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No. 895295

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

(Court of Appeals No. 68264-4-I)

DAVID A. FALSBERG,

Petitioner,

v.

GLAXOSMITHKLINE LLC, et al.

Respondents.

ANSWER TO PETITION FOR REVIEW

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I. INTRODUCTION

Plaintiff has offered no reason for this Court to take discretionary review of the Division One, Court of Appeals' decision ("Decision") affirming summary judgment in this case, *Falsberg v. GlaxoSmithKline, LLC*, 2013 WL 4822205 (Sept. 9, 2013) (unpublished). Plaintiff claims that the Decision is inconsistent with Washington appellate precedents (RAP 13.4(b)(1) and (2)), but he fails to cite a single Washington case that conflicts with the Decision. Indisputably, the FDA-approved 2007 Lamictal® label expressly and repeatedly warned 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 respondent GlaxoSmithKline LLC ("GSK"). The label conservatively advised terminating use of Lamictal® at the first sign of a rash. And it plainly identified the potential risk factors for SJS/TEN, incidence rates, appropriate dosing to minimize the danger, and the time period when the patient is most at risk when taking Lamictal®. Under the express language of the Washington Product Liability Act, RCW 7.70.010 *et seq.* ("WPLA"), and all relevant Washington precedents, a warning is adequate as a matter of law where, as here, it repeatedly and clearly warns of the risks associated with the medication. As the Decision aptly states: "The label's unequivocal warnings were accurate, clear, and consistent. No reasonable prescribing physician apprised of the label's contents

would be unaware of the risk of SJS and TEN. Under Washington law, as was true in [*Estate of*] *LaMontagne* [*v. Bristol-Meyers Squibb*, 127 Wn. App. 335, 111 P.3d 857 (2005)], the Lamictal warnings were adequate." 2013 WL 4822205 at *3.

Plaintiff contends that in addition to warning of the "danger," the label should teach the physician how to diagnose SJS/TEN. No Washington appellate decision has ever broadened the duty to warn to require a drug manufacturer – which does not know and cannot see the patient – to teach medical doctors how to diagnose diseases and carry out the practice of medicine. And Plaintiff's mischaracterization of the label as "misleading," because it conservatively advises terminating use of Lamictal® at the first sign of a rash, does not change the analysis. The Decision held that the label was not misleading, but "accurate, clear, and consistent." And that legal conclusion is buttressed by the fact that the record contains no evidence that *any* physician who treated Plaintiff was misled by the label's conservative advice in the way that Plaintiff's experts hypothesized. Thus, Plaintiff's contention that the duty to warn should be expanded to instruct physicians how to practice medicine is unsupported by any Washington appellate authority and irrelevant to this case.

Finally, Plaintiff fails to demonstrate that this case presents an issue of "substantial public interest" (RAP 13.4(b)(4)), as his proposed expansion of Washington law is completely unsupported

by the facts. The Decision accurately states that Washington precedents have uniformly, and for good reason, held that a prescription drug manufacturer has a duty to warn the prescribing physician and not the medical community at large. The wisdom of focusing the duty on the prescribing physician is underscored here where Plaintiff's use of Lamictal® was directed exclusively by the medical judgment of his prescribing physician, Dr. Jack Conway. Dr. Conway testified that he was well aware of the SJS/TEN risk from his training and reading the Lamictal® label and that he was not misled by the label in any way.

Despite his assertion that the Lamictal® label failed to adequately warn his treating physicians, Plaintiff failed to present *any* evidence from these physicians on this point. Plaintiff's experts could only speculate about what those treating physicians actually knew or whether the Lamictal® label had any impact on their clinical decisions. The Decision's conclusion that "the facts in this record do not squarely present a basis for" expanding a drug manufacturer's duty beyond a duty to the prescribing physician (2013 WL 4822205 at *5) is confirmed in a record that provides no basis for discretionary review.

For these reasons, the Court should exercise its discretion and decline review of the Decision.

II. ISSUE PRESENTED FOR REVIEW

Should the Court deny Plaintiff's Petition for Review when the Decision is consistent with Washington appellate precedent and does not raise an issue of substantial public interest that justifies discretionary review?

III. STATEMENT OF THE CASE

A. The 2007 Lamictal® Label.

Lamictal® is a life-saving, FDA-approved medication for treatment of seizures and bipolar disorder. The Lamictal® label in effect in February 2007 "unequivocally warns of the risk of SJS/TEN" (2013 WL 4822205 at *2):

> SERIOUS RASHES REQUIRING HOSPITALIZATION AND DISCONTINUATION OF TREATMENT HAVE BEEN REPORTED.... WHICH HAVE INCLUDED *STEVENS–JOHNSON SYNDROME,* ... RARE CASES OF *TOXIC EPIDERMAL NECROLYSIS* AND/OR RASH–RELATED DEATH HAVE BEEN REPORTED....
>
> NEARLY ALL CASES OF LIFE–THREATENING RASHES ASSOCIATED WITH LAMICTAL HAVE OCCURRED WITHIN 2 TO 8 WEEKS OF TREATMENT INITIATION....
>
> 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.

The "WARNINGS" section advises that a rash could be a sign of a serious condition:

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

The "PRECAUTIONS" section states that Lamictal should be immediately discontinued at the "first sign of rash":

[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

The "PATIENT INFORMATION" section also warns that a rash requires immediate attention from a physician:

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.

Id. at *2-3.

B. Dr. Conway Understood the Risks and Benefits of Lamictal®.

Dr. Conway, Plaintiff's prescribing psychiatrist, testified that he was fully aware of the risks and benefits of Lamictal® from many sources, including psychiatric texts; 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. Dr. Conway discussed the risks and benefits of Lamictal® with Plaintiff and noted it in his medical chart. CP 646, Conway Dep. at 105:1-106:8. Specifically, Dr. Conway was familiar with SJS/TEN and knew that it is characterized by "a blistering flat rash that may affect the mucous membranes." CP 628-29, Conway Dep., Ex. 2; CP 650-52, Conway Dep. at 10:21-11:9, 14:21-15:11. The term, "mucocutaneous," means involvement of both the mucous membranes and the skin. CP 771, Dunner Decl. ¶ 4. Dr. Conway told all of his patients, including Plaintiff, that they should discontinue Lamictal® at the first sign of a rash. CP 646, Conway Dep. at 105:1-19. Plaintiff relied exclusively on Dr. Conway in taking Lamictal®. CP 748, Falsberg Dep. at 28: 15-25.

Plaintiff called Dr. Conway on April 4, 2007, and told him that he was experiencing slurred speech and loss of balance. Dr. Conway asked Plaintiff whether he had a rash or any other symptoms. Plaintiff reported none and 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. Because 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, Dr. Conway directed Plaintiff to reduce his dosage to 75 mg, a dosage he had tolerated well, to ameliorate the reported symptoms. 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.

As instructed by Dr. Conway, the next morning Plaintiff went to see Dr. Martha Leigh at Swedish Ballard when his symptoms worsened. The following morning, April 6, 2007, Plaintiff was admitted to the Swedish Ballard emergency room and treated for SJS/TEN before being transferred to Harborview. CP 920-21. Plaintiff presented no evidence from Dr. Leigh or the emergency room physicians who treated him about whether they had ever read the Lamictal® label, much less whether it influenced their treatment of him.

IV. THIS COURT SHOULD NOT ACCEPT REVIEW

A. The Holdings By the Superior Court and the Court of Appeals That the Lamictal® Label Is Adequate As A Matter of Law Are Consistent With Washington Appellate Precedent.

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 v. A.H. Robins Co.*, 90 Wn.2d 9, 13-14, 577 P.2d 975 (1978). Specifically, the WPLA states that the manufacturer must warn of the "danger" presented by the product. RCW 7.72.030(1)(c). The "danger" here is the risk of SJS/TEN from taking Lamictal®, and the 2007 Lamictal® label clearly 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) ("*LaMontagne*"), the plaintiff alleged that the manufacturer of Glucophage®, a diabetes drug, failed to adequately warn of the risk of lactic acidosis in patients with kidney dysfunction. 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.[1] *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 adequately warn because it did not warn of medication's theophylline 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).

In addition to the express language of the WPLA, 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

[1] Plaintiff argues that *LaMontagne* is somehow distinguishable because the warning in that case "repeatedly mentioned the relevant contraindications in exhaustive detail." Petition at 10. But Plaintiff has never asserted that Lamictal® should have been contraindicated in patients like him. In any event, the Lamictal® label also lists "contraindications in exhaustive detail."

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).[2]

Despite this overwhelming precedent, Plaintiff argues that the Lamictal® label should explain how to diagnose SJS/TEN. Plaintiff does not cite a single case that so holds or any statutory language that supports his hypothesis. Similarly, there is no evidence in the record that any of the hundreds of FDA-approved prescription

[2] Despite Plaintiff's assertions that the adequacy of the warning should be an issue of fact for the jury, *Little v. PPG Indus. Inc.*, 92 Wn. 2d 118, 122-23, 594 P.2d 911 (1979), cited in the Petition at 7, acknowledges that Washington courts may determine the adequacy of a warning as a matter of law, as did the court in *LaMontagne*, *supra*. And *Bryant v. Technical Research Co.*, 654 F.2d 1337 (9th Cir. 1981), also cited in the Petition at 7,

medications that warn of the SJS/TEN risk also instruct physicians how to diagnose the disease. A prescription drug label should not replace the skill and training of physicians who act as learned intermediaries between pharmaceutical manufacturers and patients. Dr. Conway had treated Plaintiff for seven years. A physician's medical judgment about the best course for an individual patient is far more reliable than a diagnostic directive contained in a medication label.

In addition to being fraught with danger, Plaintiff's assertion that the label should tell physicians how to diagnose SJS/TEN 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); *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

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was decided under Idaho law and has no bearing on the application of Washington procedure.

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).[3]

The Decision's holding that the Lamictal® label is adequate as a matter of law is fully aligned with Washington law and law around the country and thus provides no basis for discretionary review.

[3] *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).

B. This Case Is Not an Appropriate Candidate For Expanding the Duty to Warn Beyond Adequately Informing the Prescribing Physician.

Washington courts have uniformly defined a manufacturer's duty to warn as a duty to inform the *prescribing* physician about the potential risk posed by the prescription medication—not, as Plaintiff requests, the medical community at large. *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."); *Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 858 P.2d 1054 (1993) (citing *Terhune,* 90 Wn.2d at 13); *LaMontagne*, 127 Wn. App. at 345 (same). The Decision thus is consistent with Washington precedents, and it details the "strong policy considerations support[ing] Washington's focus upon the prescribing physician." 2013 WL 4822205 at *4.[4]

The Decision also accurately characterizes the record when it concludes that "the facts in this record do not squarely present a basis for such a change" in the scope of a manufacturer's duty to warn. 2013 WL 4822205 at *5. In persuading this Court that the

[4] Plaintiff cites an Oregon case, *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974), but *McEwen* is not Washington law, and Oregon products liability law differs markedly from Washington's. *E.g.*, *Griffith v. Blatt*, 334 Or. 456, 51 P.3d 1256 (2002) (product liability statute limits some applications of Learned Intermediary Doctrine).

case "involves an issue of substantial public interest," RAP 13.4(b)(4), "the petitioner should point out any evidence in the record or information capable of judicial notice which demonstrates that the issue is recurring in nature or impacts a large number of persons." Washington Appellate Practice Handbook, Vol. II, §27.11 (3d ed. WSBA 2011). But Plaintiff presented no such evidence. Here, the record demonstrates that Plaintiff relied solely on Dr. Conway, his prescribing physician, in taking Lamictal®. Dr. Conway plainly knew how to diagnose SJS/TEN (rash plus mucous membrane involvement), and he was not misled by the label's conservative advice to discontinue Lamictal® at the first sign of any rash. CP 636, 646. Both the Superior Court and Court of Appeals correctly concluded 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; *see also* 2013 WL 4822205 at *5 ("[I]t appears to be speculative whether a more simplified rash plus mucosal involvement warning would have been of any significance.").

The Decision is consistent with Washington law and does not present an appropriate vehicle for expanding a manufacturer's duty under Washington law.

C. Plaintiff's Experts Could Only Speculate About Whether the Lamictal® Label Was Misleading To Plaintiff's Treating Physicians or Whether a Different Label Would Have Altered Their Treatment.

Under Washington law, Plaintiff shoulders the burden to prove that his injuries were proximately caused by the Lamictal® label's allegedly inadequate warning. *See Baughn v. Honda Motor Co., Ltd.*, 107 Wn.2d 127, 142, 727 P.2d 655 (1986). To prove this critical element of his claim, Plaintiff was required to present evidence that a different warning would have changed the behavior of the physicians who treated 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). 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.

In attempting to prove that the Lamictal® label caused Plaintiff's injury, Plaintiff "may not rely on speculation [or]

argumentative assertions" by his experts. *Doty-Fielding v. Town of S. Prairie*, 143 Wn. App. 559, 566, 178 P.3d 1054 (2008); *Moore v. Hagge*, 158 Wn. App 137, 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 that earlier mediation was possible or that they could have gone above their settlement authority). The record demonstrates that Plaintiff could not meet these requirements of Washington law.

The sole "evidence" Plaintiff presented in support of his claim that the Lamictal® label caused Plaintiff's injuries was pure speculation by his two experts, neither of whom prescribes Lamictal® to patients.[5] Those "experts" could not support their

[5] By contrast, the Court has Dr. Conway's own testimony about his knowledge of Lamictal® and SJS/TEN, and his understanding of the Lamictal® label. In addition, GSK presented expert testimony from a physician who frequently prescribes Lamictal®, Dr. David L. Dunner, a board-certified psychiatrist in the State of Washington and professor at the University of Washington School of Medicine. He testified that the psychiatric community is well 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.

hypothesis that the label is misleading with any evidence that any of Plaintiff's treating physicians found it misleading or that *any* treating physician has ever found it misleading.[6]

Plaintiff's experts admitted under oath that their hypothesis that Plaintiff's treating physicians may have been misled by the label and would have treated Plaintiff differently with their proposed label 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 warning 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 conceded: "That's where it's all speculation." *Id.*

Plaintiff's second expert, Esam A. Dajani, PhD, is not a physician, and did not review the testimony of Dr. Conway. CP 764,

[6] The Lamictal® label's simple advice that physicians stop the medication at the first sign of *any* rash is straightforward and consistent with the Decision's holding that the label is "clear and consistent." 2013 WL 4822205 at *2. Plaintiff presented no evidence that this straightforward advice ever misled any physician.

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, Dajani could not say whether Dr. Leigh, the physician who treated Plaintiff on April 5, had ever seen 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.[7] Nowhere in Dajani's declaration did he purport to have any testimonial 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.[8]

[7] Plaintiff notes (Petition at 15) that Dr. Leigh "initially misdiagnosed [Plaintiff] with an upper respiratory infection" (2013 WL 4822205 at *1), but Plaintiff then leaps to the baseless speculation that Dr. Leigh therefore must have been misled by the Lamictal® label (Petition at 15). A misdiagnosis, however, tells one nothing about the adequacy of a drug label or if it has misled anyone. There is no evidence in the record that Dr. Leigh even read the label, let alone was misled by it. The label advises discontinuation of the medication on the first sign of a rash, and Plaintiff indisputably had a rash when he went to see Dr. Leigh. 2013 WL 4822205 at *1.

[8] Plaintiff features Dr. Khandelwal in his Petition, but Plaintiff neglects to inform this Court that the Superior Court excluded Dr. Khandelwal's testimony because Plaintiff did not identify him as an expert witness in response to GSK's CR 26(b)(5) interrogatory (CP 1074-75), and Plaintiff did not assign or brief that it was error for the Superior Court to exclude Dr. Khandelwal, thus waiving any challenge to his exclusion. *See* RAP 10.3(g); *State v. Motherwell*, 114 Wn.2d 368, 788 P.2d 1066 (1990)

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 required Plaintiff to show that Plaintiff's prescribing physician was in fact misled by the Lamictal® label and that Plaintiff's injuries would have been prevented or minimized had the label contained different or additional information. There is no such evidence in this record, which the Decision accurately described as "speculative." 2013 WL 4822205 at *5.[9]

Plaintiff seeks an unjustified and unsupported expansion of Washington law. The Decision's conclusion that Plaintiff's experts

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(claimed error that is not supported by argument is deemed abandoned). In any event, Dr. Khandelwal only encountered Plaintiff at Harborview after he was being treated for SJS. He does not prescribe Lamictal® or have any knowledge of what Dr. Conway and Plaintiff's other treating physicians knew about Lamictal®.

[9] Plaintiff argues that *McEwen* is "on point where, as here, a label is false and misleading," (Petition at 13), but the case does not help Plaintiff for a number of reasons. *McEwen*, like the Washington cases, holds that a drug manufacturer has a duty to warn of "dangerous side effects," not to instruct physicians how to diagnose known diseases. 528 P. 2d at 530. And the plaintiff in *McEwen*, unlike Plaintiff here, *did* present 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] warnings." *Id.* at 539.

failed to supply any evidence that the Lamictal® label caused Plaintiff's injuries is fully consistent with Washington law and does not present a question of "substantial public interest" justifying this Court's review.

V. CONCLUSION

For the foregoing reasons, this Court should deny Plaintiff's Petition for Review.

DATED this 20 day of December, 2013.

Respectfully submitted,

PHILLIPS LAW GROUP, PLLC

By: _____
John W. Phillips, WSBA #12185

Attorneys for Respondent
GlaxoSmithKline LLC

CERTIFICATE OF SERVICE

I certify that today I caused to be served a true and correct copy of the foregoing document upon:

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DATED this 2nd day of December, 2013.

Carrie J. Gray

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Dear Clerk of Court,

Please find the attached Answer to Petition for Review for filing. Thank you.

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