No. 16-11051

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

IN RE: DEPUY ORTHOPAEDICS, INC., PINNACLE HIP IMPLANT PRODUCT LIABILITY LITIGATION

JAY CHRISTOPHER; JACQUELINE CHRISTOPHER,

Plaintiffs-Appellees-Cross-Appellants,

v.

DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,

Defendants-Appellants-Cross-Appellees.

(Caption Continued on Inside Cover)

On Appeal from the United States District Court
For the Northern District of Texas (Kinkeade, J.)
Nos. 14-cv-1994, 11-cv-2800, 12-cv-1672, 11-cv-1941, 13-cv-01071

OPENING BRIEF FOR APPELLANTS

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January 30, 2017

Consolidated with
No. 16-11052

RICHARD KLUSMANN; SUSAN KLUSMANN,

Plaintiffs-Appellees-Cross-Appellants,

v.

DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,

Defendants-Appellants-Cross-Appellees.

Consolidated with
No. 16-11053

DONALD GREER,

Plaintiff-Appellee-Cross-Appellant,

v.

DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,

Defendants-Appellants-Cross-Appellees.

Consolidated with
No. 16-11054

ROBERT PETERSON; KAREN PETERSON,

Plaintiffs-Appellees-Cross-Appellants,

v.

DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,

Defendants-Appellants-Cross-Appellees.

Consolidated with
No. 16-11056

MARGARET AOKI,

Plaintiff-Appellee-Cross-Appellant,

v.

DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,

Defendants-Appellants-Cross-Appellees.

CERTIFICATE OF INTERESTED PERSONS

Aoki et al. v. DePuy Orthopaedics, Inc. et al., Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal:

1. Margaret Aoki, Jay Christopher, Jacqueline Christopher, Donald Greer, Richard Klusmann, Susan Klusmann, Robert Peterson, Karen Peterson, Plaintiffs-Appellees;
2. DePuy Orthopaedics, Inc.; Synthes, Inc.; DePuy Synthes, Inc.; Johnson & Johnson International; Johnson & Johnson, Defendants-Appellants;
3. The Lanier Law Firm, PC (W. Mark Lanier, Richard P. Meadow); Fisher, Boyd, Johnson & Huguenard, LLP (Larry Boyd, Wayne Fisher, Justin Presnal); Neblett, Beard & Arsenault (Richard J. Arsenault, Jennifer M. Hoekstra); Simmons Hanly Conroy (Jayne Conroy); Franklin D. Azar & Associates, P.C. (Franklin D. Azar, Robert O. Fischel, Tonya L. Melnichenko, Nathan J. Axvig); Kiesel & Larson LLP (Paul R. Kiesel, Helen Zukin, Matthew A. Young); Parker Waichman LLP (Jerrold S. Parker); Kenneth W. Starr; Counsel for Plaintiffs-Appellees;

4. Kirkland & Ellis LLP (Paul D. Clement, Jeffrey M. Harris, Michael D. Lieberman, Kevin M. Neylan, Jr.); Skadden, Arps, Slate, Meagher & Flom LLP (John H. Beisner, Stephen J. Harburg, Jessica D. Miller, Geoffrey M. Wyatt); Locke Lord LLP (Michael V. Powell, Seth M. Roberts); Barrasso Usdin Kupperman Freeman & Sarver, L.L.C. (Richard E. Sarver, Andrea Mahady Price); Andrew C. White, Johnson & Johnson Services, Inc.; Counsel for Defendants-Appellants.

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STATEMENT REGARDING ORAL ARGUMENT

Appellants respectfully request oral argument. This appeal arises from a two-month-long trial in one of the largest multidistrict litigation proceedings pending in the federal court system. In light of the voluminous record and the complexity of the issues involved, Appellants believe that oral argument would assist the Court in resolving the appeal.

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STATEMENT OF JURISDICTION

The district court (Kinkeade, J.) entered final judgment on July 5, 2016, and Appellants filed a notice of appeal on July 6, 2016. The district court had jurisdiction under 28 U.S.C. §1332(a)(1). This Court has appellate jurisdiction under 28 U.S.C. §1291.

PRELIMINARY STATEMENT

In the proceedings below, the jury returned a half-billion-dollar verdict in favor of five plaintiffs who alleged defects with the implants they received during hip-replacement surgery. That colossal verdict cannot be explained by either the relevant law or the factual record, both of which make clear that the verdict is indefensible. Indeed, plaintiffs' claims never should have been submitted to the jury at all, as they are foreclosed by Texas law, preempted by federal law, and—for two of the plaintiffs—barred by the statute of limitations.

Even aside from those errors, Appellants would be entitled to a new trial, as the jury's verdict resulted from plaintiffs' deliberate strategy to inflame the jury through highly prejudicial evidence and wholly inappropriate argument. To highlight just a few egregious examples, plaintiffs' counsel accused Appellants of supporting "the henchmen of Saddam Hussein," attempted to link Appellants to "big tobacco" and the company "portrayed in the movie Erin Brockovich," and suggested repeatedly that Appellants' products caused cancer and suicide (even

though plaintiffs made no such allegations). The proceedings below careened off the rails in a number of critical respects, and this Court should enter judgment as a matter of law for Appellants or, at a minimum, remand for a new trial that focuses on relevant evidence and appropriate argument and provides basic guarantees of fairness.

* * *

The Pinnacle Ultamet ("Ultamet") is a "metal-on-metal" implant used during hip replacement surgery that was designed to solve several problems with the "metal-on-polyethylene" implants that had previously dominated the market. Like all medical devices, the Ultamet carries risks of side effects—including tissue reactions to metallic particles released from the implant—which are described in the Ultamet's Instructions For Use ("IFU").

All five plaintiffs received the Ultamet implant during hip replacement surgery. Each plaintiff, after allegedly experiencing adverse effects described in the IFU, subsequently underwent "revision" surgery. Although plaintiffs claim varying degrees of continued impairment, they testified that they remain able to swim, travel, and perform in theatrical productions (Aoki), golf, ski, and exercise daily (Peterson), travel abroad and go on sailing trips (Greer), go fishing and cut the grass (Christopher), and exercise and travel to Mexico (Klusmann).

Plaintiffs brought suit against the manufacturer of the Ultamet (DePuy Orthopaedics, Inc. ("DePuy")) and its corporate parent (Johnson & Johnson ("J&J")), alleging design defects and failure to warn about potential risks. The jury returned a staggering $502 million verdict.

That half-billion-dollar award was the product of a series of profound errors that allowed the jury to return a verdict based on inflammatory rhetoric rather than the law and the factual record. Plaintiffs' design-defect and marketing-defect claims against DePuy suffered both from fatal legal flaws (such as plaintiffs' failure to identify a safer alternative design for the Ultamet) and failures of proof on critical questions (such as the adequacy of DePuy's warnings and causation). And plaintiffs' claims against J&J should have been dismissed at the outset for lack of personal jurisdiction because J&J—as distinct from its various subsidiaries—did not have sufficient suit-related forum contacts to justify haling it into a Texas court. In all events, plaintiffs' three claims against J&J also fail on the merits: two of the three ("nonmanufacturing seller" and "aiding and abetting") are not even causes of action under Texas law, and the third ("negligent undertaking") had no basis in the trial record.

At a minimum, Appellants are entitled to a new trial for several independent reasons: the district court repeatedly admitted highly prejudicial and inflammatory evidence over Appellants' objections, improperly refused to bifurcate the punitive

damages phase of the trial (as required by Texas law), and upheld a money judgment that is unmoored from the record evidence and vastly excessive under Texas law.

* * *

All of those errors would have been bad enough even if these were the only five plaintiffs who had brought suit over the Ultamet. But this was supposed to be a "bellwether" trial that would inform future proceedings in a multi-district litigation with thousands of other pending cases. Bellwether trials are supposed to provide the parties with unbiased information about the objective value of the asserted claims. *See, e.g.*, *In re Chevron*, 109 F.3d 1016, 1020-21 (5th Cir. 1997). In that regard, this trial was an abject failure. This Court should reverse the judgment below and either enter judgment for Appellants or remand for a new trial.

STATEMENT OF THE ISSUES

1. Whether the district court erred by denying DePuy's motion for judgment as a matter of law on plaintiffs' design-defect and marketing-defect claims, and on the timeliness of Greer's and Klusmann's claims.
2. Whether the district court erred by exercising personal jurisdiction over J&J.
3. Whether J&J is entitled to judgment as a matter of law on plaintiffs' claims for "nonmanufacturing seller," aiding-and-abetting, and negligent undertaking.

4. Whether Appellants are entitled to a new trial in light of the district court's admission of highly inflammatory and prejudicial evidence and plaintiffs' counsel's improper closing argument.
5. Whether the district court erred by refusing to bifurcate the exemplary damages phase of trial from the liability phase.
6. Whether the jury's damages award was excessive.

STATEMENT OF THE CASE

A. Background on Hip Implants and the Ultamet

A hip joint involves a ball-and-socket mechanism in which the rounded head of the femur ("femoral head") meets the pelvis at a concave surface known as the acetabulum. When the structures in the hip joint become damaged, a person can suffer severe pain and impaired mobility.

Total hip replacement is a surgical procedure in which a diseased hip joint is replaced with an artificial implant. In general, a hip implant consists of four components: (1) a femoral stem, which is a metal stem implanted into the center of the femur; (2) a femoral head, which is a rounded component, most often made of metal, that attaches to the stem and replaces the rounded head of the femur; (3) an acetabular cup, also made of metal, which is secured within the acetabulum when bone grows into the porous surface or by cement; and (4) a liner, which can be made of polyethylene, metal, or ceramic, that is placed between the acetabular

cup and the femoral head. Regardless of the materials used for the head and liner (metal, polyethylene, or ceramic), small particles wear off from the surface of each component as the femoral head articulates against the liner within the cup. Reactions to those particles have always been a potential cause of complications for patients with hip replacements.

In a metal-on-metal hip implant, the femoral head and the liner inside the acetabular cup are both metal. The first widely used hip implant was a metal-on-metal device that came to prominence in the 1960s. ROA.16-11056.10810-11. Around the same time, Sir John Charnley developed a different type of device that used an acetabular cup with a liner made of polyethylene. ROA.16-11056.10114-15. For many years, this "metal-on-polyethylene" implant was the "gold standard" for hip implants. ROA.16-11056.10114-15.

Over time, however, the medical community discovered significant problems with metal-on-polyethylene implants. Polyethylene's wear rate limited the lifespan of the device, making it unsuitable for younger, active patients. ROA.16-11056.13391; ROA.16-11056.13984-85. More concerning, the movement of the metal head against the polyethylene liner generated plastic particle debris that could trigger an immune reaction causing bone loss in the area surrounding the implant (a condition called osteolysis). ROA.16-11056.10801-02, ROA.16-11056.13964.

By the 1990s, the medical community saw polyethylene as the "weak link" in hip implants, ROA.16-11056.13970; ROA.16-11056.7068-69, and began searching for new solutions. The orthopedic community eventually began to create new types of metal-on-metal implants that were designed to overcome the wear and lifespan problems plaguing metal-on-polyethylene devices, while also fixing various issues with earlier metal-on-metal devices. ROA.16-11056.13428-40; ROA.16-11056.10808-09.

What followed was a "third generation" of metal-on-metal implants. Between 1999 and 2015, FDA cleared more than 180 metal-on-metal implants from 21 different manufacturers, including different variations of the "Ultamet" device at issue here. ROA.16-11056.16052-58. The first Ultamet was implanted in a patient in March 2001, and the device was fully available to surgeons in mid-2002. ROA.16-11056.15350-51.

Like all implantable medical devices, metal-on-metal implants are not risk-free. As FDA has recognized, metal-on-metal implants may lead to "adverse tissue reaction." 47 Fed. Reg. 29,052, 29,082 (July 2, 1982). That risk, among others, is explicitly communicated to doctors on the Instructions For Use ("IFU") for the Ultamet, as well as in a Technical Monograph that DePuy made available to surgeons. *See* RE.19, 20, 21, 22. Despite those risks, FDA concluded that metal-on-metal implants can offer "relief of disabling pain and restoration of joint

function, which may result in a return to daily activities and an improved quality of life," especially for "young, active patients." 78 Fed. Reg. 4094, 4098 (Jan. 18, 2013); *see also* 47 Fed. Reg. at 29,082.

B. The MDL Proceedings

The multidistrict litigation from which this appeal arises involves the products liability claims of more than 9,000 plaintiffs who claim to have received a Pinnacle hip implant during hip replacement surgery. The plaintiffs (and their spouses) alleged they were injured by metal debris generated by the device's metal-on-metal design. Among other things, they claimed DePuy defectively designed the Ultamet and failed to adequately warn of its risks. They also sought to impose liability on DePuy's parent company, J&J, even though the Ultamet was manufactured, marketed, and sold exclusively by DePuy and other independent J&J subsidiaries.[1]

In 2011, the Judicial Panel on Multidistrict Litigation ordered the centralization in the Northern District of Texas of pretrial proceedings in all actions involving the Ultamet devices. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F. Supp. 2d 1358, 1360 (J.P.M.L. 2011). In consultation with the MDL court, Appellants and the Plaintiffs' Executive

[1] J&J is a holding company that directly or indirectly owns more than 265 operating companies in 60 countries. ROA.16-11056.852 ¶3. As relevant here, J&J owns Johnson & Johnson International, Inc., which owns DePuy Synthes, Inc., which owns a subsidiary, which owns DePuy. *See* ROA.16-11056.852 ¶¶6-7.

Committee ("PEC") agreed to establish a bellwether trial protocol. *See* Special Master's Report, No. 3:11-md-2244-K (N.D. Tex. Jan. 16, 2013), ECF No. 247. The initial order on bellwether trials provided for selection of bellwether candidates from a pool of eight cases, with four selected by the PEC and four by Appellants. *Id.* at 2.

C. The First Bellwether Trial

The PEC selected the case for the first bellwether trial. The plaintiffs were Kathleen Herlihy-Paoli, a Montana resident whose hips had both been replaced with Ultamet devices, and her husband. *See* Amended Complaint, *Paoli v. DePuy Orthopaedics, Inc.*, No. 3:12-cv-04975-K (N.D. Tex. Mar. 14, 2014), ECF No. 14. The *Paoli* trial began in September 2014 and lasted almost two months. The jury returned a complete verdict for Appellants.

D. The Second Bellwether Trial

1. The district court did not enter final judgment on the *Paoli* verdict. Instead, it *sua sponte* jettisoned the seven cases remaining from the original pool of bellwether candidates (for which discovery was nearly completed) and ordered the parties to prepare ten new cases for trial, eight of which had been selected by the PEC. *See* Order on Bellwether Trials, No. 3:11-MD-2244-K (N.D. Tex. Feb. 18, 2015), ECF No. 491.

Less than one month before the scheduled trial date, the court notified the parties that five of the cases (including four selected by the PEC) would be consolidated and tried jointly. Appellants objected, explaining that consolidation would undermine the trial's bellwether function and prejudice their defense. The court denied the motion and ordered consolidation.

The plaintiffs were Margaret Aoki, Jay Christopher, Donald Greer, Robert Peterson, and Richard Klusmann (and three of their spouses), all Texas citizens. Each had suffered from chronic hip pain for several years before receiving an Ultamet implant. Each plaintiff's surgery was initially successful, with each experiencing reduced pain and increased mobility. Several years later, however, the plaintiffs began to experience pain or discomfort in their surgically repaired hips (the cause of which was sharply disputed at trial[2]), and each subsequently underwent "revision" surgery to replace their Ultamet implants. Aoki, Greer, Peterson, and Christopher have recovered extremely well from their revision surgeries, and each testified that his or her hip feels vastly improved. Klusmann continues to experience serious difficulties, but has been able to resume walking, swimming, lifting weights, and traveling.

[2] There are many reasons wholly unrelated to alleged problems with an implant that might necessitate revision surgery.

2. At trial, plaintiffs argued that DePuy defectively designed and defectively marketed the Ultamet. But plaintiffs did not assert that the Ultamet was defectively designed compared to other types of metal-on-metal implants, nor did they offer an alternative metal-on-metal design alleged to be safer than the Ultamet. Instead, plaintiffs argued that metal-on-metal hip implants are *categorically* defective, notwithstanding FDA's clearance of more than 180 metal-on-metal devices and its recognition of their health benefits.

Plaintiffs took similar shortcuts on their failure-to-warn claim against DePuy. Instead of identifying a particular representation or omission that affected the plaintiffs' surgeons' decisions to use the Ultamet (such as some misstatement or omission in the IFU), plaintiffs argued that DePuy broadly marketed the Ultamet in journals and publications that plaintiffs' surgeons were likely to read. Not one of the plaintiffs' surgeons testified that he would not have used the Ultamet if additional or different warnings had been provided.

Plaintiffs also advanced three separate claims against J&J. First, they argued that J&J should be held liable for their injuries because it was a "nonmanufacturing seller" of the Ultamet under section 82.003 of the Texas Civil Practice & Remedies Code. Second, plaintiffs alleged that J&J aided and abetted DePuy's tortious conduct. Third, plaintiffs contended that J&J caused their injuries by undertaking to provide services for plaintiffs' protection, but then performing those services

negligently. Plaintiffs did not ask the jury to award compensatory damages against J&J, but did request exemplary damages. ROA.16-11056.5924-45. Because J&J had no involvement in the manufacture, design, or sale of the Ultamet, nearly all of the evidence plaintiffs introduced involved actions of independent J&J subsidiaries rather than of J&J itself. To obscure that fact, plaintiffs' counsel repeatedly employed loose language designed to blur the distinctions among the various companies at issue. For example, counsel repeatedly attributed the conduct of subsidiaries to "Johnson & Johnson" writ large, or, with greater imprecision, to "DePuy/Johnson & Johnson." *E.g.* ROA.16-11056.7632.

3. To distract from their evidentiary shortcomings, plaintiffs' counsel repeatedly introduced evidence and made arguments that served no plausible purpose other than to inflame the jury's passions. This "evidence" included: references to "bribes" supposedly paid to Saddam Hussein's "henchmen" by a *different nonparty* J&J subsidiary; references to risks of cancer and suicide that were *not even alleged* here; references to inflammatory allegations of racism by DePuy employees; references to over 45,000 lawsuits facing a *different nonparty* J&J subsidiary over pelvic mesh products; and attempts to link DePuy and J&J to "big tobacco," "Love Canal," and the "utility … portrayed in the movie Erin Brockovich," ROA.16-11056.14926-36. Appellants' repeated objections to this

irrelevant and highly prejudicial evidence (and their multiple motions for mistrial) were overruled or denied.

4. The jury, confronted with this wealth of irrelevant evidence and inflammatory rhetoric, found for the plaintiffs on all causes of action other than commercial bribery, and returned a colossal $502 million verdict. ROA.16-11056.5918-47. The verdict included just $536,514 in economic compensatory damages, but over *263 times* that amount—$141.5 million—in non-economic compensatory damages (*i.e.*, physical pain and mental anguish). The verdict form required the jurors to award compensatory damages in twelve separate categories, but the sums of the jury's awards to each plaintiff nonetheless equaled almost perfectly round numbers, strongly suggesting the jury simply chose a large number for each plaintiff and then worked backwards. The jury also tacked on $360 million in punitive damages ($120 million against DePuy and $240 million against J&J).

DePuy and J&J renewed their motions for judgment as a matter of law, moved for a new trial, and asked the district court to apply Texas's statutory cap on exemplary damages. Without any action by the district court on those motions, and with another six-plaintiff consolidated trial scheduled to begin in less than three months, Appellants petitioned this Court for a writ of mandamus compelling the district court to rule on the post-trial motions and enter final judgment. Shortly

after Appellants filed that petition (and four days after this Court asked plaintiffs to respond), the district court entered final judgment in both *Paoli* and this case. The district court then granted Appellants' motion to apply the statutory cap—reducing the exemplary damages to $9.6 million—and denied all other post-trial motions. *See, e.g.*, ROA.16-11056.6606-07.

Even though DePuy and J&J filed hundreds of pages of briefs in support of their post-trial motions for judgment as a matter of law and for a new trial, the district court summarily denied those motions without one word of explanation or reasoning (other than the word "DENIED"). *See* ROA.16-11056.6606-07, ROA 16-11056.38 (Dkt.288). This appeal followed.

STANDARD OF REVIEW

This Court reviews a district court's ruling on a motion for judgment as a matter of law *de novo*, applying "the same standard to review the verdict that the district court used in first passing on the motion." *Nobach v. Woodland Vill. Nursing Ctr.*, 799 F.3d 374, 377 (5th Cir. 2015). Judgment as a matter of law is appropriate if the jury did not have a "legally sufficient evidentiary basis" to find for the plaintiff, Fed. R. Civ P. 50(a)(1)(B), including when the plaintiff fails to introduce any evidence to prove an element of his or her claim, *see Anthony v. Chevron*, 284 F.3d 578, 583 (5th Cir. 2002).

This Court reviews the district court's exercise of personal jurisdiction *de novo*, applying the same standard as the district court. *Clemens v. McNamee*, 615 F.3d 374, 378 (5th Cir. 2010).

A court may grant a new trial "based on its appraisal of the fairness of the trial and the reliability of the jury's verdict." *Smith v. Transworld Drilling*, 773 F.2d 610, 612-13 (5th Cir. 1985). A new trial is appropriate if the court "finds the verdict is against the weight of the evidence, the damages awarded are excessive, the trial was unfair, or prejudicial error was committed in its course." *Id.* at 613. This Court reviews a district court's denial of a motion for new trial for abuse of discretion. *Olibas v. Barclay*, 838 F.3d 442, 449 (5th Cir. 2016).

The summary nature of the district court's rulings, however, should foreclose any claims of deference to the district court's "discretion." *See*, *e.g.*, *Rowan Cos. v. Griffin*, 876 F.2d 26, 30 (5th Cir. 1989) ("Without an assignment of reasons for the district court's action, we cannot perform the appellate function."); *In re Lloyd's Register N. Am., Inc.*, 780 F.3d 283, 290 (5th Cir. 2015) ("It is an abuse of discretion for a district court to grant or deny a motion to dismiss without written or oral explanation."); *Lone Star Ladies Inv. Club v. Schlotzsky's*, 238 F.3d 363, 367 (5th Cir. 2001). Given that the district court offered no explanation about why it denied DePuy's numerous post-trial motions, those rulings should be entitled to little, if any, deference on appeal.

SUMMARY OF ARGUMENT

The half-billion-dollar verdict in this case was a product of both legal error and a successful effort to inflame the jury with irrelevant and highly prejudicial evidence and argument. The resulting proceedings ultimately failed in their objectives of providing a fair result in these cases and providing a useful bellwether to determine the value (if any) of plaintiffs' claims. Appellants are entitled to judgment as a matter of law on each of plaintiffs' claims or, at a minimum, a new trial in which the jury is presented only with relevant and admissible evidence, not with wild accusations that Appellants aided "Saddam's henchmen" and are as evil as "big tobacco companies" and "the utility in Erin Brockovich."

I. DePuy is entitled to judgment as a matter of law on plaintiffs' design-defect and marketing-defect claims. Plaintiffs' design-defect claims never should have been submitted to the jury. First, plaintiffs did not introduce any evidence of a safer alternative design *for a metal-on-metal hip implant*. They instead argued (impermissibly under Texas law) that the safer alternative design was a *different product* altogether: namely, a metal-on-polyethylene hip implant. Second, federal law preempts plaintiffs' design-defect claims because plaintiffs' theory of the case (that all metal-on-metal hip implants are categorically defective) conflicts with FDA's considered judgment that metal-on-metal hip implants should remain

available for sale as Class III medical devices. Third, comment k to the Restatement (Second) of Torts §402A prohibits strict liability design-defect claims against manufacturers of metal-on-metal hip implants because the implants are "unavoidably unsafe" medical products that will benefit numerous patients but may also cause side effects in some subset of the population.

DePuy is also entitled to judgment as a matter of law on plaintiffs' marketing-defect claims. The Ultamet's packaging explicitly warned of the injuries plaintiffs claim to have experienced, and plaintiffs failed to introduce any expert testimony that those warnings were inadequate (as Texas law requires). And plaintiffs offered literally zero evidence that their implanting surgeons would have chosen a different implant if DePuy had provided additional warnings. Plaintiffs thus failed to show either that DePuy's warnings were inadequate or that any such inadequacy *caused* their injuries.

Greer's and Klusmann's claims are also time-barred. Texas law imposes a two-year statute of limitations for personal-injury claims that begins to run once the plaintiff knows facts that would lead a reasonable person to *make an inquiry* that would lead to discovery of the cause of action. More than two years before they brought suit, both Greer and Klusmann were experiencing pain and other symptoms with their surgically repaired hips that would have put any reasonable person on notice that there may have been a problem with their implants.

II. Plaintiffs' claims against J&J also fail for several reasons. The Supreme Court has long held that due process requires each defendant's forum contacts to be evaluated separately. Here, however, plaintiffs attempted to establish specific personal jurisdiction over J&J by conflating J&J with DePuy and other legally and functionally distinct subsidiaries. The Due Process Clause forbids such jurisdiction-by-association. When J&J's Texas contacts (or lack thereof) are considered on their own, the absence of personal jurisdiction over J&J is clear.

Plaintiffs' theories of liability against J&J fare no better. Indeed, two of the three causes of action plaintiffs asserted against J&J *simply do not exist* under Texas law. The first, what plaintiffs term "nonmanufacturing seller" liability, attempts to make J&J pay damages by proving that J&J meets the prerequisites for an affirmative defense. That theory is every bit as wrong as it sounds. No Texas court has even suggested that "nonmanufacturing seller" is a standalone cause of action in a product-liability case. Plaintiffs' second theory of liability—that J&J is liable for "aiding and abetting" DePuy's design and marketing defects—is likewise a non-starter. The Texas Supreme Court has repeatedly declined to recognize an aiding-and-abetting cause of action under Texas tort law, and bedrock principles of judicial federalism prohibit federal courts from expanding state substantive law by recognizing new causes of action.

Plaintiffs' third claim, for "negligent undertaking," at least has the virtue of being an extant cause of action under Texas law, but readily fails on the merits. Nothing in the record suggests that J&J undertook to perform services necessary for plaintiffs' protection, or that plaintiffs or their surgeons relied on anything J&J allegedly did. Plaintiffs' contrary argument depends, yet again, on cobbling together a series of actions performed by corporate entities *other than J&J*.

III. In the alternative, Appellants are entitled to a new trial. Although this was supposed to be a "bellwether" trial that provided objective information about the value of plaintiffs' claims, the trial was plagued by highly prejudicial evidentiary rulings that constitute reversible error. Over Appellants' repeated objections, the district court allowed plaintiffs to present outrageously inappropriate evidence and rhetoric to the jury: linking Appellants to Saddam Hussein, "big tobacco," Love Canal, and the Erin Brockovich movie; unproven allusions to cancer and suicide; unproven and provocative allegations of racism; and references to "thousands" of other pending cases against DePuy and J&J. These were not just offhand comments; they pervaded plaintiffs' presentation and were central to their trial strategy, as reflected in plaintiffs' counsel's closing argument to the jury, which repeatedly discussed this "evidence" while tarring DePuy as an evildoer.

A new trial also is warranted because the district court refused to bifurcate the exemplary damages portion of the trial. When a plaintiff seeks exemplary damages, Texas law expressly requires bifurcation regarding the amount of exemplary damages. The purpose of this provision is obvious—to prevent the jury's consideration of liability and compensatory damages from being skewed by evidence that may be relevant only to punitive damages. Here, however, the district court refused to order bifurcation despite Appellants' timely request, in clear contravention of substantive rights conferred by Texas law.

IV. At a minimum, the damages award must be vacated or remitted. The jury's verdict in this case—which includes just $536,500 in economic damages but $141.5 million in non-economic compensatory damages—is wholly disproportionate to plaintiffs' injuries, far exceeds the amounts awarded in similar Texas cases, and cannot be explained as anything other than a product of the jury's "passion or prejudice."

ARGUMENT

I. DePuy Is Entitled To Judgment As A Matter Of Law On Both Of Plaintiffs' Product-Liability Claims.

A. Plaintiffs' Design-Defect Claims Fail as a Matter of Law.

Plaintiffs' theory of design-defect had nothing to do with the Ultamet's design. For example, plaintiffs did not claim that the Ultamet should have been shaped differently, made of a different metal alloy, or altered in some other detail.

Instead, they claimed that metal-on-metal hip implants are *categorically* defective, and that every single metal-on-metal implant should have been banned from the market. That expansive theory of design defect is legally unsustainable for multiple independent reasons, as a matter of both state and federal law.

1. Plaintiffs failed to prove the existence of a safer alternative design.

To prevail on their design-defect claims under Texas law, plaintiffs were required to prove that "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *Casey v. Toyota*, 770 F.3d 322, 330 (5th Cir. 2014). Plaintiffs failed to satisfy the second element of this test. Instead of identifying a safer *alternative design* for a metal-on-metal hip implant, plaintiffs pointed only to an entirely *different product*: a metal-on-polyethylene hip implant. *See* ROA.16-11056.16910 (plaintiffs' counsel explaining that alternative design is "metal-on-poly"). But Texas law makes clear that pointing to "a substantially different product" will not suffice. *Brockert v. Wyeth*, 287 S.W.3d 760, 770-71 (Tex. App.—Houston [14th Dist.] 2009, no pet.).

A safer alternative design "must be one for the product at issue," *id.* at 770, and cannot involve a different product altogether. For example, a plaintiff alleging that a convertible is defectively designed cannot propose making the design safer "by fully enclosing the cab," because that would turn the convertible into "an

ordinary car." *Caterpillar v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995); *see also Damian v. Bell Helicopter Textron*, 352 S.W.3d 124, 150 n.19, 154 n.26 (Tex. App.—Fort Worth 2011, pet. denied) (lightweight helicopter and medium-weight helicopter are different products); *Hosford v. BRK Brands*, __ So.3d__, 2016 WL 4417256, at *2-*8 (Ala. Aug. 19, 2016) (ionization smoke alarms and dual-sensor smoke alarms are different products). Texas law does not "impose liability in such a way as to eliminate whole categories of useful products from the market." *Caterpillar*, 911 S.W.2d at 385.

Texas cases provide ample guidance about how to distinguish between safer alternative designs and substantially different products. In particular, a proposed alternative must do more than just serve "the same general purpose as the allegedly defective product." *Brockert*, 287 S.W.3d at 770. Instead, the alternative design must offer the same benefits, serve the same customers, and solve the same problems as the allegedly defective product. For example, in *Caterpillar*, the allegedly defective product was a front-end loader with a removable rollover-protection structure. The plaintiff argued that the loader should have been designed with a *non-removable* protective structure. But the Texas Supreme Court rejected that argument, explaining that the removable protective structure made the loader a "multi-purpose" vehicle that could "be used in low clearance areas," and a

non-removable structure would have eliminated that functionality and turned the loader into a different product. 911 S.W.2d at 384.

Similarly, in *Brockert*, the plaintiff alleged that a prescription drug (Prempro) containing both estrogen and progestin was defectively designed. 287 S.W.3d at 769. Instead of explaining how Prempro "could have been modified or improved," the plaintiff argued that the manufacturer should have sold a drug that did not contain *any* progestin. *Id.* at 770-71. The Court of Appeals rejected that proposed alternative, explaining that Prempro was "intended for a different population of women" than estrogen-only drugs because it helped "reduce the incidence of endometrial hyperplasia." *Id.* at 769-70.

Like a convertible versus a sedan or Prempro versus an estrogen-free alternative, a metal-on-metal hip implant and a metal-on-polyethylene hip implant are different *products*, not just competing *designs* for the same product. Metal-on-metal implants and metal-on-poly implants are marketed as separate products; are intended for different patient populations; provide different benefits to their users; are regulated by FDA as distinct products; and are subject to disparate regulatory requirements.

Witnesses on both sides agreed that metal-on-metal implants are designed for younger patients, who often seek not just pain relief but also the ability to resume an active lifestyle. For example, plaintiffs' witness Dr. Kearns testified that

he believed metal-on-metal implants were superior to metal-on-polyethylene implants for "an active patient who is going to run his business, teach baseball, hunt, fish, dance, get out there." ROA.16-11056.9892. Likewise, Greer acknowledged that his surgeon chose metal-on-metal because it "would stand up better to an active lifestyle." ROA.16-11056.7185. Dr. Haas, an orthopedic surgeon, testified that metal-on-metal devices were better for his "younger" and "more active" patients. ROA.16-11056.11997-98. In short, metal-on-metal and metal-on-poly implants have different benefits and risks, and surgeons chose between them based on their judgment about the specific needs of particular patients.

Moreover, just as Prempro was designed to remedy a side effect of estrogen-only drugs, *see Brockert*, 287 S.W.3d at 770-71, the Ultamet and other third-generation metal-on-metal implants were designed to remedy a side effect of metal-on-polyethylene implants (osteolysis). Instead of just modifying pre-existing metal-on-polyethylene devices in hopes of *reducing* plastic debris, DePuy developed what plaintiffs' counsel referred to as a "brand-new species" of implant—*i.e.*, a metal-on-metal device that would *eliminate* plastic debris entirely. ROA.16-11056.16898. By arguing that metal-on-polyethylene is the safer alternative design, plaintiffs are effectively arguing that DePuy should have

eliminated the very feature that made metal-on-metal implants an alternative to metal-on-poly implants.

Furthermore, FDA has long treated metal-on-metal implants and metal-on-polyethylene implants as different products. Metal-on-metal implants are regulated as Class III devices, while metal-on-polyethylene implants are Class II devices. *Compare* 21 C.F.R. §888.3330(b) *with* 21 C.F.R. §888.3310(b). Like the witnesses who testified at trial, FDA has also concluded that metal-on-metal implants are "especially beneficial in young, active patients" due to their longevity and durability. 78 Fed. Reg. at 4099.

In sum, plaintiffs were required to propose a safer alternative design *for a metal-on-metal hip implant*, but they instead pointed to a different product altogether, which is precisely what Texas courts have held that plaintiffs may *not* do. Their design-defect claims thus fail as a matter of law.

2. Federal law preempts plaintiffs' design-defect claims.

If state and federal law "directly conflict," the state law is preempted and must give way. *PLIVA v. Mensing*, 564 U.S. 604, 617 (2011). One type of conflict occurs when state tort law stands "as an obstacle to the accomplishment and execution" of federal objectives. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Here, plaintiffs sought to impose a state-law tort duty that would prohibit *all* metal-on-metal hip implants from the market as inherently unsafe. Even if plaintiffs'

expansive design-defect theory were viable under state law, *but see supra*, it would directly conflict with FDA's considered judgment that metal-on-metal devices should *not* be banned but instead should be regulated as Class III medical devices.

FDA regulates all medical devices sold in the United States, and oversees the sale of those devices by classifying them based on the potential risk they pose to the public. FDA can designate medical devices as Class I (*e.g.*, latex gloves), Class II (*e.g.*, surgical drapes), or Class III (*e.g.*, pacemakers)—or it may ban devices outright if they present "an unreasonable and substantial risk of illness or injury" that cannot be corrected or eliminated by a change in labeling. 21 U.S.C. §360f(a)(1); *see* ROA.16-11056.16049.

After carefully evaluating the safety and effectiveness of metal-on-metal hip implants, FDA determined that they may be sold so long as they comply with the requirements for Class III medical devices. 21 C.F.R. §888.3330(b). In fact, FDA has repeatedly rejected requests to ban metal-on-metal hip implants, determining that those products should remain on the market because they offer "relief of disabling pain and restoration of joint function," and "offer the potential to be especially beneficial in young, active patients." 81 Fed. Reg. 8146, 8147-48 (Feb. 18, 2016); *see also* 78 Fed. Reg. at 4099.

When the district court denied DePuy's motion for summary judgment on preemption grounds, it provided only one paragraph of analysis that confused

conflict preemption with express preemption. According to the district court, plaintiffs' claims could not be preempted because the *express* preemption provision of the Medical Device Amendments of 1976 ("MDA") applies only "to items cleared through the rigorous [premarket approval process]," and the Ultamet was instead cleared through FDA's §510(k) process. ROA.16-11056.1181. But it is well-established that an express preemption provision does not "bar[] the ordinary working of conflict pre-emption principles." *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001).

The question here is not whether the state-law tort duty is *expressly* preempted, but whether conflict preemption applies when a state-law tort duty would ban an entire class of products that FDA has concluded should remain available. The answer to that question is yes. According to plaintiffs, *all* metal-on-metal hip implants are *categorically* defective. FDA, however, has reached the exact opposite conclusion, determining that metal-on-metal implants should remain available for sale as Class III devices. The verdict below directly conflicts with FDA's expert judgment, and plaintiffs' categorical attack on metal-on-metal hip implants is preempted.

3. Plaintiffs' design-defect claims are barred by Restatement (Second) of Torts §402A comment k.

Plaintiffs' design-defect claims are also independently barred by comment k to Restatement (Second) of Torts §402A. The Supreme Court of Texas has

expressly adopted §402A—including comment k—as part of its common law. *Centocor v. Hamilton*, 372 S.W.3d 140, 165 (Tex. 2012); *New Tex. Auto Auction Servs. v. Gomez De Hernandez*, 249 S.W.3d 400, 403 (Tex. 2008). Comment k provides:

> There are some products which … are quite incapable of being made safe for their intended and ordinary use…. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous…. The seller of such products … is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

This Comment recognizes that medical products or devices may cause side effects in certain patients, but banning those products from the marketplace "would not serve the public welfare." *Brown v. Superior Court*, 751 P.2d 470, 479 (Cal. 1988). Those products "can save lives and reduce pain and suffering," even if "some risks, perhaps serious ones, might accompany their introduction." *Id.*

Texas courts have already applied comment k to unavoidably unsafe products such as prescription drugs and asbestos, *see supra*, and there is no question they would join the overwhelming majority of courts that apply comment k to implantable medical devices. *See, e.g.*, *Transue v. Aesthetech*, 341 F.3d 911, 915 (9th Cir. 2003); *Brooks v. Medtronic*, 750 F.2d 1227, 1232 (4th Cir. 1984); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 482 (W.D. Pa. 2012); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1994); *Hufft v. Horowitz*, 5 Cal. Rptr. 2d

377, 383 (Cal. Ct. App. 1992); *Perfetti v. McGhan Med.*, 662 P.2d 646, 650 (N.M. Ct. App. 1983).

Comment k lists as examples of unavoidably unsafe products the rabies vaccine, "other drugs," and "like" products that "cannot legally be sold except to physicians, or under the prescription of a physician." Hip implants fall comfortably within that class of products. "Just as drugs and vaccines are injected or ingested into the body, implant devices must be 'plugged in' to the individual, to work their effect upon or respond to complex systems imperfectly understood by medical science." *Hufft*, 5 Cal. Rptr. 2d at 383. Moreover, just as prescription drugs cannot be made perfectly safe for their intended use, the record here showed that there is no "risk-free device that you can implant in your patients today." ROA.16-11056.10018; *see also* ROA.16-11056.9591-92.

In short, hip implants are identical in all relevant respects to the products that comment k cites as examples of "unavoidably unsafe" products that are "useful and desirable" despite their risks. Plaintiffs' strict-liability design-defect claims thus fail as a matter of law. At a minimum, the district court should have instructed the jury that it could not rule for plaintiffs if metal-on-metal hip implants are "unavoidably unsafe," as that term is defined in the Restatement. *See* ROA.16-11056.4787-88 (requesting instruction).

B. Plaintiffs' Marketing-Defect Claims Fail as a Matter of Law.

DePuy is also entitled to judgment as a matter of law on plaintiffs' marketing-defect claims for several independent reasons, including the fact that DePuy explicitly warned of the injuries plaintiffs claim to have experienced.

1. A marketing defect occurs when a manufacturer knows or should know of a risk of harm, but sells its product without adequately warning of that risk. *Wright v. Ford*, 508 F.3d 263, 274 (5th Cir. 2007). A warning is adequate as a matter of law when it "specifically mentions the circumstances complained of." *Ackermann v. Wyeth*, 526 F.3d 203, 208 (5th Cir. 2008). In *Seifried v. Hygenic Corp.*, 410 S.W.3d 427 (Tex. App.—Houston [1st Dist.] 2013, no pet.), for example, the court held that warnings included with the packaging of a resistance band were adequate as a matter of law because they specifically warned of the eye injuries plaintiff suffered when the band snapped. *Id.* at 434; *see also Rolen v. Burroughs Wellcome*, 856 S.W.2d 607, 610 (Tex. App.—Waco 1993, writ denied).

Here, all five plaintiffs testified that they experienced corrosion and friction wear from their hip implants, and suffered adverse reactions to that debris. *See* ROA.16-11056.10302 (Aoki: elevated cobalt and chromium levels); ROA.16-11056.8785-86 (Greer: "metallosis and particle disease"); ROA.16-11056.9905 (Christopher: "adverse reaction to metal debris"); ROA.16-11056.11875-78 (Peterson: elevated metal ion levels in bloodstream and metallosis); ROA.16-

11056.9278-79 (Klusmann: nerve and tissue damage and elevated metal levels in bloodstream).

As required by FDA regulations, DePuy included an insert in the packaging for each of the four components of plaintiffs' hip implants entitled "Instructions For Use" (IFU). *See* ROA.16-11056.16071-75. The IFUs expressly warn about risks of the injuries alleged by the plaintiffs. The IFU for the acetabular cup warns of "allergic reactions to implant materials," "tissue reactions to implant corrosion or implant wear debris," "implant loosening caused by metallic corrosion," and "accumulation of polyethylene or metal wear debris or loose cement particles." RE.19. Similarly, the IFU for the metal liner warns about the release of "metallic ions into the body," "histological reactions [from] exposure to a foreign material," "release of metallic debris into the joint space," "nerve damage," "dislocation and subluxation," and "tissue laxity," all of which could produce "serious adverse effects" and could "necessitate surgical intervention." RE.20. Other materials DePuy made available to surgeons contained similar warnings. *See* RE.21 (Technical Monograph warning of metallic corrosion, inflammatory and immune responses to metal particles, and hypersensitivity); RE.22 (surgical technique manual warning of "tissue reaction," "peripheral neuropathy," "nerve damage," and "loosening and subsequent failure of the total hip prosthesis").

Because the warnings DePuy provided to surgeons "specifically mention[] the circumstances complained of," *Ackermann*, 526 F.3d at 208, plaintiffs' marketing-defect claims fail as a matter of law.

2. Plaintiffs' marketing-defect claims also suffer from a simple failure of proof. Under Texas law, plaintiffs must provide expert testimony to establish that a medical device was defectively marketed. *Ethicon Endo-Surgery v. Gillies*, 343 S.W.3d 205, 212 (Tex. App.—Dallas 2011, pet. denied). This requirement is a specific application of the general rule that "[e]xpert testimony is required when an issue involves matters beyond jurors' common understanding," *Mack Trucks v. Tamez*, 206 S.W.3d 572, 583 (Tex. 2006), as the adequacy of warnings provided with a specialized medical device "is not within the experience of laymen," *Ethicon*, 343 S.W.3d at 212; *see Gharda v. Control Sols.*, 464 S.W.3d 338, 348 (Tex. 2015).

Plaintiffs offered no such expert testimony. None of plaintiffs' four experts was designated as a warnings expert or opined on whether the IFUs adequately warned about adverse reactions to metal wear debris. Dr. Burstein, a mechanical engineer, was recognized as an expert only in the history, design, and effect of metal-on-metal implants, ROA.16-11056.9525, and did not testify about the warnings accompanying the Ultamet. Dr. Bernard Morrey was recognized as an expert on "metal-on-metal and metal-on-poly, the developments of them, the usage

of them, [and the] defectiveness of them." ROA.16-11056.10112-13. He did not testify about the adequacy of the IFU warnings and never claimed to have used a metal-on-metal implant or read the IFU or Technical Monograph for the Ultamet. ROA.16-11056.10114. Dr. Kearns was recognized as an expert only on whether metal-on-polyethylene was a safer alternative. ROA.16-11056.9913-15. He had "never read an [IFU] on the Pinnacle Ultamet metal-on-metal device" and did not know what it said "regarding risks for the implantation of these devices." ROA.16-11056.9949, 10020.

Plaintiffs argued below that their fourth expert, Dr. Matthew Morrey, provided the required expert testimony. But Dr. Morrey, one of the plaintiffs' treating surgeons who did not provide an expert report, was never recognized as an expert on warnings. He was recognized as an expert only on "metal-on-metal issues and problems, metal-on-poly effectiveness, the conditions [and] damages of Dr. Greer and [Klusmann] and the design defect and causation issues." ROA.16-11056.10996; *see Perez v. Goodyear*, 2016 WL 1464768, at *9 (Tex. App.—San Antonio 2016, no pet.) (affirming summary judgment on marketing-defect claim where plaintiff's only expert did "not hold himself out as a warnings expert").

In all events, Dr. Morrey never discussed whether the *actual warnings in the IFU* adequately warned of adverse risks caused by metal wear debris. In the testimony plaintiffs cited below, plaintiffs' counsel asked Dr. Morrey a series of

questions about a patient consent form DePuy used for a study that took place almost a decade before any of the plaintiffs received their hip implants. ROA.16-11056.11121-22 ("[T]his is the warning that was given to the people in the [2000] clinical trial."). Plaintiffs' counsel read aloud various warnings on that consent form and then asked Dr. Morrey whether DePuy should have included those same warnings in the IFU. ROA.16-11056.11121-22. Critically, however, Dr. Morrey never discussed whether the *warnings in the IFU* adequately warned of adverse risks caused by metal wear debris. Indeed, Dr. Morrey later conceded that the IFU warned about the types of injuries alleged by the plaintiffs. ROA.16-11056.11140-42 (acknowledging that IFU warned about allergic reactions, tissue reactions, metallic corrosion, and accumulation of metal wear debris).

3. Plaintiffs also failed to offer any evidence that the alleged marketing defects *caused* their injuries. *See Ackermann*, 526 F.3d at 213. Because the learned-intermediary doctrine applies to medical device warnings, *see Pustejovsky v. Pliva*, 623 F.3d 271, 276 (5th Cir. 2010), plaintiffs were required to prove "that a proper warning would have changed the decision *of the intermediary* to prescribe the product"—*i.e.*, that *their surgeons* would not have used the Ultamet if different warnings had been provided, *Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.3d 87, 95 (Tex. App.—Texarkana 2000, no pet.) (emphasis added).

The question of causation often turns on the testimony of the treating physician. For example, if the physician testifies that she never read the warning provided with the drug or device, then a better warning would not have prevented the alleged harm. *See Pustejovsky*, 623 F.3d at 277. Similarly, an allegedly insufficient warning does not cause the plaintiff's injuries if the treating physician was aware of the relevant risks but still chose to use the drug or device. *See Centocor*, 372 S.W.3d at 170; *Stewart v. Janssen Pharmaceutica*, 780 S.W.2d 910, 912 (Tex. App.—El Paso 1989, writ denied).

None of plaintiffs' surgeons testified that additional warnings would have affected his decision to use the Ultamet. Greer's and Peterson's implanting surgeons (Drs. Goletz and Schoch), did not testify at trial, nor did plaintiffs introduce their deposition testimony into evidence. The other plaintiffs' surgeons did testify, but their testimony actually *negates* any finding of causation. Christopher's surgeon, Dr. Kearns, admitted that he "never read an [IFU] on the Pinnacle Ultamet" and did not know what the IFU said "regarding risks for the implantation of these devices." ROA.16-11056.9949. Dr. Kearns conceded he "knew there were potential risks of the metal debris from a Pinnacle metal-on-metal hip," and was aware of "potential biological issues and tissue reactivity from metal debris," ROA.16-11056.9947-49; *see* ROA.16-11056.10015.

Similarly, Aoki's and Klusmann's surgeon (Dr. Heinrich) testified by deposition that he was aware of the "risk of ions attacking the tissue and the bone and getting in the blood," and of the "potential to develop other issues" that could lead to revision surgery. ROA.16-11056.9063-70. Dr. Heinrich never claimed to have read the Ultamet IFU and did not testify that he would have used a different implant if DePuy had provided different warnings. Because this surgeon "was aware of the possible risks of using the [Ultamet] but decided to use it anyway," the allegedly inadequate warning could not have caused plaintiffs' injuries. *Porterfield v. Ethicon*, 183 F.3d 464, 468 (5th Cir. 1999).

C. Greer's and Klusmann's Claims Are Barred by the Statute of Limitations.

Greer's and Klusmann's claims are independently barred by the statute of limitations because both discovered their injuries more than two years before they filed suit. *See* ROA.16-11052.5240; ROA.16-11052.6823.

Under Texas law, a personal injury action must be filed "not later than two years after the day the cause of action accrues." Tex. Civ. Prac. & Rem. Code §16.003(a). That limitations period is tolled "until the plaintiff discovers, or through the exercise of reasonable care and diligence should have discovered, the nature of the injury." *Porterfield*, 183 F.3d at 467. "The term 'discovered,' however, is quite broad." *Vaught v. Showa Denko K.K.*, 107 F.3d 1137, 1140 (5th Cir. 1997). A plaintiff need not know "the specific cause of the injury; the party

responsible for it; the full extent of it; or the chances of avoiding it." *Exxon v. Emerald Oil & Gas*, 348 S.W.3d 194, 207 (Tex. 2011). Rather, discovery occurs when the plaintiff acquires "knowledge of facts that would cause a reasonably prudent person to make an inquiry that would lead to discovery of the concealed cause of action." *Pirtle v. Kahn*, 177 S.W.3d 567, 573 (Tex. App.—Houston [1st Dist.] 2005, pet. denied).

Greer and Klusmann not only had enough information to inquire about their hip implants more than two years before filing suit, but they *actually made those inquiries* to their physicians. *See Vaught*, 107 F.3d at 1141 (limitations began to run when plaintiff connected her symptoms to their potential cause and contacted a lawyer). Greer, himself a doctor, brought suit on May 30, 2012—more than *four years* after he notified his surgeon that something was amiss with his hip implant. In November 2007, Greer visited his surgeon because of "a decrease in the motion in the right hip," and "pain in the side of the hip and anterior thigh." RE.23. Then, in March 2008, Greer wrote to his surgeon that his hip was "steadily growing worse" and "I am as bad off, if not worse than the day in your office when you recommended the total hip replacement." RE.24; *see* RE.25. At trial, Greer confirmed that he was "concerned that there was something wrong" with his surgically repaired hip as early as 2008. ROA.16-11056.8865-66.

Klusmann, a retired hospital executive, likewise knew about his injuries more than two years before he filed suit on October 19, 2011. When asked when his surgically repaired hip started to hurt, he replied: "I would guess it was either late 2008 or early 2009." ROA.16-11056.9357-58. Klusmann further explained that he knew "[s]omething was definitely wrong" because he felt "an intense pain" and "tremendous soreness … inside the tissues, in the muscles." ROA.16-11056.9358. In April 2009—still more than two years before he filed suit—Klusmann met with his surgeon and reported hip pain and weakness. ROA.16-11056.9359-60; *see* RE.26. Klusmann was unquestionably on inquiry notice of any alleged defects with his implant more than two years before he brought suit.

At a minimum, Appellants are entitled to a new trial, as the jury's findings on when these plaintiffs' claims accrued are hopelessly confused about the law and/or the facts. The verdict form asked the jury to determine the date by which Greer and Klusmann discovered or should have discovered their injuries. ROA.16-11056.5947. For Klusmann, the jury inexplicably chose a date *after Klusmann filed this lawsuit*. Klusmann underwent his first revision surgery in August 2011, filed this lawsuit in October 2011, and then—according to the jury—first discovered his injury in November 2011. The jury similarly found that Greer discovered his injury on February 14, 2012, the exact date of his revision surgery. But Greer was self-evidently aware that something was wrong with his hip implant

before the day on which he showed up for surgery to replace it. *See Porterfield*, 183 F.3d at 467 (rejecting argument that cause of action began to run at time of surgery). The jury's facially inconsistent and defective findings on this issue at the very least warrant a new trial.

II. Plaintiffs' Claims Against J&J Fail For Want Of Jurisdiction And On The Merits.

A. The District Court Lacked Personal Jurisdiction Over J&J.

Plaintiffs cannot maintain this suit against J&J in Texas because J&J lacks sufficient forum- and suit-related contacts to subject it to personal jurisdiction in Texas.[3]

A court may not exercise personal jurisdiction over an out-of-state defendant unless the defendant has "certain minimum contacts with the State such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014). Under the doctrine of specific personal jurisdiction, a court can exercise jurisdiction over a defendant if it has "purposefully directed" its activities at the forum state, and the plaintiff's claims "'arise out of or relate to' those activities." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472-73 (1985).

[3] J&J repeatedly raised this argument before, during, and after trial. *See* ROA.16-11056.3626; ROA.16-11056.823; ROA.16-11056.5332; ROA.16-11056.5453; ROA.16-11056.6047.

Claims do not "arise out of or relate to" a defendant's forum state activities unless the plaintiff's injuries "proximately result" from his contacts with the forum state," *Beydoun v. Wataniya Rests.*, 768 F.3d 499, 507-508 (6th Cir. 2014), or "the defendant's contacts with the forum state form the basis of the suit," *Consulting Eng'rs Corp. v. Geometric Ltd.*, 561 F.3d 273, 278-279 (4th Cir. 2009).[4] Because the specific jurisdiction inquiry "focuses on the relationship among the defendant, the forum, and the litigation," neither contacts between the plaintiff and the forum state nor between the defendant and third parties who reside in the forum state are relevant to the analysis. *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014).

Plaintiffs offered only one theory of why a Texas court would have personal jurisdiction over J&J: because J&J allegedly "sold a defective [product] to Plaintiffs in Texas which caused them harm in Texas." ROA.16-11056.6269. But *J&J* never "sold" the Ultamet in Texas (or anywhere else). The only direct evidence presented at trial was the uncontradicted testimony of Leanne Turner, a DePuy device development team leader, who testified that DePuy, not J&J, was the only company that ever sold the Ultamet. ROA.16-11056.15333-34.

DePuy's forum-related contacts cannot be attributed to J&J. "Courts have long presumed the institutional independence of related corporations, such as

[4] *See also* Petition for Writ of Certiorari, *Bristol-Myers Squibb v. Superior Ct.*, No. 16-466 (U.S. Oct. 7, 2016) (discussing circuit split regarding "arise out of or relate to" standard), *cert. granted*, 2017 WL 215687.

parent and subsidiary, when determining if one corporation's contacts with a forum can be the basis of a related corporation's contacts." *Dickson Marine v. Panalpina*, 179 F.3d 331, 338 (5th Cir. 1999). So long as the parent "observes corporate formalities, makes its subsidiaries responsible for daily operations including all personnel decisions, and allows each subsidiary to keep its records and accounts in separate books," this Court does not attribute a subsidiary's forum contacts to its parent. *Dalton v. R & W Marine*, 897 F.2d 1359, 1363 (5th Cir. 1990); *see also Southmark v. Life Inv'rs*, 851 F.2d 763, 773-74 (5th Cir. 1988). Here, plaintiffs never attempted to show that J&J failed to observe corporate formalities or exercised "complete control" over DePuy's day-to-day activities. *Hargrave v. Fibreboard Corp.*, 710 F.2d 1154, 1160 (5th Cir. 1983). DePuy's contacts with Texas are thus entirely irrelevant to whether the district court could assert jurisdiction over J&J.

Plaintiffs relied heavily on a letter from a J&J attorney to a DePuy manager saying that DePuy was "cleared to manufacture, use and sell the [Ultamet femoral head] design worldwide." PX521. That letter, however, was never entered into evidence, *see* ROA.16-11056.15580-82, and does not support plaintiffs' theory of jurisdiction. Subjecting a parent company to personal jurisdiction merely because it gave a subsidiary "clearance" to take some broad class of actions would gut the rule that a subsidiary is independent for jurisdictional purposes absent "clear

evidence" that the parent asserts "sufficient control" to make the subsidiary "its agent or alter ego." *Dickson Marine*, 179 F.3d at 338; *see Hargrave*, 710 F.2d at 1159 ("[T]he mere existence of a parent-subsidiary relationship is not sufficient to warrant the assertion of jurisdiction over the foreign parent.").

Plaintiffs also made much of the fact that J&J's logo appeared on DePuy's products and advertisements, and that J&J assisted DePuy in executing nationwide and international advertising campaigns. *E.g.*, ROA.16-11056.7307-7311, ROA.16-11056.15582-89, ROA.16-11056.15593-97, PX41, PX43, PX467, PX595. But those nationwide advertising activities do not show that J&J sold the Ultamet *anywhere* to *anyone*, let alone to *these plaintiffs* in *Texas*. And even if the advertisements were a relevant contact, plaintiffs offered no evidence that their alleged injuries "arise out of or relate to" those advertisements. Plaintiffs thus failed to establish that a Texas court could exercise personal jurisdiction over J&J consistent with due process.

B. J&J Is Entitled to Judgment as a Matter of Law.

Even if a Texas court could exercise personal jurisdiction over J&J, J&J is entitled to judgment as a matter of law on all three of plaintiffs' claims. Plaintiffs' first two claims do not even exist under Texas law, and the verdict on their third claim cannot be sustained on this trial record.

1. "Nonmanufacturing Seller" is not an independent cause of action under Texas law.

J&J is entitled to judgment as a matter of law on plaintiffs' first claim because "nonmanufacturing seller" is not a cause of action at all but is instead an affirmative defense.

Section 82.003 of the Civil Practice & Remedies Code declares that "[a] seller that did not manufacture a product is not liable for harm caused to the claimant by that product unless the claimant proves" one of seven exceptions. Tex. Civ. Prac. & Rem. Code §82.003(a). As Texas courts have emphasized, section 82.003 constitutes an "*affirmative defense*," providing "an *exception to liability*" on which the defendant has "the burden of proof." *Fields v. Klatt Hardware & Lumber*, 374 S.W.3d 543, 545 (Tex. App.—San Antonio 2012, no pet.) (emphasis added); *see also New Tex. Auto*, 249 S.W.3d at 405 (Chapter 82 "reflects a legislative intent to restrict liability for defective products to those who manufacture them"). If the defendant seller carries its burden of showing it was not the manufacturer, then the plaintiff can pursue a product-liability claim against the defendant only after proving one of the seven exceptions to the "nonmanufacturing seller" defense. *See Gonzalez v. Reed-Joseph Int'l*, 2013 WL 1578475, at *4 (S.D. Tex. Apr. 11, 2013).

The exceptions to the "nonmanufacturing seller" defense are "not causes of action." *Diamond H. Recognition LP v. King of Fans*, 589 F. Supp. 2d 772, 776

(N.D. Tex. 2008). Even where a plaintiff demonstrates the applicability of an exception, he must still invoke a valid cause of action. Section 82.003(a), in other words, is "simply a gatekeeper for Plaintiff to bring a claim against Defendants"—proving an exception to Section 82.003(a)'s affirmative defense eliminates the defense but is not itself a cause of action. *Gonzalez*, 2013 WL 1578475, at *4. The plaintiff still needs "an otherwise valid claim under Texas law, such as negligence or breach of implied warranty." *Id.*

Plaintiffs and the district court fundamentally misunderstood section 82.003, apparently believing that proving J&J fell within an exception was itself a stand-alone cause of action. Question 3 of the charge asked whether J&J was a "nonmanufacturing seller" under section 82.003. ROA.16-11056.5920. The jury answered that question in the affirmative, which means J&J would be presumptively immune from liability in any product-liability action brought against it. The charge then asked whether J&J satisfied the requirements of either of two exceptions to that immunity. *See id.* (asking whether J&J "participate[d] in the design" of the Ultamet, and whether J&J "actually kn[e]w of" a defect in the Ultamet); *see* Tex. Civ. Prac. & Rem. Code §82.003(a)(1), (a)(6). The jury answered "yes" to both exceptions, meaning that J&J would not be immune if plaintiffs had brought a valid product-liability claim against it.

This exercise was utterly bizarre—and ultimately meaningless—because *plaintiffs never brought a product-liability claim against J&J*; plaintiffs' design-defect and marketing-defect claims were brought only against DePuy. The jury's findings thus establish, at most, that *if* plaintiffs had brought a product-liability claim against J&J as a seller, then J&J would not be immune, but instead would have to defend itself on the merits. Such findings are of no more than academic interest given that plaintiffs brought no such claim against J&J.[5]

Plaintiffs have not cited a single Texas case holding (or even suggesting) that the "nonmanufacturing seller" statute provides an independent cause of action. In every case discussing section 82.003, it is the *defendant* that tries to prove it is a "nonmanufacturing seller" in order to receive the protections of the statute's immunity regime. *See, e.g.*, *Transcon. Ins. Co. v. Briggs Equip. Trust*, 321 S.W.3d 685, 701 (Tex. App.—Houston [14th Dist.] 2010, no pet.). Here, however, the *plaintiffs* sought to prove that J&J was a "nonmanufacturing seller," which is akin to a civil rights plaintiff arguing that a police officer is entitled to qualified

[5] Indeed, J&J could not have been a nonmanufacturing seller of metal-on-metal hip implants because it was *not a seller at all*. The entire structure of §82.003 is designed to recognize situations in which a non-manufacturing seller is less culpable than a seller that also manufactures an allegedly defective product (for example if Home Depot sold a lawnmower that was defective but Home Depot did not manufacture or design the lawnmower). But that provision is certainly not designed to expand liability to parent companies that were *neither* the direct seller *nor* the direct manufacturer of the product.

immunity. The "nonmanufacturing seller" statute creates no independent cause of action for affirmative relief, and the jury's verdict against J&J on that theory must accordingly be vacated.

2. Texas law does not recognize aiding-and-abetting tort claims

J&J is likewise entitled to judgment as a matter of law on plaintiffs' second claim because Texas law does not recognize aiding-and-abetting tort claims.

Plaintiffs' aiding-and-abetting claim is based on §876(b) of the Restatement (Second) of Torts. *See* ROA.16-11056.4744-45 (jury instruction). But the Texas Supreme Court has repeatedly *declined* to adopt §876, despite numerous opportunities to do so. *See Ernst & Young v. Pac. Mut. Life Ins.*, 51 S.W.3d 573, 583 n.7 (Tex. 2001) ("[W]e do not consider whether Texas law recognizes a cause of action for 'aiding and abetting' fraud separate and apart from a conspiracy claim."); *Juhl v. Airington*, 936 S.W.2d 640, 643 (Tex. 1996); *In re Dole Food Co.*, 256 S.W.3d 851, 856 (Tex. App.—Beaumont 2008, no pet.). Indeed, plaintiffs conceded below that "[t]he Texas Supreme Court has neither adopted nor rejected §876(b)." ROA.16-11056.6251 n.84.

The Texas courts' undisputed failure to recognize an aiding-and-abetting theory of tort liability is fatal to plaintiffs' claim. Federal courts must not "expand state law beyond its presently existing boundaries," lest they usurp the state's role as the ultimate authority on the content of its own laws. *Rubinstein v. Collins*, 20

F.3d 160, 172 (5th Cir. 1994). Accordingly, where "there is currently no Texas law creating a common law cause of action," this Court "will not undertake to ourselves create such a Texas common law cause of action." *Johnson v. Sawyer*, 47 F.3d 716, 729 (5th Cir. 1995) (en banc); *see also Emscor Mfg. v. Alliance Ins. Grp.*, 879 S.W.2d 894, 910 (Tex. App.—Houston [14th Dist.] 1994, writ denied) (creation of "new causes of action" under Texas law should be left to the legislature and Texas Supreme Court).

Plaintiffs' invention of an aiding-and-abetting claim under Texas tort law is foreclosed by these principles, as this is exactly the sort of "substantive innovation" in state law that this Court has wisely sought to avoid. *Galindo v. Precision Am. Corp.*, 754 F.2d 1212, 1217 n.8 (5th Cir. 1985). Indeed, this Court has refused to allow recovery under state law even where plaintiffs seek to extend a well-established state-law theory of liability to novel *factual* circumstances. *See Barfield v. Madison Cty.*, 212 F.3d 269, 273 (5th Cir. 2000); *Johnson*, 47 F.3d at 729. It follows *a fortiori* that this Court should not recognize a novel *claim* that has never been embraced by Texas courts.

Moreover, it is especially unlikely that the Texas Supreme Court would recognize aiding-and-abetting liability in a case like this one. Plaintiffs accused J&J of aiding and abetting a strict-liability tort, but even the Restatement "takes no position on whether the rules stated in [§876] are applicable when the conduct of

either the actor or the other … *involves strict liability* for the resulting harm." Restatement (Second) of Torts §876 caveat (1979) (emphasis added). Moreover, the Texas Supreme Court has suggested that even if it were to adopt §876, it would apply it only to deviant antisocial activity involving highly dangerous activities. *See Juhl*, 936 S.W.2d at 644-45 (examples of conduct covered by §876 include a group assault upon an individual, highway drag-racing, and target-shooting with a high-powered rifle).

In sum, aiding-and-abetting is simply not a recognized cause of action under Texas law, and federal courts have no authority to *expand* Texas law to encompass that theory. J&J is entitled to judgment as a matter of law on this claim.

3. The jury's verdict on "negligent undertaking" was not supported by sufficient evidence.

J&J is also entitled to judgment as a matter of law on plaintiffs' third claim, for "negligent undertaking." To prevail on that claim, plaintiffs needed to prove that: (1) J&J undertook to perform services that it knew or should have known were necessary for plaintiffs' protection; (2) J&J failed to exercise reasonable care in performing those services; and (3) plaintiffs relied upon J&J's performance. *Nall v. Plunkett*, 404 S.W.3d 552, 555-56 (Tex. 2013).

The evidence was insufficient to show that J&J "undertook to perform services that it knew or should have known were necessary for the plaintiff's protection." *Nall*, 404 S.W.3d at 555. Plaintiffs first alleged that J&J undertook a

duty to design an implant that was "safe and free of defects," because J&J "work[ed] with DePuy in designing the Ultamet device; provid[ed] DePuy access to its patented VIP self-locking taper technology; and provid[ed] one of its lead Ultima device developers to serve as a 'training' resource for DePuy's Ultamet team." ROA.16-11056.6263.

But every single one of those actions was taken by a J&J subsidiary *distinct from J&J itself*. For example, plaintiffs have asserted that J&J provided DePuy data and design information about a different device—the Ultima—which helped in developing the Ultamet. *See* ROA.16-11056.7335, ROA.16-11056.15336-37. But the Ultima *was not designed or sold by J&J*; instead, it was designed and brought to market by J&J Orthopaedics, a distinct subsidiary. *See* PX1025 at 4; PX1052 at 5. Similarly, J&J did not provide DePuy with the "patented VIP self-locking taper technology" cited by plaintiffs. Indeed, J&J did not even own the patents for that technology. Rather, the patents were obtained by Joint Medical Products and provided to DePuy by J&J Professional. ROA.16-11056.15329-30. And the "lead [Ultima device] developer," whom J&J supposedly provided "as a training resource" for DePuy's Ultamet team, was employed not by J&J but by J&J Professional. ROA.16-11056.15348-49.

Plaintiffs' allegation that J&J undertook a duty to regulate the manufacture, sale, and distribution of the Ultamet, ROA.16-11056.6263, suffers from the same

flaws. The only exhibit plaintiffs cited in support of their contention that J&J gave DePuy "clearance" to manufacture and sell the Ultamet—the same letter plaintiffs attempted to use to support their personal jurisdiction theory, *see supra* pp. 41-42—was never entered into evidence. *See* ROA.16-11056.15580-82. In all events, Texas law makes clear that a parent company undertakes a duty to protect its subsidiaries' customers only when the parent "has the controlling, primary authority for maintaining safety" in the subsidiary's operations. *Little v. Delta Steel, Inc.*, 409 S.W.3d 704, 721 (Tex. App.—Fort Worth 2013, no pet.); *see Bujol v. Entergy*, 922 So. 2d 1113, 1136 (La. 2004). Nothing in the letter suggests that J&J reviewed the designs to ensure they were safe for patients or took *any* affirmative steps for plaintiffs' protection, let alone that J&J had "controlling, primary authority" over the Ultamet's safety.

Even if plaintiffs could show that J&J undertook to provide services for the plaintiffs' protection and performed those services negligently, plaintiffs' claims still fail because they introduced zero evidence that they or their doctors "relied upon [J&J's] performance." *Nall*, 404 S.W.3d at 556. No plaintiff testified that he or she relied on J&J's performance of a duty when choosing the Ultamet; indeed, there was no evidence that any plaintiff even knew what product was implanted. Likewise, no surgeon testified that "J&J's involvement" (or the presence of its logo on the box) made him more likely to choose the Ultamet rather than another

implant. Plaintiffs' reliance argument rests on pure speculation rather than actual evidence, and their negligent undertaking claim accordingly fails as a matter of law.

* * *

For the reasons set forth above, J&J is entitled to judgment as a matter of law on all three of plaintiffs' claims against it. But if this Court reverses the judgment below on any of the three causes of action against J&J, it must order a new trial on exemplary damages for all claims. *See Zaffuto v. City of Hammond*, 308 F.3d 485, 491 (5th Cir. 2002).

III. In The Alternative, Appellants Are Entitled To A New Trial.

A. A New Trial Is Warranted in Light of the Highly Inflammatory, Irrelevant, and Prejudicial Evidence and Arguments That Plaintiffs' Counsel Presented to the Jury.

Throughout trial, plaintiffs' counsel introduced increasingly inflammatory and irrelevant evidence in an (ultimately successful) attempt to distract the jury from the legal and factual deficiencies of plaintiffs' claims. The district court consistently overruled Appellants' objections and denied Appellants' motions for mistrial, even as plaintiffs' arguments and testimony veered further away from any conceivable notion of relevance. Plaintiffs' counsel then emphasized all of these topics again in his closing argument, ensuring that the inflammatory and improper testimony was fresh in the minds of the jurors as they began their deliberations.

This evidence and argument all should have been excluded. Many of these errors would have supported a new trial by themselves, and the cumulative effect of this inflammatory and improper evidence and argument—which was compounded each time the district court placed its imprimatur on these tactics by overruling Appellants' repeated objections—is nothing short of outrageous. Because the admission of this evidence affected DePuy's "substantial rights," *Hardy v. Johns-Manville Sales Corp.*, 851 F.2d 742, 747 (5th Cir. 1988), a new trial is warranted.

1. "The Henchmen of Saddam Hussein"

At trial, plaintiffs' counsel repeatedly accused Appellants of making illegal payments to "the henchmen of Saddam Hussein." ROA.16-11056.10723-24, ROA.16-11056.10738-39. That wild accusation has no relevance to this case.[6]

In 2011, DePuy's parent company (J&J) and the federal government entered into a Deferred Prosecution Agreement related to alleged violations of the Foreign Corrupt Practices Act committed by foreign J&J affiliates that are not parties to this case ("FCPA DPA"). One of the alleged violations was that two non-party foreign affiliates made improper payments to the Iraqi government in connection

[6] The district court overruled multiple objections and denied multiple motions for mistrial regarding the FCPA DPA. *See* ROA.16-11056.7267, ROA.16-11056.7268-69, ROA.16-11056.7271-72, ROA.16-11056.7464, ROA.16-11056.7466, ROA.16-11056.7470, ROA.16-11056.7518-19, ROA.16-11056.1691-94.

with contracts for pharmaceutical products. Plaintiffs repeatedly referenced the FCPA DPA and Saddam Hussein throughout trial, ROA.16-11056.7465; ROA.16-11056.10699, 10710, 10718, 10722, 10728, 10735, 10740-41, 10762, and again mentioned "bribes to Saddam Hussein's government" during closing argument, ROA.16-11056.16918. To make matters worse, in the middle of trial, the district court ordered DePuy to produce a Rule 30(b)(6) corporate representative to testify before the jury about the FCPA DPA, *see* ROA.16-11056.10683-94, resulting in a half-day spectacle that served no purpose other than to inflame the jury's passions and distract them from the actual facts.

The FCPA DPA was inadmissible for a number of independent reasons, foremost of which is that it is entirely irrelevant to the question whether the Ultamet hip implant was defectively designed or marketed. *See* Fed. R. Evid. 401. The FCPA DPA concerned conduct in foreign countries, much of it unrelated to medical devices, and all of it irrelevant to the Ultamet and the plaintiffs in this case. The district court nonetheless admitted the FCPA DPA into evidence, finding it admissible because Appellants "opened the door" by suggesting that DePuy was a small-town Indiana company that took pride in helping people and sold its products in Europe. ROA.16-11056.7519-20; *see* ROA.16-11056.7267-68 ("Opening statement opened all that up.").

That reasoning is deeply flawed. At the outset, even if Appellants had "opened the door" to character evidence about *DePuy*, the conduct in Iraq that plaintiffs' counsel repeatedly emphasized had nothing to do with DePuy or any of its employees—it concerned the conduct of *non-party foreign subsidiaries* of J&J. Evidence of alleged wrongdoing by executives of different companies with regard to sales of different products in different countries says nothing about DePuy's "character." *See Valadez v. Watkins Motor Lines*, 758 F.3d 975, 982 (8th Cir. 2014) ("Evidence allowed through the open door must rebut something that had been elicited.").

Furthermore, even if innocuous comments about DePuy's small-town values somehow opened the door to impeachment evidence, "the Rules of Evidence do not simply evaporate when one party opens the door on an issue." *United States v. Bursey*, 85 F.3d 293, 296 (7th Cir. 1996). Rule 404 expressly prohibits evidence of a "crime, wrong, or other act … to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). That is precisely how plaintiffs used the FCPA DPA, with the added problem that the allegations about Iraq did not even involve a "crime, wrong, or other act" *of DePuy*.

The FCPA DPA was also independently inadmissible under Rule 403 because "its probative value is substantially outweighed by the danger of unfair

prejudice, confusion of the issues, or misleading the jury." *United States v. O'Keefe*, 426 F.3d 274, 280 (5th Cir. 2005); *see Shows v. M/V Red Eagle*, 695 F.2d 114, 119 (5th Cir. 1983) ("[W]e are left with the firm belief that this evidence was wafted before the jury to trigger their punitive instincts and there is a great risk that it did so."). The probative value was nonexistent given that this evidence had nothing to do with these plaintiffs, the Ultamet, or any other aspect of this case. And whatever limited relevance the FCPA DPA might have had would hardly justify introducing inflammatory statements about alleged bribes in Iraq, let alone plaintiffs' counsel's characterization of those payments as being made to "the henchmen of Saddam Hussein."

2. DePuy's "Plea of Guilty" for "Bribing Doctors"

Plaintiffs' counsel similarly mischaracterized another inadmissible DPA, telling the jury during his opening statement that DePuy "enter[ed] a plea of guilty" and "paid a massive fine" for "bribing doctors." ROA.16-11056.6913. In reality, DePuy—*without admitting any wrongdoing*—agreed to pay $84 million to the government and implement certain remedial measures under the supervision of an independent monitor to resolve claims related to alleged overpayments by Medicare and alleged violations of the federal anti-kickback statute ("2007 DPA"). The 2007 DPA resolved allegations that DePuy signed consulting agreements with

orthopedic surgeons to induce those surgeons to use DePuy's products.[7] Even though the 2007 DPA involved a compromise settlement with no admission of liability or guilt, the district court improperly allowed plaintiffs' counsel to introduce the DPA into evidence and describe it as a "guilty plea" throughout trial. *See* ROA.16-11056.7262-66, ROA.16-11056.8324, ROA.16-11056.8510, ROA.16-11056.10719.[8]

The 2007 DPA is inadmissible under Rule 408, which excludes evidence of "conduct or statements made in compromise negotiations" regarding a disputed claim. This Court has found reversible error "when a district court has admitted the *content* of a settlement agreement for the jury's consideration." *Latiolais v. Cravins*, 574 F. App'x 429, 435 (5th Cir. 2014). Such evidence is inadmissible because a settlement "may have been an attempt to purchase peace rather than an admission of liability," and because exclusion promotes "the voluntary settlement of disputes, which would be discouraged if evidence of compromise were later used in court." *Lyondell v. Occidental Chem. Corp.*, 608 F.3d 284, 294-95 (5th Cir. 2010). Indeed, evidence of a settlement is especially likely to be prejudicial

[7] Similar suits were brought against each of the major orthopedic implant companies by then-U.S. Attorney Chris Christie.

[8] DePuy repeatedly objected to this evidence. ROA.16-11056.6935; ROA.16-11056.4205; ROA.16-11056-7262; ROA.16-11056.6185.

because "[i]t is reasonable to infer that jurors would view the settlement as an admission of guilt." *McHann v. Firestone Tire*, 713 F.2d 161, 167 (5th Cir. 1983).

A DPA is the paradigmatic example of a "compromise" settlement whose admission is barred by Rule 408. *See United States v. Fokker Services B.V.*, 818 F.3d 733, 746 (D.C. Cir. 2016) ("[T]he entire object of a DPA is to enable the defendant to *avoid* criminal conviction and sentence by demonstrating good conduct and compliance with the law."). And there is no question that plaintiffs sought to use the 2007 DPA to "establish the liability of [DePuy]." *McHann*, 713 F.2d at 166-67. Plaintiffs' counsel expressly told the jury that DePuy "enter[ed] a plea of guilty" and "paid a massive fine" for "bribing doctors." ROA.16-11056.6913. That is the precise type of argument that Rule 408 prohibits.

The 2007 DPA is also inadmissible as irrelevant under Rule 401 and unfairly prejudicial under Rule 403. Any *de minimis* relevance of a compromise settlement with the government is outweighed by an overwhelming possibility of prejudice, as the jury could easily misinterpret the 2007 DPA as an admission of wrongdoing. *See Stockman v. Oakcrest Dental Ctr.*, 480 F.3d 791, 799-800 (6th Cir. 2007) (settlement offer inadmissible under both Rules 408 and 403).

3. *Doubt Is Their Product* Book

The district court also allowed plaintiffs' counsel to read to the jury multiple pages of highly inflammatory and prejudicial hearsay from a book with no

connection to this case or to hip implants. While cross-examining Appellants' toxicology expert (Dr. Boyer), plaintiffs' counsel produced a book called *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*, written by David Michaels (who was not a witness in this case). ROA.16-11056.14926. The book—which Dr. Boyer had never heard of—catalogs supposed misdeeds of companies in the tobacco, asbestos, gasoline, and chemical industries. ROA.16-11056.14926-36. Over Appellants' repeated objections,[9] plaintiffs' counsel read the jury numerous passages from this book regarding "big tobacco," "the asbestos companies," "science for hire," "Love Canal," the "utility portrayed in the movie Erin Brockovich," and "manufacturers of benzene, beryllium, chromium, MTBE … and virtually every other toxic chemical in the news today." ROA.16-11056.14926-36; *see* RE.28 (excerpts from trial testimony).

Admission of this so-called "evidence" was profoundly inappropriate. First, this material should have been excluded as hearsay. *See* Fed. R. Evid. 802. The author of the book did not testify, and Appellants could not cross-examine him to test the veracity of his provocative claims. Moreover, the book contained extensive hearsay-within-hearsay, including a passage that quoted a *Wall Street*

[9] ROA16-11056.14925; ROA16-11056.14926; ROA16-11056.14928; ROA16-11056.14929; ROA16-11056.14931; ROA16-11056.14934.

Journal report and another passage that purported to summarize the minutes from a meeting of chromium producers. ROA.16-11056.14933-35.

Admission of this material also flouted any conceivable notion of relevance, rendering it inadmissible under Rule 401. Plaintiffs claimed they were introducing *Doubt Is Their Product* to attack the credibility of certain (non-testifying) authors of articles that Dr. Boyer listed in a table in his expert report. ROA.16-11056.14926. That convoluted theory is absurd on its face. It is also belied by plaintiffs' own actions at trial. Plaintiffs' counsel invoked *Doubt Is Their Product* multiple times during his closing statement, not for anything involving impeachment of authors of articles Dr. Boyer had read, but for the sole purpose of associating DePuy and J&J with "big tobacco" and "asbestos" companies. *See* ROA.16-11056.16905, ROA.16-11056.16914, ROA.16-11056.17020 ("[T]hey don't want answers. You know why? Because doubt is their product. That's all they're about."). In all events, even if this "evidence" were tangentially relevant to some issue in this case, its *de minimis* probative value would not come close to outweighing its severe prejudicial effect.

4. References to Cancer and Suicide

In a transparent effort to manipulate the jury's emotions, plaintiffs repeatedly elicited speculative testimony about the prospect of a metal-on-metal implant

causing cancer.[10] This maneuver began when Dr. Bernard Morrey testified that he did not "want to take the chance" of using metal-on-metal implants in his patients because of the implants' alleged potential to cause cancer. ROA.16-11056.10140-41. Dr. Morrey later conceded that any cancer risk was "hypothetical" and unsupported by scientific evidence. ROA.16-11056.10159-60.

But plaintiffs nonetheless used Dr. Morrey's testimony to orchestrate a highly emotional exchange with Ms. Aoki, whom they called as their next witness. Aoki had survived cancer *before receiving her hip implant*, and she testified about going through chemotherapy and the "chemicals that make your hair fall out and sap your energy and cloud your mind and pretty much put on hold your life." ROA.16-11056.10287. Plaintiffs' counsel then asked her if she was "afraid" of contracting cancer from her metal-on-metal hip implant, and she testified that she "didn't hear about the cancer until we were here," and that Dr. Morrey's testimony "makes me think maybe I should spend some of my 401(k)." ROA.16-11056.10306-07; *see* RE.28 (excerpts from trial testimony). Appellants moved for a mistrial shortly thereafter, ROA.16-11056.4178-224, which was denied without explanation.

[10] DePuy repeatedly objected to this testimony. *See* ROA.16-11056.13659, ROA.16-11056.4216-17, ROA.16-11056.4712, ROA.16-11056.6183.

Plaintiffs then continued to make veiled and not-so-veiled references to cancer throughout trial, including by asking Appellants' expert, Dr. Campbell, a series of questions intended to mislead the jury into believing that Ms. Aoki was at risk for cancer. ROA.16-11056.13841-43. Plaintiffs also described the Technical Monograph in closing as having been "put together by an ad agency where they edited out the cancer information," ROA.16-11056.17026.

The utterly baseless suggestion that DePuy put the plaintiffs at risk of a potentially fatal disease unquestionably prejudiced DePuy's defense. *See* Fed. R. Evid. 403. This testimony had no probative value whatsoever, as Texas law does not permit recovery for fear of contracting a disease, *Kane v. Cameron Int'l*, 331 S.W.3d 145, 149-50 (Tex. App.—Houston [14th Dist.] 2011, no pet.), and none of the plaintiffs here alleged a "reasonable medical probability" of developing cancer as a result of any product defect, *see Pustejovsky v. Rapid-Am. Corp.*, 35 S.W.3d 643, 652 (Tex. 2000). Yet as this Court has emphasized, "cancer evidence is highly inflammatory and understandably incites the passions and fears of most reasonable individuals." *Smith v. A.C. & S., Inc.*, 843 F.2d 854 (5th Cir. 1988). Because the testimony's "probative value is substantially outweighed by the danger of unfair prejudice," it should have been excluded under Rule 403. *O'Keefe*, 426 F.3d at 280.

In much the same way, plaintiffs tried to link DePuy's products to an equally unproven risk of suicide. The district court allowed plaintiffs to introduce an e-mail from a non-testifying surgeon speculating that one of his patients committed suicide because of depression from complications resulting from his hip replacement surgery. ROA.16-11056.8386-87. When Appellants objected on hearsay grounds and under Rule 403, *see* ROA.16-11056.8386, plaintiffs claimed the e-mail put DePuy on notice of problems with metal-on-metal implants. The e-mail, however, was sent two years *after* any of the plaintiffs received their implants, making it entirely irrelevant as to notice. Plaintiffs' counsel then returned to the theme of suicide during a rather remarkable segment of closing argument, referencing the film *It's A Wonderful Life* and stating that he was "sure" each plaintiff had thought, like Jimmy Stewart in the movie, about jumping off of a bridge. ROA.16-11056.16938.

5. Impermissible References to "Thousands" of Other Ultamet Suits and to Unrelated Suits Regarding Transvaginal Mesh

Plaintiffs also sought to distract the jury from the evidentiary record by repeatedly alluding to "thousands" of other pending lawsuits in this MDL. *See* ROA.16-11056.6907; ROA.16-11056.8224; ROA.16-11056.8699; ROA.16-11056.12153; ROA.16-11056.8224 (overruling Rule 403 objection). And plaintiffs' counsel prominently featured those (as-yet-unadjudicated) lawsuits in his closing argument: "Thousands of people suffered. These five have their cases

being heard in front of you. But these folks, thousands of them, are—they're walking time bombs." ROA.16-11056.16905; *see* ROA.16-11056.16921-23 (denying motion for mistrial).

Evidence of other pending lawsuits is inadmissible both as hearsay and under Rule 403 because it is likely to mislead the jury by suggesting that the mere existence of other lawsuits is evidence the product is defective. Allowing plaintiffs to discuss "thousands" of other pending lawsuits "risks the jury finding against a defendant based on sheer numbers." *In re Van Waters & Rogers*, 145 S.W.3d 203, 211 (Tex. 2004). The question before the jury was whether the Ultamet was *actually* defective, not whether others had filed lawsuits *alleging* a defect. *See Nissan v. Armstrong*, 145 S.W.3d 131, 142 (Tex. 2004) ("[P]roduct defects must be proved; they cannot simply be inferred from a large number of complaints.").

It was bad enough for plaintiffs to repeatedly allude to other pending lawsuits involving the Ultamet. But they went even further by introducing testimony about pending lawsuits involving *different* products and a *different* J&J subsidiary. In particular, plaintiffs' counsel asked Dr. Plouhar, J&J's Vice President of Clinical Research, about "45,000 women" who have sued a J&J subsidiary over allegedly defective transvaginal mesh. ROA.16-11056.8226. The pending transvaginal mesh lawsuits—which involve an unrelated product manufactured and sold by a different J&J subsidiary—have no bearing on whether the Ultamet was

defectively designed or marketed. Evidence about those suits should have been inadmissible as irrelevant and unfairly prejudicial under Rules 401 and 403.

6. Unproven Allegations of Racial Discrimination

The district court allowed plaintiffs' counsel to read a letter accusing DePuy employees of making racist remarks toward the letter's author, a former DePuy employee who did not testify at trial. Plaintiffs' counsel read the following excerpt: "It is my perspective, that it has been long acceptable to treat me poorly and there has been nothing done by management and I just don't want to endure it any longer.… I will never understand the humor in a joke about me eating KFC, and yet blamed for my inability to forge relationships with people that find this humor funny. I'm tired of 'over-hearing' the word 'N-i-g-g-e-r' or words like it." ROA.16-11056.7552-53; *see* RE.27 (letter); RE.28 (excerpts from trial testimony).

This was an egregious error. The district court should have excluded the letter as irrelevant under Rule 401, unfairly prejudicial under Rule 403, and as hearsay, but it instead overruled Appellants' objections. *See* ROA.16-11056.7551. Whether this employee experienced discrimination (which was not proven at trial or otherwise) had no bearing on whether DePuy defectively designed and marketed hip implants. Indeed, plaintiffs made no effort to connect the letter to any substantive issues at trial, instead insisting the letter became relevant as "character" evidence when Appellants referred to DePuy in their opening statement as a "small

town" company with wholesome values. *See* ROA.16-11056.4586-88. But that theory just creates more problems. As discussed, Rule 404 prohibits evidence of prior wrongful acts "to show that on a particular occasion the person acted in accordance with the character." Fed. R. Evid. 404(b)(1). Moreover, even if the letter were used for the purposes suggested by the plaintiffs, it would be inadmissible hearsay because it is an out-of-court statement offered for the truth of the matter asserted—*i.e.*, that DePuy employees engaged in discrimination—and its author did not testify. *See* Fed. R. Evid. 801.

At the very least, this letter should have been excluded as unfairly prejudicial under Rule 403. Whatever conceivable relevance the letter might have to this case is outweighed by the highly inflammatory and prejudicial nature of accusations of racial discrimination. *See Manuel v. City of Chicago*, 335 F.3d 592, 597 (7th Cir. 2003).[11]

7. Improper Closing Argument

The inflammatory and prejudicial evidence discussed above was no mere afterthought in an otherwise impeccable trial. This "evidence" instead formed the centerpiece of plaintiffs' case. That is readily apparent from Mr. Lanier's closing argument, during which he marched step-by-step through each piece of inflammatory evidence. *See, e.g.*, RE.29 (excerpts from closing argument). He

[11] Two of the jurors were African-American. ROA.16-11056.7732-33.

referred to "bribes to Saddam Hussein's government," ROA.16-11056.16918, the (unproven) allegations of racism against DePuy, ROA.16-11056.16920, the (unproven) link between metal hip implants and cancer or suicide, ROA.16-11056.16903-04, ROA.16-11056.16938, ROA.16-11056.17026, the "thousands" of other (unproven) claims against J&J and DePuy, ROA.16-11056.16905, and the book *Doubt is Their Product*, claiming that plaintiffs' allegations were "[s]traight out of the book," ROA.16-11056.16905, 16914, 17020.

To make matters worse, counsel's closing included an impermissible "unit of time" argument, urging the jury "to evaluate a long period of pain and suffering, or loss, as a multiple of its smaller time equivalents." *Westbrook v. General Tire*, 754 F.2d 1233, 1239 (5th Cir. 1985). Such arguments are "impermissible because they tend to produce excessive verdicts." *Id*. at 1240. Plaintiffs' counsel first set the stage by telling the jurors they were *required* to consider smaller units of time in considering damages: "If you don't consider the damages by the day, by the hour, by the minute, then you haven't considered their damages." ROA.16-11056.16947. Then, during rebuttal, the jury was told to calculate the life expectancy for each plaintiff, and to make sure to assign each day a higher value than Appellants' experts were paid per hour for their work on the case: "if they will pay their experts a thousand dollars an hour to come in here, when you do your math back there don't tell these plaintiffs that a day in their life is worth less than

an hour's time of this fellow." ROA.16-11056.17026. A plea for the jury to base its damages calculations on the fees charged by the defense experts was a fitting end to a trial that had long since gone far off the rails.

* * *

The errors described above were pervasive and mutually reinforcing. Most of the errors warrant a new trial on their own; cumulatively they deprived DePuy of the opportunity to mount an effective defense and undermined any possible confidence in the jury's verdict. *See United States v. Riddle*, 103 F.3d 423, 435 (5th Cir. 1997) ("Turning these rulings in a different direction would have produced a very different trial.").

B. The District Court Erred by Refusing To Bifurcate the Exemplary Damages Phase of Trial.

A new trial also is required because the district court refused to order a bifurcated trial regarding the amount of punitive damages. Section 41.009 of the Texas Civil Practice & Remedies Code requires courts, upon a defendant's timely request, to bifurcate the portion of trial determining the amount of exemplary damages. The purpose of this provision is to eliminate the risk of prejudice that inevitably arises when evidence solely relevant to the amount of punitive damages—such as information about the defendant's profitability and other alleged bad acts—is introduced while the jury is considering liability issues. *Cf. Transp. Ins. Co. v. Moriel*, 879 S.W.2d 10, 30 (Tex. 1994) (bifurcation designed to "protect

against awards that are grossly excessive" by eliminating the "serious risk of prejudice" posed by evidence solely relevant to punitive damages). Here, despite Appellants' timely request, the district court refused to bifurcate the trial, holding that bifurcation "is primarily procedural in nature" and that federal procedural law—*i.e.*, Fed. R. Civ. P. 42—controls the bifurcation inquiry. ROA.16-11056.1232.

That ruling was erroneous. When a federal rule and a state law both appear to govern a question before a federal court sitting in diversity, the court applies the federal rule if it is so broad that it "control[s] the issue" and leaves "*no room* for the operation" of the state law. *Burlington N. R.R. Co. v. Woods*, 480 U.S. 1, 4-5 (1987). Here, Rule 42 and §41.009 easily co-exist. Rule 42 says nothing about punitive damages, and it "certainly does not require that the amount of punitive damages be determined in the same phase of a trial as liability." *In re USA Commercial Mortg. Co.*, 2010 WL 4702341, at *2 (D. Nev. Nov. 12, 2010). Because there was no conflict, the district court should have consulted the twin aims of *Erie* and applied the state rule to "discourag[e] forum-shopping" and "avoid[] inequitable administration of the laws." *Hanna v. Plumer*, 380 U.S. 460, 468 (1965).

Even if Rule 42 did conflict with §41.009, the district court failed to consider whether applying Rule 42 would exceed the scope of the Rules Enabling

Act. The Rules Enabling Act, 28 U.S.C. §2072, prohibits federal courts from applying federal rules that would "abridge, enlarge or modify *any* substantive right" provided by state law. *Shady Grove Orthopedic Associates, P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 423 (2010) (Stevens, J., concurring in judgment). As Justice Stevens explained in his controlling opinion in *Shady Grove*, a federal rule cannot "displace a state law that is procedural in the ordinary use of the term but is so intertwined with a state right or remedy that it functions to define the scope of the state-created right." *Id.* at 423.

The Texas statute requiring bifurcation of exemplary damages is precisely the type of state law that is "so intertwined" with a state remedy that it defines the scope of state-created rights. Texas makes certain evidence substantively relevant to punitive damages on the understanding that bifurcation will prevent that evidence from skewing deliberations on the underlying liability questions. Section 41.009, moreover, is part of a package of *substantive* rules enacted by the Texas legislature that limits the available remedies by, *inter alia*, limiting the types of claims eligible for punitive damages, §41.003, prohibiting prejudgment interest, §41.007, listing the factors a jury must consider in determining the amount of punitive damages, §41.011(a), and, of course, requiring bifurcation, §41.009. This comprehensive statutory scheme reflects a *substantive policy choice* in favor of

limiting the scope of remedies available under Texas law that cannot be abridged or modified by Rule 42.

IV. The Damages Award Must Be Vacated Or Remitted.

Damages awards may be set aside on appeal "upon a clear showing of excessiveness or upon a showing that they were influenced by passion or prejudice." *Westbrook*, 754 F.2d at 1241. The jury's verdict in this case—which includes just $536,500 in economic damages but a staggering $141.5 million in non-economic compensatory damages—is wholly disproportionate to plaintiffs' injuries, far exceeds the amounts awarded in similar reported Texas cases, and cannot be explained as anything other than the result of the jury's "passion or prejudice."

A. The Compensatory Damages Awards Were Grossly Excessive And Unsupported By The Evidence.

1. Under Texas law, "the standard for reviewing an excessive damages complaint is factual sufficiency of the evidence." *Bentley v. Bunton*, 94 S.W.3d 561, 620 (Tex. 2002). To sustain a damages award, there must be evidence showing that "the amount found is fair and reasonable compensation" for the plaintiff's injuries. *Saenz v. Fid. & Guar. Ins.*, 925 S.W.2d 607, 614 (Tex. 1996).

If the Court determines that a damages award is excessive, it "must suggest a remittitur … or direct the district court to do so." *Lebron v. United States*, 279 F.3d 321, 325 (5th Cir. 2002). This Court "determine[s] the size of the remittitur in

accordance with this circuit's 'maximum recovery rule,' which prescribes that the verdict must be reduced to the maximum amount the jury could properly have awarded." *Caldarera v. E. Airlines, Inc.*, 705 F.2d 778, 784 (5th Cir. 1983). The amount of "maximum recovery" is determined by examining awards in factually similar, reported cases in the state courts. *See Lebron*, 279 F.3d at 325.

Texas courts have allowed a maximum recovery of approximately $1 million in non-economic compensatory damages for injuries akin to (or even much worse than) those suffered by plaintiffs here. For example, in *Missouri Pacific Railroad Co. v. Roberson*, 25 S.W.3d 251 (Tex. App.—Beaumont 2000, no pet.), the plaintiff tore the meniscus of his knee, which required surgery and eventually a total knee replacement. *Id.* at 258. The plaintiff's knee swelled after physical activity, and he had "difficulty standing for long periods of time" and "difficulty ascending and descending stairs." *Id.* at 259. The appellate court upheld an award of $860,000 for past and future pain, anguish, and impairment. *See also Austin v. Shampine*, 948 S.W.2d 900, 915-16 (Tex. App—-Texarkana 1997, writ dism'd) (judgment of $950,000 for injuries requiring two total knee replacements).

In *Wal-Mart v. Crosby*, 295 S.W.3d 346 (Tex. App.—Dallas 2009, pet. denied), the plaintiff injured his back when he was struck by a motorized pallet stacker. He "experienced continuous pain" and could not "drive or even walk or stand alone for any period of time." *Id.* at 353-54. The plaintiff needed "assistance

to bathe, to get dressed and to use the toilet. He must use a cart for handicapped persons when he goes out with his family," and he could no longer engage in sports or physical activities. *Id.* The jury awarded the plaintiff $800,000 in past and future non-economic compensatory damages.

Texas courts have allowed a maximum recovery of just over $1 million in non-economic damages even where the plaintiffs' injuries included cancer, brain damage, or gunshot wounds. *See Lebron*, 279 F.3d at 325 (remitting award to plaintiff who suffered "severe, permanent brain damage" from $9 million to $1.25 million); *Osburn v. Anchor Labs.*, 825 F.2d 908, 920 (5th Cir. 1987) (reducing cancer victim's non-economic damages award from $2.1 million to $1.5 million); *PNS Stores v. Munguia*, 484 S.W.3d 503, 509-10 (Tex. App.—Houston [14th Dist.] 2016, no pet.) ($1.0485 million for organic brain injury); *Barnhart v. Morales*, 459 S.W.3d 733, 747-48 (Tex. App.—Houston [14th Dist.] 2015, no pet.) ($95,000 for herniated discs that prevented plaintiff from walking more than one-quarter mile); *Reeder v. Allport*, 218 S.W.3d 817, 820 (Tex. App.—Beaumont 2007, no pet.) ($1.45 million in non-economic damages for gunshot wound in neck and permanent confinement to wheelchair); *Jackson v. Golden Eagle Archery*, 143 S.W.3d 477, 479 (Tex. App.—Beaumont 2004, no pet.) ($6,500 in non-economic damages for multiple facial fractures and permanently impaired vision).

2. The non-economic compensatory damages awarded to the plaintiffs here are grossly excessive in light of the Texas cases discussed above and must be vacated or remitted. Indeed, the damages awarded to plaintiffs are many multiples of the maximum recovery of approximately $1 million.

Aoki: The jury awarded Aoki $14.9 million in non-economic compensatory damages. Of that award, $10.44 million was for future non-economic damages even though her surgeon reported that her recovery from revision surgery has been "uneventful," that "things look good for Ms. Aoki," and that "she's doing very well." ROA.16-11056.11826-29. Since revision surgery, Aoki has resumed traveling, working with children, and performing at renaissance fairs. ROA.16-11056.10397-402. She can swim and can walk two-and-a-half miles, and she recently joined a gym. ROA.16-11056.10305-06.

Greer: The jury awarded Greer $29.95 million in non-economic compensatory damages (an amount 576 times greater than his economic damages of $52,000). Of that award, $14.98 million was for future pain, anguish, and impairment, even though Greer's surgeon testified that he was doing "remarkably well" one month after revision surgery, and that one year after surgery, Greer was "thrilled with his progress" and felt "no numbness, tingling, weakness, [or] decreased reflex type behaviors in the leg." ROA.16-11056.11089-92. Greer (who was 79 at the time of trial) testified that his new implant was "wonderful,"

ROA.16-11056.8791, and that since his revision surgery, he had traveled to Greece "pain-free" and had gone sailing in Belize, ROA.16-11056.8870-71.

Christopher: Christopher was awarded $14.19 million in non-economic compensatory damages. Just two months after revision surgery, Christopher's medical records revealed that he had "no pain and is walking without a limp," was "happy that [he] had [his] hip replaced," and was only "complaining of slight stiffness." ROA.16-11056.10529. At a check-up in February 2015, he had "no complaints" and "walk[ed] with a normal gait." ROA.16-11056.10459-61. Christopher conceded that he is doing better now than if he had not had his hip replaced in the first place, despite the need for revision surgery. ROA.16-11056.10509-10.

Peterson: The jury awarded Peterson $30.35 million in non-economic compensatory damages, including $21.24 million for future non-economic harms. Yet Peterson, who was 76 at the time of trial, testified that he swims, walks a mile each morning, plays golf a couple times each week, skis in Park City, and still does many things to stay active and fit. ROA.16-11056.11902-03. He exercises every day, ROA.16-11056.11862-63, though he reported that he cannot "ride a bicycle in tough circumstances" or "hunt a deer and bring a deer back," ROA.16-11056.11880.

Klusmann: The jury awarded Klusmann $47.23 million in non-economic compensatory damages, which includes $28.34 million for future pain, anguish, impairment, and disfigurement. Klusmann was the most injured of the five plaintiffs, but he testified that despite the problems with his hips, he has resumed traveling, hiking, biking, swimming, and lifting weights. ROA.16-11056.9375-77, ROA.16-11056.9385-88. In all events, Klusmann's non-economic compensatory damage award is nearly 50 times greater than the maximum award under Texas law even for plaintiffs with serious and permanent injuries.

Because the damages awarded to the plaintiffs were grossly excessive and unsupported by the evidence, this Court should vacate the judgment and remand for a new trial on damages or remittitur. If this Court orders remittitur, it must also recalculate the exemplary damages cap. Tex. Civ. Prac. & Rem. Code §41.008(b).

B. The Jury Failed To Consider Each Category Of Compensatory Damages Independently.

The jury's outrageously excessive verdict was no accident. Instead of evaluating each sub-category of compensatory damages separately based on the evidence offered at trial, the jury simply assigned a massive (and round) damages figure to each plaintiff, and then worked backwards to fill in the special verdict form. That formulaic method of awarding damages underscores the excessiveness of the verdict and violates Texas law. Although juries are "given a measure of

discretion in finding damages, that discretion is limited," and juries may not "simply pick a number and put it in the blank." *Saenz*, 925 S.W.2d at 614.

For example, in *Lane v. Martinez*, 494 S.W.3d 339 (Tex. App.—Eastland 2015, no pet.), the Court of Appeals reversed a damages award because the jury "did not give careful consideration to each of the damage elements but, rather, picked a number at random and just filled in the blanks." *Id.* at 351. The charge directed the jury to consider economic damages and four separate categories of non-economic damages for each plaintiff. *Id.* The jury, instead of considering each category independently, decided at the outset to award each plaintiff a total of $1 million. *Id.* The jury then subtracted each plaintiff's pecuniary damages and divided the remaining amount equally among the four categories of damages. *Id.* That method of allocating damages "violated *Saenz*'s prohibition of simply picking numbers and putting them in the blanks." *Id.* at 347.

Here, too, the jury simply assigned an overall damages award to each plaintiff and then worked backwards to complete the special verdict form without regard to the record evidence (if any) pertaining to each category.[12] The jury began by assigning almost perfectly round numbers in total damages to each plaintiff.

[12] The special verdict form listed ten different categories of non-economic compensatory damages: past and future physical pain and mental anguish, physical impairment, disfigurement, loss of household services, and loss of consortium. ROA.16-11056.5924-39.

Aoki's awards add up to $15,000,000.14; Klusmann's awards add up to $50,000,432; Christopher's to almost exactly $15 million; Greer's to almost exactly $30 million; and Peterson's to almost exactly $32 million.

The jury then worked its way backwards through the special verdict form, assigning perfect proportions of the total award to each category. As in *Lane*, the jury began by subtracting each plaintiff's economic damages (*i.e.*, past and future medical expenses) from the total award. The remaining sum was then proportionally allocated to the remaining categories of damages for each plaintiff. For each of the three plaintiffs whose wives sought loss of consortium and loss of household services, the jury awarded *exactly* 5% of the non-economic damages to those categories, with each award equally split among past consortium, future consortium, past services, and future services. Then, for all five plaintiffs, the jury split the remaining non-economic damages proportionally among the four remaining categories. For example, the jury allocated *exactly* 15% of Peterson's remaining damages to past physical pain and mental anguish; *exactly* 15% to past physical impairment; *exactly* 35% to future physical pain and mental anguish; and *exactly* 35% to future physical impairment.

The following table summarizes the method the jury used for each plaintiff:

	Aoki	Greer	Christopher	Peterson	Klusmann
Total Compensatory Damages Award	**$15,000,000**	**$30,002,876**	**$15,000,600**	**$31,999,200**	**$50,000,432**
Past Medical Expenses	$41,762	$26,000	$41,000	$25,995	$144,000
Future Medical Expenses	$41,762	$26,000	$20,000	$25,995	$144,000
Non-Economic Damages	**$14,916,476**	**$29,950,876**	**$14,939,600**	**$31,947,210**	**$49,712,432**
Past Loss of Household Services	N/A	N/A	$186,745	$399,350	$621,405
Future Loss of Household Services	N/A	N/A	$186,745	$399,350	$621,405
Past Loss of Consortium	N/A	N/A	$186,745	$399,350	$621,405
Future Loss of Consortium	N/A	N/A	$186,745	$399,350	$621,405
Non-Economic Damages Less Consortium/Services	**$14,916,475.86**	**$29,950,876.00**	**$14,192,620.00**	**$30,349,810.40**	**$47,226,812.00**
Past Physical Pain and Mental Anguish	$2,237,471 (15%)	$7,487,719 (25%)	$2,128,893 (15%)	$4,552,592 (15%)	$7,084,022 (15%)
Past Physical Impairment	$2,237,471 (15%)	$7,487,719 (25%)	$2,128,893 (15%)	$4,552,592 (15%)	$7,084,022 (15%)
Future Physical Pain and Mental Anguish	$5,220,767 (35%)	$7,487,719 (25%)	$4,967,417 (35%)	$10,622,313 (35%)	$11,806,703 (25%)
Future Physical Impairment	$5,220,767 (35%)	$7,487,719 (25%)	$4,967,417 (35%)	$10,622,313 (35%)	$11,806,703 (25%)
Past Disfigurement	N/A	N/A	N/A	N/A	$4,722,681 (10%)
Future Disfigurement	N/A	N/A	N/A	N/A	$4,722,681 (10%)

It is inconceivable that these perfectly proportional figures bear any relation to the actual type and quantum of damages evidence introduced by each plaintiff. Indeed, the verdict was replete with duplication and repetition of various line-items, which underscores that the jury did not properly analyze each category of damages independently. For example, it is utterly implausible that each plaintiff is entitled to the *exact same amount* for past anguish as past impairment; or the *exact same amount* for future anguish as future impairment; or the *exact same amount* for future consortium as past services, despite significant differences among the plaintiffs in their ages and alleged injuries. *See Lane*, 494 S.W.3d at 351 (noting similar repetition across distinct categories of damages). Moreover, as in *Lane*, the excessiveness of the verdict was underscored by the fact that the award of non-

economic compensatory damages ($141.5 million) dwarfed the plaintiffs' economic damages ($536,513.74). *See id.*

In short, the non-economic damages awards in this case bear no resemblance to what a jury would have awarded had it "considered the non-pecuniary damage elements separately as required by the court's charge." *Lane*, 494 S.W.3d at 351; *see Saenz*, 925 S.W.2d at 614. A new trial is needed so that the jury can award damages to each plaintiff based on the evidence offered at trial, not by working backwards from an arbitrarily selected large number.

CONCLUSION

For the reasons set forth above, the Court should reverse and enter judgment in favor of Appellants. In the alternative, the Court should reverse and remand for a new trial or order remittitur.

Respectfully submitted,

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January 30, 2017

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(g)(1) of the Federal Rules of Appellate Procedure, I hereby certify that the textual portion of the foregoing brief (exclusive of the disclosure statement, tables of contents and authorities, certificates of service and compliance, but including footnotes) contains 17,491 words as determined by the word counting feature of Microsoft Word 2013. On January 25, 2017, the Court granted Appellants leave to file this brief in excess of the standard word limit.

I certify that the required privacy redactions have been made pursuant to 5th Cir. R. 25.2.13, the electronic submission is an exact copy of the paper submission, and the document has been scanned for viruses with System Center Endpoint Protection, last updated January 28, 2017, and is free of viruses.

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CERTIFICATE OF SERVICE

I hereby certify that on January 30, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system. I certify that service will be accomplished by the CM/ECF system or by electronic mail.

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