

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

ORDER

Deborah Ann Rogers,

Case No. 12-cv-2602 (SRN/SER)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Christina P. Latta,

Case No. 12-cv-2608 (JRT/HB)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Victoria Kearse,

Case No. 12-cv-2768 (JNE/SER)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Samantha Shirey and
Brian Shirey,

Case No. 12-cv-2821 (DSD/TNL)

Plaintiffs,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Melissa Robinson Watson,

Case No. 13-cv-103 (DSD/SER)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Betty Lou Shaffer,

Case No. 13-cv-278 (SRN/TNL)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Margie H. Greenman,

Case No. 13-cv-766 (PJS/KMM)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Michele Rene Jackson,

Case No. 13-cv-768 (SRN/KMM)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Andrea Jean Rupert,

Case No. 13-cv-775 (ADM/KMM)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Carrie M. Klum and
Anthony D. Klum,

Case No. 13-cv-1107 (JNE/TNL)

Plaintiffs,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Graciela Urbieta and
Mateo Urbieta,

Case No. 13-cv-1927 (ADM/LIB)

Plaintiffs,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Frances Alvarado,

Case No. 13-cv-1994 (ADM/SER)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

Libby M. Hall,

Case No. 14-cv-329 (JNE/LIB)

Plaintiff,

v.

Mentor Corporation and
Mentor Worldwide, LLC,

Defendants.

STEVEN E. RAU, United States Magistrate Judge

The above-captioned cases (the “Mentor cases”) come before the undersigned pursuant to the Administrative Order [Doc. No. 9] directing the undersigned to coordinate pretrial matters and pursuant to 28 U.S.C. § 636(b)(1)(A) and District of Minnesota Local Rule 72.1.¹ Pursuant to the Administrative Order and subsequent agreement by the parties and the Court—as explained in further detail below—Plaintiffs filed a Motion for Leave to File an Amended Complaint to Add a Claim for Punitive Damages [Doc. No. 29]. The parties chose two cases in which Plaintiffs’ motion would be heard with the understanding that the order ruling on the

¹ The Court refers to documents filed in *Jackson v. Mentor Corp.*, No. 13-cv-768 (SRN/KMM) (D. Minn.) unless otherwise specified.

motion would be issued in all Mentor cases.² For the reasons stated below, the Court denies the motion in *Jackson* and grants the motion in *Urbieta*.

I. BACKGROUND

Plaintiffs are women who were implanted with ObTape, the brand name of a transobturator vaginal sling device that was “designed, manufactured, packaged, labeled and sold by Mentor”³ to treat Plaintiffs for stress urinary incontinence.⁴ *See, e.g.*, (Compl.) [Doc. No. 1-1 ¶¶ 1, 16]. Plaintiffs allege that they “suffered serious and permanent bodily injuries, including erosion of the ObTape medical device through [their] internal bodily tissues, chronic infections, pain, exacerbation of . . . urinary incontinence, and the need for multiple additional surgical procedures and medical treatment as well as the need for extensive future medical care.” (*Id.* ¶ 19). Mentor marketed ObTape and introduced it to the United States market in 2003. (*Id.* ¶¶ 7–8). Plaintiffs allege that Mentor conducted only limited, inadequate testing prior to introducing ObTape to the U.S. market, and that it “knowingly and deliberately made material misrepresentations to the Food & Drug Administration [‘FDA’] concerning the safety, efficacy, design, and manufacture of ObTape.” (*Id.* ¶¶ 8–10). Plaintiffs allege that Mentor did not perform any “safety or efficacy testing in human vaginal tissues to confirm that the medical device was safe and effective for use in women” and “continued to manufacture, market, distribute, and sell

² These two cases are *Jackson v. Mentor Corp.*, No. 13-cv-768 (SRN/KMM) (D. Minn.) and *Urbieta v. Mentor Corp.*, No. 13-cv-1927 (ADM/LIB) (D. Minn.). The Court will use “Plaintiffs” to refer to all plaintiffs in the above-captioned cases. The motions in each case were slightly different, but no distinction was made between the two motions at the hearing. Therefore, the Court refers to Plaintiffs’ motion as a singular motion.

³ “Mentor” collectively refers to Defendants Mentor Corporation and Mentor Worldwide, LLC.

⁴ Some Plaintiffs are the spouses of these women who make loss of consortium claims. *See, e.g.*, Compl. ¶¶ 24–25, *Urbieta v. Mentor Corp.*, No. 13-cv-1927 (ADM/LIB) (D. Minn.) [Doc. No. 1-1]. For ease of reference, the Court will use the term “Plaintiffs” to refer to women implanted with ObTape.

[ObTape] to thousands of women . . .” until 2006. (*Id.* ¶¶ 11–14). Plaintiffs allege claims of strict liability, negligence, breach of express warranty, breach of implied warranty, common law fraud, constructive fraud, and negligent and intentional misrepresentation against Mentor. (*Id.* ¶¶ 20–104).⁵

Plaintiffs filed their cases in Minnesota state courts, and Mentor removed them to federal court. (Notice of Removal) [Doc. No. 1]. The cases were then transferred to the United States District Court for the Middle District of Georgia for pretrial proceedings in 2013, and were remanded to this District in 2017. (Conditional Transfer Order) [Doc. No. 3]; (Conditional Remand Order) [Doc. No. 4]. The Honorable John R. Tunheim, Chief District Judge, ordered that the undersigned coordinate all Mentor cases for settlement conferences and a pretrial scheduling order. (Admin. Order). The undersigned held a settlement conference in all Mentor cases on December 4–6, 2017, during which six cases settled. (Minute Entries) [Doc. Nos. 15–17]. The undersigned entered a Pretrial Scheduling Order in the remaining cases, instructing Plaintiffs and Mentor to each select one case in which Plaintiffs would seek Court approval to amend the complaint to add a claim for punitive damages. [Doc. No. 26 at 4]. The parties chose *Jackson v. Mentor Corp.*, No. 13-cv-768 (SRN/KMM) (D. Minn.), and *Urbieta v. Mentor Corp.*, No. 13-cv-1927 (ADM/LIB) (D. Minn.), as so-called “bellwether” punitive damages cases, with the understanding that any order issued by the undersigned would be issued in all Mentor cases. *See* (Order Dated Jan. 29, 2018) [Doc. No. 73].

The Court held oral argument and *sua sponte* raised the issue of the appropriate standard for adding punitive damages claims. *See* (Order Dated Mar. 16, 2018) [Doc. No. 104].

⁵ And, as stated above, Plaintiffs’ spouses who are part of these cases have loss of consortium claims. *See, e.g.*, Compl. ¶¶ 24–25, *Urbieta v. Mentor Corp.*, No. 13-cv-1927 (ADM/LIB) (D. Minn.) [Doc. No. 1-1].

Specifically—and as described more fully below—a split among United States Magistrate Judges in this District regarding whether a court should follow Minnesota Statute section 549.191⁶ or Rule 15 of the Federal Rules of Civil Procedure⁷ when considering this type of motion developed recently. *See (id.)*; *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, No. 15-md-2666 (JNE/FLN), 2017 WL 5187832 (D. Minn. July 27, 2017) (Noel, Mag. J.) (determining Rule 15 governs);⁸ Order Dated Mar. 8, 2018, *Inline Packaging, LLC v. Graphic Packaging Int’l, LLC*, No. 15-cv-3183 (ADM/LIB) (D. Minn.) [Doc. No. 534] (Brisbois, Mag. J.) [hereinafter *Inline Packaging Order*] (determining the punitive damages pleading statute governs).⁹ The parties submitted supplemental briefing addressing the issue, and

⁶ Upon commencement of a civil action, the complaint must not seek punitive damages. After filing the suit a party may make a motion to amend the pleadings to claim punitive damages. The motion must allege the applicable legal basis under section 549.20 or other law for awarding punitive damages in the action and must be accompanied by one or more affidavits showing the factual basis for the claim. At the hearing on the motion, if the court finds prima facie evidence in support of the motion, the court shall grant the moving party permission to amend the pleadings to claim punitive damages. For purposes of tolling the statute of limitations, pleadings amended under this section relate back to the time the action was commenced.

Minn. Stat. § 549.191. The Court refers to this statute as the “punitive damages pleading statute.”

⁷ This Order’s discussion is confined to Rule 15(a)(2), which states that “a party may amend its pleading only with the opposing party’s written consent or the court’s leave” and “[t]he court should freely give leave when justice so requires.” Although not implicated in this analysis, Rule 15 also permits parties to amend their pleadings once as a matter of course in certain situations. Fed. R. Civ. P. 15(a)(1).

Because Mentor did not consent to Plaintiffs’ proposed amendments, Plaintiffs need the Court’s permission to file amended complaints. Unless otherwise specified, all references to “Rule 15” in this Order refer to Rule 15(a)(2)’s requirement that a court should “freely give leave” to file an amended pleading “when justice so requires.”

⁸ The Honorable Joan N. Ericksen affirmed this order without discussing the governing rule. *See* Order Dated Oct. 19, 2017, *Bair Hugger*, No. 15-md-2666 (JNE/FLN) [Doc. No. 985].

⁹ This order is on appeal to the District Court. To date, no decision has been issued.

the matter is now ripe for adjudication.¹⁰ *See* (Order Dated Mar. 16, 2018); (Mentor’s Suppl. Opp’n to Pls.’ Mot., “Mentor’s Suppl. Mem.”) [Doc. No. 111]; (Pls.’ Suppl. Mem. in Supp. of Pls.’ Mot., “Pls.’ Suppl. Mem.”) [Doc. No. 113].

II. DISCUSSION

A. Legal Standard

First, this Court must determine the appropriate standard to apply. Minnesota law prohibits seeking punitive damages in an initial complaint. Minn. Stat. § 549.191. Instead, a party may amend its pleading to claim punitive damages if it shows prima facie evidence of the factual basis for the claim. *Id.* In contrast, Rule 15 of the Federal Rules of Civil Procedure states that a party may amend its pleadings—regardless of the purpose of the amendment—if “justice so requires.” Unsurprisingly, Plaintiffs argue Rule 15 applies; in contrast, Mentor argues the punitive damages pleading statute applies. (Pls.’ Suppl. Mem.); (Mentor’s Suppl. Mem.). For the reasons described below, the Court concludes Rule 15 applies.

1. District History

This District has a long and consistent history of evaluating amendments to add claims of punitive damages under the punitive damages pleading statute in diversity cases where state law governs the rule of decision. *See Bair Hugger*, 2017 WL 5187832, at *1 n.1 (citing cases). In 1990, the Honorable Bernard P. Becker, United States Magistrate Judge, concluded that Rule 15 and the punitive damages pleading statute do not directly conflict. *See Sec. Sav. Bank v. Green Tree Acceptance, Inc.*, No. 3–89–28, 1990 WL 36142, at *2 (D. Minn. Mar. 22, 1990). Specifically, he stated that Rule 15 addresses whether a party may amend its pleadings generally,

¹⁰ As discussed in further detail below, Plaintiffs also submitted an amended proposed amended complaint. *See* (Pls.’ Letter to Mag. J. Dated Mar. 23, 2018, “Pls.’ Letter”) [Doc. No. 110]; *infra* n.21.

while the punitive damages pleading statute addresses “whether or not a party should be permitted to assert a claim for punitive damages.” *Id.* Judge Becker stated that Rule 15 “does not even attempt to address the issue posed” in the statute. *Id.* Thus, Judge Becker held that the punitive damages pleading statute must be applied.¹¹ *Id.* at *3. Since then, courts in this District—including the undersigned—continued to apply the punitive damages pleading statute when considering whether a party may amend its pleading to claim punitive damages. *See, e.g., In re Levaquin Prods. Liab. Litig.*, No. 08-cv-5743 (JRT), 2010 WL 7852346, at *5–6 (D. Minn. Nov. 9, 2010) (Tunheim, J.); *Healey v. I-Flow, LLC*, 853 F. Supp. 2d 868, 872 (D. Minn. 2012) (Keyes, Mag. J.); *Streambend Prods. III, LLC v. Sexton Lofts, LLC*, 297 F.R.D. 349, 360–61 (D. Minn. 2014) (Rau, Mag. J., as adopted by Davis, C.J.). But in 2010, the United States Supreme Court issued its decision in *Shady Grove Orthopedic Assocs., P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010), which in turn caused the Honorable Franklin L. Noel, United States Magistrate Judge, to re-evaluate the District’s position. *See generally Bair Hugger*, 2017 WL 5187832. Judge Noel found that Rule 15 applies. *Id.* at *4. Eight months later, the Honorable Leo I. Brisbois, United States Magistrate Judge also examined this issue and came to the opposite conclusion—that the punitive damages pleading statute applies. *Inline Packaging Order* at 10.

2. *Shady Grove and Bair Hugger*

In *Shady Grove*, the Supreme Court considered whether a New York state statute precluded the use of Rule 23 of the Federal Rules of Civil Procedure to maintain a class action.

¹¹ Specifically, because Judge Becker found Rule 15 and the punitive damages pleading statute do not conflict, he analyzed whether the variation between litigation with the punitive damages pleading statute enforced and without it enforced was “substantial enough to raise equal protection problems or influence the choice of forum.” *See Sec. Sav. Bank*, 1990 WL 36142, at *3. Judge Becker concluded that enforcement of the punitive damages pleading statute “would likely influence the litigants[’] choice of forum” and that the statute does not “impermissibly intrude[] on the judicial function” of the court. *Id.*

559 U.S. at 396. The Court clarified some of its past holdings regarding the analysis required when a state law—which typically applies in a diversity action—conflicts with the Federal Rules of Civil Procedure. *See* 559 U.S. at 398.¹² Five justices stated that a court considering this issue “must first determine whether [the Federal Rule] answers the question in dispute.” *Id.* Finding that Rule 23 answers the question of “whether Shady Grove’s suit may proceed as a class action,” the Court next considered whether Rule 23 was valid under the Rules Enabling Act. *Id.* at 399, 406. Both the plurality and the concurrence found Rule 23 was authorized under the Rules Enabling Act, 28 U.S.C. § 2072(b), but they applied different analyses. *Compare id.* at 407 (plurality opinion) (analyzing whether the Rule is procedural—and therefore valid—in the sense that “it governs only the manner and means by which the litigants’ rights are enforced” (internal quotation marks omitted)), *with id.* at 431 (Stevens, J., concurring in part and concurring in the judgment) (analyzing whether application of Rule 23 “would abridge, enlarge, or modify New York’s rights or remedies, and thereby violate the Enabling Act”); *see also* 28 U.S.C. § 2072(b) (stating that the Federal Rules “shall not abridge, enlarge or modify any substantive right”).

In *Bair Hugger*, Judge Noel observed that prior decisions considering amendments to add punitive damages claims did not consider *Shady Grove*. 2017 WL 5187832, at *1. Judge Noel then evaluated whether Rule 15 or the punitive damages pleading statute should apply to plaintiffs’ motion to amend. *See id.* at *2–4. Judge Noel found that Rule 15 and the statute conflict because Rule 15 “answers the question in dispute.” *Id.* at *4 (internal quotation marks omitted); *see also Shady Grove*, 559 U.S. at 398 (Scalia, J.). Specifically, Judge Noel perceived a

¹² The *Shady Grove* opinion is fractured. It was authored by Justice Scalia, who wrote on behalf of five justices for Parts I and II-A, four justices for Parts II-B and II-D, and three justices for Part II-C. 559 U.S. at 395–96. Justice Stevens concurred in part and concurred in the judgment. *Id.* at 416. Specifically, Justice Stevens concurred in Parts I and II-A of the Court’s opinion. *Id.* Four justices dissented. *Id.* at 436 (Ginsburg, J., dissenting).

conflict because the punitive damages pleading statute required “prima facie evidence of deliberate disregard for the rights and safety of others,” whereas Rule 15 had no such requirement. *Id.* Judge Noel then determined that Rule 15 was valid under the Rules Enabling Act under both the plurality’s test and the concurrence’s test. *Id.* at *4. Specifically, Judge Noel found that “the procedural pleading statute for punitive damages is . . . not a ‘judgment about the scope of state-created rights and remedies,’ 559 U.S. at 432 (Stevens, J., concurring), but a judgment about how Minnesota courts should operate.” *Id.* Thus, Judge Noel concluded that Rule 15 governed the plaintiffs’ motion to amend their pleadings.¹³ *Id.*

In *Inline Packaging*, Judge Brisbois found that there was no conflict between Rule 15 and the punitive damages pleading statute. *Id.* at 8. More specifically, Judge Brisbois concluded that the “state statute . . . does not preclude the application of the Federal Rule[,]” and “at least one Minnesota United States District Court has already concluded that ‘[t]here is no direct conflict between Federal Rule 15(a) and section 549.191.’” *Id.* (alteration in original) (quoting *Sec. Sav. Bank*, 1990 WL 36142, at *2). Because a federal court has discretion to allow the amendment under Rule 15, Judge Brisbois reasoned, that discretion “does not preclude or even conflict with the consideration of whether a party has also complied with” the punitive damages pleading statute. *Id.*

3. Plaintiffs’ Motion

As described above, Judge Noel’s and Judge Brisbois’s opinions created a split in this District in the last eight months regarding whether the punitive damages pleading statute or Rule 15 governs an amendment to add a punitive damages claim. *See, e.g., Ramirez v. AMPS Staffing*,

¹³ Ultimately, Judge Noel found plaintiffs’ proposed amendments were futile—meaning they could not withstand a motion to dismiss—and denied the motion. *See Bair Hugger*, 2017 WL 5187832, at *8.

Inc., No. 17-cv-5107 (DWF/BRT), 2018 WL 1990031, at *6 (D. Minn. Apr. 27, 2018) (Thorson, Mag. J.) (acknowledging the split in the District but determining that “the outcome of the motion would be same regardless of which standard is applied”). Judge Brisbois’s order was issued after Plaintiffs filed their motion, but before oral argument; the Court then raised this issue and requested supplemental briefing.

Recently, the undersigned considered a similar issue with respect to Minnesota Statute section 604.18—which governs amendments to add bad faith insurance claims—and determined that Rule 15 governed the amendment to the pleadings. *See Selective Ins. Co. of S. Carolina v. Sela*, No. 16-cv-4077 (PJS/SER), 2018 WL 1960450 (D. Minn. Apr. 26, 2018).¹⁴ For reasons similar to the reasoning articulated in *Selective*, the Court concludes Rule 15 governs amendments to add punitive damages claims.

4. Rule 15 and Related Federal Rules

Under the opinion of five justices in *Shady Grove* and the Supreme Court’s predecessor cases, the first question is whether Rule 15 “answers the question in dispute.” *See* 559 U.S. at 398 (citing *Burlington N. R.R. Co. v. Woods*, 480 U.S. 1, 4–5 (1987)). Here, the question is whether Plaintiffs may amend their complaints to add a punitive damages claim. Rule 15 applies to amended pleadings, regardless of the nature of the amendment, and answers this question by allowing an amendment “when justice so requires.”

Both the punitive damages pleading statute and Rule 15 purport to govern the requirements a party that seeks to amend its pleading to add a punitive damages claim must meet. But the standard each requires is different. Section 549.191 requires “affidavits showing

¹⁴ This order is on appeal to the District Court. To date, no decision has been issued. Judge Noel also recently determined a motion to amend a pleading to add a bad faith claim must be analyzed under Rule 15. *Redeemed Christian Church of God Strong Tower Parish v. Auto-Owners Ins. Co.*, No. 17-cv-1379 (WMW/FLN), 2018 WL 2135018 (D. Minn. May 9, 2018).

the factual basis for the claim.” If the court “finds prima facie evidence in support of the motion,” the motion “shall” be granted. § 549.191. Thus, the punitive damages pleading statute requires that the moving party submit prima facie evidence to the court.

Rule 15 has no such evidentiary standard. Its liberal standard for granting the motion—when justice so requires—demonstrates “that amendments should be allowed, unless certain limited exceptions are present” and is not limited to the type of amendment the moving party seeks. *See Selective*, 2018 WL 1960450, at *5; *see also Foman v. Davis*, 371 U.S. 178, 182 (1962) (stating that an amended pleading should be allowed unless there is a reason such as “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc.”). As noted in *Selective*, Rule 15 is better understood in the context of Rules 8, 9, and 12. 2018 WL 1960450, at *4; *see also Karnatcheva v. JPMorgan Chase Bank, N.A.*, 704 F.3d 545, 548 (8th Cir. 2013) (“We apply federal pleading standards—Rules 8 and 12(b)(6)—to state the substantive law to determine if a complaint makes out a claim under state law.”).

Under Rule 8, “a short and plain statement of the claim showing that the pleader is entitled to relief” is required “to give the defendant fair notice of what the claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up). This “liberal notice pleading” requirement is restricted in two ways. *See Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 514 (2002) (“The liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system, which was adopted to focus litigation on the merits of a claim.”).

First, Rule 9 requires that certain matters be pleaded with more specificity. The most common example is its requirement that a party “alleging fraud or mistake . . . state with

particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). Rather than alter notice pleading, however, Rule 9(b) “simply necessitates a higher degree of notice” and a court “must interpret the requirements of Rule 9(b) in harmony with the principles of notice pleading.” *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920 (8th Cir. 2001) (internal quotation marks omitted).

Second, the Supreme Court has provided guidance regarding what is required in a pleading through its analysis of motions to dismiss for failure to state a claim under Rule 12(b)(6) in two seminal decisions: *Twombly*, cited above, and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

[T]hese cases stand for the general proposition that Rule 8 “does not require ‘detailed factual allegations,’” but claims “must [nevertheless] contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 570). That is, “[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertion[s] devoid of further factual enhancement.” *Id.* (internal quotation marks omitted) (citations omitted) (second alteration in original).

Selective, 2018 WL 1960450, at *5.

The pleading standards described in *Iqbal* and *Twombly* apply to an amended pleading considered under Rule 15. An amended pleading should be permitted when justice so requires, which excludes an amended pleading that is futile. *See Foman*, 371 U.S. at 182.¹⁵ Futility, in turn, is measured by determining whether the amended pleading could “withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure.” *Zutz v. Nelson*, 601 F.3d

¹⁵ Although *Foman* was issued in 1962, the Eighth Circuit continues to cite its principles regarding the standard to amend pleadings even after *Iqbal* and *Twombly*. *See, e.g., Julianello v. K-V Pharm. Co.*, 791 F.3d 915, 922 (8th Cir. 2015) (“A court abuses its discretion when it denies a motion to amend a complaint unless there exists undue delay, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the non-moving party, or futility of the amendment.” (internal quotation marks omitted)).

842, 850 (8th Cir. 2010) (internal quotation marks omitted). “[A]nalysis under Rules 15 and 12(b)(6) generally requires a court not consider matters outside the pleadings to determine whether leave to amend should be given.” *Selective*, 2018 WL 1960450, at *6.

In contrast, the punitive damages pleading statute requires a court to perform what is often referred to as a gatekeeping function by examining submissions outside the pleadings to determine whether the submissions amount to prima facie evidence of punitive damages. *See generally Sorin Grp. USA, Inc. v. St. Jude Med., S.C., Inc.*, No. 14-cv-4023 (RHK/JJK), 2015 WL 12803583 (D. Minn. Sept. 28, 2015) (Keyes, Mag. J.). This requirement “presents a stark contrast to the usual analysis where a federal court need only consider whether the pleading ‘contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.’” *Selective*, 2018 WL 1960450, at *7 (alteration in original) (quoting *Iqbal*, 556 U.S. at 678).

Thus, the Court concludes that Rule 15 answers the question of whether Plaintiffs may amend their complaints.¹⁶ *See Shady Grove*, 559 U.S. at 398 (stating that if a Federal Rule

¹⁶ Although not an issue here, Rules 8 and 9 may also be implicated in another facet of pleading punitive damages claims in diversity cases venued in Minnesota. Section 549.191 prohibits pleading punitive damages in a complaint “[u]pon commencement of a civil action.” But if punitive damages are considered “special damages” under the Federal Rules of Civil Procedure, there is a colorable argument that the Rules **require** the pleading of punitive damages. *See* Fed. R. Civ. P. 9(g) (“If an item of special damage is claimed, it must be specifically stated.”); *Capital Sols., LLC v. Konica Minolta Bus. Sols. U.S.A., Inc.*, Nos. 08–2027–JWL–DJW, 08–2191–KHV–DJW, 2009 WL 1635894, at *8 (D. Kan. June 11, 2009) (noting that judges in the District of Kansas “have repeatedly found that Fed. R. Civ. P. 9(g) governs the pleading of punitive damages in diversity cases filed” in the District of Kansas (internal quotation marks omitted)). *But see Bowles v. Osmose Util. Servs., Inc.*, 443 F.3d 671, 675 (8th Cir. 2006) (stating that “even if punitive damages are ‘special’ within the meaning of [Rule 9(g)],” failure to plead punitive damages in the original or amended complaint did not require reversal of the punitive damages award because defendant had notice of plaintiff’s intent to seek punitive damages); *Figgins v. Advance Am. Cash Advance Ctrs. of Mich., Inc.*, 482 F. Supp. 2d 861, 870 (E.D. Mich. 2007) (“Punitive damages are not special damages and therefore need not be pleaded with specificity under Rule 9(g).”).

answers the question in dispute, it governs unless the Rule is invalid); *Bair Hugger*, 2017 WL 5187832, at *4 (concluding Rule 15 governs whether a plaintiff may amend a complaint to add a punitive damages claim).

5. Validity of the Federal Rules

The next step requires the Court to determine whether Rule 15—as well as Rules 8, 9, and 12—conflict with the Rules Enabling Act. *Shady Grove*, 559 U.S. at 398 (stating that if a Federal Rule answers the question in dispute, a court must then determine whether the rule “exceeds statutory authorization or Congress’s rulemaking power”). The test used to make this determination is what divided the Supreme Court in *Shady Grove*. Compare *id.* at 406–10 (plurality opinion), with *id.* at 419–28 (Stevens, J., concurring in part and concurring the judgement).¹⁷ But the Court’s earlier caselaw provides a straightforward test: A rule that “really regulates procedure,” is valid under the Rules Enabling Act.¹⁸ See *Sibbach v. Wilson & Co.*, 312 U.S. 1, 14 (1941). As described in *Selective*, whether a party may add a claim under Rules 8, 9, 12, and 15 “is divorced from a merits-based analysis of whether that party can prevail on that claim under controlling substantive law.” 2018 WL 1960450, at *13.

In *Shady Grove*, Justice Stevens said that “[a] federal rule . . . cannot govern a particular case in which the rule would displace a state law that is procedural in the ordinary course of the

¹⁷ Mentor adopts the view—espoused by other courts—that Justice Stevens’s opinion controls because it is the opinion that concurs in the judgment on the narrowest grounds. (Mentor’s Suppl. Mem. at 10 n.5) (citing *Marks v. United States*, 430 U.S. 188, 193 (1977); *Davenport v. Charter Commc’ns, LLC*, 35 F. Supp. 3d 1040, 1050 (E.D. Mo. 2014)). Such a strict interpretation of *Marks* “will turn a single opinion that lacks majority support into national law.” *King v. Palmer*, 950 F.2d 771, 782 (D.C. Cir. 1991) (en banc). Thus, this Court disagrees. See *id.* (“When eight of nine Justices do not subscribe to a given approach to a legal question, it surely cannot be proper to endow that approach with controlling force, no matter how persuasive it may be.”). Regardless, the Supreme Court’s prior decisions provide sufficient guidance.

¹⁸ The Supreme Court defined “procedure” as “the judicial process for enforcing rights and duties recognized by substantive law and for justly administering remedy and redress for disregard or infraction of them.” *Sibbach v. Wilson & Co.*, 312 U.S. 1, 14 (1941).

term but is so intertwined with a state right or remedy that it functions to define the scope of the state-created right.” 559 U.S. at 423. Mentor argues the punitive damages pleading statute fails Justice Stevens’s test because the punitive damages pleading statute refers to a statute that describes the substantive requirements for punitive damages. (Mentor’s Suppl. Mem. at 11); *see also* Minn. Stat. § 549.191 (stating that a motion to amend a complaint to add a punitive damages claim “must allege the applicable legal basis under section 549.20 or other law for awarding punitive damages in the action”); *id.* § 549.20, subdiv. 1(a) (“Punitive damages shall be allowed in civil actions only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others.”). Even if the Court agreed with the premise that Justice Stevens’s test of validity under the Rules Enabling Act controls—which it does not—Mentor’s argument is unavailing. *See supra* n.17.

It is true, as Mentor asserts, that the punitive damages pleading statute specifically refers to the substantive component of punitive damages articulated in section 549.20. (Mentor’s Suppl. Mem. at 11) (“Courts in this district have recognized that these two subparts are inseparable.”). But the fact that these statutes work together is not equivalent to a determination that they are so intertwined that the punitive damages pleading statute actually defines the scope of the state-created right. *Cf. Shady Grove*, 559 U.S. at 423 (Stevens, J., concurring part and concurring in the judgment).

The Minnesota legislature made a conscious decision to separate the procedural requirement from the substantive standard of proof. *Compare* Minn. Stat. § 549.191, *with id.* § 549.20. This decision underscores that the evaluation to amend a pleading to add a punitive damages claim is different from the evaluation to allow an award of punitive damages. Courts in this District routinely highlight this distinction. *See, e.g., Ulrich v. City of Crosby*, 848 F. Supp.

861, 867 (D. Minn. 1994) (Erickson, Mag. J.) (stating that a plaintiff seeking to amend a complaint to add a punitive damages claim is required only to demonstrate an entitlement to **allege** punitive damages under section 549.191; the plaintiff is not required to demonstrate an entitlement to punitive damages per se). Further, when a party claims punitive damages under Minnesota law, the punitive damages pleading statute requires a party to “allege the applicable legal basis under section 549.20 or **other law**.” Minn. Stat. § 549.191 (emphasis added). Thus, the punitive damages pleading statute also applies when the claim for punitive damages is made under another state’s law. *See, e.g., Healey*, 853 F. Supp. 2d at 874 (stating that plaintiff asserts punitive damages under section 549.20, assuming that Minnesota law will apply, and noting that one of the defendants argues that Virginia’s punitive damages law should apply).¹⁹ This distinction further highlights that the substantive statute, not the punitive damages pleading statute, “define[s] the scope of the state-created right.” *See Shady Grove*, 559 U.S. at 423 (Stevens, J., concurring in part and concurring in the judgment). Therefore, contrary to Mentor’s assertion, even under Justice Stevens’s test, Rule 15 is valid under the Rules Enabling Act and applies in this case because it does not displace the substantive right to claim punitive damages under Minnesota law. *See id.*

As Justice Scalia observed, the Supreme Court has “rejected every statutory challenge to a Federal Rule that has come before” it. *Id.* at 407–08 (plurality opinion) (discussing cases). For the reasons described above and in *Selective*, the Court concludes that Rules 8, 9, 12, and 15 are valid under the Rules Enabling Act. *See* 2018 WL 1960450, at *12–13.

6. Futility under Rule 15

There are no issues related to undue delay, bad faith, a history of failure to cure past

¹⁹ Ultimately, the court determined that because there was no conflict between Minnesota’s and Virginia’s punitive damages laws, Minnesota law applied. *Healey*, 853 F. Supp. 2d at 875.

deficiencies, or undue prejudice. *See Foman*, 371 U.S. at 182. Thus, the remaining issue is whether Plaintiffs’ proposed punitive damages claim is futile. The Court must determine whether Plaintiffs have sufficiently alleged facts that—if true—show Mentor deliberately disregarded “the rights or safety of others.”²⁰ Minn. Stat. § 549.20, subdiv. 1(a). “Punitive damages are available against the manufacturer of a product that abuses its control over information about product risks in a manner that shows a disregard for public safety.” *Olson v. Snap Prods., Inc.*, 29 F. Supp. 2d 1027, 1036 (D. Minn. 1998) (Erickson, Mag. J.) (citing *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 733 (Minn. 1980)). Mentor deliberately disregarded the rights of others if it knew or intentionally disregarded

facts that create[d] a high probability of injury to the rights or safety of others and:

- (1) deliberately proceed[ed] to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or
- (2) deliberately proceed[ed] to act with indifference to the high probability of injury to the rights or safety of others.

Minn. Stat. § 549.20, subdiv. 1(b). In other words, the statute substantively requires “(1) knowledge of or an intentional disregard of facts that make injury to the plaintiff’s rights probable; and (2) action despite such knowledge.” *Nunn v. Noodles & Co.*, No. 09-cv-1286 (JNE/JJK), 2010 WL 3170763, at *3 (D. Minn. Aug. 6, 2010) (Keyes, Mag. J); *see also* Minn. Stat. § 549.20, subdiv. 1(a), (b).

²⁰ There is an argument that a punitive damages “claim” is not truly a claim, as contemplated by Rule 8(a)(2), but instead a remedy that is not subject to a motion to dismiss, and—by extension—not subject to a futility analysis. *See Oppenheimer v. Sw. Airlines Co.*, No. No. 13–CV–260–IEG (BGS), 2013 WL 3149483, at *3–4 (S.D. Cal. June 17, 2013). In Minnesota, however, the statute has substantive requirements and is routinely discussed as a claim. *See, e.g., Healey*, 853 F. Supp. 2d at 875 (“In order to establish **a claim** for punitive damages in Minnesota, a party must show—by clear and convincing evidence—that the Defendant acted with ‘deliberate disregard for the rights or safety of others.’” (emphasis added) (quoting Minn. Stat. § 549.20, subdiv. 1(a))). Thus, the Court proceeds with the futility analysis.

B. Analysis

To determine whether Plaintiffs' punitive damages claim survives the futility analysis, the Court must consider Plaintiffs' allegations regarding what facts Mentor knew, and when Mentor knew those facts. *See Healey*, 853 F. Supp. 2d at 876. The Court first summarizes Plaintiffs' newly added factual allegations, then determines whether the amendment should be permitted under Rule 15.

1. Summary of Allegations

As stated above, Plaintiffs allege claims of strict liability, negligence, breach of express warranty, breach of implied warranty, common law fraud, constructive fraud, and negligent and intentional misrepresentation. (Compl. ¶¶ 20–104). Their First Amended Complaint²¹ expounds on the factual bases for their claims as described below and seeks punitive damages. Although the Court has read the First Amended Complaint closely, only its most salient points are summarized below.

a. Pre-launch Allegations

Plaintiffs allege that Mentor deliberately disregarded key facts it knew before it launched ObTape in the United States on August 7, 2003. *See* (FAC ¶¶ 12, 45, 65). Specifically, Plaintiffs allege that Mentor knew of increased infections with Uratape, ObTape's predecessor; Mentor knew of increasing problems with ObTape in Europe; and Mentor rushed ObTape to market. *See* (*id.* ¶ 65).

²¹ Plaintiffs filed a proposed amended complaint with their motion. *See* [Doc. No. 29-1]. After the Court asked for supplemental briefing, Plaintiffs amended their proposed amended complaint, which the Court refers to as the First Amended Complaint, or "FAC," for ease of reference. *See* (Pls.' Letter); [Doc. No. 110-1]. The Plaintiffs assert that the First Amended Complaint was amended only to "transcrib[e] the facts as set forth" in Plaintiffs' motion for punitive damages and "do[es] not raise or allege facts or assertions not already pled or set forth" in their motion. (*Id.*). Therefore, the Court will treat the First Amended Complaint as the most recent proposed amended complaint in its analysis.

Plaintiffs allege that Uratape was associated with “increased” erosions. (*Id.* ¶ 26); *see also* (*id.* ¶ 27). Mentor then made some changes to Uratape and launched ObTape. *See* (*id.* ¶ 42). Plaintiffs allege Mentor knew that ObTape’s lack of porosity “was potentially responsible for the prevalence of erosions in European patients” and Plaintiffs allege several facts related to pore size. (*Id.* ¶ 15); *see also* (*id.* ¶¶ 12–13, 16–17). On February 7, 2003, Dr. Rosy Eloy (“Dr. Eloy”) advised Mentor that the areas where the tape was impermeable “could be a source of infection.” (*Id.* ¶ 17) (internal quotation marks omitted). Mentor also did not require a specific pore size for ObTape or ask its manufacturer about the pore measurements. *See* (*id.* ¶¶ 19–22). As of July 10, 2003—a month before ObTape launched in the U.S.—“Mentor knew the results of a three-month histological examination of ObTape in rabbits (‘rabbit study’),” which showed that “ObTape elicited a significant inflammatory and foreign body reaction, where TVT [ObTape’s competitor] did not.” (*Id.* ¶ 29).

Plaintiffs also describe facts that they allege demonstrate that Mentor rushed ObTape to market. *See* (*id.* ¶ 33). Plaintiffs’ allegations relate to Mentor’s acquisition of the rights to use transobturator technique. (*Id.* ¶¶ 34–35, 38–41). “Mentor decided not to wait . . . [for] further evaluation of erosion and infection reports in Europe,” and instead planned to obtain a 510(k)²² for ObTape and use the amount of time it would take to obtain this approval “to assess ObTape.” (*Id.* ¶ 37) (internal quotation marks omitted). In August 2003, around the same time Mentor launched ObTape in the United States, it “received a serious thigh abscess report from Germany,” and it “had reasonable doubts that its changes to Uratape had addressed the infection

²² “A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to [Premarket Approval application].” *Premarket Notification 510(k)*, Med. Devices, U.S. Food & Drug Admin., <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last updated Mar. 27, 2018).

problems [meaning] ObTape was in a position to produce similar serious injuries.” (*Id.* ¶ 42). “After discussions within Mentor about the German case, . . . Mentor disregarded the safety of women and moved forward with the U.S. launch.” (*Id.* ¶ 43).

b. Post-launch Allegations

Plaintiffs allege Mentor was aware of additional facts after ObTape launched in the United States, but nonetheless continued to market and sell ObTape. *See (id.* ¶ 65). On August 7, 2003, Mentor’s marketing manager, Delia Cook (“Cook”), circulated a summary of an ObTape white paper to another Mentor employee. (*Id.* ¶ 45). Cook created the ObTape white paper by replacing “Uratape” with “ObTape” in the white paper for Uratape. (*Id.* ¶ 46).

If a physician complained to a sales representative “that ObTape had poor tissue ingrowth due to small pore size,” sales representatives were instructed to tell the physician “that Mentor had a human *in vivo* study showing tissue ingrowth and rabbit studies showing tissue ingrowth and angiogenesis.” (*Id.* ¶ 55). Although Mentor had the rabbit study that showed “negative data,” that information was not shared with implanting surgeons. (*Id.*); *see also (id.* ¶ 60). Mentor did not perform an ObTape-specific *in vivo* tissue ingrowth study and instead “committed scientific fraud in place of such studies.” (*Id.* ¶ 56).

Plaintiffs also provide a lengthy timeline that allegedly demonstrates that “Mentor knowingly marketed and sold ObTape despite knowing of the increased risk to patient safety with the product[.]” (*Id.* ¶ 62). The majority of these allegations describe Mentor learning about erosions and infections from their sales force and key opinion leaders in both the United States and France. *See (id.* at 15–18, 20–22, ¶ 59). Some employees pushed for more clinical support and opined that Mentor should suspend sales. (*Id.* at 16, ¶ 59). In May 2004, a surgeon who was in the process of signing a consulting agreement with Mentor “put the agreement on hold

because he believed the ObTape erosion rate was ‘alarmingly high’” and he had a “second erosion out of approximately 20 cases.” (*Id.* at 17). In July 2004, a U.S. surgeon terminated his consulting agreement with Mentor “because of the number of ObTape complications he had observed over the past year . . . [in] patients who underwent the ObTape procedure.” (*Id.*) (internal quotation marks omitted). “He chose to discontinue use of ObTape until long-term follow-up data became available, saying ‘As a clinician, I would find it very difficult to support . . . ObTape when discussing risks/benefits preoperatively with my patients.’” (*Id.*). That same month, a doctor who is “an expert in terms of implantable materials” reported two infection cases he believed were caused by ObTape and declined to participate in a clinical study that he had previously agreed to because of “his strong doubts concerning” ObTape. (*Id.* at 17–18) (internal quotation marks omitted).

In November 2004, a mentor employee noted that a French ObTape opinion leader opined “that ObTape should not be implanted anymore” and that there was a risk that a French regulatory committee “would declare that ObTape be withdrawn from the market or at least that ObTape not be sold anymore.” (*Id.* at 19). Also in November 2004, key French opinion leaders continued to challenge Mentor and opine that ObTape “should not be available on the market as it increases the risk of too serious infections [sic].”²³ (*Id.*).

In January 2005, Mentor knew that three of its key opinion leaders stopped implanting ObTape and the head of European marketing reported “that the doctors felt that it was out of the question and unethical to place ObTape given the information about it in the French scientific

²³ Although it’s somewhat unclear, it appears that French key opinion leaders also believed “the PIDS should be modified,” which it was not. (FAC at 19–20, 20 n.9). Based on oral argument, the Court understands the PIDS to be information about ObTape that is provided to physicians using it.

community.”²⁴ (*Id.* at 21).

ObTape sales were temporarily suspended in France following an erosion and infections report in August 2005, but Mentor’s compliance officer in the United States “contradicted the report.” (*Id.* at 25). A Mentor employee in France asked management for a communications strategy following the August 2005 report, but “was told to ensure full radio silence” until they received further information from the compliance officer in the United States. (*Id.*).

In February 2006, the Agency for Sanitary Safety of Health Products in France told Mentor executives that the level of erosions for ObTape was 10%; “that there was a real public health issue”; and “that the marketing of ObTape should be stopped and required a recall by the manufacturer.” (*Id.* at 26) (internal quotation marks omitted). Mentor was given ten days to make a decision before the Agency finalized its decision. (*Id.*). Later that month, Mentor-Porges²⁵ advised the Agency that “there was no more inventory of ObTape remaining with any French customers, no further deliveries were scheduled, and that Mentor had already decided” to focus on its new product. (*Id.*) (internal quotation marks omitted). Mentor stated that “the end of the commercial life of ObTape worldwide has been scheduled at March 31, 2006.” (*Id.*) (internal quotation marks omitted). Mentor stopped selling ObTape in the U.S. on that date. (*Id.*).

Plaintiffs allege that Mentor knew of these facts, these facts created a high probability of injury to the rights and safety of others, and Mentor deliberately acted in conscious or intentional disregard of the high probability of injury to others. (*Id.* ¶ 65).

2. Application of Rule 15

Plaintiffs’ allegations are alarming because they describe serious medical complications

²⁴ It is unclear whether these key opinion leaders were based in the United States or France. *See* (FAC at 21).

²⁵ Mentor-Porges is a subsidiary of Mentor. *See* (FAC ¶ 65).

that appear to be associated with ObTape. But they do not lead to the conclusion that Mentor disregarded facts that made injuries probable. For example, Mentor’s experience with Uratape, ObTape’s predecessor, is not clearly connected to Mentor’s experience with ObTape. *See* (FAC ¶¶ 24, 26–27). Plaintiffs’ allegation that Mentor rushed ObTape to the U.S. market does not, as alleged here, demonstrate that Mentor knew that patients were likely to be injured. *See (id.* ¶¶ 33–43). Similarly, Mentor’s alleged misrepresentations related to the white paper and rabbit study demonstrate its knowledge that its product was not on as sound of scientific footing as it purported to be, but does not demonstrate that Mentor disregarded the high probability of injury to others. *See (id.* ¶¶ 29, 46–52, 55–56, 60). Mentor’s knowledge of erosions, infections, and other complications lack any context that shows that Mentor disregarded the high probability of injuries. It is generally understood that all surgery carries risks, and a recitation of complications does not explain whether the complications were outside the realm of what should be expected with products like ObTape. In other words, Mentor’s allegations lack the “factual enhancement” required for the Court to conclude that, assuming the allegations are true, Mentor deliberately disregarded others’ rights or safety. *See Iqbal*, 556 U.S. at 678 (stating that a complaint does not “suffice if it tenders naked assertions devoid of further factual enhancement” (cleaned up)).

Mentor launched ObTape in the United States in August 2003. (*Id.* ¶ 12). Only five months later, a key opinion leader “complained about erosions believed to result from the design of ObTape.” (*Id.* at 15). Mentor received continued reports of erosions and in March 2004, a U.S. surgeon stopped using ObTape until he could get additional information. (*Id.* at 16). Two months later, a key opinion leader in the process of signing a consultation agreement with Mentor “put the agreement on hold” because he thought the erosion rate for ObTape was “alarmingly high.” (*Id.* at 17) (internal quotation marks omitted). Up until July 2004, Plaintiffs’ allegations could

amount to negligence or gross negligence, which does not rise such a level that punitive damages may be claimed. *See Ulrich*, 848 F. Supp. at 868.

But on July 16, 2004, a U.S. surgeon who already had a consulting agreement with Mentor terminated it. (FAC at 17). This surgeon cited the number of patients with complications who had ObTape implanted as his reason for terminating the agreement, stating “[a]s a clinician, I would find it very difficult to support . . . ObTape when discussing risks/benefits preoperatively with my patients.” (*Id.*) (internal quotation marks omitted). This physician was a “learned intermediary”²⁶ who had entered into an agreement with Mentor related to ObTape. Thus, he was a third party who, through his consulting agreement, was predisposed to support and promote ObTape. Nonetheless, he lost faith in the product based on his patients’ adverse experiences and could no longer support it. *See (id.)*. The demise of this agreement should have been a watershed moment that prompted Mentor to take some action beyond maintaining its sale and promotion plans. *See (id.* ¶ 62). Instead, Mentor continued to sell and market ObTape. The Court finds that as of July 16, 2004, Mentor knew of facts that created a high probability of injury to others and that continuing to sell and market ObTape despite knowing those facts constitutes a deliberate disregard for others’ rights or safety.

III. APPLICATION

The Court’s conclusion impacts the above-captioned cases in the following way. Because the Court concludes that as of July 16, 2004, Mentor knew facts that created a high probability of injury, not all Plaintiffs are entitled to amend their complaints to claim punitive damages. Instead, only those Plaintiffs who were implanted with ObTape **after** July 16, 2004, may amend

²⁶ A “learned intermediary” is a physician or other medical professional who “is in the best position to understand [a] patient’s needs and assess the risks and benefits of a particular course of treatment.” *See Greiner v. Sofamor, S.N.C.*, No. Civ. 4–95–645 (RHK/JMM), 1999 WL 716891, at *5 (D. Minn. Mar. 8, 1999) (Kyle, J.) (internal quotation marks omitted).

their complaints to claim punitive damages. Plaintiffs who were implanted with ObTape **before** July 16, 2004, may not amend their complaints because, at the time of their implants, consistent with this Order, Mentor did not know facts that created a high probability of disregard for others' rights.

The two cases in which this motion was filed are apt examples. Michele Rene Jackson was implanted with ObTape in March 2004, and therefore may not amend her complaint to claim punitive damages. *See* (Compl. ¶ 16). Graciela Urbieta was implanted with ObTape in March 2005, and therefore may amend her complaint. *See* Compl. ¶ 16, *Urbieta v. Mentor Corp.*, 13-cv-1927 (ADM/LIB) (D. Minn.) [Doc. No. 1-1].

IV. PROCEDURAL INSTRUCTIONS

Plaintiffs may not file amended complaints in the appropriate cases until either the time period to object to this Order passes, or a district judge affirms this Order or provides other instructions.

Any objections to this Order may only be filed on the *Jackson* and *Urbieta* dockets. In cases apart from *Jackson* and *Urbieta*, the objecting party must file a letter advising the district judge that an objection to this Order has been filed and identify the case in which the objection was filed (i.e., *Jackson*, *Urbieta*, or both).

V. CONCLUSION

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiffs' Motion for Leave to File an Amended Complaint to Add a Claim for Punitive Damages is **GRANTED in part** and **DENIED in part** as follows:

1. A plaintiff in the above-captioned cases who was implanted with ObTape before July 16, 2004, may not amend her complaint to add a claim for punitive damages.

2. A plaintiff in the above-captioned cases who was implanted with ObTape after July 16, 2004, may amend her complaint to add a claim for punitive damages.
3. In *Jackson v. Mentor Corp.*, 13-cv-768 (SRN/KMM) (D. Minn.), Plaintiff's Motion for Leave to File an Amended Complaint to Add a Claim for Punitive Damages [Doc. No. 29] is **DENIED**.
4. In *Urbieta v. Mentor Corp.*, 13-cv-1927 (ADM/LIB) (D. Minn.), Plaintiffs' Motion for Leave to File an Amended Complaint to Add a Claim for Punitive Damages [Doc. No. 28] is **GRANTED**.
5. The filing of amended complaints and objections will be conducted as follows: Plaintiffs may not file amended complaints in the appropriate cases until either the time period to object to this Order passes, or a district judge affirms this Order or provides other instructions. Any objections to this Order may only be filed on the *Jackson* and *Urbieta* dockets. In cases apart from *Jackson* and *Urbieta*, the objecting party must file a letter advising the district judge that an objection to this Order has been filed and identify the case in which the objection was filed (i.e., *Jackson*, *Urbieta*, or both).

Dated: May 15, 2018

s/Steven E. Rau
STEVEN E. RAU
United States Magistrate Judge