UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE LEVAQUIN PRODUCTS LIABILITY LITIGATION	MDL No. 08-1943 (JRT)
CLIFFORD STRAKA, Plaintiff, v. JOHNSON & JOHNSON; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL PHARMACEUTICAL; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT Defendants.	Civil No. 08-5742 (JRT) **MEMORANDUM OPINION AND ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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Plaintiff Clifford Straka brought this action against Johnson & Johnson; Johnson & Johnson Pharmaceutical Research and Development, LLC; Ortho-McNeil-Janssen Pharmaceuticals, Inc.; and Ortho-McNeil Pharmaceutical, Inc. (collectively

"Defendants"). Straka asserts both failure to warn and fraud claims, seeking damages for injuries he claims resulted from the Defendants' failure to adequately warn about the risks of taking the drug Levaquin. Straka's action has been selected by the Court as the third bellwether case to be tried from many plaintiffs whose claims have been consolidated for coordinated trial proceedings into multi-district litigation ("MDL"). Defendants move for summary judgment on all of Straka's claims. Because the Court finds that material issues of fact exist regarding the adequacy of Defendants' warnings and whether the prescribing doctor read the drug's package insert, the Court will not grant summary judgment.

BACKGROUND

I. STRAKA'S LEVAQUIN DOSE AND TENDON INJURY

In 2006, Straka began experiencing symptoms of an upper respiratory infection or inflammation. (Dana M. Lenahan Aff., Ex. K, Clifford Straka Dep. at 27:5-10, Aug. 18, 2009, Docket No. 46; Ronald S. Goldser Decl., Ex. A, Katayoun Baniriah Disc. Dep. at 57:7-15, Aug. 23, 2011, Docket No. 55.) Dr. Katayoun Baniriah diagnosed Straka with pneumonia and prescribed a ten-day course of Levaquin. (Baniriah Disc. Dep. at 61:13-18.) After taking Levaquin for nine days, Straka suffered bilateral Achilles tendon ruptures. (Compl. ¶ 108, Docket No. 1.)

Dr. Baniriah does not remember if she had read the package insert for Levaquin before prescribing it to Straka. (Goldser Decl., Ex. 2, Baniriah Trial Dep. at 97:15-23, Aug. 23, 2011, Docket No. 55.) She testified that she was not aware of the risk of tendon

injury associated with Levaquin or other fluoroquinolones at the time of the prescription – nor did she become aware of the risk or the warning on the label until a couple of years ago. (*Id.* 98:18-99:9.)

II. PACKAGE INSERTS

Levaquin, the brand name for the drug levofloxacin, is a member of the fluoroquinolone class of antibiotics. (Compl. ¶¶ 15-16.) Since its release in 1997, Levaquin's package insert (sometimes referred to as the "label") has contained a warning of the risk of tendon rupture associated with the drug's use. (Compl. ¶ 15; Lenahan Aff., Ex. A., 1997 Package Insert, Docket No. 46.) In 2001, Defendants changed the label to include the following language, "Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant steroid, especially in the elderly." (Compl. ¶ 65.) In 2004, the label was updated again to state:

> **Tendon Effects**: Ruptures of the shoulder, hand, Achilles tendon, *or other tendons* that require surgical repair or result 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. Levofloxacin should be discontinued if the patient experiences pain, inflammation or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur during or after therapy with quinolones, include levofloxacin.

(Lenahan Aff., Ex. C, 2004 Package Insert at 6, Docket No. 46 (emphasis in original).) This warning was in place at the time of Straka's prescription.

In 2005, the FDA received a citizen petition from the Illinois Attorney General's office asking that the FDA require all fluoroquinolone manufacturers to include a black

box warning on their labels highlighting the risk of tendinopathies. (Lenahan Aff., Ex. E, May 18, 2005, 2005 Citizen Petition, Docket No. 46.) In a 2005 internal memorandum, two divisions of the FDA declined to recommend the addition of a black box warning because they concluded that a black box warning " may miscommunicate the full safety profile of the drug since several other adverse events of potentially equal or more serious (even fatal) sequelae are also included in the WARNING section." (Second Dana M. Lenahan Aff., Dec. 7, 2011, Ex. I, FDA Memos. at 10, Docket No. 83.)

In 2008, the FDA, in response to new data and an additional citizen petition submitted by the Office of the Illinois Attorney General (*see* Lenahan Aff., Ex. F, Aug. 29, 2006, 2006 Citizen Petition, Docket No. 46.), ordered the addition of a black box warning emphasizing the association between fluoroquinolone use and tendon injury to the label of all fluoroquinolones. (Lenahan Aff., Ex. G, FDA Letter, July 24, 2008, Docket No. 46.) In 2008, Defendants also issued a "Dear Doctor" letter noting that the label had been updated to include the black box warning.[1]

III. EVIDENCE OF COMPARATIVE TOXICITY

As part of the review that ultimately led to the black box warning, the FDA also addressed concerns that levofloxacin had a higher number of tendon-related adverse events than other fluoroquinolones. (*See* Lenahan Aff., Ex. J, Department of Health and Human Services Memo. at 6, April 30, 2008, Docket No. 46.) The FDA reviewed the

[1] Although the Defendants reference this letter in their briefs, the letter was not submitted as an exhibit. A copy of the letter is available at http://www.fqresearch.org/pdf_files/Levaquin_11_2008_ortho_mcneil_dear_dr_letter.pdf.

available medical literature, including three new studies, and found that the data do not "suggest a robust difference in the risk for tendon rupture between these [fluoroquinolone] agents." (*Id.* at 8.) Neither party has offered evidence of a randomized clinical study that has demonstrated a statistically significant increase in the risk of tendinopathies with Levaquin compared to other fluoroquinolones. (*See, e.g.*, Lenahan Aff., Ex. I, Cheryl Blume Dep. at 103:23-105:12.)

DISCUSSION

I. STANDARD OF REVIEW

Summary judgment is appropriate where there are no genuine issues of material fact and the moving party can demonstrate that it is entitled to judgment as a matter of law. Fed R. Civ. P. 56(a). A fact is material if it might affect the outcome of the suit, and a dispute is genuine if the evidence is such that it could lead a reasonable jury to return a verdict for either party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). A court considering a motion for summary judgment must view the facts in the light most favorable to the non-moving party and give that party the benefit of all reasonable inferences that can be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

II. STRAKA'S FAILURE TO WARN CLAIMS

Straka asserts both strict liability and negligent failure to warn claims. (*See* Complaint ¶¶ 118, 124.) Straka asserts that the Defendants breached their duty to warn by (1) failing to adequately communicate the changes that were made to the label, (2) not

disclosing that there is a greater risk of tendon injuries with Levaquin than with other fluoroquinolones, (3) failing to request FDA approval for the addition of a black box warning before the date of Straka's prescription,[2] and (4) failing to further strengthen the label without adding a black box warning.[3]

Under Minnesota law, to prove a failure to warn claim,[4] Straka must establish that (1) Defendants had a duty to warn, (2) Defendants breached that duty, and (3) the breach caused Straka's injuries. *See Balder v. Haley*, 399 N.W.2d 77, 81 (Minn. 1987). Whether there is a duty to warn of a danger is a question of law. *Germann v. F.L. Smithe Mach. Co.*, 395 N.W.2d 922, 924 (Minn. 1986). If a legal duty to warn is found, the factual issue of the adequacy of the warning, breach of the duty, and causation are considered by the factfinder. *Balder*, 399 N.W.2d at 81. Defendants assert that (1) they had no duty to warn other than through the label and (2) regardless of the adequacy of the label, Straka is unable to prove causation because Dr. Baniriah did not read the label before prescribing Levaquin to Straka.

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[2] The Defendants also assert that Straka is trying to bring a failure to warn claim based on Defendants' failure to include a black box warning at the time of Straka's prescription and that this claim is preempted. (*See* Part IV, *infra*.) Straka contends that he "will not be asserting that Defendants should **unilaterally** have instituted a black box warning sooner. However, evidence pertaining to the FDA-mandated black box warning is admissible . . . [to show] that Defendants could have requested FDA approval to introduce a black box warning." (Pl.'s Mem. Opp. Summ. J. at 19-20, Nov. 28, 2011, Docket No. 54 (emphasis added).)

[3] Straka suggests that additional bold lettering could have been added or that the order of the warnings in the label could have been altered.

[4] The Minnesota Supreme Court has determined that strict liability and negligent failure to warn claims are properly analyzed using the same standard. *Bilotta v. Kelley*, 346 N.W.2d 616, 622 (Minn. 1984). The following analysis therefore applies both to Straka's strict liability failure to warn claim and to his negligent failure to warn claim.

A. Duty to Warn

The Court has previously held that the Defendants had a duty to warn of the dangers of tendon injury associated with Levaquin. *See Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, -- F. Supp. 2d --, 2011 WL 3837104, at *7 (D. Minn. Aug. 26, 2011). Whether written communication of the dangers in the label was sufficient or whether something more was required is a question of **adequacy**, not duty. The adequacy of Defendants' warning is a question for the jury. *Balder*, 399 N.W.2d at 81.

Glorvigen v. Cirrus Design Corp. does not change the analysis. 796 N.W.2d 541 (Minn. Ct. App. 2011), *review granted* 2011 Minn. LEXIS 389 (Minn. June 28, 2011). In *Glorvigen*, a products liability action brought against an airplane manufacturer, the Minnesota Court of Appeals determined that a manufacturer did not have a duty to provide training to proficiency when adequate written information putting the user on notice of the dangers was provided. *Id.* at 552. Importantly, the respondents in *Glorvigen* did **not** claim the written instructions were inadequate to put the pilot "on notice of the dangers associated with piloting" the plane. *Id.* The Court interprets *Glorvigen* to hold that a manufacturer's duty to warn by providing adequate instructions for a product's safe use does not include a duty to provide separate training aside from the written warnings **if the written warnings were adequate**. *See id.* Because Straka asserts that the warnings at the time of the prescription were inadequate, the Court declines to follow *Glorvigen*.

The Court concludes that determining whether the Defendants' warning was adequate – and what type of communication was required to make it adequate – is a question of fact for the jury.

B. Causation

Straka's failure to warn claims do not fail because he is unable to prove causation. Although causation is generally a question of fact, where an adequate warning could not have prevented a plaintiff's injuries, causation does not exist as a matter of law. *See Balder*, 399 N.W.2d at 81. Defendants assert that Dr. Baniriah admits she did not read the Levaquin label and, therefore the failure to warn claim should be precluded. *See J & W Enters. v. Econ. Sales*, 486 N.W.2d 179, 181 (Minn. Ct. App. 1992) (finding that failure to read a warning precludes a claim that warning was inadequate). Although Dr. Baniriah admitted she did not remember reading the Levaquin package insert in 2006 (Banirah Video Dep. at 97:15-18), she did not state that she had **never** read the Levaquin package insert prior to her prescribing decision. (*Cf.* Def. Mem. Supp. Summ. J. at 8, Docket No. 45.) Rather, she merely testified that she was not aware of the language regarding tendon disorders in the package insert. (Banirah Video Dep. at 98:18-99:1.)

Because there is a factual dispute regarding the adequacy of the warning about Levaquin and whether Dr. Banirah read the warnings in the label insert, the Court will deny summary judgment on Straka's failure to warn claims.

III. STRAKA'S FRAUD CLAIMS

Straka asserts that Defendants violated Minnesota's Consumer Fraud Act ("CFA"), Minn. Stat. § 325F.69, and are liable for an additional civil penalty under Minnesota's Senior Citizen and Handicapped Person Consumer Fraud Act ("SCHPCFA"), Minn. Stat. § 325F.71. Because the Court concludes at this time that Straka has demonstrated a public benefit, Defendants' motion for summary judgment will be denied with respect to these claims.

A. CFA Claim

The CFA does not provide for a private cause of action. *See* Minn. Stat. § 325F.70. An individual plaintiff may, however, bring a CFA claim under the Minnesota Private Attorney General Act ("Private AG Act"). Minn. Stat. § 8.31; *Wehner v. Linvatech Corp.*, Civ. No. 06-1709, 2008 WL 495525, at *3 (D. Minn. Feb. 20, 2008). To bring a claim under the Private AG Act, a plaintiff must show that his cause of action will benefit the public. *Ly v. Nystrom*, 615 N.W.2d 302, 313 (Minn. 2000).

The Defendants assert that Straka's claim does not benefit the public because (1) he seeks only individual damages and (2) the labels complained of at the time of his prescription now contain the strongest warning warranted.[5] The Court previously addressed and rejected Defendants' assertions that an action does not benefit the public

[5] Defendants also assert that Straka's CFA claim must fail because there is no causal connection between the allegedly deficient warning and Straka's injuries. (*See* Part II.B, *supra*.) Because the Court finds there is a factual dispute regarding when (or whether) Dr. Baniriah read the label and thus relied on it, it will not address this argument.

unless the plaintiff seeks more than money damages. *In re Levaquin Prods. Liability*, 752 F. Supp. 2d 1071, 1078 (D. Minn. 2010). Ruling on a motion for judgment on the pleadings and thus construing all the plaintiffs' allegations as true, the Court allowed a CFA claim to move forward because it found the lawsuit might indirectly lead to the strengthening of Levaquin's label. *Id.* Straka argues, as have previous plaintiffs, that the earlier Levaquin warnings were inadequate because they did not sufficiently warn that Levaquin was comparatively more tendon toxic than other fluoroquinolones. *See id.* That inadequacy, he alleges, is continuing. Thus, consistent with its previous rulings, the Court finds that this lawsuit may indirectly cause Defendants to redress a public safety hazard, a result that would benefit the public, as required by the Private AG Act. The Court also rejects Defendants' argument that the Levaquin label now contains the strongest warning warranted; it is at least theoretically possible that comparative labeling or stronger language could be added to the label, and additional enumeration of the drug's risks could potentially provide a public benefit.

The Court admits to lingering doubts concerning whether there is standing to bring the CFA claim and specifically, about the sufficiency of Straka's (and other plaintiff's) claim of a public benefit necessary to provide standing. The Court will evaluate this claim further during the trial and may consider the claim again on a Rule 50 motion if evidence that bears on whether there is a public benefit conferred by this case is deemed lacking.

B. SCHPCFA Claim

The SCHPCFA provides for an additional civil penalty in certain circumstances if the conduct prohibited by the CFA is perpetrated upon senior citizens. *See* Minn. Stat. § 325F.71 subds. 1(a), 2(a). Straka's SCHPCFA claim stands or falls with his claim under the CFA. *In re Levaquin*, 752 F. Supp. 2d at 1079. Since the Court declines to grant summary judgment on Straka's CFA claim at this time, the Court will also deny Defendants' summary judgment motion on the SCHPCFA claim.

IV. PREEMPTION

Defendants assert that all of Straka's label-based claims are preempted by the Supreme Court's ruling in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011) (holding that a generic drug manufacturer meets the burden of impossibility preemption for state failure to warn claims by showing that it could not independently satisfy state duties due to its position in the FDA's regulatory scheme). The Court has previously addressed Defendants' argument that the standard from *Mensing* should apply to the cases in the MDL, and concluded:

> Taken together, *Wyeth* [*v. Levine*, 555 U.S. 555 (2009)] and *Mensing* stand for the proposition that to trigger pre-emption, a brand-name manufacturer must show that the FDA would not have approved a proposed label change that is the basis for a state law failure to warn claim; indeed, the brand name manufacturer likely must proffer evidence of the FDA's **rejection of an actual label change**. Such a rejection was not in evidence in *Wyeth*, nor in the instant case.

Schedin, 2011 WL 3837104, at *3-4. (internal citations omitted) (emphasis in original). The Court found the "independent action" standard of *Mensing* inapplicable to a brand

name manufacturer *Id.* at *2. The Court rejects Defendants' assertion that Straka's label-based claims are preempted by *Mensing* for the same reasons set forth in its previous orders.

In the alternative, Defendants assert that the FDA's 2005 Internal Memorandum is conclusive evidence that the FDA would have rejected a label change proposed by Defendants. At the time of the memorandum, the FDA was considering only a citizens' petition, not a request from a brand name manufacturer. Because a brand name manufacturer has the responsibility to update a label with new safety information, *see Wyeth* at 571, the FDA could have responded differently to a petition from the Defendants than it did to the citizens' petition. Therefore, the Court finds that the Defendants have not proffered evidence that the FDA would have denied defendants' request for a label change. The label-based claims are thus not preempted under *Wyeth*.

ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Defendants' Motion for Summary Judgment [Docket No. 44] is **DENIED.**

DATED: December 28, 2011
at Minneapolis, Minnesota.

s/ John R. Tunheim
JOHN R. TUNHEIM
United States District Judge