

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT**

United States Court of Appeals
Fifth Circuit

FILED

April 25, 2018

Lyle W. Cayce
Clerk

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

No. 16-11051

JAY CHRISTOPHER,

Plaintiff–Appellee
Cross–Appellant,

JACQUELINE CHRISTOPHER,

Plaintiff–Appellee,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants
Cross–Appellees.

* * * * *

No. 16-11052

RICHARD KLUSMANN,

Plaintiff–Appellee
Cross–Appellant,

SUSAN KLUSMANN,

Plaintiff–Appellee,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants
Cross–Appellees.

* * * * *

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

No. 16-11053

DONALD GREER,

Plaintiff–Appellee
Cross–Appellant,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants
Cross–Appellees.

* * * * *

No. 16-11054

ROBERT PETERSON,

Plaintiff–Appellee
Cross–Appellant,

KAREN PETERSON,

Plaintiff–Appellee,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants
Cross–Appellees.

* * * * *

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

No. 16-11056

MARGARET AOKI,

Plaintiff–Appellee
Cross–Appellant,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants
Cross–Appellees.

* * * * *

No. 17-10030

MARGARET AOKI,

Plaintiff–Appellee,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants.

* * * * *

No. 17-10031

JAY CHRISTOPHER; JACQUELINE CHRISTOPHER,

Plaintiffs–Appellees,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

* * * * *

No. 17-10032

DONALD GREER,

Plaintiff–Appellee,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants.

* * * * *

No. 17-10034

RICHARD KLUSMANN; SUSAN KLUSMANN,

Plaintiffs–Appellees,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants.

* * * * *

No. 17-10035

ROBERT PETERSON; KAREN PETERSON,

Plaintiffs–Appellees,

versus

DEPUY ORTHOPAEDICS, INCORPORATED;
JOHNSON & JOHNSON,

Defendants–Appellants.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Appeals from the United States District Court
for the Northern District of Texas

Before SMITH, BARKSDALE, and HIGGINSON, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

These appeals and cross-appeal are from the second in a series of bell-wether trials from the Pinnacle Hip multidistrict litigation (“MDL”), in which several thousand plaintiffs claim injuries from Pinnacle hips manufactured and sold by DePuy Orthopaedics, Incorporated (“DePuy”).¹ The five plaintiffs in this consolidated action—Margaret Aoki, Jay Christopher, Donald Greer, Richard Klusmann, and Robert Peterson²—received Pinnacle’s metal-on-metal (“MoM”) design, suffered complications, and required revision surgery. They sued DePuy and its parent corporation, Johnson & Johnson (“J&J”),³ and secured a half-billion-dollar jury verdict. Defendants’ various post-trial motions—for judgment as a matter of law (“JMOL”), dismissal of claims against J&J for lack of personal jurisdiction, and a mistrial—were denied. Defendants renew all three lines of argument on appeal, attacking the verdict on nearly twenty independent bases. Plaintiffs cross-appeal, claiming Texas’s exemplary-damages cap violates the state and federal constitutions. In a companion appeal, defendants appeal the denial of relief from judgment under

¹ For background, see *In re DePuy Orthopaedics, Inc.*, 870 F.3d 345 (5th Cir. 2017).

² Three spouses—Jacqueline Christopher, Susan Klusmann, and Karen Peterson—alleged loss of consortium. Their claims were consolidated as well.

³ More precisely, J&J owns Johnson & Johnson International, Incorporated, which owns DePuy Synthes, Incorporated, which owns a subsidiary, which owns DePuy.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Federal Rule of Civil Procedure 60(b)(3) on the ground that plaintiffs' counsel, Mark Lanier, concealed payment arrangements with two key expert witnesses.

Disposing of the two sets of appeals together,⁴ we conclude that only a few of plaintiffs' claims fail as a matter of law but that the district court's evidentiary errors and Lanier's deceptions furnish independent grounds for a new trial. Hence, we reverse in part, vacate the judgment and the order denying Rule 60(b)(3) relief, and remand.

I. Background

In 2011, the Judicial Panel on MDL ordered centralization of pretrial proceedings in the Northern District of Texas for cases involving the Pinnacle Acetabular Cup System hip implants. The parties agreed to a protocol for bellwether trials and, together, identified a pool of eight cases from which to select the candidates. The first bellwether trial lasted two months and ended in a jury verdict for J&J and DePuy (jointly "defendants"). The district court then jettisoned the seven remaining cases and ordered the parties to prepare ten new ones for trial. Five of those were consolidated, over defendants' objection, for the second bellwether trial, which lasted nine weeks and forms the basis of these appeals and cross-appeal.

At trial, plaintiffs claimed DePuy defectively designed and marketed its MoM implant and that J&J was liable, as a "nonmanufacturer seller," for aiding and abetting and for negligent undertaking. At the heart of the claims lay the contested science of modern hip prosthetics, and we begin with the narrow points of agreement. As outlined in both sides' briefs, prosthetic hips are designed to replicate the hip's ball-and-socket function and typically consist of

⁴ Plaintiffs' cross-appeal is meritless, and we dispose of it by footnote.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

four components: a *stem* inserted into the femur, a femoral *head* attached to the stem (the hip “ball”), a *cup* implanted into the hip socket (the acetabulum), and a metal *liner* that fits into the cup and against which the ball articulates.

The liner can be made from metal, polyethylene, or ceramic. The product at issue is Pinnacle’s MoM design, in which both head and liner (Ultamet) are made of metal. Plaintiffs received the Ultamet but, several years later, required revision to metal-on-plastic (“MoP”) or metal-on-ceramic designs.

The briefs and trial transcripts present competing histories on hip-implant technology. Both sides agree the story begins in the 1960s with “first-generation” MoMs, the earliest models to achieve widespread use. The parties further agree that these early MoMs carried certain health risks and were quickly displaced by Sir John Charnley’s metal-on-plastic (“MoP”) design, long described as the industry’s “gold standard.”

Here, we reach a fork. Defendants suggest that, in the 1990s, MoP was viewed as the industry’s “weak link” because of its tendency to cause osteolysis, bone loss in the area surrounding the implant. When the metal ball articulates against the plastic liner, it generates debris from plastic wear that can cause dissolving of the surrounding bone, which, in turn, can require revision surgery. Defendants, along with several other manufacturers, promoted MoMs in the early 2000s to address this Achilles’ heel and offer high-activity patients an alternative that would wear out more slowly than plastic.

Plaintiffs meanwhile tell a less rosy story. They claim defendants hastily reintroduced Ultamet to market, without conducting any clinical tests, for the sole purpose of increasing market share. Medical science had long discovered that plastic-wear debris, and the attendant risk of osteolysis, could be reduced considerably if the plastic liner was “cross-linked,” that is, sterilized through

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

radiation. Yet, the theory goes, defendants lured surgeons away from cross-linked plastic's proven success through an intricate misinformation campaign of false advertisements and DePuy-authored academic papers.

On the core issue of marketing and design, the parties waged a war of the experts. Plaintiffs elicited testimony from engineers and medical scientists that Ultamet's MoM design was a producing cause of their injuries and that cross-linked MoP was a safer alternative. They also offered evidence that defendants, before bringing the product to market, were made aware of the considerable, and arguably unjustifiable, risks of MoM. Defendants' experts countered that, although MoP might be better suited to older patients, the risk-benefit calculus for younger, more active patients might still favor MoM. Defendants further maintained they had always been forthcoming with treating physicians about this risk calculus. The district court admitted several pieces of inflammatory character evidence against defendants—including claims of race discrimination and bribes to Saddam Hussein's Iraqi "regime"—reasoning the defendants had "opened the door" by repeatedly presenting themselves as "wonderful people doing wonderful things."

The jury found for plaintiffs on the five above-mentioned causes of action and returned a \$502 million verdict. It awarded just \$500,000 in economic compensatory damages and \$141.5 million in non-economic compensatory damages, and DePuy and J&J were assessed exemplary damages of \$120 million and \$240 million, respectively. The defendants made numerous post-trial motions—for JMOL on all claims, for dismissal on jurisdictional grounds, and for mistrial. All were denied, save the request that the court apply Texas's statutory exemplary-damages cap, which reduced the \$360 million to \$9.6 million. Defendants appeal the judgment, and plaintiffs cross-appeal

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

application of the cap.

In a companion appeal, defendants request relief from judgment under Federal Rule of Civil Procedure 60(b)(3), based on plaintiffs' counsel's failure to disclose payments to two purportedly "nonretained" experts—Dr. Bernard Morrey ("Morrey Sr.") and Dr. Matthew Morrey ("Morrey Jr."). In preparation for the third bellwether trial, defendants discovered that before the second trial, plaintiffs' counsel Mark Lanier had made a \$10,000 donation to a charity of Morrey Sr.'s choosing, that Morrey Jr. had expected to be paid when testifying, and that the doctors had received post-trial payments totaling \$65,000. Defendants moved for relief, the court denied the motion, and defendants again appeal.

II. Claims Against DePuy

JMOL is warranted only if "a reasonable jury would not have a legally sufficient evidentiary basis" to find for the nonmovant. FED. R. CIV. P. 50(a)-(1)(B). We review the denial of JMOL *de novo*, applying "the same standard . . . the district court used in first passing on the motion." *Nobach v. Woodland Vill. Nursing Ctr.*, 799 F.3d 374, 377 (5th Cir. 2015) (quotations omitted). DePuy claims plaintiffs' design and marketing claims fail categorically and that Klusmann's and Greer's claims are barred by the relevant statute of limitations.⁵

⁵ Several of defendants' theories implicate the murkier areas of Texas tort law. In considering these challenges, we are guided by the en banc court's admonition:

[I]t is not for us to adopt innovative theories of state law, but simply to apply that law as it currently exists We are emphatically not permitted to do merely what *we* think best; we must do that which we think the [state] [s]upreme [c]ourt would deem best. . . . If the law of [the state] is to be changed, it is up to the [s]upreme [c]ourt of [the state] and not this court to change the substantive law of that state.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

A. Design Defect

To establish a design defect, plaintiffs had 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 Motor Eng’g & Mfg. N.A.*, 770 F.3d 322, 330 (5th Cir. 2014) (citations omitted). Texas law defines a safer alternative design as one that “would have prevented or significantly reduced the risk of the claimant’s personal injury . . . without substantially impairing the product’s utility.”⁶ Consistent with this risk-utility framework, a plaintiff “must show the safety benefits from [the] proposed design are foreseeably greater than the resulting costs, including any diminished usefulness or diminished safety.” *Casey*, 770 F.3d at 331 (quoting *Hodges v. Mack Trucks, Inc.*, 474 F.3d 188, 196 (5th Cir. 2006)). The Texas Supreme Court and intermediate courts have held that a “substantially different product” cannot constitute a safer alternative design.⁷

Jackson v. Johns–Manville Sales Corp., 781 F.2d 394, 397 (5th Cir. 1986) (en banc) (quotation and alterations omitted). As a practical matter, our inquiry turns on the following predictive indicia:

- (1) decisions of the [state] [s]upreme [c]ourt in analogous cases,
- (2) the rationales and analyses underlying [state] [s]upreme [c]ourt decisions on related issues,
- (3) dicta by the [state] [s]upreme [c]ourt,
- (4) lower state court decisions,
- (5) the general rule on the question,
- (6) the rulings of courts of other states to which [state] courts look when formulating substantive law and
- (7) other available sources, such as treatises and legal commentaries.

Centennial Ins. Co. v. Ryder Truck Rental, Inc., 149 F.3d 378, 382 (5th Cir. 1998) (citations omitted).

⁶ TEX. CIV. PRAC. & REM. CODE ANN. § 82.005(b). The alternative design must also be economically and scientifically feasible, see *Honda of Am. Mfg., Inc. v. Norman*, 104 S.W.3d 600, 608 (Tex. App.—Houston [1st Dist.] 2003, pet. denied), but those requirements are easily satisfied, given that DePuy sold a line of MoP devices.

⁷ See *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760, 770 (Tex. App.—Houston [14th

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Defendants seek JMOL on three accounts: (1) MoP is a different product, not an alternative MoM design, (2) plaintiffs’ design-defect theory is preempted because it conflicts with the goals enshrined in relevant Food and Drug Administration (“FDA”) regulations, and (3) medical-device liability is foreclosed by comment k to Restatement (Second) of Torts § 402A. Defendants fail on all three.

1.

Defendants’ first contention—that MoP is a different product from MoM—implicates thorny questions of identity and definition, practically impossible to settle in the abstract.⁸ In select instances, nonidentity will be obvious: For example, a proposal to add two additional wheels to a motorcycle or to “fully enclos[e] the cab” of a convertible. *Caterpillar*, 911 S.W.2d at 385. But this case does not lend itself to such straightforward resolution, as the parties dispute how to characterize the relevant product: Is it a “high-stability, low-wear” implant, of which MoP and MoM are merely two alternative iterations? Or is it the discrete MoM design, in which case MoP is a completely different beast? Hewing carefully to guidance provided by Texas courts, we conclude, based on the record, that MoP is a viable alternative design to MoM.

The alternative-design/different-product distinction emerges from two Texas cases, both distinguishable from the present. In *Caterpillar*, the Texas Supreme Court considered whether a front-end loader with a removable rollover-protection structure (“ROPS”) was defectively designed. *Id.* at 383–

Dist.] 2009, no pet.); *see also Caterpillar Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995).

⁸ *Cf. Jackson v. Firestone Tire & Rubber Co.*, 788 F.2d 1070, 1076 (5th Cir. 1986) (“It is important, but difficult, to determine at the outset the appropriate level of generality at which to assess appellant’s [products liability] claims.”); *Bell Helicopter Co. v. Bradshaw*, 594 S.W.2d 519, 529 (Tex. Civ. App.—Corpus Christi 1979, writ ref’d n.r.e.).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

85. The court rejected the plaintiff’s proposed alternative—in which the ROPS was rendered non-removable—because the non-removable structure would thwart the ROPS’s “intended” function of enabling access to “low clearance areas.” *Id.* at 384–85. The court refused to “impose liability in such a way as to eliminate whole categories of *useful products* from the market.” *Id.* at 385 (emphasis added).

In *Brockert*, 287 S.W.3d at 769, the Texas Court of Appeals applied this principle in the pharmaceutical context to conclude that an estrogen-only drug was not a safer alternative design to Prempro, a combination of estrogen and progestin, despite that both served “the same general purpose” of treating menopausal symptoms, *id.* The plaintiff claimed her estrogen-only alternative eliminated the risk of breast cancer introduced by Prempro. *Id.* The court rejected the argument, explaining that progestin helped “reduce the incidence of endometrial hyperplasia,” *id.* at 770, and that the plaintiff had failed to “explain how Prempro could have been modified or improved” without compromising that function, *id.* at 771. Thus plaintiff’s theory was rejected as a “categorical attack” on the relevant product. *Id.*

Doctrinally, it is notable that both *Caterpillar* and *Brockert* rejected a plaintiff’s proposed alternative for failing to perform the discrete *kinds* of functions for which the alleged defective was designed—*e.g.*, accessing low clearance areas or reducing incidence of endometrial hyperplasia. But neither case clearly supports the proposition that a slight difference in *degree*—that is, that the alternative does all of the things for which the allegedly defective product was designed, but does not do one of them quite as well—automatically renders the plaintiff’s proposed alternative an entirely different product. Though this kind/degree distinction cannot dispel the underlying problem of

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

characterization,⁹ it finds direct support in the above caselaw and coheres with the overall structure of Texas design-defect law.

Texas’s risk-utility test plainly contemplates that a proposed alternative design might reduce a product’s utility—that is, its capacity to perform a function for which it was designed—without rendering the alternative an entirely different product.¹⁰ If any distinction in degree rendered the proposed alternative a different product as a matter of law, that would effectively moot the substantive balancing test for liability. Where the distinction is one of degree only, the risk-utility framework provides the proper mode of analysis.

Defendants claim to have identified two relevant functional distinctions between MoM and MoP: (a) Metal is more durable than plastic and, therefore, more suitable to younger patients “who often seek not just pain relief but also the ability to resume an active lifestyle”; and (b) metal remedies osteolysis by “*eliminat[ing]* plastic debris entirely.” Neither purported distinction, however, shows MoP to be an “entirely different product” under the above, proper framework. *See Brockert*, 287 S.W.3d at 770. To the first: Durability is a distinction in degree rather than kind. All hip implants—plastic, metal, or ceramic—are designed with the twin goals of minimizing wear debris and affording maximal longevity. Defendants’ own promotional materials characterize both their MoP (AltrX LD) and their MoM (Ultamet XL) as “high stability, low wear” hip implants; they never suggest the latter enables the implantee to perform discrete tasks otherwise impossible with the former. *Brockert* and *Caterpillar* are thus distinguishable.

⁹ For example, parties could merely dispute the level of generality at which the product’s function should be described.

¹⁰ TEX. CIV. PRAC. & REM. CODE ANN. § 82.005(b) (stating that a proposed alternative design must not “*substantially* impair[] the product’s utility”) (emphasis added).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

The question then is whether plastic substantially impairs the hip implant’s utility along the durability axis. *See Bell Helicopter*, 594 S.W.2d at 529. And though defendants presented evidence that metal was an “attractive option” for younger patients, plaintiffs presented contrary evidence that cross-linked plastic was preferable “a hundred times out of a hundred” and that it outperformed metal along the survivorship dimension by a wide margin. On this evidentiary record, we cannot conclude, as a matter of law, that MoP substantially impairs the implant’s utility in terms of stability and rate of wear.

As for reduction of osteolysis, plaintiffs rightly observe that cross-linked polyethylene was intended to do the same thing. The question then is whether the risk of osteolysis from cross-linked MoP substantially reduces MoM’s utility, and the record says not. A DePuy executive conceded that MoM, too, can cause osteolysis, and DePuy seems to have known, when it sold Ultamet, that cross-linked plastic significantly reduced the relevant risk.¹¹ Thus, defendants have not identified a sufficiently discrete functional advantage to prove

¹¹ Defendants shift course in their reply brief, stressing that MoM “eliminate[s] *plastic debris*.” That distinction is real but “of little analytical value.” *Bell Helicopter*, 594 S.W.2d at 529. MoM was believed to constitute an improvement over MoP not because it eliminated the use of plastic, but because it purported to reduce the occurrence of *adverse conditions* associated with plastic debris (osteolysis).

Put differently, plastic elimination was only the means, never the functional endgame. And though plaintiffs must do more than show that MoP has “the same general purpose as the allegedly defective product,” *Brockert*, 287 S.W.3d at 770, the facts of *Brockert* show that performing the defective product’s basic function, while simultaneously reducing the probability of a specific side effect, is sufficiently particularized for the purposes of alternative-design analysis, *see id.* at 769–70; *see also* RESTATEMENT (THIRD) OF TORTS: Products Liability § 2, cmt. f, illustration 8 (explaining that when a defendant markets a new television antenna that utilizes the electrical system in the buyer’s home, and “improves reception compared with traditional television antennas, but also introduces significant risks of electrical shock and electrocution,” the plaintiff may point to “traditional television antennas” as a reasonable alternative design and is “not confined to offering variations of television antennas that rely on electrical wiring systems” because the novel wiring method is “*merely a*

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

MoP is fundamentally a different product.

At oral argument, defendants suggested the different-product/-alternative-design question should be decided from the *ex ante* perspective, when DePuy believed MoM would eliminate osteolysis and substantially outperform plastic. That those marginal benefits may have failed fully to materialize is ostensibly irrelevant to the inquiry. But defendants cite no cases for this contestable proposition¹²; and regardless, its application here would require the equally contestable factual assumption that defendants did not, and could not, reasonably foresee the risks of instability and metallosis that, according to plaintiffs, dwarf MoM's purported benefits. Plaintiffs presented evidence that defendants knew, even before December 2004 (the earliest date on which any plaintiff received his or her implant) that cross-linked MoP meaningfully addressed the osteolysis risk and that MoM carried potentially catastrophic risks of failure. Thus, the jury could reasonably conclude, even under defendants' *ex ante* framing, that plaintiffs had identified a viable alternative design.¹³

means of achieving the objective of improved television reception" (emphasis added)).

¹² Defendants' proposal presents interrelated problems of proof and incentives. On the incentive side, sophisticated actors could exploit the rule by making sub-optimal investments in *ex ante* risk detection, blinding themselves to the potential dangers of a particular product. And, as for proof, how should courts go about discerning the manufacture's "*ex ante*" intentions? Should we ask the engineers how they expected the innovation to perform relative to its market alternatives? Must we credit a designer's self-serving speculation as to the magnitude of expected benefit as well? *See generally* STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 237–38 (2004). These and other evidentiary problems counsel caution. Additionally, the purpose of the "different product" rule is to guard against "eliminat[ing] whole categories of *useful* products from the market," *Caterpillar*, 911 S.W.2d at 385 (emphasis added); and, obviously, the aspiration for usefulness does not, by itself, imply its attainment.

¹³ *See Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895, 901 n.8 (E.D. Va. 2010) (reading *Brockert* for the proposition that the question whether minor "changes would fundamentally

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Defendants draw our attention to several other cases applying the alternative-design/different-product distinction, but none disturbs the above conclusion. First is *Theriot v. Danek Medical, Inc.*, 168 F.3d 253 (5th Cir. 1999), in which the plaintiff alleged a design defect in pedicle screws used for spinal stability. The plaintiff identified “external neck braces or internal systems that use hooks or wires” as potential alternative designs, *id.* at 255, and, applying Louisiana law, we rejected that theory as “tak[ing] issue with the choice of treatment [i.e., the use of pedicle screws] made by Theriot’s physician, not with a specific fault of the pedicle screw sold by [the defendant],” *id.* As the facts of that case make clear, Theriot’s proposed alternatives were obviously of a different categorical and structural ilk. Any analogy from that case to this one flatly begs the underlying issue of characterization.¹⁴

Defendants also cite *Hosford v. BRK Brands, Inc.*, 223 So. 3d 199 (Ala. 2016), holding that ionization smoke alarms and dual-sensor smoke alarms are different products. The plaintiffs argued ionization alarms were defective because they “fail to provide adequate warning” of a fire that “begins as . . . slow [and] smoldering,” *id.* at 204, and they identified the “more expensive”

transform [an allegedly defective product] into a completely different product [may be] a genuine issue of fact appropriate for jury resolution”).

¹⁴ *Cf. Michael v. Wyeth, LLC*, No. 2:04–0435, 2011 WL 2150112, at *12 (S.D.W.V. 2011) (finding that “synthetic” and “natural” progestin are “within the same class of [hormone replacement therapy] drugs that allegedly injured” the plaintiff, and distinguishing *Theriot* accordingly). Defendants also cite *Damian v. Bell Helicopter Textron Inc.*, 352 S.W.3d 124 (Tex. App.—Fort Worth 2011, pet. denied), but that case actually supports plaintiffs’ position. There, plaintiffs were injured in a helicopter crash that occurred after a bird penetrated the windshield, and they sued the manufacturer, alleging defective design. *Id.* at 130–31. The court rejected the claim because installation of a larger, bird-resistant windshield would require that the helicopter be completely restructured, turning a small and agile chopper into a heavier model. *Id.* at 150 n.19, 154 n.26. As in *Theriot*, the proposed alternative would require a dramatic restructuring of the product; here, in contrast, the plastic and metal liners are effectively interchangeable parts in the Pinnacle hip set. The contrast is obvious.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

dual-sensor alarms, which incorporate both ionization and “photoelectric technology,” as a safer alternative, *id.* Applying *Brockert* and *Caterpillar*, the court deemed them two different products, based primarily on the wide disparity in price. *Id.* at 207. That court feared liability would drive the “less expensive [option] from the market . . .[,] result[ing] in no smoke alarm being present” in homes like the plaintiffs’. *Id.*

Here, that empirical judgment is obviously inapposite, given that several plaintiffs were revised to the very alternative they propose. None of defendants’ cases counsels reversal on our facts.

2.

Defendants suggest the design-defect claims are preempted because they “stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives” reflected in the MoM-related regulations of the FDA. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). Defendants’ obstacle-preemption theory fails at two levels, misconstruing both the FDA’s objectives with respect to MoMs and the alleged state-law obstacle in its path.

We begin with the federal objective. Before 1976, the Federal Food, Drug, and Cosmetic Act left “the introduction of new medical devices . . . largely for the States to supervise.” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). Congress stepped in with the Medical Device Amendments of 1976 (MDA) and imposed, for the first time, “a regime of detailed federal oversight,” which authorized the FDA to regulate medical devices under a three-tiered, risk-based classification scheme. *Id.* at 316. Devices classified as class I or II can be made reasonably safe through compliance with FDA’s “general controls” or “special controls,” whereas class III is reserved for cases in which “insufficient information exists to determine” whether general or special controls can

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

ensure the product’s “safety and effectiveness.” 21 U.S.C. § 360c(a)(1)(A)–(C). In addition, Congress granted the FDA discretionary authority to ban outright any product that “present[s] . . . an unreasonable and substantial risk of illness or injury.” *Id.* § 360f(a)(1); *see generally Riegel*, 552 U.S. at 315–17.

Before class III devices can be brought to market, they generally must survive the FDA’s rigorous premarket approval (“PMA”) process, designed to ensure a device’s “safety and effectiveness.” 21 U.S.C. § 360e(d)(1)(A). That process is “quite time consuming,” requiring “an average of 1,200 hours [for] each submission.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344–45 (2001) (quotation omitted). The statute carves out an exception for “predicate” devices that were on the market before 1976, which can remain in circulation “until the FDA initiates and completes the PMA process.” *Id.* at 345; *see also* 21 U.S.C. § 360e(b)(1)(A). And “to avoid the potentially monopolistic consequences of th[e] . . . exception,” the MDA also exempts any “substantial equivalents” of these predicate devices. *See Buckman*, 531 U.S. at 345; 21 U.S.C. § 360e(b)(1)(B). These equivalents enter the market through what is known as the “510(k) process,” which requires an applicant to show that the device either “has the same technological characteristics as the predicate device” or “is as safe and effective as a legally marketed device.” 21 U.S.C. § 360c(i)(1)(A)(i)–(ii).

The 510(k) process does not “denote official approval of the device”; to create a contrary “impression . . . constitutes misbranding.” 21 C.F.R. § 807.97. The process “provide[s] little protection to the public” because it is “focused on *equivalence*, not safety.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (quotations omitted). More recently, however, the agency has clarified, in guidance documents, that “principles of safety and effectiveness underlie the

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

substantial equivalence determination in every 510(k) review.”¹⁵

The MDA contains an express-preemption provision that prohibits states from “establish[ing] . . . any requirement[] (1) which is different from, or in addition to any [MDA] requirement applicable . . . to the device, and (2) which relates to [its] safety or effectiveness.” 21 U.S.C. § 360k(a). The clause covers class III, PMA products, *Riegel*, 552 U.S. at 322–23, but not 510(k)-approved products, *id.* at 322; *Lohr*, 518 U.S. at 493–94.

As relevant here, MoMs were sold before 1976 and have traditionally been treated as pre-amendment class III devices that can be brought to market through the 510(k) process. Ultamet followed that route in December 2000, when defendants characterized the product as a substantial equivalent of Ultima, one of J&J’s eventually recalled MoMs. In 2013, shortly after the FDA issued a proposed order requiring that all MoMs receive PMA, defendants chose to remove Ultamet from the market. The FDA finalized its order three years later and has not since granted PMA to any MoMs having a structure resembling Ultamet’s.¹⁶

Defendants suggest plaintiffs’ *theory* of liability—that MoMs are “categorically defective”—flouts the FDA’s considered judgment that MoMs should not be banned outright but rather regulated, and should remain available, as

¹⁵ U.S. Dep’t of Health and Human Servs., et al., *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications* 6 (July 28, 2014), <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf>. *But see Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1318 (11th Cir. 2017) (holding the district court did not abuse its discretion in excluding evidence of 510(k) review in a products-liability suit because the “510(k) review process is not relevant to a product’s safety”).

¹⁶ *See* 21 C.F.R. § 888.3330(b); U.S. Food & Drug, *Premarket Approval (PMA)*, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. At oral argument, defendants conceded as much.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

class III medical devices. That theory fails at two levels.

First, plaintiffs' *burden* was to show only that Ultamet was defective, not that all MoMs were. And because Ultamet was off the market before the trial, the verdict cannot have thwarted the FDA's objectives in that narrow respect. Defendants reply that plaintiffs' only colorable theory at trial covered the MoM interface writ large. Maybe so, but defendants' position assumes, without any support, that our obstacle-preemption inquiry looks through the verdict and judgment to the arguments that lie beneath them. This seems unlikely, as it is the judgment, and not the parties' assertions, that carries binding effect and the attendant power to disrupt the federal regulatory scheme.¹⁷

But even under defendants' look-through inquiry, it is not the case that plaintiffs' theory reached *all possible MoMs*. All would agree that, despite the sweeping language with which plaintiffs presented their case, their claims were impliedly limited to presently available technologies and the adverse health effects they allegedly engender.¹⁸

This seemingly pedantic point is fatal to defendants' preemption argument. The FDA effectively withdrew all MoMs from the market with its February 2016 final rule and left open a single door in the form of PMA. Arguably, the final rule contemplates the possibility that every MoM then on the market would (and perhaps should) fail PMA. That the FDA chose not to ban MoMs as a class proves no more than that it wished to give manufacturers an opportunity to create MoMs not contemplated by plaintiffs' theory of liability.

¹⁷ *United States v. Shirey*, 359 U.S. 255, 261 n.5 (1959) (Frankfurter, J.) ("Th[e] Court reviews judgments, not arguments . . . seeking to sustain them.").

¹⁸ For example, a claim that all MoPs are defective, if made before the development of cross-linked MoPs, would probably not reach next-generation, cross-linked plastic that reduces the very risks that made first-generation MoPs defective.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Unless and until the FDA actually grants PMA to an extant MoM that carries the risks that made Ultamet defective, defendants cannot prove that even plaintiffs' theory of liability obstructs the FDA's regulatory objectives.

3.

Defendants assert plaintiffs' claims are foreclosed by comment k to Restatement (Second) of Torts § 402A:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like

RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k. The Texas Supreme Court has incorporated § 402A into its common law, *New Tex. Auto Auction Servs. v. Gomez de Hernandez*, 249 S.W.3d 400, 403 (Tex. 2008), and has considered comment k in the prescription-drug context, *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 165 (Tex. 2012). But it has never expressly extended the immunity rule to medical implants, let alone 510(k)-cleared devices, on either a categorical or a product-by-product basis.¹⁹

Jurisdictions are split on whether medical devices enjoy blanket

¹⁹ Defendants' suggestion that Texas has already rejected the case-by-case approach is unfounded. They rely on a lone federal district court decision from the prescription-drug context; but that decision relied on no more than its own policy judgment and three decisions from other jurisdictions. See *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

immunity,²⁰ with the majority of courts favoring the case-by-case methodology.²¹ Defendants ask that we deviate from that trend and foreclose all implant-based litigation, based on the conjecture that Texas courts might one day redraw liability boundaries in their favor. But defendants present scant predictive indicia *from Texas* to that effect, and we decline to step so far ahead of Texas courts, and against the majority view, in foreclosing broad avenues to suit.²² Comment k does not bar plaintiffs' claims.

B. Marketing Defect

To prevail on their marketing-defect claims, plaintiffs had to show (a) “the warning was defective” and (b) the defect “was a producing cause of the injury.” *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008) (citation omitted). Defendants seek JMOL on three grounds: The relevant warnings were adequate as a matter of law, plaintiffs presented no properly designated warning expert, and they failed to prove causation. We conclude that defendants are entitled to JMOL for want of causation, but only as to Greer’s and Peterson’s marketing-defect claims.

²⁰ Compare *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 383 (Cal. Ct. App. 1992), with *Hill v. Searle Labs.*, 884 F.2d 1064, 1067–69 (8th Cir. 1989).

²¹ See *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 n.2 (9th Cir. 2003) (collecting relevant decisions).

²² *Galindo v. Precision Am. Corp.*, 754 F.2d 1212, 1217 (5th Cir. 1985) (“[I]t is not for us to adopt innovative theories of recovery or defense for Texas law, but simply to apply that law as it currently exists.” (emphasis added)); *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662, 679 (N.D. Tex. 2010) (“The court will not take a leap not taken by Texas courts and apply [comment k] to an over-the-counter drug[.]”). Defendants have not preserved the argument that, under a product-by-product approach, Ultramet should enjoy immunity under comment k. But even if they had, Texas caselaw offers almost no guidance on how to go about that case-by-case inquiry. Here, we are resolved to the proposition that a reasonable jury could find defendants’ product was not of the kind contemplated by comment k. See, e.g., *Hill*, 884 F.2d at 1068–69 (reserving comment k for products “incapable of being made safe given the present state of human knowledge but possess[ing] such a high degree of social need so that [their] use is warranted, provided warnings are adequate”).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

1.

The adequacy of a warning is generally a question of fact. “However, if a warning specifically mentions the circumstances complained of, then the warning is adequate as a matter of law.” *Seifried v. Hygenic Corp.*, 410 S.W.3d 427, 433 (Tex. App.—Houston [1st Dist.] 2013, no pet.) (citations omitted). Defendants claim this is such a case.

By defendants’ description, plaintiffs all “experienced corrosion and friction wear from their hip implants” and “suffered adverse reactions to that debris.” Defendants claim specifically to have warned of these circumstances in the two “Instructions for Use” pamphlets (IFUs) inserted into their acetabular cup and metal liner packages. The cup’s IFU warns that “[t]issue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergic reactions, or the accumulation of polyethylene or metal wear debris or loose cement particles” are among “the most frequently encountered adverse events . . . in hip arthroplasty.” The liner’s IFU additionally warns of “[s]ubclinical nerve damage . . . associated with surgical trauma,” “subluxation resulting from importer position and/or muscle and fibrous tissue laxity,” “[h]istological reactions [from] exposure to a foreign material,” “higher ion release” where “bone cement is not used,” and the “potential for release of metallic debris into the joint space.” Defendants maintain these warnings reach all of plaintiffs’ purported conditions and were therefore adequate as a matter of law.

But in determining whether warnings are adequate as a matter of law, Texas courts subject them to a demanding standard of specificity. In *Jordan v. Geigy Pharmaceuticals*, 848 S.W.2d 176, 182 (Tex. App.—Fort Worth 1992, no writ), where the plaintiff suffered renal failure from an anti-inflammatory, the court reversed a summary judgment for the defendant on the plaintiff’s

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

failure-to-warn claim. It held that the warning at issue—which described “renal pathology in *long-term* administration to animals” and “overt renal failure . . . *typically followed by recovery to the pretreatment state*”—did not sufficiently address “irreversible renal failure” or “acute renal failure,” both suffered by the plaintiff. *Id.* at 181–82. Plaintiffs’ position here is at least as compelling.

As for the cup IFU, it was drafted *before* the Ultamet liner was ever created, and it addresses only general adverse events relevant to all hip arthroplasty. Assuming Ultamet is defective for the reasons plaintiffs allege, the warning fails to put surgeons on notice as to the distinctive risks that arise from MoM—“metallosis,” “pseudotumors,” and “tissue necrosis”—or the magnitude of those risks. The liner IFU fares no better: It fails squarely to address “metal wear debris” that occurs when the metal ball articulates against the metal liner, the underlying cause of plaintiffs’ injuries. And, taken in context, its warnings about nerve damage, dislocation, and ion release concern complications not at issue in this case—*e.g.*, surgical trauma and the implant’s adaptation to the bone.

Not until after the FDA issued its proposed rule in 2013 did defendants specifically warn about the metallosis, pseudotumors, and tissue necrosis—the sorts of conditions that plaintiffs maintained caused their revision surgery. In short, though defendants’ IFUs identified metal debris generally, a reasonable jury could conclude that the warning failed to describe with reasonable specificity the source of the wear-debris problem, the conditions to which it gives rise, and the magnitude of the risk. Texas law requires a closer match than these defendants can show.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

2.

Defendants alternatively suggest plaintiffs failed to provide expert testimony that the device was defectively marketed. They note that Morrey Jr., plaintiffs' only expert to testify on the allegedly inadequate warning, was never designated as an expert on warnings *per se*²³ and never testified directly on the contents of Ultamet's IFUs. Both claims are unpersuasive. To the first: Plaintiffs designated Morrey Jr. as their warnings expert before trial, and as the surgeon-intermediary tasked with interpreting and applying the warning, he was likely equipped to assess its adequacy. To the second: Plaintiffs' counsel read excerpts from warnings included in an FDA study in 2000 but later excised from the IFUs. Morrey Jr. replied that physicians "should have been made aware of those things, because those are the same risks that you're going to tell your patient when you're counseling them." This was sufficient to allow a reasonable jury to conclude the IFUs' warnings were inadequate.

3.

Defendants claim plaintiffs failed to show the inadequate warning actually caused their physicians to select Ultamet. Under the learned-intermediary ("LI") doctrine, which Texas applies in "medical products liability actions,"²⁴ "the manufacturer . . . satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a 'learned intermediary,' who then assumes the duty to pass on the necessary warnings to the end user." *Centocor*, 372 S.W.3d at 142. Where the LI doctrine applies, plaintiffs must show that, but for the inadequate warning, their doctors would have

²³ See *Perez v. Goodyear Tire & Rubber Co.*, No. 04-14-00620-CV, 2016 WL 1464768, at *9 (Tex. App.—San Antonio 2016, no pet.).

²⁴ *Porterfield v. Ethicon Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (citing *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App.—Houston [14th Dist.] 1998, no pet.)).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

recommended different treatment, *see Ackermann*, 526 F.3d at 208, 214, or provided additional warnings that would have led plaintiffs to withhold consent, *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006).²⁵ The issue is generally a fact question, but “[w]hen the prescribing physician is aware of the product’s risks and decides to use it anyway, any inadequacy [in] the product’s warning, as a matter of law, is not the producing cause of the patient’s injuries.” *Centocor*, 372 S.W.3d at 170.

At the threshold, the parties debate the relevance, under Texas law, of “objective evidence”—that is, evidence “that a different warning would have affected the decision of a reasonable doctor.” *Id.* at 171. The Texas Supreme Court referenced “objective evidence” just once, in *Centocor*, noting that the plaintiffs not only “lack[ed] subjective evidence [about what the particular physician would have done] but presented no *objective evidence* that a different warning would have affected the decision of a reasonable doctor to prescribe [the relevant drug] for [plaintiff’s] condition.” *Id.* (emphasis added). Here, plaintiffs proffered objective evidence in Morrey Jr.’s testimony that, if the full risks of MoM were known to physicians, “they would run to polyethylene.”

At least one federal district court has dismissed *Centocor*’s language as *dictum*²⁶—but that is error. As our caselaw makes plain, non-binding language from the state supreme court is the second- or third-best predictive indicium of how that court might decide an underdetermined legal question. *Centennial*,

²⁵ Plaintiffs posit only that DePuy had a duty to warn Aoki and Klusmann directly of Ultamet’s risks. *See Murthy v. Abbott Labs*, 847 F. Supp. 2d 958, 971–73 (S.D. Tex. 2012). Because we conclude that the jury’s causation findings as to those patients are not unreasonable even if LI applies, we need not consider this alternative theory.

²⁶ *In re Mentor Corp.*, MDL Docket No. 2004 4:08-MD-2004 (CDL), Case No. 4:13-cv-229 (Burke), 2016 WL 4611572, at *3 (M.D. Ga. Sept. 2, 2016).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

149 F.3d at 382. Though the *dictum* here is weak—the court was emphasizing how thoroughly the *Centocor* plaintiffs had failed to make their case, *Centocor*, 372 S.W.3d at 171, rather than affirmatively describing the types of proof that might sustain plaintiffs’ burden—it suggests objective evidence is at least relevant to the inquiry.

Relevance, however, does not imply sufficiency. In the LI context, causation entails *two distinct factual predicates*: first, that the doctor would have read or encountered the adequate warning²⁷; and second that the adequate warning would have altered his treatment decision for, or risk-related disclosures to, the patient.²⁸ *Centocor* addressed only the latter, suggesting a jury *might* be allowed to presume a particular physician would respond “reasonably” to fuller disclosure. But that presumption must yield to contrary subjective testimony by the treating physician,²⁹ and *Centocor* fails to explain how objective evidence would apply to whether that doctor would have read or encountered the warning in the first instance.³⁰ When considered for the limited purpose intimated in *Centocor*, objective evidence would have little

²⁷ *Pustejovsky v. Pliva Inc.*, 623 F.3d 271, 277 (5th Cir. 2010) (rejecting, at summary judgment, failure-to-warn claim where treating physician “did not recall ever reading the package insert” and plaintiff offered no more than “speculat[ion] about other ways an adequate warning might have reached [the treating physician] and altered her decision”).

²⁸ See *Centocor*, 372 S.W.3d at 170; *Ackermann*, 526 F.3d at 208; *McNeil*, 462 F.3d at 373.

²⁹ See *Centocor*, 372 S.W.3d at 170; *Ackermann*, 526 F.3d at 208.

³⁰ *Pustejovsky*, 623 F.3d at 277. Relatedly, our court has expressed “doubt” that Texas recognizes either prong of the “read-and-heed” presumption in the LI context. *Ackermann*, 526 F.3d at 213; *Ebel v. Eli Lilly & Co.*, 321 F. App’x 350, 358 (5th Cir. 2009). *But see Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 557 (N.D. Tex. 2006) (describing a modified read-and-heed presumption under which the “physician would have incorporated the additional risk into his decisional calculus,” and speculating “this is the likely analysis applied by Texas Courts”). At most, the *dictum* in *Centocor* addresses the “heed” half of the presumption, but it says nothing of whether the physician would “read” the warning in the first place.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

bearing on any of plaintiffs' claims.

Take Greer and Peterson. Their treating physicians, Goletz and Schoch, did not testify, and plaintiffs offer no record evidence suggesting the two actually read or encountered defendants' inadequate warnings. On appeal, plaintiffs cite only their own statements for support: Greer testified Goletz told him his "[MoM] would not wear, [and] would last [his] lifetime," and according to Peterson, Schoch said the same "because [Peterson's MoM] wouldn't have any plastic to wear out." But these snippets say nothing of how the doctors came to hold their respective views. Did Schoch and Goletz rely upon defendants' representations in choosing Ultamet, or did they learn of MoM's purported advantages by some other means? If the latter, how would better disclosure have reached the doctors? Not even "objective evidence" can fill these discrete evidentiary voids. The jury was left to guess, and plaintiffs' claims fail as a result. *See Pustejovsky*, 623 F.3d at 277.

Aoki's and Klusmann's claims are more complex, given that the testimony from their treating physician, Heinrich, contains somewhat mixed signals. On the one hand, Heinrich claimed he was aware of the "risk of ions attacking the tissue and the bone and getting in the blood" when he chose to implant both patients with MoM. *See Centocor*, 372 S.W.3d at 169–71. And yet, his testimony also suggests defendants' omissions and misrepresentations played some part in his treatment decisions of both patients.

In Aoki's case, Heinrich testified he used aSphere, Pinnacle's metal femoral head, because DePuy's "simulator data" suggested it "minimize[d] th[e] wear-in phase"—the immediate post-operative period in which articulation causes "an increased release of ions"—relative to alternative metal head designs. Heinrich "asked" "DePuy people" about "aSphere" and "made the

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

decision” to use the product “based on” their representations. Meanwhile, plaintiffs presented Heinrich with emails suggesting DePuy knew its claims about aSphere were untrue, a deception Heinrich seemed to know nothing about. Heinrich also acknowledged more generally that “J&J[/]DePuy” said nothing of the increased “problems” with MoMs in “2008, 2009, maybe even in 2010.”

Klusmann’s case presents a similarly mixed bag. He received bilateral MoM implants in 2004 and 2005 and began to experience intermittent pain as early as 2006. Heinrich consistently treated Klusmann with “conservative care” until 2011, when he first recommended revision. In explaining that delay, Heinrich testified that “doing things like checking ion levels and things of that nature” was less common then. Plaintiffs’ counsel then read a letter from a DePuy physician criticizing MoMs for their potentially “catastrophic complications” and detailing the proper post-operative detection procedures. He then asked Heinrich, “[I]f DePuy had sent you this information—it certainly would have changed the way you were treating Mr. Klusmann, wouldn’t it?” Heinrich offered a qualified replied: “To a certain degree. The only thing I would say is that he put in here that once he has ruled out other issues like back problems, loose implants, tendinitis, then he goes on to this workup. And so from that standpoint, yes, I agree.” At the least, this testimony suggests DePuy’s omission altered the course of Klusmann’s post-operative care.

To summarize: Though Heinrich had general awareness of the possibility that metal wear debris could cause adverse tissue reactions, he seems to have been unaware of (a) the magnitude of the risk, (b) the proper post-operative procedures to be followed with MoM patients who experience pain (Klusmann), and (c) DePuy’s misstatements about aSphere’s wear-related

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

advantages (Aoki). Additionally, Heinrich relied on disclosures by DePuy’s representatives in making his treatment decisions. A reasonable jury could discern causation on two bases. First, Heinrich’s mixed messages may have been too equivocal to rebut plaintiffs’ objective evidence, *cf. Centocor*, 372 S.W.3d at 169; and second, the subjective testimony itself—which included evidence of both deception and reliance—likely permitted an inference of causation. Either way, there is nothing unreasonable in the causation findings as to Aoki and Klusmann.

Christopher’s case is the most straightforward of the lot. Kearns, his treating physician, testified, “The metal liner, according to the data supplied by the company, through publication and representatives, [could] last much longer than all the other product liners available at the time.” Kearns claimed he “got [his] information from” “a DePuy consensus panel,” a “brochure that [his] DePuy representative gave [him],” “word of mouth, from [his] partners, and from the literature . . . scientific journals.” Yet, he was “never told” that the newer MoM designs were “unpredictable” and could lead to “a sudden catastrophic breakdown of the bearing.” Defendants stress that Kearns never read the Ultamet’s IFUs, but that concession, by itself, is not fatal. For Kearns’s testimony makes clear he relied on DePuy to apprise him of the risks, and it plausibly suggests he would have learned of Ultamet’s risks by other means. *Cf. Pustejovsky*, 623 F.3d at 277. Christopher’s claim easily succeeds.

In short, defendants were entitled to JMOL on marketing-defect claims by Greer and Peterson. That is not so for Aoki, Christopher, or Klusmann.

C. Statute of Limitations

Defendants suggest Greer’s and Klusmann’s claims are barred by Texas’s statute of limitations, which requires that personal injury suits be filed

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

“not later than two years after the day the cause of action accrues.” TEX. CIV. PRAC. & REM. CODE ANN. § 16.003(a). Under Texas’s discovery rule, limitations is tolled “until the plaintiff discovers, or through the exercise of reasonable care and diligence should have discovered, the nature of the injury.”³¹ “The term ‘discovered[]’ . . . is quite broad,”³² and it occurs whenever the plaintiff “has knowledge of facts which would cause a reasonable person to diligently make inquiry to determine his or her legal rights.”³³

Greer and Klusmann received their MoM implants in 2004 and 2005, respectively, underwent revision surgery between 2011 and 2012, and sued within a few months of revision. Defendants claim that both began to experience hip-related pain as early as 2008, placing them on inquiry notice as to potential defects in their implants outside the statutory window. That assertion assumes pain was a “fact” sufficient to motivate an inquiry into the implant’s defect. But both the record and Texas caselaw suggest otherwise.

The record shows that despite plaintiffs’ and their surgeons’ diligence, neither group linked plaintiffs’ symptoms to a potential defect in Ultamet for several years post-implant. And Texas caselaw confirms that appellate courts will reverse the factfinder’s judgment on the accrual date only where the connection between the treatment decision and the pain is obvious—for example, when the plaintiff or his physician expressly connects the symptom to the

³¹ *Porterfield*, 183 F.3d at 467; see also *Moreno v. Sterling Drug, Inc.*, 787 S.W.2d 348, 351 (Tex. 1990).

³² *Vaught v. Showa Denko K.K.*, 107 F.3d 1137, 1140 (5th Cir. 1997).

³³ *Bell v. Showa Denko K.K.*, 899 S.W.2d 749, 754 (Tex. App.—Amarillo 1995, writ denied); see also *Pirtle v. Kahn*, 177 S.W.3d 567, 571 (Tex. App.—Houston [1st Dist.] 2005, pet. denied).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

allegedly defective product.³⁴ Because none of defendants' record citations proves this, we lack a sufficient evidentiary basis to reverse the finding of timeliness.

III. Personal Jurisdiction

J&J claims it was never a proper party because the district court lacked personal jurisdiction over it. The due-process standard is familiar: A defendant must make "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) (quotations and alterations omitted).³⁵ Jurisdiction may be general or specific. The former requires "continuous and systematic" forum contacts and allows for jurisdiction over all claims against the defendant, no matter their connection to the forum. *Id.* (citations omitted). In contrast, the latter obtains only where a defendant "purposefully direct[s]" his activities toward the state, *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985), and the plaintiff's claim "aris[es] out of or [is] related to" the defendant's forum contacts, *J. McIntyre Mach., Ltd.*

³⁴ See *Porterfield*, 183 F.3d at 467 (holding that limitations began to run when plaintiff "knew" her abdominal symptoms were associated with a mesh implant, despite that surgery revealed for the first time that the mesh had attached to her stomach and liver); *Bell*, 899 S.W.2d at 755 (holding that limitations began to run as soon as plaintiffs associated their symptoms with the ingestion of a nutritional supplement that caused the disease); *Vaught*, 107 F.3d at 1139 (same).

³⁵ "A federal court sitting in diversity may exercise personal jurisdiction over a non-resident defendant (1) as allowed under the state's long-arm statute; and (2) to the extent permitted by the Due Process Clause of the Fourteenth Amendment." *Mullins v. Test-America, Inc.*, 564 F.3d 386, 398 (5th Cir. 2009). Here, "[b]ecause the Texas long-arm statute extends to the limits of federal due process, the two-step inquiry collapses into one federal due process analysis." *Johnston v. Multidata Sys. Int'l Corp.*, 523 F.3d 602, 609 (5th Cir. 2008).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

v. Nicastro, 564 U.S. 873, 881 (2011) (quotation omitted).³⁶

“This court reviews a district court’s exercise of personal jurisdiction *de novo*,” *In re DePuy*, 870 F.3d at 353, and its underlying “jurisdictional findings of fact” for clear error, *In re Chinese-Manufactured Drywall Prods. Liab. Litig.*, 753 F.3d 521, 529 (5th Cir. 2014). “A factual finding is not clearly erroneous as long as it is plausible in the light of the record read as a whole.” *Walker v. City of Mesquite*, 402 F.3d 532, 535 (5th Cir. 2005) (quotation omitted). The plaintiff “bears the burden of establishing” personal jurisdiction, *WNS, Inc. v. Farrow*, 884 F.2d 200, 203 (5th Cir. 1989), and though he need only make a *prima facie* case at the Rule 12(b)(2) stage, his burden escalates to “preponderance of the evidence” “by the end of trial.” *Travelers Indem. Co. v. Calvert Fire Ins. Co.*, 798 F.2d 826, 831 (5th Cir. 1986) (citations omitted).³⁷

Plaintiffs’ principal jurisdictional theory is “stream of commerce.” That doctrine recognizes that a defendant may purposely avail itself of the protection of a state’s laws—and thereby will subject itself to personal jurisdiction—“by sending its goods rather than its agents” into the forum. *Nicastro*, 564 U.S. at 882. In *Asahi Metal Industry Co. v. Superior Court of California, Solano County*, 480 U.S. 102 (1987), neither Justice Brennan nor Justice O’Connor could marshal a majority on the question whether mere awareness that a product will be sold in the forum state suffices to support jurisdiction under the

³⁶ The test for specific personal jurisdiction has a third requirement: Assertion of jurisdiction must be fair and reasonable. *Nuovo Pignone, SpA v. STORMAN ASIA M/V*, 310 F.3d 374, 382 (5th Cir. 2002). Defendants shoulder the burden and must make a “compelling case.” *Id.* (quoting *Burger King*, 471 U.S. at 477). Because J&J does not assert that exercising jurisdiction would be unfair or unreasonable, it has forfeited any argument under this prong.

³⁷ Where the district court conducts a pre-trial evidentiary hearing on jurisdiction, the preponderance-of-the-evidence standard applies. *Travelers*, 798 F.2d at 831. There was no hearing in this case.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

stream-of-commerce doctrine. The issue divides the circuits, with ours having embraced Justice Brennan’s more expansive view. *See Choice Healthcare, Inc. v. Kaiser Found. Health Plan of Colo.*, 615 F.3d 364, 373 (5th Cir. 2010). Accordingly, plaintiffs need only show that J&J delivered the product that injured them “into the stream of commerce with the expectation that it would be purchased by or used by consumers in the forum state.” *Ainsworth v. Moffett Eng’g, Ltd.*, 716 F.3d 174, 177 (5th Cir. 2013).

J&J insists that it cannot be subject to personal jurisdiction because DePuy—its executives, engineers, and salespeople—and not J&J, played the principal role in developing and selling the Ultamet. Preliminarily, it cannot be, as J&J suggests, that nonmanufacturing parents categorically lie beyond the stream of commerce no matter the nature of their contributions. Personal jurisdiction does not turn on labels or *relative* connection to the forum.³⁸ Instead, we look to “the relationship among the defendant, the forum, and the litigation.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014). Minimum-contacts analysis is more “realistic”³⁹ than “mechanical,”⁴⁰ turning on matters of “substance” rather than “form.”⁴¹ Recognizing that a nonmanufacturing parent

³⁸ *See Irving v. Owens-Corning Fiberglas Corp.*, 864 F.2d 383, 386 (5th Cir. 1989) (“The label attached to [a defendant’s] role in the distribution scheme is not the critical question.”); *see also Doan v. Consumer Testing Labs. (Far E.) Ltd.*, 105 F.3d 654 (5th Cir. 1996) (unpublished) (implying that personal jurisdiction is properly exercised over a defendant “sufficiently connected with a particular product so as actually to ‘touch’ the product”).

³⁹ *Burger King*, 471 U.S. at 479.

⁴⁰ *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 319 (1945); *Luv N’ care, Ltd. v. Insta-Mix, Inc.*, 438 F.3d 465,471 (5th Cir. 2006) (declining to credit “technicalities”) (citing *Oswalt v. Scripto, Inc.*, 616 F.2d 191, 197 n.8 (5th Cir. 1980)); *see also Nuovo Pignone*, 310 F.3d at 381 n.8; *Dontos v. Vendomation NZ Ltd.*, 582 F. App’x 338, 345 (5th Cir. 2014) (expressing hesitation about per se rules in the jurisdictional context).

⁴¹ *Bd. Of Cty. Comm’rs v. Umbehr*, 518 U.S. 668, 680 (1996) (“In determining what is due process of law regard must be had to substance, not to form.”) (quoting *Chicago, B. &*

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

will sometimes lie within the stream (even where the corporate veil remains intact), we conclude that J&J’s marketing and sales role crosses the necessary threshold.

J&J’s role in Ultamet’s design, promotion, and sale demonstrates that J&J significantly contributed to the product’s placement into the stream of commerce.⁴² On design, the record suggests J&J (a) merged DePuy with another subsidiary that developed Ultamet’s precursor Ultima,⁴³ (b) integrated the design teams, and (c) transferred a helpful patent to DePuy. On marketing and sale, J&J (a) reviewed, edited, and approved DePuy’s Pinnacle ads, product brochures, journal articles, public statements, and representations to regulators promoting Pinnacle MoMs⁴⁴; (b) provided substantial funding for certain of DePuy’s promotional activities; (c) independently promoted MoMs via a satellite telecast to physicians all over the country, including Texas, and a website, hipreplacement.com, which referred visitors to Texas surgeons and allowed Texas residents to have Ultamet-related information mailed directly to them; (d) referred to the product as its own; (e) granted DePuy “market clearance” to “manufacture, use, and sell” Ultamet worldwide;⁴⁵ (f) placed its

Q.R.R. Co. v. City of Chi., 166 U.S. 226, 235 (1897)).

⁴² See *Irving*, 864 F.2d at 386–87 (rejecting argument that defendant’s role in the stream-of-commerce chain was “too minor” to give rise to personal jurisdiction where, among other things, the defendant “held itself out as the seller,” “derived economic benefits from” sale of the product, and “placed no geographic limits” on where downstream broker could operate).

⁴³ In seeking the FDA’s 510(k) clearance, DePuy characterized Ultamet as Ultima’s “substantial equivalent.”

⁴⁴ A number of these materials, in particular the brochures and advertisements, included misleading statements related to MoM’s “fluid film lubrication,” limited wear debris, and general survivorship rate. Plaintiffs’ claims were based in part on these statements.

⁴⁵ J&J asserts that the clearance document was never admitted into evidence. The

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

logo on the packaging of the product as received in Texas; and (g) “monitored” Texas surgeon-consultants promoting Ultamet. Also, DePuy generated considerable revenue for J&J’s subsidiary Medical Device & Diagnostic.⁴⁶ Finally, although it is neither necessary to nor determinative of the jurisdictional question, we note that both the district court and jury found, under Texas tort law, that J&J was a “seller” of Ultamet. This combination of factors—collectively showing that J&J participated in developing Ultamet, greenlighted its sale worldwide, held the product out as its own, independently promoted the product, exercised ultimate controlling authority over the product’s design and promotion, and derived revenue from its sale—is sufficient to show that J&J was a link in the stream-of-commerce chain.

These factors also distinguish J&J’s role from the passive parent-

trial record confirms that it was.

⁴⁶ See *Choice Healthcare, Inc.*, 615 F.3d at 373 (“Deriving revenue from such commercial activity is the quid pro quo for requiring the defendant to suffer a suit in the foreign forum.”); see also *Luv N’ care*, 438 F.3d at 470 (“Where a defendant knowingly benefits from the availability of a particular state’s market for its products, it is only fitting that the defendant be amenable to suit in that state.”). We have held that a person who designed and licensed a product sold by a third-party lay outside the stream-of-commerce for jurisdictional purposes. In *Seifert v. Helicopteros Atuneros, Inc.*, 472 F.3d 266, 269–70 (5th Cir. 2006), a worker’s estate sued a pair of nonresident defendants in Mississippi after the worker had died on a defective helicopter platform. One of the defendants leased the helicopter to a non-party, which then installed the defective platform; the other codefendant, Camus, had designed, patented, and licensed the platform to that same non-party. He also served as a pilot for the non-party and had incidentally flown the helicopter with the platform at issue into Mississippi and inspected it there before the accident. *Id.* As to Camus, we held “[t]he stream-of-commerce theory does not provide a basis for jurisdiction, because [he] did not place a product into the stream, but merely licensed a design to [the non-party].” *Id.* at 275. Camus’s contributions to the introduction of the helicopter platform into Mississippi differ in both kind and degree from J&J’s role here. The plaintiff in *Seifert* presented no evidence that Camus exercised control over whether and where the offending product could be sold, participated in its marketing, directly derived revenue from its sale, or placed his logo on the product and held it out as his own.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

subsidiary relationship that we have held insufficient to support jurisdiction.⁴⁷ Where all the above considerations obtain, a parent corporation like J&J has “purposely avail[ed] itself of the privilege of conducting activities” in the states it expects the product to be sold, “thus invoking the benefits and protections of [that state’s] laws.” *Nicastro*, 564 U.S. at 880 (quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)). “[W]here individuals ‘purposefully derive benefit’ from their interstate activities, it may well be unfair to allow them to escape having to account in other States for consequences that arise proximately from such activities; the Due Process Clause may not readily be wielded as a territorial shield to avoid interstate obligations that have been voluntarily assumed.” *Burger King*, 471 U.S. at 473–74 (citation omitted) (quoting *Kulko v. Cal. Superior Court*, 436 U.S. 84, 96 (1978)).

Accordingly, J&J’s significant role in placing the Ultamet into the stream of commerce with the expectation that it would be purchased by consumers in Texas rendered J&J amenable to suit for injuries caused by the Ultamet in Texas. The district court properly exercised personal jurisdiction over J&J.

IV. Claims Against J&J

J&J avers that the claims against it—aiding and abetting, non-manufacturer seller, and negligent undertaking—all fail on the merits. We agree with J&J only as to aiding and abetting.

A. Aiding and Abetting

Plaintiffs’ cause of action for aiding and abetting derives from

⁴⁷ See, e.g., *Dickson Marine v. Panalpina*, 179 F.3d 331, 338 (5th Cir. 1999); *Dalton v. R & W Marine, Inc.*, 897 F.2d 1359, 1363 (5th Cir. 1990).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Section 876(b) of the Restatement (Second) of Torts, which provides that, “[f]or harm resulting to a third person from the tortious conduct of another, one is subject to liability if he . . . knows that the other’s conduct constitutes a breach of duty and gives substantial assistance or encouragement” The Texas Supreme Court “has not expressly decided whether Texas recognizes a cause of action for aiding and abetting,”⁴⁸ and the parties disagree at length about whether Texas courts, if squarely presented with the question, would fashion an aiding-and-abetting cause of action, outside of the conspiracy context, when the predicate offense sounds in strict liability.

But that debate is beside the point. When sitting in diversity, a federal court exceeds the bounds of its legitimacy in fashioning novel causes of action not yet recognized by the state courts.⁴⁹ Here, despite ample warning, the district court exceeded its circumscribed institutional role and “expand[ed] [Texas] law beyond its presently existing boundar[y].” *Rubinstein*, 20 F.3d at 172.

Plaintiffs offer two responses, neither persuasive. First, they suggest treating the state courts’ abstention as a *de facto* rejection would effectively eviscerate the *Erie* analysis.⁵⁰ Not so. *Erie* authorizes us to wager a guess

⁴⁸ *First United Pentecostal Church of Beaumont v. Parker*, 514 S.W.3d 214, 224 (Tex. 2017) (citing *Juhl v. Airington*, 936 S.W.2d 640, 643 (Tex. 1996)).

⁴⁹ *Johnson v. Sawyer*, 47 F.3d 716, 729 (5th Cir. 1995) (“As there is currently no Texas law creating a common law cause of action for a statutory violation for which violation there is an express and comprehensive statutory cause of action, we will not undertake to . . . create such a Texas common law cause of action.”); *Rubinstein v. Collins*, 20 F.3d 160, 172 (5th Cir. 1994) (“It is axiomatic, of course, that we will not expand state law beyond its presently existing boundaries.”); *Harmon v. Grande Tire Co.*, 821 F.2d 252, 259 (5th Cir. 1987) (“As an *Erie* court, however, it is not our job to lay down broad new rules of state law.”); *Galindo*, 754 F.2d at 1217 n.8 (counseling against “substantive innovations” in state law).

⁵⁰ See also *In re Hous. Reg’l Sports Network, L.P.*, 547 B.R. 717, 759 n.19 (Bankr. S.D.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

about how the state court might fill the interstices of existing doctrinal frameworks; inventing a new framework *ex nihilo* is another matter entirely.

Plaintiffs also cite three Texas cases,⁵¹ for the proposition that Texas has long recognized aiding-and-abetting claims “in some form.” But none of the three speaks, let alone clearly, to the question. *Pippen* involved a principal-agent relationship,⁵² *Kinzbach Tool* a joint-tortfeasor matter,⁵³ and *McKinnon & Van Meter* transferee liability in a fraudulent-transfer case.⁵⁴ And even if we were to construe these as stealth aiding-and-abetting decisions, their half-century-old judgments would have to yield to the court’s more timely and direct pronouncements to the contrary. J&J is entitled to JMOL on plaintiffs’ aiding-and-abetting claim because no such claim exists in Texas.

B. Nonmanufacturer Seller

J&J challenges plaintiffs’ “nonmanufacturer seller” claim. Section 82.003(a) of the Texas 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. Question 3 of the jury charge asked whether J&J was a “nonmanufacturing seller” under section 82.003 and then whether J&J satisfied the requirements of

Tex. 2016) (asserting the same *ipse dixit* that *Erie* has no purpose if federal courts lack the power to fashion entirely novel causes of action under state law).

⁵¹ *City of Fort Worth v. Pippen*, 439 S.W.2d 660, 665 (Tex. 1969); *Kinzbach Tool Co. v. Corbett-Wallace Corp.*, 160 S.W.2d 509, 514 (Tex. 1942); *McKinnon & Van Meter v. Reliance Lumber Co.*, 63 Tex. 30, 31 (1885)

⁵² *Pippen*, 439 S.W.2d at 665.

⁵³ *Kinzbach Tool*, 160 S.W.2d at 514 (applying “settled . . . law of [Texas] that where a third party knowingly participates in the breach of duty of a *fiduciary*, such third party becomes a joint tortfeasor”) (emphasis added).

⁵⁴ *McKinnon & Van Meter*, 63 Tex. at 31.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

either of two exceptions to that immunity—whether it “participate[d] in the design” of the Ultamet and whether it “actually kn[e]w of” a defect in the Ultamet. The jury answered yes to both questions.

J&J claims “nonmanufacturer seller” is an affirmative defense rather than a standalone cause of action. The verdict proves that J&J could be found guilty under one of the exceptions to the affirmative defense, but only if it had also been found liable for a standalone cause of action such as design or marketing defect. It claims no such finding was made—ergo, the nonmanufacturer-seller charge was “bizarre” and “meaningless.”

But J&J creates confusion from whole cloth. The first two questions in the jury charge concerning design and marketing defects focus on the product, rather than the conduct or identity of the responsible parties,⁵⁵ because that is the focus of Texas products-liability law.⁵⁶ Though Questions 1 and 2 mention DePuy and not J&J, those references serve only to fix the relevant temporal frame—i.e., what condition was the product in *when* it left DePuy’s possession?—rather than to exclude other nonmanufacturer sellers from

⁵⁵ Question 1 reads in relevant part,

Was there a design defect in the Pinnacle Ultamet Hip Implant at the time it left the possession of DePuy Orthopaedics, Inc. . . . ? . . .

. . .

In answering this question, you are instructed to consider only the condition of the Pinnacle Ultamet Hip Implant, and not the conduct of DePuy Orthopaedics, Inc. The Pinnacle Ultamet Hip Implant may have a design defect even if DePuy Orthopaedics, Inc. exercised all possible care in designing it.

Question 2 asked, “Was there a defect in the warnings at the time the Pinnacle Ultamet Hip Implant left the possession of DePuy Orthopaedics, Inc. . . . ?”

⁵⁶ *Gonzales v. Caterpillar Tractor Co.*, 571 S.W.2d 867, 871 (Tex. 1978) (“Strict liability looks at the product itself and determines if it is defective. Negligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production”).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

liability. This is especially so, given that the Ultamet was never “in” or “left” J&J’s possession. Hence, in the instructions that precede Question 3, the charge specifically instructs, “Answer Question 3 only if you have answered ‘yes’ to Question 1 or Question 2. Otherwise do not answer Question 3.” As is obvious from this language, the district court had the jury determine J&J’s liability through a combination of questions: first, whether the product was deficiently designed or marketed, and then whether those defects were imputable to J&J as a nonmanufacturer seller. J&J cites no procedural rule that prohibited the court from dividing the elements of a cause of action in this way, and we decline to invent one now.⁵⁷

C. Negligent Undertaking

J&J maintains that plaintiffs’ negligent-undertaking claim fails for insufficient evidence. Negligent undertaking requires a finding that (1) J&J undertook to perform services that it knew or should have known were necessary for plaintiffs’ protection (here, a duty to design Ultamet for safe use and to regulate its marketing, sale, and distribution); (2) J&J failed to exercise reasonable care in performing those services; and (3) plaintiffs or their physicians relied on J&J’s performance, *or* J&J’s performance increased plaintiffs’ risk of harm. *Nall v. Plunkett*, 404 S.W.3d 552, 555–56 (Tex. 2013). Disagreement lies primarily at the first prong: Plaintiffs recite J&J’s laundry list of Ultamet-related contacts, which J&J dismisses as “typical of a parent-subsidiary relationship” and thus insufficient to “disregard the corporate form.”

Texas caselaw reveals no precise control threshold a parent must cross before undertaking a duty to its subsidiary’s customers. Texas courts have

⁵⁷ In a footnote, defendants question whether J&J was properly deemed a seller under Section 82.003. They cite no cases for that under-defended theory, so we do not consider it.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

made clear that mere possession of “the authority to compel” a subsidiary is not enough—the parent “must actually” exercise that authority in a manner relevant to the undertaking inquiry.⁵⁸ At the same time, it is plainly *sufficient* to show the parent has “the controlling, primary authority for maintaining safety at [its subsidiary’s] facilities.”⁵⁹

The gap between these two poles is wide, and there is little guidance. Nothing J&J points to in Texas law suggests “primary authority for maintaining safety” is *necessary* to sustain an undertaking claim. Given that plaintiffs have identified several instances in which J&J actually exercised its veto authority, especially in the marketing context, we cannot say every “reasonable” juror reviewing J&J’s role in Ultamet’s design, marketing, and distribution would find that J&J had not undertaken a duty to Ultamet users.⁶⁰ The challenge is to sufficiency of the evidence, and there is nothing unreasonable in the jury’s determination.⁶¹

⁵⁸ See *Little v. Delta Steel, Inc.*, 409 S.W.3d 704, 721 (Tex. App.—Fort Worth 2013, no pet.) (quoting and contrasting *White v. Elcor Corp.*, No. 09-00-0031-CV, 2001 WL 359833 (Tex. App.—Beaumont Apr. 12, 2001, no pet.) (unpublished)).

⁵⁹ *Id.*

⁶⁰ See *Johnson v. Abbe Eng’g Co.*, 749 F.2d 1131, 1133–34 (5th Cir. 1984).

⁶¹ See *Bagby Elevator Co. v. Schindler Elevator Corp.*, 609 F.3d 768, 773 (5th Cir. 2010) (requiring “great deference to the jury’s verdict” and reserving reversal for situations in which “the court believes that reasonable jurors could not arrive at any contrary conclusion” (quotation omitted)). Defendants plausibly suggest that if we find for J&J on even one of the claims against it, we must remand for a new trial on exemplary damages on all claims. Cf. *Robertson Oil Co. v. Phillips Petroleum Co.*, 871 F.2d 1368, 1376 (8th Cir. 1989) (reversing some but not all of plaintiff’s claims and remanding for a new trial on punitive damages because each of the plaintiff’s theories of liability “involve[d] different conduct” and would therefore “support a different amount of punitive damages”). We need not reach that question, given our holding, which we will explain, that evidentiary errors warrant a new trial on all surviving claims.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

V. Request for New Trial

In the alternative, defendants request a new trial based on irrelevant and prejudicial evidence. A district court can grant a new trial if it finds “the verdict [was] against the weight of the evidence, the damages awarded [were] excessive, the trial was unfair, or prejudicial error was committed in its course.” *Smith v. Transworld Drilling Co.*, 773 F.2d 610, 613 (5th Cir. 1985) (discussing FED. R. CIV. P. 59(a)). We review that decision for abuse of discretion, “especially” where, as here, the motion “ha[s] been denied.” *Knight v. Texaco Inc.*, 786 F.2d 1296, 1299 (5th Cir. 1986) (citations omitted). Because the errors are sufficiently egregious, multiple, and prejudicial to pierce the usual deference, we order a new trial.

A. The Deferred Prosecution Agreement and Saddam Hussein

We begin with the most problematic evidence: the bribes paid by non-party J&J subsidiaries to the “henchmen” and “regime” of Saddam Hussein in Iraq. In 2011, J&J entered into a Deferred Prosecution Agreement (“DPA”) in which it “admit[ted], accept[ed], and acknowledg[ed] that it [was] responsible for” violations of the Foreign Corrupt Practices Act committed by non-party affiliates. One of the alleged violations involved bribes by two such affiliates to the Iraqi government, then under Hussein’s control. In the middle of trial, the court ordered DePuy to produce a Federal Rule of Civil Procedure 30(b)(6) corporate representative to testify before the jury at length about the DPA. Plaintiffs’ counsel then mentioned it several times, including during closing arguments.

The district court allowed these repeated references to Hussein and the DPA because defendants had supposedly “opened the door” by eliciting testimony on their corporate culture and marketing practices. This justification is

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

strained, given that J&J owns more than 265 companies in 60 countries, and the Iraqi portion of the DPA addresses conduct by *non-party* subsidiaries.

“[T]he Rules of Evidence do not simply evaporate when one party opens the door on an issue.”⁶² And a party cannot introduce evidence of prior bad “acts . . . to show that on a particular occasion the person acted in accordance with the character.” FED. R. EVID. 404(b)(1). Our Rule 404(b) inquiry proceeds in two steps: “First, it must be determined that the extrinsic offense evidence is relevant to an issue other than the defendant’s character. Second, the evidence must possess probative value that is not substantially outweighed by its undue prejudice and must meet the other requirements of rule 403.”⁶³ Though our inquiry is deferential and “inclusi[ve],”⁶⁴ we go well beyond rational-basis review. Even where the evidence serves some conceivable non-character purpose such as impeachment, we still must carefully consider whether the introducing party was actually “attempting to convince the jury that [the defendant] was a bad man” who acted in conformity with his bad character in the case at hand.⁶⁵ If yes, the unduly prejudicial effect of such an argument will very likely substantially outweigh its probative value.

The Rule 404(b) question lends itself to just one reasonable resolution. During closing arguments, Lanier suggested unequivocally that the jury treat

⁶² *United States v. Bursey*, 85 F.3d 293, 296 (7th Cir. 1996) (quotation omitted); see also *United States v. Young*, 470 U.S. 1, 6–14 (1985).

⁶³ *United States v. Beechum*, 582 F.2d 898, 911 (5th Cir. 1978) (en banc); see also *United States v. Mendez*, 643 F. App’x 418, 426–27 (5th Cir.), cert. denied, 137 S. Ct. 164, and cert. denied, 137 S. Ct. 198, and cert. denied, 137 S. Ct. 198 (2016).

⁶⁴ *United States v. Shaw*, 701 F.2d 367, 386 (5th Cir. 1983), abrogated on other grounds by *Green v. Miller*, 483 U.S. 756, 763 (1987).

⁶⁵ *Id.*

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

the DPA not as impeachment, nor even as otherwise-inadmissible rebuttal evidence offered “curatively,”⁶⁶ but as a proxy for J&J’s liability:

If you go back and look at the DPA, that’s the deferred prosecution agreement where the company paid money one time because of kickbacks to doctors in America, the other time because of the bribes to Saddam Hussein’s government, the bribes in Greece, Romania, Poland and other places where they were bribing people to put in . . . their products. The DPA has [J&J] admitting its responsibility in it. J&J is admitting that they’re responsible. They have already taken this issue out of your hands realistically. *That alone is a winner. . . . [J&J] has admitted their responsibility for this. That ought to be enough.* [Emphasis added.]

Indeed. Lanier tainted the result by inviting the jury to infer guilt based on no more than prior bad acts, in direct contravention of Rule 404(b)(1). That alone provides grounds for a new trial.⁶⁷

Plaintiffs insist the DPA was admissible because it went to defendants’ “intent, knowledge, plan, motive, and opportunity.” But that suggestion is as dubious as it is vague. The record makes plain that the DPA and Hussein were “wafted before the jury to trigger their punitive instinct.”⁶⁸ Lanier repeatedly referenced bribes to the Hussein “regime,” despite that the alleged bribes involve neither DePuy nor its products. Crucially, he then invited the jury to

⁶⁶ 1 MCCORMICK ON EVID. § 57 (7th ed. Updated June 2016).

⁶⁷ At oral argument, Lanier suggested the underlying issue in questions 3, 4, and 5 was whether J&J was a “seller,” and his reference to the DPA served only to show J&J previously had claimed responsibility for its subsidiary’s bad acts. That theory is doubly flawed: First, counsel expressly referenced the bribes in Iraq, which involved *nonparty* subsidiaries, and second, questions 4 and 5—J&J’s liability for negligent undertaking and aiding and abetting—clearly require more than the conclusion that J&J was a “seller”—e.g., that it knew or should have known the product was defective. Considered in context, Lanier’s statements obviously invited the jury to infer liability based solely on J&J’s admissions in the DPA.

⁶⁸ *Shows v. M/V RED EAGLE*, 695 F.2d 114, 119 (5th Cir. 1983), *abrogation on other grounds recognized by Coursey v. Broadhurst*, 888 F.2d 338, 342 n.4 (5th Cir. 1989).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

infer J&J's *liability* based solely on that. Nothing in our otherwise inclusive Rule 404(b) jurisprudence countenances such a tactic.⁶⁹

Plaintiffs lastly suggest that any error was harmless, because the court instructed the jury generally not to treat counsel's statements as evidence. But the court "gave no cautionary instruction at the time of the improper argument," *United States v. McPhee*, 731 F.2d 1150, 1153 (5th Cir. 1984), and its subsequent generic instruction made no mention of the DPA. Granted, "in some instances, the district court may determine that a specific curative instruction is inappropriate because it would merely call further attention to the evidence, and thus be more harmful than the original comment." *United States v. Thomas*, 548 F. App'x 987, 990 (5th Cir. 2013) (citation omitted). But the references to Hussein were both recurring and "highly prejudicial," presented as if sufficient to prove liability. *Id.*

A general instruction at the close of trial was "grossly inadequate under the circumstances." *McPhee*, 731 F.2d at 1153. Lanier's statement was among "the last thing[s] the jury heard before retiring to deliberate," *United States v. Polasek*, 162 F.3d 878, 887 (5th Cir. 1998), and a colossal verdict followed. Because the taint is unmistakable, the verdict cannot stand.

B. Allegations of Race Discrimination

Lanier coupled his impermissible references to Saddam Hussein with

⁶⁹ Plaintiffs alternatively suggest the DPA was admissible under Federal Rule of Evidence 406 as evidence of a "routine practice" of bribing doctors. Not so. In *United States v. West*, 22 F.3d 586, 592 (5th Cir. 1994), we held a handful of questionable transactions by the FDIC did not prove a routine "when considered in light of the FDIC's dealings with literally thousands of debtors during the mid- to late 1980s." The DPA reveals kickbacks by J&J and subsidiaries in four countries over the course of ten years. When considered in light of the fact that J&J directly or indirectly owns more than 265 companies operating in 60 countries, that record is far too slim to show a repetitious and semi-automatic routine of behavior.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

hearsay allegations of race discrimination. While questioning DePuy's president, Andrew Ekdahl, Lanier read the following excerpts from a resignation letter by a former DePuy employee: "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 . . ." And, to quote counsel, "she goes on and on and on." Before the letter was read, defendants objected on hearsay and Federal Rule of Evidence 403 grounds and, after a lunch recess, moved for a mistrial. The court overruled the objections and denied the motion. As with Hussein, reference to a "filthy . . . racial email" resurfaced once more during Lanier's closing argument, in his explanation of why J&J had participated in Ultamet's design and knew of its defects.⁷⁰

Plaintiffs again suggest defendants placed their character in issue by describing DePuy as an employee-friendly workplace. *See Croce v. Bromley Corp.*, 623 F.2d 1084, 1092–93 (5th Cir. 1980). But even if that were so, the letter is valid impeachment only if introduced to prove the matter asserted: that racism infected DePuy's workplace culture. That is impermissible hearsay.

Plaintiffs posit that the letter was admissible under Federal Rule of Evidence 801(d)(2)(D), as a statement by an employee on a matter within the scope of employment. But Rule 801(d)(2)(D) does not apply to resignation letters, where the employee is no longer "inhibited by [his] relationship with the principal." *Young v. James Green Mgmt., Inc.*, 327 F.3d 616, 622 (7th Cir.

⁷⁰ His exact words were, "J&J participated in the design all the way up to aSphere where the president of [J&J] is getting updates from the head of marketing at DePuy, Richard Berman of the filthy email fame and the racial email fame. Did [J&J] know of the defect?"

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

2003) (quotation omitted). A contrary rule would badly flout Rule 801’s underlying rationale. In reading the letter to the jury, Lanier refocused its attention on serious, and seriously distracting, claims of racial discrimination that defendants had no meaningful opportunity to rebut via cross-examination. This spectacle fortifies our conviction that a new trial is required.⁷¹

⁷¹ The same is true of counsels’ unit-of-time argument, made during closing argument. Lanier’s co-counsel first told the jury, “If you don’t consider the damages by the day, by the hour, by the minute, then you haven’t considered their damages.” Then, during rebuttal, Lanier elaborated, “[P]lease, please, please, if they [the defendants] 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, or people they put on the stand.” The court promptly overruled defendants’ objection.

As a general matter, unit-of-time arguments like this one are impermissible because they can lead the jury to “believ[e] that the determination of a proper award for . . . pain and suffering is a matter of precise and accurate determination and not, as it really is, a matter to be left to the jury’s determination, uninfluenced by arguments and charts.” *Foradori v. Harris*, 523 F.3d 477, 512 (5th Cir. 2008) (quotation omitted). Lanier’s reference to expert fees was meant simultaneously to activate the jury’s passions and to anchor their minds to a salient, inflated, and irrelevant dollar figure. The inflammatory benchmark, bearing no rational relation to plaintiffs’ injuries, easily amplified the risk of “an excessive verdict.” *Westbrook v. Gen. Tire & Rubber Co.*, 754 F.2d 1233, 1240 (5th Cir. 1985). The argument was “design[ed] to mislead,” *Foradori*, 523 F.3d at 512, and tainted the verdict that followed.

Plaintiffs urge that the district court could cure the problem by offering a “specific cautionary instruction” that the unit-of-time claim reflects the lawyer’s private opinion, “which the jury is free to disregard.” *Colburn v. Bunge Towing, Inc.*, 883 F.2d 372, 377 (5th Cir. 1989). In *Colburn*, we vacated damages because counsel had presented “a ‘unit of time’ argument without a specific cautionary instruction,” raising a “substantial and ineradicable doubt as to whether or not the jury has been properly guided in its deliberations.” *Id.* at 377–78 (quotation omitted). Here, the record reveals only a general instruction that “any statement or arguments made by the lawyers are not evidence and are not instructions on the law.” *Colburn* explicitly deemed this inadequate. *Id.*

We decline to address defendants’ remaining evidentiary challenges regarding DePuy’s 2007 DPA, the *Doubt is Their Product* book, cancer and suicide, the “thousands” of pending Ultamet suits, and unrelated transvaginal mesh suits. The district court should weigh carefully the applicability of Rules 403 and 404(b) and, where necessary, should issue specific instructions to avoid undue prejudice. *See, e.g., Croce*, 623 F.2d at 1092.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

VI. Rule 60(b)(3) Motion

In their companion appeal,⁷² defendants challenge the district court’s denial of a motion for relief from judgment under Rule 60(bA)(3) on the ground that Lanier concealed payments to two key expert witnesses. We agree and reverse.

A. Facts

The story begins in August 2015, when, in preparation for the second bellwether trial (*Aoki*), plaintiffs’ counsel made expert disclosures listing Morrey Sr. and Morrey Jr. as expert witnesses “who ha[v]e not been retained or specially employed to provide expert testimony in this litigation.”⁷³ In December of that year, Lanier met with Morrey Sr. to discuss the history of

⁷² In their cross-appeal, plaintiffs assert that Section 41.008 of the Texas Civil Practice and Remedies Code—which caps exemplary damages at twice the amount of economic damages, plus non-economic damages not exceeding \$750,000—violates the state constitutional right to “open courts,” TEX. CONST., art. 1, § 13, and the federal Constitution’s equal protection clause. Those claims are frivolous.

To the first, Texas courts have uniformly held that Section 41.008 does not violate the “open courts” provision. *See Waste Disposal Ctr., Inc. v. Larson*, 74 S.W.3d 578, 588 (Tex. App.—Corpus Christi 2002, pet. denied) (“[T]he open courts provision of the Texas Constitution serves to protect only private rights and interests, [whereas] the statutory cap on exemplary damages affects only public punishment interests[.]” (citation omitted)); *Hall v. Diamond Shamrock Ref. Co., L.P.*, 82 S.W.3d 5, 22 (Tex. App.—San Antonio 2001) (same), *rev’d on other grounds*, 168 S.W.3d 164 (Tex. 2005); *cf. Seminole Pipeline Co. v. Broad Leaf Partners, Inc.*, 979 S.W.2d 730, 758 (Tex. App.—Houston [14th Dist.] 1998, no pet.). To the second, plaintiffs suggest the cap’s differentiation between economic and non-economic injury effectively discriminates based on wealth. But even if that were so, the law need only survive rational-basis review, *Smith v. Botsford Gen. Hosp.*, 419 F.3d 513, 519–20 (6th Cir. 2005), and Section 41.008 does so by injecting predictability into exemplary damages awards and preempting potentially unconstitutional awards. *Cf. State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 426 (2003); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574–75 (1996) (recognizing constitutional limits on a punitive-damages award). The cross-appeal fails.

⁷³ Non-retained, or uncompensated, experts need not prepare expert reports in advance of their testimony. FED. R. CIV. P. 26(a)(2)(B).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

MoM implants. Toward the end of their meeting, Lanier offered payment, which Morrey Sr. declined. Lanier then asked whether there was a charity to which he could contribute, and Morrey identified his alma mater, St. Rita's Catholic School in Fort Worth. Lanier wrote it a \$10,000 check, dated December 4, 2015—five weeks before to trial.

The *Aoki* trial began January 11, 2016. Plaintiffs claim Morrey Sr. first agreed, and was called on, to testify two weeks after the trial had already begun.⁷⁴ Yet, he appears in the trial transcripts as early as opening statements, when plaintiffs' counsel described him as "Mayo trained" and "eminently qualified to give [his opinion]." Once Morrey Sr. did eventually take the stand, Lanier explained how he had "*hoped* you [Morrey Sr.] would be testifying." Recounting their meeting in December, Lanier described to the jury how they shared the "best apple pie in the world." St. Rita's and the \$10,000 check went unmentioned.

Morrey Sr. was a compelling witness. He walked the jury through the history of MoP and MoM designs and explained that he used MoP, a safer alternative, on all his patients, including Billy Graham and former-President George H.W. Bush. During both the direct and redirect, Lanier repeatedly emphasized Morrey Sr.'s independence—reflected in his peer-reviewed work, royalty-collection practices, and continuing-education lectures—and contrasted that independence with the purportedly biased and self-interested

⁷⁴ On the eve of Morrey Sr.'s testimony, defendants filed a late-night motion asserting that plaintiffs had improperly designated him as a "nonretained" expert—he was not a treating physician of any of the plaintiffs, and his opinions were not formed in the course of treatment—and that his testimony should therefore be excluded. At trial the next day, the court allowed Morrey Sr. to testify, but only on condition that he later provide a written report and make himself available for a deposition and future cross-examination. Plaintiffs eventually provided defendants with an expert report summarizing his testimony, but it made no mention of any compensation agreement, and the doctor never reviewed it.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

work of DePuy's doctors.

His son, Morrey Jr., also an orthopaedic surgeon, performed Greer's revision surgery and evaluated Klusmann. Before Morrey Jr.'s testimony, defendants moved to exclude any testimony that would exceed his role as a treating physician. During arguments on the motion, Lanier emphasized how "very important" it was "for the Court to know and the record to reflect that Dr. Morrey was properly and timely disclosed as nonretained. We have no economic arrangement with him. We do not fund him. We do not pay him his time" ⁷⁵ Echoing his father, Morrey Jr. testified MoP was "always . . . a safer alternative than" MoM, and that there is no "benefit in using [MoM] that outweighs [the] risk."

Long after the Morreys had exited the scene, Lanier reminded the jury of their compelling *pro bono* testimony, which he contrasted repeatedly with the "bought testimony" of defendants' paid experts. For example, when defense expert pathologist Scott Nelson claimed he was compensated "like all experts," Lanier seized the opportunity: "Dr. Matt Morrey wasn't compensated. Bernard Morrey wasn't compensated. . . . For him to say --." The court cut short and quickly sustained the objection. And again on cross, Lanier returned to the subject, reminding the jury that "Dr. Morrey, Sr. . . . the one that put in President Bush's metal-on-poly hips . . . came and testified here, *on his own*." Additionally, the Morreys featured prominently in Lanier's closing statement: "Dr. Morrey senior, no expense coming to this courtroom, not a paid witness." And again:

If President Bush could talk to the surgeon and pick him, he's good

⁷⁵ The judge allowed the testimony on the condition that Morrey Jr. file a report and be available for cross-examination. Morrey Jr. later provided a summary of his testimony, and defendants did not recall him for further cross.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

enough for me. And to pick a metal-on-poly hip, good enough for me. That's who did the surgery. That's the kind of [implant] that he put in. And the reason that he was here is I called his son and said what happened here. He said I don't use this kind of hip. Why not? My dad told me not to. *That's not bought testimony.* That's not conjured. That's not rehearsed. *That's real life.* That's the way they lived. [Emphasis added.]

The jury was instructed that it could “consider any bias evidence that the expert witness has been or will be paid for . . . reviewing the case and testifying.” As between “real life” and “bought testimony,” it chose the former by a margin of \$502 million.

But that choice was a false one, manufactured entirely by Lanier. During preparation for the third bellwether trial, details emerged suggesting that (a) Morrey Sr. had directed a \$10,000 donation to his alma mater before trial, (b) Morrey Jr. had expected compensation from the start, and (c) both received sizeable sums after the verdict. The revelations began when plaintiffs' counsel chose to bring back the Morreys and redesignate them as traditional expert witnesses for the next trial. After shifting designations, plaintiffs produced two letters from Lanier, both dated April 7, 2016, thanking the Morreys for their “pro bono” testimony at the *Aoki* trial and enclosing generous checks—\$35,000 to Morrey Sr. and \$30,000 to Morrey Jr.

The checks raised red flags. And so defendants' counsel questioned Morrey Sr. during a deposition about whether he had received “any other compensation” for his testimony. His reply revealed, for the first time, the existence of the donation: “[Lanier and I] had a preliminary discussion, and a check was given to a charitable organization[,] . . . St. Rita's Catholic School in Fort Worth.”

A similarly striking revelation emerged during Morrey Jr.'s deposition.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

He told defendants' counsel that he had expected payment from the start and had even inquired of plaintiffs' counsel about how to receive payment. Rather than rebuffing that request as inappropriate, plaintiffs' team told Morrey Jr. "don't worry about that." What truly surprised Morrey Jr. was not the fact of payment, but the amount—\$30,000 was apparently "twice" what he had been expecting. As for the "factual basis" of his expectations, Morrey explained that it flowed from his understanding of what happens "*whenever you're involved in these as a witness* [W]e have a fee sheet that we fill out our hours involved and we submit it afterwards." (Emphasis added.)

Misrepresentations in hand, defendants moved for relief from judgment under Rule 60(b)(3), which affords redress in cases of "fraud . . . , misrepresentation, or misconduct." FED. R. CIV. P. 60(b)(3). The district court denied the motion. It found no "agreement for compensation" at the time of trial; and it reasoned that, regardless, defendants had "not shown how evidence of [p]laintiffs' experts receiving a fraction of the compensation of [d]efendants' experts would have produced a different result at trial."

B. Analysis

Defendants had a heavy burden, in the district court, to show by clear and convincing evidence that plaintiffs had engaged in misrepresentation that prevented defendants from fully and fairly presenting their case. *Wilson v. Thompson*, 638 F.2d 801, 804 (5th Cir. Unit B Mar. 1981). Our review is doubly deferential: We consider the trial court's factual findings to the contrary for clear error, *id.*, and we reverse only if its clear-error judgment constitutes abuse of discretion, *Hesling v. CSX Transp., Inc.*, 396 F.3d 632, 638 (5th Cir. 2005). This is the rare case in which counsel's deceptions were sufficiently obvious, egregious, and impactful to penetrate the layers of deference that

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

would ordinarily shield against reversal.

The district court misstated the substantive test under Rule 60(b)(3). The inquiry is not whether the misrepresentation altered the result,⁷⁶ but whether it “prevented the losing party *from fully and fairly presenting his case or defense.*”⁷⁷ Defendants need only show that the alleged misrepresentations foreclosed potentially promising cross-examination tactics; the misrepresentations need not be outcome-determinative, nor even intentional, to compel reversal.⁷⁸

Now, to the question whether Lanier, knowingly or unknowingly, misled the jury in representing repeatedly that the Morreys had neither pecuniary interest nor motive in testifying. The facts speak pellucidly: The pre-trial donation check, Morrey Jr.’s expectation of compensation, and the post-trial payments to both doctors are individually troubling, collectively devastating.

Consider first the check to St. Rita’s. In December, Lanier and Morrey Sr. met at the latter’s house, they discussed the contents of his testimony, and Lanier made a donation to a charity of Morrey Sr.’s choosing, all before trial.⁷⁹

⁷⁶ *Wilson*, 638 F.2d at 804 (“[A] party . . . may prevail without showing that the alleged fraud affected the outcome of the prior trial.”).

⁷⁷ *Rozier v. Ford Motor Co.*, 573 F.2d 1332, 1345 (5th Cir. 1978) (emphasis added) (quotation omitted). In *Rozier*, *id.* at 1349, we reversed the denial of plaintiff’s Rule 60(b)(3) motion after defendants had failed to produce a potentially inculpatory document before trial. “Mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation,” *id.* at 1344 (citations omitted), and prior disclosure could “have made a difference in the way plaintiff’s counsel approached the case or prepared for trial,” *id.* at 1342 (quotation omitted).

⁷⁸ See *Lonsdorf v. Seefeldt*, 47 F.3d 893, 897 (7th Cir. 1995); accord *Bros Inc. v. W.E. Grace Mfg. Co.*, 351 F.2d 208, 211 (5th Cir. 1965).

⁷⁹ Plaintiffs’ counsel did not disclose the check until *after* oral argument in a Fifth Circuit Rule 28(j) letter. Interestingly, plaintiffs’ briefing relies on Morrey Sr.’s deposition

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

Plaintiffs had already designated Morrey Sr. as a non-retained expert who might testify, and they had been priming the jury for his appearance as early as opening statements. Once it was “formally” decided that Morrey Sr. would testify, Lanier’s failure to disclose the donation, and his repeated insistence that Morrey Sr. had absolutely no pecuniary interest in testifying, were unequivocally deceptive.⁸⁰

In his defense, Lanier asserts the date of the donation “confirms [it] was a ‘thank you’ for time spent with [plaintiffs’ counsel] rather than a promise by [Lanier] to make a charitable contribution in exchange for Dr. Morrey’s testimony.” Before interrogating this story, let us speak plainly: Lawyers *cannot* engage with a favorable expert, pay him “for his time,” then invite him to testify as a purportedly “non-retained” neutral party. That is deception, plain and simple. And to follow that up with post-trial “thank you” check merely compounds the professional indiscretion.

As for counsel’s explanation, we cannot rule out the possibility Lanier believes what he says. But our inquiry turns on the various actors’ conduct and what it reasonably suggests, rather than self-serving ex-post statements as to state of mind. A lawyer would not make a \$10,000 donation to an expert’s charity of choice—a “gift” for his time—without realizing the “gift” would likely induce subsequent testimony.

Granted, the record includes no evidence that Lanier stated *expressly*

testimony for the proposition that the check was tendered *after* his testimony. And when pressed at oral argument that a pre-trial date would invite “devastating impeachment,” Lanier’s co-counsel conceded, “I agree with your logic. I do agree with your logic. But Mr. Lanier is not sure exactly when it was done.”

⁸⁰ *Saunders v. Comm’r*, 720 F.2d 871, 873 (5th Cir. 1983) (“One need not personally receive the taxable benefits provided one has the power to determine the recipient. . . . One may not assign income actually earned and thereby avoid the tax impact.”).

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

that the donation came with strings attached. But sometimes, in matters of persuasion, what goes without saying is best left unsaid. Take Lanier's post-trial checks. At oral argument, he acknowledged those thank-you payments were designed to induce the Morreys to testify at the next bellwether trial, despite never expressly making that request. The pattern leaves little doubt about the desired effects of the donation.⁸¹

Morrey Jr.'s expectation of payment is equally troubling. Lanier claims Morrey Jr. did not necessarily expect payment "*by the Plaintiffs,*" and even if he had, Lanier and crew were not "mind-readers" and cannot be expected to have divined Morrey Jr.'s secret wishes. Such suggestions require a suspension of common sense. As Morrey Jr.'s deposition makes clear, his expectation of payment derived from his intuitive understanding that expert witnesses are entitled to payment for their services. That intuition led him to inquire about payment *with the plaintiffs*, the parties that solicited and directly benefited from his services.

As for "mind reading," plaintiffs' counsel has it backward: This is a free-market society in which Morrey Jr.'s expectation of compensation was the standard one. We find, by the "clear and convincing" evidence of common sense, that Lanier misled the jury in creating the impression that Morrey Jr. had neither pecuniary incentive nor motive in testifying. Neither our double deference nor counsel's specious reasoning can alter that conclusion.

Finally, the deceptions obviously prevented defendants from "fully and

⁸¹ Suppose we did believe Lanier's various and independent explanations for why he could pay his expert *before and after* trial without ever compromising the witness's non-retained status. An opinion countenancing his behavior would read like a blueprint on how to evade Rule 26 with impunity. Parties could pay experts "for their time" before trial and later exchange compelling "pro bono" testimony for sizable, post-trial "thank you" checks.

Nos. 16-11051, 16-11052, 16-11053, 16-11054, 16-11056,
17-10030, 17-10031, 17-10032, 17-10034, 17-10035

fairly” defending themselves. *See Rozier*, 573 F.2d at 1339. Lanier emphasized to the court the “importan[ce]” of Drs. Morreys’ pro bono testimony, and Lanier repeatedly leveraged the false contrast between defendants’ paid mercenaries and plaintiffs’ unpaid altruists to his clients’ advantage. At the least, disclosure would have enabled defendants to try to impeach the Morreys with evidence of compensation.⁸² The district court abused its discretion in concluding otherwise. Calculated or not, falsehoods marred plaintiffs’ victory. The verdict cannot stand.

Conclusion

DePuy is entitled to JMOL on Greer’s and Peterson’s defective marketing claims, and J&J is entitled to JMOL on all plaintiffs’ aiding-and-abetting claims. The remaining claims avoid JMOL, though a new trial is required for the district court’s serious evidentiary errors and counsel’s misrepresentations. The judgments are REVERSED in part, and the judgment and the order denying Rule 60(b)(3) relief are VACATED, and the remaining claims are REMANDED for a new trial consistent with this opinion.⁸³

⁸² Plaintiffs respond that the “possibility of bias was exponentially greater with Defendants’ experts,” because they were paid far greater sums of money “over many years.” They add that Morrey Sr.’s decision to divert the \$10,000 to a charity would only serve to bolster his credibility. But these jury arguments confuse the inquiry. The central question is not whether the non-disclosure was outcome-determinative but, instead, whether disclosure would have opened up potentially promising impeachment tactics on cross-examination, which it patently did.

⁸³ As the court confirmed by questions at oral argument, the defendants, despite their serious critiques of the district judge’s actions in this case and related MDL proceedings, *see In re DePuy Orthopaedics, Inc.*, 870 F.3d 345, 351 (5th Cir. 2017) (finding “grave error”), have not asked us to require these cases to be reassigned to a different judge under “this court’s supervisory power to reassign,” *United States v. Stanford*, 883 F.3d 500, 516 (5th Cir. 2018). We express no view on the issue but note that reassignment is both “extraordinary” and “rarely invoked.” *Id.* (citation and internal quotation marks omitted).