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ORIGINAL

No. 68264-4-I

IN THE COURT OF APPEALS
OF THE STATE OF WASHINGTON
DIVISION I

DAVID A. FALSBERG,

Appellant,

v.

GLAXOSMITHKLINE LLC,

Respondent.

BRIEF OF RESPONDENT GLAXOSMITHKLINE LLC

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I. INTRODUCTION AND SUMMARY

Plaintiff alleges that GlaxoSmithKline LLC ("GSK") failed to adequately warn of the risk of Stevens-Johnson Syndrome and toxic epidermal necrolysis (collectively "SJS/TEN") associated with the use of Lamictal®, a prescription medicine manufactured by GSK—despite the fact that the Lamictal® label expressly and repeatedly warns of both potential risks. He further alleges that the inadequate warnings supposedly misled his physicians, and that he would not have been injured had different warnings been in place—despite the fact that he offered no evidence to support such speculation. This Court should affirm the Superior Court's summary judgment decision in favor of defendant GSK for two independent reasons.

First, as a matter of law, the Lamictal® label adequately warned of the risk of SJS/TEN. Under the Washington Product Liability Act ("WPLA") and the Learned Intermediary Doctrine, GSK's duty is to warn prescribing physicians of the potential "danger" of using the product—in this case, that Lamictal® may cause SJS/TEN. The FDA-approved 2007 Lamictal® label repeatedly warned of this life-threatening risk. It conservatively advised terminating use of Lamictal® at the first sign of a rash. And it plainly identified the potential risk factors for this event, incidence rates, appropriate dosing to minimize the danger, and the time period when the patient is most at risk when taking Lamictal®. Plaintiff concedes these points, as he must.

Instead, Plaintiff asserts that the Lamictal® label not only should warn of the danger but also explain to doctors how to diagnose SJS/TEN (skin rash plus mucous membrane involvement) and further explain what "mucous membrane involvement" means. App. Br. at 8. No Washington court has ever extended the duty to warn, as Plaintiff urges, to require a drug manufacturer to teach medical doctors the practice of medicine. To do so would be dangerous; the label does not and should not replace physician training and experience regarding how to diagnose and treat known diseases. This Court should affirm the Superior Court's holding that "the 2007 Lamictal® label . . . when read as a whole, is adequate as a matter of law. The label warned the prescribing physician, Dr. Conway, of the specific risk of SJS/TEN from taking Lamictal®." CP 1079. The Superior Court properly rejected Plaintiff's attempt to transform GSK's FDA-approved label into a diagnostic manual for the practice of medicine, in a manner that would be both unlawful and dangerous.

Second, Plaintiff cannot meet his burden to establish proximate cause—specifically, that different or additional warnings would have changed Dr. Conway's decision to prescribe Lamictal® for him. Plaintiff presented no evidence that Dr. Conway or any other physician who treated Plaintiff on April 5 and 6, 2007, was unaware of the risk of SJS/TEN in patients taking Lamictal® or was unaware that SJS/TEN are diseases characterized by rash and

involvement of the mucous membranes. In fact, the evidence showed that Dr. Conway was well aware of these facts as well as recommendations and treatment guidelines that might reduce the risk of SJS/TEN. This evidence refutes the speculation—supported by no evidence—that a different warning would have made any difference to Dr. Conway.

Plaintiff also cannot tell this Court, despite multiple extensions of the discovery deadline at Plaintiff's request, that any of his other treating physicians even read the 2007 Lamictal® label—much less point to evidence that they were in any way misled by it in treating Plaintiff on April 5 and 6, 2007. Plaintiff's experts cannot help him establish that the label allegedly caused Plaintiff's injuries because they have no idea what Plaintiff's physicians knew or read and admit they can only "speculate."

Accordingly, this Court also should affirm the Superior Court's holding that (1) "Plaintiff fail[ed] to present any evidence that Dr. Conway found the label false or misleading. Dr. Conway specifically recalls warning Plaintiff of the risk of serious and potentially life-threatening rash when he prescribed Lamictal® [to Plaintiff] in February 2007." CP 1079; and (2) that "Plaintiff . . . failed to present any testimony from the prescribing physician, Dr. Conway, or any other physician who treated Plaintiff in April 2007, showing that they were misled by the 2007 Lamictal® label and

would have treated Plaintiff differently if the label had been changed in the manner that Plaintiff has proposed." CP 1079.

For these two fundamental reasons, this Court should affirm summary judgment for GSK.

II. STATEMENT OF THE CASE

A. History of Plaintiff's Suits and Claims.

Plaintiff first sued in 2008, blaming Dr. Conway, his psychiatrist, and the Walgreens pharmacy at which he filled his Lamictal® prescription, for injuries caused by SJS/TEN. He filed a certificate of merit by Dr. Jay Cohen certifying that Dr. Conway and Walgreens acted below the standard of care, and alleged that their negligence caused his injuries from SJS/TEN. CP 617-26. Plaintiff did not allege that GSK's label for Lamictal® was inadequate or misleading in any way. *Id.*¶¶ 1.1-5.3. Plaintiff voluntarily dismissed this case.

In 2010, he filed a new suit through new counsel against Dr. Conway again, and this time also against GSK. The Court dismissed the claims against Dr. Conway on statute of limitations grounds on July 22, 2011. CP 565-69. On September 9, 2011, the Court dismissed Plaintiff's claim against GSK under the Washington State Consumer Protection Act. CP 581-85.

On December 9, 2011, GSK moved for summary judgment on Plaintiff's three remaining claims for strict product liability, negligence, and breach of express and implied warranties—all of

which constitute a single cause of action under the WPLA. CP 589-613. On January 6, 2012, the Superior Court denied Plaintiff's motions to strike the Declaration of David L. Dunner, M.D., and deposition testimony of Dr. Jack Conway, taken by Plaintiff in his first malpractice suit, both submitted in support of GSK's summary judgment motion. CP 1076-77.[1] On January 11, 2012, the Superior Court granted GSK summary judgment on Plaintiff's remaining claims. CP 1078-80.

On January 27, 2012, Plaintiff filed a notice of appeal challenging the Superior Court's dismissal of Plaintiff's claims against Dr. Conway in July 2011 and Plaintiff's claims against GSK in January 201 2. CP 1081-1106.

B. The 2007 Lamictal® Label.

Dr. Conway prescribed Lamictal® in February 2007 to treat Plaintiff's bipolar disorder. CP 27, Am. Compl. ¶ 2.3; CP 633, Conway Dep. at 40:4-8. Lamictal® is an FDA-approved prescription medication indicated for the management of bipolar disorder. CP 39, Am. Compl. ¶ 8.8. It is also FDA-approved for treating epilepsy. CP 676-78. Lamictal®, like hundreds of other

[1] While Plaintiff appealed the Superior Court's orders denying his attempt to exclude the testimony of Drs. Conway and Dunner, Plaintiff failed to assign error to these rulings or to argue in his opening brief that the rulings were wrong. He has therefore waived his challenge to them. *See* RAP 10.3(g).

medications, including regularly-used over-the-counter medications, has been associated with SJS/TEN in rare cases.

The Lamictal® label in effect in February 2007 (hereafter "the 2007 Lamictal® label") plainly and repeatedly warned of the risk of SJS/TEN. For example, the label included a boxed warning that stated:

> SERIOUS RASHES REQUIRING HOSPITALIZATION AND DISCONTINUATION OF TREATMENT HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF LAMICTAL. THE INCIDENCE OF THESE RASHES, WHICH HAVE INCLUDED STEVENS-JOHNSON SYNDROME, IS APPROXIMATELY 0.8% (8 PER 1,000) IN PEDIATRIC PATIENTS (AGE <16 YEARS) RECEIVING LAMICTAL AS ADJUNCTIVE THERAPY FOR EPILEPSY AND 0.3% (3 PER 1,000) IN ADULTS ON ADJUNCTIVE THERAPY FOR EPILEPSY. IN CLINICAL TRIALS OF BIPOLAR AND OTHER MOOD DISORDERS, THE RATE OF SERIOUS RASH WAS 0.08% (0.8 PER 1,000) IN ADULT PATIENTS RECEIVING LAMICTAL AS INITIAL MONOTHERAPY AND 0.13% (1.3 PER 1,000) IN ADULT PATIENTS RECEIVING LAMICTAL AS ADJUNCTIVE THERAPY. IN A PROSPECTIVELY FOLLOWED COHORT OF 1,983 PEDIATRIC PATIENTS WITH EPILEPSY TAKING ADJUNCTIVE LAMICTAL, THERE WAS 1 RASH-RELATED DEATH. IN WORLDWIDE POSTMARKETING EXPERIENCE, RARE CASES OF TOXIC EPIDERMAL NECROLYSIS AND/OR RASH-RELATED DEATH HAVE BEEN REPORTED IN ADULT AND PEDIATRIC PATIENTS, BUT THEIR NUMBERS ARE TOO FEW TO PERMIT A PRECISE ESTIMATE OF THE RATE.
>
> OTHER THAN AGE, THERE ARE AS YET NO FACTORS IDENTIFIED THAT ARE KNOWN TO PREDICT THE RISK OF OCCURRENCE OR THE SEVERITY OF RASH ASSOCIATED WITH LAMICTAL. THERE ARE SUGGESTIONS, YET

> TO BE PROVEN, THAT THE RISK OF RASH MAY ALSO BE INCREASED BY (1) COADMINISTRATION OF LAMICTAL WITH VALPROATE (INCLUDES VALPROIC ACID AND DIVALPROEX SODIUM), (2) EXCEEDING THE RECOMMENDED INITIAL DOSE OF LAMICTAL, OR (3) EXCEEDING THE RECOMMENDED DOSE ESCALATION FOR LAMICTAL. HOWEVER, CASES HAVE BEEN REPORTED IN THE ABSENCE OF THESE FACTORS.
>
> NEARLY ALL CASES OF LIFE-THREATENING RASHES ASSOCIATED WITH LAMICTAL HAVE OCCURRED WITHIN 2 TO 8 WEEKS OF TREATMENT INITIATION. HOWEVER, ISOLATED CASES HAVE BEEN REPORTED AFTER PROLONGED TREATMENT (E.G., 6 MONTHS). ACCORDINGLY, DURATION OF THERAPY CANNOT BE RELIED UPON AS A MEANS TO PREDICT THE POTENTIAL RISK HERALDED BY THE FIRST APPEARANCE OF A RASH.
>
> ALTHOUGH BENIGN RASHES ALSO OCCUR WITH LAMICTAL, IT IS NOT POSSIBLE TO PREDICT RELIABLY WHICH RASHES WILL PROVE TO BE SERIOUS OR LIFE THREATENING. ACCORDINGLY, LAMICTAL SHOULD ORDINARILY BE DISCONTINUED AT THE FIRST SIGN OF RASH, UNLESS THE RASH IS CLEARLY NOT DRUG RELATED. DISCONTINUATION OF TREATMENT MAY NOT PREVENT A RASH FROM BECOMING LIFE THREATENING OR PERMANENTLY DISABLING OR DISFIGURING.

CP 676, Conway Dep. Ex. 13.

The "WARNINGS" section of the 2007 Lamictal® label also warned of "serious rashes requiring hospitalization and discontinuation of LAMICTAL." CP 678, Conway Dep. Ex. 13. It also stated:

> It is important to note that early manifestations of hypersensitivity (e.g., fever, lymphadenopathy) may be

> present even though a rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. LAMICTAL should be discontinued if an alternative etiology for the signs or symptoms cannot be established.
>
> **Prior to initiation of treatment with LAMICTAL, the patient should be instructed that a rash or other signs or symptoms of hypersensitivity (e.g., fever, lymphadenopathy) may herald a serious medical event that the patient should report any such occurrences to a physician immediately**.

Id. (emphasis in original).

In the "PRECAUTIONS" section, the 2007 Lamictal® label explained that "[s]erious rashes associated with hospitalization and discontinuance of LAMICTAL have been reported" and that "rare deaths" have also been reported. The label informed physicians that the risk of such serious rashes may be increased by coadministration of Lamictal® with valproate, exceeding the recommended initial dose, or exceeding the recommended dose escalation for Lamictal®. *Id.*

The "PRECAUTIONS" section also stated that:

> [I]t is not possible to predict reliably which rashes will prove to be serious or life threatening. **ACCORDINGLY, LAMICTAL SHOULD ORDINARILY BE DISCONTINUED AT THE FIRST SIGN OF RASH, UNLESS THE RASH IS CLEARLY NOT DRUG RELATED. DISCONTINUATION OF TREATMENT MAY NOT PREVENT A RASH FROM BECOMING LIFE THREATENING OR PERMANENTLY DISABLING OR DISFIGURING.**

CP 679, Conway Dep. Ex. 13 (Emphasis in original).

The "PRECAUTIONS" section also included the following:

> **Information for Patients:** Prior to initiation of treatment with LAMICTAL, the patient should be instructed that a rash or other signs or symptoms of hypersensitivity (e.g. fever, lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrence to a physician immediately.

Id.

The "ADVERSE REACTIONS" section of the 2007 Lamictal® label explained that "[s]erious rash requiring hospitalization and discontinuation of LAMICTAL, including Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis, have occurred in association with therapy with LAMICTAL." CP 680, Conway Dep. Ex. 13.

The "DOSAGE AND ADMINISTRATION" section explains that there are suggestions that the "risk of severe, potentially life-threatening rash may be increased" by exceeding the recommended dose escalation, thus, "it is important that the dosing recommendations be followed closely." The label recommends an escalation regimen for patients with bipolar disorder that begins with 25 milligrams and increases to 50 milligrams in the third week. CP 684, Conway Dep. Ex. 13.

The "CONTRAINDICATIONS" section of the 2007 Lamictal® label explained that:

> It is important to note that early manifestations of hypersensitivity (e.g., fever, lymphadenopathy) may be present even though a rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately. LAMICTAL should be discontinued if an alternative etiology for the signs or symptoms cannot be established. Prior to initiation of treatment with LAMICTAL, the patient should be instructed that a rash or other signs or symptoms of hypersensitivity (e.g., fever, lymphadenopathy) may herald a serious medical event and that the patient should report any such occurrences to a physician immediately.

CP 678, Conway Dep. Ex. 13.

The "PATIENT INFORMATION" section of the 2007 Lamictal® label warned:

> It is not possible to predict whether a mild rash will develop into a more serious reaction. **Therefore, if you experience a skin rash, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, or swelling of lips or tongue, tell a doctor immediately since these symptoms may be the first signs of a serious reaction. A doctor should evaluate your condition and decide if you should continue taking LAMICTAL.**

CP 685, Conway Dep. Ex. 13 (emphasis in original).

C. Dr. Conway Knew The Risks and Benefits of Lamictal®.

Dr. Conway analyzes the potential risks and benefits when making a prescribing decision in consultation with his patients. CP 636, Conway Dep. at 52:15-22. He received information about the risks and benefits of Lamictal® from many sources, including a number of psychiatric texts and scientific reference materials and the Physicians' Desk Reference, a compilation of manufacturers' labels for prescription medications. CP 628, Conway Dep. at 10:21-12:21.

When Dr. Conway prescribed Lamictal® to Plaintiff, he was aware of the contents of the 2007 Lamictal® label. CP 632 and 644, Conway Dep. at 35:21-36:10, 97:16-19. As detailed above, the 2007 Lamictal® label included a boxed warning and discussed the risks, side effects and a recommended dosing schedule for Lamictal®. Dr. Conway discussed these subjects with Plaintiff and noted it in his medical chart. CP 646, Conway Dep. at 105:1-106:8. Dr. Conway was aware of the dosing guidelines on the Lamictal® label when he prescribed Lamictal® for Plaintiff. CP 644-45, Conway Dep. at 97:16-22, 101:2-9.

When Dr. Conway prescribed Lamictal® to Plaintiff, he also relied upon other resources in his office, including **The Carlat Psychiatry Report Medication Fact Book**, which states:

> **Stevens-Johnson Syndrome (a blistering flat rash that may affect the mucous membranes)** occurs in about 1/5000 patients, a risk not greater than with other anti-convulsants. In controlled trials for mood disorders, no cases of [SJS] occurred out of 1198 patients.

CP 628-29 (emphasis added), Conway Dep, Ex. 2; CP 650-52, Conway Dep. at 10:21-11:9, 14:21-15:11.

Dr. Conway also had read about Lamictal® and its risks in **Manic-Depressive Illness: Bipolar Disorders and Recurrent Depression**. CP 630-31, Conway Dep. at 24:19-25:13; CP 670-75, Conway Dep, Ex. 9. Among other things, this psychiatric textbook informed Dr. Conway of the following:

TABLE 20-4. Estimated Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis among Anticonvulsants

Anticonvulsant	*Risk per 10,000 New Users*
Phenytoin	8.3
Phenobarbital	8.1
Lamotrigine	2.5
Carbamazepine	1.4
Valproate	0.4

Source: The German Rash Registry, Mockenhaupt et al., 2005

Of particular concern with lamotrigine [Lamictal], however, are reports of severe dermatological reactions associated with rapid initial upward titration of the dose, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

. . .

Because benign rashes are not uncommon with this drug . . . , it is important to be able to distinguish them from those rare cases in which a rash may signal the development of Stevens-Johnson syndrome or toxic epidermal necrolysis.

. . .

Figure 20-1 provides a decision-making flowchart for dealing with rash in patients taking lamotrigine. **Dangerous rashes typically are confluent (covering virtually all of the skin) and/or involve the facial or genital area given the proximity of each to mucous membranes; also, dangerous rashes are almost always accompanied by systemic symptoms such as fever, elevated white blood cell count, and flu-like symptoms.**

Id. (emphasis added).

In addition to these texts, Dr. Conway also received a letter from GSK (then called "Glaxo Wellcome Inc.") in 2000 that specifically discussed Lamictal® and its risks. Among other things, GSK's letter told Dr. Conway that "SJS and TEN are two related serious blistering mucocutaneous disorders that form a continuous spectrum in terms of severity." CP 629, Conway Dep. at 15:22-16:1; CP 654-69, Conway Dep., Ex. 3. The term, "mucocutaneous," means involvement of both the mucous membranes and the skin. CP 771, Dunner Decl. ¶ 4.

The above evidence established that Dr. Conway knew that SJS/TEN was associated with taking Lamictal® and that the diseases were characterized by a rash and involvement of the mucous membranes. Plaintiff presented no evidence to dispute these uncontradicted facts.

D. Dr. Conway's Prescription of Lamictal® to Plaintiff.

At the time Dr. Conway prescribed Lamictal® for Plaintiff in February 2007, Plaintiff had expressed to Dr. Conway that he felt depressed and was having significant side effects from the lithium he had been taking for bipolar disorder, including a tremor that required him to take Neurontin® for that side effect. Up to that point, the medicines that Dr. Conway had prescribed to Plaintiff for his bipolar disorder included lithium, Neurontin®, Depakote®, Wellbutrin®, and Zyprexa®, none of which Plaintiff had tolerated well. CP 640-

42, Conway Dep. at 83:15-90:1. In Dr. Conway's clinical judgment, he felt that Lamictal® would offer Plaintiff significant potential improvements in his overall treatment. CP 643, Conway Dep. at 94:2-11. Given Plaintiff's condition, after discussing the risks and benefits of Lamictal®, Dr. Conway recommended it as the best alternative for Plaintiff with the best chance of improving his response. CP 642, Conway Dep. at 89:4-14.

Dr. Conway was aware of the risk of SJS/TEN when he prescribed Lamictal® to Plaintiff. CP 634, Conway Dep. at 41:13-42:4. Dr. Conway describes the risk of SJS and TEN to all of his patients when they discuss Lamictal®. He describes it as a "life-threatening rash," and as a severe rash, equivalent to a scalding burn. CP 636, Conway Dep. at 50:23-51:21. Dr. Conway specifically recalls warning Plaintiff of the risk of serious and potentially life-threatening rash when he prescribed Lamictal® to him in February 2007. CP 646, Conway Dep. at 105:1-19.

Dr. Conway was aware that a rapid increase in dosage may be associated with an increased risk of SJS. CP 632-33, Conway Dep. at 36:15-37:3. Exercising his clinical judgment and following recommendations in medical literature, Dr. Conway prescribed a dosing schedule that began at a low dose of 25 milligrams and increased to the therapeutic dose of 150 milligrams. CP 634-35, 637, Conway Dep. at 42:22-46:11, 60:13-21. This dosing schedule was gradual but different from the recommended gradual dosing

schedule in the 2007 Lamictal® label. CP 644-45, Conway Dep. at 97:20-98:1; 101:2-102:8.

As he does for all of his patients on Lamictal®, Dr. Conway told Plaintiff that to minimize the risk of developing SJS/TEN, it is very important that he take Lamictal® exactly as prescribed, following the detailed dosage schedule on the prescription. He made it clear to Plaintiff that if he increased the dosage too rapidly, there was a potentially increased risk of life-threatening rash. Dr. Conway also tells all of his patients that if they stop following the dosage schedule, they may need to start all over at the very low dose and re-start the slow dosage schedule from the beginning. CP 632-33, 636, Conway Dep. at 36:15-37:3, 51:25-52:14.

Dr. Conway also told Plaintiff that the risk of developing the serious, life-threatening rash was rare, 1 in 10,000 to 3 in 10,000, but that there was a 5 to 10 percent chance that he could develop a common, day-to-day drug rash. Consistent with the 2007 Lamictal® label, Dr. Conway told Plaintiff that if he developed *any* rash, he needed to report it, and the medication would be stopped immediately. CP 636, 646, Conway Dep. at 50:23-51:12, 105:1-19.

Plaintiff did not follow the prescribed dosage schedule. He obtained 78 tablets of Lamictal® (25 milligrams each) on February 15, 2007. Under Dr. Conway's prescribed dosing schedule, Plaintiff ran out of tablets by March 18, 2007. The pharmacy records show that Plaintiff did not obtain additional Lamictal® tablets until March

25, 2007, when he obtained 150 mg tablets—thus leaving a one-week gap in the supply of Lamictal® tablets. CP 743, Phillips Decl. Ex. C. There is no evidence that Dr. Conway was made aware of Plaintiff's one-week discontinuation of Lamictal® before re-starting at a high dose of 150 mg on March 25, 2007.

On April 4, 2007, nine days later, Plaintiff called Dr. Conway and said he was experiencing slurred speech and loss of balance.[2] Dr. Conway interrogated Plaintiff about any other symptoms, and Plaintiff reported none. Plaintiff specifically denied having a rash. Dr. Conway did not consider the symptoms of slurred speech and loss of balance to be sufficient to herald a serious medical event or to be suggestive of SJS. CP 638-39; CP 647-49, Conway Dep. at 76:1-77:16, 118:2-20, 122:3-12, 132:12-21. It is common for patients who move to a higher dose of Lamictal® to have Central Nervous System effects such as those reported by Plaintiff, so Dr. Conway directed Plaintiff to reduce his dosage to 75 mg, a dosage he had tolerated well, to ameliorate that symptom. CP 647, Conway Dep. at 118:2-20. He also told Plaintiff that if his condition worsened he should go to his physician or an emergency room, and that if he developed any kind of rash he should stop taking the medication. CP 639, 646.

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[2] Dr. Conway's testimony, corroborated by his medical chart, is the only actual evidence of the symptoms Plaintiff reported to Dr. Conway on April 4, 2007, and they included only slurred speech and loss of balance.

As instructed by Dr. Conway, the next morning Plaintiff went to see Dr. Leigh at Swedish Ballard when his symptoms worsened. The following morning, April 6, 2007, he was admitted to the Swedish Ballard emergency room and treated for SJS/TEN before being transferred to Harborview. CP 920-21.

III. ARGUMENT

A. Standard of Review

This Court reviews de novo an order granting summary judgment. *Rivas v. Overlake Hosp. Med. Ctr.*, 164 Wn.2d 261, 266, 189 P.3d 753 (2008). Summary judgment should be affirmed if "there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law." CR 56(c). A "material fact" is a "fact upon which the outcome of the litigation depends, in whole or in part." *Lamon v. McDonnell Douglas Corp.*, 91 Wn.2d 345, 349, 588 P.2d 1346 (1979). The Court should affirm summary judgment if "reasonable persons could reach but one conclusion." *Seattle Police Officers Guild v. City of Seattle*, 151 Wn.2d 823, 830, 92 P.3d 243 (2004).

Once GSK establishes that it is entitled to judgment as a matter of law, the burden shifts to Plaintiff to present a genuine issue for trial. *See Young v. Key Pharms., Inc.*, 112 Wn.2d 216, 225, 770 P.2d 182 (1989). Plaintiff may not rely on mere allegations, denials, opinions, or conclusory statements to create a genuine issue of material fact. *Int'l Ultimate, Inc. v. St. Paul Fire & Marine Ins. Co.*,

122 Wn. App. 736, 744, 87 P.3d 774 (2004). A party opposing summary judgment "may not rely on speculation [or] argumentative assertions that unresolved factual issues remain." *Doty-Fielding v. Town of S. Prairie*, 143 Wn. App. 559, 566, 178 P.3d 1054 (2008). Instead, Plaintiff must come forward with "specific facts showing that there is a genuine issue for trial." CR 56(e). Because Plaintiff has failed to do so, this Court should affirm summary judgment in GSK's favor.

B. GSK's Lamictal® Warnings Are Adequate As a Matter of Law.

1. The 2007 Lamictal® Label Satisfies Washington Law by Warning of the Specific Danger at Issue.

Plaintiff concedes on appeal that his only claim is under the WPLA for alleged failure to warn. App. Br. at 24. Washington courts have adopted Restatement (Second) of Torts § 402A, Comment k, recognizing that "unavoidably unsafe products," such as prescription medications, are incapable of being made safe for their intended use, although they play an important role in treating illnesses and saving lives. *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 12, 577 P.2d 975 (1978) (quoting cmt. k (1965)); *see also Ruiz-Guzman v. Amvac Chemical Corp.*, 141 Wn.2d 493, 508-09, 7 P.3d 795 (2000) (incorporating cmt. k under WPLA). Thus, the manufacturer of an unavoidably unsafe product, such as a prescription medication, is not subject to strict product liability when the product is properly prepared and adequately warns of the risk of

injury from the drug's use. *Terhune*, 90 Wn.2d at 13-14. Specifically, the WPLA states that the manufacturer must warn of the "dangers" presented by the product—not, as Plaintiff contends, that it must teach doctors how to diagnose illnesses. RCW 7.72.030(c).

The "danger" here is the risk of SJS/TEN from taking Lamictal®, and the 2007 Lamictal® label plainly and repeatedly warns about this risk.

In every reported Washington decision addressing prescription medications, Washington courts have identified the "danger" about which the manufacturer must warn as the specific adverse event or risk that has been associated with use of the medication. For example, in *Estate of LaMontagne v. Bristol-Meyers Squibb*, 127 Wn. App. 335, 111 P.3d 857 (2005), the plaintiff alleged that the drug manufacturer failed to adequately warn of the risk of lactic acidosis for patients with kidney dysfunction using the diabetes drug, Glucophage®. 127 Wn. App. at 337. The court affirmed summary judgment for the manufacturer, holding that the warnings were adequate as a matter of law because the label specifically warned of the risk of lactic acidosis in Glucophage®-treated patients with impaired renal function. *Id.* at 350-51. The prescribing physicians' choice to prescribe the medication despite the label's warning that it should not be used in that context was "a matter of medical judgment." *Id.* at 351; *accord Adams v. Synthes*

Spine, 298 F.3d 1114, 1116-18 (9th Cir. 2002) (applying Washington law, court held that label warned of risk of device breakage and advised that medical device should be removed after healing and, thus, warnings were adequate as a matter of law even though plaintiff's surgeon decided not to remove device that later broke); *Washington State Physicians Ins. Exchange v. Fisons Corp*, 122 Wn.2d 299, 315, 858 P.2d 1054 (1993) (manufacturer failed to warn because it did not warn of medication's theophiline toxicity); *Terhune*, 90 Wn.2d at 9, 13, 18 (defendant satisfied duty to warn by warning prescribing physician of the risk that contraceptive device could perforate the uterus, the injury suffered by plaintiff).

Washington case law is entirely consistent with leading case law from around the country, holding that a prescription medication manufacturer satisfies its duty to warn as a matter of law by warning of the specific injury that the plaintiff experienced. *See, e.g.*, *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) (prescription-drug label adequately warned of increased blood pressure and need for regular monitoring and did not need to explain to physicians the possible consequences of high blood pressure); *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 519–21 (7th Cir. 2003) (prescription asthma medication label warned that "rare instances of glaucoma, increased intraocular pressure, and cataracts have been reported" and, thus, warnings were adequate as a matter of law when plaintiff experienced these injuries); *Plummer v.*

Lederle Labs., 819 F.2d 349, 352–53, 357 (2d Cir. 1987) (label warned of possibility of contracting paralytic disease and so was adequate as a matter of law when plaintiff developed paralytic poliomyelitis).

Because the Lamictal® label warned of the precise danger at issue here, it was adequate as a matter of Washington law.

2. Plaintiff Proposes an Adequacy Standard That Is Unsupported by the Law and Dangerous to Patients.

Plaintiff departs from Washington law and suggests that the 2007 Lamictal® label not only should have warned of the risk of SJS/TEN, but also should have taught physicians how to diagnose and recognize the symptoms of SJS/TEN. App. Br. at 8.[3] No Washington court has ever imposed such a duty to warn. Nor would it, as a policy matter, be wise to do so.

Among the hundreds of medications that have been associated with SJS/TEN, Plaintiff has not identified any drug label that purports to tell physicians how to diagnose and treat SJS/TEN, and Plaintiff cites no cases imposing such a duty on a drug manufacturer. Moreover, Plaintiff's proposed warnings would be dangerous for patients. Compared to the 2007 Lamictal® label advising physicians to stop the medication at the first sign of *any*

[3] Plaintiff describes the "danger" as a risk that doctors will misdiagnose the disease, App. Br. at 25, but this is just a semantic game. The danger posed by a product is the specific injury associated with its use and the risk factors that make it more likely that the injury will occur.

rash—which is precisely the advice that Dr. Conway followed in treating Plaintiff (CP 636, 646)—Plaintiff's two experts[4] would prefer that the label instruct physicians that they should try to distinguish between a serious and non-serious rash while continuing to administer the drug. *See* CP 951 at ¶¶ 13-14; CP 904 at ¶¶ 25-26. That would be more dangerous than the label's current direction, while also interfering with a doctor's professional judgment based on his or her superior knowledge of the patient.

A prescription drug label should not replace the skill and training of physicians who act as learned intermediaries between

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[4] Plaintiff also relies on the opinion of a third expert, Dr. Khandelwal, in his Opening Brief. Pursuant to KCLR 56(e), GSK moved to exclude Dr. Khandelwal's declaration because Plaintiff had not identified Dr. Khandelwal as an expert witness in response to GSK's CR 26(b)(5) interrogatory. Judge Yu granted GSK's motion. Pursuant to CR 56(h), Judge Yu's order granting summary judgment listed the evidence she considered on summary judgment, and she excluded Dr. Khandelwal's declaration from the list of evidence she considered. CP 1074-75. Plaintiff's Opening Brief ignores the record and does assign error to Judge Yu's exclusion of Dr. Khandelwal. Plaintiff thus has waived any challenge to the exclusion of Dr. Khandelwal here. *See* RAP 10.3(g); *State v. Motherwell*, 114 Wn.2d 368, 788 P.2d 1066 (1990) (claimed error that is not supported by argument is deemed abandoned); *cf. State v. Lee*, 82 Wn. App. 298, 917 P.2d 159 (1996) ("This court generally does not consider issues raised for the first time by reply brief, as there is no opportunity for an opposing party to respond."), *aff'd,* 135 Wn.2d 369, 957 P.2d 741 (1996). Even if the exclusion of Dr. Khandelwal were reviewable, Judge Yu plainly did not abuse her discretion in excluding Dr. Khandelwal's untimely submission. *See Detwiler v. Gall, Landau & Young Const. Co.*, 42 Wn. App. 567, 572-73, 712 P.2d 316 (1986) (superior court did not abuse discretion in excluding untimely expert whose opinions were not identified in discovery); *M/V La Conte, Inc. v. Leisure*, 55 Wn. App. 396, 402, 777 P.2d 1061 (1989) (same).

pharmaceutical manufacturers and patients. The physician knows the patient and his medical history, and based on training and experience, is in the best position to exercise medical judgment in the care of the patient. Dr. Conway had treated Plaintiff for seven years. A physician's medical judgment about the best course for a patient is far more reliable than a diagnostic directive contained in a drug label. Plaintiff's argument invites a dangerous and unfounded extension of a manufacturer's duty to warn by placing the manufacturer—who does not know and cannot observe the patient—in the position of medically-trained physicians, an argument that has no support under Washington law and has been rejected by courts across the country. "There is no requirement that the warning apprise the doctor of how to properly diagnose the condition that renders use dangerous." *Nichols v. Clare Cmty. Hosp.*, 476 N.W.2d 493, 495 (Mich. App. 1991) (holding that warning about risk of using product in patient with herpes did not need to provide information about diagnosing the condition).

As the FDA has explained, "Labeling is not intended to be a dispositive treatise of all possible data and information about a drug. It is intended instead to advise about potential hazards and to convey documented statements concerning safety and effectiveness . . . ." 44 Fed. Reg. 37434, 37441 (1979). The physician, not the manufacturer, is best positioned to make treatment decisions:

> Doctors are in a unique position to determine how best to treat their patients - a much better position than that of a far-away official in a pharmaceutical company, whose job is merely to write warnings. The law does not mandate that pharmaceutical manufacturers and marketers provide such specific instructions that they leave little room for doctors' reasonable medical judgment.

In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 813-14 (N.D. Ohio 2004) (rejecting plaintiffs' argument that the drug label should have provided guidance on proper treatment for the condition warned of and granting summary judgment in favor of pharmaceutical manufacturers), *aff'd*, 447 F.3d 861 (6th Cir. 2006).

Put simply, a prescription drug manufacturer's duty does not extend to the practice of medicine. "[T]he warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006) (finding that warning of the risk of SJS/TEN with amoxicillin was adequate as a matter of law and also that risk was well-recognized in the medical community and by the prescribing doctor). "A manufacturer fulfills its duty to the medical community when it warns of the risk inherent in use of the drug. There is no requirement that the warning apprise the doctor of how to properly diagnose the

condition that renders use dangerous." *Nichols v. Clare Cmty. Hosp.*, 476 N.W.2d at 495.[5]

Moreover, the precise symptoms that Plaintiff claims should have been described in the Lamictal® label are already well known to psychiatrists who treat bipolar patients—the target audience for the label. Dr. David L. Dunner, a board-certified psychiatrist in the State of Washington and professor at the University of Washington School of Medicine, testified without contradiction that the psychiatric community is aware that Lamictal® is associated with SJS/TEN and that the diseases are characterized by skin rash and mucous membrane involvement. CP 772-73, Dunner Decl. ¶¶ 13, 18, 20. As a professor at the University of Washington, Dr. Dunner estimates that he has trained and consulted with most psychiatrists in the State of Washington, and that "it is commonly understood by psychiatrists and other clinicians that [Lamictal®] is associated with SJS/TEN and that these are mucocutaneous disorders." CP 773,

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[5] *Accord Guevara v. Dorsey Labs.*, 845 F.2d 364, 367–68 (1st Cir. 1988) (rejecting plaintiff's argument that a warning about "allergic reactions" should also have identified skin rash because physicians should generally be aware that skin rash was a potential outcome of an allergic reaction); *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 268 (5th Cir. 2002) (rejecting plaintiff's argument that the drug label should have warned about "liver failure" and "death" in addition to hepatitis because physicians were expected to know that these were possible outcomes of hepatitis); *Plenger v. Alza Corp.*, 13 Cal.Rptr.2d 811, 819 (Cal. App. 1992) (rejecting plaintiff's argument that label should have warned that failure to treat the identified adverse event might lead to death).

Dunner Decl. ¶ 18. According to Dr. Dunner, the standard of care for the psychiatric community is not only to be aware of the serious risks of a drug, but also to have an understanding of the signs and symptoms of such serious risks—relying on product labeling *and* relevant medical literature, medical training, clinical experience, practice guidelines, and continuing medical education courses. CP 772, Dunner Decl. ¶ 13.[6] As such, Dr. Dunner believes it is well-known within the relevant medical community—Washington psychiatrists who prescribe Lamictal®—that taking Lamictal® may cause SJS/TEN and that these conditions are characterized by a skin rash and involvement of the mucous membranes. CP 773, Dunner Decl. ¶ 20.[7]

Plaintiff offered no expert psychiatric testimony to dispute Dr. Dunner, and Plaintiff's experts (one of whom is not even a

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[6] Plaintiff's suggestion that a published article of a study that was sponsored by GSK and partially written by GSK employees somehow proves that GSK knew that the 2007 Lamictal® label was inadequate (App. Br. at 13), reflects Plaintiff's persistent confusion between the role of the FDA-approved label and the practice of medicine. The article is simply another example of scientific literature that contributes to the knowledge and training of treating physicians. Such articles improve the practice of medicine, but they do not reflect what is required in an FDA-approved label.

[7] Plaintiff concedes that "[t]he standard of care also requires physicians evaluating adverse drug reactions to be aware of the[] signs and symptoms [of an adverse reaction] and of their potentially life-threatening consequences." App. Br. at 12.

physician) have never prescribed Lamictal®. Both of Plaintiff's experts readily admitted (see pp. 25-26 below) that they are unaware of what prescribing physicians know about SJS/TEN.

In sum, the 2007 Lamictal® label plainly and repeatedly warned that taking Lamictal® presents a danger of SJS/TEN, the precise condition at issue here. The label is therefore adequate as a matter of law. Plaintiff's attempt to transform the label into a medical manual is inconsistent with Washington law and would be bad policy.[8]

3. GSK Fulfilled Its Duty to Warn Dr. Conway.

On appeal, Plaintiff concedes that under the Learned Intermediary Doctrine, GSK has a duty to warn physicians and there is no duty to warn Plaintiff directly. App. Br. at 26. In every case in which Washington courts have interpreted the Learned Intermediary Doctrine with respect to a prescription drug manufacturer's duty to

[8] Plaintiff also suggests that the label is "misleading" because it states that "[a]lthough benign rashes also occur with Lamictal, it is not possible to predict reliably which rashes will prove to be serious or life threatening." The statement is patently true, however. None of Plaintiff's experts identified any way to distinguish whether an early rash will develop into SJS/TEN. That is why the Lamictal® label conservatively advises prescribing physicians simply to stop the medication when a rash appears unless there are obvious other reasons to explain the rash, such as a contact dermatitis (*e.g.*, poison ivy). The fact that the disease is diagnosed by the additional development of mucous membrane involvement does not render the conservative warning in the label either wrong or misleading. Notably, other than offering his misinterpretation of the label, Plaintiff has *no* evidence that *any* treating physician has ever been misled by the label as his experts hypothesize.

warn, the courts have defined that duty as a duty to inform the *prescribing* physician about the potential risk posed by the prescription medication. *E.g.*, *Terhune*, 90 Wn.2d at 13 ("[T]he duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it."); *LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. at 345 (same). Under Washington law, the manufacturer does not have a duty to warn other physicians.

Even if such a duty existed, GSK is entitled to summary judgment because: (1) the 2007 Lamictal® label plainly warned of the precise injury at issue, and therefore *any* physician who read the label would be aware of that danger, and (2) Plaintiff presented *no* evidence of what any physician other than Dr. Conway knew about the 2007 Lamictal® label or the risk of SJS/TEN. More specifically, he presented no evidence that any of them read the label or lacked knowledge that would have prevented Plaintiff's injury.

Not only did the 2007 Lamictal® label inform physicians that Lamictal® has been associated with SJS/TEN, but it also provided specific information on the incidence rates and risk factors relating to SJS/TEN. When Dr. Conway prescribed Lamictal® for Plaintiff in February 2007, he was familiar with the 2007 Lamictal® label and knew about the risk of developing SJS/TEN from taking Lamictal®. Accordingly, under Washington law, GSK fulfilled its duty to warn Dr. Conway of the specific risk of Lamictal® at issue

here, and this Court should affirm that as a matter of law the 2007 Lamictal® label is adequate.

C. The Record Contains No Evidence That Allegedly Inadequate Warnings Caused Plaintiff's Injury.

Even if GSK's extensive and repeated warnings about the risk of SJS/TEN were not deemed legally adequate, the record is devoid of evidence that any alleged label deficiency actually caused Plaintiff's injury. Plaintiff attempts to circumvent this problem first by trying to write the causation requirement out of Washington product liability law and then by pretending that he presented evidence that the label caused his injuries when in fact he didn't. The absence of *any* evidence that the 2007 Lamictal® label caused Plaintiff's injuries compelled the Superior Court's grant of summary judgment, which this Court should affirm.

1. Plaintiff Must Prove That the Label Caused Plaintiff's Injuries.

Plaintiff asserts, in the last sentence of his brief, that he is "not required to 'prove' that Dr. Conway himself was misled or that he would have acted differently had the warnings been adequate." App. Br. at 39. The statement is simply wrong. Plaintiff must prove exactly that. Under Washington law, Plaintiff has the burden to prove that his injuries were proximately caused by GSK's allegedly inadequate warning. *See Baughn v. Honda Motor Co., Ltd.*, 107 Wn.2d 127, 142, 727 P.2d 655 (1986). To meet this burden,

Plaintiff must show that GSK's label was a "but-for" cause of Plaintiff's injury. *Id.* To do so, Plaintiff must present evidence that a different warning by GSK would have changed the prescribing physician's treatment of Plaintiff. *See, e.g., Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 258, 978 P.2d 505 (1999) (in a product liability case, as a matter of law, proximate causation was not established when there was no evidence that additional warnings would have led plaintiff to change her actions and avoid injury); *cf. Fisons*, 122 Wn.2d at 314 (proximate cause established where physician testified he would have treated patient differently had he been warned of the danger by drug manufacturer).[9]

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[9] This fundamental requirement of Washington law is consistent with pharmaceutical product liability case law from around the country. *See, e.g., Sauls v. Wyeth Pharms., Inc.*, No. 9:04-22297-HMH, --- F. Supp. 2d ---, 2012 WL 724794, *3 (D.S.C. Mar. 7, 2012) (Plaintiff could not establish proximate causation without admissible evidence from his prescribing physician showing what his physician would have done if the drug were accompanied by different or additional warnings); *In re Zyprexa Prods. Liab. Litig.*, No. 04-MD-1596 (JBW), 2009 WL 3596982, at *11 (E.D.N.Y. Oct. 20, 2009) (granting summary judgment in favor of the prescription drug manufacturer when the plaintiff "offered no evidence suggesting that his physicians would have altered their prescription decisions had [the] warning been different"); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (affirming summary judgment and declining to "presume causation" when plaintiff had no evidence that her proposed warning "would have changed the treating physician's decision to prescribe the product for the plaintiff").

Where, as here, the prescribing physician actually knew the information supposedly omitted from the label, proximate cause cannot, as a matter of law, be established. As the Washington Supreme Court has explained, "a drug manufacturer's failure to warn a prescribing physician cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved in the use of the drug." *Fisons Corp.*, 122 Wn.2d at 315. Inadequate warnings cannot be the "but for" cause of an injury when the warning's intended audience was already aware of the risk. *See Baughn*, 107 Wn.2d at 143-44 (inadequate warnings were not cause-in-fact of accident when consumers were aware of risk).[10]

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[10] This principle of Washington law is fully supported by case law from around the country. *See Ames v. Apothecon, Inc.*, 431 F. Supp. 2d at 573 (court held that plaintiff could not prove that the drug label caused her injuries from SJS/TEN because her prescribing physician knew of the risk and the signs and symptoms of SJS/TEN); *Smith v. Johnson & Johnson*, 2012 WL 3139566 at *5 (5th Cir. Aug. 2, 2012) ("If . . . the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury and the plaintiff's recovery must be denied.") (citing *Ebel v. Eli Lilly & Co.*, 321 Fed. Appx. 350, 356 (5th Cir. 2009) and *Ackerman v. Wyeth Pharm.*, 526 F.3d 203, 208 (5th Cir. 2008)); *Centeroc, Inc. v. Hamilton*, --- S.W.3d ---, 2012 WL 2052783, *25-26 (Tex. June 8, 2012) (proximate causation is not satisfied when both of the prescribing physicians were already aware of the potential risk but chose to prescribe the medication in spite of those risks and when there was no evidence that additional warnings would have caused the physicians to change their prescription); *Plummer v. Lederle Labs.*, 819 F.2d, 349 (2d Cir. 1987) (applying California law) ("[N]o harm could have been caused by failure to warn of a risk already known.").

Plaintiff relies on *Mohr v. Grantham*, 172 Wn. 2d 844, 262 P.3d 490 (2011) (App. Br. at 37-38), but that case held merely that "loss of chance" was a "compensable injury" in medical malpractice cases. The holding focused solely on "the nature of the injury," not on changing standards for proving causation. *Id.* at 853. The *Mohr* court could not have been clearer in stating that its holding "relies on established tort theories of causation" and that it simply defined loss of a chance as a "compensable injury." *Id.* at 857. *Mohr* thus is of no help to Plaintiff.

Plaintiff also looks to an Oregon case, *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974), for support, (App. Br. 28-34), but *McEwen* does not control here and is inapposite for a number of reasons. First, the Oregon courts' interpretation of the relationship between its product liability statute and the Learned Intermediary Doctrine differs from the established law of Washington. *See Griffith v. Blatt*, 334 Or. 456, 51 P.3d 1256 (2002) (product liability statute limits some application of Learned Intermediary Doctrine). Thus, Plaintiff's irrelevant claim that *McEwen* supports extending GSK's duty to warn to physicians other

than the prescribing physician has no application to Washington law.[11]

Moreover, *McEwen* simply does not support Plaintiff's argument that GSK failed to satisfy its duty to warn or that this alleged failure to warn was the proximate cause of his injury. Consistent with Washington law, *McEwen* holds that a drug manufacturer has a duty to warn of "dangerous side effects." 528 P. 2d at 530. GSK plainly and repeatedly warned of the "dangerous side effects" (*i.e.,* SJS/TEN) associated with Lamictal®. And on the issue of proximate causation, the plaintiff in *McEwen*, unlike Plaintiff here, *did* present evidence regarding the knowledge and conduct of her treating physician whose conduct would have been affected by a different warning. *Id.* at 539 (plaintiff presented evidence that one of her treating physicians had read the package insert, knew of plaintiff's symptoms, yet allowed her to continue taking the medication "consistent with defendants' [inadequate]

[11] Plaintiff also cites Restatement (Third) of Torts: Products Liability, § 6(d)(1), as part of his argument to extend the duty to warn beyond the prescribing physician. Plaintiff concedes that Washington courts have not adopted this provision of the Restatement (App. Br. at 32), and given the irrelevance of the issue to this case and its outcome, this case does not present an appropriate vehicle for considering an expansion of Washington law.

warnings").[12] As discussed below, Plaintiff has presented no such evidence here.

2. Plaintiff Cannot Prove That the 2007 Lamictal® Label Caused His Injury.

Plaintiff argues that had Plaintiff's treating physicians not been misled by the 2007 Lamictal® label, they would have treated him differently and his injuries would have been avoided or reduced. App. Br. at 39. But Plaintiff presented *no* evidence regarding any treating physician to substantiate his hypothesis, and the only evidence before the Court—provided by Dr. Conway—flatly contradicts such a hypothesis.

Dr. Conway testified that when he prescribed Lamictal® for Plaintiff in February 2007, he was familiar with the risks and benefits set forth in the 2007 Lamictal® label, specifically the risk of SJS/TEN. CP 632, 644, Conway Dep. at 35:21-36:2, 97:16-19. He knew that SJS and TEN were serious, life-threatening diseases. CP 636, Conway Dep. at 50:23-51:21. Dr. Conway also knew that SJS/TEN are diseases that include both a rash and involvement of the mucous membranes. *E.g.*, CP 655, Medical Information Letter, Conway Dep. Ex. 3 (informing Dr. Conway that "SJS and TEN are two related serious blistering mucocutaneous disorders that form a

[12] Moreover, the standard of proof for causation in tort cases in Oregon is different than in Washington. *Compare Baughn*, *supra*, (employing "but for" test) *with Joshi v. Providence Health System of Oregon*, 342 Or. 152, 161, 149 P.3d 1164 (2006) (adopting "substantial factor" test).

continuous spectrum in terms of severity"); CP 629-30, Conway Dep. at 14:21-15:11; 15:24-16:7; 24:19-24; CP 650-53, Conway Dep., Ex. 2; CP 670-75, Conway Dep., Ex. 9. Dr. Conway expressed no confusion concerning the 2007 Lamictal® label. Dr. Conway's undisputed testimony is reinforced by Dr. Dunner's testimony (also undisputed) that psychiatrists in Washington know that SJS and TEN are diseases characterized by skin rash and involvement of the mucous membranes. CP 772-73.

As for any other treating physician (*i.e.*, Dr. Leigh, who treated Plaintiff on April 5, and the emergency room physicians who saw him on April 6), Plaintiff presented *no* evidence about whether they had read the 2007 Lamictal® label at any time, what they knew or did not know about SJS/TEN, whether they were misled in any way by the Lamictal® label, or whether they would have altered their treatment of Plaintiff if Plaintiff's proposed changes to the already-approved labeling had been made and approved by the FDA.

The sole "evidence" of causation to which Plaintiff points is not evidence, but speculation by his two experts. They suggest that had Plaintiff's treating physicians not been misled by the 2007 Lamictal® label, Plaintiff's injuries would have been avoided or been less severe. But Plaintiff's experts admitted under oath that their hypothesis is pure speculation.

Dr. Lindberg, a burn doctor from Colorado, has never prescribed Lamictal® and does not consider himself an expert on

Lamictal®. CP 754, Lindberg Dep. at 103:15-104:1. Dr. Lindberg does not claim to have consulted with Dr. Conway or any other physician who treated Plaintiff, and so he has no knowledge of what those physicians would have done if his proposed warnings had been included in the 2007 Lamictal® label. CP 901-909. When asked whether Dr. Conway's conduct would have been altered by a different label, Dr. Lindberg could only say that Dr. Conway "might have" referred Plaintiff to the emergency room. CP 759-60. Lindberg Dep. at 197:4-198:23. He readily admitted: "That's where it's all speculation." *Id.*

Dr. Dajani, who is not a physician and who cannot prescribe Lamictal® or provide any medical treatment, did not even review the testimony of Dr. Conway. CP 764, Dajani Dep. at 106:21-107:3. He insisted that "I don't want to speak for Dr. Conway." CP 763, Dajani Dep. at 105:19-20. He did not know what Dr. Conway knew about the signs and symptoms of SJS/TEN. *Id.* at CP 763-64, Dajani Dep. at 105:14-106:8. Moreover, Dr. Dajani could not say whether Dr. Leigh, the physician who treated Plaintiff on April 5, even looked at the Lamictal® label and could only speculate about whether Dr. Leigh would have changed her treatment of Plaintiff if different information were contained in the Lamictal® label. *Id.* at CP 765, Dajani Dep. at 166:19-167:22. Dr. Dajani has no training or experience in psychiatry, internal medicine, or emergency medicine. *See id.* at CP 923-48. Despite his argument that Plaintiff's

prescribing or treating physicians would have acted differently if the label had included different warnings, nowhere in his declaration does he purport to have any personal knowledge about what those physicians knew or did not know or whether they even read the label in making treatment decisions for Plaintiff. *See* CP 949-56.[13]

Plaintiff attempts to cure these deficiencies in his experts' testimony via argumentative assertions. But unsupported contentions that contradict an expert's sworn admission that he can only speculate about what Plaintiff's physicians actually knew and would have done had the warning been different does not forestall summary judgment. A party opposing summary judgment "may not rely on speculation [or] argumentative assertions that unresolved factual issues remain." *Doty-Fielding*, 143 Wn. App. at 566; *Moore v. Hagge*, 158 Wn. App 137, 156-58, 241 P.3d 787 (2010) (affirming summary judgment when plaintiff had no memory of events and expert testimony on proximate causation was mere speculation based on plaintiff's purported habit of behavior); *Griswold v. Kilpatrick*, 107 Wn. App. 757, 760-63, 27 P.3d 246 (2001) (affirming summary judgment in legal malpractice case when plaintiff's expert asserted that earlier settlement would have resulted in a higher award, despite the fact that plaintiff failed to get statement from initial defendants

[13] Dr. Khandelwal, whose exclusion by the Superior Court is not at issue in this appeal (see p. 22, n.4 above), did not purport to address the pivotal question of causation in any way.

that earlier mediation was possible or that they could have gone above their settlement authority).

Plaintiff did not bring a product liability suit in the abstract. He sued GSK on the theory that the 2007 Lamictal® label failed to adequately warn of the risk of SJS/TEN and that his suggested revisions to the labeling would have prevented or reduced Plaintiff's injuries from SJS/TEN. The law thus requires Plaintiff to show that Dr. Conway was in fact misled and would have actually changed his treatment of Plaintiff. There is no such evidence in this record. To the contrary, the evidence before the Court demonstrates that Dr. Conway knew that SJS/TEN was the primary danger in taking Lamictal® and knew that SJS/TEN was characterized by skin rash and involvement of the mucous membranes—the very point on which Plaintiff hypothesizes Dr. Conway was misled.

IV. CONCLUSION

For all the foregoing reasons, this Court should affirm summary judgment dismissing Plaintiff's suit against GSK.

DATED this 27th day of September, 2012.

Respectfully submitted,

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