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December 30 2010
Ed Smith
CLERK OF THE SUPREME COURT
STATE OF MONTANA

DA 10-0029

IN THE SUPREME COURT OF THE STATE OF MONTANA

2010 MT 282

PEGGY L. STEVENS,

Plaintiff, Cross-Appellant and Appellee,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Appellant.

APPEAL FROM: District Court of the Fourth Judicial District,
In and For the County of Missoula, Cause No. DV 08-100
Honorable John W. Larson, Presiding Judge

COUNSEL OF RECORD:

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Argued and Submitted: September 23, 2010

Decided: December 30, 2010

Filed:

Clerk

Justice W. William Leaphart delivered the Opinion of the Court.

¶1 A Missoula County jury returned a verdict awarding Peggy Stevens (Stevens) $3,200,000.00 in compensatory damages in Stevens' action for negligence against Novartis Pharmaceuticals Corporation (Novartis). Stevens alleged that Novartis failed to properly warn that its drug, Zometa, causes osteonecrosis of the jaw (ONJ) in patients who undergo dental surgery while taking the drug. The District Court denied Novartis' motions for summary judgment, ruled against Novartis on several evidentiary issues, and denied post-trial motions for judgment as a matter of law and for a new trial. Novartis appeals these rulings. Stevens cross-appeals, claiming that the trial court erred in denying Stevens permission to file an amended complaint, in dismissing a Novartis sales representative from the action, and in offsetting social security disability benefits against the jury award.

¶2 We affirm in part and reverse in part.

¶3 We consider the following issues on appeal:

¶4 ***1. Whether the District Court erred in denying Novartis' motion for summary judgment.***

¶5 ***2. Whether the District Court erroneously instructed the jury as to Novartis' duty to warn.***

¶6 ***3. Whether the District Court erred in refusing Novartis permission to amend its complaint to include an apportionment defense.***

¶7 ***4. Whether the District Court erred in excluding statements in prior pleadings that were allegedly inconsistent with Novartis' liability.***

¶8 ***5. Whether the District Court erred in admitting testimony regarding a change to Novartis' warning label.***

¶9 ***6. Whether Novartis is entitled to judgment as a matter of law because Stevens failed to prove proximate causation.***

¶10 ***7. Whether the District Court erred in refusing Stevens permission to amend her complaint to include a claim for punitive damages.***

¶11 ***8. Whether the District Court erred in offsetting social security disability benefits against the general damages awarded by jury.***

¶12 ***9. Whether the District Court erred in dismissing Stevens' negligence claims against Patrick Doyle, a sales representative for Novartis.***

FACTUAL AND PROCEDURAL BACKGROUND

¶13 Peggy Stevens was diagnosed with follicular lymphoma in October 2000 by Dr. Judy Schmidt (Dr. Schmidt), a Missoula oncologist. At the time, Stevens served as the house supervisor at Community Medical Center, where she had been employed for nearly 20 years. In April 2002, Dr. Schmidt prescribed Novartis' drug Zometa to Stevens after finding lymphoma in Stevens' spine, pelvis and ribs. Zometa, like other drugs in the "bisphosphonate" family, is administered intravenously to cancer patients who are at risk of bone fractures and other bone-related problems due to cancer-weakened skeletal systems. Zometa works by attacking cells called "osteoclasts" that normally dissolve old bone, which has the result of hardening bones to make them more resilient. At the time Dr. Schmidt prescribed Zometa to Stevens in April 2002, the drug had only recently been

approved by the Federal Drug Administration (FDA), and no serious reports of any negative side effects had arisen.

¶14 Experts soon began to take note, however, of the large number of ONJ patients who were also taking bisphosphonates. Several months after Stevens began taking Zometa, Dr. Robert Marx, a leading national expert, published an award-winning medical textbook which first mentioned the possible link between ONJ and bisphosphonates. Novartis responded in September 2003 by changing the Zometa label to include a mention of ONJ, stating that "cases of [ONJ], primarily of the jaws, have been reported since market introduction." The label also stated, however, that ONJ has "other well-documented risk factors," and "it is not possible to determine if [cases of ONJ] are related to Zometa." The label pointed to chemotherapy and smoking as the more likely and more well-established causes of ONJ.

¶15 Dr. Marx continued to sound the alarm, writing of a "growing epidemic" of ONJ in bisphosphonate patients. In December 2003, Novartis convened an advisory panel on the subject in coordination with the American Society of Clinical Oncology. The panel included Dr. Marx and another expert, Dr. Salvatore Ruggiero, who had echoed Dr. Marx's reports of ONJ-bisphosphonate linkage. In March 2004, a second panel was convened at Novartis headquarters, again with Dr. Marx, Dr. Ruggiero, and other leading national figures present. A main goal of this second panel was to draft a "white paper" on the topic, which was eventually published in June 2004. The white paper was met with heavy criticism from Dr. Marx and others. They asserted that the paper failed to admit the clear causal relationship between bisphosphonates and ONJ, and that it

misleadingly identified other factors such as chemotherapy and smoking as the more likely causes of ONJ in bisphosphonate patients. In the same month the paper was released, Novartis again changed its Zometa label, adding that the majority of reported cases of ONJ were "in cancer patients attendant to a dental procedure" and advising that "although causality cannot be determined, it is prudent to avoid dental surgery as recovery may be prolonged."

¶16 Stevens continued visiting Guardian Oncology for treatment, although her relationship with Dr. Schmidt no longer included active consultation. Instead, Stevens interacted with the nursing staff and visiting physicians at the clinic. She began having pain in her jaw in August 2004, and was subsequently advised that her tooth was cracked and she would need to have surgery to remedy the problem. Stevens called Guardian Oncology on August 31, 2004, in connection with the upcoming dental procedure. She advised clinic staff and locum tenens physicians that she needed to have dental work done and was planning on having her tooth extracted (a much less expensive procedure than alternative possibilities such as root canal therapy and crown lengthening) in the near future. No concerns regarding ONJ were raised, and Stevens made an appointment with Dr. Eugene Morris, an oral surgeon, for the procedure. Dr. Morris was unaware that Stevens was taking Zometa, but testified that even if he had known, it would not have made a difference as he was unaware of the relationship between Zometa and ONJ until 2006. Dr. Morris performed the extraction on September 27, 2004.

¶17 Within days, Stevens began having additional pain at the extraction site. She went on an antibiotic regimen, but the pain failed to abate. Stevens reported the continuing

problem to Dr. Schmidt, who ordered an MRI in early 2005. The MRI suggested that Stevens had contracted ONJ, which was confirmed by further testing. Stevens stopped taking Zometa around this time, although the drug was still present in her body as it has a half-life of over a decade. While Stevens' ONJ continued to develop into a serious problem, her cancer was in remission, as it has been ever since. In October 2006, exposed bone first became visible at the extraction site. In April 2007, Stevens took what was intended to be a temporary break from work, but could not return to work without pain medication. Because Community Hospital requires its employees to abstain from all narcotics while on duty, however, Stevens was forced to abandon her position. She has been out of work ever since. ONJ has no cure and is progressive, and thus Stevens' condition will only deteriorate as more of her jawbone dies. Like all ONJ patients, Stevens suffers from chronic pain and constant infection, and manages her condition with antiseptic mouthwash, antibiotics, and powerful narcotics for pain.

¶18 The growing recognition of a link between ONJ and bisphosphonates caused reverberations in the courtroom as well as the medical community. On September 15, 2005, three class action suits were filed against Novartis in federal court in Tennessee. In one of these suits, *Susan Becker, et al. v. Novartis Pharms. Corp.*, No. 3:05-0719 (M.D. Tenn.), counsel for the named plaintiffs sought to represent a worldwide class of plaintiffs who contracted ONJ after using Zometa. The suit alleged failure to warn, among other claims, and sought damages for personal injuries. Class certification was eventually denied and claims were ordered severed on November 14, 2007. During the pendency of the suit, the linkage between bisphosphonates, dental surgery, and ONJ had

become widely accepted. Novartis had long since sent a "Dear Doctor" letter to doctors regarding Zometa and other bisphosphonates, admitting that the ONJ-bisphosphonate link was no longer an unproven hypothesis, but rather an established medical conclusion.

¶19 In August 2007, Stevens brought an action against Dr. Schmidt and Dr. Morris before the Montana Medical Legal Panel (MMLP), alleging failure to warn of the risk of contracting ONJ as a result of dental surgery while on Zometa. Dr. Schmidt responded that she did not have knowledge of these risks, and Dr. Morris responded that there were no other feasible options available to Stevens. In January 2008, after the conclusion of the MMLP proceedings, Stevens filed suit in Missoula County District Court against Dr. Schmidt, Guardian Oncology, and several fictitious defendants, claiming that they knew of the risk of ONJ but negligently failed to warn her. Stevens substituted Novartis and its sales representative, Patrick Doyle, for the fictitious defendants named in the complaint in January 2009. Novartis immediately raised a statute of limitations defense and moved for summary judgment. The District Court denied Novartis' motion on the basis that the complaint was timely filed as to the fictitious defendants, and that Novartis had failed to show that it was not properly substituted. Novartis had failed to show that the substitution was improper, explained the court, because "the nature of Novartis' alleged culpability may have been unknown at the time of Plaintiff's original complaint." A protective and confidentiality order was entered in May 2009, and the case proceeded to discovery. Stevens settled her claims against Dr. Schmidt and Guardian Oncology in June 2009, and they were dismissed from the case in July. Numerous motions were filed refining the scope of issues at trial. The parties were both denied leave to amend the

pleadings, and additional cross-motions seeking to postpone the trial date were denied as well. Novartis again moved for summary judgment on its statute of limitations defense, but was again denied. The case proceeded to trial on October 13, 2009, before the Hon. John Larson.

¶20 Eight days later, a Missoula County jury returned a verdict of $3,200,000.00 in Stevens' favor. A hearing on potential offsets was held in January 2010, after which the District Court entered an order reducing the award to $2,657,257.32. The offsets included the amount Stevens received in settlement with Dr. Schmidt and Guardian Oncology, the amount she received in short-term disability for six months in 2007, and the social security disability benefits she had received and would receive in the future. Stevens was awarded her costs. Novartis filed post-trial motions for a new trial and for judgment as a matter of law, which were denied. Novartis timely appealed.

¶21 We held oral argument on September 23, 2010, directing the parties' attention to two issues: Stevens' alleged statute of limitations violation and Novartis' duty to warn.

STANDARD OF REVIEW

¶22 We review a district court's grant or denial of a motion for summary judgment de novo. *State v. Butte-Silver Bow Co.*, 2009 MT 414, ¶ 17, 353 Mont. 497, 220 P.3d 1115; *Goettel v. Est. of Ballard*, 2010 MT 140, ¶ 10, 356 Mont. 527, 234 P.3d 99. Applying the criteria contained in M. R. Civ. P. 56, we determine whether the moving party has established both the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. *Goettel*, ¶ 10 (citing *Watson v. Dundas*, 2006 MT 104, ¶ 16, 332 Mont. 164, 136 P.3d 973).

¶23 We review jury instructions for abuse of discretion to determine whether the jury instructions, as a whole, fully and fairly instructed the jury on the applicable law. *State v. Johnston*, 2010 MT 152, ¶ 7, 357 Mont. 46, 237 P.3d 70. We review evidentiary rulings for an abuse of discretion, and a district court possesses broad discretion to determine the admissibility of evidence. *Malcolm v. Evenflo Co.*, 2009 MT 285, ¶ 29, 352 Mont. 325, 217 P.3d 514 (citing *Sunburst Sch. Dist. No. 2 v. Texaco, Inc.*, 2007 MT 183, ¶ 74, 338 Mont. 259, 165 P.3d 1079).

¶24 We review a district court's findings of fact to determine whether they are clearly erroneous. *Emmerson v. Walker*, 2010 MT 167, ¶ 20, 357 Mont. 166, 236 P.3d 598. We review questions of law de novo. *In re Fair Hrg. of Hanna*, 2010 MT 38, ¶ 13, 355 Mont. 236, 227 P.3d 596. We review a district court's interpretation of a statute for correctness. *Signal Perfection, Ltd. v. Rocky Mt. Bank-Billings*, 2009 MT 365, ¶ 10, 353 Mont. 237, 224 P.3d 604.

DISCUSSION

¶25 ***1. Whether the District Court erred in denying Novartis' motion for summary judgment.***

¶26 Novartis has strenuously argued over the life of this litigation that Stevens' claims are time-barred. Montana's three-year statute of limitations for personal injury actions, § 27-2-204, MCA, ostensibly began to run on March 18, 2005, when Stevens was first informed she had ONJ as a result of undergoing dental surgery while taking Zometa. Stevens filed a timely complaint in January 2008 against Dr. Schmidt, Guardian Oncology, and John Does one through four. She amended the complaint to substitute

Novartis for one of the fictitious defendants in January 2009, three years and 10 months after the statute of limitations began to run. Stevens maintains that Novartis was timely served because parties who are fictitiously named pursuant to § 25-5-103, MCA, are considered part of the action from its inception. M. R. Civ. P. 4(E)(2). Novartis counters that the fictitious name statute applies only when the plaintiff is unaware of the defendant's identity. Given that Stevens was fully aware of Novartis' name and that Zometa had caused or contributed to her ONJ, Novartis contends, she cannot escape her failure to timely name Novartis as a defendant.

¶27 In the alternative, Stevens argues that the statute of limitations was tolled by the *Becker* class action suit. In this suit, plaintiffs' counsel sought class certification for a worldwide class of patients who took Zometa and later contracted ONJ. *Becker*, No. 3:05-0719 (M.D. Tenn.). The suit contained claims for strict product liability and negligence for failure to warn doctors and consumers of the danger of Zometa-induced ONJ. Plaintiffs sought medical monitoring, compensatory damages, and punitive damages. The suit was pending from September 15, 2005, until November 14, 2007, when the district court denied class certification and ordered that the claims be severed and individual amended complaints filed. Stevens asserts that because the *Becker* class action contained a request for worldwide class certification, and contained a claim for failure to warn against the dangers of Zometa-induced ONJ, the statute of limitations was tolled as to Stevens, along with all other potential class members, under the "class action tolling" rule. Because the statute of limitations was tolled for over two years during the pendency of the *Becker* class action, argues Stevens, the amended complaint was timely

filed as to Novartis regardless of whether it relates back to the original complaint via the fictitious name statute. Novartis replies that the class action tolling rule ought not apply to the current situation for a variety of reasons, most notably that the class action suit in question was filed in a different jurisdiction than the present suit.

¶28 In reviewing the District Court's conclusions on whether Stevens' claims are barred by the statute of limitations, we are mindful that we will uphold a district court when it reaches the correct result, regardless of the court's reasoning. *Peterson v. Eichhorn*, 2008 MT 250, ¶ 37, 344 Mont. 540, 189 P.3d 615. Thus, we will uphold the District Court here if we find that Novartis was properly substituted as a fictitious defendant *or* that the limitations period was tolled during the pendency of the *Becker* class action suit.

¶29 After careful consideration of the principles at issue, we are persuaded that the class action tolling rule logically applies here. We thus conclude that Stevens' amended complaint was timely filed. We will therefore not reach the issue of whether Novartis was properly substituted for a fictitious defendant.

¶30 Class action tolling is a matter of first impression in Montana. The doctrine was first established by the United States Supreme Court in the landmark case *American Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 94 S. Ct. 756 (1974). In *American Pipe*, several companies were accused of antitrust violations for the alleged price-fixing of steel and concrete pipe projects, and faced both criminal and civil complaints filed by the federal government. After the conclusion of the criminal case and the filing of a consent judgment in the civil case, the State of Utah filed suit, professing to represent a class

consisting of various state and local governmental bodies damaged by the companies' price-fixing scheme. Utah's suit was filed in federal district court within eleven days of the expiration of the applicable statute of limitations. Seven months later, the court denied class certification, concluding that the class was not so numerous as to be impracticable—thus failing the numerosity requirement for class certification under Fed. R. Civ. P. 23(a). When more than 60 governmental bodies that had been claimed as members of the original class filed motions to intervene as plaintiffs eight days after class action status was denied, the court denied their motion on the basis that the statute of limitations had run.

¶31 The Ninth Circuit reversed. It concluded that "as to the members of the class Utah purported to represent, and whose claims it tendered to the court, suit was actually commenced by Utah's filing," reasoning that "[t]he claims of appellants were then before the court and the only question was as to the manner in which they should be entertained on the merits." *Utah v. American Pipe & Constr. Co.*, 473 F.2d 580, 584 (9th Cir. 1973). The United States Supreme Court granted certiorari to "consider a seemingly important question affecting the administration of justice in the federal courts." *American Pipe*, 414 U.S. at 545, 94 S. Ct. at 762.

¶32 The Supreme Court affirmed the Ninth Circuit, holding that "the commencement of the [class action suit] satisfied the purpose of the limitation provision as to all those who might subsequently participate in the suit as well as for the named plaintiffs." The Court pinned its reasoning on the furtherance of judicial economy. "To hold to the contrary," the Court opined, would invite "precisely the multiplicity of activity" that the

federal rules of procedure were designed to avoid, as individual plaintiffs would be forced to file preventative motions to join or intervene as parties if the class action status was still pending at the expiration of the statute of limitations. *Id.* at 551, 94 S. Ct. at 765. Furthermore, continued the Court, "no different a standard should apply to those members of the class who did not rely upon the commencement of the class action (or who were even unaware that such a suit existed)," and who thus "cannot claim that they refrained from bringing timely motions for individual intervention or joinder because of a belief that their interests would be represented in the class suit." *Id.* The Court reasoned that "[n]ot until the existence and limits of the class have been established and notice of membership has been sent does a class member have any duty to take note of the suit or to exercise any responsibility with respect to it," and thus, it would be illogical to require active participation before such point for other purposes such as class action tolling. *Id.* at 552, 94 S. Ct. at 765.

¶33 The Court also noted that class action tolling "is in no way inconsistent with the functional operation of a statute of limitations." The Court explained that limitation periods are designed to ensure justice by preventing surprise, but no surprise exists where defendants are already on notice of the substantive claims being brought against them, as they may be when a class action suit has been filed. *Id*. at 554-55, 94 S. Ct. at 766-67. "Within the period set by the statute of limitations," the Court concluded, "the defendants have the essential information necessary to determine both the subject matter and size of the prospective litigation, whether the actual trial is conducted in the form of a class action [or not]." *Id.* at 555, 94 S. Ct. at 767.

¶34 Recognizing that it was stepping into unknown territory, the Court limited its holding to instances in which the plaintiffs seek to *intervene* in a class action where class certification has been denied. The Court broadened this narrow holding, however, in *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345, 103 S. Ct. 2392 (1983), making clear that the statute of limitations is tolled not only as to those class members seeking to intervene in the class action, but also as to *individual* actions filed by members of the putative class.[1] The rule established by these two decisions is instructive, but gives little guidance as to the outer limits of the doctrine, as has been noted by courts and secondary sources.

¶35 For example, the rule applies to cases filed in federal court, but states are free to fashion their own class action tolling rules and are not bound by *American Pipe*. Another open question is whether the rule should apply equally to all class actions, or whether distinctions should be recognized, such as between mass tort class actions and securities class actions. Most importantly for the present case, authorities conflict as to whether the rule applies when the individual action is filed in a different jurisdiction than the class action. So called "cross-jurisdictional tolling" has rarely been addressed, and the few state courts and secondary sources to have considered the doctrine have expressed widely divergent viewpoints.

[1] *Crown, Cork & Seal* also dispensed with *American Pipe's* limitation to instances in which class certification was denied for failure to satisfy the numerosity requirement of Fed. R. Civ. P. 23(a). The class in *Crown* was denied certification for several additional reasons. Other courts applying class action tolling in the years since then have followed *Crown*'s lead, and the specific basis for denial of class certification has rarely been considered a significant factor.

¶36 Novartis urges this Court not to adopt class action tolling in Montana in the present case for two principal reasons. First, Novartis argues that the doctrine is premised on the provision of fair notice to defendants through the claims made in the class action, and that no such notice was provided in the present case. It contends that the type of class action suit at issue today—a mass tort—is generally unsuited for class action tolling. Second, Novartis argues that the more well-reasoned and widely adopted view of the doctrine rejects cross-jurisdictional tolling, and therefore, as the class action suit was filed in Tennessee, it should not toll Montana's statute of limitations. We address these arguments in turn.

¶37 We first consider the contention that the doctrine should not apply because Novartis was not afforded proper notice of Stevens' claims. Novartis advances both generic and specific arguments on this point. In general, Novartis argues that mass torts are unsuited for class action tolling, because a central principle of the tolling doctrine—notice to defendants—is not present. Specifically, Novartis argues that it did not receive effective notice of Stevens' claim through the *Becker* class action suit. Novartis contends that the policy of affording notice to defendants through statutes of limitation is not satisfied where neither the individual plaintiffs' injuries nor the facts necessary to the claims are substantially similar. Advocates of this view draw a contrast with other class action suits, such as for securities offerings, where the facts constituting the individual claims are all but identical. Several courts have found this distinction persuasive. In *Bell v. Showa Denko K.K.*, 899 S.W.2d 749 (Tex. App. 1995), a Texas court declined to extend its existing class action tolling rule to a personal injury class action suit,

concluding that the distinction between personal injury class actions and other class actions "is important in determining whether the defendants have received fair notice of the existence of a claim by the filing of a class suit," especially given "the variety of claims necessarily involved in [personal injury cases]." *Bell*, 899 S.W.2d at 758.

¶38 Similarly, in *Jolly v. Eli Lilly & Co.*, 751 P.2d 923 (Cal. 1988), the California Supreme Court reversed a lower court's application of the class action tolling rule in a suit for personal injuries caused by a defective pregnancy drug. While the decision turned on the fact that the individual suit sought damages for personal injury while the class action suit did not, the court offered a variety of reasons why it considered *American Pipe* inapposite. The court noted that the elements of personal injury claims "vary widely from claim to claim," and that personal injury class action suits might be "presumptively incapable of apprising defendants of the substantive claims being brought against them" as a result. *Id*. at 937 (citation and internal quotation marks omitted). The court concluded that the class action suit did not "sufficiently put defendants on notice of the substance and nature of plaintiff's claims," and that such notice was "a prerequisite, in our view, to the application of *American Pipe*." *Id.* at 936-37.

¶39 Novartis contends that the present facts parallel those in *Jolly*, and do not support the rationale behind *American Pipe* because the class action suit failed to put Novartis on sufficient notice of Stevens' claims. While we may later encounter a situation in which a class action suit does not afford sufficient notice to the defendants of subsequent plaintiffs' claims, we do not believe we are faced with such an instance today. Novartis' alleged failure to warn, and the injury caused as a result, serve as the underpinning for

both the class action suit and Stevens' claim, and the warnings issued by Novartis to healthcare professionals around the country were presumably the same or substantially similar.

¶40 More importantly, it is not necessary that the claims be identical. *Tosti v. L.A.*, 754 F.2d 1485, 1489 (9th Cir. 1985) ("[w]e find no persuasive authority for a rule which would require that the individual suit must be identical in every respect to the class suit for the statute to be tolled."). We are not convinced that the nature of the individual plaintiffs' claims in *American Pipe* and its progeny were of substantially greater variance than the nature of the plaintiffs' claims in the *Becker* class action. Under modern pleading rules, Novartis is only entitled to be noticed of the *nature* of claim, rather than the damages alleged, which need not be pleaded specifically. The argument that mass torts are unsuited for class action tolling seems to afford too little weight to the critical distinction between variance in damages and variance in the nature of claims. We are unpersuaded that mass torts are unsuitable for class action tolling.[2] We conclude that Novartis was effectively put on notice of Stevens' claim by the *Becker* suit, and allowing class action tolling in this context would not unfairly prejudice Novartis for lack of notice.

¶41 We next consider Novartis' argument that class action tolling should not be applied here because the class action suit and Stevens' suit were filed in different jurisdictions. Novartis correctly observes that state courts have rarely adopted

[2] There have been class certifications in mass tort suits. *See e.g. In re Agent Orange Prod. Liab. Litig.*, 818 F.2d 145, 166-67 (2d Cir. 1987). Likewise, courts have extended class action tolling in mass tort cases. *See e.g. Staub v. Eastman Kodak Co.*, discussed *infra* n. 5.

cross-jurisdictional tolling, and that the doctrine has been rejected by courts in several states. The large majority of courts to consider the issue, however, have stopped short of outright adoption or rejection. While Novartis claims that the doctrine has been "widely rejected," in reality the doctrine has seldom been squarely addressed, and it is clear that its outlines are still in the process of developing. Many of the cases Novartis cites as "rejecting" the doctrine, for example, are merely circuit court decisions looking to existing state law, finding no authority one way or the other, and declining to decide the issue without guidance from the state's high court. In *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1025 (9th Cir. 2008), for example, the Ninth Circuit declined to import the doctrine to California law, observing that "[t]he California Supreme Court has not adopted such cross-jurisdictional tolling," and deferring to "California's interest in managing its own judicial system."

¶42 Two recent decisions rejecting the doctrine shed light on the rationale behind limitation of the class action tolling rule to actions filed in the same jurisdiction. In *Portwood v. Ford Motor Co.*, 701 N.E.2d 1102 (Ill. 1998), the Illinois Supreme Court affirmed the dismissal of state court claims brought by plaintiffs, who sought to rely on a federal class action suit to toll the statute of limitations. The court reasoned that while class action tolling in the *same* court system furthered judicial economy and was sound policy, tolling across jurisdictional boundaries "may actually increase the burden" on the court system of the state adopting cross-jurisdictional tolling, "because plaintiffs from across the country may elect to file . . . in that state solely to take advantage of the generous tolling rule." *Id*. at 1104. The Illinois court thus rejected the doctrine, claiming

that "[b]y rejecting cross-jurisdictional tolling, we ensure that the protective filings predicted by plaintiffs will be dispersed throughout the country rather than concentrated in Illinois." *Id*. at 1105.

¶43 In *Maestas v. Sofamor Danek Group, Inc.*, 33 S.W.3d 805 (Tenn. 2000), the Tennessee Supreme Court rejected cross-jurisdictional tolling for essentially the same reason. "Adoption of the doctrine," opined the court, "would run the risk that Tennessee courts would become a clearinghouse for cases that are barred in the jurisdictions in which they otherwise would have been brought . . . [w]e cannot sanction such forum shopping." *Id.* at 808. Fearing a "mass exodus of rejected putative class members from federal court to Tennessee," the court affirmed a lower court's ruling that the plaintiffs' suit was time-barred. *Id.* at 809. The court also expressed distaste at a perceived lack of state sovereignty, observing that adoption of the doctrine would give federal courts control over the running of Tennessee state statutes of limitation.

¶44 Nearly all other negative treatments of the doctrine have either declined to extend it in the limited circumstances in which it was presented, or have ruled based on existing precedent established in cases such as *Portwood* and *Maestas*.[3] It is clear that the main

[3] Many of the cases cited by Novartis, much like *Clemens v. DaimlerChrysler*, are federal court decisions that decline to extend the doctrine before the state's highest court has had the opportunity to consider the issue. *See e.g. In re Vioxx Prods. Liab. Litig.*, 522 F. Supp. 2d 799, 811 (E.D. La. 2007) (declining to expand Puerto Rico's class action tolling jurisprudence to include cross-jurisdictional tolling); *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1082 (D. Kan. 2009) (declining to expand Tennessee's class action tolling jurisprudence to include cross-jurisdictional tolling in antitrust cases); *Thelen v. Mass. Mut. Life Ins. Co.*, 111 F. Supp. 2d 688, 694-95 (D. Md. 2000) (same, for Maryland); *Wade v. Danek Med., Inc.*, 182 F.3d 281, 287 (4th Cir. 1999) (same, for Virginia); *In re Enron Corp. Secs.*, 465 F. Supp. 2d 687, 722 (S.D. Tex. 2006) (same, for Texas); *Love v. Wyeth*, 569 F. Supp. 2d 1228, 1237 (N.D. Ala. 2008) (same, for Alabama).

reason state courts decline to adopt cross-jurisdictional tolling is the fear that doing so while the doctrine is not yet widely accepted will trigger a rush on the courts of that state. Courts rejecting the doctrine have paid scant attention to any perceived unfairness to defendants, with rare exceptions. *See e.g. Bell v. Showa Denko K.K.*, 899 S.W.2d at 758. Thus, the reasons for rejection of cross-jurisdictional tolling do *not* generally include a perceived incompatibility with principles underlying statutes of limitation.

¶45 We conclude that the *Becker* class action fairly put Novartis on notice of the substance of Stevens' claims. This is doubly true because Stevens' complaint was filed ten months after the alleged expiration of the limitations period—in stark contrast to drastic scenarios such as that confronted by the *Portwood* court, where the plaintiffs

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Other courts have concluded that state legislatures are the proper avenue for adoption of the doctrine, or have otherwise based their decision on a lack of statutory authority. *Senger Bros. Nursery, Inc. v. E.I. Dupont de Nemours & Co.*, 184 F.R.D. 674, 683 (M.D. Fla. 1999); *Thoubboron v. Ford Motor Co.*, 624 A.2d 1210, 1213 (D.C. 1993). The only courts that actually *have* rejected the doctrine, besides *Portwood* and *Maestas*, are *Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 933-38 (Cal. 1988) (rejecting cross-jurisdictional tolling because the class action suit in question did not provide adequate notice to the defendants, as the class action only sought monitoring and the individual action was for personal injury. The court explicitly left the door open for cross-jurisdictional class action tolling in other contexts, but expressed doubt that it would ever find the doctrine applicable to mass-tort class action suits.), and *Bell v. Showa Denko K.K.*, 899 S.W.2d 749, 756-58 (Tex. App. 1995) (declining to toll the Texas statute of limitation by a personal injury class action filed in New Mexico, as a matter of policy and because it was not properly preserved for appeal); *Ravitch v. Price-Waterhouse*, 793 A.2d 939, 941-44 (Pa. Super. 2002) (denying cross-jurisdictional tolling after examining the split in authority and finding *Portwood*'s "reasoning persuasive."). Other cases rejecting the doctrine have merely applied these cases as precedent. *See e.g. Ottaviano v. Home Depot, Inc., USA*, 701 F. Supp. 2d 1005, 1012-13 (N.D. Ill. 2010) (applying *Portwood*); *In re Aredia and Zometa Prods. Liab. Litig.*, No. 3-06-MD-1760 (M.D. Tenn.) (applying *Maestas*).

sought to get around a limitations failure of over a decade through a class action suit that had been pending for a full nine years.[4]

¶46 We are convinced that the decisions adopting cross-jurisdictional tolling more effectively balance the considerations at issue.[5] In *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160 (Ohio 2002), the Ohio Supreme Court heard the claims of a plaintiff, Vaccariello, injured by a medical device known as a "pedicle screw," implanted in her spine to relieve back pain. The trial court denied the defendant's motion for summary judgment, concluding that the statute of limitations was tolled during the pendency of a nationwide class action against the device manufacturer filed in Pennsylvania federal district court, of which Vaccariello was a potential class member. The intermediate court reversed, and the Ohio Supreme Court allowed a discretionary

[4] The *Portwood* plaintiffs filed suit in 1991 for property damages allegedly occurring between 1976 and 1979, when the plaintiffs' Fords suffered from a defect causing the cars to shift without warning. The plaintiffs claimed that the statute of limitations was tolled by a class action suit filed in 1981 and not dismissed until 1990. *Portwood*, 701 N.E.2d at 1102-03.

[5] *Hyatt Corp v. Occidental Fire & Casualty Co.*, 801 S.W.2d 382, 389 (Mo. App. 1990) (applying cross-jurisdictional tolling in personal injury suit without recognizing a distinction between intra-jurisdictional and cross-jurisdictional tolling); *Staub v. Eastman Kodak Co.*, 726 A.2d 955, 961-68 (N.J. Super. App. Div. 1999) (applying cross-jurisdictional tolling in a personal injury suit against a drug manufacturer, wherein the court observed that "[w]e see no reason for tolling to depend on whether the class action is pending in state or federal court," and that application of cross-jurisdictional tolling "would tend to promote the efficiency of both state and federal court systems because suits asserting the individual claims of the class members might be filed in either court system or in both." *Id.* at 967 n. 4); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 162-63 (Ohio 2002) (discussed above); *Lee v. Grand Rapids Bd. of Educ.*, 384 N.W.2d 165, 168 (Mich. App. 1986) (applying cross-jurisdictional tolling in a state equal protection suit for claims which were certified in federal court, without recognizing a distinction between intra-jurisdictional and cross-jurisdictional tolling). Other decisions have indicated approval of the doctrine. *In re W. Va. Rezulin Litig. v. Hutchison*, 585 S.E.2d 52, 66 n. 10 (W. Va. 2003) (deciding the case on other grounds, but stating that the lower court's concern over differing limitations periods applying to the numerous plaintiffs was misplaced because of the probable application of the class action tolling rule, and not recognizing a distinction for cross-jurisdictional tolling); *see also Knouse v. Gen. Am. Life Ins. Co.*, 391 F.3d 907, 914-15 (8th Cir. 2004); *In re Linerboard Antitrust Litig.*, 223 F.R.D. 335 (E.D. Pa. 2004).

appeal. Noting that Ohio's own class action rule was virtually identical to the federal rule, the court concluded that "a class action filed in federal court serves the same purpose as a class action filed in Ohio," and "[w]hether a class action is filed in Ohio or in the federal court system, the defendant is put on notice of the substance and nature of the claims against it." *Id.* at 162-63. "Therefore," concluded the court, "allowing the filing of a class action in the federal court system to toll the statute of limitations in Ohio does not defeat the purpose of the statute." *Id.* at 163.

¶47 The *Vaccariello* court then proceeded to discuss *Portwood*, explaining why it did not find the holding persuasive:

> In *Portwood v. Ford Motor Co.* (1998) (citation omitted), the Supreme Court of Illinois rejected cross-jurisdictional tolling "because plaintiffs from across the country may elect to file a subsequent suit in that state solely to take advantage of the generous tolling rule," thereby burdening Illinois' court system. We are not persuaded that this is a realistic potential problem.
>
> Our holding today merely allows a plaintiff who could have filed suit in Ohio irrespective of the class action filed in federal court in Pennsylvania to rely on that class action to protect her rights in Ohio. To do otherwise would encourage all potential plaintiffs in Ohio who might be part of a class that is seeking certification in a federal class action to file suit individually in Ohio courts to preserve their Ohio claims should the class certification be denied. The resulting multiplicity of filings would defeat the purpose of class actions.

Id. We agree with these considerations. We do not expand access to Montana's courts beyond the access to which out-of-state plaintiffs are already entitled. Our state's policy is plainly stated in the Montana Constitution: "[c]ourts of justice shall be open to every person, and speedy remedy afforded for every injury to person, property, or character." Mont. Const. art. II, § 16. The right of access to our court system is "unrestricted by

reference to residence or citizenship," and an out-of-state plaintiff has "the same rights and duties as a citizen of this state." *LaBella v. Burlington N.*, 182 Mont. 202, 207, 595 P.2d 1184, 1187 (1979) (internal citations and quotation marks omitted); § 49-1-204, MCA. Any citizen of the United States may file suit in Montana's courts, provided that jurisdiction may properly be asserted over the defendant. Thus, our decision today does not expand the class of potential plaintiffs in Montana.

¶48 We concede, however, that in adopting cross-jurisdictional tolling we may well create the incentive complained of in *Portwood* and *Maestas*, for out-of-state plaintiffs to file suit in Montana courts when their claims are time-barred in other jurisdictions. We do not dismiss this concern lightly. While the *Vaccariello* court opined that "[o]ur holding does not invite plaintiffs who have no relationship to Ohio to file suit in our courts," we acknowledge that our holding today may indeed encourage plaintiffs with "no relationship to Montana" to file suit in our courts, if their claims are stale elsewhere. *Vaccariello*, 763 N.E.2d at 163. But as we have observed above, *all* plaintiffs, regardless of residency, are constitutionally guaranteed the right to file suit in Montana. We conclude that the best judge of these competing arguments will be experience. As we have noted when faced with similar situations, "if a substantial increase in this type of litigation is called to our attention in the future we will reexamine the situation in light of what we have herein stated." *Labella*, 182 Mont. at 207, 595 P.2d at 1187 (quoting *State ex rel. Great N. Ry. v. Dist. Ct.*, 139 Mont. 453, 457, 365 P.2d 512, 514 (1961), and concluding that Montana's open court policy, as set out in Mont. Const. art II, § 16, guarantees out-of-state plaintiffs the right to file in Montana state courts.).

¶49 Thus, although avoiding the possibility of a rush of out-of-state plaintiffs filing in our court system is concededly a valid policy objective, we consider this objective less compelling than competing considerations. We suspect that a greater burden on the court system will be imposed by *not* adopting the rule, as plaintiffs would be required to file protective individual suits in Montana courts to avoid limitations defenses, while otherwise relying on a pending class action suit filed elsewhere. This directly conflicts with the rationale underlying the class action tolling rule: to promote judicial economy by encouraging individual plaintiffs to defer to class action suits to protect their claims. We see no reason why jurisdictional boundaries should operate as a bar to the application of this policy. Where, as here, the defendants are already on fair notice of the claims against them through a timely class action suit, the policies underlying the limitations period are not subverted.

¶50 We recognize that in some instances a class action suit may *not* fairly put the defendants on notice. Our adoption of the rule is therefore limited to situations in which defendants are fairly put on notice of the substantive claims against them. Were we confronted with a case such as that faced by the California Supreme Court in *Jolly*, where the individual claim sought damages for personal injuries but the class action suit sought only monitoring, we would likely not see fit to extend the doctrine. *Jolly*, 751 P.2d at 936. Similarly, the present case involved an alleged limitations failure of under a year. Were we to confront a situation such as the one faced by the *Portwood* court—where the class action suit was alleged to have tolled the statute of limitations for *over a decade*—we might find the principles of notice and fairness to defendants not met and the doctrine

inapplicable. Thus, before tolling the statute of limitations during the pendency of a class action suit, we must examine the circumstances present in the case to ensure that defendants are not unfairly prejudiced, regardless of the jurisdictions in which the actions are filed. On the facts before us today, we conclude that tolling our state statute of limitations best upholds the competing policies at issue.

¶51 Because we determine that the statute of limitations was tolled during the pendency of the *Becker* suit, we conclude that Stevens' complaint was timely filed. We thus do not reach the question of whether Novartis was properly named as a fictitious defendant under § 25-5-103, MCA.

¶52 ***2. Whether the District Court erroneously instructed the jury as to Novartis' duty to warn.***

¶53 Novartis contends that it is entitled to a new trial because the District Court incorrectly instructed the jury that it had a duty to warn health care professionals other than Stevens' prescribing physician. Under the "learned intermediary" doctrine adopted by Montana in *Hill v. Squibb & Sons, E. R.*, 181 Mont. 199, 206, 592 P.2d 1383, 1387-88 (1979), Novartis argues, its duty to warn extends *only* to the prescribing physician—in this case, Dr. Schmidt. Stevens counters that Novartis misrepresents the holding in *Hill*, and that the District Court correctly stated the duty to warn as set out in the Restatement (Third) of Torts (hereafter, "the Restatement"), which provides that warnings must be provided to "prescribing and other healthcare providers who are in a position to reduce risks of harm." *Restatement (Third) of Torts: Products Liability* § 6(d)(1) (1998). Novartis asserts that the Restatement's version of the doctrine is in conflict with the

majority view, which has been adopted by Montana. Novartis supports this contention by noting that Montana has not adopted this latest version of the Restatement. Stevens responds that the distinction made by Novartis between Montana law and the Restatement is a false one, and that the particular facts surrounding Stevens' care support the Restatement's expression of the doctrine.

¶54 The learned intermediary doctrine has been widely accepted, in some form, for the better part of the past century. Although Novartis asserts that we adopted a controlling interpretation of the doctrine in *Hill*, that case was decided on entirely different grounds and contained no discussion, or even specific mention, of the learned intermediary doctrine. We thus agree with Stevens that Novartis ascribes improper weight to dicta in *Hill*, and conclude that the greater body of common law offers a fuller, more perspicacious perspective on the doctrine.

¶55 Despite its wide acceptance, the doctrine has constantly been under attack, and has evolved through the years to confront the changing nature of the healthcare system. Part of this evolution has been a movement away from limiting the doctrine's applicability to the prescribing physician alone. The version of the doctrine set out in the Restatement, which includes "other healthcare providers" in the possible class of learned intermediaries, reflects this modern trend. In traditional doctor-patient relationships, the doctor provides the patient with the resources to make an informed choice, through explanation of the risks and benefits involved with a certain drug and knowledge of the patient's medical history. In these conventional, individualized doctor-patient relationships, the doctor is in the best position to understand and communicate warnings

effectively to the patient—the "learned intermediary" standing in between the patient and the pharmaceutical company. The modern healthcare system, however, places far less emphasis on these traditional relationships, and patients today often receive the majority of their care from nurses, nurse practitioners, physicians' assistants, and physicians other than the prescribing physician. Appropriately, in situations where the underlying rationale of the doctrine—the traditional doctor-patient relationship—is no longer present, the doctrine has adapted to fit the realities of the situation.

¶56 This evolution has occurred on two principal fronts. The first of these, which has received the lion's share of the attention but is not at issue today, is when the duty to warn is extended not only to other healthcare providers, but to *patients*—thus, not applying the doctrine at all.[6] The second, which is directly relevant to our discussion, is

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[6] Three exceptions to the doctrine, imposing a duty to warn the consumer, have arisen in the courts. First, public health clinics and mass immunization programs have commonly been found to lack the requisite doctor-patient relationship. *See e.g. Davis v. Wyeth Laboratories*, 399 F.2d 121, 131 (9th Cir. 1968) (manufacturer of polio vaccine was not protected by the learned intermediary doctrine because the vaccine was dispensed at a mass immunization clinic, outside the context of the doctor-patient relationship); *accord Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276-77 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096, 95 S. Ct. 687 (1974). Second, when the patient is actively involved in choosing to use a given drug, some courts have not applied the doctrine. This exception has usually arisen in relation to birth control pills. *See e.g. MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d. 65, 68-70 (Mass. 1985); *Hill v. Searle Laboratories*, 884 F.2d 1064, 1070-71 (8th Cir. 1989). Third, some courts have declined to apply the doctrine where there has been excessive direct-to-consumer advertising of the drug. *See e.g. State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 901 (W. Va. 2007).

Secondary sources have vigorously argued for both preservation of the doctrine, and for its elimination in some (or all) circumstances. For a defense of the traditional form of the doctrine, see Jennifer Girod, Note, *The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present*, 40 Ind. L. Rev. 397, 398 (2007) (arguing that while doctor-patient relationships have changed since the doctrine was first adopted, the doctrine is as relevant as ever because the disparity between physician and patient knowledge still exists). For arguments against the doctrine's continued relevancy, see Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 Wm. Mitchell L. Rev. 931, 934-37 (1993); Teresa Moran Schwartz, *Consumer-Directed Prescription*

the evolution of the doctrine through an expansion of the possible class of learned intermediaries. This development, likewise spurred by the fact that the medical professionals with whom patients most commonly interact are often no longer primary physicians, has led courts and secondary sources such as the Restatement to suggest that a variety of different healthcare providers may be considered learned intermediaries, depending on the unique facts of the patients' treatment scenario.[7]

Drug Advertising and the Learned Intermediary Rule, 46 Food Drug Cosmetic L. J. 829, 829-31 (1991).

[7] *See Holley* and *McEwen*, discussed *infra* ¶¶ 57-58; *Whitley v. Cubberly*, 210 S.E.2d 289, 292 (N.C. 1974) (requiring warnings to all members of the "medical profession" using the drug); *Singleton v. Airco*, 314 S.E.2d 680 (Ga. 1984) (considering the adequacy of warnings directed at trained nurse anesthesiologists); *Mazur v. Merck & Co.*, 964 F.2d 1348, 1356 (3d Cir. 1992) (declining to extend the doctrine to a school nurse, but indicating that the doctrine would extend to nonprescribing physicians, physicians' assistants, and nurses acting in an area of special expertise); *Walker v. Merck & Co.*, 648 F. Supp. 931, 934-35 (M.D. Ga. 1986), *aff'd*, 831 F.2d 1069 (11th Cir. 1987) (finding that Georgia law considered nurse practitioners to be learned intermediaries); *Rohrbough v. Wyeth Labs.*, 719 F. Supp. 470, 478 (N.D. W. Va. 1989) (designating registered nurses who administered vaccines as learned intermediaries); *Wyeth-Ayerst Lab Co. v. Medrano*, 28 S.W.3d 87, 92-94 (Tex. Ct. App. 2000) (concluding that the doctrine applies to advanced practice nurses who prescribe medication and treat patients without the supervision of a physician); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973) (extending the duty to warn to treating as well as prescribing physicians).

For secondary sources arguing for or observing the doctrine's evolution to fit modern healthcare, see Robert J. Friedman, *Take Two of These and Sue Me in the Morning: Efficacy of the Learned Intermediary Doctrine in Prescription Drug Failure to Warn Cases*, 22 St. Thomas L. Rev. 278 (2010); Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. Det. Mercy L. Rev. 267, 267-68 (2004); Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 Seton Hall L. Rev. 193, 198 (2004); Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 Cardozo L. Rev. 2241, 2254-56 (2004); Daniel Richardson, Note, *The Lost Child of Products Liability: New Thoughts about Advertising and the Learned Intermediary Doctrine*, 27 Vt. L. Rev. 1017, 1018 (2003); Paul F. Strain & Christina Gaarder, *Direct-to-Consumer Advertising and the Learned Intermediary Doctrine: Unsettling a Settled Question*, 30 U. Balt. L. Rev. 377, 382-83 (2001); Mitchell S. Berger, *A Tale of Six Implants: The* Perez v. Wyeth Laboratories Norplant *Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 Food & Drug L.J. 525, 551 (2000); Timothy A. Pratt & John F. Kuckelman, *The Learned Intermediary Doctrine & Direct-*

¶57 For example, in *Holley v. Burroughs Wellcome Co.*, 330 S.E.2d 228, 235-36 (N.C. App. 1985), the court considered a registered nurse anesthesiologist who was responsible for the patient's anesthesia to be a learned intermediary to whom the manufacturer owed a duty to warn. The CRNA failed to recognize a known adverse reaction, which caused permanent brain damage in the patient. Just as Novartis argues today, the manufacturer asserted that its duty to warn was satisfied because the learned intermediary doctrine limited the scope of its duty to warn to the prescribing physician. The court was not persuaded. Noting that it was "standard practice" for CRNAs to be responsible for monitoring, maintenance, and supervisory care of anesthetized patients, the court dismissed the argument that the duty to warn only extended to the prescribing physician as "unpersuasive in the present context," and "not appropriate in actions like the present one." *Id.* at 235. The court reasoned that while the "[d]efendants' argument would be appropriate in cases . . . where a nurse only administered a medicine . . . but was otherwise not responsible for the patient's care," the nurse anesthesiologist in *Holley* was responsible for all aspects of patient treatment. Thus, the court concluded, the duty to warn ought to apply to her as the primary healthcare provider standing in between the patient and the manufacturer. *Id.*

To-Consumer Advertising of Prescription Drugs, 51 Fed'n. Ins. & Corp. Counsel Q. 17 (2000), available at http://www.thefederation.org/documents/pratt.htm (April 5, 2004); Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 Stan. L. Rev. 1343, 1349 n. 24 (1999); Edward W. Gerecke & Harvey L. Kaplan, *The Restatement (Third) of Torts and its Projected Impact Upon Manufacturers of Prescription Drugs and Medical Devices,* Drug and Medical Device Litigation: Defense Perspectives, 2 Def. Research Inst. 70, 71 (1998); 63A Am. Jur. 2d Products Liability §§ 1206-07 (1997); Jerry J. Phillips, *Products Liability in a Nutshell* 225-29 (4th ed., West 1993) (hornbook discussion of the doctrine).

¶58 Similarly, in *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 528-30 (Or. 1974), the court reviewed the underlying premise of the doctrine and extended the duty to warn beyond the prescribing physician. The plaintiff had been prescribed a contraceptive, but received treatment for a negative reaction to the drug from other physicians. The court explained that "[a]lthough the ethical drug manufacturer's duty to warn has been discussed most often with reference to the prescribing physician, the [doctrine's] reasoning applies with equal force to the treating physician . . . [who] may be more likely to observe the actual symptoms of the drug's untoward consequences." The court concluded that the manufacturer's duty to warn "extends, then, to all members of the medical profession who come into contact with the patient in a decision-making capacity." *Id.* at 529.

¶59 The realities of modern medicine increasingly conflict with the learned intermediary doctrine's underlying premises. Unsurprisingly, the doctrine is in a state of flux as it adapts to new medical practices. We need not set out the precise confines of the doctrine as it would apply to numerous hypothetical scenarios. We concur with authorities who consider the learned intermediary to be the healthcare professional actually responsible for making decisions related to the patient's care, especially when the prescribing physician is no longer involved with the continuing treatment and supervision of the patient. In these instances, the underlying rationale of the individualized relationship between the prescribing physician and the patient is truly no longer present. Here, it is clear that Stevens received much of her treatment from nurses, treating physicians, and nurse practitioners, and that Dr. Schmidt was rarely, if ever, a

participant in her continuing care. Most importantly, when Stevens called Dr. Schmidt's practice to discuss the risk of dental surgery while on Zometa, she spoke with a locum tenens physician rather than Dr. Schmidt herself.

¶60 These facts suggest that the scope of Novartis' duty to warn, in this case, would presumably include at least the treating locum tenens physicians at Guardian Oncology who counseled Stevens on dental surgery, if not the nurses who routinely administered Zometa to Stevens.[8] We do not find the Restatement, nor the District Court's instructions, at odds with the body of law in this area, or with any precedent set out by this Court in *Hill*. We need not conclusively decide this issue today, however, because Novartis cannot demonstrate that the instruction resulted in prejudicial error.

¶61 Novartis cannot demonstrate prejudicial error because the jury verdict form allowed the jury to find Novartis negligent *without* relying on the allegedly deficient jury instruction. The jury verdict form asked whether Novartis was negligent "in its label *or* information to Dr. Judy Schmidt and Guardian Oncology treating professional staff." (Emphasis added.) Accordingly, the jury had two options: (A) the label was inadequate, or (B) the information provided to Dr. Schmidt and the treating staff was inadequate. The error complained of—an overbroad scope of the duty to warn—is *only* implicated

[8] The trial court also seemed to include Dr. Morris, the oral surgeon, within the scope of the duty to warn. Novartis asserts that this was erroneous; however, any such error could not have affected the verdict, as the jury verdict form asked only whether Novartis was negligent in its warnings to Dr. Schmidt and Guardian Oncology staff—thus excluding Dr. Morris from consideration.

with regard to (B), the "information," and *not* with regard to (A), the label.[9] Accordingly, Novartis cannot demonstrate that the duty to warn was even considered by the jury in reaching its verdict, and therefore cannot demonstrate prejudicial error as a result of the instruction.

¶62 Thus, while we would tend to conclude that the jury instruction correctly instructed the jury on the applicable law, we need not definitively resolve this issue today. It is clear that because the instruction was not implicated by one of the two mutually exclusive alternatives, Novartis cannot demonstrate that the instruction resulted in prejudicial error. We affirm the District Court.

¶63 ***3. Whether the District Court erred in refusing Novartis permission to amend its complaint to include an apportionment defense.***

¶64 We review the denial of a motion to amend, like other discretionary rulings made by a district court, for an abuse of discretion. *Deschamps v. Treas. St. Trailer Ct., Ltd.*, 2010 MT 74, ¶ 18, 356 Mont. 1, 230 P.3d 800. The trial court's decision will not be reversed in the absence of an affirmative showing of abuse of that discretion resulting in prejudice. *Id.* (citing *Callan v. Hample*, 73 Mont. 321, 326, 236 P. 550, 551-52 (1925)). Amendments are permitted by M. R. Civ. P. 15(a), which provides that a party may amend the party's pleading by leave of the court. The proposed amendment should be

[9] The "information" provided by Novartis appears from the record to consist of two items: 1) the label, that is, the package insert in every Zometa package, and 2) a letter that Novartis sent to Dr. Schmidt, in response to an inquiry Dr. Schmidt made regarding two Zometa patients who had developed ONJ. As Dr. Schmidt was apparently the only recipient of this letter, the "information" received by Dr. Schmidt and other clinic staff was arguably different, which implicates the scope of Novartis' duty to warn. The label, in contrast, was obviously the same for all and was received by everyone at the clinic, and thus does *not* implicate the scope of the duty to warn.

permitted, in keeping with the policy that leave to amend "shall be freely given when justice so requires," unless: (1) the "motion causes undue delay, is made in bad faith, is based upon a dilatory motive on the part of the movant, or is futile," or (2) "the party opposing the amendment would incur substantial prejudice as a result of the amendment." *Stundal v. Stundal*, 2000 MT 21, ¶ 12, 298 Mont. 141, 995 P.2d 420.

¶65 The District Court denied Novartis permission to amend its complaint to assert a defense seeking to apportion liability between Novartis and Dr. Schmidt for the damages suffered by Stevens. The court's stated basis was that Novartis had not acted with reasonable promptness, given that almost two months had passed since the notice of settlement between Dr. Schmidt and Stevens. The court reasoned that to allow amendment to include a completely new defense with less than a month before trial would substantially prejudice Stevens, who had repeatedly sought to discover whether Novartis planned on asserting that any third parties shared responsibility for Stevens' injuries.

¶66 We conclude that it was within the District Court's discretion to deny leave to amend the pleadings. Novartis sought to introduce an entirely new defense shortly before the trial date and offers no persuasive reason for its delay in doing so. Stevens' counsel had clearly been trying for some time to learn whether Novartis sought to add this defense, which would plainly be a central and vigorously contested issue at trial, in an effort to prepare adequately should Novartis seek to apportion liability. We see no reason aside from an attempt to gain an advantage why Novartis should not have made clear its intention to blame Dr. Schmidt from its initial appearance in the case. Its delay in doing

so until Dr. Schmidt no longer had a reason to defend herself speaks volumes. Novartis' complaint that the District Court's ruling on this issue caused it irreparable harm by "preventing it from making the case for the liability of Dr. Schmidt" is a far cry from an accurate representation of the proceedings below. Novartis easily could have made such a case, were it upfront about its intention to do so at any time in the eight months after it was joined as a party. We affirm the District Court's denial of leave to amend.

¶67 ***4. Whether the District Court erred in excluding statements made in prior pleadings that were allegedly inconsistent with Novartis' liability.***

¶68 Novartis argues that it was deprived of a fair trial by the District Court's exclusion of two statements made in prior pleadings: a statement made by Stevens in her initial complaint in the present case, and a statement made by Dr. Morris in an answer filed in response to Stevens' complaint against him before the MMLP. We will first set out the general framework governing admissibility of prior pleadings, and then address each statement in turn.

¶69 ***A. Admissibility of prior pleadings in general.***

¶70 At common law, statements in pleadings were generally not admissible as evidence. This rule arose from the former nature of pleadings, which were filled with hypothetical allegations and legal conclusions framing the issues of the case in terms of numerous fictional common-law counts.[10] These pleadings served technical and discovery purposes, and statements made therein were rightly considered attributable to

[10] Note, *The Admission in Evidence of Pleadings Under the Codes and Under the Federal Rules of Civil Procedure*, 106 U. Pa. L. Rev. 98, 98 (1958).

the attorney rather than the client on whose behalf the pleading was prepared.[11] But with the adoption of the modern rules eschewing technical pleading in favor of fact-based pleading, the underlying rationale behind the rule began to fade away. As the modern system requires parties to plead facts, the statements made in pleadings are now often considered to have evidentiary value. Modern pleadings also service a notice function and permit hypothetical and inconsistent claims, however, so some limitations do exist.

¶71 The manner in which these statements are admissible in court depends on a variety of factors. Such factors may include: whether the statements in the pleadings are sought as substantive evidence or as impeachment evidence, whether the pleadings have been since amended or superseded, whether the pleadings were filed in the same case or in an unrelated action, or whether the statements are of fact or law, among other considerations. Admissibility is of course also subject to traditional evidentiary considerations, such as relevance, materiality, and prejudice. The common law rule barring the evidentiary use of pleadings has survived only as an exception, as some courts have declined to hold parties responsible for allegations in their pleadings when it is evident that they truly had little idea of the contents therein.[12]

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[11] Patrick Hughes, *Evidence: Can What I Said Be Held Against Me?: Admitting Settlement Agreements and Prior Pleadings in Multiple-Defendant Comparative Negligence Actions*, 32 Washburn L.J. 260, 269 n. 58 (1993).

[12] 81 Am. Jur. 2d *Witnesses* § 908 (2004) provides:

> As a general rule, statements made in a pleading are admissible to discredit or impeach the pleader when he or she becomes a witness . . . except where the pleader cannot be personally charged with responsibility for the allegations of the pleading, as where he or she was not aware of the contents of the pleading, or did not sign or authorize it or have knowledge of the allegations in question.

¶72 ***B. Stevens' statement.***

¶73 In the present suit, before Novartis was joined to the case, Stevens alleged that Dr. Schmidt was aware of the risks associated with Zometa and was negligent in failing to communicate those risks. This statement was made in Stevens' original complaint, and was repeated in her amended complaint, expert disclosures, and discovery responses to Dr. Schmidt. In the lower court, Novartis offered two rationales for the admissibility of these statements. First, Novartis argued that the statements were admissible as judicial admissions. Alternatively, Novartis argued that the positions taken in these pleadings were inconsistent with Stevens' position at trial and that Stevens should therefore be judicially estopped from denying their veracity. We discuss these contentions in turn.

¶74 Novartis first argues that the statements made by Stevens in her prior pleadings are judicial admissions. Montana's general rule is that "allegations, statements, or admissions contained in a pleading are conclusive as against the pleader, and are admissible as against the party making them in the litigation as proof of the facts which they admit." *Meadow Lake Ests. Homeowners Ass'n v. Shoemaker*, 2008 MT 41, ¶ 45, 341 Mont. 345, 178 P.3d 81 (quoting *Anderson v. Mace*, 99 Mont. 421, 427-28, 45 P.2d 771, 773-74 (1935)). Judicial admissions may clearly be made at "any point during the litigation process," including "during discovery, pleadings, opening statements, direct and cross-examination, as well as closing arguments." *In re Est. of Hill*, 281 Mont. 142, 149-50, 931 P.2d 1320, 1325 (1997) (quoting *Kohne v. Yost*, 250 Mont. 109, 112, 818 P.2d 360, 362 (1991)). In Montana, a judicial admission "has a conclusive effect upon the party who makes it, and prevents that party from introducing further evidence to

prove, disprove, or contradict the admitted fact." *In re Raymond W. George Trust*, 1999 MT 223, ¶ 36, 296 Mont. 56, 986 P.2d 427 (quoting *DeMars v. Carlstrom*, 285 Mont. 334, 337, 948 P.2d 246, 248 (1997)). A judicial admission is not binding, however, unless it is an unequivocal statement of *fact*, as opposed to a conclusion of law or the expression of an opinion. *Id.* at ¶ 37 (emphasis added) (citing *DeMars*, 285 Mont. at 338, 948 P.2d at 249; *Kohne*, 250 Mont. at 113, 818 P.2d at 362).

¶75 In *George Trust*, we held that a statement made by a party relating to that party's ownership of an interest in trust property was a conclusion of law, not a statement of fact, and was thus not a judicial admission. In the present case, the statements made by Stevens through her attorney were allegations made on the flawed information available to Stevens at the time, which demonstrates that they were mere expressions of opinion and conclusions of law, rather than statements of fact. "[A] judicial admission applies to facts, not to legal theories or positions." *Stanley L. and Carolyn M. Watkins Trust v. Lacosta*, 2004 MT 144, ¶ 34, 321 Mont. 432, 92 P.3d 620. The District Court correctly ruled that Stevens' statements made in prior pleadings were not judicial admissions because they were not statements of fact.

¶76 Novartis next contends, in the alternative, that Stevens should be judicially estopped from denying the statements made in her prior pleadings. The doctrine of judicial estoppel precludes a party from taking a position inconsistent with previously made declarations in a subsequent action or proceeding. *Watkins Trust*, ¶ 33. Judicial estoppel applies only when: (1) the estopped party had knowledge of the facts at the time he or she took the original position; (2) the estopped party succeeded in maintaining the

original position; (3) the position presently taken by the estopped party is inconsistent with its original position; and (4) the original position misled the adverse party so that allowing the estopped party to change its position would injuriously affect the adverse party. *Id.* (citing *Kauffman-Harmon v. Kauffman*, 2001 MT 238, ¶ 16, 307 Mont. 45, 36 P.3d 408).

¶77 We conclude that the doctrine of judicial estoppel is not applicable here. First, the present case is not a "subsequent action or proceeding"—it is the same proceeding, as Stevens correctly observes. Furthermore, there is nothing to suggest that Novartis was "misled" by Stevens' alleged prior positions. Nor has Novartis shown that Stevens had knowledge of the facts surrounding Novartis' prior warnings to Dr. Schmidt at the time—to the contrary, the record suggests that Stevens believed that the failure to warn was attributable to Dr. Schmidt rather than Novartis.

¶78 Novartis also raises the argument, for the first time on appeal, that the pleadings are admissible pursuant to M. R. Evid. 801(d)(2), as statements of a party offered against a party. While sometimes referred to as "admissions against interest," statements under Rule 801(d)(2) need not be against the party's interest at the time the party made the statement, nor need be a statement of fact rather than a legal opinion or position. Kristine C. Karnezis, *Admissibility of Party's Own Statement Under Rule 801(d)(2)(A) of the Federal Rules of Evidence*, 191 A.L.R. Fed. 27, 72-78 (2003). Statements made by an attorney in prior pleadings, discovery materials, and the like are generally admissible against clients under the federal rule, which is "identical" to the Montana rule. Commn. Comments, M. R. Evid. 801(d)(2)(A); Karnezis, 191 A.L.R. Fed 27 at 170-81; *Totten v.*

Merkle, 137 F.3d 1172, 1176 (9th Cir. 1998); *Dugan v. EMS Helicopters, Inc.*, 915 F.2d 1428, 1431-34 (10th Cir. 1990). But regardless of the strength or weakness of this theory, the trial court must be given the opportunity to weigh such an argument against traditional evidentiary considerations such as prejudice and relevance, which might still tip the scales in favor of the inadmissibility of the statement. We will not fault the District Court for failing to rule on an issue it was never given the opportunity to consider. The rule is well established that this Court will not address an issue raised for the first time on appeal. *State v. Gomez*, 2007 MT 111, ¶ 21, 337 Mont. 219, 158 P.3d 442 (citing *State v. Peterson*, 2002 MT 65, ¶ 24, 309 Mont. 199, 44 P.3d 499).

¶79 For the reasons above, we affirm the District Court's exclusion of the prior statements made by Stevens concerning Dr. Schmidt's alleged culpability.

¶80 ***C. Dr. Morris' statement.***

¶81 Novartis maintains that the trial court erred by excluding a statement contained in a pleading filed by Dr. Eugene Morris before the Montana Medical Legal Panel (MMLP). The response, prepared by Dr. Morris' attorney, was filed in answer to Stevens' MMLP complaint against Dr. Morris. Novartis sought to use the answer, which stated that extraction of Stevens' tooth through dental surgery was "the only realistic treatment option," to impeach Dr. Morris' trial testimony that alternatives to extraction did exist. Novartis maintains that this evidence was critical to its argument as to proximate cause, because it shows that Stevens had no option but to undergo the dental surgery, and that a failure to warn could thus not have caused Stevens' injury.

¶82 Two considerations relate to the statement's admissibility. First, the parties dispute whether the statement is admissible for impeachment purposes as a prior inconsistent statement made by Dr. Morris. The trial court supported Stevens' argument that the statement should be excluded because it was not a statement of the witness, Dr. Morris—it was a statement of the witness' attorney, unsigned by the witness, and thus could not be used to impeach the witness. Second, the parties dispute the holding in *Linder v. Smith*, 193 Mont. 20, 30, 629 P.2d 1187, 1192 (1981), a Montana Supreme Court case that held a prior statutory bar on use of MMLP proceedings for impeachment purposes unconstitutional. Novartis maintains that the decision made all parts of the MMLP proceedings available for impeachment purposes, while Stevens asserts that the holding is limited to sworn testimony given during a MMLP hearing. We will first consider whether the statement is available for impeachment purposes as a prior inconsistent statement.

¶83 M. R. Civ. P. 801 provides that if a declarant testifies at trial, is subject to cross-examination, and makes a statement which is inconsistent with a prior statement, then the prior inconsistent statement is by definition not subject to the hearsay bar. Clearly, the statement made in Dr. Morris' prior pleading was inconsistent with his testimony in trial. But while some jurisdictions condition admissibility of prior pleadings on whether they are signed or otherwise verified,[13] in Montana, parties are responsible for all statements made by their attorneys within the scope of representation, whether made

[13] For a list of cases, see Note, *supra* n. 10, at 100 nn. 13-14; Floyd E. Lawson, Jr., *Pleadings and Practice—Evidence—Admissibility of Pleadings into Evidence in Missouri*, 27 Mo. L. Rev. 258, 265 n. 55 (1962).

in pleadings or in open court. *Est. of Hill*, 281 Mont. at 149, 931 P.2d at 1325; *Kohne*, 250 Mont. at 112, 818 P.2d at 362; *Rasmussen v. Heebs Food Ctr.*, 270 Mont. 492, 496-97, 893 P.2d 337, 340 (1995).[14] We therefore conclude that the District Court erred to whatever extent it based its decision to exclude the statement on the fact that the pleadings were prepared by Dr. Morris' attorney.[15] We will uphold the District Court if it reaches the right result for the wrong reason, however, and thus we must consider whether the statement was otherwise inadmissible, and whether any error constitutes grounds for reversal.

¶84 Dr. Morris' prior inconsistent statement arose out of the action filed against him by Stevens before the MMLP. The proceedings of the Panel are similar in form to regular court actions, but are entirely a creature of statute, separate and distinct from regular courts and the rules applicable to regular court actions. It is therefore incorrect to assume that principles applicable to standard proceedings are also applicable to MMLP proceedings, despite their outward similarity. The Act stresses that MMLP hearings are "confidential and informal," and that "the Montana Rules of Evidence shall not apply to hearings before the Panel." Section 27-6-502, MCA, Rule 15(c). It is unclear, however, to what degree the statutorily-mandated confidentiality of the proceedings overrides competing principles. In *Linder*, we severed part of the Act *sua sponte*, on the basis that

[14] Stevens' counsel stressed that the answer filed by Dr. Morris in the MMLP proceeding was informal and that Dr. Morris had little awareness of its contents, seeking (without stating as much) an exception in Montana law for situations in which the statements of counsel are *not* fairly attributed to the party. We express no opinion on the merits of such an exception—we merely observe that the position Stevens advanced, and that the District Court apparently agreed with, is not the law in Montana.

[15] We note that the basis for the lower court's ruling on this matter is somewhat unclear, and may have included consideration of arguments advanced by counsel but not repeated on the record.

it unconstitutionally infringed on the right to impeach the sworn testimony of a witness, by providing that "[no] statement made by any person during a hearing before the panel may be used as impeaching evidence in court." *Linder*, 193 Mont. at 30, 629 P.2d at 1192. This holding involved *testimony* before the MMLP panel, and not pleadings in the proceeding, as Stevens correctly observes. Conversely, however, as pleadings are not specifically addressed, it is unclear whether the general confidentiality provisions of the MMLP Act would trump the right to impeach a witness with a prior inconsistent statement made in the pleadings.[16]

¶85 Furthermore, assuming that the holding in *Linder* makes only sworn testimony available for use for impeachment purposes, it still remains unclear whether inconsistent statements made during other parts of the proceeding would be available for

[16] Our decision in *State ex rel. Hufford v. Montana Medical-Legal Panel*, 223 Mont. 73, 724 P.2d 186 (1986), provides a slight modicum of clarity on the issue. In *Hufford*, we considered plaintiffs' contention that the right to cross-examine witnesses at trial required that a transcript of MMLP proceedings be made available to them. The District Court ruled that the inability to access the transcript amounted to a denial of due process, but we reversed, explaining that "the very nature of the purpose of the Panel is advisory and therefore confidential," and that "denial of a transcript does not destroy the right of a party to fully cross-examine witnesses at trial." We cited *Linder* for the latter proposition, noting that with the exception of the stricken provision relating to witness testimony, we had upheld the constitutionality of the Act in our prior decision. *Hufford* thus suggests, without explicitly stating as much, that only the sworn testimony given during the MMLP hearing at issue in *Linder* must be exempted from the Act's overall imposition of confidentiality on the proceedings for the Act to give full effect to parties' rights to fairly cross-examine witnesses. Under this view, the proceedings would remain confidential, unless of course "no participant objects," as we recognized in *Hufford*. Ultimately, we concluded, "[w]hile a transcript of Panel proceedings would certainly assist a litigant in cross-examination at trial, it is not essential to exercise that right." *Hufford*, 223 Mont. at 76, 724 P.2d at 188. *See generally* Karlen J. Moe, *The Montana Medical Malpractice Panel Act: Origin, Procedure, and Effect*, 44 Mont. L. Rev. 281, 285-86 (1983).

impeachment should they be *voluntarily* made available to opposing parties.[17] The present case suggests no clear resolution. Perhaps understandably, given the breadth and depth of other issues on appeal, the parties have focused their attention elsewhere and have made only cursory, largely unsupported arguments on this issue. As we have previously held, it is not our obligation to conduct legal research, guess at precise positions, or develop legal analysis that may lend support to the parties' positions. M. R. App. P. 23; *State v. Lewis*, 2007 MT 295, ¶ 44, 340 Mont. 10, 171 P.3d 731. Because we find that any error alleged by Novartis was harmless, we decline to dive into these unexplored waters today.

¶86 In order for the erroneous admission of evidence to constitute grounds for a new trial, the error must be so significant as to materially affect the substantial rights of the complaining party. Section 25-11-102, MCA; *Stevenson v. Felco Indus.*, 2009 MT 299, ¶ 16, 352 Mont. 303, 216 P.3d 763. Our rule is that no reversible error occurs unless the evidence in question was of such character as to have affected the outcome of the trial. *Seltzer v. Morton*, 2007 MT 62, ¶ 65, 336 Mont. 225, 154 P.3d 561. While the evidence here may well have assisted Novartis in undermining Dr. Morris' credibility, we cannot conclude that this evidence was of such character as to have affected the outcome of the trial. Dr. Morris was merely one of many medical professionals at trial who testified that

[17] In the present case, Novartis' procurement of the pleading went largely unnoticed until the last moment, as it was apparently inadvertently produced through a subpoena of Dr. Schmidt's files at deposition. The trial court did not address whether the pleading was still protected by the confidentiality provisions of the Act, or whether it was voluntarily disclosed because no objection was made by Stevens at the time. These important determinations are properly made at the trial level, not by an appellate court.

there were alternatives to the surgery Stevens ultimately elected, and Novartis had ample opportunity to cross-examine both Dr. Morris and the other medical professionals, and to introduce its own evidence that no alternatives existed. Furthermore, the statement arose in an informal and confidential proceeding where Dr. Morris' counsel would be expected to file highly protective initial answers, and as such was likely of low probative value in any case.

¶87 For the reasons stated above, we affirm the District Court with respect to both the exclusion of statements made in Stevens' complaint and Dr. Morris' answer before the MMLP.

¶88 ***5. Whether the District Court erred in admitting testimony regarding a change to Novartis' warning label.***

¶89 Novartis contends that it is entitled to a new trial because the trial court erroneously admitted evidence of a change to Novartis' Zometa warning label, allegedly in order to demonstrate that Novartis should have given the later warning *prior* to the surgery. Novartis argues that the evidence is inadmissible under M. R. Evid. 407, which provides that evidence of subsequent remedial measures is "not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning instruction." Novartis asserts that the trial court erred in permitting Nurse Joni Landes, Dr. Schmidt's office manager, to testify to a change in the label, and contends that Landes' testimony was offered as "proof that [Novartis'] prior warnings were not adequate."

¶90 Stevens paints a starkly different picture. She responds that the "remedial measure" testified to by Landes, and complained of by Novartis, was actually a change in Guardian Oncology's office protocol, not a change in Novartis' label. Stevens asserts that any reference to Novartis' later label was in passing and not offered as substantive evidence. Furthermore, asserts Stevens, M. R. Evid. 407 is not applicable here because it only governs subsequent remedial measures taken by a *party*, not a non-party such as Guardian Oncology, in keeping with the premise of the rule: to dissuade parties from failing to remedy dangerous situations out of fear that their remedies will be seen as admissions of guilt. Lastly, Stevens asserts that even had the remedial measure been Novartis', it was not admitted to show liability, but rather to show that adequate warnings *would* have been passed on to Stevens were they given to Dr. Schmidt—a point which Novartis vigorously disputed.

¶91 We agree with Stevens that two distinct remedial measures are referenced by the parties. The first is the change in Novartis' warning label in February 2005, which more explicitly warned about the risk of ONJ. The second is the change in Guardian Oncology's office protocol for patients at risk of ONJ, also initiated in February 2005. We agree with Stevens that M. R. Evid. 407 is not applicable in the latter situation, and thus any evidence of the change in Guardian Oncology's office protocol is not prohibited by the rule. Evidence of Novartis' subsequent change in label, however, if offered to demonstrate the insufficiency of the warning that was given at the time of the surgery, *would* conceivably fall within the prohibition of the rule.

¶92 On closer examination of the trial transcript, it is clear that Novartis significantly mischaracterizes the uses to which Stevens put evidence of Novartis' changed label. While it is true that Landes did reference Novartis' change in label in early 2005, she did so only when contrasting information freely available in 2005 to information on the label at the time of Stevens' dental surgery in 2004, in an attempt to explain why Guardian Oncology had changed its office protocol. Landes explained that she initiated the change in office protocol as a result of receiving an Oncological Nursing Society bulletin detailing the risk of ONJ, which she received *before* Novartis changed its label. The change to the label was referenced only to provide chronological context for the receipt of the Nursing Society bulletin. Furthermore, Landes' testimony was introduced in order to rebut Novartis' argument that even if Guardian Oncology had received adequate warnings, the warnings would not have been passed on to patients like Stevens. Thus, while it is true that Landes spent some time discussing a remedial measure, and true that she did reference Novartis' change in label, it is not at all accurate to portray Landes' testimony as an attempt to introduce evidence of a subsequent remedial measure on Novartis' part. Novartis' attempt to conflate the clinic's change in procedure with Landes' brief reference to the changed label is entirely unpersuasive.

¶93 We conclude that the District Court correctly ruled that M. R. Evid. 407 was not applicable here. M. R. Evid. 407 does not prohibit evidence of subsequent remedial measures taken by non-parties. Nor does it prohibit "evidence" of a change in Novartis' package insert, in this case. Stevens did not use the subsequent label to show negligence or need for a warning, and thus the evidence is not prohibited by the rule. Rather,

Stevens referred to the subsequent Zometa label only in passing while discussing the change in Guardian Oncology office protocol. It was not offered as substantive evidence. Novartis' argument on this issue is utterly misleading and without merit.

¶94 We affirm the District Court.

¶95 ***6. Whether Novartis is entitled to judgment as a matter of law because Stevens failed to prove proximate causation.***

¶96 Novartis contends that Stevens failed to present evidence establishing proximate cause, because Stevens did not show that there were any options available to treat her fractured tooth that would have prevented her from developing ONJ. Given that Stevens needed an invasive dental procedure, Novartis argues, she did not show that the *specific* procedure undertaken was any more likely to cause ONJ than other procedures, such as crown lengthening, that might have been undertaken.

¶97 Stevens responds by summarizing the testimony of several experts called at trial. She contends that this expert testimony clearly shows that other procedures were available, and that the injury which caused her ONJ would not have occurred were she to have undergone these procedures. While we are sympathetic to the fact that the other procedures available to Stevens also carried a risk of ONJ, the unstated premise of Novartis' argument is that because all procedures carried some risk of ONJ, it would be *impossible* for Stevens to establish proximate cause. We do not agree. Expert testimony at trial showed that the trauma caused by tooth extraction caused Stevens' ONJ, and that this particular trauma to Stevens' jawbone would have been avoided by choosing less invasive options. The testimony also showed that Dr. Morris would not have undertaken

the tooth extraction if he had known of the risks of ONJ in Zometa patients such as Stevens. Stevens offered evidence of all links in the causal chain. We affirm the District Court.

¶98 ***7. Whether the District Court erred in refusing Stevens permission to amend her complaint to include a claim for punitive damages.***

¶99 On cross-appeal, Stevens claims that the District Court abused its discretion by not allowing her to amend her complaint to include a claim for punitive damages. Stevens previously petitioned this court for a writ of supervisory control on this issue, which we denied. The trial court ruled that to allow amendment of the pleadings at the time Stevens' petition was filed would unduly prejudice Novartis, because the entirely new issue of intent would be raised by a punitive damage claim.

¶100 While Stevens claims that the allegations would "not require additional time by [Novartis] to defend because they arose out of the same operative facts which served as the basis for [Novartis'] liability," it is immediately apparent that this is not the case. Defending against a charge of actual fraud or actual malice would have required Novartis to address an entirely new argument, and the facts related to such an argument would *not* be the same as those already at issue. The defense would have taken careful preparation and would have involved substantial discovery, and Novartis could not have adequately prepared in the three weeks before the end of the discovery period. The District Court had a legitimate interest in ensuring an efficient progression to the trial date, and we conclude that it did not abuse its broad discretion to deny leave to amend. The matter of amendment "rests within the sound discretion of the trial court, and its action will not be

reversed in the absence of an affirmative showing of abuse of that discretion resulting in prejudice." *Deschamps v. Treas. St. Trailer Ct., Ltd.*, 2010 MT 74, ¶ 18, 356 Mont. 1, 230 P.3d 800 (quoting *Callan v. Hample*, 73 Mont. 321, 326, 236 P. 550, 551-52 (1925)). No prejudice exists here. Stevens had ample time to alert Novartis to this claim and did not do so, and was thus properly prevented from adding it at the eleventh hour.

¶101 We affirm the District Court.

¶102 ***8. Whether the District Court erred in offsetting social security disability benefits against the general damages awarded by jury.***

¶103 Our final inquiry concerns whether the District Court erred in offsetting social security disability benefits from general damages. Stevens observes that under § 27-1-308, MCA, a plaintiff's recovery may only be reduced by "collateral sources," defined in § 27-1-307, MCA, as ". . . something that is later included in a tort award and which is made to or for the benefit of a plaintiff . . . ." As the jury only awarded general damages, Stevens argues, it is impossible to determine whether the damages that Novartis seeks to offset were included in the jury verdict. Novartis counters that the trial court correctly included all amounts "paid or payable" under the statute, and that the verdict was properly reduced.

¶104 Our decision in *Busta v. Columbus Hosp.*, 276 Mont. 342, 916 P.2d 122 (1996), controls resolution of this issue. In *Busta*, the defendant hospital sought to offset benefits received by the plaintiff from the Veterans' Administration against the damages awarded in the plaintiff's wrongful death action. As here, the jury was instructed that its award could include damages for economic loss, reasonable compensation for mental anguish,

and loss of "comfort, guidance, . . . care, protection and companionship," among other compensable losses. The jury returned a verdict with a single amount for all damages, without any breakdown of damages allotted to each of the losses. We held that without a breakdown of damages attributable to each loss, the lower court could not have properly determined how much of the award was attributable to damages for which the plaintiff would be compensated by collateral sources, as would be a prerequisite for any offset. Section 27-1-308, MCA, allows offsets only against "that part of a recovery which . . . [is] compensated by a collateral source." Thus, we concluded, ". . . there was no method by which the District Court could calculate what, if any amount, the hospital was entitled to offset by the amount of . . . benefits awarded," and no offset could be applied. *Busta*, 276 Mont. at 375, 196 P.2d at 142.

¶105 Here, as in *Busta*, the jury verdict does not set out what portion of its damage award is attributable to items subject to collateral source offsets—in this instance, losses due to diminished wage-earning capacity, for which Stevens will be compensated by social security disability benefits. Without this "line-item" breakdown of the damages awarded by jury, the District Court could not have complied with the mandate of § 27-1-308, MCA, that jury awards may only be reduced by amounts attributable to losses which are compensated by collateral sources. There was no basis on which to conclude that the disability benefits would compensate Stevens in whole or in part for damages which were included in the jury's award. Without a factual basis for the offset, the District Court erred in concluding that Novartis was entitled to offset the jury award by Stevens' disability benefits. No offset should have been permitted.

¶106 For the reasons above, we reverse the judgment of the District Court as to the social security disability benefits offset, and remand for further proceedings consistent with this opinion.

¶107 ***9. Whether the District Court erred in dismissing Stevens' negligence claims against Patrick Doyle, a sales representative for Novartis.***

¶108 Because we affirm the District Court on issues 1 through 7, we need not consider this issue.

¶109 Affirmed in part, reversed in part, and remanded for further proceedings consistent with this opinion.

/S/W. WILLIAM LEAPHART

We concur:

/S/ MIKE McGRATH
/S/ JAMES C. NELSON
/S/ PATRICIA COTTER
/S/ MICHAEL E WHEAT
/S/ BRIAN MORRIS
/S/ JIM RICE