IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

DANNY E. COWLEY and
GLENDA COWLEY,

Plaintiffs,

v.

ABBOTT LABORATORIES, INC. and
EXPRESS SCRIPTS, INC.,

Defendants.

MEMORANDUM AND ORDER

06-C-532-S

Plaintiffs Danny E. Cowley and Glenda Cowley commenced this products liability action against defendants Abbott Laboratories, Inc. and Express Scripts, Inc. in Jackson County Circuit Court seeking monetary relief. Defendant Abbott Laboratories, Inc. removed this action pursuant to 28 U.S.C. § 1441(a) citing 28 U.S.C. § 1332(a) as grounds for removal. Defendant Express Scripts, Inc. consented to the removal. Jurisdiction is based on 28 U.S.C. § 1332(a)(1). The matter is presently before the Court on defendants' motion for summary judgment. The following facts are either undisputed or those most favorable to plaintiffs.

BACKGROUND

Plaintiffs Danny E. Cowley and Glenda Cowley are citizens of the State of Wisconsin residing in Hixton, Wisconsin. Defendant Abbott Laboratories, Inc. (hereinafter defendant Abbott) is a Delaware Corporation with its principal place of business in Abbott Park, Illinois. Defendant Abbott is engaged in the business of

developing and manufacturing pharmaceutical drugs and medications. Defendant Express Scripts, Inc. (hereinafter defendant Express) is a Delaware corporation with its principal place of business in Maryland Heights, Missouri. Defendant Express is a pharmacy benefit manager.

On January 28, 2002 plaintiff Danny E. Cowley (hereinafter plaintiff Cowley) went to see Dr. Kimberly Carter Cerveny (hereinafter Dr. Cerveny) because he was experiencing pain and swelling in his wrist. Dr. Cerveny is licensed to practice medicine in the State of North Carolina and she practices in Elizabeth City, North Carolina. Additionally, she is a board certified rheumatologist. On April 16, 2002 Dr. Cerveny diagnosed plaintiff Cowley with rheumatoid arthritis.

Dr. Cerveny initially prescribed Prednisone to treat plaintiff Cowley's rheumatoid arthritis (hereinafter RA) and Prednisone proved effective in alleviating his symptoms. However, Prednisone carries a high risk of side-effects such as weight gain, diabetes, coronary disease, cataracts, glaucoma, thinning of the skin, and infections. As such, Dr. Cerveny likewise prescribed Methotrexate in hopes that plaintiff Cowley could be weaned from Prednisone use. Additionally, on January 21, 2003 Dr. Cerveny began prescribing Plaquenil. On March 6, 2003 Dr. Cerveny removed Prednisone from plaintiff Cowley's treatment regimen.

However, on July 1, 2003 Dr. Cerveny noted a recurrence of plaintiff Cowley's pain and swelling. Plaintiff Cowley explained

that he had stopped taking his Methotrexate and Plaquenil because he felt fatigued. According to Dr. Cerveny, fatigue is a common side-effect of these medications. As such, Dr. Cerveny determined that it might be appropriate for plaintiff Cowley to consider treatment with a TNF inhibitor. A TNF inhibitor is an anti-tumor necrosis factor anti-body.

Humira is one example of a TNF inhibitor. It is manufactured by defendant Abbott and is available only by prescription. Humira is a biologic, disease-modifying anti-rheumatic drug indicated for: (1) reducing signs and symptoms, (2) inducing major clinical response, (3) inhibiting progression of structural damage; and (4) improving physical function in adults with moderate to severely active RA. Humira works by binding to tumor necrosis factor alpha and blocking its interaction with TNF receptors which neutralizes the human body's inflammatory response and alleviates RA symptoms. Humira was approved by the Food and Drug Administration (hereinafter FDA) on December 31, 2002.

Additionally, on December 31, 2002 the FDA approved Humira's product insert which references both Humira's possible side-effects and adverse events identified in clinical trials. Humira's product insert has been revised several times. However, each revision has warned about possible neurological side-effects including

demyelinating disorders such as multiple sclerosis.[1] For example, Humira's product insert contains a heading entitled "What important information do I need to know about side effects with HUMIRA?" Under this heading the insert provides in relevant part as follows:

> Nervous system diseases: There have been rare cases of disorders that affect the nervous system of people taking HUMIRA or other TNF blockers. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs and dizziness.

Additionally, Humira's product insert contains a section entitled "WARNINGS" which provides in relevant part as follows:

> Neurologic Events
>
> Use of TNF blocking agents, including HUMIRA, has been associated with rare cases of exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease. Prescribers should exercise caution in considering the use of HUMIRA in patients with preexisting or recent-onset central nervous system demyelinating disorders.

Finally, every revision of Humira's product insert contains a section entitled "Other Adverse Events" which provides the following relevant information:

> Nervous System: Confusion, multiple sclerosis, paresthesia, subdural hematoma, tremor

Defendant Abbott conducted clinical trials for Humira use in RA patients during the development process. In the original

[1]A demyelinating disorder is a medical condition where the myelin sheath is damaged. The myelin sheath surrounds nerves and is responsible for transmission of impulses to the brain. Damage to the myelin sheath results in muscle weakness, poor coordination, and possible paralysis.

clinical trials, defendant Abbott monitored 2,334 patients taking Humira[2] and these trials demonstrated that a number of patients experienced various side-effects while taking Humira. For example, approximately 5% of patients reported experiencing some neurological side-effects such as demyelinating disorders. Defendant Abbott reported all adverse events to the FDA in support of its application for approval.

Dr. Cerveny testified that she informed plaintiff Cowley about risks associated with TNF inhibitors (including Humira) during his July 1, 2003 visit. According to Dr. Cerveny, such risks include the inability to fight infections, reactivation of latent Tuberculosis, bone marrow abnormalities, and demyelinating disorders such as multiple sclerosis and optic neuritis. Dr. Cerveny testified that she described the meaning of demyelinating disorders to plaintiff Cowley specifically referencing multiple sclerosis. Further, Dr. Cerveny testified that she provided plaintiff Cowley with information concerning three TNF inhibitors: Humira, Enbrel, and Remicade including Humira's product insert.

However, plaintiff Cowley testified that he cannot remember whether Dr. Cerveny discussed nervous disorders. Additionally, he testified that he does not know what demyelinating disorders are. Finally, plaintiff Cowley testified that Dr. Cerveny did not

[2]Starting in July 2004, Humira's product insert provided data based on monitoring 2,468 clinical trial patients.

provide him with any written documentation or information concerning Humira.

Dr. Cerveny ultimately recommended that plaintiff Cowley take Humira for treatment of his RA because she believed it was his best option despite the risk of associated side-effects. Plaintiff Cowley deferred to her judgment because she was an expert in the field of rheumatology. Accordingly, Dr. Cerveny prescribed Humira for plaintiff Cowley on August 11, 2003. Dr. Cerveny testified that she reviewed the product inserts before prescribing Humira to plaintiff Cowley. Dr. Cerveny is the only doctor who prescribed Humira to plaintiff Cowley and she prescribed it exclusively in the State of North Carolina.

In January of 2004, plaintiffs moved to Wisconsin. During their move, plaintiff Cowley noticed that he developed neurological symptoms which his primary care physician Dr. Delbert W. Rogers attributed to his use of Humira. Accordingly, plaintiff Cowley discontinued treatment with Humira in May of 2004. However, Dr. Cerveny testified that she does not believe defendant Abbott failed to adequately inform her about Humira's risks. Additionally, she testified the warnings provided by defendant Abbott were adequate. Finally, Dr. Cerveny testified that she understood the warnings concerning Humira's side-effects and she did not have any questions regarding Humira's product insert.

MEMORANDUM

Defendants assert plaintiffs have failed to either identify or produce any evidence in support of their claims that defendants negligently developed, produced, manufactured, and distributed Humira. Additionally, defendants assert North Carolina law governs this action. As such, defendants assert they cannot be liable under plaintiffs' failure to warn claim pursuant to the Learned Intermediary Doctrine because defendant Abbott's warnings to Dr. Cerveny were adequate. Finally, defendants assert they cannot be strictly liable under plaintiffs' claim that Humira is unreasonably dangerous because such a claim is precluded by North Carolina statute. Alternatively, defendants assert plaintiffs claims fail as a matter of Wisconsin law. Accordingly, defendants argue their motion for summary judgment should be granted.

Plaintiffs assert genuine issues of material fact remain concerning whether defendants negligently developed, produced, manufactured, and distributed Humira. Additionally, plaintiffs assert issues of material fact remain concerning whether defendants failed to adequately warn consumers about Humira's side-effects. Finally, plaintiffs assert Wisconsin law governs this action. As such, plaintiffs assert defendants are strictly liable because Humira is unreasonably dangerous under the consumer-consumption test. Accordingly, plaintiffs argue defendants' motion for summary judgment should be denied.

A. Standard of Review

Summary judgment is appropriate where the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A fact is material only if it might affect the outcome of the suit under the governing law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). Disputes over unnecessary or irrelevant facts will not preclude summary judgment. Id. Further, a factual issue is genuine only if the evidence is such that a reasonable fact finder could return a verdict for the non-moving party. Id. A court's role in summary judgment is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Id. at 249, 106 S.Ct. at 2511.

To determine whether there is a genuine issue of material fact for trial courts construe all facts in the light most favorable to the non-moving party. Heft v. Moore, 351 F.3d 278, 282 (7th Cir. 2003)(citation omitted). Additionally, a court draws all reasonable inferences in favor of that party. Id. However, the non-movant must set forth "specific facts showing that there is a genuine issue for trial" which requires more than "just speculation or conclusory statements." Id. at 283 (citations omitted). If a

court determines that the material facts are not in dispute then the "sole question is whether the moving party is entitled to judgment as a matter of law." Santaella v. Metro. Life Ins. Co., 123 F.3d 456, 461 (7th Cir. 1997)(citation omitted).

B. Choice-of-Law

As a threshold matter, the Court must determine whether North Carolina or Wisconsin law governs this action. A federal court sitting in diversity must apply the choice-of-law rules of the forum state. Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496, 61 S.Ct. 1020, 1021-1022, 85 L.Ed. 1477 (1941). Accordingly, the Court must apply Wisconsin's choice-of-law rules to this action.

Under Wisconsin law, the "first rule" in the choice-of-law analysis is "'that the law of the forum should presumptively apply unless it becomes clear that nonforum contacts are of the greater significance.'" State Farm Mut. Auto. Ins. Co. v. Gillette, 2002 WI 31, ¶ 51, 251 Wis.2d 561, 588, 641 N.W.2d 662, 676 (citation omitted). Accordingly, Wisconsin law presumptively applies unless it becomes clear that North Carolina's contacts are of greater significance.

When faced with a choice-of-law question Wisconsin courts apply five choice-influencing factors. Drinkwater v. Am. Family Mut. Ins. Co., 2006 WI 56, ¶ 40, 290 Wis.2d 642, 658, 714 N.W.2d 568, 576 (citations omitted). These five factors are as follows:

(1) predictability of results, (2) maintenance of interstate and international order, (3) simplification of the judicial task, (4) advancement of the forum's governmental interests; and (5) application of the better rule of law. Heath v. Zellmer, 35 Wis.2d 578, 596, 151 N.W.2d 664, 672 (1967). Application of Wisconsin's five choice-influencing factors makes it clear that North Carolina's contacts are of greater significance. Accordingly, North Carolina law governs this action.

The first factor, predictability of results concerns the parties' expectations. Gillette, at ¶ 54, 251 Wis.2d at 589, 641 N.W.2d at 676 (citation omitted). This factor clearly favors North Carolina. Plaintiff Cowley was a North Carolina resident when he sought medical treatment for his wrist pain and swelling. He received treatment from Dr. Cerveny, a physician licensed by the State of North Carolina practicing in Elizabeth City, North Carolina. Additionally, Dr. Cerveny diagnosed plaintiff Cowley with RA and prescribed Humira for his treatment exclusively in North Carolina. Finally, plaintiff Cowley took Humira in North Carolina for approximately five months. Accordingly, plaintiff Cowley had to assume that any dispute concerning Dr. Cerveny's prescription of Humira would be resolved under North Carolina law. Additionally, it is reasonable for defendants to expect that they would be required to defend themselves in North Carolina where resident physician Dr. Cerveny prescribed defendant Abbott's

product. *See* Stupak v. Hoffman-La Roche, Inc., 287 F.Supp.2d 968, 973 (E.D. Wis. 2003). Accordingly, the first factor points to applying North Carolina law.

The second factor, maintenance of interstate and international order "requires that the jurisdiction that is minimally concerned defer to the jurisdiction that is substantially concerned." Gillette, at ¶ 55, 251 Wis.2d at 589-590, 641 N.W.2d at 676 (citation omitted). Wisconsin is certainly concerned with this action because the traditional role of the State is to protect the health and safety of its citizens. Peters v. Astrazenca, LP, 417 F.Supp.2d 1051, 1055 (W.D. Wis. 2006). Plaintiffs are currently Wisconsin residents and plaintiff Cowley's neurological symptoms initially manifested during his move to Wisconsin. As such, it cannot be said that Wisconsin lacks an interest in protecting plaintiff Cowley's health and welfare.

However, in their brief (filed in response to defendants' motion for summary judgment) plaintiffs argue that "[t]here was no medical need to prescribe Humira to Mr. Cowley and [Humira] was way too strong for the condition Mr. Cowley presented. The only reason a physician would resort to Humira in the face of good responses to prednisone and methotrexate is the over-promotion of Humira by Abbott Labs." (Pls.' Br. Opp'n Defs.' Mot. for Summ. J. at pages 13-14). Accordingly, plaintiffs' main argument and concern directly implicates both Dr. Cerveny's medical treatment of

plaintiff Cowley's RA and her prescribing decision all of which occurred in the State of North Carolina. North Carolina has a substantial interest in overseeing the conduct of physicians it licenses. Additionally, North Carolina has a substantial interest in protecting the health and welfare of its residents who receive treatment from North Carolina physicians. Accordingly, Wisconsin must defer to North Carolina and the second factor likewise favors application of North Carolina law.

The third factor is simplification of the judicial task. The Court finds this factor is neutral to the choice-of-law determination. This factor stands for the proposition that a "simple and easily applied rule of substantive or procedural law is to be preferred." Heath, at 597, 151 N.W.2d at 672. While a "court's task is rarely simplified when...[it] must apply [itself] to foreign rather than forum law," Id. at 597, 151 N.W.2d at 673, this is not a concern in this action because North Carolina substantive law is simple and easy to apply. North Carolina has adopted the Learned Intermediary Doctrine in products liability actions, *See* Foyle v. Lederle Laboratories, 674 F.Supp. 530, 535-536 (E.D.N.C. 1987), which is very straight-forward in application. Wisconsin courts apply the consumer-contemplation test in all strict products liability cases. Green v. Smith & Nephew AHP, Inc., 2001 WI 109, ¶ 46, 245 Wis.2d 772, 807, 629 N.W.2d 727, 743. This consumer-contemplation test is likewise straight-forward in

application even in complex cases. As such, the Court could easily apply either jurisdiction's law to this action. Accordingly, this factor is not dispositive of the choice-of-law analysis.

The fourth factor is advancement of the forum's governmental interests. Wisconsin has a "strong interest in compensating its residents who are victims of torts." Gillette, at ¶ 61, 251 Wis.2d at 592, 641 N.W.2d at 677. Plaintiffs are currently Wisconsin residents. As such, it cannot be said that Wisconsin lacks an interest in ensuring that they are compensated if they have been wronged. However, plaintiffs were not Wisconsin residents at the time any alleged tort occurred. Rather, they were North Carolina residents. Plaintiffs' claims directly implicate both Dr. Cerveny's prescription of Humira and events leading up to said prescription all of which occurred in North Carolina. Accordingly, under the facts of this action it is clear that North Carolina's interests outweigh Wisconsin's interests despite the fact that plaintiffs currently call Wisconsin home. As such, the fourth factor points to application of North Carolina law.

The fifth and final factor is application of the better rule of law. On this question, "reasonable parties can and do disagree." Stupak, at 974. The Court cannot say that North Carolina's adoption of the Learned Intermediary Doctrine "is anachronistic or fails to reflect modern trends." Gillette, at ¶ 66, 251 Wis.2d at 593, 641 N.W.2d at 678. In fact, "[t]he

overwhelming weight of the law in other jurisdictions is to absolve the manufacturer from a requirement to warn the patient when there has been a warning to the treating physician." Foyle, at 535 (citing e.g. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974); Hoffman v. Sterling Drug Inc., 485 F.2d 132, 142 (3rd Cir. 1973); Ortho Pharmaceutical Corp. v. Chapman, 180 Ind.App. 33, 388 N.E.2d 541 (1979)).

However, Wisconsin law in the area of products liability is "founded on a rational basis and [it] serves a discernable purpose," Gillette, at ¶ 66, 251 Wis.2d at 594, 641 N.W.2d at 678, because it is premised on the concern that individuals "be more fully financially compensated for losses suffered by them." Stupak, at 974. The Court is not in a position to determine which jurisdiction's policy better serves justice and the public interest. Such a determination is "entrusted to the legislatures of the respective states." Id. As such, the Court finds this factor is neutral in the analysis. However, application of Wisconsin's choice-influencing factors as a whole makes it clear that North Carolina's contacts are of greater significance which leads to the conclusion that North Carolina law governs.

C. Negligent Development, Production, Manufacturing, and Distribution Claims

Plaintiffs assert "[t]here are issues of material fact as to whether Abbott Laboratories Inc.'s drug Humira was negligently

developed, produced, and manufactured....Additionally, there are issues of material fact[] as to whether Express Scripts Inc. negligently distributed Humira." (Pls.' Br. Opp'n Defs.' Mot. for Summ. J. at page 1). However, plaintiffs failed to either propose or submit any findings of fact in support of their assertion.

Additionally, plaintiff Cowley testified that he has no information that defendant Abbott "violated some ordinary standard of care...that other reasonable manufacturers would use in the manufacture, development, or marketing of Humira." (Pl. Cowley's Dep. at page 78 lines 10-17). Further, plaintiffs admitted they have no facts or evidence to assert any claim of independent negligence against defendant Express based upon its sale of Humira. (Pls.' Resp. to Req. to Admit Number 2). Plaintiffs bear the burden of proof on these claims at trial. However, there is no evidence upon which a reasonable fact finder could return a verdict in their favor on these claims. Anderson, at 248, 106 S.Ct. at 2510. Plaintiffs as non-movants must set forth "specific facts showing that there is a genuine issue for trial" which requires more than "just speculation or conclusory statements." Heft, at 283 (citations omitted). This they have failed to do. Accordingly, defendants are "'entitled to judgment as a matter of law'" on these claims because plaintiffs have "failed to make a sufficient showing on an essential element of [their] case with respect to which [they have] the burden of proof" at trial. Toro

Co. v. Krouse, Kern & Co., Inc., 827 F.2d 155, 162 (7th Cir. 1987)(citations omitted).

D. Failure to Warn and Strict Liability Claims

North Carolina possesses a statute often referred to as the Learned Intermediary Doctrine. This Doctrine governs claims based on inadequate warnings or instructions. North Carolina's adoption of the Learned Intermediary Doctrine is codified as N.C. Gen. Stat. Ann. § 99B-5 which provides in relevant part as follows:

> ...(c) Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician...who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.[3]

Humira is only available by prescription and Dr. Cerveny is the only physician who prescribed Humira to plaintiff Cowley. Dr. Cerveny testified that she does not believe defendant Abbott failed to adequately inform her about Humira's risks. Additionally, Dr. Cerveny testified the warnings provided by defendant Abbott were adequate. Finally, Dr. Cerveny testified that she understood the warnings concerning Humira's side-effects and she did not have any

[3]Defendants assert defendant Abbott was not required by FDA regulations to directly warn consumers regarding Humira. Plaintiffs do not dispute their assertion.

questions regarding Humira's product insert. Accordingly, defendant Abbott satisfied its burden under N.C. Gen. Stat. Ann. § 99B-5(c) to adequately inform Dr. Cerveny about Humira's dangers and side-effects.[4]

Plaintiffs do not appear to dispute the fact that defendant Abbott adequately warned Dr. Cerveny about Humira's risks and side-effects. Rather, plaintiffs argue the warnings and instructions defendant Abbott provides to physicians are not adequate to "persuade the physician of the best course to follow in treatment of [RA]." (Aff. of Dr. Michael M. Murphy at ¶ 6). However, that is neither defendant Abbott's role nor the test under North Carolina law. The doctor (and not a drug manufacturer) is the person responsible for "gathering the information, weighing the dangers and benefits, and making a decision in the best interest of the patient." Foyle, at 536. Accordingly, plaintiffs' argument cannot preclude summary judgment.

Additionally, plaintiffs argue an ordinary user would not contemplate what a demyelinating disorder is when listed as a Humira side-effect especially if the physician failed to explain that such disorders are a possible side-effect of Humira.

[4]Plaintiffs argue defendant Abbott lost its protection under the Learned Intermediary Doctrine because it engages in direct-to-consumer advertising. Plaintiffs cite Perez v. Wyeth Laboratories, Inc., 161 N.J. 1, 734 A.2d 1245 (1999) in support of their argument. However, there is no evidence that North Carolina has adopted such an exception to the Learned Intermediary Doctrine.

Plaintiff Cowley testified that he does not know what demyelinating disorders are and that Dr. Cerveny did not provide him with any written documentation or information concerning Humira. However, even construing such facts as true, they are not material because they would not affect the outcome of the suit under governing North Carolina law. Anderson, at 248, 106 S.Ct. at 2510. Defendant Abbott had an obligation under § 99B-5 to adequately warn Dr. Cerveny about Humira's risks. Defendant Abbott satisifed this obligation. Any duty Dr. Cerveny then owed to plaintiff Cowley to adequately inform him about Humira's risks is independent of the claims involved in this action. Accordingly, defendants are entitled to summary judgment as a matter of law on plaintiffs' failure to warn claim.

Finally, in their complaint, plaintiffs allege defendants are strictly liable to plaintiff Cowley for his injuries and damages because Humira is an unreasonably dangerous product. (Pls.' Compl. at ¶¶ 9-10). However, defendants are likewise entitled to summary judgment as a matter of law on this claim because North Carolina law expressly rejects strict liability in products liability actions. Warren v. Colombo, 93 N.C.App. 92, 102, 377 S.E.2d 249, 255 (1989); Smith v. Fiber Controls Corp., 300 N.C. 669, 678, 268 S.E.2d 504, 510 (1980); N.C. Gen. Stat. Ann. § 99B-6(d).

Accordingly, defendants' motion for summary judgment is granted.[5]

ORDER

IT IS ORDERED that defendants' motion for summary judgment is GRANTED.

IT IS FURTHER ORDERED that judgment be entered in favor of defendants against plaintiff dismissing their complaint and all claims contained therein with prejudice and costs.

Entered this 28th day of February, 2007.

BY THE COURT:

S/

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JOHN C. SHABAZ

District Judge

[5]In light of the Court's ruling defendants' preemption arguments need not be addressed.