UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

VINCENT JACKSON CIVIL ACTION NO. 10-cv-1113

VERSUS

JOHNSON & JOHNSON, ET AL MAGISTRATE JUDGE HORNSBY

MEMORANDUM RULING

Introduction

Vincent Jackson ("Plaintiff") filed this civil action against defendants associated with the prescription drug Levaquin. He alleged that he had an adverse reaction to the drug and that the defendants were liable under Louisiana law. Defendants (Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Johnson & Johnson Pharmaceutical Research and Development, LLC) have filed a Motion for Summary Judgment (Doc. 37) and challenged all possible theories of liability. For the reason that follow, the Motion for Summary Judgment will be granted.

Summary Judgment Standard

Summary judgment is proper when the movant can demonstrate that there is no genuine dispute of material fact and that he is entitled to judgment as a matter of law. All facts and inferences must be construed in the light most favorable to the non-movant. Kirschbaum v. Reliant Energy, Inc., 526 F.3d 243, 248 (5th Cir. 2008). But where the non-moving party fails to establish the existence of an element essential to that party's case,

and on which that party will bear the burden of proof at trial, no genuine dispute of material fact can exist. McLaurin v. Noble Drilling (US) Inc., 529 F.3d 285, 288 (5th Cir. 2008).

Inadequate Warning; Learned Intermediary

Defendants argue in their motion that any causes of action outside the scope of the Louisiana Products Liability Act are not cognizable, and they challenge on the merits each of the four available theories of liability under the Act. Plaintiff's Memorandum in Opposition (Doc. 41) argues only a single theory of potential liability: The warning provided with the drug did not adequately inform the physician of the risks associated with it.

To maintain a failure to warn claim under the LPLA, a plaintiff must demonstrate that the product has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic. Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 264 (5th Cir. 2002). Defendants do not dispute that Levaquin has a potentially damage-causing characteristic. It is known to sometimes cause side effects including angioedema, airway obstruction, and nausea. The parties do dispute whether Defendants used reasonable care to provide adequate warnings regarding these characteristics.

Whether a drug manufacturer used reasonable care to provide an adequate warning about a potentially damage-causing characteristic is subject to the learned intermediary doctrine. Under this doctrine, "a drug manufacturer discharges its duty to consumers by reasonably informing prescribing physicians of the dangers of harm from a drug." Stahl, 283 F.3d at 265. A two-prong test governs when the doctrine applies. "First, the plaintiff must

show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician." Id. at 265-66. "Second, the plaintiff must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury." Id. at 266.

Relevant Facts

Plaintiff sought care for a work-related injury in June 2009, and he was diagnosed with a contusion to the left knee. He saw Dr. Soeller, an orthopedic surgeon, on June 30, 2009. Dr. Soeller suspected a pre-patellar infection (an infection of the skin/soft tissue overlying the kneecap), and he prescribed the antibiotic Bactrim.

Plaintiff returned to Dr. Soeller on July 10, 2009 and reported that he still had pain in his knee. Dr. Soeller noted fluid beneath the skin, and he used a needle aspiration procedure to sample the fluid. It appeared cloudy, which made him suspect an infection that was not responding to the Bactrim. Dr. Soeller prescribed Levaquin, a broad-spectrum antibiotic, in case Plaintiff was infected with a bacterial pathogen not covered by the first antibiotic. He testified that he believed it important to find an antibiotic that would treat the infection and avoid the necessity of surgery.

Plaintiff states that he took his first and only dose of Levaquin on July 11, 2009 and, within hours, had an adverse reaction. Plaintiff sought care from the emergency department at Christus Schumpert Highland Hospital. He complained that he threw up an hour earlier and that his uvula was swollen. The emergency room physician had the clinical impression of uvula hydrops (swelling of the structure in the back of the mouth) and allergic reaction to

Levaquin. He recommended that the Levaquin be discontinued. He gave Plaintiff a steroid and an antihistamine. Plaintiff was released to go home.

Plaintiff's expert, Dr. Arthur Hadley, testifies by affidavit that Plaintiff was evaluated by Dr. Henry Hollier on July 20, 2009, nine days after his trip to the emergency room. It does not appear the medical records from the visit are in the court record, but Dr. Hadley testifies that Dr. Hollier described Plaintiff's episode as difficulty with facial swelling, vomiting, trouble focusing, throat pain, and feeling like his throat was closing up. Dr. Hollier reportedly found some edema and swelling of the uvula and soft pallet, and tenderness in the left upper neck around the hyoid area. He treated the swelling with an injection of Celestone. Plaintiff returned two days later and said he felt "like his throat had not opened up at all since he first took the Levaquin antibiotic." Dr. Hollier found minimal edema of the uvula and soft pallet, but treated Plaintiff with an oral steroid and antihistamine to reduce swelling.

Dr. Hadley testifies in his affidavit that Plaintiff also complained at this visit of difficulty breathing at night, daytime sleepiness, and that his wife said she had witnessed apneic episodes while Plaintiff was sleeping. Dr. Hollier evaluated the symptoms further and found Plaintiff to have severe sleep apnea. Dr. Hadley testifies that, in all medical probability, the swelling brought on by the adverse drug reaction compromised Plaintiff's airway, which either caused or exacerbated his symptoms of sleep apnea.

At the time Plaintiff was prescribed Levaquin, the FDA-approved Prescribing Information listed nausea among the most common adverse reactions. It also warned that "[a]naphylactic reactions ... , serious, occasionally fatal, may occur after first dose." Under

the heading WARNINGS AND PRECAUTIONS is paragraph 5.2, headed Hypersensitivity Reactions. It provides (with emphasis added):

> ***Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with fluoroquinolones, including LEVAQUIN®. These reactions often occur following the first dose. Some reactions have been accompanied by*** cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, ***angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress)***, dyspnea, urticaria, itching, and other serious skin reactions. LEVAQUIN® should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity. Serious acute hypersensitivity reactions may require treatment with epinephrine and other resuscitative measures, including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated [see Adverse Reactions (6); Patient Counseling Information (17.3)].

Dr. Hadley, Plaintiff's expert, was read this language and asked if he believed Plaintiff suffered a reaction as described in the document. Dr. Hadley answered, "Yes."

Dr. Soeller, the prescribing physician, was asked if he was aware at the time he prescribed the Levaquin that the PDR at the time warned of hypersensitivity and/or anaphylactic reactions. Dr. Soeller testified that he had not heard of that before, but he agreed it was in the relevant PDR at the time of the prescription. Dr. Soeller testified at his deposition that he "did not read the PDR and go through every one of the risks and complications before I gave him this Levaquin." He later submitted an errata sheet that he described as a clarification of and addendum to his deposition. Dr. Soeller stated that his office did not use the printed PDR manual. Instead, he uses a computer-based program. He wrote, "From this source my PA would have gone through the common complications (a

printout of these is attached)." The printout warns of adverse reactions including nausea, vomiting, and anaphylaxis. Dr. Soeller testified that he considered the benefits and risks involved with prescribing the drug and, if a patient came in today with the same history and symptoms as Plaintiff had, he would again prescribe Levaquin.

Analysis

A prescription drug warning is not deemed adequate as a matter of law simply because the warning label contains a clear and unambiguous reference to the adverse reaction suffered by the plaintiff. "For summary adjudication of an inadequate warning claim to be appropriate, the plaintiff's prescribing physician must also unequivocally testify that the warning was adequate to inform him or her of the risks involved in prescribing the drug." Stahl, 283 F.3d at 267. The doctor's testimony provides added assurance that the language in the package insert was worded strongly enough to adequately inform him of the actual level of risk involved. Id.

Plaintiff's memorandum makes no argument with respect to this issue. His only argument against summary judgment is that, even though "some of his symptoms were consistent with the warnings that were provided," the warnings were inadequate because "the chronic nature and severity of the symptoms (he suffered) were not warned of." Plaintiff argues that his complications were more than a simple allergic reaction and have resulted in continuing problems with swelling in his throat, difficulty swallowing, shortness of breath, and sleep apnea.

The warning materials warn of certain reactions, but there is nothing to support Plaintiff's suggestion that the materials concern only temporary allergic reactions that quickly resolve. Rather, the materials warn of "serious and occasionally fatal hypersensitivity" that include cardiovascular collapse, the angioedema he suffered, airway obstruction, and other reactions.

The warnings section of the package insert in Stahl warned of the possibility of cholestatic hepatitis, which Plaintiff developed. Summary judgment was deemed appropriate on the plaintiff's claim that there was not adequate warning of that risk. The plaintiff also made a claim that the package insert did not adequately warn physicians that liver failure and death could result from use of the drug. The Fifth Circuit reasoned that liver failure and resulting death were widely recognized to be possible outcomes in a severe case of hepatitis, so those risks were adequately addressed by the warnings provided in the insert. It was deemed an obvious risk that needed no warning, because any prescribing physician who was forewarned of a risk of systematic liver dysfunction and coleostatic hepatitis would find it obvious that there was an attendant possibility of liver failure and death. Stahl, 283 F.3d at 268.

The same rationale applies in this case. Any prescribing physician who was warned of serious and occasionally *fatal* reactions of a kind at issue in this case would find it obvious that there was a possibility that there could be continuing difficulties stemming from effects such as angioedema, airway obstruction, and shortness of breath. Defendants point to evidence that Plaintiff suffered from apnea long before he took Levaquin and argue that there

is no medical evidence to support his claim of any chronic or lasting conditions caused by Levaquin. The court need not reach that issue. The warning at issue was adequate to contemplate more than a brief or temporary period of difficulty with the warned-of side effects.

Accordingly, Defendants' Motion for Summary Judgment (Doc. 37) is granted. The Motions in Limine (Docs. 43 and 44) are denied as moot. A final judgment will be entered in accordance with this ruling.

THUS DONE AND SIGNED in Shreveport, Louisiana, this 25th day of June, 2012.

MARK L. HORNSBY
UNITED STATES MAGISTRATE JUDGE