

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: LEVAQUIN PRODUCTS
LIABILITY LITIGATION,

MDL No. 08-1943 (JRT)

This Document Relates to:

JOHN SCHEDIN,

Civil No. 08-5743 (JRT)

Plaintiff,

v.

JOHNSON & JOHNSON; ORTHO-MCNEIL
PHARMACEUTICAL, INC.; JOHNSON &
JOHNSON PHARMACEUTICAL
RESEARCH & DEVELOPMENT, LLC; and
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC.;

**ORDER GRANTING PLAINTIFF'S
MOTION TO AMEND COMPLAINT
TO ADD DEMAND FOR PUNITIVE
DAMAGES**

Defendants.

Ronald S. Goldser, **ZIMMERMAN REED, PLLP**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402-4123; and Lewis J. Saul, **LEWIS SAUL & ASSOCIATES**, 183 Middle Street, Suite 200, Portland, ME 04101, co-lead counsel for plaintiff Schedin.

John Dames, **DRINKER BIDDLE & REATH LLP**, 191 North Wacker Drive, Suite 3700, Chicago, IL 60606-1698; William H. Robinson, Jr., **LECLAIR RYAN**, 1100 Connecticut Avenue N.W., Suite 600, Washington, DC 20036; and Tracy J. Van Steenburgh, **NILAN JOHNSON LEWIS, PA**, 400 One Financial Plaza, 120 South Sixth Street, Minneapolis, MN 55402, liaison and lead counsel for defendants.

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RICHARD D. SLETTEN
JUDGMENT ENTD _____
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Before the Court is a motion brought by a plaintiff whose lawsuit has been consolidated with hundreds of other cases in this multidistrict litigation (“MDL”). Plaintiffs assert injuries resulting from the use of Levaquin, an antibiotic agent. (*See generally* Plfs.’ Stat. of the Case, MDL Docket No. 37¹.) Plaintiff John Schedin’s “bellwether” trial is set to commence November 15, 2010. Schedin has moved to amend his complaint to add a demand for punitive damages. The Court heard oral argument on the motion on September 28, 2010. For the reasons stated below, the Court grants the motion.

BACKGROUND

As this Court is considering Schedin’s motion to amend his complaint to assert a claim for punitive damages, *see* Minn. Stat. §§ 549.191, 549.20, “the facts are recounted from a fair reading of the Plaintiff’s version of the evidence.” *Olson v. Snap Prods., Inc.*, 29 F. Supp. 2d 1027, 1029 (D. Minn. 1998).

Levaquin is the brand name for levofloxacin, a broad spectrum synthetic antibiotic used to treat a variety of upper respiratory infections, urinary tract infections, prostatitis, and other bacterial infections. (Compl. ¶ 15, Docket No. 1.) It is part of a class of antibiotics, including ciprofloxacin (“Cipro”) and ofloxacin (“Floxin”), known as fluoroquinolones. (*Id.* ¶ 16.) In February 2005, Schedin, then seventy-seven years old, consumed Levaquin prescribed to him to treat an upper respiratory infection. (*Id.* ¶ 108.) Schedin used Levaquin for approximately eight days, after which he suffered partial,

¹ Record citations reference the docket in Schedin’s case unless otherwise noted.

bilateral Achilles tendon tears. (*Id.*) Schedin alleges that as a result of his Levaquin-induced tendon tears, his “ability to perform normal daily tasks has been compromised and his quality of life has been severely diminished.” (*Id.*) Defendants were involved in the development, testing, manufacturing, marketing, and sale of Levaquin. (*Id.* ¶ 110.)

According to one of Schedin’s expert witnesses, levofloxacin’s pharmacological properties and effects are similar to its predecessor antibiotic, ofloxacin. (*See* Cialkowski Aff., July 30, 2010, Ex. 19 at 4-5, Docket No. 25.) Daiichi, the company that developed oxofloxacin, isolated levofloxacin, one of two biologically active enantiomers in ofloxacin. *Ortho-McNeil Pharm., Inc. v. Lupin Pharm., Inc.*, No. 06-4999, 2009 WL 1228448, at *1 (D. N.J. May 1, 2009). Enantiomers are “chemical components that are complete mirror images of each other.” *Id.* The United States Food and Drug Administration (“FDA”) approved ofloxacin tablets for sale in the United States in 1990, and the drug was marketed under the brand name Floxin. *Id.* In its New Drug Application (“NDA”) for Levaquin submitted to the FDA, defendants asserted that levofloxacin had a “nonclinical pharmacology . . . qualitatively similar to that of ofloxacin.” (*See* Cialkowski Aff., Ex. 22 at 12, Docket No. 25.)

Schedin asserts that fluoroquinolones have long been associated with serious side effects. (*See, e.g.*, Cialkowski Aff., Exs. 1-16, Docket No. 25.) In particular, research indicates that fluoroquinolones can cause tendon ruptures. (*See, e.g., id.*, Ex. 27.) Schedin cites studies of fluoroquinolones, including ofloxacin **but not levofloxacin**, beginning in the mid-1990s suggesting that patients over sixty years old, especially those using corticosteroids, may be at an increased risk of tendon injury. (*See id.*, Exs. 1, 2, 40.)

As early as 1996, medical research suggested that **ofloxacin had a greater capacity to injure tendons than other fluoroquinolones**. (*See id.*, Ex. 3.) Defendants were aware of this medical literature. (*See, e.g., id.*, Exs. 37-38.)

Levaquin was first introduced to the U.S. market in 1997 after acquiring FDA approval. *Ortho-McNeil Pharm., Inc.*, 2009 WL 1228448, at *2. In 1999, a Daiichi representative wrote to defendants and reported that “[a]n increase in the reporting rate of . . . tendons [sic] disorders has been seen with levofloxacin cases received from some License Partners during the last six-month period.” (Cialkowski Aff., Ex. 31, Docket No. 25.) Minutes from a subsequent meeting between marketing partner representatives² about the issue state that defendants noted an increase of tendon disorders associated with levofloxacin use from seven cases in 1997 to fifteen cases in 1998. (*Id.*, Ex. 32 at 3.) Meeting participants observed that “the concomitant use with steroid [sic] was reported to increase of [sic] the rate of tendon disorders.” (*Id.*)³

Levaquin’s initial label included the warning that the FDA required for all fluoroquinolones: “Ruptures of the shoulder, hand and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving

² Aventis Pharmaceutical (“Aventis”), the company which manufactured, distributed, and marketed levofloxacin in Europe under the brand name Tavanic, was a marketing partner of defendants.

³ However, the rate of tendon injury reports associated with the drug was apparently lower in Japan. (*Id.*) Schedin asserts that defendants “mised the FDA” in 1999 when its report of the worldwide failure rate for Levaquin included the “inexplicabl[y]” low rate of tendon injury in Japan without acknowledging that other countries experienced “much higher rates.” (*See Pl.’s Mem. in Supp. at 9, Docket No. 24.*)

quinolones. Levofloxacin should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon.” (Compl. ¶¶ 44, 48.) The warning was, according to Schedin, “buried in a long list of potential adverse reactions.” (*Id.* ¶ 45; *see also id.* ¶ 64 (“It was the last of the warnings listed, with no header or any other identification to alert a practitioner to this unusual side effect. The warning was behind gastrointestinal affects, hypersensitivity reactions, and even the rare event of anaphylactic shock.”).)

Medical research in the early 2000s, of which defendants were aware, continued to suggest that the risk of tendonitis was highest following the use of ofloxacin as compared to other fluoroquinolones. (*See, e.g., id.*, Ex. 41 at 50; *see also id.*, Ex. 38.) Schedin also proffers research, of which defendants were aware, suggesting that **tendon injury occurred most frequently with levofloxacin as compared to other fluoroquinolones, and that older age and use of steroids were factors that increased the risk.** (*See, e.g., id.*, Ex. 14 (“[C]ertain indications and levo are independently associated with a higher reporting of cases of tendon disorders and ruptures. Sales figures . . . cannot explain a higher reporting with levo than with other [fluoroquinolones].”), Ex. 15 (“Levofloxacin was the fluoroquinolone associated with the highest rate of serious tendon disorders”), Ex. 16 (“[A]fter the change of prescription recommendations, there was a sudden increase of Achilles tendon disorders among elderly patients in the region.”); *see also* Exs. 47-49.)

By 2001, motivated by this literature several European regulatory authorities decided to take corrective action such as imposing labeling changes to strengthen the warning for levofloxacin. (*See id.*, Ex. 55.) In France, for example, a “Dear-Doctor-

Letter” and labeling change were imposed regarding the high risk of tendon disorders for elderly patients under corticosteroid therapy. (*Id.*, Ex. 55 at 2.) Schedin argues that defendants were concerned about the repercussions of these regulatory actions in Europe regarding levofloxacin’s label. In an email sent July 26, 2001, one employee of defendants stated that “[t]he repercussions from an adverse regulatory decision in France . . . would be immediate and devastating so let’s acts [sic] promptly.” (*Id.*, Ex. 63.)

In a July 24, 2001 meeting with defendants and Daiichi, Aventis—defendants’ marketing partner for levofloxacin in Europe – proposed conducting an epidemiological study using data from the U.S. health insurance provider Aetna. (*Id.*, Ex. 59.) The original meeting notes capture a comment from defendants that “[u]sing Aetna consisting of data collected in US is not acceptable because **if the result of the study were not preferable, it would affect [the] levofloxacin market in US.**” (*Id.* (emphasis added).) The meeting notes were subsequently amended to characterize defendants’ concern as follows: “[u]sing Aetna [information] consisting of data collected in [the] US is not entirely acceptable because if [defendants] had no input into the design of the proposed investigation and/or if the result of the study were not as expected, it could affect [the] levofloxacin market in US.” (*Id.*, Ex. 61.)

A few days later, defendants’ epidemiologist, Dr. James Kahn, debriefing the meeting with Aventis and Daiichi and the “very worrisome regulatory situation that is developing in France[,]” explained the “urgent” circumstances:

Though no cases of tendon rupture were documented in the course of AVENTIS’ NDA regulatory trials, there has been a high reporting rate of TAVANIC (levofloxacin)-associated tendon-related mishaps – including

actual ruptures – in France since the drug launched there in late 2000 These French patients tended to be elderly, with a mean age 69, and two-thirds had been taking corticosteroids concomitantly These data should be considered against a prevailing background perception that both ofloxacin and levofloxacin might have greater tendinopathic potential than other fluoroquinolones **In our US post-marketing LEVAQUIN experience, we see has [sic] a higher reporting rate for tendon disorders than for virtually any other [Adverse Event] commonly regarded as part of the fluoroquinolone profile.**

(*Id.*, Ex. 18 at LEVP00577789 (emphasis added).) On July 26, 2001, Dr. Kahn proposed in a memorandum that defendants “do[] the correct epidemiologic study ourselves” because “[w]e have far more at stake than does AVENTIS”⁴ (*Id.*) According to Dr. Kahn, “it is imperative is [sic] to help regulators at the earliest possible time appreciate that the high reporting rates they are seeing are most likely not the result of the molecule in question (levofloxacin) but a byproduct of the way local physicians are using it.” (*Id.*)

Aventis meanwhile conducted its own three studies using European data to assess the propensity of fluoroquinolones to cause tendon injury (*Id.*, Ex. 73.) It found no case of tendon rupture resulting from levofloxacin use following more than 15,000 prescriptions. (*Id.*, Ex. 73 at LEVP00670103.) It did find a small increase in tendinopathy; one database suggested a “less than 2 fold increase of risk associated with levofloxacin use in comparison with ciprofloxacin, but the risk ratio was not significantly different from all the other fluoroquinolones included in the study.” (*Id.*) The Medicines and Healthcare Products Regulatory Agency (“MHRA”) of the United Kingdom decided

⁴ Aventis sold several other antibiotic agents besides Tavanic. (*See id.*, Ex. 64, Kahn Depo., May 7, 2008, at 494-95.)

that “[a]lthough we cannot exclude a slightly higher risk of tendon rupture with levofloxacin or ofloxacin (currently available data are inconclusive), such estimates are still likely to be rare or very rare.” (Cialkowski Aff., Ex. 87, Docket No. 25.) Aventis agreed “to base any additional actions” on the results of defendants’ study using Aetna data. (*Id.*, Ex. 78.) According to Schedin, Aventis also convinced European regulators to postpone further corrective action on Levaquin’s warning until defendants completed their study (“the Ingenix Study”).

Schedin characterizes defendants as heavily invested in ensuring a commercially favorable outcome for the Ingenix Study. Besides discussions about Aventis’ interactions with European regulatory agencies, he also points to Dr. Kahn’s internal email communication regarding Levaquin in which Kahn stated “I’m sure we’ll all continue to act as if the entire franchise were riding on this single toss!” (Van Steenburgh Aff., Sept. 7, 2010, Ex. E, Docket No. 31; *see also* Cialkowski Aff., Ex. 25, Docket No. 25 (email of another employee of defendants stating that “the market is too competitive to not aggressively defend our label. **The commercial impact of a label change of this kind could be very negative. We would not like to take the risk and therefore should do whatever it takes.**”) (emphasis added).)

Schedin alleges several purposeful flaws and weaknesses in the Ingenix Study, which was available to regulators in July 2002 although it was not ultimately published until 2006. (*See* Cialkowski Aff., Exs. 83 (interim report), 84 (published version), Docket No. 25.) According to Schedin’s expert, the study failed to manage the conflict of interest presented by defendants’ sponsorship of the study, chose a study population

that greatly underrepresented the elderly (who were more likely to suffer tendon injuries), and utilized an algorithm that excluded nearly two thirds of levofloxacin-exposed Achilles tendon rupture diagnoses. (*See id.*, Bisson Report at 22-23, Ex. 86.) **Schedin's experts have concluded that the Ingenix Study was designed to achieve defendants' desired result.** (*See id.* ¶ 45; *see also* Wells Report ¶ 4, Ex. 103.) Schedin alleges that the Ingenix Study had the intended effect of preventing the MHRA and other European regulatory agencies from further strengthening the levofloxacin label.

Besides manufacturing an intentionally flawed study to mislead regulators regarding the tendon toxicity of levofloxacin, defendants also allegedly mischaracterized the drug as having a strong safety profile. (*See, e.g.*, Cialkowski Aff., Ex. 89 (referencing Levaquin's "unsurpassed safety"), Ex. 91 ("We really need to sell [Levaquin's] safety track record everywhere right now"), Ex. 92 ("DO confidently differentiate the excellent safety track record for LEVAQUIN."), Ex. 115, Docket No. 25.) One way in which defendants promoted Levaquin was, according to Schedin, through their extensive use of "ghostwriting." Defendants hired DesignWrite, a publication planning company, to provide literature to support the appropriate use of Levaquin and differentiate the drug from competitors' products. (Cialkowski Aff., Exs. 100-02, Docket No. 25.)

In 2002, defendants added the following warning to Levaquin's label: "Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly." (Compl. ¶ 65, Docket No. 1.) Schedin alleges, however, that the 2002 warning "flipp[ed] the confounders." (*Id.* ¶ 68.) Medical research and adverse event reports of which defendants were aware

had already indicated that **all elderly people were at increased risk of tendon injury from fluoroquinolone use, particularly those concomitantly ingesting corticosteroids.** (*Id.*) In Schedin's view, the label should have indicated that the risk is increased in elderly individuals, especially those concomitantly using corticosteroids.

In April 2007, the FDA imposed another label change for Levaquin and all other fluoroquinolones. Schedin acknowledges that this label "did state that indeed the elderly are at an increased risk of tendon injury, and unequivocally stated that the risk of tendon injuries is increased with concomitant use of corticosteroids, contrary to the results of Defendant's Ingenix study." (*Id.* ¶ 101.)

Schedin alleges that Levaquin was defective in design and unreasonably dangerous because it was sold to him without adequate warnings regarding

the propensity of Levaquin to cause serious tendon injuries; the post-marketing experience with Levaquin; the increased risk of tendon injury in patients over the age of 60; the numbers of tendon-related adverse events reported; and the probability of suffering an acute tendon injury when ingesting corticosteroids concomitantly with Levaquin or post-Levaquin use.

(Compl. ¶ 116, Docket No. 1.) According to Schedin, although defendants knew of studies indicating the drug's tendon toxicity, they "manipulated scientific information to avoid threats to [their] market share." (Mem. in Supp. of Mot. to Am. at 2, Docket No. 24.)

Schedin seeks relief including damages for past and future medical expenses and emotional harm, double or treble damages, disgorgement of profits, a full refund of the cost of his Levaquin prescription, and attorney fees, expenses, and costs. He has also

moved the Court to grant him leave to amend his complaint to add a demand for punitive damages.

ANALYSIS

I. STANDARD OF REVIEW

Under Minnesota law, this Court must grant Schedin's motion to amend if he has proffered prima facie evidence to support a punitive damages award. Minn. Stat. § 549.191. Minnesota Statute § 549.20 permits an award of punitive damages in a civil action:

[O]nly upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others. . . . A defendant has acted with deliberate disregard for the rights or safety of others if the defendant **has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others** and . . . (1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.

Id. at subd. 1 (emphasis added). Clear and convincing evidence is “more than a preponderance of the evidence but less than proof beyond a reasonable doubt.” *Weber v. Anderson*, 269 N.W.2d 892, 895 (Minn. 1978). “A mere showing of negligence is not sufficient” to sustain a claim for punitive damages. *Admiral Merchs. Motor Freight, Inc. v. O'Connor & Hannan*, 494 N.W.2d 261, 268 (Minn. 1992). Deliberate disregard requires proof of intent or indifference to threaten the rights or safety of others. *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1008 (D. Minn. 2003).

On a motion to amend the complaint to assert a claim for punitive damages, however, “[a] plaintiff need not demonstrate an entitlement to punitive damages *per se*, but only an entitlement to allege such damages.” *Id.* At this stage, Schedin need only offer evidence which, if un rebutted, would constitute clear and convincing evidence of deliberate disregard for the rights or safety of others. *Swanlund v. Shimano Indus. Corp., Ltd.*, 459 N.W.2d 151, 154 (Minn. Ct. App. 1990). “[A] prima facie case simply means one that prevails in the absence of evidence invalidating it.” *Tousignant v. St. Louis Cnty.*, 615 N.W.2d 53, 59 (Minn. 2000) (citation omitted). In evaluating Schedin’s motion, “the Court makes no credibility rulings, and does not consider any challenge, by cross-examination or otherwise, to the plaintiff’s proof.” *Berczyk*, 291 F. Supp. 2d at 1008 n.3.

II. CHOICE OF LAW

As a preliminary matter, the Court must consider defendants’ challenge to the application of Minnesota law to the punitive damages issue. Defendants acknowledge that Minnesota courts have often applied Minnesota’s punitive damages law in product liability cases governed by substantive Minnesota law without engaging in a choice of law analysis. *See, e.g., Olson*, 29 F. Supp. 2d at 1034; *see also BBSerCo, Inc. v. Metrix Co.*, 324 F.3d 955, 960 n.3 (8th Cir. 2003) (law of forum state applies by default if choice of law issue is not raised by either party). Nonetheless, defendants assert that while Minnesota law governs issues of liability and compensatory damages, New Jersey law should govern Schedin’s request for punitive damages.

Federal courts exercising diversity jurisdiction apply the choice of law rules of the forum state. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 495-97 (1941); *Cicle v. Chase Bank USA*, 583 F.3d 549, 553 (8th Cir. 2009). Under Minnesota law, the Court must first determine whether an actual conflict between the states' laws exists. *Jepson v. Gen. Cas. Co. of Wis.*, 513 N.W.2d 467, 469 (Minn. 1994). A conflict of law exists if choosing the law of one state over the law of another state will determine the outcome of the case. *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 590 N.W.2d 670, 672 (Minn. Ct. App. 1999).

The New Jersey Product Liability Act ("NJPLA") prohibits punitive damages awards for injuries caused by a drug approved by the FDA or recognized as safe and effective under FDA conditions unless the manufacturer knowingly withheld from or misrepresented required information to the FDA. N.J. Stat. § 2A:58C-5(c). In addition, New Jersey law limits the recovery of punitive damages to the greater of five times the amount of compensatory damages or \$350,000. *Id.* § 2A:15-5.14(b). Minnesota, by contrast, does not impose comparable restrictions. *See* Minn. Stat. §§ 549.191, 549.20.

Schedin's argument that he would rely on the same evidence under Minnesota's punitive damages regime as he would under New Jersey's is unavailing. The evidence necessary under either law's standard may overlap, but unlike Minnesota's statutes, New Jersey's approach to punitive damages begins with a rebuttable presumption against an award of punitive damages and allows that presumption to be overcome only through evidence of misrepresentations to the FDA. Moreover, Schedin likely does not have a claim for punitive damages under the NJPLA because the New Jersey Appellate Division

has concluded that the NJPLA's punitive damages provision is preempted by the FDA's regulatory scheme. *See McDarby v. Merck & Co., Inc.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), *cert. denied as improvidently granted*, 200 N.J. 267 (2009). Minnesota's punitive damages statute is not subject to a preemption challenge.

Having determined that an actual conflict between the states' approaches to punitive damages exists, the Court next evaluates whether both states' laws can be applied constitutionally. *Jepson*, 513 N.W.2d at 469. "[F]or a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 312-13 (1981).

Here, both parties seem to presume that the laws of both Minnesota and New Jersey could be constitutionally applied. Schedin was prescribed and consumed Levaquin in Minnesota, and it is where his alleged injury occurred. New Jersey is where defendants are headquartered and where many of the pertinent decisions regarding the development, testing, labeling, and marketing of Levaquin were made. (*See Noel Aff.*, Aug. 21, 2010, ¶¶ 3-6, Docket No. 33.) Both states "have sufficient contacts such that the law of either state could be constitutionally applied." *Jepson*, 513 N.W.2d at 470.

The next step in a choice of law analysis is usually an evaluation of Professor Leflar's five factor test adopted by the Minnesota Supreme Court in *Milkovich v. Saari*, 203 N.W.2d 408, 412 (Minn. 1973), to determine which state's law should govern. *Jepson*, 513 N.W.2d at 470. However, the Minnesota Supreme Court follows "the almost

universal rule that matters of procedure **and remedies** [are] governed by the law of the forum state.” *Davis v. Furlong*, 328 N.W.2d 150, 153 (Minn. 1983) (emphasis added); *see also Nesladek v. Ford Motor Co.*, 46 F.3d 734, 736 (8th Cir. 1993) (describing the determination of whether a law is procedural or substantive as “the first issue that must be resolved” under Minnesota law in a conflict of law analysis); *Schumacher v. Schumacher*, 676 N.W.2d 685, 690 (Minn. Ct. App. 2004). “The *Milkovich* methodology is **applicable only to conflicts of substantive law.**” *Davis*, 328 N.W.2d at 153 (emphasis added). In Minnesota, “[i]t has long been recognized that substantive law is that part of law which creates, defines, and regulates rights, as opposed to adjective or remedial law, which prescribes method [sic] of enforcing the rights or obtaining redress for their invasion.” *Zaretsky v. Molecular Biosys., Inc.*, 464 N.W.2d 546, 548 (Minn. Ct. App. 1990) (citation omitted) (alteration in original).

In the Court’s view, Minnesota’s punitive damages statute is a remedial law. It does not create or restrict any cause of action; rather, it establishes a standard for obtaining a certain form of redress in civil actions dependent on the availability of rights prescribed by other statutes. *See* Minn. Stat. § 549.20; *see also Stern v. Dill*, 442 N.W.2d 322, 324 (Minn. 1989) (finding a Minnesota statute to be procedural for purposes of extending filing deadlines because “it does not change [plaintiff’s] basic right to sue for negligence”); *Jacobs v. Farmland Mut. Ins. Co.*, 377 N.W.2d 441, 446 (Minn. 1985) (punitive damages not recoverable where plaintiffs did not establish “the requisite kind of actual or compensatory damages”); *United Prairie Bank-Mountain Lake v. Haugen*

Nutrition & Equip., LLC, 782 N.W.2d 263, 273 (Minn. Ct. App. 2010) (“**A claim for punitive damages is not an independent claim.**” (emphasis added)).

As Schedin observes, defendants have not cited a single case in which a court has characterized Minnesota’s punitive damages statute as substantive. *Cf. Ulrich v. City of Crosby*, 848 F. Supp. 861, 866 (D. Minn. 1994) (“In the Federal Courts of this District, the pleading of a punitive damage claim, under causes of action premised upon the Laws of the State of Minnesota, must generally conform to the requisites of Minnesota Statutes Sections 549.191 and 549.20.”) Instead, they have cited cases in which courts engaged in a conflict of law analysis regarding conflicts between states’ punitive damages statutes without pausing to consider whether such statutes are substantive or remedial. *See, e.g., Deutsch v. Novartis Pharms. Corp.*, Nos. 09-CV-4677, 09-CV-4678, 2010 WL 2803038, at *3 (E.D.N.Y. July 16, 2010); *Aguirre Cruz v. Ford Motor Co.*, 435 F. Supp. 2d 701, 705 (W.D. Tenn. 2006).

Given the clear direction of the Minnesota Supreme Court to limit conflict of law analyses to conflicts of substantive law and the absence of any precedent regarding Minnesota’s statutes as substantive, the Court concludes that the availability of punitive damages is a remedial matter governed by Minnesota law.⁵ *See Bannister v. Bemis Co., Inc.*, No. 07-1662, 2008 WL 2002087, at *3 (D. Minn. May 6, 2008) (concluding that

⁵ The substantive/remedial determination for a conflict of law analysis under Minnesota law is a different inquiry than that posed to courts determining whether to apply a federal or state law under the *Erie* doctrine. *See Sec. Sav. Bank v. Green Tree Acceptance, Inc.*, 739 F. Supp. 1342, 1352 (D. Minn. 1990) (explaining that “under *Erie* analysis, federal courts must apply [Minn. Stat. §] 549.191 in diversity cases to avoid forum shopping”).

Minnesota law governs requests for attorney fees in conflict between the attorney fees provisions of Minnesota and Arkansas because “an award of attorney’s fee [sic] relates to a remedy”)

Moreover, even assuming that the conflict between New Jersey and Minnesota’s approach to damages poses an actual conflict of substantive law, an application of the *Milkovich* test favors Minnesota law. The relevant factors are: “(1) predictability of result; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum’s governmental interest; and (5) application of the better rule of law.” *Jepson*, 513 N.W.2d at 470. The first and third factors, however, “have little value in tort cases” *Burks v. Abbott Labs.*, 639 F. Supp. 2d 1006 1013 (D. Minn. 2009); *see also Jepson*, 513 N.W.2d at 472 (“The third factor, simplification of the judicial task, is not a significant factor . . . because the law of either state could be applied without difficulty.”); *Myers v. Gov’t Employees Ins. Co.*, 225 N.W.2d 238, 242 (Minn. 1974) (“Predictability of results [the first factor] applies primarily to consensual transactions where the parties desire advance notice of which state law will govern in future disputes.”).

Further, the second factor, maintenance of interstate order, has been deemed “unimportant” where, as here, both states have “sufficient contacts” with the case. *U.S. Fire Ins. Co. v. Goodyear Tire & Rubber Co.*, 920 F.2d 487, 491 (8th Cir. 1990) (affirming a district court’s conclusion that “advancement of the forum’s governmental interest” factor weighed heavily in favor of application of Minnesota law and was therefore dispositive in choice of law analysis); *see also Hughes v. Wal-Mart Stores, Inc.*,

250 F.3d 618, 620-21 (8th Cir. 2001) (“The [second] factor is generally not implicated if the state whose law is to be applied has ‘sufficient contacts with and interest in the facts and issues being litigated’” (quoting *Myers*, 225 N.W.2d at 242)). The fifth *Milkovich* factor is irrelevant if the first four factors are determinative. See *Nodak*, 604 N.W.2d at 96 (“[T]his court has not placed any emphasis on this [better rule of law] factor in nearly 20 years.”).

The Court therefore focuses its analysis on the fourth factor, advancement of the forum’s governmental interest. Defendants mischaracterize this factor as an evaluation of the advancement of the varying government interests of the two states with conflicting laws. Defendants cite the Second Restatement of Conflicts of Law, which provides that “[t]he law governing the right to exemplary damages need not necessarily be the same as the law governing the measure of compensatory damages.” Restatement (Second) of Conflicts of Law § 171, Reporter’s Note, cmt. d (1971). The Restatement continues, “[t]his is because situations may arise where one state has the dominant interest with respect to the issue of compensatory damages and another state has the dominant interest with respect to the issue of exemplary damages.” *Id.*

Defendants cite cases outside Minnesota in which courts, **applying other states’ conflict of law analyses which often rely upon the Second Restatement**, have concluded that the state in which the defendant’s alleged misconduct occurred has a greater interest in the application of punitive damages even where liability for compensatory damages are appropriately governed by another state’s law. See, e.g., *Deutsch*, 2010 WL 2803038, at *3 (applying New Jersey law to punitive damages issue

under New York's choice of law analysis in which "the law of the jurisdiction having the greatest interest in the litigation is applied"); *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 68 (D. N.J. 2009) (applying Second Restatement analysis to conflict of law and concluding that "New Jersey's interest in limiting the liability of a corporation headquartered within its borders . . . would be compromised if the company were subjected to the law of states that do not limit punitive recovery in consumer fraud cases") (quotation and citation omitted); *Aguirre Cruz*, 435 F. Supp. 2d at 705 (applying the Second Restatement's conflict of law analysis, as adopted by the Tennessee Supreme Court); *Kelly v. Ford Motor Co.*, 933 F. Supp. 465, 469 (E.D. Pa. 1996) (applying the Second Restatement's analysis, under which the "defendant's contacts [are] the relevant contacts in a choice of law analysis for a punitive damages claim").

Schedin concedes that "the decision making manifesting Defendant's deliberate disregard for Plaintiff's rights and safety took place in New Jersey" (Pl.'s Reply Mem. at 9, Docket No. 45.) However, **under Minnesota law the Court evaluates only the advancement of the forum's governmental interest.** See *Jepson*, 513 N.W.2d at 470. Unlike the analyses adopted by other states, Minnesota choice of law analysis does not require a comparison between Minnesota's interest with the governmental interest of the other state.

Turning to Minnesota's interest, in a case in which the laws of Minnesota and Georgia regarding the insurability of punitive damages presented an actual conflict, the Eighth Circuit affirmed the district court's conclusion that "Minnesota has a strong interest in preventing injury to its citizens, and thus allows for punitive damages as

punishment to wrongdoers [and that] **the state's interest in protecting its citizens and punishing wrongdoers could be furthered only if the responsible parties felt the effects of punitive damages awards.**" *U.S. Fire Ins. Co.*, 920 F.2d at 491 (emphasis added); see also *Mrozka v. Archdiocese of St. Paul and Minneapolis*, 482 N.W.2d 806, 812 (Minn. Ct. App. 1992) ("Awarding punitive damages furthers [Minnesota's] interest in protecting its citizens from harm by deterring and punishing such conduct. The state is not only concerned with compensating plaintiffs, but also ensuring that similar conduct does not harm others in the future." (citation omitted)).

The district court in *U.S. Fire Insurance Co.* explicitly rejected the argument, raised here by defendants, that Minnesota's only governmental interest in punitive damages was "the compensation of Minnesota residents who are victims of torts." *U.S. Fire Ins. Co. v. Goodyear Tire & Rubber Co.*, 726 F. Supp. 740, 745 (D. Minn. 1989). Rather, the court concluded that although the defendant "may have different expectations when it does business in other states, when it does business in Minnesota, it must expect the same treatment as would be given a Minnesota corporation." *Id.* at 743. The Eighth Circuit affirmed, finding no fault in the district court's determination that Minnesota's strong governmental interest in enforcing its punitive damages statute was dispositive of the conflict of law issue. *U.S. Fire Ins. Co.*, 920 F.2d at 491. Notably, **neither the district court nor the Eighth Circuit considered Georgia's interest in facilitating insurance for punitive damages.**

Accordingly the Court concludes that Minnesota law governs Schedin's request for punitive damages. Minnesota Statute § 549.20 is a remedial provision to which a

conflict of law analysis does not apply; and even if it were not, Minnesota's unique emphasis on only the government interest of the forum state in a conflict of law analysis, as articulated in *U.S. Fire Ins. Co.*, would dictate the application of Minnesota law to the issue of punitive damages in this case.

III. SCHEDIN MAY ALLEGE PUNITIVE DAMAGES UNDER MINNESOTA LAW

If believed, Schedin's evidence would constitute clear and convincing evidence that defendants deliberately disregarded the rights and safety of others. Under Minnesota law, "[p]unitive damages are available against the manufacturer of a product that abuses its control over information about product risks in a manner that shows a disregard for public safety." *Olson*, 29 F. Supp. 2d at 1036 (citing *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727, 733 (Minn. 1980)). From Schedin's evidence, detailed above, a jury could reasonably infer that defendants:

- had knowledge of or intentionally disregarded medical research regarding Levaquin's tendency to cause tendon injuries, particularly in seniors using corticosteroids;
- sought to prevent European regulatory action regarding levofloxacin's risks that would negatively impact the drug's reputation;
- manipulated the Ingenix Study to produce a commercially favorable result;
- failed to adequately warn Schedin and his doctor of dangers, despite knowing the particular risks of tendon injury Levaquin posed to seniors using

corticosteroids, and the higher risk posed by Levaquin as compared to other fluoroquinolones;⁶

- affirmatively misrepresented Levaquin's safety profile through its marketing campaign and other means.

Defendants harness the evidence regarding Aventis, the Ingenix Study, and European regulatory agencies determinations to tell a different story, but the question before the Court is whether Schedin's evidence, if believed in its entirety, could amount to clear and convincing proof of defendants' deliberate disregard for the right and safety of others. Defendants note that in response to European research indicating Levaquin's tendon toxicity, they initiated a label change for Levaquin in October 2001 which added the admonition that the risk of tendon injury "may be increased in those taking corticosteroids, especially the elderly." A jury, however, may believe Schedin's characterization of the 2002 warning as stating the two increased risk factors – age and corticosteroid use – in a misleading way. Schedin asserts that the medical research shows that all elderly people are at an increased risk of tendon injury, particularly those using corticosteroids.

Defendants object to several studies proffered by Schedin which do not include an assessment of Levaquin. (*See, e.g., Cialkowski Aff., Exs. 1, 3, 4, Docket No. 25.*) However, these studies do consider ofloxacin, from which levofloxacin was derived and

⁶ Defendants argue that because the FDA did not and has not required a warning distinguishing Levaquin from other fluoroquinolones, the absence of such a warning cannot serve as the basis for liability, let alone a punitive damages award. As explained in the Court's Order regarding plaintiff's *Daubert* challenge of Dr. Waymack, however, Schedin may proceed on this theory even in the absence of an FDA directive. *See Wyeth v. Levine*, 129 S. Ct. 1187 (2009).

which defendants characterized as pharmacologically similar to levofloxacin on their NDA for Levaquin. At least one study challenged by defendants actually includes a finding that fluoroquinolones in general pose an increased risk of tendon injury for older individuals. (*See id.*, Ex. 1.)

Defendants further attempt to invalidate studies cited by Schedin as methodologically flawed and defend the Ingenix study as more comprehensive and reliable than the other studies on which Schedin relies. These types of factual disputes should not preclude Schedin from asserting a punitive damages claim. *See In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 573 (8th Cir. 2009) (award of punitive damages could be supported by jury's finding "that although each study added to the evidence suggesting a risk of [injury from use of a drug], [defendant] nevertheless continued to engage in a practice of both inaction and mitigation"). Moreover, Schedin has proffered research, unchallenged by defendants in the instant motion, suggesting that tendon injury occurred most frequently in levofloxacin as compared to other fluoroquinolones, and that older age and use of steroids were factors that increased the risk. (*See, e.g.*, Cialkowski Aff., Exs. 5, 14-16, Docket No. 25.)

Likewise, defendants' challenge of Schedin's characterizations of employee communications cannot serve to deny Schedin the opportunity to present his theory to a jury. For example, Dr. Kahn's statement that "I'm sure we'll all continue to act as if the entire franchise were riding on this single toss" may not be lynchpin evidence that defendants planned to skew the results of the Ingenix Study as Schedin claims, but a jury could infer that the statement is one of several pieces of evidence that, taken together,

show defendants knew of and sought to discredit commercially harmful medical research through the publication of a flawed study.

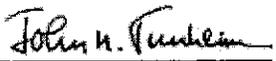
Schedin's evidence is readily distinguishable from the inadequate affidavit and exhibits presented in *Berczyk*, on which defendants rely. The primary affidavit in *Berczyk* was "simply an amalgam of legal argument, rhetorical invective, conclusory surmise, and hearsay stacked upon hearsay" that summarized relevant evidence instead of attesting to the veracity of attached exhibits. 291 F. Supp. 2d at 1010. Here, plaintiffs have included over 100 exhibits including medical research, deposition testimony, internal email communications, and expert reports. Moreover, the "expert report" in *Berczyk* was an "unsworn letter" that was "rife with concessions that he had been 'advised' of certain predicates to his opinion, or that he had an 'understanding' as to certain predicate facts." *Id.* at 1015. *Berczyk* does not, as defendants suggest, stand for the proposition that an expert report cannot be considered evidence warranting a right to assert punitive damages; rather, it reaffirms the principle that prima facie evidence of punitive damages cannot be based on conjecture and conclusion. *See id.* at 1016 (concluding that the expert report was "predicated on many of the same documents that we found to be an inadequate basis on which to establish a claim of deliberate disregard.").

A jury need not believe Schedin's allegations nor award him punitive damages. At this stage, this Court's role is to ascertain whether he has presented prima facie evidence that, if uncontroverted, would provide a jury a basis for punitive damages under Minnesota law. *See Ulrich*, 848 F. Supp. at 868. Schedin has met this standard.

ORDER

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiff John Schedin's Motion to Amend the Complaint to Add a Demand for Punitive Damages [Docket No. 23] is **GRANTED**.

DATED: November 9, 2010
at Minneapolis, Minnesota.

s/ 

JOHN R. TUNHEIM
United States District Judge