrs. Cecchi and Seeger have certainly not

[77] The only other explanation for this request is that Messrs. Cecchi and Seeger had forgotten about CMO No. 3 after their lengthy period of non-involvement in the litigation.

[78] *Cooperstock v. Pennwalt Corp.*, 820 F. Supp. 921, 926 (E.D. Pa. 1993) (citing *Lindy Bros. Builders v. Am. Radiator & Stanley Sanitary Corp.*, 487 F.2d 161, 165 (3d Cir. 1973) ("*Lindy I*") and *Lindy Bros. Builders v. Am. Radiator & Stanley Sanitary Corp.*, 540 F.2d 102 (3d Cir. 1976) ("*Lindy II*").

[79] *Cooperstock*, 820 F. Supp. at 926 (citing *Lindy II*, 540 F.2d at 113, 117-18; and *Lindy I*, 487 F.2d at 167-168). *See also Citysdale Archives, Ltd. v. New York City Health and Hospital Corp.*, 37 F. Supp. 2d 652, 658 (D.N.J. 1999) ("In evaluating the proper amount of attorney's fees . . . the Third Circuit most recently been guided by [two cases in which] the Supreme Court adopted the 'lodestar' formula, which requires multiplying the number of hours reasonably expended by the reasonable hourly rate.") (citations omitted).

provided any reasons why the use of the well-recognized lodestar method in CMO No. 3 is inappropriate in the instant matter.

2. The PLC Majority complied with CMO No. 3.

In 18-pages of briefing, Messrs. Cecchi and Seeger devote just four paragraphs to identifying ways in which they believe the PLC Majority "overlooked" the requirements of CMO No. 3 in its Motion to Disburse.

a. Messrs. Cecchi and Seeger were given notice.

First, Messrs. Cecchi and Seeger argue the PLC Majority did not follow this clause in CMO No. 3: "Reimbursement for costs and/or fees for services of all plaintiffs' counsel performing functions in accordance with this Order will be set at a time and in a manner established by the Court, after due notice to all counsel." That claim is inaccurate. On April 18, 2018, Waters & Kraus, on behalf of the PLC Majority, filed and properly served on all counsel a Motion Seeking Disbursements from Common Benefit Fund [Doc. 972] and noticed that motion for hearing on the Court's Motion Day of May 21, 2018.[80] Formal responses to that motion were due on May 7, 2018. Messrs. Cecchi and Seeger did not file a formal response nor did they request oral argument on that motion pursuant to Local Rule 78.1. That was,

[80] Notice of Electronic Filing by the Court's clerk dated April 19, 2018 [no document number issued].

of course, their choice. However, they cannot now claim the PLC Majority's disbursement request was not properly noticed.

b. The Court received and considered the PLC Majority's recommendation.

Second, Messrs. Cecchi and Seeger confusingly claim that the Court did not "receive and consider recommendations from Plaintiffs' Liaison Counsel concerning distribution of the Common Benefit Fund."[81] They make this assertion despite the fact that: (1) the June 7th Order was entered pursuant to the recommendation of the PLC Majority; and (2) Messrs. Cecchi and Seeger sent two letters to the Court containing their own recommendations prior to the entry of the June 7th Order. Messrs. Cecchi and Seeger also overlook the fact that the PLC Majority attached far more documentation in support of their recommendations than either of the CBF disbursement requests made by Messrs. Cecchi and Seeger back in 2012. In fact, one of those requests, made by Mr. Cecchi on December 12, 2012, did not contain *any* documentation – or even a recitation of the number of hours and amount of costs he was seeking to recover.[82]

In sum, the procedure utilized by the PLC Majority for obtaining the June 7th Order was completely in-line with both the provisions of CMO No. 3 and prior practice in this litigation.

[81] Mot. to Reconsider at 12.
[82] *See* Letter from J. Cecchi to Mag. Judge Arleo, dated Dec. 12, 2012 [Doc. 143].

c. The Majority PLC gave Messrs. Cecchi and Seeger the "opportunity" to participate in the process prior to filing their Motion to Disburse.

Third, Messrs. Ceechi and Seeger claim that the PLC Majority did not comply with paragraph 9 of CMO No. 3 because "Co-Liaison Counsel were not made aware of whether any 'determinations . . . [were] timely communicated to each firm' and whether 'each firm [was] given an opportunity."[83] It is not entirely clear what conduct or omissions Messrs. Cecchi and Seeger are complaining of in this nonsensical passage. In any event, the PLC Majority certainly invited the input of Messrs. Cecchi and Seeger prior to filing their Motion to Disburse, writing in a letter sent on February 12, 2018:

> Pursuant to an inquiry made by our office, Zimmer's counsel informed us that there was $3,288,170.40 in the CBF as of December 12, 2017. It is our firm belief that it is in everyone's best interests for Plaintiffs' Liaison Counsel to make a joint recommendation to the Court regarding the distribution of these funds. To that end, **we suggest that each of the five firms that constitute Plaintiffs' Liaison Counsel submit its common benefit expenses and hours**. For guidance on what expenses and hours are compensable from the CBF, please consult paragraph 9 of CMO No. 3. Once each firm has submitted its expenses and hours, we can then discuss the appropriate manner in which the CBF funds should be distributed and hopefully make a joint recommendation to the Court.[84]

[83] Mot. to Reconsider at 13.
[84] Mot. to Disburse at Ex. C, Letter from G. Henderson to Plaintiffs' Liaison Counsel, dated Feb. 9, 2018 [Doc. 972-5] (emphasis added).

Although they chose to ignore that letter, Messrs. Cecchi and Seeger cannot now complain that they were not given the *opportunity* to participate in the process that preceded the filing of the PLC Majority's Motion to Disburse. Moreover, since all members of the PLC Majority provided documentation supporting their requested common benefit fees and costs, Messrs. Cecchi and Seeger certainly had the *opportunity* to request a review of those fees and costs prior to the entry of the June 7th Order. Again, for whatever reason, they chose not to do so.

Waters & Kraus must also note again that Messrs. Cecchi and Seeger's past CBF requests contained far less documentation than what was provided to the Court with the at-issue Motion to Disburse. If the scant documentation Messrs. Cecchi and Seeger submitted in 2012 was adequate, then certainly the supporting materials provided by the PLC Majority with their Motion to Disburse must be considered sufficient.

d. Messrs. Cecchi and Seeger's attempt to minimize the efforts of Waters & Kraus and enhance the significance of their own acts does not withstand close scrutiny.

Fourth, Messrs. Cecchi and Seeger claim that:

> The Court's June 7th Order is inconsistent with the requirement that "[p]ayments may be made from the Common Benefit Fund to attorneys who provide services or incur expenses *for the joint common benefit of plaintiffs in addition to their own client(s),*

> including services provided and expenses incurred in preparation and trial of the bellwether cases . . . .[85]

In support of their contention that "Waters & Kraus did not provide any joint and common benefit to the plaintiffs in the MDL," they cite exclusively to Mr. Seeger's declaration, which consists largely of his speculative "beliefs" and self-serving opinions.[86] Missing from Mr. Seeger's lengthy exercise in revisionist history is any explanation for why, if he "believed" he was on the cusp of reaching an "early and productive global resolution" in this litigation back in 2012,[87] he did not simply inform Waters & Kraus and ask for additional time to complete that agreement. After all, a simple phone call or email conveying this message would have sufficed.

Also absent from Mr. Seeger's declaration is any explanation for why, if he so vehemently disagreed with Waters & Kraus's legal strategy between 2012 and 2016, he did not speak up. After all, both he and Mr. Cecchi were members of Plaintiffs' Liaison Counsel throughout that time period, and Waters & Kraus would have been thrilled to have additional firms to help it bear the tremendous costs of litigating against a multi-billion dollar company.

[85] Mot. to Reconsider at 13 (emphasis in original).
[86] *See, e.g.*, Mot. to Reconsider at Decl. of Christopher A. Seeger [Doc. 986-2] at ¶ 4 ("It was my **belief** that the case was on its way to early and productive global resolution.") (emphasis added); and ¶ 5 ("Instead of working cooperatively with existing MDL leadership to finalize a global and early resolution, Waters & Kraus implemented a different agenda which, **I believe**, was solely focused on developing its own inventory of cases . . . .") (emphasis added).
[87] Mot. to Reconsider at 4.

The reality is Messrs. Cecchi and Seeger were not "active participants in this litigation,"[88] as they now claim. In fact, for several years they did *nothing*. Indeed, Mr. Seeger has publicly *admitted* as much. In the process of fighting other lawyers for common benefit fees in a different MDL,[89] Mr. Seeger publicly stated in early 2017 that he could say "100 percent confidently that [he had] **worked exclusively** on [*that litigation*] for two years."[90] Now, suddenly, he was an "active participant" in *this litigation* during those same years.

Mr. Seeger's claim to be an "active participant" throughout the litigation is not just contradicted by his own public statement, but also by the MDL docket. Specifically, of the almost 1,000 docket entries in this litigation, Messrs. Cecchi and Seeger's firms contributed a paltry *four* filings prior to 2016: a letter rescheduling a teleconference with the Court;[91] *two requests for the disbursement of money from the CBF*;[92] and a 2015 letter from Mr. Cecchi complaining that Zimmer was not actively mediating cases and announcing that, as a result, "Plaintiffs no longer agree to delay discovery . . . ."[93]

[88] *Id*.
[89] This appears to be Mr. Seeger's *modus operandi*. *See* **Exhibit B**, M. Fainura-Wada, *Lawyers, Others Vie for Pieces of NFL Concussion Settlement*, espn.com, Mar. 29, 2017.
[90] *Id*.
[91] Letter from L. Taylor (of Carella, Byrne, Cecchi, Olstein, Brody & Agnello) to Mag. Judge M. Arleo, dated Dec. 17, 2010 [Doc. 26].
[92] Letter from J. Cecchi to Mag. Judge M. Arleo, dated Mar. 2, 2012 [Doc. 111]; and Letter from J. Cecchi to Mag. Judge M. Arleo, dated Dec. 12, 2012 [Doc. 143].
[93] Letter from J. Cecchi to Mag. Judge S. Mannion, dated Aug. 5, 2015 [Doc. 741], at 2.

The latter correspondence illustrates just how uninvolved Messrs. Cecchi and Seeger were in the litigation. Far from agreeing to stay discovery indefinitely, Waters & Kraus conducted a massive amount of "common issue" discovery over the previous three years – including the taking of 30-plus depositions of Zimmer employees, physician consultants, and sales representatives;[94] and the review of over 30,000 Durom Cup-related documents produced by Zimmer.[95] As the Court is well aware, a considerable amount of motion practice preceded the production of these witnesses and documents. By the time Mr. Cecchi threatened to "resume" discovery against Zimmer, Waters & Kraus had already put together an entire liability case for the Durom Cup, located and developed general issue experts for the litigation, deposed Zimmer's general issue experts, and tried bellwether cases in three different jurisdictions[96] – one of which produced a liability verdict that was recently upheld by the California Court of Appeals.[97] Waters & Kraus has received and accommodated many requests by other plaintiffs' counsel for the "trial kit" it put together; in fact, they continue to receive those requests to this day.[98] Even if one

[94] Mot. to Disburse at Ex. A, "Common Benefit Depositions Lead [*sic*] by Plaintiffs' Liaison Counsel" [Doc. 972-3].
[95] *See* Decl. of George G. Tankard, III, dated Jan. 26, 2015 [Doc. 972-4].
[96] *See* **Exhibit C**, Pls.' Mot. for Leave to Amend Their Compl. to Include a Prayer for Relief Seeking Punitive Damages Against Def. Zimmer, Inc. and Incorporated Mem. in Supp. Thereof in the *Santas* Matter, St. Clair County, Ill.
[97] *See* **Exhibit D**, Opinion in *Kline v. Zimmer, Inc.*, B269317, Court of App. of the State of Cal., Second Appellate Dist., dated Apr. 27, 2018.
[98] **Exhibit E**, Decl. of Gibbs Henderson, dated June 28, 2018.

accepted the counterintuitive premise that aggressively litigating this case did not benefit all MDL plaintiffs, that still would not change the fact that "services provided and expenses incurred **in preparation and trial of the bellwether cases**" – a description that covers much of what was submitted by Waters & Kraus – are *explicitly* compensable under CMO No. 3.[99]

It is also important to remember that Messrs. Cecchi and Seeger's lone contribution to this lawsuit, negotiating the so-called global settlement program ("Settlement Program"), was not nearly as heroic as they like to imagine. As the Court may recall, there were separate negotiations ongoing between Waters & Kraus and Zimmer in late 2015. Indeed, the Court was an active participant in those negotiations, hosting settlement conferences on November 12, 2015, and December 7, 2015.[100] Pursuant to the Court's instructions, those negotiations continued into January 2016 – indeed, right up to the point Waters & Kraus was informed *by Zimmer* that it had reached a "global deal" with Messrs. Cecchi and Seeger.

Importantly, Messrs. Cecchi and Seeger did not negotiate or authorize the Settlement Program in any formal capacity as Plaintiffs' Liaison Counsel and did not have the express consent of other Plaintiffs' counsel to negotiate on their behalf.

[99] CMO No. 3 at ¶ 10 (emphasis added).
[100] *See* Am. Scheduling Order, dated June 25, 2015, at 1 (setting settlement conferences for four bellwether cases for Nov. 12); and Minute Entry, dated Dec. 8, 2015 (reflecting settlement conference was held before Magistrate Judge Mannion on Dec. 7, 2015).

By conducting their negotiations in secret, without advising any of the other attorneys on Plaintiffs' Liaison Counsel, Messrs. Cecchi and Seeger not only directly undercut the negotiating efforts of Waters & Kraus; they damaged *all MDL plaintiffs* by letting Zimmer know that Plaintiffs' Liaison Counsel were not negotiating as a united front. Not surprisingly, Zimmer exploited this rift within Plaintiffs' Liaison Counsel, and the resulting deal consisted of terms that were opposed by the majority of MDL plaintiffs.[101] To wit, 32 Plaintiffs' firms, representing *more than half of the total number of Plaintiffs* in this MDL, formally objected to the Settlement Program negotiated by Messrs. Cecchi and Seeger.[102] Undeterred in the face of this overwhelming opposition by the parties they were supposedly working on behalf of, Messrs. Cecchi and Seeger joined forces with Zimmer to make participation in the Settlement Program mandatory, and to stay the litigation indefinitely while that process played out. At that point, the remaining MDL Plaintiffs had little choice but to settle.

All that said, to the extent Messrs. Cecchi and Seeger have the required documentation, they may be entitled to some modest amount of reimbursement under CMO No. 3's fee formula for the time he spent "assist[ing] scores of plaintiffs and plaintiff's attorneys in enrolling in the settlement program . . . respond[ing] to

[101] Letter from G. Henderson to Judge S. Wigenton, dated Mar. 31, 2016 [Doc 891].
[102] *Id.*

countless questions regarding the settlement procedures and in some instances, help[ing] resolve disputes between enrolled plaintiffs and Defendant's counsel."[103] For whatever reason, however, they have chosen not to submit those alleged hours, despite being told by Zimmer on June 14th that an additional $1,688,001.58 will remain in the CBF even *after* the disbursements ordered by the June 7th Order are paid.[104]

D. An Order Staying the June 7th Order is Neither Warranted nor Necessary.

As discussed above, Messrs. Cecchi and Seeger have not carried their high burden of showing why the June 7th Order should be reconsidered/vacated pursuant to their Motion to Reconsider. Regardless, a stay of the June 7th Order is unnecessary. On June 25, 2018, Zimmer informed the Court and parties that it had not yet disbursed any monies pursuant to the June 7th Order, and that, "[i]n light of the Motion to Stay, we intend to maintain the status quo and not disburse the Common Benefit Funds until we receive further direction from the Court."[105] Given these circumstances, Messrs. Cecchi and Seeger cannot show they will be "irreparably harmed" without an order staying the June 7th Order while the Motion to Reconsider is decided.

[103] Mot. to Reconsider at 6.
[104] **Exhibit F**, Letter from A. Campbell to Pls.' Liaison Counsel, dated June 14, 2018.
[105] Letter from A. Campbell to Judge S. Wigenton, dated June 25, 2018 [Doc. 988].

IV. CONCLUSION

A motion to reconsider is not an appeal.[106] It is an extremely limited procedural vehicle intended to allow a litigant to either (a) present previously-unavailable evidence or law or (b) highlight previously-presented evidence or law that it believes the court overlooked in rendering its original decision. Here, Messrs. Cecchi and Seeger have done neither of these things.

Based on the foregoing reasons, Waters & Kraus requests that the Court enter an order denying the Motion of Plaintiffs' Co-Liaison Counsel for Reconsideration and Stay of Court Order Allocating and Disbursing Fees and Expenses from Common Benefit Fund.

DATED: June 29, 2018

Respectfully submitted,

WATERS & KRAUS, LLP

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[106] *Wyndham Hotels and Resorts, LLC v. Rhonda & Sons, Inc.*, Civil Action No. 2:10-cv-2868, 2011 WL 1560666, at *1 (D.N.J. Apr. 25, 2011). *See also Mondelli v. Delzotti*, Civ. No. 10-3393-WJM, 2011 WL 2517254, at *1 (D.N.J. June 23, 2011) ("A motion for reconsideration should not be treated as an appeal of a prior decision.").

EXHIBIT A

February 9, 2018

Via E-Mail

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Re: *In Re: Zimmer Durom Hip Cup Products Liability Litigation*

Dear Fellow Plaintiffs' Liaison Counsel:

I am writing regarding the disbursement and distribution of Zimmer MDL settlement money in the court-established Common Benefit Fund ("CBF"). As you know, the CBF was established by Case Management Order No. 3 [Doc. 33] ("CMO No. 3") on January 21, 2011, "to provide for the fair and equitable sharing among plaintiffs of the **costs of services performed** and **expenses incurred** by Plaintiffs' Liaison Counsel and other attorneys acting for and providing a common benefit of all plaintiffs in this complex litigation . . . ."[1] Consistent with that stated purpose, CMO No. 3 provides that the distribution of funds paid into the CBF should be determined by documented expenses and documented time spent on the litigation.[2]

CMO No. 3 only permits CBF disbursements pursuant to a Court order.[3] The only attorneys eligible for payments from the CBF are "Plaintiffs' Liaison

[1] CMO No. 3 [Dkt. 33] at 1 (emphasis added).
[2] *See* CMO No. 3 at 3-9.
[3] *See* CMO No. 3 at ¶ 13.

Counsel, and other attorneys performing responsibilities approved by Plaintiffs' Liaison Counsel in MDL-2158."[4] The manner in which those distributions are made (*i.e.*, who gets what) is determined pursuant to the recommendation of Plaintiffs' Liaison Counsel.[5] Specifically, CMO No. 3 states: "The Court shall receive and consider recommendations from Plaintiffs' Liaison Counsel concerning distribution of the Common Benefit Fund."[6]

Pursuant to an inquiry made by our office, Zimmer's counsel informed us that there was $3,288,170.40 in the CBF as of December 12, 2017. It is our firm belief that it is in everyone's best interests for Plaintiffs' Liaison Counsel to make a joint recommendation to the Court regarding the distribution of these funds. To that end, we suggest that each of the five firms that constitute Plaintiffs' Liaison Counsel submit its common benefit expenses and hours. For guidance on what expenses and hours are compensable from the CBF, please consult paragraph 9 of CMO No. 3. Once each firm has submitted its expenses and hours, we can then discuss the appropriate manner in which the CBF funds should be distributed.

If you have any questions or suggestions, please do not hesitate to call either Peter or me. Thank you for your attention to this matter.

Regards,

Gibbs C. Henderson

/gch

cc: Peter A. Kraus – Via E-mail
Erin M. Wood – Via E-mail

[4] CMO No. 3 at ¶ 10.
[5] *See* CMO No. 3 at ¶ 9.
[6] CMO No. 3 at ¶ 9.

In Re: Zimmer Durom Hip Cup Products Liability Litigation

Cindy Lopez to: dbraslow, wfleishman, cseeger, JCecchi 02/09/2018 11:58 AM
Cc: Gibbs Henderson, Erin Wood, Peter Kraus

Dear Counsel,

Please see attached correspondence forwarded on behalf of attorney Gibbs C. Henderson in regard to the above-referenced matter.

Thank you.

Cindy Lopez | Paralegal
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www.waterskraus.com

2.9.18 Ltr Liaison County for Plfs re cbs.pdf

EXHIBIT B

Lawyers, others vie for pieces of NFL concussion settlement

Mark Fainaru-WadaESPN Staff Writer Mar 29, 2017

The $1 billion NFL concussion settlement -- nearly six years in the making yet still to deliver a penny to former players and their families for brain injuries stemming from football -- is revealing the underbelly of the legal system to former players and their families.

As they finally close in on being compensated for brain injuries stemming from football, those former players and their families have been facing an onslaught of issues -- from attorney retainer fees that could reach as high as 40 percent to lawyers poaching clients from competing attorneys; from a slew of opportunists seeking a piece of the pie to lawyers effectively threatening to sue former players to ensure they get their fees.

"This case has done nothing but show lawyers at their worst," said Jason Luckasevic, a Pittsburgh attorney who filed the first concussion-related case against the NFL in 2011 and represents about 500 former players.

Said another attorney, who spoke to Outside the Lines only on the condition of anonymity: "It's a feeding frenzy right now. It's dirty out there, and I don't like it. I have to shower twice a day."

In 2011, Luckasevic and two other lawyers filed the first of what would become hundreds of lawsuits brought by thousands of former players and their families, alleging that the NFL had concealed the link between football and brain damage. A settlement was announced in 2013; however, initial concerns by the judge overseeing the settlement about its adequacy and a series of objections kept the case from being finalized until just a few months ago.

Recent interviews by Outside the Lines with lawyers and wives of former players, and a review of dozens of court records, texts and emails reveal behind-the-scenes clashes that have ratcheted up concerns from families that the lawyers will be the ones mainly cashing in on player payouts:

- Two dozen wives of former players recently sent a plea to the judge overseeing the case, asking her to address concerns that legal fees will be cutting heavily into money that was supposed to go their families. They cited lawyers charging "exorbitant" retainer fees to players and their families despite the same lawyers being eligible to collect from a $112.5 million fund set aside to pay attorneys who worked on the case. Attorneys also stand to collect an additional 5 percent surcharge for future work related to the case.

- Poaching of players and their families by competing attorneys has become so pervasive, with attorneys promising lower contingency fees and bigger payouts, that lawyer-on-lawyer battles have broken out, putting players in the middle of the disputes. A slew of motions have been filed by lawyers seeking to place liens on the players who left them so they can collect a percentage of their former clients' awards. Players and their families worry they will be left with little after they pay off the current and former lawyers.

- A virtual cottage industry of opportunist lawyers, doctors, predatory lenders and other professionals has cropped up. The lead counsel in the case has sought injunctions against at least two companies, asking the judge to punish them for using "false and misleading" tactics to try to gain business.

- Christopher Seeger, the founding partner of Seeger Weiss in New York and the architect of the billion-dollar settlement between the players and the NFL, has extensive experience leading massive class-action lawsuits. He told Outside the Lines the amount of poaching of clients is unprecedented.

- "I've seen it in the past, but not even close" to this, Seeger said. "I think it's mostly a function of the fact that it's former NFL players. Lawyers really gravitate toward them and like representing them, like being around them and saying they represent them. There's just something about this NFL case that attracts it."

- At the core of the dispute is the $112.5 million set aside for lawyers who played roles in negotiating the settlement. That money is being paid by the NFL. Apart from that, plaintiffs' attorneys have individual retainer fees ranging anywhere from 15 to 40 percent for work done on behalf of their clients, according to some plaintiffs and court filings; that cut is expected to come out of whatever monies the players or their families are awarded.

- In the case of about two dozen lawyers or law firms, attorneys stand to collect both from the $112.5 million fund and from their individual clients. Seeger, who says he has only about two dozen clients, has said he will not collect on individual retainers. In 2013, Outside the Lines reported that he had tried to do so from at least one client. Seeger said it had been a mistake. Within hours of the story being reported, the judge appointed a special master to evaluate "financial aspects" of the settlement.

- The $112.5 million lawyer fund and the 5 percent surcharge still require court approval.

- Last week, Liz Nicholson Sullivan says she coordinated a phone call with about 40 wives of former NFL players who are eligible to receive payouts from the settlement. Sullivan's husband, Gerry, was an offensive lineman with the Browns from 1974 to '81. By 2005, doctors had determined Sullivan had a "total and permanent" disability related to chronic brain injury from playing football.

- As with many of the former players, Sullivan, now unable to handle his affairs, turned the management of his legal case over to his wife. When Liz and the other women spoke on the phone, they all shared similar stories -- of being solicited by other lawyers and predatory lenders, of feeling like they were being overcharged, of concerns that attorneys would be getting rich off their cases while they continued to scramble to pay for care.

- They were all well aware of the circumstances of Kevin Turner, a former running back who was a class representative in the case and died last year from ALS. Turner's estate is battling with Steven Marks of the firm Podhurst Orseck. As one of the lead attorneys in the case, Marks stands to collect from the $112.5 million the NFL has committed to plaintiffs' lawyers; but according to court filings, Marks' separate retainer agreement with Turner also would entitle him to 40 percent of the $5 million the estate is in line to receive. Marks stated in filings his firm only intended to take 25 percent. The New York Daily News first reported the dispute.

- In a letter sent to Judge Anita Brody, dated March 20 and signed by Liz Nicholson Sullivan and dozens of other women, the wives referred to the Turner case and said they "felt compelled as a group of plaintiffs' wives to ensure that the Court is aware of the existence of thousands of similar fee disputes among Class plaintiffs and Class Counsel involved in this settlement."

- The letter added, "For many of us, our husband's medical care is dependent upon these monetary awards and they cannot survive another delay. ... As wives and caregivers, we have struggled to keep the family unit intact on a shoestring budget, while managing the burden of their costly care. Our husbands need every penny they are entitled to receive out of this settlement. ... Many of our men are now either gone or completely 'lost' to us. We have chosen to stand by them because we realize they were victims."

- Tia McNeill was among those who signed the letter. McNeill's husband, Fred, played 12 seasons with the Minnesota Vikings and died in 2015 after suffering for years from dementia. The McNeills are represented by Luckasevic, and while Tia says she has great respect for the efforts and time Luckasevic has put into the case, she's struggling with the idea that Luckasevic will get a cut of the $112.5 million, while still taking 25 percent of their payout.

- "I feel like we were represented and [taken] care of, and now there is contention with this person repping you," McNeill says. "This was his case. He filed this for his firm, so part of me feels bad for him -- but it doesn't feel [25] percent bad for him. I'm just being honest."

- Luckasevic, who says he first started exploring a possible suit against the NFL back in 2006, said he understands the frustration but insists he stands to get very little from the $112.5 million lawyer fund. A filing with the court suggests he could end up with about $700,000, which he said is a pittance for the number of hours he has put into the case.

- "I'll waive the common benefit money so I can get 25 percent," said Luckasevic, whose fury is mostly directed at Seeger and the leaders of the case. "What the hell, I have $1.7 million of my firm's costs into this case, and I'm gonna get $700,000?"

- Charles Zimmerman says his firm, Zimmerman Reed LLP, represents about 350 to 400 players. Zimmerman stands to benefit significantly from the $112.5 million fund, as well as through individual retainer fees, but he says that's not unusual or problematic in class-action cases.

- "That's not double dipping," Zimmerman told Outside the Lines. "It happens in every case."

- He said that in a different case he worked on, "the common benefit fund applied to people who did common benefit work, and the contingency was for individual contracts with clients. You can't get paid twice for the same work, you can get paid for each. They're very separate. You're getting paid to do work on an individual's medical case, submitting it for compensation and advising and directing the individual injury case through different channels it has to go through to get it paid. That happens in law, in every fund that you've ever seen developed in a mass tort case."

- Luckasevic and other lawyers have complained that Seeger is effectively the puppet master over the $112.5 million. Assuming the judge approves the plan, Seeger will oversee the distribution of

the money. Luckasevic believes he should be compensated for the thousands of hours he spent researching and building toward filing in 2011.

- "If he really believes that to be true," said Seeger, "he needs to file the papers and make that argument to the judge and ask her to award him whatever he thinks is fair." Seeger also suggested that Luckasevic has overstated his value to the case.

- Luckasevic, several other lawyers and many of the wives interviewed are particularly angered by an additional 5 percent "hold back" that Seeger has requested to cover future legal work that could be done over the 65 years the deal is in play.

- Court records show the 5 percent -- which could amount to as much as $50 million -- would be drawn from the individual lawyers' retainer fees rather than from the players' awards; or, if a player is working without an attorney, it would come out of their share.

- "Why would they need an extra 5 percent when they spent all that time negotiating for the $112 million?" said Catherina Watters, a lawyer who represents several players in disability claims and is working pro bono in the concussion case for Steve Smith, a former NFL running back suffering from ALS. Watters, whose husband is former NFL running back Ricky Watters, helped draft the letter with Nicholson, and she says she told the wives their focus now should be less on any ire they feel toward the league and more on "what the lawyers are doing to our players. Why are they continuing to take?"

- Several lawyers, including Luckasevic, filed objections to the 5 percent hold back, asking the judge either to dump it altogether or reduce it to as low as 1 percent.

- "You want my $700,000 [from the common fund], Chris, have it, choke on it," says Luckasevic. "Just don't take 5 percent of my hard work. You didn't put this case together, you didn't sign up guys that were truly injured. You didn't rep them for 5½ years. I did that work; don't go reaching into my pants."

- Said Seeger: "We believe the set-aside is appropriate, as substantial future efforts will be necessary for the common benefit of the class over the 65-year life of the settlement."

Seeger has engendered considerable enmity from fellow attorneys throughout the case, and his request for his share of the $112.5 million probably has done nothing to ease those feelings. He calculated his firm put in more than 21,000 hours over the past four years, amassing $18,124,869.10 in fees alone. Seeger himself billed for 6,955 hours -- or the equivalent of 290 full days -- at a rate of $985 an hour, for approximately $6,851,561.50 in fees. The petition for fees asks the judge to assign a multiplier of 2.6 to the fees and expenses, which, if applied, would garner Seeger's firm more than $51 million.

In addition to playing a lead role in the lawsuit against the NFL, Seeger and his firm, according to the firm's website, have had ongoing leadership roles over the past several years in dozens of class-action cases, including several involving pharmaceutical products.

Asked about his fees and the amount of money he stands to gain from the NFL case, Seeger said, "I can tell you 100 percent confidently that I worked exclusively on the NFL for two years. I lived this case, and I'm still kind of living it."

EXHIBIT C

IN THE CIRCUIT COURT
TWENTIETH JUDICIAL CIRCUIT
ST. CLAIR COUNTY, ILLINOIS

MICHAEL SANTAS, *et al.*,	)	Case No. 11-L-136
	)	
Plaintiffs,	)	
vs.	)	
	)	
ZIMMER, INC., a corporation; *et al.*,	)	
	)	
Defendants	)	

PLAINTIFFS' MOTION FOR LEAVE TO AMEND THEIR COMPLAINT TO INCLUDE A PRAYER FOR RELIEF SEEKING PUNITIVE DAMAGES AGAINST DEFENDANT ZIMMER, INC. AND INCORPORATED MEMORANDUM IN SUPPORT THEREOF

Now come Plaintiffs, by and through their attorneys, and file this Motion for Leave to Amend Their Complaint to Include a Prayer for Relief Seeking Punitive Damages Against Defendant Zimmer, Inc. and Incorporated Memorandum in Support Thereof. Plaintiffs would show the Court as follows:

I. PRELIMINARY STATEMENT

Illinois law permits plaintiffs to add a claim for punitive damages when there is evidence that a defendant has acted with "wanton disregard" for their safety. In the instant matter, there is extensive evidence of such conduct by Defendant Zimmer, Inc. ("Zimmer").

Zimmer released the hip implant product that eventually failed in Plaintiffs without conducting *any* clinical or animal testing, despite being told it needed to do so by several different sources – including the designers of the device. It proceeded to release that product on to the market even after the FDA directly contradicted Zimmer's assumptions about how the device would achieve long-term fixation in the human body. At the time of the product's release, Zimmer undertook no efforts to ensure that the surgeons who would be implanting the device were aware that this hip implant required a unique surgical technique. Its marketing of

the device relied, in part, on creating false impressions in the minds of surgeons and its own sales representatives about the product's history and attributes. Following the product's release, Zimmer ignored the concerns and recommendations of engineers it had previously employed and the very surgeons it hand-picked to test out the product. Only after one of those surgeons went public with his high failure rate did Zimmer undertake any sort of effort to determine the cause of the problems surgeons and patients were experiencing with this device. Even then, it made no real attempt to ascertain the reasons for the device's problems, much less actually fix them, choosing instead to conduct an outcome-driven investigation that blamed surgeons for the scores of failures occurring across the country.

"The purposes of punitive damages are to punish a specific defendant and to deter similar conduct in the future."[1] Here, Zimmer's conduct in connection with this product demonstrated, time and again, an utter disregard for the health of patients, including the Plaintiffs in this lawsuit. The risks it imposed on Plaintiffs and others were significant and known to Zimmer. The company had numerous opportunities to prevent Plaintiffs' injuries from occurring, and, in fact, was repeatedly warned that product failures on a large scale would occur if it failed to act. As set out below, Zimmer repeatedly ignored these warnings and recommendations. In doing so, it exhibited precisely the kind of corporate behavior that warrants punishment and needs to be deterred.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Factual History

1. The History of the EU Durom Cup

According to an internal Zimmer memorandum, the original idea for the device that would eventually become known as the "Durom Cup" in both Europe and the United States

[1] *In re Estate of Feinberg*, 6 N.E.3d 310, 330 (Ill. App. Ct. 2014).

came from British surgeon Paul Roberts ("Dr. Roberts") and Greek surgeon Peter Grigoris ("Dr. Grigoris"), who approached Sulzer/Centerpulse, a Swiss company Zimmer eventually acquired, about a potential product in 1997.[2] The proposed implant, which ultimately became known as the Durom Hip Resurfacing System, was comprised of two parts: an acetabular component (hereinafter, the "EU Durom Cup") and a femoral stem. According to Dr. Roberts, the EU Durom Cup was designed to achieve long-term fixation in the patient's hip socket "by a bony ingrowth into the pure titanium vacuum plasma sprayed coating which was applied to the chrome cobalt substrate of the cup itself."[3] The project had progressed to the point that the Durom Hip Resurfacing System was cleared by the European Union for clinical evaluation in May 2001.[4]

a. The EU Durom Cup utilized a plasma spray coating that was subjected to both animal and clinical testing.

By the late 1990s, plasma spray coatings had been used on other acetabular components.[5] Nevertheless, prior to beginning the clinical trial on the EU Durom Cup, Sulzer/Centerpulse conducted an animal study to confirm, in the words of Dr. Roberts, whether the EU Durom Cup's "plasma coating was going to perform as we would expect other plasma coatings had in the past."[6] When asked why, in light of the fact that other plasma sprays had already proven successful, Sulzer/Centerpulse felt an animal study was necessary, Dr. Roberts explained: "It is essentially because this was a new product . . . and therefore we as clinicians, with a duty to our

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[2] *See* Exhibit A, Durom_AAE 00020992-998 (Common Issue Witness ("CIW") Ex. 3), Zimmer Mem. re: "Durom Summary Design and Development Time Plan" at 2. *See generally* Exhibit B, Deposition Transcript of Dr. Paul Roberts, dated Apr. 25, 2014 ("Dr. Roberts Dep. Tr.") at 22-26.

[3] Ex. B, Dr. Roberts Dep. Tr. at 34:20-22.

[4] Ex. A, Durom_AAE 00020992-998 (CIW Ex. 3), Zimmer Mem. re: "Durom Summary Design and Development Time Plan" at 3-4.

[5] Ex. B, Dr. Roberts Dep. Tr. at 34:19-22.

[6] *Id.* at 43:7-15 ("[O]bviously the next concern was, was this plasma coating going to perform as we would expect other plasma coatings had in the past. That is difficult to show in vivo early on, so . . . Sulzer arranged to carry out laboratory testing using an animal model which has been used before by Sulzer in one of the hospital laboratories in Germany.").

patients and Sulzer as also a responsible implant company, wanted to obtain as much information as possible before inserting the product into humans."[7]

In addition to the animal study on the new coating, Sulzer/Centerpulse conducted a clinical trial on the EU Durom Cup prior to its release.[8] Between May 2001 and September 2002, a total of 108 patients participated in the clinical evaluation of the new hip resurfacing system.[9] On November 14, 2002, "the results for the first 30 patients were documented in a clinical evaluation report . . . ."[10]

Finally, Sulzer/Centerpulse also initiated a RSA study prior to the Durom Hip Resurfacing System's release in Europe. Dr. Roberts explained the perceived need for and purpose of this study as follows:

> In addition, because of our concerns and indeed Sulzer's concerns about this technology, we wanted to carry out an additional clinical study that would give us early data about the efficacy of the secondary ingrowth – the biological ingrowth into the socket. The method that was most appropriate for that was RSA which . . . is a computerized radiological technique in which x-rays are taken at 90° to each other simultaneously and then are computer-analysed.[11]

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[7] *Id.* at 44:18-45:8 ("Q. Given this track record why did you and the designers of the European Durom cup that you worked with there at Sulzer feel as though this mini pig study was necessary? A. It is essentially because this was a new product . . . and therefore we as clinicians, with a duty to our patients and Sulzer as also a responsible implant company, wanted to obtain as much information as possible before inserting the product into humans.").

[8] *Id.* at 47:10-13 ("So we had to carry out an ethically approved clinical study in the hospitals where the patients were being operated on because we were using a non-CE marked product.").

[9] Ex. A, Durom_AAE 00020992-998 (CIW Ex. 3), Zimmer Mem. re: "Durom Summary Design and Development Time Plan" at 4.

[10] *Id.*

[11] Ex. B, Dr. Roberts Dep. Tr. at 48:4-15 ("In addition, because of our concerns and indeed Sulzer's concerns about this technology, we wanted to carry out an additional clinical study that would give us early data about the efficacy of the secondary ingrowth – the biological ingrowth into the socket. The method that was most appropriate for that was RSA which . . . is a computerized radiological technique in which x-rays are taken at 90° to each other simultaneously and then are computer-analysed.").

Following this extensive testing, the EU Durom Cup was approved for market introduction as part of the Durom Hip Resurfacing System in Europe on February 14, 2003.[12]

b. Sulzer/Centerpulse implemented a strict surgeon-to-surgeon training program at the time of the EU Durom Cup's launch.

At the time of its release in Europe, Sulzer/Centerpulse initially had the surgeons who were invited or allowed to use the Durom Hip Resurfacing System train in-person with either Dr. Roberts or Dr. Grigoris before implanting the device on their own.[13] Those surgeons, in turn, trained other surgeons in a surgeon-to-surgeon manner in their own countries.[14] As Dr. Roberts explained, the importance and purpose of this surgeon-to-surgeon training was to convey to surgeons that implanting the EU Durom Cup required a unique surgical technique, one that was different from inserting other acetabular components.[15]

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[12] Ex. A, Durom_AAE 00020992-998 (CIW Ex. 3), Zimmer Mem. re: "Durom Summary Design and Development Time Plan" at 4.

[13] Ex. B, Dr. Roberts Dep. Tr. at 59:19-60:6 ("So from the very start the small number of surgeons who were invited or allowed to use the product either underwent surgeries with myself or Peter Grigoris in Glasgow and Newport. We trained surgeons from Montreal in Canada. We trained surgeons from Germany. Once they were trained and experienced in the technique, they then began training in their own countries, so it was very much a surgeon-to-surgeon teaching programme at the time with relatively small numbers of surgeons being trained. This was in the early 2000s.").

[14] *Id.* at 59:19-60:6 ("So from the very start the small number of surgeons who were invited or allowed to use the product either underwent surgeries with myself or Peter Grigoris in Glasgow and Newport. We trained surgeons from Montreal in Canada. We trained surgeons from Germany. Once they were trained and experienced in the technique, they then began training in their own countries, so it was very much a surgeon-to-surgeon teaching programme at the time with relatively small numbers of surgeons being trained. This was in the early 2000s.").

[15] *Id.* at 61:11-62:17 ("Q. Having conducted this training for all of these surgeons that you just discussed, what was the benefit of this training for those surgeons? A. . . . So the biggest difference really was the insertion of the acetabular component. . . . They thought they were coming really to learn about how to prepare the femoral head because that is the unique bit to hip resurfacing. But all of them pretty quickly realised without prompting that actually the most difficult bit was the exposure and that had to be taught in a specific manner if you were not familiar with it. And also that, actually far more difficult than the preparation of the femoral head . . . was getting the acetabular component in and in the right orientation.").

2. The Development of the US Durom Cup

By the mid-2000s, the absence of a large-head metal-on-metal total hip replacement system constituted a void in Zimmer's American product portfolio as compared to some of its competitors, many of whom already marketed such devices.[16] In fact, sales representatives were reporting to Zimmer that they felt as though they were at a "competitive disadvantage" without such a product to market to surgeons.[17]

According to an April 2005 monthly report, the original "concept" of introducing a total hip replacement system utilizing the Durom acetabular component to fill this void was initiated in March 2004.[18] That internal memorandum states that Zimmer initially planned to obtain FDA clearance for the EU Durom Cup for sale as part of this total hip replacement system.[19] It appears from that same memorandum, however, that after taber abrasion testing revealed that the "debris generation" for the EU Durom Cup was four times that of the FDA guideline of "65 mg/100 cycles," the decision was made to develop a new plasma spray coating for the Durom acetabular component designed for release in the United States (hereinafter, the "US Durom Cup").[20] Another consideration in Zimmer's decision to develop a new coating for the US

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[16] *See* **Exhibit C**, Deposition Transcript of Brian Jones, dated August 22, 2013 ("B. Jones Dep. Tr.") at 32 (explaining that the Durom Cup was intended to "give [Zimmer] an entrance into the market of large head metal, something that our competitors were already selling and marketing in the States.").

[17] **Exhibit D**, Deposition Transcript of Donald Secor, dated Feb. 6, 2014 ("Secor Dep. Tr.") at 31:11-32:6 ("Q. As a sales representative attempting to facilitate the sale of Zimmer hip devices, did you feel like, prior to the Durom Cup's introduction, you were at a competitive disadvantage without a large-head metal-on-metal system to market? A. Yes. Q. Do you recall ever communicating to anyone at Zimmer that sentiment? A. Uh-huh. Yes. . . . Q. And the reason you felt like you were at a competitive disadvantage was that all the other manufacturers already had large-head metal-on-metal hip implant systems already out? A. Correct.").

[18] *See* **Exhibit E**, End of Month Report April 2005 at Durom_AAA 000003236-37.

[19] *See id.* at Durom_AAA 000003236-37 (noting that "[o]riginal project [was] to use existing coating, not create a new coating.").

[20] *See id.* at Durom_AAA 000003236-37.

Durom Cup was the company's desire to be able to market the coating as "porous," which required that the coating satisfy the numerical requirements found in 21 CFR 888.3358.[21]

a. The US Durom Cup was rushed through the developmental process.

Pascal Weiderkehr ("Weiderkehr"), a Zimmer employee in Winterthur, Switzerland, was selected to serve as the project manager for the development of a new coating for the US Durom Cup.[22] In a July 7, 2005 email, he explained that "this project has a **high priority** and a **tight schedule** . . . ."[23] This sense of urgency within Zimmer to get this product to market quickly was felt on both sides of the Atlantic. In a November 8, 2005 email, sales executive Mark Price ("Price") stressed that "the success of our Hip business in 2006 rests largely in the delivery of new products . . . [and n]eedless to say, product delays will have significant impact to our 2006 sales growth."[24] In that same email Price went on to identify the US Durom Cup as one of the key components of Zimmer's "2006 sales plan."[25]

Others were less enthusiastic about the plan to introduce a Durom-based total hip replacement system in the United States. According to Dr. Roberts, the designing surgeon, his initial reaction was that "the cup that we had designed would not be suitable for the use in America because of differences in surgical technique, quite widespread differences, between

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[21] *See* **Exhibit F**, Deposition Transcript of David Weidenbenner, dated May 28, 2014 ("Weidenbenner Dep. Tr.") at 39:13-15 ("Our intent was to market the device the same way we marketed our other devices with the same coating, and that was porous, yes."); and **Exhibit G**, Deposition Transcript of Laura Williams, dated Oct. 15, 2013 ("L. Williams Dep. Tr.") at 104:8-15 ("Q. Okay. And what this particular portion of the code, Section 888.3358 entitled hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, what this thing, this regulation contains is the various numerical requirements that the FDA imposes for a device to be labeled porous, correct? A. Right.").

[22] **Exhibit H**, Deposition Transcript of Pascal Wiederkehr, dated April 30, 2014 ("Weiderkehr Dep. Tr.") at 31:5-10 ("Q. My understanding is that the project that you ran during that time in 2005 was intended to develop a Durom acetabular component that had a new coating that was consistent with FDA requirements; correct? A. It was just a coating.").

[23] *See* **Exhibit I**, Email from P. Weiderkehr to P. Osorio, dated July 7, 2005 (Durom_AAA 00088202) (emphasis added).

[24] *See* **Exhibit J**, Email from M. Price to C. Blakely, et al., dated Nov. 8, 2005 (Durom_AAA 00153163).

[25] *See id.*

European surgeons and American surgeons in the manner in which they insert the acetabular component."[26] He further testified that both he and Dr. Grigoris specifically expressed these concerns to various executives at Zimmer.[27]

b. Zimmer ignored concerns inside and outside the company that animal testing on the new coating was necessary.

Based on his concerns about the US Durom Cup's new coating, Dr. Roberts made the following recommendations to his contacts at Zimmer:

> Yes, the discussions we had with various people from Zimmer, both informally and formally, was that **the testing should be same as we carried out in Europe prior to the release of that coating, that that was animal testing and ideally an RSA study**, although the practicalities of an RSA study were such that that would be a much longer term goal. **Our minimum, we felt at the time, was that an animal study should be carried out to determine the efficacy of the coating** and that ideally an RSA study should be done, but accepting that that would take probably several years to set up.[28]

This testimony is consistent with a Zimmer internal memorandum dated December 8, 2005, which states that Drs. Roberts and Grigoris "**demanded** an animal study to show that the

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[26] Ex. B, Dr. Roberts Dep. Tr. at 83:11-22 ("Q. What was your initial reaction to the news that Zimmer planned to introduce Durom total hip replacement system in the United States? A. Our initial plan, which had already been discussed because of the concerns about the cup in Europe, was that the cup that we had designed would not be suitable for the use in America because of differences in surgical technique, quite widespread differences, between European surgeons and American surgeons in the manner in which they insert the acetabular component.").

[27] *Id.* at 86:18-87:5 ("Q. Upon learning about Zimmer's plans to introduce a Durom total hip replacement system in the United States, did you have any conversations with anyone at Zimmer in which you expressed your concerns about the suitability of American surgical techniques for this device? A. Yes, initially with Robert Gnoss in the meeting in Lisbon for the Efort meeting and in subsequent meetings indeed as well and also much later on, well, not much later, in 2006 onwards in the multi-surgeon development group that had been set up by Sheryl Conley."); and Ex. B, Dr. Roberts Dep. Tr. at 87:6-11 ("Q. Do you recall ever hearing Dr. Grigoris express similar concerns to you? A. Yes, and the date here I am not absolutely clear on, but it was probably round about 2006 or 2007.").

[28] *Id.* at 112:12-113:4 ("Q. Do you ever recall the possibility of conducting clinical trials on the American Durom cup prior to its release on the market being discussed in any meetings with Zimmer? A. Yes, the discussions we had with various people from Zimmer, both informally and formally, was that the testing should be same as we carried out in Europe prior to the release of that coating, that that was animal testing and ideally an RSA study, although the practicalities of an RSA study were such that that would be a much longer term goal. Our minimum, we felt at the time, was that an animal study should be carried out to determine the efficacy of the coating and that ideally an RSA study should be done, but accepting that that would take probably several years to set up.") (emphasis added).

modified Durom coating for the US market and the current Durom coating are equally good."[29] In fact, that same memorandum shows that Zimmer executive Cheryl Blanchard ("Blanchard") actually "agreed" to the "need for an animal study of the modified Durom coating for the US market" and authorized Zimmer personnel to take the steps necessary to prepare one.[30] For reasons that no one at Zimmer has been able to explain, however, those plans were not carried through.

Drs. Roberts and Grigoris were not alone in believing that the new coating should be subjected to an animal study. Wiederkehr himself felt one was necessary upon observing how different the new coating looked from the EU Durom Cup's coating, and raised the subject with supervisors Claude Rieker and Adrian Spiegel ("Spiegel").[31] According to Wiederkehr, he and his design team were eventually "convinced that based on the experience [Spiegel] had [and] Marcus Windler, who was . . . one of the authors of the initial animal study . . . that this kind of minor modification compared to the knowledge the industry had . . . about titanium structures . . . [was] not something which would obviously require an animal study[.]."[32] Spiegel also tried to

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[29] *See* Exhibit K, Zimmer Memorandum from P. Weiderkehr to C. Blanchard, et al., dated Dec. 8, 2005 (Durom_AAQ 0000001) (emphasis added).

[30] Ex. K, Zimmer Memorandum from P. Weiderkehr to C. Blanchard, et al., dated Dec. 8, 2005 (Durom_AAQ 0000001).

[31] Ex. H, Weiderkehr Dep. Tr. at 133:20-134:23 ("Q. Apart from those conversations with Drs. Roberts and Grigoris, do you recall independently in any other discussions on the subject of animal testing in 2005? A. Yes, that was within the team we had that, the initial risk assessment, we just were not really sure about it because we saw that the coating looks optically different, so we were not that sure. So, we [contacted] our supervisors . . . [a]nd we were convinced that based on the experience our supervisor had mainly also Adrian Spiegel's supervisor, Marcus Windler, who was part of, indeed, one of the authors of the initial animal study . . . that this kind of minor modification compared to the knowledge the industry had that about titanium structures, rough structured or rough surfaces, that this is not something which would obviously require an animal study as the primary stability, if the rims press fit all stays the same, we have the same surgical techniques. So we, in the design team, we were sure that we do not need that for the safety of the device.").

[32] *Id.* at 133:20-134:23 ("Q. Apart from those conversations with Drs. Roberts and Grigoris, do you recall independently in any other discussions on the subject of animal testing in 2005? A. Yes, that was within the team we had that, the initial risk assessment, we just were not really sure about it because we saw that the coating looks optically different, so we were not that sure. So, we [contacted] our supervisors . . .

convince Dr. Roberts that an animal study on the new coating was not necessary, but Dr. Roberts was not persuaded.[33] Ultimately, the concerns of Dr. Roberts and others were cast aside by Zimmer, and it proceeded to the FDA clearance process without any animal testing on the US Durom Cup's brand new coating.

c. The FDA clearance process raised additional concerns about the US Durom Cup's new coating.

Laura Williams ("Williams") was the Zimmer employee in charge of obtaining FDA clearance for the US Durom Cup. Williams elected to seek clearance for the device by way of a 510(k) filing, rather than as a PMA. She explained the difference between the two clearance routes as follows: "The fundamental premise for clearance of a 510(k) is substantial equivalence to a product that is legally marketed in the United States. The basis for approval of a PMA is a determination that the device is safe and effective."[34] Stated conversely, the 510(k) clearance process does not involve a determination by the FDA that the at-issue device is safe and effective.

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[a]nd we were convinced that based on the experience our supervisor had mainly also Adrian Spiegel's supervisor, Marcus Windler, who was part of, indeed, one of the authors of the initial animal study . . . that this kind of minor modification compared to the knowledge the industry had that about titanium structures, rough structured or rough surfaces, that this is not something which would obviously require an animal study as the primary stability, if the rims press fit all stays the same, we have the same surgical techniques. So we, in the design team, we were sure that we do not need that for the safety of the device.").

[33] *Id.* at 133:20-134:23 ("Q. Apart from those conversations with Drs. Roberts and Grigoris, do you recall independently in any other discussions on the subject of animal testing in 2005? A. Yes, that was within the team we had that, the initial risk assessment, we just were not really sure about it because we saw that the coating looks optically different, so we were not that sure. So, we [contacted] our supervisors . . . [a]nd we were convinced that based on the experience our supervisor had mainly also Adrian Spiegel's supervisor, Marcus Windler, who was part of, indeed, one of the authors of the initial animal study . . . that this kind of minor modification compared to the knowledge the industry had that about titanium structures, rough structured or rough surfaces, that this is not something which would obviously require an animal study as the primary stability, if the rims press fit all stays the same, we have the same surgical techniques. So we, in the design team, we were sure that we do not need that for the safety of the device.").

[34] Ex. G, L. Williams Dep. Tr. at 47.

Zimmer filed a Traditional 510(k) Premarket Notification ("US Durom Cup 510(k)") for the US Durom Cup with the FDA on December 16, 2005.[35] In the device description portion of that document, consistent with Dr. Roberts' assessment above, Zimmer represented to the FDA that "[l]ong-term secondary fixation [of the Durom Cup] is achieved by bone in-growth into the *Porolock* Ti-VPS porous coating on the outer surface of the cup."[36]

i. The so-called "predicate devices" did not share all of the key design features of the US Durom Cup.

Zimmer's US Durom Cup 510(k) was premised on its contention that the device was "substantially equivalent" to three predicate devices already cleared by the FDA: (1) Biomet M2A Magnum System; (2) Wright Metal Transcend; and (3) Centerpulse Epsilon Metasul System.[37] Significantly, none of the predicate devices utilized a sub-hemispherical shape, fins, and a plasma spray coating like the US Durom Cup.[38] Furthermore, all three of the so-called predicate devices, as Williams conceded, used a coating that was deemed "porous" by the FDA, whereas the US Durom Cup's coating was not considered "porous" by the FDA.[39]

ii. Zimmer fails in its effort to obtain a "porous coating" designation.

Although it performed no clinical or animal testing with respect to the US Durom Cup prior to filing its 510(k), Zimmer did perform some testing relating to "different elements of the [device's] design," and it attached the results of that testing to its 510(k).[40] Significantly, Williams conceded that neither of those tests is intended to measure how the coating performs in

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[35] *See* **Exhibit L**, Traditional 510(k) Premarket Notification (CIW Ex. 4).
[36] *See* Ex. L, Traditional 510(k) Premarket Notification (CIW Ex. 5) at 0015.
[37] *See* Ex. L, Traditional 510(k) Premarket Notification (CIW Ex. 5) at 0091.
[38] Ex. G, L. Williams Dep. Tr. at 74:1-8 ("Q. Okay. And is it fair to say based on your summary here of the various predicates that none of the predicates used both a reduced hemisphere and fins like the Durom Cup did? A. It would appear so . . . .").
[39] *See id.* at 74-75.
[40] *See id.* at 58-59.

the human body.[41] One of the "elements of the design" that was tested was the coating's so-called morphological properties – *i.e.*, the volume porosity percentage, the thickness, and the average pore size. The purpose of this testing was to show to the FDA that at least certain morphological properties of the US Durom Cup's coating were within the specified ranges of a "porous coating" under 21 CFR 888.3358.

21 CFR 888.3358 unambiguously states that a coating must fall within all three of the specified ranges in order to obtain a "porous" designation.[42] However, of the figures listed for the US Durom Cup's coating in the 510(k), only one fell within the ranges specified by the FDA. Specifically, the coating had:

- a "thickness" of 453 microns, but 21 CFR 888.3358 requires a thickness of between 500 and 1,000 microns;
- an average pore size of 51 microns, but 21 CFR 888.3358 requires an average pore size between 100 and 1,000 microns; and
- a volume porosity of 31.5%, which barely fell within 21 CFR 888.3358's required range for volume porosity of 30 to 70%.[43]

Despite the plain language of the statute, Williams testified that Zimmer expected to receive a "porous" designation from the FDA because the FDA had granted Zimmer a "porous" designation on another device that only satisfied one of the three requirements.[44] Zimmer's expectations proved misguided. The FDA's reviewer, Peter Allen ("Allen"), explained to Williams that the US Durom Cup's coating failed to meet all three requirements for a "porous" designation and, accordingly, would not receive that designation.[45] Williams responded to that

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[41] *Id.* at 59:15-20 ("Q. All right. And just be clear, there's – none of these tests on page 20 [of the 510(k) filing] relate to or measured how this coating performed in the human body, correct. A. Correct.").
[42] *See* **Exhibit BBB**, 21 CFR 888.3358.
[43] *See* Ex. L, Durom_510k 000001-333, Traditional 510(k) Premarket Notification at 0178.
[44] *See* Ex. G, L. Williams Dep. Tr. at 102-103.
[45] *See* **Exhibit P**, Durom_McAllister_DISC 00002347, Email from Peter Allen to Laura Williams, dated Mar. 3, 2006 (CIW Ex. 9).

email by arguing that a previous product, the ZMR, had been granted a "porous" coating designation even though it only met one of the three numerical requirements found within 21 CFR 888.3358.[46] In his response to that email, Allen informed Williams that he had discovered during his review that Zimmer had overstated the volume porosity of the US Durom Cup's coating in its 510(k) by almost 5 percentage points.[47] Thus, the actual volume porosity (26%) fell outside the accepted range of 30-70% – meaning that the US Durom Cup's coating met none of the three requirements.

Williams conceded that this was a "significant" error on Zimmer's part.[48] More specifically, she agreed that the error, at least in Zimmer's mind (albeit incorrectly), made the difference between getting a "porous" designation and not getting such a designation.[49] In other words, there is some reason to believe the volume porosity was purposely misstated. According to Williams, the error was committed by Spiegel, who was the project manager in Winterthur.[50] However, she also admitted that Spiegel's report would have been reviewed by at least eight persons before being submitted to the FDA.[51] When asked what Spiegel said when being told of his mistake, Williams testified: "I believe it was 'Bummer.'"[52] Williams said that though she

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[46] *See* **Exhibit M**, Durom_McAllister_DISC 00002349, Email from Laura Williams to Peter Allen, dated Mar. 7, 2006 (CIW Ex. 10).
[47] *See* **Exhibit N**, Durom_McAllister_DISC 00002351, Email from Peter Allen to Laura Williams, dated Mar. 9, 2006 (CIW Ex. 11)
[48] Ex. G, L. Williams Dep. Tr. at 90:15-91:8 ("Q. So someone messed up when they stated the porosity as 31.5 percent two other times in the report, didn't they? . . . A. It was -- it was an error, yes. Q. Okay. And it was an error that at least the eight reviewers who looked at this 510(k) submission prior to it being filed with the FDA did not catch, correct? . . . A. Correct. Q. Okay. And this error did have some significance in terms of what it meant for the US version of the Durom Cup, that product's chances of obtaining a porous coating designation from the FDA, correct? A. Yes.").
[49] *Id.* at 117:21-118:4 ("Q. Well, let me ask it this way. In your mind, the difference between obtaining -- between a volume porosity of 26.8 percent and 31.5 percent was the difference between obtaining this porous designation from the FDA and not obtaining it? A. Yes.").
[50] *See id.* at 91.
[51] *See id.* at 95-96.
[52] Ex. G, L. Williams Dep. Tr. at 111.

was "extremely disappointed" in Spiegel's mistake,[53] she is not aware of any actions Zimmer took against Spiegel to reprimand him.[54]

In any event, Allen ultimately explained to Williams that meeting one out of the three numerical requirements would not have led to a "porous" coating designation for the US Durom Cup anyway, and that the designation of the ZMR's coating as "porous" was, in fact, an error on the FDA's part because it did not meet all three of 21 CFR 888.3358's numerical requirements.[55] For those reasons, the FDA ultimately upheld its initial ruling that Zimmer could not use the term "porous" in association with the US Durom Cup, and it also informed Zimmer that the device could not market the device as one that promoted "biological fixation."[56] It stood by that decision even after Zimmer, in a last-ditch effort, submitted the mini-pig study on the EU Durom Cup's coating in hopes that Allen would find the US Durom Cup's coating to be substantially equivalent to that device.[57]

Ultimately, Williams re-submitted a revised 510(k) that omitted any use of the terms "porous" or "biological fixation" on behalf of Zimmer.[58] Williams also informed her superiors at Zimmer that in order to use those terms vis-à-vis the device in the future, Zimmer would have to "conduct an animal study demonstrating biological fixation of the coating equivalent to that of

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[53] *Id.* at 112.
[54] *See id.* at 126.
[55] *See* **Exhibit O**, Durom_AAG 00142363-65, Email from Laura Williams to Various, dated Mar. 10, 2006 (CIW Ex. 14).
[56] *See* Ex. P, Durom_McAllister_DISC 00002347, Email from Peter Allen to Laura Williams, dated Mar. 03, 2006 (CIW Ex. 8).
[57] Ex. G, L. Williams Dep. Tr. at 177:20-178:8 ("Q. Okay. Well, if bony on-growth did allow for the designation of a product as promoting biological fixation, Mr. Allen's ruling would have been different, correct? A. Well, but what his -- it doesn't -- his notes don't say he concluded that there was surface on-growth. He said what the authors were talking about was not in-growth but on-growth. So I don't see any conclusion that he made there relative to a similar coating and on-growth. I can't speak for what he might have concluded that he didn't write. Q. In any event, [the minipig study on the European Durom Cup's coating] didn't change his ruling? A. It didn't change his decision.").
[58] *See* **Exhibit Q**, Durom_McAllister_DISC 00002352, Email from Laura Williams to Peter Allen, dated Mar. 12, 2006 (CIW Ex. 15).

another device legally marketed as 'porous' in the U.S."[59] In response to Williams' news, a Winterthur executive (whose name was redacted) declared that it was "imperative to obtain data [from an animal test] that demonstrates equivalent performance [with respect to] 'biological fixation' compared to a 'porous device.'"[60] Despite this declaration, no such animal study was conducted prior to the device's release in May 2006. Indeed, no such testing was performed on the US Durom Cup until well after the sale of the product was suspended in July of 2008.

3. The Release of the US Durom Cup

The US Durom Cup was given a limited release as part of the Metasul LDH Total Hip Replacement System in the United States in May 2006. Zimmer marketing employee Brian Parker ("Parker") was given the title of product manager for this device and charged with managing its introduction on to the market.

a. Zimmer did not institute a mandatory surgeon-to-surgeon training program for the US Durom Cup like Sulzer/Centerpulse did for the EU Durom Cup.

Prior to this limited release in the United States, Dr. Roberts specifically warned Zimmer that "there are specific technique-related factors closely elided to the design of this implant which requires [sic] explanation and training and that if that doesn't take place . . . surgeons would struggle with this implant."[61] Parker himself acknowledged that, prior to the US Durom

[59] *See* Ex. O, Durom_AAG 00142363-365, Email from Laura Williams to Various, dated Mar. 10, 2006 (CIW Ex. 14).

[60] *See* **Exhibit R**, Durom_AAG 00011920-921, Email from [REDACTED] to Laura Williams, et al., dated Mar. 14, 2006 (CIW Ex. 21).

[61] Ex. B, Dr. Roberts Dep. Tr. at 133:15-134:5 ("Q. As the designing surgeon of the original Durom acetabular component, was it ever your intention for the device to be used by surgeons who hadn't been trained specifically on how to implant that particular device? A. It certainly wasn't. As I have previously explained, there are specific technique-related factors closely elided to the design of this implant which requires explanation and training and that if that doesn't take place, as we had previously expressed throughout 2005, and earlier, surgeons would struggle with this implant.").

Cup's release, there was an awareness at Zimmer that the device required a surgical technique that was different from what American surgeons were used to, explaining:

> This one, we felt – the thing with the Durom Cup was we wanted to make sure surgeons just didn't accept this as oh, it's another acetabular cup, or it's just like the Biomet Magnum large metal cup, or it's just like the Wright Medical Conserve cup. We wanted to make sure they understood, no, this design is different, and you need to adjust your technique different.[62]

Despite this awareness, Parker conceded that Zimmer never even considered a mandatory surgeon-to-surgeon training program of the sort that was implemented by Sulzer/Centerpulse at the time of the EU Durom Cup's release.[63] Ultimately, Zimmer put no mandatory surgeon training of any type in place at the time the US Durom Cup was released on to the market in May 2006. As far as voluntary training goes, Dr. Roberts testified that when he was asked to assist the company in devising a new surgical training program for the US Durom Cup in 2008, he concluded based on interviews with several Zimmer employees:

> **[T]here had been little, if any, teaching programme put in place for the introduction of the Durom cup into the United States.** . . . **That clearly should not have happened and nobody I think could disagree with that**. If surgeons had been taught correctly how to insert the cup, or indeed by the time this cup had been launched a more appropriately design, as we had previously discussed, been available, I think on balance a lot of the problems would have been avoidable.[64]

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[62] **Exhibit S**, Deposition Transcript of Brain Parker, dated Apr. 3, 2014 ("Parker Vol. I Dep. Tr.") at 94:3-11 ("This one, we felt -- the thing with the Durom Cup was we wanted to make sure surgeons just didn't accept this as oh, it's another acetabular cup, or it's just like the Biomet Magnum large metal cup, or it's just like the Wright Medical Conserve cup. We wanted to make sure they understood, no, this design is different, and you need to adjust your technique different.").

[63] *Id.* at 124:2-9 ("Q. Given Zimmer's awareness that the technique for implanting the U.S. Durom Cup was unique in some ways, was there any discussion that you can recall about requiring mandatory training from surgeons before using the device? A. I don't recall much of a discussion, if any at all.").

[64] Ex. B, Dr. Roberts Dep. Tr. at 166:20-167:16 ("Q. Based on your participation in these meetings and your interactions with American surgeons during those meetings, do you believe that the problems that arose with the American Durom cup prior to April 2008 could have been prevented? A. It was apparent to me there had been little, if any, teaching programme put in place for the introduction of the Durom cup into the United States. That was effectively told to me by the Zimmer employees who I was working with at the time, which obviously was regrettable. That clearly should not have happened and nobody I think could disagree with that. If surgeons had been taught correctly how to insert the cup, or indeed by the time this cup had been launched a more appropriately design, as we had previously discussed, been available, I think on balance a lot of the problems would have been avoidable.") (emphasis added).

b. Zimmer's surgical technique documents had key omissions.

Despite conceding Zimmer's understanding that it "need[ed] to be clear with U.S. surgeons that this technique is different[,]"[65] Parker said that there was no consideration given to putting an unambiguous statement in the surgical technique instructions for the US Durom Cup that stated something to the effect of: "Dear Surgeon, you cannot implant this device using the same technique that you used for other acetabular components."[66] Zimmer also did not include anything in the original surgical technique warning surgeons about the danger of repositioning the US Durom Cup after impaction, even though they knew doing so would result in cup failure.[67] Such a warning was not included even though it was well known among both surgeons and sales representatives that repositioning acetabular components after impaction is a common practice among American orthopedic surgeons.[68] The significance of this missing warning was

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[65] Ex. S, Parker Vol. I Dep. Tr. at 89:15-19 ("So the one thing that was identified is we need to be clear with U.S. surgeons that this technique is different. And you need to treat this cup differently when implanting the cup.").

[66] *Id.* at 92:12-93:11 ("Q. [I]n the lead-up to the rollout of the U.S. Durom Cup, was -- do you recall any discussions about putting a statement in the surgical technique instructions explicitly saying, Dear Surgeon, you cannot implant this device using the same technique that you used for other acetabular components? . . . A. . . . Do we say – you know, do we want to put in the technique – you know, to your point, U.S. surgeon, we want to call your attention to this? No, we did not do that.").

[67] Ex. S, Parker Vol. I Dep. Tr. Vol. I at 133:18-134:1 ("Q. But in any event, Zimmer ultimately opted not to include any sort of warning explicitly advising surgeons not to reposition the cup after final impaction in the original marketing materials, correct? . . . A. We did not . . ."); and *id.* at 125:12-25 (acknowledging that Zimmer was aware before the US Durom Cup was put on to the market that it was a "one shot cup").

[68] **Exhibit T**, Deposition Transcript of Dr. Lawrence Dorr, dated May 23, 2014 ("Dr. Dorr Vol. I Dep. Tr.") at 87:21-88:13 ("Q. Okay. If the Durom cup couldn't be adjusted intraoperatively, do you think that's something that should have been included in the surgical technique? . . . A. Yes. Q. Why? A. Well, that's an important technical maneuver that's kind of commonly done if you're a press-fit cup surgeon. Some surgeons commonly put screws in all the time. Well, you can't do that with this cup. So the option, if you don't like your position is -- or for better stability or whatever reason you make the decision to do it, you change the position of the cup. So I mean that's kind of a routine intraoperative maneuver."); **Exhibit U**, Deposition Transcript of Richard Cadarette, dated Feb. 7, 2014 ("Cadarette Dep. Tr.") at 168:7-19 ("Q. You mentioned earlier that one thing you observed in your time as a medical device distributor with acetabular components was a habit of doctors to reposition them during surgery. A. Yes. Q. And that was based on you witnessing a number of these surgeries over the years. Correct? A. Yes. Q. And it was something that you saw in many doctors. Correct? A. Yes."); and Ex. B, Dr. Roberts Dep. Tr. at 86:7-13 ("Much later on in discussions about the development of the product line with

explained by Dr. Roberts: "If [surgeons reposition the cup after impaction] the Durom cup . . . would fail immediately. Its position cannot be changed because of the engagement between the circumferential fins and the rim of the acetabular."[69]

c. Zimmer's marketing of the US Durom Cup was misleading.

Part of Zimmer's marketing strategy for the US Durom Cup was to leverage the success of the EU Durom Cup to convince American surgeons to use the device. In order to do so, Zimmer needed to create the impression that the two implants were identical. To that end, Zimmer's business plans for the US Durom Cup emphasized the need to "keep quiet the development of the new coating."[70] That same business plan shows that Zimmer sought to reinforce the notion among surgeons that the two coatings were the same by giving the US Durom Cup's coating the same name as the EU Durom Cup's coating: *Porolock*.[71]

Based on the testimony given by several Zimmer sales representatives, Zimmer's efforts worked. Specifically, many of the Zimmer sales representatives who testified in this litigation recalled that they: (a) cited the EU Durom Cup's track record in marketing the US Durom Cup to American surgeons; and (b) were never told by anyone at Zimmer that the coating on the EU Durom Cup was different than the coating on the US Durom Cup.[72] To quote but one of these sales representatives, Don Secor ("Secor"):

American surgeons who were part of the group, it was clear and one of them estimated at 50% of surgeons in the US in 2006 were still using the line-to-line insertion and adjustment with an osteotome to change the position of the cup.").

[69] Ex. B, Dr. Roberts Dep. Tr. at 86:14-17.

[70] **Exhibit V**, Business Plan, Durom Hip Cup New Coating: Phase 1 and 2 Review (CIW Ex. 133), at Durom_AAA 00076402.

[71] *See* Ex. V, Business Plan, Durom Hip Cup New Coating: Phase 1 and 2 Review (CIW Ex. 133), at Durom_AAA 00076402 ("Therefore we will use the trademark Porolock as well for the new coating. So there will be only little changes in the existing brochures and the cup will not be exposed to strong critics.").

[72] **Exhibit W**, Deposition Transcript of Michael Falivena, dated Sept. 12, 2013 ("Falivena Dep. Tr.") at 33:11-23 ("Q. All right. At the time of the Durom Cup's introduction, were you made aware by Zimmer that the product had been available in Europe for several years? A. Yes, I did know that. Q. And was

Q. Were you ever told by anyone at Zimmer that the European version was different than the American version?

A. No.

Q. Was its track record – was the Durom Cup's track record in Europe something that you used in your efforts to promote the product at any time?

A. Yes. . . .

Q. Did you ever tell a surgeon, you know, 'Look, this product had a successful track record in Europe'?

A. Yes.[73]

Not surprisingly, given the sales force's lack of awareness about the differences between the EU and US Durom Cups, this false impression trickled down to the surgeons who implanted the device. Multiple surgeons cited in their testimony the fact that the Durom had an established track record in Europe as one of the reasons why they elected to implant the US Durom Cup.[74]

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this something that -- was that fact something that you used in your promotion of the Durom Cup to your surgeons? A. Yes, it was. Q. Okay. Do you recall being made aware of any differences between the European Durom Cup and the American Durom Cup? A. No, I do not."); **Exhibit X**, Deposition Transcript of Brien Huscher, dated Aug. 23, 2013 ("Huscher Dep. Tr.") at 19:24-20:16 ("Q. Yeah. Was the fact the Durom Cup had been on the market in Europe for several years something that you used in your sales pitches to surgeons that you sold to? A. I do recall occasionally I mentioned that they were having good results. Q. . . . Were you -- when you found out that it was available in Europe and it was, I think you said, shortly after the product came out -- A. Uh-huh. Q. -- were you made aware by anyone at Zimmer that there were differences between the European Durom Cup and the U.S. version? A No."); and Ex. C, B. Jones Dep. Tr. at 34:20-35:1 ("Q. And when you began selling the Durom cup to your customers, was the success that the product had in Europe something used in your sales pitch? . . . A. Yes. I mean, we would say that it was already in use and being used in Europe with good clinical results."); and Ex. C, B. Jones Dep. Tr. at 51:23-52:3 ("Q. Okay. Were you aware at this point in 2006, 2007, that the coating on the U.S. Durom cup was different than the one on the European Durom cup? . . . A. No, I was not.").

[73] Ex. D, Secor Dep. Tr. at 36:25-37:8 ("Q. And that was my next question. Were you ever told by anyone at Zimmer that the European version was different than the American version? A. No. Q. Was its track record -- was the Durom Cup's track record in Europe something that you used in your efforts to promote the product at any time? A. Yes. . . . Q. Did you ever tell a surgeon, you know, 'Look, this product had a successful track record in Europe'? A. Yes.");

[74] *See, e.g.*, **Exhibit Y**, Deposition Transcript of Dr. Stephen Mikulak, dated Jan. 14, 2014 ("Dr. Mikulak (Kline) Dep. Tr.") at 14:22-24 ("Was one of the appealing things about the product that it had an established track record in Europe? A. Yes."); and **Exhibit Z**, Deposition Transcript of Dr. John

These same surgeons were not aware that the US Durom Cup had a different coating than the EU Durom Cup.[75] As prominent Californian orthopedic surgeon Dr. Larry Dorr ("Dr. Dorr") testified, this lack of awareness about these differences influenced his decision to use the device:

> Q. You said a second ago that you – you had not been aware of the differences between the U.S. cup and the European cup. What did you mean by that?
>
> A. Well, I subsequently learned that the grit-blasted surface that they had approved and used in Europe was not the same as they got approved and/or was using here in the United States.
>
> Q. **Had you known of that difference before you started implanting the Durom cup what, if anything, would you have done differently**? . . .
>
> A. **I hope I would have asked to see some animal data or plug data, or some data that showed that the coating was effective, because I think I was assuming the surface was the same and that they had a large clinical experience in Europe that had proved the efficacy of that coating**. If they were going to give me a brand-new coating, I think I probably would have . . . I think I would have said, you know, it's not that much trouble to put a plug in a dog here. We can make sure you get the same fixation.[76]

McCallum, dated Dec. 16, 2013 (Dr. McCallum Dep. Tr.") at 72:11-73:2 ("Q. And you said that, in becoming aware of the Durom Cup, that it had been made available in Europe prior to its introduction in the United States; is that correct? A. Correct. Q. And that was one of the appealing things of the product, that it had an established track record in Europe? A. Correct.").

[75] *See, e.g.,* Ex. Y, Dr. Mikulak (Kline) Dep. Tr. at 15:1-11 ("At the time that you became familiar with the product, did you know that there were differences between the Europ- -- U.S. Durom Cup and the European version of the product? A. No. Q. Did you ever become aware of any differences between those two different products? A. No."); and Ex. Z, Dr. McCallum Dep. Tr. at 72:11-73:2 ("Q. At the time that you became familiar with the product, did you know that there were differences between the U.S. Durom Cup and the European version of the product? A. No. Q. Did you ever become aware of any of the differences between those two products? A. No, I didn't know there was.").

[76] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 53:19-54:17 ("Q. You said a second ago that you -- you had not been aware of the differences between the U.S. cup and the European cup. What did you mean by that? A. Well, I subsequently learned that the grit-blasted surface that they had approved and used in Europe was not the same as they got approved and/or was using here in the United States. Q. Had you known of that difference before you started implanting the Durom cup what, if anything, would you have done differently? . . . A. I hope I would have asked to see some animal data or plug data, or some data that showed that the coating was effective, because I think I was assuming the surface was the same and that they had a large clinical experience in Europe that had proved the efficacy of that coating. If they were going to give me a brand-new coating, I think I probably would have . . . I think I would have said, you know, it's not that much trouble to put a plug in a dog here. We can make sure you get the same fixation.") (emphasis added).

In the same vein, the testimony of Zimmer sales representatives and implanting surgeons also reflects that the former passed along incorrect information about the US Durom Cup's coating to the latter. For example, Plaintiff John Pugliese's surgeon, Dr. John McCallum, testified that his Zimmer sales representative led him to believe that the US Durom Cup would achieve long-term fixation through "biological fixation"[77] – a term that the FDA had specifically told Zimmer it could not use in marketing the device. Other surgeons expressed that they were under the impression that the coating on the US Durom Cup was "porous," even though the FDA had expressly ruled that it was not.[78] These misconceptions arose out of the fact that Zimmer chose not to tell its sales representatives about the FDA's rulings on what terms could not be used in the marketing of the device – *i.e.*, that the device was "porous" or promoted "biological fixation."[79]

d. Zimmer hand-picked Drs. Dorr and Long to serve as "surgeon-investigators" for the US Durom Cup.

Dr. Dorr's lack of knowledge about the differences between the EU and US Durom Cups is all the more significant given that he and his colleague, Dr. William Long ("Dr. Long"), were

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[77] Ex. Z, Dr. McCallum Dep. Tr. at 25:13-22 ("Q. Understood. But do you remember discussions with anyone from Zimmer as to, for instance, what the coating was? Did anybody talk to you specifically about what type of coating they had? A. Correct, they did. Q. They did. And what was your understanding? A. That it was a biological fixation that was going to occur.").

[78] *See, e.g.*, **Exhibit AA**, Deposition Transcript of Dr. Stuart Smith, dated Nov. 19, 2013 ("Dr. Smith Dep. Tr.") at 22:20-24 ("Q. Okay. And then what was your understanding as to how the Durom cup was supposed to achieve secondary fixation? A. Through bony ingrowth into the porous coating."); **Exhibit ZZ**, Deposition Transcript of Dr. Joseph Assenmacher, dated June 2, 2014 ("Dr. Assenmacher Dep. Tr.") at 63:13-17 ("Q. What was you --- is your understanding of how the Durom cup would achieve long-term fixation? A. Well, it's a bony ingrowth. A porous surface on the back with a truncated design, different that a lot of the cups that we place."); and **Exhibit AAA**, Deposition Transcript of Dr. William Kurtz, II, dated May 21, 2014 ("Dr. Kurtz Dep. Tr.") at 105:12-18 ("Q. So in what ways are you familiar with the Durom cup? A. It relies on porous – basically, friction between the porous coating and the acetabular bone. There is no option for additional supplementary screws like a traditional acetabular component would have.").

[79] *See, e.g.*, Ex. D, Secor Dep. Tr. at 37:2-24 ("Q. What was your understanding, if you had one, as to how the Durom Cup would achieve long-term fixation in the human body? A. **The porous coating**. . . . Q. Okay. Were you aware that the FDA, during the product clearance process, had told Zimmer that it could not use the word 'porous' on the Durom Cup's packaging? A. No.") (emphasis added).

two of the first surgeons allowed to implant the device and were actually hand-picked by Zimmer to evaluate the implant and provide feedback on it (as so-called "surgeons-investigators").[80] This fact has been established not just by Dr. Dorr's testimony, but by the testimony of Secor, a Zimmer sales representative in his territory.[81] Dr. Dorr was not only a hand-picked evaluator of this device; he was also asked by Zimmer distributors to give presentations on the device to other surgeons and explain his surgical technique for implanting the US Durom Cup.[82] This fact was known to Zimmer, and is confirmed by Zimmer's own documents.[83]

4. **Surgeon Concerns Following the US Durom Cup's Release**

Shortly after the US Durom Cup's limited release in May of 2006, Dr. Aaron Hoffman ("Dr. Hoffman"), a Utah surgeon who had previously performed consulting work for Zimmer, expressed blunt concerns about the product to top Zimmer engineer Erin Johnson ("Johnson"), stating: "I really want to see the science. I certainly trust the team at Zimmer but I can't be the only doubter in the world. The coating feels 'smooth' and lools [sic] shiney [sic] – **things we**

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[80] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 39:1-8 ("Q. . . . [W]as it your understanding that you were still doing any work in the relation to the Durom cup? A. Yes. No, [Zimmer] specifically wanted us to do the conventional hip with the Durom and – and – and, quote, evaluate that."); and **Exhibit BB**, Deposition Transcript of William Long, dated Sept. 12, 2012 ("Dr. Long Vol. I Dep. Tr.") at 19:1-2 ("And in 2004 or 2005, I was approached by Zimmer to become a surgeon/investigator for the Durom cup").

[81] Ex. D, Secor Dep. Tr. at 38:15-39:7 ("Q. And you mentioned the term 'original investigators.' [Dr. Dorr] was also selected by Zimmer to be an investigator for this device as well. Correct? A. Yes. Q. And what do you mean by 'investigator'? A. Investigator is when -- the first people to get the implants and instruments, and he was the first one to put them in, and then he usually follows them and reports on his results. Q. Okay. And so you -- you certainly became aware, since he was within your territory, that he had been selected for that role by Zimmer. Correct? A. Absolutely.").

[82] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 113:3-17 (Dorr: "I gave talks on the Durom. I gave several talks on the Durom, and I -- my job in those talks was to give the design features of it, why -- why we felt large head metal-on-metal was a good idea. And then I would show technique on how to do the operation. . . . Q. When you gave these talks on the Durom cup, was Zimmer aware you were doing it? A. Yes. I mean, I gave talks at Zimmer meetings.").

[83] *See* **Exhibit CC**, US Sales Significant Events Report, dated May 2007 (CIW Ex. 530) at 817 ("Hosted Dr. Larry Dorr for dinner lecture on 5/15 and Grand Rounds at UK-Lexington on 5/16. Dinner lecture on LDH attended by 40.").

don't see in porous coating that work."[84] Dr. Hoffman's July 2006 prediction that he was not "the only doubter in the world" concerning the US Durom Cup was, of course, accurate. As set out above, a number of surgeons, engineers, and even the FDA had already questioned the efficacy of the US Durom Cup's coating by that point, and this steady drum beat of doubt about the product continued through the end of 2006 and into 2007. Among those who expressed concerns directly to Zimmer about the US Durom Cup were two surgeons it had specifically asked to provide the company with feedback on the device: Drs. Dorr and Long.

a. Dr. Long expressed concerns to Zimmer within months of the US Durom Cup's release.

Dr. Long "noticed immediately that the cup was hard to put in."[85] In fact, his first three attempts at putting the device resulted in the US Durom Cup "fall[ing] out" of the patient's acetabulum – something Dr. Long remarked "was like nothing we had seen with any other cup we had used."[86] These implantation problems prompted Dr. Long to meet face-to-face with Parker in the summer of 2006 so he could discuss these issues with him directly.[87] Despite its awareness of the struggles of Dr. Long, a surgeon it had hand-picked to test out the new device, Zimmer did not undertake any additional efforts in 2006 to train other surgeons.

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[84] **Exhibit DD**, Email from A. Hoffman to E. Johnson, dated July 17, 2006 (Durom_AAA 00000065) (emphasis added).
[85] **Exhibit EE**, Deposition Transcript of Dr. William Long, dated Oct. 30, 2012 ("Dr. Long Vol. II Dep. Tr.") at 385:16-17.
[86] *Id.* at 385:19-20.
[87] *Id.* at 386:24-387:8 ("Q. Okay. And you raised these concerns with Brian Parker, I believe you said? A. Yes. Q. Okay. And these led to this meeting at McDonald's that we talked about? A. Yes. Q. And I'm trying to get my hand on when that meeting at McDonald's occurred. A. Less than three months after the first implant was attempted to be put in.").

b. Dr. Dorr repeatedly expressed concerns about the US Durom Cup to Zimmer.

i. Dr. Dorr immediately recognized problems with the US Durom Cup's coating.

Dr. Dorr's concerns about the US Durom Cup's coating pre-dated the product's release in the United States. As far back as February 2006, he correctly noted in an email to Zimmer executive David Weidenbenner ("Weidenbenner") that the device "did not have [a] porous coating" and argued that it could only be "salvage[d]" by applying a different, hydroxyapatite-sprayed (HA) coating.[88] His advice was unambiguous: "I think we need to make a quick and dedicated change on the surface treatment of this cup to salvage its usefulness."[89]

Dr. Dorr's willingness to use the device despite his reservations was based, in large part, on the fact that he believed that the coating had a successful track record in Europe.[90] He later testified that had he known that the coating on the US Durom Cup was different than the EU Durom Cup's coating, he would have demanded data in the form of an animal study from Zimmer to assure himself that the coating was effective.[91]

ii. Dr. Dorr took his concerns directly to two different Zimmer CEOs.

Even though he wrongly believed the coating had a proven clinical record in Europe, Dr. Dorr still had strong enough concerns about the US Durom Cup's coating that he raised the issue

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[88] **Exhibit FF**, Email from PJ Paul to D. Weidenbenner, dated Feb. 22, 2006 (CIW Ex. 253) at Durom_AAP 00000002).

[89] *Id.*

[90] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 54:8-11 ("I think I was assuming the surface was the same and that they had a large clinical experience in Europe that had proved the efficacy of that coating.").

[91] *Id.* at 54:2-17 ("Q. Had you known of that difference before you started implanting the Durom cup what, if anything, would you have done differently? . . . A. I hope I would have asked to see some animal data or plug data, or some data that showed that the coating was effective . . . If they were going to give me a brand-new coating, I think I probably would have -- because I had the history of us doing that at Centerpulse. I think I would have said, you know, it's not that much trouble to put a plug in a dog here. We can make sure you get the same fixation.").

again with Zimmer's then-CEO, Ray Elliott ("Elliott"), in October 2006.[92] Specifically, he once again requested that Zimmer conduct testing on a US Durom Cup with a modified HA coating.[93] His advice was once again ignored by Zimmer. So, too, were his repeated pleas in early 2007 that "the technique manual for the Durom needs some changes . . . [because] it does not emphasize [important points] enough for the surgeon and also you need to use the method of repetition to really hammer home those things that need to be done differently."[94] Parker was dismissive of the problems Drs. Dorr and Long were experiencing with the US Durom Cup, testifying that, "you know, there was an American style of putting in acetabular cups that we wanted surgeons to move from. I think Dr. Dorr and Dr. Long's experience was, you know, a classic example of just that."[95] Inexplicably, it did not occur to Parker that, if accomplished surgeons such as Drs. Dorr and Long were having problems with the implant, that other doctors might be having those same issues.

Although Parker repeatedly tried to assure Dr. Dorr that he was putting together additional surgical technique documents during the first half of 2007, Dr. Dorr was frustrated enough by the lack of progress that he felt compelled to complain to Zimmer's then-CEO, David Dvorak ("Dvorak"), in an email dated July 12, 2007.[96] In that email, Dr. Dorr informed Dvorak that he had already had four revisions among the patients he had implanted with the US Durom

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[92] *See* **Exhibit GG**, Email from Raymond Elliott to Various, dated Oct. 23, 2006 (CIW Ex. 231) at Durom_AAA 00150996 ("Larry has requested . . . we produce 40-50 Durom shells HA sprayed in ordr to perform a small random research project.").

[93] *See id.*

[94] **Exhibit HH**, Email from PJ Paul to B. Parker, dated Mar. 21, 2007 (CIW Ex. 258), at Durom_AAP 00000004.

[95] Ex. S, Parker Vol. I Dep. Tr. at 167:25 ("Q. And that was my next question. Did it – was there any concern that hey, we're hearing this stuff from Dr. Dorr because Dr. Dorr has a direct line of communication with Zimmer, we should be concerned that other doctors are experiencing this, we're just not hearing from them? A. I go back to we predicted, you know, that, you know, there was an American style of putting in acetabular cups that we wanted surgeons to move from. I think Dr. Dorr and Dr. Long's experience was, you know, a classic example of just that.").

[96] **Exhibit II**, Email from PJ Paul to D. Dvorak, dated July 12, 2007 (CIW Ex. 135), at Durom_AAD 00015573.

Cup, with two others potentially pending."[97] He also advised Dvorak that he and his colleagues were getting "frequent calls already [from other surgeons] for tips and explanations of why patients are painful and why cups are loose."[98] Dr. Dorr was blunt in his assessment of what needed to be done, and what the stakes were: "What we need to do is **be sure that all surgeons get educated** on the correct technical maneuvers **so that there is not a rash of loose cups and painful patients**."[99] Future events proved that Dr. Dorr's warning was prescient.

5. Zimmer's lack of responsiveness eventually prompted Dr. Dorr to go public with his concerns.

After months of urging Zimmer to change the coating on the US Durom Cup and revise the surgical technique materials for surgeons, Dr. Dorr finally went public with his concerns about the device at a seminar for Current Concepts in Joint Replacement (CCJR) in December 2007, telling the small audience, "I was having failures with [the US Durom Cup], and I didn't recommend anybody using it."[100] He also told several Zimmer executive at that same meeting that they should take the US Durom Cup off the market.[101] When asked why, Dr. Dorr explained:

> Because the failures were – by that time we were having a large volume of failures, unexplainable, inexplicable failures. I mean, by that time I was – **I knew . . . it wasn't technique**. I had made all these technical changes, and even with technical changes, cups were still failing. So **I knew it was a design issue** by that time.[102]

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 132:13-14.
[101] *Id.* at 132:23-24 ("I told them I thought they should take the cup off the market.")).
[102] *Id.* at 133:1-8.

Following additional talks with Zimmer executives about the product in early 2008, Zimmer informed Dr. Dorr that they had no plans to pull the US Durom Cup from the market.[103] At that point, Dr. Dorr decided to send a public letter to all members of the American Association of Hip and Knee Surgeons (AAHKS). That letter, dated April 22, 2008, informed Dr. Dorr's fellow orthopedic surgeons that he and his colleagues had been forced to revise 10 of the 165 US Durom Cups they had implanted in patients, with an additional four revisions pending.[104] He also alerted the AAHKS members of the insidious, almost undetectable nature of the problems with the device, and how the loosening took time to reveal itself, explaining:

> In the first year the x-rays looked perfect. We have revised four that did not have any radiolucencies or migration . . . These early cups fooled us, but the symptoms were so classic for a loose implant that we operated the patients. When we hit the edge of the cup it would just pop free.[105]

For other surgeons who had US Durom Cup patients complaining of pain, but with x-rays that did not suggest a loose device, Dr. Dorr's letter confirmed their own experiences with the product.[106] As Nashville, Tennessee, orthopedic surgeon Dr. Stuart Smith explained:

> Well . . . **everything he describes is what I was experiencing as well**, that is, that they -- that **I was having a much higher revision rate than I would expect** in that subset of patients that I had done using this implant, and that they follow a fairly typical clinical situation in that typically they have good pain relief and then they start to develop symptoms primarily of groin pain.
>
> **And then when he speaks of the findings at the time of surgery when you do revise them, that mirrors my experience as well** . . . you tap it a few times and then it will just completely spin out of – you know, 90 degrees out of the socket,

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[103] Ex. T, Dr. Dorr Vol. I Dep. Tr. at 135:7-11 ("Four or six weeks later [Weidenbenner] called me on the phone. He said they had made a decision they weren't going to do anything. So I said -- I said, Dave, that's your decision, I said, but I am going to put that information out.").

[104] **Exhibit JJ**, Letter from Dr. Dorr to AAHKS, dated April 22, 2008 (CIW Ex. 23), at Durom_AAG 00004467.

[105] *Id.*

[106] *See, e.g.*, Ex. Y, Dr. Mikulak (Kline) Dep. Tr. at 38:11-15 ("Were Dr. Dorr's experiences with the Durom Cup, as stated in that passage, consistent with your own with respect to the patients that you revised? A. Yes").

> so they have some stability, it's just that **they have no bony ingrowth at all**, is what my experience was.[107]

6. Zimmer's post-market surveillance program failed to collect crucial information concerning revisions of US Durom Cups.

Zimmer would have been aware of these negative surgeon experiences with the US Durom Cup much earlier if it had put in place an effective post-market surveillance system. The program by which Zimmer collected information about product failures and complaints was called the Product Experience Report (PER) program.[108] The program predated the introduction of the US Durom Cup.[109] Throughout the existence of the US Durom Cup, Zimmer had procedures and policies in place as to how and when to file a PER for both its own employees and its independent sales force.[110] Those procedures required Zimmer employees and sales representatives to file a PER every time a "serious injury" with a Zimmer device occurred – a term that included any situation that necessitated a revision surgery.[111]

Although those procedures and policies may have existed on paper, the depositions of Zimmer sales representatives showed there was widespread confusion and even ignorance about Zimmer's PER program. One sales representative reported that he considered when to file a

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[107] Ex. AA, Dr. Smith Dep. Tr. at 34:6-35:17.

[108] **Exhibit KK**, Deposition Transcript of Sidney Dale Miller, dated Feb. 11, 2014 ("Miller Vol. I Dep. Tr.") at 52:20-53:1 ("Q. And my understanding is that during that time period, one of the ways in which Zimmer collected complaints about its products was through the Product Experience Report program; is that accurate? A. Yes, that's accurate.").

[109] *Id.* at 53:12-16 ("Q. Are you aware of when Zimmer first instituted a PER program? A. I'm not aware of the -- when the program was instituted. It predates my role as complaint supervisor in January of 2000.").

[110] *Id.* at 54:5-12 ("Q. Okay. And Zimmer has procedures in place for the filing of and when to file PERs for Zimmer employees and Zimmer distributors, correct? A. Zimmer has a procedure in place for the filing of PERs by Zimmer employees. There is also a procedure that has been developed for use by our sales force to train the sales force on filing Product Experience Reports.").

[111] *Id.* at 59:1-14 ("Q. All right. And looking if we can at page 2 of this document, here, there at the bottom of the page, we see that definition of serious injury in 21 CFR Part 803 that you and I discussed earlier, correct? A. Yes. That's correct. Q. And there are three subparts to it, the last one being, quote, an injury or illness that necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Do you see that? A. Yes, I see that.").

PER as a "gray area," and testified that no one from Zimmer ever discussed the policy with him.[112] Another testified that he was unaware that he had a responsibility to file a PER each time one of his surgeons had to revise a Zimmer implant that he had sold.[113]

As far back as December 2006, Zimmer was cited by the FDA following an inspection of the company's Winterthur, Switzerland plant because "[c]omplaint handling procedures for reviewing and evaluating complaints have not been implemented."[114] "Specifically," the FDA report went on to state, "[Zimmer] received **several complaints of device loosening (Durom Cup) which have not been investigated** . . . ."[115]

Given this evidence, it is in no way surprising that Zimmer did not timely receive reports of revisions involving the US Durom Cup between the time of its release, in May 2006, and Dr. Dorr's April 2008 letter. Tellingly, at the time of Dr. Dorr's CCJR comments, Zimmer had no record of any US Durom Cup revisions by Dr. Dorr, even though he had personally informed Zimmer's CEO that he had performed four US Durom Cup revisions in July of 2007.[116] Perhaps nothing better illustrates the extent to which Zimmer's post-market surveillance system failed to

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[112] **Exhibit LL**, Deposition Transcript of Phillip Mosser, dated Sept. 12, 2013 ("Mosser Dep. Tr.") at 22:13-23:5 ("Q. Okay. Well, as a sales representative there at InterMed Orthopedics, were you ever made aware of the product experience reporting process? . . . A. I -- I can't recall if it was ever specifically laid out to me. No. Q. Did you ever at any point develop an understanding that -- at InterMed Orthopedics -- you were required to file a product experience report whenever any one of your surgeons had a problem with a Zimmer product? A. It is -- it was -- it's kind of a gray area -- I think it still is today. I'm not sure -- what a problem with the product would be."); and Ex. LL, Mosser Dep. Tr. at 25:1-10 ("Q. Okay. And as far as InterMed Orthopedics' policy with respect to filing P.E.R.s, was that ever discussed with you by Mr. Secor or Mr. Cadarette? A. No. I'm not -- InterMed Orthopedics, I don't believe had a policy. It was Zimmer's policy. Q. Okay. Did anyone with Zimmer ever discuss with you 'Here's what the policy is with respect to P.E.R.s"? A. They never discussed the policy per se.").

[113] Ex. C, B. Jones Dep. Tr. at 73:14-20 ("Q. I'm not asking about the document. My question is: Were you required as a sales rep to fill out a PER every time you had one of your surgeons have to revise a Zimmer product that you had sold? A. I don't think I was completely aware of that, no.").

[114] **Exhibit MM**, FDA Inspection Report, dated Dec. 7, 2006 (Durom_AAB 00040121-122) (CIW Ex. 22).

[115] *Id.* (emphasis added).

[116] Ex. II, Email from PJ Paul to D. Dvorak, dated July 12, 2007 (CIW Ex. 135), at Durom_AAD 00015573.

timely collect information about US Durom Cup revision surgeries than the fact that, within weeks of Dr. Dorr's April 22 letter to the AAHKS, the number of US Durom Cup revisions known to Zimmer shot from two to over fifty.[117]

7. Zimmer's 2008 Investigation

Only after Dr. Dorr's letter to all American orthopedic surgeons and the attending fall-out, which resulted in Zimmer receiving word of dozens more revisions involving the US Durom Cup, did Zimmer decide to launch a formal investigation into the problems with the device. Even before the investigation was launched, however, Zimmer post-market surveillance head Dale Miller ("Miller") explained that it was the "pet theory" of the US Durom Cup product manager, Parker, that the product was failing because surgeons were using the wrong surgical technique in implanting the device.[118] Zimmer's actions during the course of the investigation indicate that Parker's "pet theory" was the preferred theory of the entire investigative team because, if true, it would allow Zimmer to blame the surgeons, rather than its product.

a. Zimmer once again ignored advice from engineers to conduct an animal study on the coating.

In the immediate aftermath of Dr. Dorr's April 22 letter, Zimmer heard from numerous voices outside of the company urging it to immediately undertake testing on the US Durom

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[117] Ex. KK, Miller Vol. I Dep. Tr. at 221:8-222:6 ("Q. April 22 to be exact. And looking at the PER chart, what this reflects is that within three weeks of Dr. Dorr's letter, Zimmer had received dozens of reports of revisions involving the Durom Cup, correct? A. I haven't done that analysis. I know that there was a certain point at which in May we were referring to approximately 45 to 50, so that appears consistent, but -- Q. And in May you're reporting somewhere between 45 and 50; is that correct? A. I believe that was the ball park figures we had used with our first contact with FDA. Q. And at the, at least according to this chart, at the beginning of the year your internal data is showing two, correct? A. That's correct. Q. All right. So it went from two to approximately 50 in a matter of months, correct? A. That's correct.").

[118] Exhibit NN, Deposition Transcript of Brian Parker, dated May 30, 2014 ("Parker Vol. II Dep. Tr.") at 438:24-439:6 ("Q. Yesterday we talked about during the February meeting that you called that there were discussions of modifications to the surgical technique, and I believe that those primarily came from Brian Parker, and you described that as Brian's, quote, pet theory at that time. Do you remember that? A. Yes. Yes.").

Cup's coating. Among those voices was Roy Bloebaum, Ph.D. ("Dr. Bloebaum"), a medical device researcher that Zimmer and Sulzer/Centerpulse had contracted with previously on "numerous occasions."[119] In a May 2, 2008 email addressed to the head of the Zimmer Durom investigative team, Johnson, Dr. Bloebaum wrote: "If ever there was a need for independent review of retrieved implants it is now! . . . **How many people need to be hurt before we get it right?**"[120] Ten days later, on May 12, 2008, Dr. Bloebaum contacted Johnson again, this time urging Zimmer to conduct testing immediately on the US Durom Cup to demonstrate "skeletal attachment of the plasma spray coating on the Durom [in] higher order load bearing animals (sheep, dog, or pig) . . . ."[121]

The designing surgeons of the original Durom acetabular component, Drs. Roberts and Grigoris, were also among those urging Zimmer to conduct animal testing on the US Durom Cup's coating following Dr. Dorr's AAHKS letter. Specifically, they authored a letter to Zimmer executive Weidenbenner, also a member of the Zimmer Durom investigative team, saying that in order to "prove" that the problems were not related to the new coating on the US Durom Cup, Zimmer needed to conduct:

> (a) a small RSA study using cups with the U.S. coating at Lund University, Professors Rydholm and Dr. Kesteris, the surgeons who carried out the original Durom RSA study; and (b) a mini-pig study to assess the in-growth potential of

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[119] **Exhibit OO**, Deposition Transcript of Erin Johnson, dated May 15, 2014 ("Johnson Vol. I Dep. Tr.") at 247:2-17 ("Q. [P]rior to May of 2008, did you have any sort of business dealings with Roy Bloebaum? A. Yes. I have worked with Roy on numerous occasions through many years. Q. Okay. And what is your understanding as to what Mr. Bloebaum's occupation is? A. He's a researcher. Q. And what occasions had you had to work with him on projects? A. Through the Centerpulse organization we had worked with him on different types of studies or different retrieval MOM studies. Through the Zimmer organization, I was his primary contact as it related to any retrieval or any work that we wanted done through his lab, so I was his primary point of contact.").

[120] **Exhibit PP**, Email from R. Bloebaum to E. Johnson, dated May 2, 2008 (CIW Ex. 406) at Durom_AAA 00000583 (emphasis added).

[121] **Exhibit QQ**, Email from R. Bloebaum to E. Johnson, dated May 12, 2008 (CIW Ex. 407) at Durom_AAA 00000584.

> the U.S. coating at Marburg University, Germany, Professor Wilke, identical to the one they have already performed for the original coating.[122]

As Dr. Roberts noted in his deposition testimony, these were the same two tests that he had urged Zimmer to conduct prior to the US Durom Cup's launch.[123] Once again, Zimmer ignored the advice of the device's two designing surgeons.

b. Zimmer's investigation was outcome-driven.

Instead of finally conducting the animal and clinical studies that had been recommended to it since 2005, the main thrust of Zimmer's Durom investigation consisted of in-person interviews with surgeons. One of the surgeons that Zimmer met with was California orthopedic surgeon Dr. Stephen Mikulak, who described his experience with a female Zimmer employee sent to interview him as follows:

> Q. Did someone tell you that Zimmer was blaming the surgeons?
>
> A. Cheryl Blanchard.
>
> Q. And how did she tell you that?
>
> A. She said that I needed to go for training on how to put a cup in, and that my loosening – the component loosening was due to the way I was putting the cup in. **And she didn't listen to what I was saying** about doing all these cases before and not having loosening and now having loosening in these cases. **She was looking for a way not to be responsible**. That was my opinion. . . . It left a bad taste in my mouth.[124]

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[122] **Exhibit RR**, Letter from P. Roberts & P. Grigoris to David Weidenbenner, dated July 14, 2008 (CIW Ex. 552) at Durom_AAA 00128243.

[123] Ex. B, Dr. Roberts Dep. Tr. at 153:15-154:13 ("Q. And what specifically did you suggest to Mr. Weidenbenner in this letter as far as in order to prove that it wasn't the surface coating that was causing the problems? A. Exactly what we had suggested before. Again, we stressed the importance of carrying out an RSA study. . . . . So that was our first suggestion and we thought we would get enough information out of that by six months to get reassurance that iff it was performing as expected. The second, again, it becomes repetition, but to suggest the mini pig study again, but by this stage we realised it had not been carried out. But, again, you could get data from that within 12 weeks.").

[124] Ex. Y, Dr. Mikulak (Kline) Dep. Tr. at 120:15-121:5 (emphasis added).

In the course of the investigation, Zimmer identified groups of surgeons who had "good" outcomes with the US Durom Cup and surgeons who had "bad" outcomes with the device, and used perceived differences in the two groups' surgical techniques as a basis for the investigative team's ultimate conclusion that the root cause of the failure of some US Durom Cups was improper surgical technique.[125] Based on that root cause conclusion, Zimmer decided in mid-July 2008 not to recall the US Durom Cup, but rather to temporarily suspend the sale of the device until an updated surgical technique manual and program could be devised.[126] Critically, one of the main authors of the updated surgical technique, Dr. Roberts, testified that there was nothing in this new surgical technique document that was not known to him or that he would not have included in such a document back in 2006 – had he been asked to assist Zimmer in drafting the original surgical technique document.[127] Among the additions to the updated surgical technique document that Zimmer distributed in August 2008 was an explicit statement warning surgeons not to reposition the cup after impaction.[128] Zimmer also finally implemented a

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[125] *See* Ex. S, Parker Vol. I Dep. Tr. at 302:1-12 ("Q. And I think we discussed this earlier. As we discussed, one of the bases for the plan that was adopted as reflected in the July 17, 2008, minutes was a comparison that the persons on the team did between a group of surgeons that Zimmer determined were having good results with the Durom Cup versus the techniques used by surgeons that Zimmer believed was having bad outcomes with the product, correct?
. . . A. Yes, correct.").

[126] *See* Ex. F, Weidenbenner Dep. Tr. at 235:1-18 ("Q. It's your understanding that ultimately the investigation that was launched following Dr. Dorr's letter to the AAHKS reached the conclusion that the root cause for the revision rates that some surgeons were reporting with respect to the American Durom Cup was a result of surgical technique; is that accurate? A. That is correct. Q. And as a result of that root cause conclusion, Zimmer temporarily suspended the sale of the American Durom Cup so that it could update its surgical technique brochure and implement a surgical training program. Is that consistent with your understanding? A. Yes.").

[127] Ex. B, Dr. Roberts Dep. Tr. at 164:17-22 ("Q. You said you identified crucial steps in the implantation technique. Were any of those crucial steps that you identified in the course of these meetings unknown to you in 2006? A. No, this was standard technique and teaching that we had been using since 2003.").

[128] Ex. S, Parker Vol. I Dep. Tr. at 134:6-12 ("Q. Ultimately, after the sale suspension and re-introduction of the Durom Cup in September of 2008, an explicit warning about repositioning the cup after final impaction was included in the surgical technique instructions, correct? A. Correct.").

mandatory surgeon training program.[129] Both of these actions had been recommended to Zimmer as far back as 2006.

c. Subsequent events show the flawed nature of Zimmer's investigation.

One of the surgeons whom Zimmer deemed as having "good" outcomes with the device, and who it relied upon in devising the new surgical technique that they promulgated in the August 2008, was Dr. Russell Illgen ("Dr. Illgen") of Wisconsin.[130] A fact that speaks volumes about the adequacy of Zimmer's investigation and chosen remedial measures, as well as the validity of its root cause conclusion, is that less than one year after Zimmer deemed Dr. Illgen's clinical outcomes "good," he submitted a paper for publication in which he announced a one-year failure rate of 11.1% among patients he and his practice group had implanted with the US Durom Cup.[131]

Following the reintroduction of the US Durom Cup back on to the market in September of 2008, sales of the device were so poor that at least one Zimmer sales representative referred to it as a "dead product."[132] The US Durom Cup was formally pulled from the market permanently in December of 2010.[133]

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[129] *See* Ex. NN, Parker Dep. Tr. at 336:9-16 ("Q. Okay. And at the end of the root cause investigation that was conducted in the summer of 2008, one of the programs that Zimmer put in place for the reintroduction of the American Durom Cup was mandatory web training for all surgeons who wanted to use the device, correct? A. Correct.").

[130] *See* Ex. NN, Parker Vol. II Dep. Tr. at 429:8-13 ("Q. Do you have an understanding as to why Dr. Illgen's participation was sought for the surgical training meeting? A. I understand these were surgeons using the product that during the investigation showed good results.").

[131] **Exhibit SS**, Richard L. Illgen, M.D., et al., *Large-Head Metal-on-Metal Total Hip Arthroplasty Using the Durom Acetabular Component at Minimum 1-Year Interval*, 25 J. ARTHROPLASTY 6, Supp. 1 (2010) at 26-30 (submitted on July 16, 2009).

[132] Ex. C, B. Jones Dep. Tr. at 142:10-13 ("Q. Okay. And in fact, it had gotten so bad that you were referring to the Durom cup here as a, quote, "dead product," weren't you? A. I did.").

[133] Ex. NN, Parker Vol. II Dep. Tr. at 431:7-12 ("Q. Do you recall at what point in 2010 the American Durom Cup was eventually pulled from the market by Zimmer? A. It was December.").

8. Known vs. Actual Revision Rate

According to Zimmer's own internal records, the company sold 17,186 US Durom Cups during the time the device was on the market in the United States.[134] Of these, Zimmer was aware of 1,762 US Durom Cups that have been revised as of December 31, 2013.[135] Thus, the *known* revision rate is 10.25%.[136] However, as Zimmer post-market surveillance executive Miller acknowledged, the *known* or *reported* revision rate is not the same thing as the *actual* revision rate.[137] As the emphasized language indicates, the 10.25% revision rate that Zimmer admits consists only of those revisions that Zimmer has become aware of through its internal complaint reporting system. There is considerable evidence that suggests the actual revision rate for the device is much higher.

First, Zimmer's former vice president of regulatory affairs, Michael Carter ("Carter"), admitted that "the medical device industry knows, in general, **it's a broad-brushed systemic issue in the industry that complaints are underreported**."[138] Carter listed several reasons why revisions are underreported: (1) the sales representatives whom Zimmer counts on to report issues are given no incentive to report revisions or other problems;[139] (2) if a revised Zimmer product is replaced with a non-Zimmer product, a sales representative would not be in the

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[134] *See* **Exhibit TT**, Letter from J. Mortier to G. Henderson, dated Apr. 30, 2014.
[135] *See id.*
[136] *See id.*
[137] Ex. KK, Miller Vol. I Dep. Tr. at 240:5-23 ("Q. Okay. And just by way of background here, a revision rate, as you alluded to, the denom -- in order to calculate a revision rate, you have a denominator which is the total amount of Durom cups sold and then -- or Durom cups implanted rather? A. Implanted. Q. And then the numerator is the number of Durom Cups revised, correct? A. Yes. Q. Is that what we're talking about when we talk about a Durom Cup revision rate? A. **Yes, or at least our known revision rate**. Q. Right. A. So the -- Q. And I guess that's a -- A. -- revised cups. Yeah. In fact, in many cases I would -- in my conversations **I would refer to it as a reported revision rate**.") (emphasis added).
[138] **Exhibit UU**, Deposition Transcript of Michael Carter, dated Nov. 15, 2013 ("Carter Dep. Tr.") at 108:14-17 (emphasis added).
[139] *Id.* at 152:6-11 ("Well, sales -- sales reps, especially in orthopedics, they're also tech support during the surgery and they're not necessarily incentivized if -- while they're in the surgical suite, if there's an issue, to recognize it and report it. There's really no incentive for them to do that.").

surgical suite for the revision surgery, and thus, would not be aware of the revision;[140] and (3) a lack of complaint report training for sales representatives.[141] Consistent with Carter's last cited factor, Zimmer's former head of post-market surveillance, Miller, admitted that, in the course of his employment at Zimmer, he had "come across instances of sales reps reporting that they are unaware" of their obligation to report product complaints.[142] In sum, there is ample testimony from current and former Zimmer employees to suggest that the *actual* revision rate for the US Durom Cup is much higher than the *reported* revision rate of 10.25%.

Second, published clinical studies also indicate that the *actual* revision rate for the US Durom Cup is higher than 10.25%. As noted above, Dr. Illgen, a surgeon who Zimmer identified as using the proper surgical technique during its 2008 investigation, reported a revision rate of 11.1% among the patients he and his colleagues implanted with the US Durom Cup *after just one year.*[143] Meanwhile, in the peer-reviewed article Drs. Long and Dorr ultimately published on their experience with the US Durom Cup, they reported a revision rate of 15% among patients they implanted with the device *after just two years.*[144] Other surgeons have testified to revision rates exceeding 40% after eight years.[145]

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[140] *Id.* at 153:8-16 ("Q. In your experience, if a surgeon is going to perform a revision surgery of a Zimmer product and put in a competitor's product, do you know if the Zimmer sales representative would -- would attend that surgery? A. No, and that – . . . that would be one -- one way revision surgeries would fly under, you know, the radar and us never know about it.").

[141] *Id.* at 153:2-5 ("Q. Are there other reasons for underreporting? Certainly training is a possible aspect of that.").

[142] Ex. KK, Miller Vol. I Dep. Tr. at 80:21-22.

[143] Ex. SS, Richard L. Illgen, M.D., et al., *Large-Head Metal-on-Metal Total Hip Arthroplasty Using the Durom Acetabular Component at Minimum 1-Year Interval*, 25 J. ARTHROPLASTY 6, Supp. 1 (2010) at 26-30.

[144] **Exhibit VV**, William T. Long, et al., *Failure of the Durom Metasul Acetabular Component*, CLIN ORTHOP RELAT RES (2010) 468:400-405.

[145] **Exhibit CCC**, Deposition Transcript of Dr. Cambize Shahrdar, dated June 11, 2014 ("Dr. Shahrdar Dep. Tr.") at 24:6-11 ("So then out of those 77 implants over 30 have been revised. . . . That's very high. That would be over 40 percent in less than eight years.").

Even if the *actual* revision rate for the US Durom Cup was 10.25%, as Zimmer reports, it would still be far in excess of what is considered an acceptable rate. For example, Dr. Roberts testified that up through 2013, the government of the United Kingdom considered a 1% failure rate a year for a hip implant product to be the baseline for what is considered "acceptable."[146] Obviously, a failure rate of 10.25% for hips between three and seven years old[147] would be significantly in excess of that number.

B. Procedural History

On March 16, 2011, Plaintiffs – at that time eleven persons – filed their Complaint alleging that each and every Plaintiff had been "implanted with the defectively designed and manufactured Zimmer Total Hip Replacement Components."[148] Since that filing, additional US Durom Cup recipients have been added as Plaintiffs to the lawsuit.[149]

Pursuant to the Case Management Order entered on November 14, 2013, the deadline for "all common issue fact discovery" was May 30, 2014.[150] The trial for the first bellwether Plaintiff, John Pugliese ("Pugliese"), is set for November 3, 2014.[151]

III. STANDARD OF REVIEW

735 ILCS 5/2-604.1 (hereinafter, "Section 2-604.1") states, in relevant part, that "a plaintiff may, pursuant to a pretrial motion and after a hearing before the court, amend the complaint to include a prayer for relief seeking punitive damages." According to Section 2-604.1, leave should be granted "if the plaintiff establishes at such a hearing **a reasonable likelihood** of proving facts at trial sufficient to support an award of punitive damages." "When

[146] Ex. B, Dr. Roberts Dep. Tr. at 355:2-4 ("Well, in the United Kingdom up until two months ago the accepted failure rate was approximately 1% a year . . . .").
[147] All US Durom Cups were implanted between 2006 and 2010.
[148] Pls.' Compl. at ¶ 19.
[149] *See* Pls.' Eighth Am. Compl.
[150] Case Management Order, dated Nov. 14, at ¶ B.5.
[151] *Id.* at ¶ D.10.

faced with conflicting evidence, "the question of whether a defendant's conduct was sufficiently willful or wanton to justify the imposition of punitive damages is for the jury to decide.""[152] A circuit court's ruling on this issue will not be reversed absent an abuse of discretion.[153]

IV. ARGUMENTS AND ANALYSIS

According to a leading Illinois Supreme Court case on the subject of punitive damages, *Loitz v. Remington Arms Co., Inc.*, 563 N.E.2d 397 (Ill. 1990), punitive damages may be awarded in a tort case where the "torts are committed with fraud, actual malice, deliberated violence or oppression, or when the defendant acts willfully, or with such gross negligence as to indicate a wanton disregard of the rights of the others."[154] The *Loitz* Court explained that willful and wanton misconduct includes situations in which the defendant "deliberately inflicts a highly unreasonable risk of harm upon others in conscious disregard of it."[155]

In the instant matter, Plaintiffs have asserted strict products liability and negligence causes of action arising out of Zimmer's design, manufacture, and marketing of the US Durom Cup.[156] These claims are discussed in turn, *infra*.

A. Plaintiffs' Strict Products Liability Claims

To recover on a strict products liability cause of action, "a plaintiff must plead and prove that the injury resulted from a condition of the product, that the condition was an unreasonably dangerous one, and that the condition existed at the time the product left the manufacturer's

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[152] *Jablonski v. Ford Motor Co.*, 923 N.E.2d 347, 395 (Ill. App. Ct. 2010) (quoting *Cirrincione v. Johnson*, 703 N.E.2d 67, 70 (Ill. 1998)).
[153] *Proctor v. Davis*, 682 N.E.2d 1203, 1216 (Ill. App. Ct. 1997) (citing *Levy v. Markal Sales Corp.*, 643 N.E.2d 1206 (Ill. 1994)).
[154] *Loitz v. Remington Arms Co., Inc.*, 563 N.E.2d 397, 402 (Ill. 1990) (quoting *Kelsay v. Motorola, Inc.*, 384 N.E.2d 353 (Ill. 1978)).
[155] *Id.* (quoting *Breslund v. Ideal Roller & Graphics Co.*, 501 N.E.2d 830 (Ill. 1986)).
[156] *See* Pls.' 8th Am. Pet.

control."[157] A product may be found unreasonably dangerous in three different ways: "by virtue of a physical flaw, a design defect, or a failure of the manufacturer to warn of the danger or instruct on the proper use of the product as to which the average consumer would not be aware."[158] Meanwhile, the essential elements of willful and wanton conduct in a product liability case include: (1) knowledge of the defect; (2) knowledge or notice that the defect was likely to cause injury; and (3) failure to warn of or remedy a known defect or take some other affirmative action to avoid the injury.[159]

In the instant matter, Plaintiffs' experts have identified a myriad of ways in which the US Durom Cup was "unreasonably dangerous," including, but not limited to: (1) a design defect in the device's coating; and (2) a failure of Zimmer to warn surgeons about the dangers of repositioning the device after impaction. As discussed below, the evidence shows that Zimmer was aware of these defects, knew they would likely cause harm, and yet took no action to prevent the harm from occurring.

1. **Strict Products Liability – Design Defect**

According to Plaintiffs' expert Dr. Bloebaum, *supra*, a Research Professor in the Departments of Orthopaedics, Bioengineering and Biology at the University of Utah, "[t]he coating and surface treatment of the Zimmer US Durom Cup prevented bone ongrowth and ingrowth to secure the implant to the skeleton causing loosening and patient discomfort."[160] Notably, Dr. Bloebaum has been hired by Zimmer on previous occasions to analyze surface coatings prior to their release.[161] In analyzing the US Durom Cup's coating for this litigation,

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[157] *Sollami v. Eaton*, 772 N.E.2d 215, 219 (Ill. 2002) (citation omitted).
[158] *Id.* (citation omitted).
[159] *Jablonski*, 923 N.E.2d at 395 (quoting *Collins v. Interroyal Corp.*, 466 N.E.2d 1191, 1999 (1984)).
[160] **Exhibit WW**., Expert Report of Roy D. Bloebaum, Ph.D., dated June 16, 2014 ("Dr. Bloebaum Expert Report"), at 23.
[161] *See id.* at 2-3.

Dr. Bloebaum cited, *inter alia*, the coating's lack of pore openings, the presence of surface contaminants as a result of grit blasting on the coating, and the coating's smoothness as factors in rendering it defective.[162] Dr. Bloebaum concluded that "the coating on the US Durom Cup was unreasonably dangerous, and should have never been released on to the market."[163]

As set out above, there is ample evidence that Zimmer was aware of problems with the coating on the US Durom Cup.[164] Numerous persons, both inside and outside the company, raised concerns about it prior to the US Durom Cup's market release in May of 2006.[165] Indeed, the FDA itself directly disagreed with Zimmer's stated assessment that the US Durom Cup's coating was "porous" and would promote "biological fixation."[166] Zimmer was further aware that if this coating did not adequately promote "biological fixation," it would fail in humans.[167] In the months following its release, experts Zimmer had previously trusted continued to raise doubts about the efficacy of the coating.[168] In spite of all this, Zimmer took no affirmative steps to improve the coating or even verify its efficacy until *after* Dr. Dorr's April 2008 letter to the AAHKS. When it finally performed the animal testing Dr. Roberts had been urging since 2005, the protocol it used was scientifically unsound and rendered the results meaningless.[169] Taken together, this conduct represents Zimmer deliberately inflicting a highly unreasonable risk of harm upon the patients implanted with the US Durom Cup in conscious disregard of the risk the device posed.

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[162] *See id.* at 9.
[163] *Id.* at 26.
[164] *See supra* §II.A.2.b-c, *see also supra* §II.A.4.
[165] *See supra* §II.A.2.b-c, *see also supra* §II.A.4.
[166] *See supra* §II.A.2.c.
[167] *See* Ex. OO, Johnson Vol. I Dep. Tr. at 36:1-14 ("Q. All right. And the success of any total hip arthroplasty or resurfacing procedure involving either version of the Durom Cup depended in part on whether that Durom Cup achieved long-term fixation in the acetabulum, correct? . . . A. Yes, that's correct.").
[168] *See supra* §II.A.4.
[169] *See* Ex. WW, Dr. Bloebaum Report at 21-22.

2. Strict Products Liability - Failure to Warn

As noted above, Dr. Roberts, the designing surgeon of the Durom acetabular component, testified that repositioning the US Durom Cup after impaction will result in almost certain failure of the implant.[170] He further noted that the practice of repositioning acetabular components after impaction among a large number of American orthopedic surgeons is well known, a fact that has been corroborated by surgeons and Zimmer sales representatives.[171] Within a few months of the product's release, Zimmer's CEO was actually told by Zimmer's hand-picked surgeon-investigator, Dr. Dorr, that he was repositioning the device after impaction.[172] Given these circumstances, there is evidence that Zimmer both knew of the danger posed by the US Durom Cup if it was repositioned after impaction and was aware that repositioning after impaction was a common practice among American surgeons, yet it failed to include any warning or instruction **not** to reposition the US Durom Cup in its official surgical technique until August of 2008 – over two years after the product was released on to the market. Again, this conduct shows Zimmer deliberately inflicting a highly unreasonable risk of harm upon the patients implanted with the US Durom Cup in conscious disregard of the risk the device posed when implanted in the manner described above. Indeed, even its own former director of clinical affairs, Russell Schenck, agreed that if Zimmer was putting out a product that could not be repositioned during surgery that they needed to tell surgeons that fact.[173]

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[170] *See supra* §II.A.3.b.
[171] *See supra* §II.A.3.b; *see also supra* FN 67.
[172] *See* Ex. GG, Email from Raymond Elliott to Various, dated Oct. 23, 2006 (CIW Ex. 231) at Durom_AAA 00150996.
[173] **Exhibit XX**, Deposition Transcript of Russell Schenck, dated May 22, 2014 ("Schenck Dep. Tr.") at 71:15-72:5 ("Q. Okay. Let me -- one final thing in Mr. Cadarette's deposition. There's this last statement here or question and answer at the end of page where it says: "Question: Would you agree that if Zimmer was putting out a product that could not be repositioned during surgery that they needed to tell surgeons that fact? "Answer: Yes." Do you agree with Mr. Cadarette on that point that Zimmer had a

B. Negligence Claims

In order to add punitive damages claims to negligence causes of action, a plaintiff must establish a reasonable likelihood that he or she can prove: (1) "the basic elements of a negligence claim – that the defendant owed a duty to the plaintiff, that the defendant breached that duty, and that the breach was a proximate cause of the plaintiff's injury"; and (2) that the defendant had "either a deliberate intention to harm or a conscious disregard for the plaintiff's welfare."[174]

1. Negligent Design

Manufacturers have "a nondelegable duty to design reasonably safe products."[175] In order to evaluate whether a product is reasonably safe, "the plaintiff must provide some evidence that the manufacturer: (1) deviated from the standard of care that other manufacturers in the industry followed at the time that the product was designed; or (2) knew or should have known, in the exercise of ordinary care, that the product was unreasonably dangerous and that it failed to warn of the product's dangerous propensity."[176] Given the technical nature of these claims, "the plaintiff must provide expert testimony on the standard of care and a deviation from that standard in order to establish either of these propositions."[177]

In the instant matter, Plaintiffs' expert Dr. Bloebaum has identified the coating on the US Durom Cup as "unreasonably dangerous" for the reasons discussed above.[178] Additionally, he contrasted the standard of care shown by Sulzer/Centerpulse in developing the EU Durom Cup with the standard of care exhibited by Zimmer in developing the US Durom Cup, explaining that

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responsibility to warn surgeons that they could not reposition this particular cup? A. So -- so, as stated, I would agree with the statement.").

[174] *Jane Doe-3 v. McLean Cnty. Unit Dist. No. 5 Bd. of Directors*, 973 N.E.2d 880, 887 (Ill. 2012).

[175] *Salerno v. Innovative Surveillance Tech.*, 932 N.E.2d 101, 111 (Ill. App. Ct. 2010) (quoting *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 264 (Ill. 2007))

[176] *Id.* at 111-12 (quoting *Blue v. Envtl. Eng., Inc.*, 828 N.E.2d 1128, 1141 (Ill. 2005)).

[177] *Id.* at 112 (citing *Blue v. Envtl. Eng., Inc.*, 828 N.E.2d 1128, 1143 (Ill. 2005)).

[178] *See supra* §III.A.2.b-c.

the latter did none of the pre-market testing – animal, clinical or RSA – that the former did.[179] Meanwhile, Dr. George Samaras ("Dr. Samaras"), an engineer specializing in regulated medical devices, set out in his report the numerous ways in which Zimmer's design process for the US Durom Cup deviated from well-accepted engineering standards and governmental regulations.[180] Taken together, these acts and omissions evidence a "conscious disregard" for the welfare of patients.

In fact, the egregiousness and nature of Zimmer's omissions are similar to those cited by the Fifth District in *Jablonski*, *supra*, where the court was asked to review the sufficiency of the evidence supporting a punitive damages award against Ford on a theory of negligent design of a fuel tank system that exploded when the plaintiffs' Lincoln Town Car was rear-ended.[181] There, the Fifth District upheld the punitive damages verdict on the basis of evidence showing that: (1) Ford had knowledge that the at-issue fuel tank system had a higher rate of post-collision fires than other fuel tank systems;[182] and (2) Ford's own engineers had advised it to stop using the at-issue fuel tank system because of post-collision fire concerns.[183] As in *Jablonski*, there is evidence in this case that: (1) Zimmer had knowledge early on that the US Durom Cup was

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[179] Ex. WW, Dr. Bloebaum Expert Report at 6 ("The steps taken by Sulzer to validate the efficacy of the coating on the European Durom Cup represent the actions of a responsible company, and stand in stark contrast to those later taken (or not taken) by Zimmer vis-à-vis the US Durom Cup's coating.").

[180] **Exhibit YY**, Expert Report of George Samaras, Ph.D., dated June 16, 2014 ("Dr. Samaras Expert Report"), at 4-5.

[181] *See Jablonski*, 923 N.E.2d at 356 (explaining that plaintiffs' claims were "focused upon the design of the fuel tank system in the 1993 Lincoln Town Car.").

[182] *See id.* at 396 ("Here, although the evidence of Panther platform vehicles involved in prior similar occurrences represented a small percentage of the total Panther platform vehicles manufactured, additional evidence presented by the plaintiffs revealed that Panther platform vehicles had a higher rate of postcollision fires when subjected to a higher rate of postcollision fires when subjected to high-speed rear-end collisions than vehicles designed with a forward-of-the-axle fuel tank. The evidence was compiled by a Ford employee prior to the accident in this case.").

[183] *See id.* at 396 ("In addition . . . . Ford's own engineers had advised it not to use aft-of-the-axle fuel tanks in its vehicles long before the Panther platform was manufactured, due to safety concerns related to postcrash fires . . . . .").

failing at an abnormally high rate;[184] and (2) the product's own designers had raised concerns about the device before it was put on to the market.[185]

2. Negligent Failure to Warn

"A manufacturer has a duty to warn where the product possesses dangerous propensities and there is unequal knowledge with respect to the risk of harm, and the manufacturer, possessed of such knowledge, knows or should know that harm may occur absent a warning."[186] As set out above, Zimmer was well aware of both the dangers posed by repositioning the US Durom Cup after impaction and the fact that many Americans typically repositioned acetabular components after impaction, yet it failed to include any warning about this practice until August of 2008.[187] Again, this inaction demonstrated a "conscious disregard" for the health of patients.

3. Other Acts and Omissions

Plaintiffs believe that numerous other factors support a finding of punitive damages beyond the issues cited herein, including but not limited to, the failure of the PER system, the failure of Zimmer to timely supplement and update the surgical techniques, poor design of the monoblock cup causing deformation, failure to address complaints launched in Europe about EU Durom Cup failures and the failure of Zimmer to timely address the concerns of Dr. Dorr or to cease sales of the product during the 2008 investigation. However, Plaintiffs have limited this motion to only a few of the many willful and wanton actions of Zimmer for the purposes of judicial economy. Plaintiffs hereby reserve their right to rely upon all of Zimmer's willful and wanton conduct in support of their punitive damage case at trial.

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[184] Zimmer was aware of several failures in patients implanted with the US Durom Cup by its hand-picked surgeon-investigator Dr. Dorr as early as July 2007. *See supra* §II.A.4.
[185] *See supra* §II.A.2.b.
[186] *Sollami*, 772 N.E.2d at 219 (citation omitted).
[187] *See supra* §II.A.3.b; *see also supra* FN 67.

V. CONCLUSION

For the reasons discussed above, Plaintiffs hereby request that the Court grant Plaintiffs leave of court to amend their complaint to include a prayer for relief seeking punitive damages.

DATED: June 30, 2014.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing instrument was served upon the attorneys of record of all parties to the above cause via e-mail, on this 30th day of June, 2014.

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EXHIBIT D

Filed 4/27/18 Kline v. Zimmer, Inc. CA2/8

NOT TO BE PUBLISHED IN THE OFFICIAL REPORTS

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION EIGHT

GARY KLINE, Plaintiff and Appellant, v. ZIMMER, INC., Defendant and Appellant.	B269317 (Los Angeles County Super. Ct. No. BC444834)

APPEAL from orders of the Superior Court of Los Angeles County, Amy D. Hogue, Judge. Affirm in part; reversed in part and remanded.

Waters Kraus & Paul and Michael B. Gurien for Plaintiff and Appellant.

Reed Smith, Paul D. Fogel, Lisa M. Baird, David J. de Jesus; Faegre Baker Daniels, Tarifa B. Laddon, J. Stephen Bennett and J. Joseph Tanner for Defendant and Appellant.

* * * * * *

This appeal and cross-appeal arise out of Gary Kline's two hip surgeries. The hip is a ball and socket joint; a total hip replacement involves replacing both with components that mimic the ball and socket. In May 2007, plaintiff Kline underwent a total hip replacement, which included implantation of the Durom Acetabular Component (Durom Cup), a component manufactured by defendant Zimmer, Inc. (Zimmer). The Durom Cup, a metal component, was implanted around another metal component and was fixated in Kline's body without screws. The Durom Cup replaced the acetabulum, i.e., the socket portion of the hip joint. Kline claims that the Durom Cup was defective.

Kline's second operation, in September 2008, involved the removal and replacement of the Durom Cup. At trial, Kline claimed that the Durom Cup was defective; Zimmer failed to adequately test it prior to selling it in the United States; and Zimmer failed to provide adequate warnings. The 17-day trial was interspersed with numerous objections and motions for mistrial. Ultimately, after deliberating for three hours, jurors found in Kline's favor awarding him $153,317 in economic damages and $9 million in noneconomic damages, substantially more than Kline's counsel had requested during closing argument.

Following the jury verdict, the trial court denied Zimmer's motion for a judgment notwithstanding the verdict, finding sufficient evidence to support the verdict. The trial court granted Zimmer's motion for a new trial on two grounds—irregularity in the proceedings caused by Kline's counsel's misconduct and excessive damages. With respect to the misconduct, the court concluded that Kline's counsel improperly suggested to jurors that they "should award large damages for any finding of

liability." (Italics, underscoring and capitalization omitted.) The court ordered a new trial unless Kline accepted a reduced amount of damages, an alternative Kline rejected.

We affirm in part and reverse in part. We affirm the order granting Zimmer's motion for new trial on damages. The trial court acted well within its discretion in concluding that the damages were excessive. However, we find no support for Zimmer's argument that the case warranted another trial on liability. Although the trial court found that Kline's counsel committed misconduct amounting to irregularities in the proceedings, the misconduct was almost entirely directed at the amount of damages. With limited exceptions, it had no bearing on liability. Review of the lengthy trial record shows that no improper evidence was admitted with respect to liability, and no improper argument was made concerning liability. Because Zimmer suffered no prejudice with respect to liability, the new trial should be limited to damages.

We further reject Zimmer's challenge to the sufficiency of the evidence to demonstrate a design defect, which the trial court considered in the context of Zimmer's motion for a judgment notwithstanding the verdict on both the design defect and failure to warn claims. Compelling evidence supported Kline's theory that the coating on the Durom Cup was defective. The coating did not have sufficient porosity for bone ingrowth or ongrowth necessary for fixation without screws. With respect to Kline's failure to warn theory, we conclude Kline failed to present any evidence of causation. We remand the case to the trial court for a new trial on damages related to the design defect of the Durom Cup.

FACTS

1. Hip Replacement Surgery and the Durom Cup

A total hip replacement involves removing a small layer of bone in a person's hip socket, impacting a shell into the socket, wedging a prosthesis into the bone, and placing the ball into the shell. The Durom Cup is a shell used to surround the ball. The version of the Durom Cup sold in the United States had a smoother coating than the Durom Cup sold in Europe.

Bone growth was necessary to permanently stabilize the Durom Cup, and without such stability a patient would experience pain. A rough surface is required to achieve bone ingrowth or ongrowth. It was undisputed that the version of the Durom Cup sold in the United States was smoother than the European version, which preceded the American one.

Dr. Roy Bloebaum, a research professor in bioengineering and biology, concluded that the coating on the Durom Cup sold in the United States was defective because it did not allow for bone ingrowth or ongrowth. Bloebaum explained the coating is "defective in the context that it didn't achieve the goals for ingrowth and attachment, the appropriate material presentation to the bone so you could achieve attachment. It didn't have the proper open porosity for the bone to grow into it."

Dr. Bloebaum further explained that the American Durom Cup had a different coating than the European one. According to Bloebaum, tests of the European coating do not show that the coating in the United States could achieve skeletal attachment. Bloebaum expressed concern that Zimmer did not conduct an animal study to test the new coating. He testified: "[I]t's a basic scientific principle that when you make a change, you need to

test that change." Prior to this case, Zimmer repeatedly hired Bloebaum and credited him as a reliable researcher.

Dr. Paul Roberts, along with others, developed the European version of the Durom Cup. The European coating was tested on animals. The test was designed to determine the quality of bone ingrowth. Roberts was involved in discussions about the development of a new coating for the American Durom Cup because the "European-type coating didn't meet the FDA[1] requirements." Roberts expressed concern that that pore size, porosity, surface roughness, and adhesive strength were not independent. One could not be altered without affecting the others. Roberts testified that the proposed change to the American coating "may adversely affect the biological fixation of the cup in the long term." Roberts recommended Zimmer conduct the same testing on the American coating that had been conducted on the European coating. This included an animal study. Roberts testified "that testing should be carried out before marketing to at least show that it was as good in an animal model and that over time in vivo studies . . . should go ahead."

Zimmer did not clinically test the coating on the American Durom Cup prior to selling it. Zimmer conducted no tests to "establish[] scientifically that its coating would be effective at achieving skeletal attachment." The FDA did not require animal testing, and Zimmer did not conduct any.

After Zimmer started selling the Durom Cup in the United States, it asked Dr. William Thomas Long, an orthopedic surgeon specializing in hip and knee replacement, to investigate the Durom Cup. Long observed that the coating on the Durom Cup

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1 United States Food and Drug Administration.

was not rough. Long discussed with Zimmer representatives his concerns "about the cup's ability to achieve bony fixation." Prior to Kline's surgery, Long warned Zimmer that the Durom Cup had a significant failure rate. Zimmer took no action as a result of Long's warnings. When Long removed the Durom Cup from patients, who (like Kline) required revision surgeries, he found no bone ingrowth.

Zimmer's business plan reflected an effort to conceal the difference between the European and American coatings. Porolock was the name of the coating on the European version of the Durom Cup. Zimmer's business plan provided: "To avoid unpleasant rumors on the markets and attacks from competitors, we have to keep quiet the development of the new coating. Therefore we will use the trademark Porolock as well for the new coating so there will be only little changes in the existing brochures and the cups will not be exposed to strong critics."

2. Kline's Condition and His Hip Surgeries

Before he developed osteoarthritis in his right hip, Kline enjoyed using the gym, playing golf, hiking, bike riding, motorcycle riding, and hunting. As a result of osteoarthritis, Kline suffered severe pain daily. He had difficulty walking and climbing stairs. Putting on his shoes and socks was painful, and Kline used narcotic and anti-inflammatory medication to control his pain. As a result of his hip pain, Kline visited orthopedic surgeon Dr. Stephen Mikulak in 2007. At the time he visited Mikulak, Kline had suffered from hip pain for two years.

Kline decided to have hip replacement surgery, and at the age of 51, underwent the procedure. As part of Kline's first hip surgery, Dr. Mikulak implanted a Durom Cup. When using the

Durom Cup, Mikulak generally "ream[s] line to line, which is the exact size of the cup." Brian Huscher, a representative of Zimmer was present in the operating room during Kline's initial surgery.[2]

Initially, Kline progressed well after his hip replacement surgery. Then, just over a year after the surgery, Kline began experiencing regular "jolts" in his hip, causing him excruciating pain. When his hip "froze," and he suffered "severe pain," he visited Dr. Mikulak again. Mikulak informed Kline that the Durom Cup may be loose and that he may need another surgery. Until he underwent the revision surgery, Kline experienced severe pain, rendering him immobile. Such pain was unusual following hip replacement surgery. Mikulak testified that about 95 to 98 percent of his patients fully recovered after a total hip replacement.

Following the revision surgery, Kline's pain improved. But his recovery was complicated by the need for two major surgeries (the hip replacement and the revision surgery) in a 15-month period. The multiple surgical procedures may have caused Kline to suffer damage to his right leg.

A "couple years" after his revision surgery, Kline developed stiffness and discomfort in his right hip. Beginning in September 2010, Kline visited a rheumatologist for this pain. In addition to hip pain, Kline also suffered from hand pain, back pain, muscle aches, and knee pain. Kline had osteoarthritis near his tail bone

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[2] Dr. Mikulak did not read Zimmer's brochure describing the surgical technique to implant the Durom Cup because, according to him, he had performed numerous surgeries and did not "need a person in a suit to tell me how to do surgery . . . ." However, Mikulak testified that he expected that Zimmer's representative would have informed him of any necessary special technique, and Huscher did not inform him of any such special technique.

and in his low back. His rheumatologist concluded that he had damage to muscles, nerves and tissues in his right leg because of his multiple hip surgeries.

The rheumatologist prescribed prednisone (an anti-inflammatory), Skelaxin (a muscle relaxant), and meloxicam (an anti-inflammatory). In 2012, when Kline stopped taking prednisone, he felt pain. As a result, Kline continued to take prednisone, which eventually could cause osteoporosis, diabetes, elevated blood pressure, adrenal insufficiency, and weight gain. Kline's discomfort in his right hip would return each time he stopped taking prednisone.

Kline stopped playing golf, hiking and biking because of pain in his right hip. Kline sometimes walked with a cane. As a witness for Zimmer acknowledged, Kline's recovery may have been hampered by having two surgeries instead of one. Additional surgeries increase the chance of infection as well as scar tissue.

All of Kline's witnesses testified that Dr. Mikulak properly performed both the initial and the revision surgery. Mikulak testified that nothing he did or failed to do in the operating room caused the Durom Cup to fail. Dr. Ryan Nunley, an orthopedic surgeon, testified that he had no criticism of Mikulak's surgery. According to Nunley, "[i]t was done well and very standard." He also believed Mikulak properly performed the revision surgery.

In addition to testifying that Dr. Mikulak properly performed the surgeries, Dr. Nunley testified that successive operations may cumulatively affect a patient. He testified that Kline's Durom Cup was not permanently secured and that a loose cup can cause severe pain. According to him, nothing "would have prevented a full recovery after implantation with a non-

defective component." Nunley estimated that absent implantation with the defective Durom Cup, Kline would have been able to perform 95 percent of the activities he previously enjoyed. According to Nunley, following a revision surgery, patients recover about 75 to 85 percent of their prior ability to perform activities.

3. Dr. Mikulak's Experience with the Durom Cup Including Kline's Durom Cup

As noted, Dr. Mikulak performed both Kline's initial hip replacement surgery and the revision surgery in which Kline's Durom Cup was replaced. The revision surgery confirmed Mikulak's suspicion that the Durom Cup was loose. Mikulak observed that "[t]here was no bone anchoring the cup." According to Mikulak, the Durom Cup did not work as intended because bone did not grow onto it to permanently stabilize it.

Dr. Mikulak had not been informed that the coating on the American Durom Cup differed from the European one. Zimmer's sales representative responsible for working with Mikulak was not aware that there were differences in the coating between the European Durom Cup and the American version (both of which bore the same name).

Dr. Mikulak testified that he performed about 30 operations to remove Durom Cups, and none had bone ingrowth or ongrowth. According to Mikulak, the surface of the Durom Cup when it was removed looked the same as when it had been implanted. Mikulak testified that the failure rate of the Durom Cup was significantly higher than with other cups except the "Inter-Op Cup." Absent infection, the acceptable failure rate of an implant in the first two years was 0 percent. Other witnesses

also concluded that the failure rate of the Durom Cup was unacceptably high, and the elevated revision rate demonstrated a defect in the Durom Cup.

4. FDA Review of the Durom Cup

Other than the coating, the European and American versions of the Durom Cup were the same. The texture of the American version was modified to comply with FDA regulations.

The FDA reviews new medical devices more extensively from those categorized as equivalent to existing devices. New devices require premarket approval, a process by which the FDA determines if the device is safe and effective. Other devices are analyzed under the FDA's premarket notification (510(k) process), which is less rigorous. As one court has explained: "The 510(k) process allows some medical devices to avoid the strict safety testing requirements imposed by the Medical Device Amendments ('MDA') to the Federal Food, Drug, and Cosmetic Act, so long as the device is 'substantially equivalent' to a pre-1976 device already in use at that time. [Citation.] Thus, devices approved under the 510(k) process 'may be marketed without premarket approval' as would be required by the MDA, although they 'are subject to "special controls . . . that are necessary to provide adequate assurance of safety and effectiveness." ' [Citation.] In this respect, although the process is certainly not a rubber stamp program for device approval, it does operate to exempt devices from rigorous safety review procedures." (*In re C.R. Bard, Inc.* (4th Cir. 2016) 810 F.3d 913, 920.) " 'Thus, even though the FDA may well examine 510(k) applications . . . with a concern for the safety and effectiveness of the device,' the agency's clearance rests only on whether the device is

'substantially equivalent to one that existed before 1976' before allowing it 'to be marketed without running the gauntlet of the [MDA premarket approval] process.' " (*Id.* at pp. 920-921.)

Zimmer applied for and received clearance for the Durom Cup under the FDA's 510(k) process. George Samaras, a biomedical engineer and former employee of the FDA, testified that the 510(k) process considers whether other similar products are already on the market and compares the product under review to the similar products. It does not determine whether a product is safe and effective. The FDA sent Zimmer a letter indicating that it could sell the Durom Cup in the United States. Samaras testified that the coating in the United States had "not been tested for its intended use with intended users." As noted, the FDA did not require animal testing.

5. Zimmer's Evidence

Zimmer disputed the evidence that Kline's Durom Cup did not work as intended and presented expert opinion that it was *not* loose. There were scratches on Kline's Durom Cup, and Zimmer's witnesses concluded that the scratches showed the cup was difficult to remove, which in turn showed that bone had grown onto or into it.

Zimmer disputed the conclusion that the Durom Cup's coating was defective and that its testing was insufficient. Kevin Ong, a mechanical engineer who evaluated medical devices, testified that the Durom Cup was not defective. He testified specifically that the coating was not defective and expressly disagreed with Dr. Bloebaum's conclusions. Ong testified that animal studies were a "last resort" because they required sacrificing the participant animals. Ong was not concerned with

the Durom Cup's revision rate because the Durom Cup was a metal on metal component and that type of component "tend[ed] to be placed into a younger patient population." Younger patients tend to be more active and put more pressure on their implants. However, Ong admitted that the revision rate was higher in the Durom Cup than other cups.

Zimmer disputed the inference that it gave the American coating the same name as the European coating in an effort to mislead consumers. A Zimmer representative testified that Zimmer used the same name to forestall concern from European doctors that their product was lesser. (Dr. Roberts also expressed concern over how European physicians would perceive a change in the Durom Cup's coating.)

It was undisputed that Zimmer complied with all FDA administrative requirements and received clearance to sell the Durom Cup. It also was undisputed that Dr. Mikulak properly implanted the Durom Cup. Like Kline's witnesses, all of Zimmer's witnesses uniformly testified that Mikulak properly implanted the Durom Cup. In other words, *no* witness testified that Mikulak improperly implanted the Durom Cup. *No* witness testified that an improper implantation technique injured Kline.

With respect to damages, Dr. James Pritchett, an orthopedic surgeon, testified that hip replacement surgery was not a panacea and could not reasonably be expected to relieve all pain. He further testified that after Kline's Durom Cup had been removed, Kline could not continue to suffer pain as a result of it.

6. Closing Arguments

During closing argument, Kline's counsel emphasized warnings Zimmer received about the coating on the American

Durom Cup from Dr. Roberts, Dr. Long, and Dr. Bloebaum. Counsel emphasized the high failure rate of the Durom Cup. Counsel criticized Zimmer for ignoring the warnings, refusing to test the new coating, and referring to the coating in the United States as the same as the European coating. Counsel reminded jurors of Dr. Mikulak's testimony that no bone had grown onto or into Kline's Durom Cup in the 15 months it was implanted.

Kline's counsel summarized the evidence of Kline's damages and argued that jurors should award Kline $153,317 for his medical bills, $2 million for the pain he had suffered and $4 million for the pain he would suffer. (Counsel's argument ignored a joint stipulation that "Kline's past medical expenses in relation to his failed Durom Cup" were $73,153.)

Defense counsel argued the Durom Cup was thoroughly tested; Kline's cup was not loose; and the Durom Cup did not cause Kline's injuries. Counsel argued that, at the time Kline had his initial surgery, Zimmer was not aware of evidence that revisions in the Durom Cup were necessary. Counsel argued that the American coating was not new, and the Durom Cup was not a new device but an evolution. Counsel further argued that scratches on Kline's cup indicated that Dr. Mikulak had to remove bone when he removed the Durom Cup. With respect to damages, Zimmer's counsel argued that Kline's condition had improved since his initial hip surgery and that any pain caused by the Durom Cup would have stopped once the cup was removed.

PROCEDURE

1. Complaint

Kline and others filed a complaint in September 2010. Kline's case was tried first. Kline's theories remaining at trial were failure to warn and design defect.

2. Order Granting Zimmer's Motion in Limine Concerning Subsequent Remedial Measures

Prior to trial, in a motion in limine, Zimmer sought the exclusion of the following six items of evidence: "(1) Zimmer's 7/22/08 urgent device correction letter to surgeons announcing the results of its investigation and plan to temporarily suspend sales of the Durom Cup; [¶] (2) Zimmer's 7/22/08 communication to the FDA concerning the results of its investigation; [¶] (3) Zimmer's 8/16/08 revisions to its Durom Cup surgical brochure and [i]nstructions for use; [¶] (4) Changes and additions Zimmer made to the training offered to surgeons who performed or intended to perform Durom Cup implants (8/16/08); [¶] (5) Zimmer's voluntary suspension of sales of the Durom Cup from July 22–August 16, 2008; [¶] (6) Zimmer's 8/18/08 letter to patients regarding potential problems."

The trial court's April 13, 2015, order, which is relevant to Zimmer's claims that Kline's counsel committed misconduct, provided: "The Court finds that admitting the subsequent conduct would be unfairly prejudicial to Defendant under [Evidence Code] Section 352. In this case, the actions that Zimmer undertook to advise physicians and strengthen its warnings occurred a year after Plaintiff's surgery, long after it devised its initial warnings. Without evidence tying this subsequent conduct to what Zimmer knew before it issued its

initial warnings, evidence of the subsequent conduct provides, at best, a tangential relevant inference that the earlier warnings were inadequate when made. The probative value of the improved warnings is therefore quite weak. [¶] On the other hand, evidence of what appears to be an admission that the original instructions were inadequate is highly prejudicial. The prejudice is compounded because Zimmer has little means of effectively rebutting the inference of an admission. If the subsequent warnings were admitted, Zimmer would want [to] present evidence of good reasons why it decided to strengthen the warning or take other remedial measures. Assuming that Zimmer strengthened its warning in response to reports of complaints or surgical failures, Zimmer faces a Hobson's choice. To demonstrate that the strengthened warnings were a responsible response to prevent failures, Zimmer would have to introduce the highly prejudicial evidence of reported failures. That evidence, which tends to prove that the product was defectively manufactured or designed would not otherwise come into this case because, for policy reasons, Plaintiffs are not permitted to sue Zimmer under a theory of strict products liability based on defective design. The prejudicial nature of this evidence leaves Zimmer with no viable basis to rebut the inference that the improved warnings were an admission that the earlier warnings were inadequate."

The court therefore concluded that "Zimmer's subsequent conduct is not admissible under [Evidence Code] Section 1151 and that the prejudicial value of Zimmer's subsequent conduct outweighs its probative effect. [T]he Court finds that testimony and documents relating to the six items identified in Zimmer's Motion in Limine at trial are inadmissible."

3. Pretrial Stipulations

The parties stipulated that Kline's medical expenses totaled $73,153 and that Kline was not required to provide evidence of each separate medical bill.

The parties also stipulated that they would not admit evidence "regarding recalls or complaints about Zimmer products other than either the US version of the Durom Cup or the EU version of the Durom Cup." They also agreed not to admit: "Any evidence, testimony, documents, or arguments relating to the total amount paid to expert witnesses. The parties further agree[d] that they may ask experts whether they are being paid as an expert to testify, how much they are being paid per hour, and what percentage of their time is spent in litigation and litigation related matters."

4. Special Verdict

In a special verdict, jurors concluded all of the following: Zimmer manufactured the Durom Cup implanted in Kline. Zimmer was negligent in designing the Durom Cup. Zimmer's negligent design was a substantial factor in causing harm to Kline. Zimmer failed to adequately warn of potential risks, which would not have been apparent to an ordinary consumer. The lack of sufficient instructions or warnings was a substantial factor in causing harm to Kline. Jurors awarded Kline $153,317 in past medical expenses (more than double the stipulated amount). Jurors awarded Kline $2.4 million for past noneconomic loss and $6.6 million for future noneconomic loss.

5. New Trial

The trial court denied Zimmer's motion for a judgment notwithstanding the verdict and granted Zimmer's motion for a new trial. In its written order granting a new trial, the court expressed concern over the jury's "extraordinarily short deliberation," of only three hours. The trial court explained: "After weighing the evidence in the entire record and considering all reasonable inferences, the Court is convinced . . . *that the resulting damage award was excessive, and that the jury clearly should have reached a verdict awarding less damages*." (Italics added.) Ultimately, the court granted a retrial unless Kline accepted a reduced award. Kline did not accept the reduced award. Kline's appeal and Zimmer's cross-appeal followed. Both the order granting a new trial and the order denying the motion for judgment notwithstanding the verdict are appealable. (Code Civ. Proc. § 904.1, subd. (a)(4).)

DISCUSSION

We first discuss Zimmer's argument that the trial court should have granted its motion for a judgment notwithstanding the verdict. Finding the design defect cause of action viable, we then turn to Kline's argument that the trial court erred in granting a new trial.

1. Judgment Notwithstanding the Verdict

Products liability may be based on design defect or failure to warn. (*Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1231.) Kline claimed both. Zimmer argues that neither theory was supported by substantial evidence and

that the trial court should have granted its motion for a judgment notwithstanding the verdict.

In evaluating a motion for a judgment notwithstanding the verdict, any conflict in the evidence must be resolved in favor of Kline. (*Cooper v. Takeda Pharmaceuticals America, Inc.* (2015) 239 Cal.App.4th 555, 572-573.) As we shall explain, we conclude ample evidence supported the verdict on the design defect claim, but the causation element of the failure to warn claim was not supported by substantial evidence.

a. Design Defect

"A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective." (*Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1303.) According to Kline, his theory of design defect "was premised on a defect in the Durom Cup's . . . coating." Specifically, according to Kline, the coating failed to permit skeletal attachment. As we shall explain, compelling evidence supported the jurors' finding that the Durom Cup's design was defective.

Viewed in the light most favorable to the judgment, the evidence showed the coating on the Durom Cup did not allow the bone growth necessary to permanently stabilize the cup. When Dr. Mikulak removed Kline's Durom Cup, he observed *no* bone ingrowth or ongrowth. Mikulak conducted 30 revision surgeries on patients with implanted Durom Cups and discovered none had bone ingrowth or ongrowth.

Dr. Bloebaum testified that Zimmer failed to conduct studies on its American coating to ensure that the coating would facilitate bone growth. As explained by Bloebaum, a roughened surface is essential for bone ingrowth or ongrowth. The coating

on the American version of the Durom Cup was smoother than on the European version. Dr. Long noticed the smooth surface. Samaras testified that the coating used on the Durom Cup sold in the United States had not been tested for its intended use. Nevertheless, internal Zimmer documents indicated that the company concluded it had "to keep quiet the development of the new coating." Therefore it used the same name for the coating in the United States as in Europe even though the coatings were different. Based on this evidence, a reasonable trier of fact could conclude that Zimmer failed to adequately test the American coating and that it misled consumers to believe the coatings were the same.

Zimmer is incorrect that Kline failed to present evidence of the standard of care. The following evidence was sufficient. Animal studies were commonly used to test the efficacy of coatings. Dr. Bloebaum testified that a new coating must be tested and that Zimmer failed to perform the necessary tests. Bloebaum expressly opined that the coating on the Durom Cup was defective. He explained: "[I]t's defective in . . . that it didn't achieve the goals for ingrowth and attachment, the appropriate material presentation to the bone so you could achieve attachment. It didn't have the proper open porosity for the bone to grow into it. And then its surface was contaminated." Bloebaum was especially credible as Zimmer regularly hired him to test medical devices.

Other witnesses also testified that an animal study was necessary to evaluate the new coating. Dr. Roberts suggested an animal study was important to determine the efficacy of the American coating. Zimmer considered conducting animal tests but ultimately chose not to conduct any tests. Even when

Dr. Long informed a Zimmer representative that the coating may not be effective, Zimmer did not implement a test to evaluate whether it encouraged bone growth.

Based on the foregoing evidence, reasonable jurors could have concluded that a medical device manufacturer should test the coating on a proposed implant and that Zimmer failed to perform the tests. The evidence also strongly supported the inference that tests would have shown the deficiency in the coating as animal tests successfully were used to determine the efficacy of the European coating.

Finally, Zimmer's argument that clearance by the FDA of the Durom Cup shows that it complied with the standard of care and was dispositive of Kline's design defect claim lacks merit.[3] That argument is inconsistent with the evidence at trial as well as with general legal principles. The evidence at trial showed that although Zimmer received FDA clearance to sell the Durom Cup, the coating in the United States "had not been tested for its intended use with intended users."

Additionally, the United States Supreme Court has held that the FDA 510(k) process—the only process employed by the FDA in this case—does not preempt state court tort actions. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 493-494.) The high court explained: "The § 510(k) notification process is by no means comparable to the PMA [(premarket approval)] process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." (*Id*. at pp. 478-479.)

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[3] We assume for purposes of this appeal that Zimmer preserved this argument.

The high court later reiterated that 510(k) review "is ' "focused on *equivalence*, not safety," ' " and devices entering the market through this review are not evaluated for " 'safety or efficacy.' " (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 323; see *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 348 [510(k) process "requires only a showing of substantial equivalence to a predicate device," not an evaluation of the "risks and efficacy of each device"].) *Riegel* held that the preemption clause in title 21 of United States Code section 360k barred state common law claims concerning the safety and effectiveness of a medical device. (*Riegel, supra*, at pp. 322-324.) But it was critical to the court's decision that the device had "received premarket approval from the FDA." (*Id*. at p. 320; see *Robinson v. Endovascular Technologies, Inc.* (2010) 190 Cal.App.4th 1490, 1496-1497 [discussing federal preemption].)

Premarket approval may result in preemption of any conflicting state tort requirements. (*Blanco v. Baxter Healthcare Corp.* (2008) 158 Cal.App.4th 1039, 1053.) That is because when a device is evaluated for safety and efficacy, a state cannot impose additional requirements relating to safety and efficacy. (*Jessen v. Mentor Corp.* (2008) 158 Cal.App.4th 1480, 1486-1487.) But here Zimmer did not subject the Durom Cup to the premarket approval process and therefore cannot rely on laws applicable to devices that have successfully completed that process. (See, e.g., *Lewis v. Johnson & Johnson* (S.D.W.Va. 2014) 991 F.Supp.2d 748, 752 ["Because of the differences in these processes, tort claims regarding medical devices cleared through the 510(k) process are not preempted by federal law, while tort claims regarding medical devices approved through the premarket approval process generally are preempted."].) In

short, the FDA clearance of the Durom Cup does not shield Zimmer from Kline's design defect claim.

b. Failure to Warn

A failure to warn defect cause of action is based on a theory "that the product is dangerous because it lacks adequate warnings or instructions." (*Chavez v. Glock, Inc., supra*, 207 Cal.App.4th at p. 1304.) For both negligent and strict liability failure to warn, Kline was required to show that Zimmer's failure to warn was a substantial factor in causing his injuries. (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 125.) The requirement to show causation is undisputed. For reasons we shall explain, we conclude that Kline failed to present evidence supporting the inference that Zimmer's failure to warn caused him any injury. Therefore a judgment notwithstanding the verdict on this cause of action was warranted.

According to Kline, his theory of failure to warn was that "[t]he Durom Cup required a special implantation technique to achieve optimal contact with the bone in the hip socket. This was known by Defendant Zimmer, but it failed to adequately warn or instruct surgeons on this technique. As a result, Dr. Mikulak did not use this technique when he implanted Mr. Kline's Durom Cup."

Although Dr. Roberts testified that the Durom Cup required a specific implantation technique, no witness testified that Dr. Mikulak used the wrong technique.[4] Kline asks us to

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[4] According to Dr. Roberts, in the United States surgeons ream the socket to the size of the cup; there is no press-fit. For press-fit, a surgeon must "under-ream[]" the socket and put in a cup that is "bigger than the socket." Roberts testified that if a

reach that conclusion based on Mikulak's testimony that he "ream[ed] line to line, which is the exact size of the cup." Significantly, *no* witness testified that Mikulak used the wrong technique when he reamed line to line, and thus Kline's conclusion lacks evidentiary support.

Even assuming Dr. Roberts's testimony was sufficient to demonstrate that Dr. Mikulak used the wrong technique when he implanted Kline's Durom Cup, there was no evidence that Mikulak's technique harmed Kline. *All* of the evidence showed just the opposite. Mikulak testified that in his opinion nothing he did or failed to do "in operating on Mr. Kline led to the failure of his Durom Cup." He testified that "everything went well in that initial implant surgery . . . ." Dr. Nunley, another orthopedic surgeon, testified that he had "[n]o criticism" of Mikulak's surgery. It was "done well and very standard." He further testified that nothing occurred that would have prevented Kline's full recovery with a nondefective component.

Dr. Pritchett, another orthopedic surgeon, testified that there was no indication Dr. Mikulak had difficulty with the surgery implanting the Durom Cup. He testified: "I think the care that Dr. Mikulak provided was caring, attentive, in every way proper in all ways. I don't have any concerns whatsoever about the primary surgery, the revision surgery, the post-operative care, or anything else." Ong also testified that there was no evidence Mikulak failed to properly place the Durom Cup. Even Kline's counsel described Mikulak as "well-trained" and suggested that Mikulak knew "exactly what [he was] doing." To reiterate, no witness testified Mikulak failed to properly implant

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surgeon reamed the socket to the size of the cup the Durom Cup would "fail immediately."

the Durom Cup in Kline or that Mikulak's surgical technique in any way caused Kline harm.[5] Because Kline failed to present evidence of causation, a judgment notwithstanding the verdict on his failure to warn claim was warranted.

2. New Trial

As noted the trial court granted Zimmer's motion for a new trial on the grounds of irregularity in the proceedings and excessive damages. We now turn to Kline's argument that the trial court erred in granting a new trial. In the alternative, Kline argues that if a new trial is warranted, it should be limited to damages. As we explain, only the latter argument has merit.

Kline argues that the trial court erred in concluding that "the awards for past and future noneconomic losses [we]re excessive." He emphasizes his testimony that after both the initial and revision surgeries, he suffered pain and was required to curtail his activities, testimony corroborated by his wife and daughter.[6] Kline also emphasized Dr. Nunley's testimony that

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[5] Kline cites Dr. Nunley's testimony that "an inability to get that cup into the hole as intended" would be a defect in the design. That testimony does not support the inference that Kline was injured because of Zimmer's failure to warn Dr. Mikulak of the proper surgical technique regarding the size of the hole for the Durom Cup. Nunley testified that Mikulak properly performed the surgery. He did not testify that anything related to Mikulak's surgical technique caused Kline harm. Moreover, the cited evidence was unrelated to Kline's surgery.

[6] Kline's statement that the trial court relied only on other cases and failed to consider the evidence in this case is contrary to the record. In its order, the court summarized the evidence related to plaintiff's ability to participate in activities prior to any

absent the revision surgery he would likely have recovered to 95 percent of his active lifestyle and his rheumatologist's testimony that Kline's right leg was damaged as a result of multiple surgical procedures. Kline continued to require medication to relieve his pain, and each time he attempted to stop taking prednisone, the pain in his right hip returned.

"The standards for reviewing an order granting a new trial are well settled. After authorizing trial courts to grant a new trial on the grounds of '[e]xcessive . . . damages' or '[i]nsufficiency of the evidence,' [Code of Civil Procedure] section 657 provides: '[O]n appeal from an order granting a new trial upon the ground of the insufficiency of the evidence . . . or upon the ground of excessive or inadequate damages, . . . *such order shall be reversed as to such ground only if there is no substantial basis in the record for any of such reasons*.' (Italics added.) Thus, we have held that an order granting a new trial under section 657 'must be sustained on appeal unless the opposing party demonstrates that no reasonable finder of fact could have found for the movant on [the trial court's] theory.' " (*Lane v. Hughes Aircraft Co.* (2000) 22 Cal.4th 405, 411-412 (*Lane*).) In deciding whether to grant a new trial, "[t]he only relevant limitation on [the trial court's] discretion is that the trial court must state its reasons for

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surgery, following the initial surgery and following the revision surgery. The court summarized the evidence presented by Kline as well as that presented by Zimmer. After the court summarized the evidence, it concluded the evidence did not warrant the amount of damages awarded. The court did not simply rely on awards in other cases as found improper in *Bigboy v. County of San Diego* (1984) 154 Cal.App.3d 397, 406. The fact that the court must base its conclusion on evidence in the case under review does not render decisions in other cases irrelevant.

granting the new trial and there must be substantial evidence in the record to support those reasons." (*Id.* at p. 412.)

" '[T]he trial court's factual determinations, reflected in its decision to grant the new trial, are entitled to the same deference that an appellate court would ordinarily accord a jury's factual determinations.' " (*Baker v. American Horticulture Supply, Inc.* (2010) 186 Cal.App.4th 1059, 1068.) As one court explained: " 'The amount of damages is a fact question, first committed to the discretion of the jury and next to the discretion of the trial judge on a motion for new trial. They see and hear the witnesses and frequently . . . see the injury and the impairment that has resulted therefrom.' " (*Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 299 (*Bigler-Engler*).)

a. Excessive Damages

At the outset, it is undisputed that although during closing argument Kline's counsel requested $153,317 in economic damages, he had stipulated that his expenses were $73,153. It is further undisputed that the trial court properly reduced the award of economic damages to the stipulated amount. The crux of the parties' dispute is whether the noneconomic compensatory damages—$9 million—were excessive. As we shall explain, Kline fails to demonstrate that the trial court abused its discretion in concluding that the damages were excessive. In coming to this conclusion, we defer to the findings of the trial court as required when reviewing an order granting a new trial. (*Lane, supra*, 22 Cal.4th at pp. 411-412.)

i. The Court Adequately Specified Its Reasons for Finding Excessive Damages

Kline is correct to the extent he argues the trial court was required to specify its reasons for granting a new trial. (Code

Civ. Proc., § 657 ["When a new trial is granted, on all or part of the issues, the court shall specify the ground or grounds upon which it is granted and the court's reason for granting the new trial upon each ground stated."].) "A new trial shall not be granted upon the ground of insufficiency of the evidence to justify the verdict or other decision, nor upon the ground of excessive or inadequate damages, unless after weighing the evidence the court is convinced from the entire record, including reasonable inferences therefrom, that the court or jury clearly should have reached a different verdict or decision." (Code Civ. Proc., § 657.) A statement of reasons assists in "promot[ing] judicial deliberation before judicial action" and in making "the right to appeal from the order more meaningful." (*Mercer v. Perez* (1968) 68 Cal.2d 104, 113.)

The trial court complied with the requirement that it state its reasons.[7] In its lengthy new trial order, the court summarized both Kline's evidence and Zimmer's evidence regarding the extent of Kline's damages. The court stated: "While it is true, of course, that the jury has broad discretion to decide the amount of damages to award for pain and suffering and that the reasonableness of its award depends on the facts and circumstances of the case, the 125 multiple in this case is not proportionate to the medicals, the testimony about damages, or to the circumstances of a hip replacement and revision surgery for a patient with pre-existing conditions." The court then cited numerous cases to support its conclusion. The court's explanation that a less sizeable verdict was required because the

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[7] Even if the court failed to supply adequate reasons, its order would be defective, not void. (*Cassady v. Morgan, Lewis & Bockius LLP* (2006) 145 Cal.App.4th 220, 229.)

evidence did not support the verdict is a sufficient reason in light of the court's summary of the evidence. The reasons were adequate to explain why the trial court deemed the amount excessive. (*Kolar v. County of Los Angeles* (1976) 54 Cal.App.3d 873, 879 ["The reasons make it clear to us that, in exercising its discretion with respect to the credibility of witnesses and the burden of proof, the trial court simply concluded plaintiffs had failed to establish that they were damaged in the sum of $25,000."].)

The court's conclusion was supported by the following evidence, which the court had summarized: Prior to Kline's Durom Cup implant he suffered severe pain, which improved after his first surgery. After his revision surgery, Kline improved and no longer was under Dr. Mikulak's care. He enjoyed many activities even though his lifestyle was not as active as it had been two years before his initial surgery. Based in large part on this evidence, the trial court exercised its discretion to conclude that Kline's noneconomic damages for past and future pain and suffering did not amount to $9 million. "Under well-established rules of law the trial judge was vested, not only with the power, but also with the duty to grant a new trial upon the issue of damages if he was of the considered opinion that the damages as assessed by the jury were too high." (*Los Angeles v. Bitter* (1951) 103 Cal.App.2d 385, 387.)

ii. The Trial Court Acted Well Within Its Discretion in Concluding the Damages Were Excessive

The recent case *Bigler-Engler, supra*, 7 Cal.App.5th 276 shows the trial court did not abuse its discretion in ordering a new trial based on excessive damages. In *Bigler-Engler*, the trial court denied a motion for new trial and the appellate court was

required to indulge all presumptions in favor of the trial court's decision and could order a new trial only if " 'the verdict is so large that, at first blush, it shocks the conscience and suggests passion, prejudice or corruption on the part of the jury.' " (*Id.* at p. 299.) The *Bigler-Engler* court concluded damages were excessive under this exacting standard. Applying that holding here, the significantly higher damage award also was excessive.

In *Bigler-Engler*, a high-school student (Engler) sued her doctor and others after she suffered injuries by using a device called the PolarCare 500, which had been recommended by her doctor. (*Bigler-Engler, supra*, 7 Cal.App.5th at p. 284.) The PolarCare device delivered "cold therapy" to a surgical site similar to an icepack. (*Id.* at p. 286.) As a result of using the device, Engler was required to undergo an additional knee surgery followed by a week of convalescence in the hospital. (*Id.* at p. 289.) That surgery "left a large open wound, which took nine additional procedures . . . to clean and close." (*Id.* at p. 289.) Each surgical procedure was painful. (*Ibid.*) After the 10 surgical procedures, Engler had a large scar and underwent two additional scar reduction procedures. (*Ibid.*) Engler's knee was painful to touch, and she felt numbness and itching. (*Ibid.*) Engler had difficulty with certain activities including kneeling, riding horses competitively, dancing, and riding a bike while holding a leash. Jurors awarded $68,270 in economic damages and $5,127,950 in noneconomic damages. (*Id.* at p. 284.) Despite the trial court's rejection of a motion for a new trial on excessive damages, the appellate court concluded that the award of noneconomic damages was excessive. (*Id.* at pp. 285, 298-299.)

The appellate court first noted that Engler suffered a serious injury and was required to undergo multiple, painful

surgical procedures. (*Bigler-Engler, supra*, 7 Cal.App.5th at p. 302.) The circumstances caused emotional distress, anxiety, and embarrassment in addition to physical pain. (*Ibid.*) But, her condition improved and jurors appeared to have compensated her the same amount after her condition improved as when she was in extreme pain. (*Ibid.*) With respect to future damages, although additional surgeries may be necessary, "[t]here was no suggestion of the prospect of suffering a significant future disability, shortened life expectancy, inability to succeed professionally, or a distrust of doctors or other fiduciary advisors." (*Ibid.*) Ultimately, the appellate court ordered a new trial unless Bigler-Engler (Engler's representative) agreed to a reduction of the noneconomic damages to $1.3 million. (*Id.* at pp. 332-333.)

Whereas Engler was forced to undergo 10 additional surgeries from the use of the PolarCare, Kline was forced to undergo only one from the implantation of the defective acetabular component. Although strong evidence linked Kline's pain in the period between the initial and revision surgeries to the defective Durom Cup, evidence linking his ongoing pain after the revision surgery to the Durom Cup was less plentiful. Neither loss of income nor loss of earning potential was claimed. There was no evidence of a shortened life expectancy. Even if Kline's expectation of returning to his physical state two years before his initial surgery was reasonable (as implied by Dr. Nunley), the trial court did not abuse its discretion in concluding that Kline's reduction in physical ability did not support a $9 million noneconomic award, almost $4 million more than that found excessive in *Bigler-Engler* and $7.7 million more than what the appellate court in *Bigler-Engler* found to be

reasonable after reduction. (See *Collins v. Union Pacific Railroad Co.* (2012) 207 Cal.App.4th 867, 884 [finding no abuse of discretion in conditionally granting new trial on excessive damages where conflicting evidence on amount of future damages existed and there were irregularities during closing argument]; *Thompson v. John Strona & Sons* (1970) 5 Cal.App.3d 705, 712 [affirming order granting new trial based on excessive damages].)

b. Irregularity in the Proceedings

In addition to concluding jurors awarded excessive damages, the trial court concluded there were irregularities in the proceedings because of Kline's counsel's misconduct. With respect to the irregularity in the proceedings, the court explained: "In this case, the Court finds that a series of mistakes and misjudgments on the part of Plaintiff's counsel caused the jury to arbitrarily inflate its award of damages rather than decide on an amount of damages supported by evidence. Defendant suffered prejudice when counsel (1) twice stated that Zimmer is in a multi-billion dollar industry; (2) introduced evidence, in violation of a stipulation and order, that Zimmer's expert witness received $79,000 in compensation; and (3) misrepresented the amount of paid medical expenses and (4) falsely represented, in closing argument, that Zimmer paid to have its witnesses testify while Plaintiff's expert trial witnesses testified without compensation. The Court finds that Zimmer suffered additional prejudice when, in violation of the Court's written *in limine* order, Plaintiff introduced prejudicial evidence of subsequent remedial measures, implying that after Plaintiff's implant surgery, Zimmer either recalled or removed the Durom Cup from the market." The prejudice identified by the court is that "a series of mistakes and misjudgments on the part of Plaintiff's counsel *caused the jury to*

arbitrarily inflate its award of damages rather than decide on an amount of damages supported by evidence." (Italics added.) The trial court identified no prejudice bearing on the jury's determination of liability.

As already explained, the trial court did not abuse its discretion in concluding that jurors awarded Kline excessive damages. Moreover, in addition to the factors set forth above, the record supported the trial court's conclusion that Kline's counsel's misconduct contributed to the elevated damage award. In challenging this conclusion, Kline ignores the cumulative prejudice created by his counsel's decision to (1) ignore the trial court's order limiting reference to the value of the medical device industry; (2) ignore the parties' stipulations regarding the introduction of evidence of payment to experts; (3) falsely represent such payments during closing argument; and (4) ignore the parties' stipulation as to the amount of Kline's medical bills, which was less than half of what counsel represented to jurors. Taken together, these incidents support the conclusion that the jury award was " ' "so high as to suggest passion or prejudice," ' " and jurors may have been influenced by " 'improper considerations.' " (*Bigler-Engler, supra*, 7 Cal.App.5th at p. 299.) While Kline argues that his counsel's statements were all relevant and that errors were unintentional, the court was not required to condone the repeated violation of its orders and the parties' agreements. (*Id.* at p. 295 ["[R]epeated violations of pretrial in limine rulings, despite sustained objections, is misconduct."].) Further, Kline's postverdict acceptance of the corrected amount of his economic damages does not correct the prejudice caused by the misrepresentation of the amount made during closing argument.

We now turn to the misconduct related to the purported mention of a recall of the Durom Cup, which Zimmer argues supported a new trial on liability (in addition to the new trial on damages). As we shall explain, we conclude the retrial should be limited to damages. The only prejudice identified by the trial court was an inflated damage award, and Zimmer fails to show that a new trial on liability was warranted. We begin with additional background on the two incidents of misconduct unrelated to the amount of damages and then consider prejudice.

i. Recall of Inter-Op Cup

The trial court expressed concern that Kline's counsel, when questioning Dr. Mikulak (Kline's surgeon) referred to a recall of the Inter-Op Cup (not the Durom Cup). The relevant colloquy was as follows:

"Q. Have you ever seen a device with widespread failure of bony ingrowth like the Durom Cup?

"A. The Inter-Op Cup.

"Q. And that was manufactured and effected a recall of that product—"

Defense counsel then objected and the court ruled (in front of jurors): "[T]here is nothing in this case about a recall . . . . And I am concerned that you're trying to get something into the case that the jury is not going to have to think about or consider. So I think, as I will make it clear, anything about a recall of some other product just isn't in this case."

ii. Purported Removal of Durom Cup from the Market

The second claim of misconduct concerns evidence that the Durom Cup was no longer sold—evidence which was stricken

from the record. The relevant colloquy between Kline's counsel and Dr. Mikulak was as follows:

"Q. Okay. Now, you're not an expert in titanium plasma coatings, are you?

"A. No.

"Q. And you've not had any reason to conduct a study on the nature and properties of the Durom coating, correct?

"A. Correct.

"Q. There's no reason to do one on a cup that isn't sold anymore, right?"

"[DEFENSE COUNSEL]: Your Honor, I'm going to object.

"THE WITNESS [Dr. Mikulak]: Correct.

"THE COURT: Sustained, and that will be stricken.

"[DEFENSE COUNSEL]: May I ask two questions, [Y]our Honor, just a very brief follow-up?"

The court found that the stricken evidence violated its prior order, which the court characterized as prohibiting Kline from suggesting that Zimmer had taken or failed to take subsequent remedial measures. For purposes of this appeal in which we must defer to the trial court's finding of misconduct, we conclude Kline's counsel violated the court's order on Zimmer's motion in limine.[8] The remaining issue is whether Zimmer suffered prejudice.

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[8] We have quoted the trial court's April 13, 2015, order. The order appears to reference six specific remedial measures, not encompassed in Kline's counsel's question. Neither Zimmer's motion nor the trial court's order references the fact that the Durom Cup was no longer sold, which could occur for a variety of reasons. Nevertheless, we assume for purposes of this appeal that taking the Durom Cup was off the market was a remedial

iii. Prejudice

Even in the context of the grant of a new trial motion, legal issues are subject to independent review. (*Twedt v. Franklin* (2003) 109 Cal.App.4th 413, 417.) Following the denial of motion for a new trial, the appellate court independently reviews the prejudice suffered from attorney misconduct. (*Bigler-Engler*, *supra*, 7 Cal.App.5th at p. 296; *Garcia v. ConMed Corp*. (2012) 204 Cal.App.4th 144, 149.) Regardless whether we independently review prejudice or defer to the trial court, the result in this case is the same because the trial court found no prejudice with respect to liability.

" 'In order to justify a new trial, the party must demonstrate that the misconduct was prejudicial.' " (*Bigler-Engler*, *supra*, 7 Cal.App.5th at p. 296; see *Martinez v. State* (2015) 238 Cal.App.4th 559, 568.) Prejudice asks whether it is reasonably probable Zimmer would have " 'achieved a more favorable result in the absence of that portion of [attorney conduct] now challenged.' " (*Garcia v. ConMed Corp., supra*, 204 Cal.App.4th at p. 149.) " ' "[T]he trial court is bound by the rule of California Constitution, article VI, section 13, that prejudicial error is the basis for a new trial, and there is no discretion to grant a new trial for harmless error. [Citation.] . . . The grant of a new trial for harmless error violates the constitutional provision and wastes judicial time and resources to no purpose. [¶] Accordingly, the order granting a new trial is valid only if prejudicial error occurred at the trial." ' " (*Garcia v. Rehrig Int'l, Inc.* (2002) 99 Cal.App.4th 869, 875.)

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measure, and that Kline's counsel's question violated the trial court's order under a broad interpretation.

Here, Zimmer identifies *no* prejudice related to liability, and we find none. Therefore, to the extent the court ordered a new trial on liability, such order was unwarranted. As previously quoted, the *only* prejudice identified by the trial court was that counsel's "mistakes and misjudgments on the part of Plaintiff's counsel caused the jury to arbitrarily inflate its award of damages rather than decide on an amount of damages supported by evidence." Because prejudice concerned only damages, the retrial should be limited to damages.

The reference to the fact that an Inter-Op Cup was recalled does not support the inference that the Durom Cup also was recalled. Kline's case concerned only the Durom Cup, and the brief reference to a different device was irrelevant. Moreover, the evidence arguably was in Zimmer's favor as it showed that the Durom Cup was not the only device with a high revision rate. To the extent Zimmer was concerned with the simple mention of the word "recall" that was not encompassed in its motion in limine, and in any event, the trial court told jurors that no recall was at issue in this case. The irrelevant evidence of the Inter-Op Cup recall could not have affected the jury's determination of liability.

The other question referred expressly to the Durom Cup and therefore was relevant. However, the single, isolated, fleeting reference to the fact that the Durom Cup was no longer sold—which was stricken from the record—in the context of a lengthy trial did not prejudice Zimmer. The brief reference to evidence which was stricken from the record does not show a reasonable probability that Zimmer would have achieved a more favorable result on liability.

The parties presented sharply contradictory evidence of the efficacy of the Durom Cup's coating and the adequacy of the

testing of the coating. The parties also presented contrasting evidence of whether bone grew onto Kline's Durom Cup. During closing argument, counsel emphasized the conflicting evidence and neither counsel referred to a recall or to any suggestion that the Durom Cup was no longer sold. Thus, jurors were guided to consider liability based on the merits of the parties' competing evidence, not based on improper considerations.

The court's instructions further supported the conclusion that jurors limited their consideration to the evidence in the case. The court instructed jurors: "You must consider all the evidence and decide what you think happened. You must decide the facts based *only* on the evidence admitted in this trial." (Italics added.) The court further instructed jurors "[w]hat the attorneys say during the trial is not evidence." "Likewise, the attorneys' questions are not evidence. Only the witnesses' answers are evidence. Don't think that something is true just because an attorney's question suggested it was true." "If I sustained an objection to a question, you have to ignore the question and don't guess why I sustained the objection. If the witness did not answer, don't guess what he or she might have said. If the witness already answered, you have to ignore the answer if I sustained the objection." "If I struck testimony, then you must disregard it altogether as if it didn't exist." There was no suggestion that jurors were unable or unwilling to follow the trial court's instructions.

The trial court's own oral analysis rejecting Zimmer's motion for a mistrial supported the conclusion that the new trial should be limited to damages. The court stated: "[I]t's very clear from the instructions and the special verdict form that the case has nothing to do with the recall. I've told them that it has

nothing to do with the recall. [¶] The instructions that I just read clearly ask them to determine liability based on the date of Mr. Kline's surgery. So the jury would effectively be disobeying my instructions if they were to think about [a] recall. [¶] So I trust them not to do that. That's why I do not think it's such irreparable harm." The court did not revise its analysis in its written new trial order.

In short, the fleeting reference to evidence stricken from the record did not prejudice Zimmer. Kline's counsel's misconduct was not "so pervasive nor so egregious, that it prevented the jury from rationally considering the evidence admitted at trial." (*Bigler-Engler, supra*, 7 Cal.App.5th at p. 297.) Zimmer makes *no* showing that the liability verdict was tainted by Kline's counsel's misconduct.

Finally, Zimmer correctly points out that if a limited retrial is prejudicial or would result in an injustice, the court should grant a new trial on all issues. (*Ryan v. Crown Castle NG Networks, Inc.* (2016) 6 Cal.App.5th 775, 790.) But, Zimmer demonstrates no such prejudice or injustice. "Even if an excessive damage award is the product of passion and prejudice, it does not necessarily follow that the verdict as to liability was similarly influenced." (*Izell v. Union Carbide Corp.* (2014) 231 Cal.App.4th 962, 981, fn. 8; see *Bellman v. San Francisco High School Dist.* (1938) 11 Cal.2d 576, 588-589 [finding damages excessive but no new trial on liability warranted].) "Society has a manifest interest in avoiding needless retrials: they cause hardship to the litigants, delay the administration of justice, and result in social and economic waste." (*Mercer v. Perez, supra*, 68 Cal.2d at p. 113.)

DISPOSITION

The order denying the judgment notwithstanding the verdict on failure to warn is reversed. The order denying the judgment notwithstanding the verdict on design defect is affirmed. The order granting a new trial on damages is affirmed. To the extent the trial court ordered a new trial on liability, that order is reversed. The case is remanded to the trial court for a retrial on Kline's damages caused by the design defect of the Durom Cup. The parties shall bear their own costs on appeal.

HALL, J.*

I CONCUR:

RUBIN, J.

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* Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

Rubin, J. – Concurring:

I join in the majority opinion which I have signed. I write separately because in my view the trial court did not in fact grant a new trial on the issue of liability but only on damages. As I see it, the court's disposition might be more accurately stated, in part, as an affirmance of the order granting a new trial on the issue of damages only. The majority accomplishes the same result through a slightly different approach. Either way the retrial will be limited to damages on the failure to warn theory. In limited respect, I differ with Justice Bigelow's concurring and dissenting opinion which concludes the trial court ordered a retrial on liability and damages, and that such an order should be affirmed.

I agree with much of Justice Bigelow's opinion. Although the trial court's order was thoughtful and complete, words taken here and there might suggest the court was intending to grant a new trial on liability as well. But I am guided by the appellate maxim not to parse a trial court's order too finely or seize on a word or phrase, whether here or there. "The true measure of an order . . . is not an isolated phrase appearing therein, but its effect when considered as a whole. [Citations.] In construing orders they must always be considered in their entirety, and the same rules of interpretation will apply in ascertaining the meaning of a court's order as in

ascertaining the meaning of any other writing." (*In re Ins. Installment Fee Cases* (2012) 211 Cal.App.4th 1395, 1429.)[1]

My assessment that the trial court only ordered a new trial on damages could almost start and end with the order's caption and its conclusion. The caption expressly states that the order is a *conditional* order granting a new trial.[2] A conditional order granting a new trial is provided for in Code of Civil Procedure section 662.5, subdivision (a)(2): "If the ground for granting a new trial is excessive damages, [the court may in its discretion] issue a conditional order granting the new trial unless the party in whose favor the verdict has been rendered consents to the reduction of so much thereof as the court in its independent judgment determines from the evidence to be fair and reasonable."

The conditional order for new trial is statutorily limited to excessive (and inadequate) damages. The other statutory grounds for granting a new trial, including "irregularit[ies] in the proceedings" (Code of Civ. Proc., § 657, subd. (1)), do not authorize the court to conditionally order a new trial, nor do the grounds even lend themselves to that type of order. For example,

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[1] For example I agree with Justice Bigelow that the phrase "In the alternative" might suggest that the procedural irregularities discussion that precedes the phrase applied to a new trial on liability and what followed "in the alternative" was limited to damages. As I explain in the text, however, I cannot square that with the overall import of the order which is to grant only a conditional order for new trial on damages.

[2] The order's caption is: "Order Conditionally Granting Defendant Zimmer Inc.'s Motion for a New Trial."

how would a judge fashion a conditional order for a new trial due to misconduct of the jury under section 657, subdivision (2)?

That the trial court here granted only a conditional new trial on damages is supported by language throughout the order, and reaches its dénouement in the order's last paragraph. Under "Conclusion," the court states: " 'In a civil action where after trial by jury an order granting a new trial limited to the issue of damages would be proper, the trial court may in its discretion . . . issue a conditional order granting the new trial unless the party in whose favor the verdict has been rendered consents to the reduction of so much thereof as the court in its independent judgment determines from the evidence to be fair and reasonable.' (Code Civ. Proc., § 662.5(a)(2).) Because the Court finds that there were prejudicial procedural irregularities and that the damage award was excessive, the Court conditionally GRANTS Defendant's motion for a new trial. The Court will proceed with trial readiness conference on December 18, 2015 at 9:00 a.m. and commence a retrial on January 12, 2015, at 9:00 a.m., unless, on or about December 16, 2015, Plaintiff consents to reduce his award to $823,153 ($73,153 for past economic damages, $250,000 for past noneconomic damages, and $500,000 for future noneconomic damages)."

This language unmistakably informs counsel that there will be a new trial unless plaintiff "consents to reduce his award." The corollary to that statement is that if plaintiff does consent to reduce his award, there will be no new trial. Imagine for a moment what would have happened if plaintiff had filed with the court a written notice that he accepted the conditional reduction in damages. Based on the quoted language above, the court

would have entered judgment in the amount of $823,153 – no new trial, no further trial court proceedings.

It is not necessarily easy to square my conclusion that the trial court limited the new trial to damages with the court's lengthy discussion of irregularity in the proceedings. In one sense, the discussion is somewhat superfluous to a finding of excessive damages. Hence my partial agreement with Justice Bigelow's concurrence.

But I am loathe to ignore a significant part of a trial court's order. I reconcile this dilemma by treating the trial court's discussion suggesting that procedural irregularities were a partial *cause* of the excessive damages and nothing else. In other words, a conditional new trial is ordered because (1) plaintiff counsel's repeated violations of orders and stipulations constituted significant procedural irregularities resulting in an award excessive damages; and (2) even without those irregularities, the jury verdict was on its own excessive. My conclusion is supported by language the trial court used at the end of its introduction to the order. On page 2, the court writes: "After weighing the evidence in the entire record and considering all reasonable inferences, the Court is convinced that counsel's mistakes were procedurally irregular, that the resulting damage award was excessive, and that *the jury clearly should have reached a verdict awarding less damages."* (Italics added.) Not that in the trial court's view, sitting as the 13th juror, the jury should have reached a verdict for the defense, but that the jury "should have reached a verdict awarding less damages." Based on its view that damages were excessive, the trial court conditionally granted a new trial. It even went so far as setting a

date for the new trial "unless, on or before December 16, 2015, plaintiff accepts a remitted award of $828,153 . . . ."[3]

For all these reasons, I conclude the trial court properly granted a conditional new trial based on excessive damages and when plaintiff refused to accept the remitted award, the order directed a new trial on damages only. As that is the result reached by the majority, I concur.

RUBIN, J.

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[3] That the court found procedural irregularities were a cause of excessive damages is borne out by the subheadings in the trial court's order. Under part "II. Analysis: Motion for New Trial," subheading "B" states: "Plaintiff's Counsel's Mistakes Gave the Jury a False Impression that It Should Award Large Damages for Any Finding of Liability." This heading plainly draws the connection between counsel's misconduct and the jury's award of excessive damages.

BIGELOW, P.J., Concurring and Dissenting:

I concur in the majority's reversal of the order denying the judgment notwithstanding the verdict on failure to warn. However, I disagree with the majority's conclusion that the order granting a new trial should be reversed on the issue of liability.

"A reviewing court should not modify an order granting a new trial on all issues to one granting a limited new trial 'unless such an order should have been made as a matter of law.' " (*Schelbauer v. Butler Manufacturing Co.* (1984) 35 Cal.3d 442, 456 (*Schelbauer*).) I do not believe the majority is adhering to this principle. Here, the trial court found a new trial was warranted based on both "prejudicial procedural irregularities *and* that the damage award was excessive." (Italics added.) Given the trial court's own language, I would not find that an order limiting the new trial to damages should have been made as a matter of law. As a result, I would order the case be remanded for a complete retrial on the design defect of the Durom Cup and damages.

There is no dispute there were irregularities in the underlying proceedings because of Kline's counsel's misconduct. As the majority points out, the trial court found Zimmer suffered prejudice when Kline's counsel, "(1) twice stated that Zimmer is in a multi-billion dollar industry; (2) introduced evidence, in violation of a stipulation and order, that Zimmer's expert witness received $79,000 in compensation; (3) misrepresented the amount of paid medical expenses and (4) falsely represented, in closing argument, that Zimmer paid to have its witnesses testify while

[Kline's] expert trial witnesses testified without compensation." Kline's counsel also introduced prejudicial evidence of subsequent remedial measures in direct violation of the trial court's written *in limine* order.

The order granting a new trial made clear that Kline's counsel's misconduct was so pervasive it also prejudiced the jury's verdict on liability. The reason its new trial order emphasized Kline's counsel's breach of the order prohibiting any evidence of subsequent remedial measures, and the false theme of Kline's counsel's closing argument improperly attacking the credibility of Zimmer's expert witnesses was to highlight the prejudicial effect of the misconduct on the jury's verdict on liability. It was also apparent to the trial court that the jury could not have considered liability based solely on the merits of the parties' admissible competing evidence. As pointed out in its written ruling, the jury's hasty verdict was "far too short for the number of witnesses, the volume of written evidence, and the often technical testimony presented to the jury." The trial court further explained, "The jury's rapid decision on the verdict before consulting the late-delivered instructions and exhibits [was] evidence that the irregularity was prejudicial." I would not substitute my judgment for that of the trial judge, who witnessed the entire trial first hand.

Finally, I also disagree with the concurring opinion, which asserts that the trial court's issuance of a remittitur in this case means the order granting a new trial was limited to damages. Only after the trial court pointed out the impact of the misconduct on liability did the text of its order focus on excessive damages, stating, "*In the alternative*, the Court orders a new trial on the grounds of excessive damages." (Italics added.) I would

find that because the trial court's order was not limited to the issue of excessive damages, it was an abuse of discretion to have issued a remittitur. An invalid conditional remittitur does not invalidate a trial court's order. (*Schelbauer*, *supra*, at p. 455.) " '[A] void condition can have no effect on an otherwise valid order. The condition is simply disregarded and the order stands.' " (*Ibid*.) The mistaken disposition here does not define the trial court's definitive order. The concurrence finds otherwise, believing in the flawed idea that the tail wags the dog.

BIGELOW, P. J.

EXHIBIT E

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 This Document Relates To All Cases

DECLARATION OF GIBBS HENDERSON

I, GIBBS HENDERSON, hereby state the following:

1. I am an attorney-at-law of the State of Texas and a member of the firm Waters & Kraus, LLP ("WK"), attorneys for Plaintiffs. I am submitting this Declaration in support of WK's Response to the Motion of Plaintiffs' Co-Liaison Counsel for Reconsideration and Stay of Court Order Allocating and Disbursing Fees and Expenses from Common Benefit Fund. I have personal knowledge of the matters stated herein.

2. Between 2012 and 2018, WK received and accommodated requests from at least 12 different firms representing Zimmer Durom Cup plaintiffs either in the MDL or state court. The most recent of these requests occurred the week of June 18, 2018.

3. The materials requested and shared included documents produced by Zimmer, deposition transcripts, trial transcripts, and attorney work product.

I declare by penalty of perjury that the foregoing statements are true.

DATED: June 28, 2018.

Gibbs C. Henderson

EXHIBIT F

To:
Cc:
Bcc:
Subject: Fw: Durom Cup MDL - Common Benefit Fund

From: "Campbell, Andrew L." <Andrew.Campbell@FaegreBD.com>
To: Gibbs Henderson <ghenderson@waterskraus.com>, "Fleishman, Wendy R." <WFLEISHMAN@lchb.com>, Chris Seeger <cseeger@seegerweiss.com>, James Cecchi <JCecchi@carellabyrne.com>, "Richard.Meadow@LanierLawFirm.com" <Richard.Meadow@LanierLawFirm.com>
Cc: "Bennett, James Stephen" <Stephen.Bennett@faegrebd.com>, "Tanner, John Joseph" <Joe.Tanner@faegrebd.com>, "Russo, Stephanie N." <Stephanie.Russo@FaegreBD.com>, "Gongaware, Micki M." <Micki.Gongaware@FaegreBD.com>
Date: 06/14/2018 04:04 PM
Subject: Durom Cup MDL - Common Benefit Fund

All,

After making the disbursements from the Common Benefit Fund per Judge Wigenton's attached Order, there will be $1,688,001.58 remaining in the Fund. Please let me know if you have questions.

Thanks.

Andy

Andrew L. Campbell
Partner
andrew.campbell@FaegreBD.com

Direct: +1 317 237 1011
Cell: +1 317 417 4746

FaegreBD.com Download vCard

FAEGRE BAKER DANIELS LLP
300 N. Meridian Street
Suite 2700
Indianapolis, IN 46204, USA

pdf.pdf

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 This Document Relates To All Cases

ORDER GRANTING PLAINTIFFS' MOTION
SEEKING DISBURSEMENT FROM COMMON BENEFIT FUND

THIS MATTER, having been opened to the Court by Plaintiffs, by and through their attorneys Waters & Kraus, LLP, on application seeking disbursement from in accordance with Case Management Order 3, and the Court having considered the parties submissions; and for good cause appearing,

IT IS THIS 7th day of June 2018

ORDERED that disbursements from the Common Benefit Fund be issued to Plaintiffs' counsel as follows:

Waters & Kraus, LLP	Expenses: Fees:	$788,709.25 $1,578,418.50
Pogust Braslow & Millrood, LLC	Fees:	$23,154.80
Lieff Cabraser Heimann & Bernstein, LLP	Expenses Fees	$100,349.43 $739,505.84

HON. SUSAN D. WIGENTON, U.S.D.J.

1552440.1

EXHIBIT G

June 15, 2016

Via E-Mail

Mr. Derek T. Braslow
FOGUST BRASLOW MILLROOD, LLC
Eight Tower Bridge
161 Washington St., Ste. 1520
Conshohocken, PA 19428
dbraslow@pbmattorneys.com

Ms. Wendy R. Fleischman
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New York, NY 10013-1413
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Mr. Christopher A. Seeger
SEEGER WEISS LLP
550 Broad Street
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cseeger@seegerweiss.com

Mr. James E. Cecchi
CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C.
5 Becker Farm Rd.
Roseland, NJ 07068
JCecchi@carellabyrne.com

Re: *In Re: Zimmer Durom Hip Cup Products Liability Litigation*

Dear Fellow Plaintiffs' Liaison Counsel:

I am writing regarding the disbursement and distribution of Zimmer MDL settlement money in the court-established Common Benefit Fund ("CBF"). As you know, the CBF was established by Case Management Order No. 3 [Doc. 33] ("CMO No. 3") on January 21, 2011, "to provide for the fair and equitable sharing among plaintiffs of the costs of services and expenses incurred by Plaintiffs' Liaison Counsel and other attorneys acting for and providing a common benefit of all plaintiffs in this complex litigation . . . ."

In its capacity as Plaintiffs' Co-Liaison Counsel, and for the benefit of all MDL Plaintiffs in this litigation, Waters & Kraus has taken or defended over 50 "common issue" depositions, *see* **Exhibit A**, and reviewed over 30,000 "common issue" documents produced by Zimmer, *see* **Exhibit B**. In 2013 and 2014 alone, Waters & Kraus spent *thousands* of attorney and staff hours working these cases up, as reflected in this breakdown:

Depositions	212.00 hrs;
Documents Reviewed	524.09 hrs; and
Attorney & Staff Billed Hours	3,906.25 hrs.

The extent of Waters & Kraus commitment to this litigation is not just measurable in hours. Although we are in the process of determining the exact amount, our preliminary analysis shows we have spent over $900,000 in conducting activities that had a "common benefit" for all Plaintiffs in the MDL.

The depositions, documents, and work product Waters & Kraus accumulated in the course of these efforts have been shared with at least 20 other Plaintiffs' attorneys in this litigation. *See* **Exhibit C**. This material and information also served as the foundation for four Durom Cup bellwether trials litigated by Waters & Kraus – including one such trial in the MDL. Additionally, in terms of making sure the CBF is adequately funded, Waters & Kraus has taken the lead in opposing numerous efforts by settling Plaintiffs to reduce the 4% standard common benefit fee established by CMO No. 3.

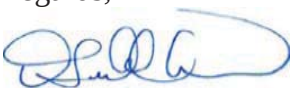
Given the status of the litigation, we believe it would be prudent to begin discussing the manner in which the funds paid into the CBF will be distributed. CMO No. 3 only permits CBF disbursements pursuant to a Court order. *See* CMO No. 3 at ¶ 13. The manner in which those distributions are made (*i.e.*, who gets what) is determined pursuant to the recommendation of Plaintiffs' Liaison Counsel. *See* CMO No. 3 at ¶ 9.

Pursuant to an inquiry made by our office, Zimmer's counsel informed us that there was $179,200 in the CBF as of March 25, 2016. Prior to any settlement offers being made as part of the current settlement program, Waters & Kraus plans to file a motion seeking the disbursement of this money. Given the scope of our efforts over the last few years, as outlined above, we believe we are entitled to the lion's share of the current money in the CBF, as well as any future amounts paid into it.

As a first step toward determining the exact breakdown of how these funds should be disbursed, we believe each Plaintiffs' Liaison Co-Counsel should submit their "common benefit" hours and expenses. We can then discuss the appropriate percentage each firm should get from the CBF in all future disbursements.

Please call me if you have any questions.

Regards,



Gibbs C. Henderson

/gch
Attachments.

cc: Peter A. Kraus – Via E-mail

Common Benefit Depositions Lead by Plaintiff's Liaison Counsel in *In re Zimmer Durom Hip Cup Products Liability Litigation*, MDL-2158.

I. Bellwether Trial Depositions

Christine Brady	Pltff	10/17/2013
Dr. Cambize Shahrdar	Treater	6/10/2014
Maryann Ruttenbur	Pltff	4/7/2014
Dr. Erik Kubiak	Treater	5/30/2014
Dr. Aaron Hofmann	Treater	11/17/2014

II. Common Issue Depositions

Erin Johnson	Comm Issue Wit	5/15/2014
Erin Johnson	Comm Issue Wit	9/11/2014
Erin Johnson	Comm Issue Wit	9/12/2014
Don Secor	Comm Issue Wit	2/6/2014
Rich Cadarette	Comm Issue Wit	2/7/2014
Sheryl Conley	Comm Issue Wit	3/6/2014
Brian Parker	Comm Issue Wit	4/3/2014
Brian Parker	Comm Issue Wit	5/30/2014
David Weidenbenner	Comm Issue Wit	5/28/2014
Paul Roberts	Comm Issue Wit	4/25/2014
Paola Vivoda	Comm Issue Wit	4/28/2014
Adrien Spiegel	Comm Issue Wit	4/29/2014
Adrien Spiegel	Comm Issue Wit	8/25/2014
Ralph Howald	Comm Issue Wit	4/30/2014
Ralph Howald	Comm Issue Wit	8/27/2014
Pascal Wiederkehr	Comm Issue Wit	4/30/2014
Carlo Ventre	Comm Issue Wit	8/26/2014
Robert Schenck	Comm Issue Wit	5/22/2014
Lawrence Dorr	Comm Issue Wit	5/23/2014
Lawrence Dorr	Comm Issue Wit	6/13/2014
Lawrence Dorr	Comm Issue Wit	8/8/2014
Laura Williams	Comm Issue Wit	10/15/2013
Michael Hawkins	Comm Issue Wit	10/16/2013
Michael Hawkins	Comm Issue Wit	1/3/2014
Michael Carter	Comm Issue Wit	11/15/2013
Janet Krevolin	Comm Issue Wit	11/20/2013
Dale Miller	Comm Issue Wit	2/11 and 2/12/2014
Cheryl Blanchard	Comm Issue Wit	1/29 and 1/30/2014
Tom Troup	Comm Issue Wit	10/3/2014

EXHBIIT A

III. Expert Depositions

James Grimes	Plaintiff	8/1/2014
James Grimes	Plaintiff	9/26/2014
Roy Bloebaum	Plaintiff	8/14/2014
Roy Bloebaum	Plaintiff	8/15/2014
Kurt Kitziger	Plaintiff	8/15/2014
Kurt Kitziger	Plaintiff	8/22/2014
George Samaras	Plaintiff	8/7/2014
George Samaras	Plaintiff	9/23 and 9/24/2014
Ryan Nunley	Plaintiff	8/1/2014
Ronald Johnson	Defendant	9/11/2014
Robert Schmidt	Defendant	9/12/2014
Jon Fryzek	Defendant	9/17/2014
R. Cuyler Robinson	Defendant	9/18/2014
Judd Day	Defendant	10/1/2014
Kevin Ong	Defendant	10/2/2014
Joyce Tsuji	Defendant	10/2/2014
James Pritchett	Defendant	10/4/2014
Patrick Biggins	Defendant	10/8/2014
Hollace Rhodes	Defendant	10/9/2014

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 This Document Relates To All Cases

DECLARATION OF GIBBS C. HENDERSON

GIBBS C. HENDERSON hereby declares as follows:

1. I am an attorney licensed to practice law in the states of Texas and a partner of the firm Waters & Kraus, LLP, attorneys for Plaintiffs. I am submitting this Declaration in support of Liaison Counsel's Brief in Opposition to Plaintiff Tracy Pelphrey and John Pelphre's Motion to Waive Contribution to Common Benefit Fund. I have personal knowledge of the matters stated herein.

2. A total of 83,344 documents were collected and placed into the MDL Database (Catalyst).

3. A total of 33,216 of those documents were reviewed by Waters & Kraus attorneys and staff.

4. Of the 33,216 documents reviewed, a total of 27,047 documents were used for some purpose related to some aspect of the plaintiffs' Zimmer Durom Cup common issue liability case work up.

EXHIBIT B

5. Total hours spent on common issue case work by Waters and Kraus attorneys and staff as of March 2015 was 3,906.25.

I declare by penalty of perjury that the foregoing statements are true.

DATED: February 22, 2016.

Gibbs C. Henderson

Miller v. Zimmer, et al. **MDL NO. 2158**

CONFIDENTIALITY AGREEMENT LOG

Name	Law Firm	Date Signed
Binstock, Robert	Reich and Binstock, LLP	2/24/2014
Davis, Mike	Slack & Davis, LLP	3/23/2015
Dolejsi, Holly H.	Robins, Kaplan, Miller & Ciresi LLP	2/18/2014
Dorr, Lawrence (Zimmer Expert)	N/A	2/28/2014
Duane, John C.	Reich and Binstock, LLP	2/21/2014
Fedota, Mark C.	Fedota Childers PC	8/11/2014
Franiskato, Brian	Nash Franciskato	5/12/2014
Folger, Bryan	LawOffices of Bryan M. Folger PLLC	10/20/2014
Garrett, D. Mitchell	Garrett Law Center, PLLC	2/24/2014
Keyes, Barton R.	Cooper & Elliott, LLc	2/17/2015
Lennox, Doug	Klein Lyons	2/25/2014
Maglio, Altom M.	Maglio Christopher &Toale	2/28/2014
Matthews, Brian P.	LeClair Ryan	6/24/2014
Millrood, Tobias	Pogust Braslow & Millrood LLC	5/21/2014
O'Brien, Kevin M.	Pogust Braslow & Millrood LLC	5/21/2014
Pankauskas, Molly	Anderson Rasor & Partners, LLP	8/5/2014
Pope, Kirk	Pope McGlamry	1/13/2015
Quinton, Jackqualyn R.	The Edwards Law Firm	2/21/2014
Sayeg, Ilyas	Maglio Christopher &Toale	2/28/2014
Sheinkop, Mitchell B.	Fedota Childers PC	8/12/2014
Sloan, Jim	Donohue Brown Mathewson & Smyth LLC	9/17/2014
Smith, Terrence	Davis, Saperstein & Salomon, PC	2/26/2014
T. Joe Snodgrass	Larson King	10/29/2014
Stepaneas, Telly	Cantwell & Cantwell	9/29/2014
Thetford, Mark S.	The Edwards Law Firm	2/21/2014
Ward, Navan	Beasley Allen	2/24/2014
Wurgaft, Jack	Javerbaum Wurgaft Hichk Kahn Wikstrom & Sinins	7/22/2014
Van den boom, Peter	Frost Van den Boom, P.A.	8/26/2015
Shah, Tayjes M.	The Miller Firm, LLC	9/2/2015
Warriner, Calvin	Searcy Denney Scarola Barnhart & Shipley	9/18/2015
Richman, Gerald	Richman Greer	9/22/2015
Freire, Leora B.	Richman Greer	9/22/2015

EXHIBIT C

From:	Cindy Lopez/Paralegal/Dallas/W&K
To:	dbraslow@pbmattorneys.com, cseeger@seegerweiss.com, wfleishman@lchb.com, jcecchi@carellabyrne.com
Cc:	Gibbs Henderson/Attorney/Dallas/W&K@AWPK, Peter Kraus/Attorney/Dallas/W&K@AWPK
Date:	06/15/2016 02:54 PM
Subject:	In Re: Zimmer Durom Hip Cup Products Liability Litigation

Dear Counsel:

Please see attached correspondence forwarded on behalf of attorney Gibbs C. Henderson in regard to the above-referenced matter.

Thank you.

waterskraus
Cindy Lopez | Paralegal
3219 McKinney Avenue | Dallas, TX 75204
Toll Free 800-226-9880 | Phone 214-357-6244 | Fax 214-357-7252
www.waterskraus.com

6.15.16 Ltr Ps Liaison Counsel re CBF.pdf

EXHIBIT H

To:
Cc:
Bcc:
Subject: Fw: Zimmer Common Benefit

From: "Fleishman, Wendy R." <WFLEISHMAN@lchb.com>
To: 'Gibbs Henderson' <ghenderson@waterskraus.com>
Date: 02/21/2018 05:20 PM
Subject: RE: Zimmer Common Benefit

Yes. I do and Yes. I will send it to you.

Are there a lot of common costs?

Lieff Cabraser Heimann & Bernstein
Attorneys at Law

Wendy R. Fleishman
Partner
wfleishman@lchb.com
t 212.355.9500 ext. 6619
m 917.992.4550
f 212.355.9592
Lieff Cabraser Heimann & Bernstein, LLP
250 Hudson Street, 8th Floor
New York, NY 10013
www.lieffcabraser.com

From: Gibbs Henderson [mailto:ghenderson@waterskraus.com]
Sent: Wednesday, February 21, 2018 6:11 PM
To: Fleishman, Wendy R.
Subject: Zimmer Common Benefit

Wendy:

Do you have a itemized list of your firm's common benefit expenses and hours? We are planning to submit ours and Pogust Braslow Millrood's next month. Let me know if you want us to include yours in that filing.

Regards,
Gibbs

waterskraus
Gibbs C. Henderson | Attorney
3141 Hood Street, Suite 700 | Dallas, TX 75219
Toll Free 800-226-9880 | Phone 214-357-6244 | Fax 214-357-7252
www.waterskraus.com

EXHIBIT
I

From: "Fleishman, Wendy R." <WFLEISHMAN@lchb.com>
To: Erin Wood <ewood@waterskraus.com>
Cc: Gibbs Henderson <ghenderson@waterskraus.com>
Date: 03/21/2018 04:07 AM
Subject: Re: CBF Motion - Zimmer Durom MDL

Yes. Thanks

Sent from my iPhone

On Mar 20, 2018, at 7:30 PM, Erin Wood <ewood@waterskraus.com<
mailto:ewood@waterskraus.com>> wrote:

Hi Wendy,
I've attached our draft of the Motion Seeking Disbursements from the Common Benefit Fund in the Zimmer Durom MDL. Could you plug in your hours/fees and expenses? Please let me know if you have any questions.

Thanks very much,
Erin

<mime-attachment.jpg>
Erin M. Wood | Attorney
3141 Hood Street, Suite 700 | Dallas, TX 75219
Toll Free 800-226-9880 | Phone 214-357-6244 | Fax 214-357-7252
www.waterskraus.com<http://www.waterskraus.com/>

<Motion Seeking Disbursements from Common Benefit Fund.docx>

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 This Document Relates To All Waters & Kraus Cases

CERTIFICATION OF GIBBS C. HENDERSON IN SUPPORT OF PLAINTIFFS' RESPONSE TO PLAINTIFFS' CO-LIAISON MOTION FOR RECONSIDERATION OF JUNE 7, 2018 ORDER GRANTING MOTION FOR DISBURSEMENT OF FEES AND EXPENSES FROM COMMON BENEFIT FUND AND EXPENSES FOR A STAY OF THAT ORDER [DOC. 986]

GIBBS C. HENDERSON, hereby certifies as follows:

1. I am an attorney-at-law of the State of Texas and a member of the firm Waters & Kraus, LLP, attorneys for Plaintiffs. I am submitting this Certification in support of Plaintiffs' Motion Seeking Disbursement from Common Benefit Fund. I have personal knowledge of the matters stated herein.

2. Attached hereto as **Exhibit A**, is a true and correct copy of a Letter from G. Henderson to Co-Liaison Counsel, dated Feb. 2, 2018.

3. Attached hereto as **Exhibit B**, is a true and correct copy of an article by M. Fainura-Wada, *Lawyers, Others Vie for Pieces of NFL Concussion Settlement*, espn.com, Mar. 29, 2017.

4. Attached hereto as **Exhibit C**, is a true and correct copy of a Pls.' Mot.

for Leave to Amend Their Compl. to Include a Prayer for Relief Seeking Punitive Damages Against Def. Zimmer, Inc. and Incorporated Mem. in Supp. Thereof in the *Santas* Matter, St. Clair County, Ill.

5. Attached hereto as **Exhibit D**, a is a true and correct copy of the Opinion in *Kline v. Zimmer, Inc.*, B269317, Court of App. of the State of Cal., Second Appellate Dist., dated Apr. 27, 2018.

6. Attached hereto as **Exhibit E**, is a true and correct copy of the Declaration of Gibbs Henderson, dated June 28, 2018.

7. Attached hereto as **Exhibit F**, is a true and correct copy of a letter from A. Campbell to Pls.' Liaison Counsel, dated June 14, 2018.

I certify that the foregoing statements by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

DATED: June 28, 2018.

Respectfully submitted,

WATERS & KRAUS, LLP

/s/ Gibbs C. Henderson

Gibbs C. Henderson
3141 Hood Street, Suite 700
Dallas, Texas 75219
(214) 357-6244
(214) 357-7252 (facsimile)
ghenderson@waterskraus.com

ATTORNEYS FOR PLAINTIFFS

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 This Document Relates To All Waters & Kraus Cases

CERTIFICATE OF SERVICE

GIBBS C. HENDERSON, hereby certifies as follows:

1. I am an attorney-at-law of the State of Texas and a member of the firm Waters & Kraus, LLP, attorneys for Plaintiffs.

2. On June 28, 2018, I caused a true copy of the forgoing Response, Certification of Gibbs C. Henderson and Exhibits thereto, and this Certificate of Service, to be served upon Defendants' Counsel of Record by CM/ECF.

3. On June 28, 2018, I caused a true copy of the forgoing Response, Certification of Gibbs C. Henderson and Exhibits thereto, and this Certificate of Service, to be served upon the Hon. Susan D. Wigenton, U.S.D.J., U.S. District Court of the District of New Jersey, Martin Luther King Building and CM/ECF.

I certify that the foregoing statements by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

DATED: June 28, 2018

WATERS & KRAUS, LLP

/s/ Gibbs C. Henderson
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(214) 357-7252 (facsimile)
ghenderson@waterskraus.com

ATTORNEYS FOR PLAINTIFFS