

**UNITED STATES DISTRICT COURT**  
**DISTRICT OF MINNESOTA**

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JOHN SCHEDIN,

Civil No. 08-5743 (JRT)

Plaintiff,

v.

**MEMORANDUM OPINION AND  
ORDER DENYING DEFENDANT'S  
MOTION FOR JUDGMENT AS A  
MATTER OF LAW**

ORTHO-MCNEIL-JANSSEN  
PHARMACEUTICALS, INC.,

Defendant.

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Mikal C. Watts, **WATTS LAW FIRM, LLP**, 555 North Carancahua, Suite 1400, Corpus Christi, TX 78478; Ronald S. Goldser, **ZIMMERMAN REED, PLLP**, 651 Nicollet Mall, Suite 501, Minneapolis, MN 55402; and Lewis J. Saul, **LEWIS SAUL & ASSOCIATES**, 183 Middle Street, Suite 200, Portland, ME 04101, lead counsel for plaintiff Schedin.

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Plaintiff John Schedin brought claims against defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Ortho-McNeil”) for failure to warn about certain risks he was taking in using its drug, Levaquin, namely tendon rupture. His case was the first case tried in a larger multi-district litigation involving numerous plaintiffs. The jury found for Schedin, and defendant has moved for judgment as a matter of law. Ortho-McNeil argues that Schedin’s failure to warn claims required the jury to return a verdict that is

inconsistent with, and thus preempted by, federal law, specifically Food and Drug Administration (“FDA”) regulations made pursuant to the Food, Drug, and Cosmetic Act (“FDCA”). *See, e.g.*, 21 C.F.R. § 201.57 (requirements on the format and labeling for prescription drugs). Ortho-McNeil contends that the Levaquin label was approved by the FDA and was subject to strict guidelines related to changes of labeling that left it unable to alter the warnings on the drug’s label. Further, Ortho-McNeil argues that Schedin’s state punitive damages claim is based on “fraud on the FDA” and is therefore similarly pre-empted. Because the Court finds that Schedin’s state law failure to warn claims are not preempted by the FDCA, Ortho-McNeil had many options at its disposal to effectuate an adequate warning, and Schedin’s case does not hinge on a defrauding of the FDA, the Court denies the motion.

### **BACKGROUND**

Schedin was prescribed Levaquin for an upper respiratory infection in February 2008 and, after eight days of consuming the drug, suffered bilateral Achilles tendon ruptures. (Compl. ¶ 108, Docket No. 1.) At the time Schedin was prescribed Levaquin, the drug contained a warning regarding tendon rupture stating:

**Tendon effects:** Ruptures of the shoulder, hand, Achilles tendon, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including levofloxacin. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly.

(Def. Ex. 12.) Schedin claims this label alone was inadequate to warn him of the risk he was taking in using Levaquin, in part because of the way the warning was worded, where

it was located in the label insert and not easily noticed, and because it did not warn that Levaquin had higher tendon toxicity than other fluoroquinolones.

At the time Schedin was prescribed Levaquin, it was already subject to class labeling as a fluoroquinolone, a class of broad-spectrum antibiotics, and the FDA had not yet mandated a black box warning for the specific injury Schedin suffered.<sup>1</sup> Ortho-McNeil asserts that it could not have instituted a black box warning independently without an FDA mandate. *See* 21 C.F.R. § 201.80(e) (“If a boxed warning is required, its location will be specified by the [FDA].”). Schedin concedes that Ortho-McNeil probably could not have unilaterally instituted a black box warning. However, he contends that Ortho-McNeil knew of the risk posed by Levaquin and could have taken numerous other steps to warn consumers about those risks, such as sending out “Dear Doctor” letters, having sales representatives meet and confer with doctors, hosting training seminars, and other such measures to draw attention to the risks. As a result, Schedin argues his state law claims are not pre-empted by the FDCA.

## ANALYSIS

### I. STANDARD OF REVIEW

Under Rule 50 of the Federal Rules of Civil Procedure, judgment as a matter of law is appropriate if no reasonable juror could return a verdict for the nonmoving party. *Weber v. Strippit, Inc.*, 186 F.3d 907, 912 (8<sup>th</sup> Cir. 1999). In analyzing a Rule 50 motion,

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<sup>1</sup> The FDA required just such a black box warning in 2008, which reads: “Fluoroquinolones, including Levaquin, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, [and] in patients taking corticosteroid drugs . . . .” (Levaquin Label 2008.)

the Court must consider the evidence in the light most favorable to the nonmovant, resolve all factual conflicts in the nonmovant's favor, and give the nonmovant the benefit of all reasonable inferences. *Ogden v. Wax Works, Inc.*, 214 F.3d 999, 1002 (8<sup>th</sup> Cir. 2000). “[J]udgment as a matter of law is proper when the record contains no proof beyond speculation to support the verdict.” *Heating & Air Specialists, Inc. v. Jones*, 180 F.3d 923, 932–33 (8<sup>th</sup> Cir. 1999) (internal quotation marks omitted).

## II. FAILURE TO WARN CLAIMS

### A. Pre-emption Principles

Whether Schedin's state law failure to warn claims are pre-empted by conflict pre-emption with federal law is the central question posed by Ortho-McNeil's motion for judgment as a matter of law. The Supremacy Clause of the United States Constitution provides that the “Laws of the United States . . . shall be the supreme Law of the Land.” U.S. Const. art. VI, cl. 2. The principle of pre-emption is the application of this clause, resulting in the rule that any “state law that conflicts with federal law is without effect.” *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (internal quotation marks omitted). “Preemption is disfavored in areas of historic importance to the states' police powers – areas such as public health and safety.” *In re St. Jude Med. Inc. Silzone Heart Valves Prod. Liab. Litig.*, No. 01-MDL-1396, 2004 WL 45503, at \*5 (D. Minn. Jan. 5, 2004) (citing *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6<sup>th</sup> Cir. 2000)).

Pre-emption can be either express or implied. Express pre-emption is found when Congress “pre-empt[s] state law by so stating in express terms.” *Hillsborough Cnty., Fla.*

*v. Automated Med. Labs, Inc.*, 471 U.S. 707, 712-13 (1985) (citing *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). In addition to express pre-emption, “a court may find that Congress impliedly preempted such claims by ‘conflict’ if 1) compliance with both federal and state law is impossible, or 2) the claims would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 608 (8<sup>th</sup> Cir. 2009) (alteration and quotation marks omitted) (citing *Crosby v. Nat’l Foreign Trade Council*, 530 U.S. 363, 372–73 (2000)), *cert. granted*, 78 U.S.L.W. 3522 (U.S. Dec. 10, 2010) (No. 09-993). Therefore, “a conflict arises when compliance with both federal and state regulations is a **physical impossibility . . .**” *Automated Med. Labs, Inc.*, 471 U.S. at 712–13. (emphasis added) (internal quotations omitted); *see also, Mensing*, 588 F.3d at 608 (finding no conflict pre-emption for manufacturers of generic drugs in a state failure to warn action). “Impossibility pre-emption is a demanding defense.” *Wyeth v. Levine*, 129 S. Ct. 1187, 1199 (2009). The Supreme Court recently evaluated the FDCA and pre-emption and described the process by which such determination should be made:

Our answer to [the] question [of pre-emption] must be guided by two cornerstones of our pre-emption jurisprudence. First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

*Wyeth*, 129 S. Ct. at 1194–95 (internal citations, alternations, and quotation marks omitted).

Articulating Congress’ purpose in the enactment of and amendments to the FDCA, the *Wyeth* Court noted:

[When Congress] enlarged the FDA’s powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, [it] took care to preserve state law. . . . In 2007, . . . Congress . . . granted the FDA statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug’s initial approval. In doing so, however, Congress did not enact a provision in the Senate bill that would have required the FDA to preapprove all changes to drug labels. . . . [T]hrough many amendments to the FDCA and to FDA regulations, **it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.**

*Id.* at 1196–98 (emphasis added) (internal citations, quotation marks, and alterations omitted).

With the *Wyeth* Court’s interpretation of Congress’ intent in mind, the remaining question is whether, in the instant case, compliance with both state and federal law regarding adequate warnings presented Ortho-McNeil a “physical impossibility” such that state law must yield to the federal law. *Automated Med. Labs, Inc.*, 471 U.S. at 713. “The question before this court is whether [Ortho-McNeil] can both fulfill a state law duty to warn and comply with the FDCA. Does federal law forbid [Ortho-McNeil] from taking steps to warn [its] customers?” *Mensing*, 588 F.3d at 610–11.

## **B. Defendant’s Obligation to Maintain Adequate Warnings**

Ortho-McNeil argues that since Levaquin was already subject to an FDA approved label, FDA regulations would not have permitted Ortho-McNeil to alter the label to provide stronger warnings. Even **if** Ortho-McNeil is correct about an inability to

strengthen the warnings on the label, Ortho-McNeil still had various other options at its disposal to warn consumers, such as “Dear Doctor” letters, or training by sales representatives with individual doctors. It could also have **proposed** an alteration to the label. As the Eighth Circuit noted in *Mensing*: “In this case we need not decide whether . . . manufacturers may unilaterally enhance a label warning . . . because the . . . defendants could have at least **proposed** a label change that the FDA could receive and impose . . . if approved.” *Mensing*, 588 F.3d at 608 (emphasis original). Given the Supreme Court’s central holding in *Wyeth*, that the manufacturer bears responsibility for the content of its label at all times, the Court is also not convinced that FDA regulations prohibited Ortho-McNeil from making a label change, let alone from proposing one.

The FDA provides a process whereby a manufacturer can alter or propose an alteration to an already approved label to reflect new information about a drug. 21 C.F.R. § 314.70. “Major changes” require the FDA’s prior approval through a prior approval supplement. 21 C.F.R. § 314.70(b). Manufacturers may implement “moderate changes,” including changing a label to strengthen a warning based on newly acquired information, through a Changes Being Effected (“CBE”) supplement. 21 C.F.R. § 314.70(c)(6)(iii)(A)-(D). Manufacturers may implement CBE changes before the FDA formally approves them. *Id.*

In *Wyeth*, the defendant claimed that using the CBE process would have rendered its drug misbranded, in violation of 21 U.S.C. § 352. *Wyeth*, 129 S. Ct. at 1197. The Supreme Court disagreed. Rather, the Court held that the statute regarding misbranding would apply to a drug “that fail[ed] to include ‘adequate warnings.’” *Id.* (citing 21

U.S.C. § 352(f) (noting that a drug is misbranded if it does not contain “adequate warnings against use . . . in such manner and form, as are necessary for the protection of users”)).

The Supreme Court noted that the CBE regulation

provides that if a manufacturer is changing a label to “add or strengthen a contraindication, warning, precaution, or adverse reaction” or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

*Id.* at 1196 (citing 21 C.F.R. § 314.70(c)(6)(iii)(A), (C)).

Ortho-McNeil asserts that the CBE process is not applicable to the instant litigation, and therefore the holding of *Wyeth* is inapposite, since Ortho-McNeil could not have unilaterally instituted a black box warning, could not utilize comparative data in its labeling of Levaquin, and was bound by class labeling for fluoroquinolones. Ortho-McNeil argues that these options made it a “physical impossibility” to comply with both state and federal law therefore it is entitled to judgment as a matter of law. *See Automated Med. Labs, Inc.*, 471 U.S. at 713. Keeping in mind that these were not the only options available to defendant to warn its consumers, the Court evaluates each of these arguments in turn.

### **1. Black Box Warnings**

In the instant case, the FDA ultimately ordered Ortho-McNeil to include a black box warning about tendon rupture. The FDA requires certain drugs with “[s]pecial problems, particularly those that may lead to death or serious injury, . . . to [have a

warning] placed in a prominently displayed box [a ‘black box’].” 21 C.F.R. § 201.80(e). Schedin’s experts concede that Ortho-McNeil probably could not have unilaterally instituted a black box warning. (*See, e.g.*, Aff. of Dana M. Lenahan, Nov. 16, 2010, Ex. E, at 49–50, Docket No. 150.)<sup>2</sup> FDA regulations on black box warnings, while reserving the inclusion of the black box to the discretion of the FDA, note that a manufacturer’s “desires about location and wording of boxed warnings, however, will be considered.” 44 Fed. Reg. 37,434, 37,448 (June 26, 1979). This guidance implies a role for the manufacturer in the design and content of black box warnings.

Regardless, Ortho-McNeil’s potential inability to unilaterally institute a black box warning is not a hindrance to state tort liability since it could have instituted other label changes short of a black box warning or proposed a black box warning instead of waiting for the FDA to act. Ortho-McNeil points out that the FDA did not institute a black box warning after requests from citizens’ petitions in 2005, 2006, and 2007. Ortho-McNeil cites *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7<sup>th</sup> Cir. 2010), as support for the proposition that the FDA’s failure to alter the label in the face of these citizens’ petitions constitutes “clear evidence” that it would not have approved of the change had Ortho-McNeil proposed it. The *Robinson* court held that “a court cannot order a drug company to place on a label a warning if there is ‘clear evidence’ that the FDA would not approve it.” *Id.* at 873 (citing *Wyeth*, 129 S. Ct. at 1198). However, in *Robinson* the

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<sup>2</sup> However, Schedin’s expert, Dr. Cheryl Blume, noted there was a recorded instance on the FDA website of a drug manufacturer utilizing the CBE process to alter or add a black box warning to its labeling. (Lenahan Aff., Ex. E, at 49–50, Docket No. 150.)

**manufacturer** had submitted a proposed label change that the FDA rejected, and the court cited the “clear evidence” standard as one reason of several to uphold the lower court’s refusal to allow the plaintiff, on the eve of trial, to add a breach of implied warranty claim. *Id.* The Court was not addressing the applicability of failure to warn claims under state tort law. In contrast, Ortho-McNeil presents no evidence as to what action the FDA might have taken had Ortho-McNeil proposed or requested a black box warning. *See, e.g., Bartlett v. Mutual Pharm. Co., Inc.*, No. 08-358, 2010 WL 2889114, at \*9 (D.N.H. July 22, 2010) (discussing and allowing expert testimony regarding the issue of whether a manufacturer should have requested a black box warning).

Therefore, assuming without deciding that Ortho-McNeil could not have added a black box warning without FDA approval, it has not demonstrated that it was “physically impossible” for it to request one from the FDA. Further, instituting a black box warning was not the only option available to Ortho-McNeil to adequately warn prescribing doctors. Schedin’s claim are failure to warn claims, not failure to institute a black box warning claims and as such, Ortho-McNeil’s protestations that it was “physically impossible” to change its label are both legally inadequate and immaterial.

## **2. Comparative data**

Ortho-McNeil argues that it could not have altered its label through the CBE process to include comparative data regarding Levaquin relative to other fluoroquinolones due to the lack of an “adequate and well-controlled study.” 21 C.F.R. § 201.57(c)(2)(iii). Inclusion of comparative information could have alerted physicians

to the higher tendon toxicity of Levaquin as compared to other fluoroquinolones. The FDA requires either an “adequate and well-controlled stud[y]” or a waiver from this requirement when a manufacturer intends to make statements in the “[i]ndications and usage” section of the label comparing the safety or effectiveness of the drug with other agents for the same indication. *Id.* The same regulation notes that to make changes to the “[w]arnings and precautions” section of the label, such a change should be made “to include a warning about a clinically significant hazard **as soon as there is reasonable evidence** of a causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R. § 201.57(c)(6)(i) (emphasis added). Conspicuously absent from the regulation governing the “[w]arnings and precautions” section is a requirement of adequate and well-controlled studies supporting such warnings.

Here, both parties concede that a “well-controlled study” as defined by the FDA cannot be conducted ethically since such a study requires a placebo concurrent control group that could be fatal to elderly patients with respiratory infections. *See* 21 C.F.R. § 314.126(b)(2)(i); (Aff. of Ronald Goldser, July 30, 2010, Ex. B at 31:12 to 36:18, 08-MDL-1943 Docket No. 1659). Regardless, Ortho-McNeil has presented no evidence that it applied for a waiver from that requirement as the regulation permits. 21 C.F.R. § 314.126(c).

Ortho-McNeil similarly presents no case law, and the Court is not aware of any, distinguishing between the requirements to alter the “[i]ndications and usage” section and the “[w]arnings and precautions” section, where the comparative information likely would belong. Courts have compared the “[i]ndications and usage” section of a drug’s

label to its advertising, indicating that stricter requirements for what manufacturers can claim in that section are potentially aimed at preventing false advertising. *See, e.g., Proctor & Gamble Pharms., Inc. v. Hoffmann-LaRoche Inc.*, No. 06-0034, 2006 WL 2588002, at \*6–7 (S.D.N.Y. Sept. 6, 2006).

Textual differences between sections within the same statute demonstrate that such differences may have been intentional. *See, e.g., King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 n.9 (1991) (discussing the interpretation of congressional intent when presented with textual differences in the Veterans' Reemployment Rights Act). Had Congress intended alterations to the “[w]arnings and precautions” section of a manufacturer’s label to be subject to the same limitations of an “adequate and well controlled study” as specified in the “[i]ndications and usage section,” it could have included that language. Congress did not. Given that the regulations urge a change to the “[w]arnings and precautions” section “as soon as there is reasonable evidence of a causal association” and make no mention of “adequate and well-controlled studies” the Court finds support for the proposition that changes to the “[w]arnings and precautions” section do not require manufacturers to submit such studies.

Additionally, Ortho-McNeil asserts that a manufacturer is under no duty to provide information about the superiority of other drugs. *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6<sup>th</sup> Cir. 1990); *Pluto v. Searle Labs.*, 690 N.E.2d 619, 621 (Ill. Ct. App. 1997). In *Pluto*, the court held that an Intrauterine Device (“IUD”) manufacturer was not obligated to disclose that IUD’s posed an “increased risk” of sexually transmitted

diseases (“STDs”) as compared to other forms of birth control, since the purpose of the IUD was to prevent pregnancy, not STDs. *Pluto*, 690 N.E.2d at 621.

In *Ackley*, the Sixth Circuit upheld summary judgment for a manufacturer of an “unavoidably unsafe” drug describing the risks posed by that drug. *Ackley*, 919 F.2d at 405. The court held that such a manufacturer need not discuss alternative medicines in its label. *Id.* These cases are distinguishable from the instant case, however, since information on comparative drugs was germane to the particular condition at issue and Levaquin has not been classified as “unavoidably unsafe.” *See* Restatement (Second) of Torts § 402A(k) (defining unavoidably unsafe products their warnings). Further, while the Sixth Circuit has adopted the general proposition that a manufacturer is under no duty to provide information about the superiority of other drugs, it also recognizes the principle that “[t]he manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug.” *Id.*

Therefore, the Court finds that Ortho-McNeil could have submitted the comparative data<sup>3</sup> demonstrating “evidence of a causal association” to the FDA to alter the “[w]arnings and precautions” section of Levaquin’s label through the CBE process. At the very least, Ortho-McNeil has not demonstrated “physical impossibility” of the nature required to satisfy the principles of conflict pre-emption, particularly given its

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<sup>3</sup> Schedin’s complaint details the many studies comparing the tendon toxicity of Levaquin with other fluoroquinolones of which Ortho-McNeil was aware as evidenced by the sending of “Dear Doctor” letters in Italy, France, and Belgium — all prior to Schedin’s prescription. (Compl. ¶¶ 30–38, 56–62, Docket No. 1.) The complete studies are included in the record as Exhibits to the Affidavit of Ron Goldser. (Docket No. 1651.)

burden at this stage of the litigation and taking all inferences in favor of the nonmovant. *Ogden*, 214 F.3d at 1002.

Again, as with the black box warning, Schedin's claims are failure to warn claims, not failure to provide comparative data claims. Ortho-McNeil had other means by which it could have warned prescribing physicians of the dangers of Levaquin, even if it was unable to utilize the comparative data of which it had knowledge to alter its label.

### **3. Class labeling**

Ortho-McNeil asserts, without reference to statutes or case law, that since Levaquin was subject to class labeling, it was unable to alter the labeling through the CBE process to include more adequate warnings about tendon toxicity. Again, the Court fails to see how this precluded Ortho-McNeil from proposing a label change to the FDA. Indeed, its own expert testified about numerous other drugs, also subject to class label requirements, whose labels included information that went beyond the class-required labeling. (Aff. of Ronald Goldser, Aug. 13, 2010, Ex 1, 08-MDL-1943 Docket No. 1853.) For example, the drug Floxin has an insomnia warning different from other drugs in its class. (*Id.* at 18–19.) The drug Baycol has warnings related to combined use with other drugs that differs from the class label. (*Id.* at 185–87.) The same is true for Paxil (*id.* at 190–92), Bextra (*id.* at 193–94), and Ortho-Evra (*id.* at 195–96). Further, Schedin notes at least three differences in labeling between Levaquin and other fluoroquinolones. (Pl.'s Mem. in Opp'n at 11 (Docket No. 157).) Defendant's expert concedes that Ortho-McNeil could have used the CBE process despite class labeling.

(Goldser Aff., Ex. 1 at 18, 08-MDL-1943 (Docket No. 1853).) As a result, the Court finds that class labeling, at least in practice, creates a floor below which no label in the class can fall, but does not preclude a manufacturer from including more information in its label. This finding is consistent with the central holding of *Wyeth* that “the manufacturer bears responsibility for the content of its label at all times.” *Wyeth*, 129 S. Ct. at 1197-98.

In summation, the Court finds that Ortho-McNeil has not demonstrated “physical impossibility” as required to satisfy the principles of conflict pre-emption. Even if its contentions about black box warnings, the inclusion of comparative data, and deviations from class warnings were accurate, Ortho-McNeil provides no explanation for not proposing label changes and offers no argument that other methods of warning were “physically impossible.”

### **III. FRAUD ON THE FDA**

Ortho-McNeil argues that Schedin’s punitive damages claim amounts to a “fraud on the FDA” claim, because it is predicated on a finding that Ortho-McNeil misled the FDA in obtaining and maintaining approval to market Levaquin. In *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 348 (2001), the Supreme Court found implied pre-emption when a plaintiff brought a claim predicated entirely on a theory of fraud on the FDA because “policing fraud against federal agencies is hardly a field which the States have traditionally occupied.” 531 U.S. at 347–48 (internal quotation marks omitted). The Eighth Circuit has opined that *Buckman* preempts claims where “the

plaintiff [is] suing **because** the conduct violates the FDCA . . . .” *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8<sup>th</sup> Cir. 2010) (emphasis original) (internal quotation marks omitted). In other words:

[T]o avoid being impliedly preempted under *Buckman*, a claim must rely on traditional state tort law . . . . [T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law – and that would give rise to liability under state law even if the FDCA had never been enacted.

*Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (internal quotation marks and citations omitted).

Here, Schedin’s claim for punitive damages implicates evidence that Ortho-McNeil took actions to mislead the FDA, such as the design and administration of the Ingenix study. (See Goldser Aff., Ex. 1-6, 08-MDL-1943 (Docket No. 1651) (a study alleged by Schedin to have been constructed by Ortho-McNeil to find no greater tendon toxicity of Levaquin as compared to other fluoroquinolones).) However, the claims do not **hinge** on a defrauding of the FDA. Defrauding the FDA is not a necessary finding for any tort claims relevant to this litigation under Minnesota law. Further, punitive damages can only be recovered if “plaintiff[ has] established the requisite kind of actual or compensatory damages . . . .” *Jacobs v. Farmland Mut. Ins. Co.*, 377 N.W.2d 441, 446 (Minn. 1985); see also *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.”). Therefore, punitive damages claims under Minnesota law, by their very nature, rely on the existence of a state tort law claim. As a result, the Court finds *Buckman* inapplicable to the instant case.

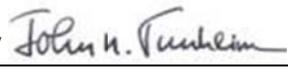
In sum, the Court finds Ortho-McNeil has not demonstrated it was “physically impossible” to comply with state law regarding adequate warnings and the FDCA. Even if it could not have instituted a black box warning, Ortho-McNeil could have requested one, and even if it could not have altered the “[i]ndications and usage” section of the label to include comparative data, it could have applied for a waiver from that requirement. It is also not clear that the type of data at its disposal was inadequate to alter the “[w]arnings and precautions” section of the label, even without an “adequate and well controlled study.” The Court finds unavailing the argument that the class designation of Levaquin left Ortho-McNeil unable to supplement the mandated class label, in the face of abundant evidence that other manufacturers have supplemented class labels in numerous other instances, including Levaquin itself. Finally, Ortho-McNeil has proffered no evidence that other methods of warning physicians, such as “Dear Doctor” letters, targeted meetings with sales representatives, or other techniques short of label changes were “physically impossible” such that the claims against it are pre-empted.

Further, the specific type of pre-emption articulated in *Buckman* is not applicable to the punitive damages claim here where the claim does not **hinge** on a defrauding of the FDA. Evidence of potential fraud committed on the FDA is simply a portion of Schedin’s evidence offered to support the punitive damages claim. The Motion for Judgment as a Matter of Law is denied.

**ORDER**

Based on the foregoing, and the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that Defendant's Motion for Judgment as a Matter of Law [Docket No. 149] is **DENIED**.

DATED: March 4, 2011  
at Minneapolis, Minnesota.

s/   
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JOHN R. TUNHEIM  
United States District Judge