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NO. 68264-4-I

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

DAVID A. FALSBERG,

Petitioner,

v.

GSK, PLLC, or GLAXO SMITH KLINE, INC., a foreign corporation, also d/b/a GSK, L.L.C., GSK CONSUMER HEALTHCARE, L.P., GSK BIOLOGICALS, NORTH AMERICA, GSK CONSUMER HEALTHCARE, L.L.C., and GSK SERVICES, INC., and JACK S. CONWAY, M.D.

Respondents.

PETITION FOR REVIEW

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IDENTITY OF PETITIONER & CITATION TO DECISION

Petitioner David Falsberg asks this Court to accept review of the Court of Appeals decision, ***Falsberg v. GlaxoSmithKline, PLC***, Washington State Court of Appeals No. 68264-4-1 (Sept. 9, 2013); Motions to Publish denied, Oct. 14, 2013 (copies attached).

INTRODUCTION

The appellate court misapprehended the main issue, erroneously stating that "David Falsberg asks this court to expand the existing Washington drug manufacturer warning standards to include diagnostic tips for any physician who may treat complications from the use of the drug." Slip. Op. 1. Rather, David asked – and now asks this Court – whether summary judgment was improper where, as here, three experts (including David's treating physician) opined that this warning label is not only inadequate, but false and misleading?

David also raised an important issue of first impression: should our courts adopt the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6, requiring adequate and accurate labeling sufficient to warn all treating physicians – not just the prescribing doctor – where, as here, there is an unreasonably high risk of misdiagnosis? The appellate court refused to consider this

question, holding that this is not the right case. But several doctors missed David's diagnosis, and this record contains strong evidence that virtually every doctor initially misses the diagnosis. This warning label is inadequate, false and misleading.

Finally, David asks this Court to address an important issue of potential statutory conflict: is it true, as the appellate court apparently believed, that "accrual" for purposes of the disability tolling statute (RCW 4.16.190(1)) must be synonymous with the date of the physician's last "act or omission alleged to have caused the injury or condition" for purposes of the statute limitations for medical malpractice (RCW 4.16.350(3))? The appellate court essentially wrote "accrual" out of the disability tolling statute.

This Court should accept review under RAP 13.4(b)(1), (2) & (4). The appellate decision conflicts with decisions of this Court and of other appellate courts. It also raises important issues of first impression, including potential adoption of the third RESTATEMENT, and an apparent conflict in the medical malpractice statutes that the appellate decision purports to resolve by writing the common-law concept of "accrual" out of the statute. In any event, summary judgment is clearly inappropriate, where three experts opined that GSK's warning label is inaccurate, false and misleading.

ISSUES PRESENTED FOR REVIEW

1. Did the trial court err in ruling that GSK did not have a duty to warn medical providers that rash plus mucosal involvement indicates SJS, where it knew or should have known of the danger of frequently missed diagnoses?

2. Did the trial court err in determining that GSK's warnings were "adequate as a matter of law," where several experts opined that they were not only inadequate, but false and misleading?

3. Did the trial court err in granting summary judgment, where expert opinions raised genuine issues of material fact on whether GSK's warning labels were grossly inadequate and misleading?

4. In light of those expert opinions, did the trial court err in determining causation as a matter of law?

5. Did the trial court err as a matter of law in failing to give David Falsberg the benefit of the disability-tolling provisions of RCW 4.16.190(1) because his cause of action did not "accrue" at the time of Dr. Conway's last act or omission under RCW 4.16.350?

6. Are there genuine issues of material fact on whether and when David Falsberg was an incapacitated person under RCW 11.88.010(1)(a), entitling him to disability tolling under RCW 4.16.190(1)?

STATEMENT OF THE CASE

A. Doctors frequently misdiagnose SJS/TEN caused by Lamictal because they will likely see only one or two cases in a lifetime and because GSK's warning label is both inadequate and misleading.

The appellate court correctly notes that David contracted Stevens Johnson Syndrome (SJS) and Toxic Epidural Necrosis (TEN) due to defendant psychiatrist Dr. Jack Conway's prescription of Lamictal, an anticonvulsant manufactured and marketed by defendant GlaxoSmithKline (GSK). Slip Op. 2-3. The Court also correctly states that "SJS and TEN are characterized by a rash combined with mucosal involvement, such as bloodshot eyes, sore throat, and other pains involving erosion of the mucous membranes." *Id.* at 2. But the Court nowhere states – because it cannot – that GSK's label gives doctors that simple warning.

The appellate court is far too understated[1] in noting that GSK "was aware of cases in which Lamictal-caused SJS had been misdiagnosed." *Id.* In fact, GSK was aware that SJS and TEN are routinely misdiagnosed. *See, e.g.*, BA 7-14; CP 902, 950-52, 954, 966. GSK knew this (in part) because its own 2005 study, *Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in*

[1] Because this is a review of a summary judgment, all facts and reasonable inferences must be taken in the light *most* favorable to David. Slip Op. 4. The appellate court failed to do so here.

New Users of Antiepileptics, identified substantial incidence of misdiagnosis under GSK's existing warning label. BA 13-14.

This GSK research warned that physicians must be given specific information so that they can teach their patients how to distinguish a serious rash from a benign rash. CP 952-53. This information is crucial because – as the appellate court noted – the "conditions are relatively rare and share symptoms with more common diseases." Slip Op. 2. Indeed, a doctor is likely to see only one or two cases in a lifetime. BA 13-14; CP 960. This research was published roughly two years before David's injury, but GSK has never made the recommended changes to its warnings.

But not only is GSK's warning label inadequate, it is also false and misleading. David's treating physician at the Harborview burn unit, Dr. Khandelwal, opined that GSK's warning label is inadequate, false and misleading: while it mentions the risk of SJS in the "black box warning," the last paragraph misleadingly claims that it is not possible to distinguish between benign and life-threatening rashes, which is categorically "false" (CP 966-67):

> 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 (emphases added).

Indeed, David's treating physician and experts agreed this paragraph is triply misleading. First, it suggests that a physician cannot distinguish a benign from a life-threatening rash; second, it fails to tell a prescribing physician how to make that distinction, as GSK was required to do. CP 902, 903, 951, 954, 955, 966-67, 969. Third, while this warning says one should "ordinarily" discontinue Lamictal at the first sign of rash, it adds the caveat, "unless the rash is clearly not drug related." CP 676. Again, without an explanation of how to distinguish between benign and life-threatening rashes – *i.e.*, look for mucosal involvement – this label is misleading.

B. There are genuine issues of material fact on whether David Falsberg was incapacitated on April 4, 2010, and when his cause of action accrued.

The appellate court notes that Dr. Conway's last negligent act was April 4, 2010, when the Falsbergs called him about David's symptoms. Slip Op. at 2, 11 n.28. It also acknowledges that David was very sick at that time and that he collapsed the next morning. *Id.* at 2-3. David's incapacity is for the jury.

ARGUMENT WHY THIS COURT SHOULD ACCEPT REVIEW

A. There is (at least) a question of fact on whether GKS's label is false and misleading – as three doctors opined: the appellate decision conflicts with many precedents, applying an unheard of and incorrect legal standard.

Focusing on warnings about SJS/TEN, the appellate decision selectively quotes the warning label. Slip Op. 6-7. But when it reaches the real issue here – whether the label is false and misleading – the appellate court merely states that David "does not present a compelling argument that the label actually contains any false information or misrepresentation," so his claim fails as a matter of law. Slip Op. 8. That is not the correct legal standard.

Whether the label is inadequate or misleading is unquestionably a question of fact for the jury. *See, e.g.*, ***Little v. PPG Indus. Inc.***, 92 Wn.2d 118, 122-23, 594 P.2d 911 (1979) (under RESTATEMENT (SECOND) OF TORTS § 402, "the court may declare as a matter of law that an adequate warning was not given, but ... in most cases the question is one for the jury");[2] ***Bryant v. Technical Research Co.***, 654 F.2d 1337, 1345 (9th Cir. 1981)

[2] Similarly, under the RESTATEMENT (THIRD) OF TORTS, § 2, cmt. i, "[w]hether the warning actually given was reasonable in the circumstances is to be decided by the trier of fact." As discussed below, David asked the lower courts to apply this RESTATEMENT, specifically § 6. But even under the old Restatement, the trial and appellate courts contradicted a great deal of law by taking this issue from the jury.

("The adequacy of a warning under products liability is a question of fact to be left to the jury"). Many more cases could be cited for this widely accepted proposition. The appellate decision flies in the face of all of them. RAP 13.4(b)(1) & (2).

And as the appellate court acknowledges, the facts must be taken in the light most favorable to David. *Id.* at 4 (citing ***Vallandigham v. Clover Park Sch. Dist. No. 400***, 154 Wn.2d 16, 26, 109 P.3d 805 (2005)). Again, a great many precedents from this and other appellate courts could be cited for this standard. The appellate decision conflicts with all of them. RAP 13.4(b)(1) & (2).

The facts too are clear: no fewer than three experts – including David's treating physician at the Harborview Burn Unit, Dr. Khandelwal – opined that this label is both false and misleading (CP 902, 951, 966-67): (1) it suggests that physicians cannot distinguish a benign from a life-threatening rash, which is false because mucosal involvement distinguishes a benign rash from SJS; (2) it fails to warn even prescribing physicians to teach their patients how to make that distinction, as GSK's own research enjoins; and (3) it undermines its warning to "ordinarily" discontinue Lamictal at the first sign of rash with a caveat, "unless the rash is clearly not drug related" – again without warning doctors to teach

their patients how to make that distinction. *See, e.g.*, CP 676, 902, 903-04, 951, 954, 955, 966-67, 969. If patients were instructed that rash plus mucosal involvement is SJS, they would know both to stop the drug immediately and to tell any physician whose care they seek that they have SJS, saving them endless pain and suffering, and maybe even saving their lives. *Id.*

An accurate label would have provided information to the prescribing physician to transmit to patients that rash plus mucosal involvement is SJS. The patient would know both to stop the drug immediately and to tell any physician whose care they seek that they have SJS, saving them endless pain and suffering, and maybe even saving their lives. Instead, the label informed both prescribing and treating doctors that there is no way to distinguish between a benign rash and SJS. This false information, according to at least three experts, led to the misdiagnosis of this condition by one or more physicians in virtually every case.

Whether appellate judges find all of this sworn expert testimony "compelling" is irrelevant. Adequacy – and accuracy – are for the jury. The trial and appellate courts applied the wrong legal standard. This Court should grant review and reverse.

Besides failing to acknowledge these genuine issues of material fact, the appellate court entirely relies on ***Estate of LaMontagne v. Bristol-Meyers Squibb***, 127 Wn. App. 335, 111 P.3d 857 (2005). Slip Op. 5-8. ***LaMontagne*** addressed whether a label adequately warned the prescribing physician of the risks the patient suffered. 127 Wn. App. at 337. But there, unlike here, the manufacturer's warnings repeatedly mentioned the relevant contraindications in exhaustive detail. *Id.* at 348-51. Specifically, "the warnings instruct physicians that Glucophage® should not be used in patients with creatinine levels in the upper limit of normal" – precisely injured patient's circumstances. *Id.* at 350-51. Therefore, the warnings were adequate as a matter of law. *Id.*

LaMontagne is not controlling here. It does not address the issue presented: warnings that not only fail to disclose what the manufacturer knew or should have known to be essential information due to the high incidence of misdiagnosis under its existing label (*i.e.*, rash plus mucosal involvement is SJS) but even contained the false and misleading assertion that it is not possible to distinguish between benign and life-threatening rashes. CP 676, 952-53. This label omits critical information – and even contains misleading information – according to GSK's own research.

It is a question of first impression whether summary judgment is appropriate when three qualified experts opine that a warning label is false and misleading. Taking the facts in the light most favorable to David, a jury could agree with these three experts. Nothing in ***LaMontagne*** or in RESTATEMENT § 402A permits summary judgment here. The Court should grant review.

B. This appeal also presents a question of first impression on whether Washington should adopt the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6.

The appellate court noted that whether a prescription drug manufacturer provides adequate warnings to physicians is governed by the negligence standard under RESTATEMENT (SECOND) OF TORTS § 402A, *comment k* (1965). Slip Op. 4 (citing ***Terhune v. A. H. Robins Co.***, 90 Wn.2d 9, 577 P.2d 975 (1978)). But David requested – and the trial and appellate courts rejected – application of the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6:

> § 6 Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices
>
> ...
>
> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings;

Comment d further explains this rule (paragraphing added):

> Failure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices. ...
>
> . . . . [W]arnings of unavoidable risks allow the health-care provider, and thereby the patient, to make an informed choice whether to utilize the drug or medical device.
>
> Beyond informing prescribing health-care providers, a drug or device manufacturer may have a duty under the law of negligence to use reasonable measures to supply instructions or warnings to nonprescribing health-care providers who are in positions to act on such information so as to reduce or prevent injury to patients.

David also cited ***McEwen v. Ortho Pharm. Corp.***, 270 Or. 375, 528 P.2d 522 (1974), which this Court cited with approval in ***Terhune***, 90 Wn.2d at 13-14. In ***McEwen***, plaintiff went partially blind after taking prescribed oral contraceptives. 528 P.2d at 526. The label warnings specifically identified this risk, but falsely discounted it, and (as here) warned doctors to discontinue use only after serious symptoms arose – as the ***McEwen*** court put it, "the disputed warning advises that the barn door should be closed after the horses have fled." *Id.* at 535-36. The Oregon Supreme Court affirmed a jury verdict in favor of the plaintiff. *Id.* at 544.

McEwen is on-point where, as here, a label is false and misleading.[3] ***McEwen*** notes that drug manufacturers have a duty to warn doctors of any dangerous side effects of which it knows, or should know, a continuous duty requiring manufacturers to keep abreast of scientific developments and supplement its warnings based on information discovered from use of the drug. *Id.* at 528.[4]

Crucially here, this duty extends not only to the prescribing physician, but to "all members of the medical profession who come into contact with the patient in a decision-making capacity." *Id.* at 529. The warnings must be sufficient to apprise both the general practitioner and the "'unusually sophisticated medical man' of the dangerous propensities of the drug." *Id.* (citing ***Stromsodt***, 411 F.2d at 1400). This is simply because a treating physician facing concerning symptoms "may be more likely to observe the actual symptoms of the drug's untoward consequences" than the doctor who originally prescribed the drug. *Id.* In sum, the manufacturer

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[3] The appellate court relies on ***Terhune***, but it did not involve a false and misleading warning label. Slip Op. 9-10.

[4] Citing, *inter alia*, ***Sterling Drug, Inc. v. Cornish***, 370 F.2d 82 (8th Cir. 1966); ***Parke-Davis & Co. v. Stromsodt***, 411 F.2d 1390 (8th Cir. 1969); ***Stevens v. Parke, Davis & Co.***, 9 Cal. 3d 51, 107 Cal. Rptr. 45, 507 P.2d 653 (1973); ***Love v. Wolf***, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); ***Krug v. Sterling Drug, Inc.***, 416 S.W.2d 143 (Mo.1967); 2 RESTATEMENT (SECOND) OF TORTS 300, § 388 (1965).

has "a duty to warn the medical profession of untoward effects which the manufacturer knows, or has reason to know, are inherent in the use of its drug." *Id.* at 530. (numerous citations omitted). ***McEwen*** ultimately holds that the jury reasonably found the warnings inadequate, if not misleading. *Id.* at 535-38.

Applying ***McEwen*** here, there is no question that GSK had a duty to warn doctors of dangers of which it was or should have been aware under the WPLA. RCW 7.72.030(1). Under the same statute, this is a continuing duty, requiring manufacturers to keep abreast of new research – such as the research GSK itself sponsored, reported in the *Nuerology* article authored by its former researcher – and update its warnings as necessary. RCW 7.72.030(1)(c). It is undisputed that GSK failed to do so for two years after the article appeared.

The appellate court refused to apply this modern rule here for two reasons: (1) Washington's learned-intermediary doctrine properly focuses on the prescribing physician; and (2) the facts of this case do not support its application. Slip Op. at 8-11. The first point begs the question, the second misunderstands the facts.

While it is true that the existing learned intermediary doctrine currently focuses on the prescribing physician alone, the question

presented by § 6 is whether it should continue to do so. Extending the doctrine to include all physicians who might encounter a patient suffering an adverse drug reaction in no way limits its existing application to prescribing physicians. Thus, saying the doctrine is currently limited to them begs the question whether it should be.

This leaves only the court's incorrect facts. Inexplicably, the appellate opinion erroneously concludes that this case does not raise the question whether warnings should be given to all treating physicians, rather than just to prescribing physicians. Slip Op. 8-11. But taking the facts in the light most favorable to David, there is no dispute on this record that several doctors failed to diagnose David's SJS/TEN before a dermatologist finally recognized it. CP 227, 907, 967-68. Indeed, the appellate opinion acknowledges this. Slip Op. at 3 ("He was initially misdiagnosed with an upper respiratory infection . . ."). These facts ask whether all treating doctors must be adequately warned – and not misled.

Moreover, not only did numerous treating doctors miss the diagnosis in this case, but failure to diagnose SJ/TEN is endemic. Out of the numerous SJS/TEN patients treating-physician Khandelwal has seen, **all of them** had previously been evaluated by one or more physicians, and **in "virtually every instance** . . .

the diagnosis of SJS/TEN was initially missed BY ONE OR MORE PHYSICIANS." CP 966 (bolding added). Similarly, David's expert Dr. Dajani reviewed thousands of GSK-produced records documenting adverse events from the time Lamictal was approved for use until the time David suffered SJS/TEN. CP 950. Fully confirming Dr. Khandelwal's testimony, these records show many clinical reports of patients who had rash plus mucosal involvement and were seen by one or more clinicians who failed to make the SJS or TEN diagnoses. *Id.* It is essential that the label instruct all physicians that if a patient has a rash plus mucosal involvement, they have SJS or TEN. CP 951. It negligently fails to do so, and even misleads treating physicians. CP 953-54.

In short, the evidence in this record shows that doctors confronting SJS/TEN routinely miss the diagnosis. This is an excellent case for this Court to adopt § 6 and to extend warnings to all physicians confronting the rare patient suffering this disfiguring, and sometimes fatal adverse drug reaction. The trial and appellate courts erred in failing to do so. This Court should accept review of this issue of substantial public interest. RAP 13.4(b)(4).

C. The trial and appellate courts improperly granted summary judgment to Dr. Conway based on the statute of limitations, rendering "accrual" under the disability tolling statute a nullity and conflicting with precedent.

The Court should accept review of an additional issue under RAP 13.4(b)(1) (conflict with this Court's precedent), (2) (conflict with other appellate courts) & (4) (substantial public interest). The issue involves the relationship between (a) "the time the cause of action accrued" under the disability tolling statute (RCW 4.16.190(1)), and (b) the date of the last "act or omission alleged to have caused the injury or condition" under the statute of limitations for medical malpractice (RCW 4.16.350(3)). CP 472; Slip Op. at 11-14. Under disability tolling, David's action could not have "accrued" until he knew or should have known all of the elements of his cause of action, knowledge which he plainly could not obtain until after he suffered a significant injury. *See, e.g.*, ***Ruth v. Dight***, 75 Wn.2d 660, 667-68, 453 P.2d 631 (1969). David's injury occurred in the days following Dr. Conway's last act or omission (reducing, instead of stopping, David's Lamictal dosage). At that time, and for months after, David was incapacitated.

But the trial and appellate courts determined that "accrual" for purposes of disability tolling must be synonymous with the date

of the last act or omission triggering the statute of limitations. Slip Op. at 12-14. This analysis conflicts with the disability tolling statute. Nothing in that statute requires that an actual disability – as defined in RCW ch. 11.88 – must exist at the time of the doctor's last act or omission in order for disability tolling to apply.

The appellate court's analysis would mean that disability tolling often cannot apply to medical malpractice. For instance, a patient is presumably not disabled whenever a doctor warns him about the adverse effects of a medication, but fails to give him an adequate warning. Under the appellate court's analysis, every time such a failure to warn results in a disability a few days or a few weeks later (as adverse drug reactions normally take some time to accrue) the patient is deprived of disability tolling, even though his cause of action did not "accrue" until he suffered from the harm.

The same would be true for all sorts of medical negligence, such as a typical out-patient surgery; for instance, the patient is released the same day and does not discover until many months later that the doctor left an object in him, or otherwise injured him, negligence that has now left him comatose. The patient did not know of the negligence before he fell into the coma, and when it is "discovered," he is incapacitated. Yet under the appellate court's

analysis, the doctor's last act occurred long before the malpractice action "accrued" under the disability tolling statute, so there is no disability tolling. This contradicts the plain language of the statute.

In short, the appellate court's analysis renders RCW 4.16.190(1) a nullity in a great many cases. Indeed, the appellate decision effectively writes "accrual" – a purely common law concept – out of the disability tolling statute, simply because that word does not appear in RCW 4.16.350(3) – the statute of limitations. Slip Op. at 13-14 (discussing ***Gunnier v. Yakima Heart Center***, 134 Wn.2d 854, 860-62, 953 P.2d 1162 (1998)). This analysis is untenable.

The appellate court fails to acknowledge that its decision is wholly inconsistent with ***Rivas v. Overlake Hospital Medical Center***, 164 Wn.2d 261, 189 P.3d 753 (2008). Slip Op. at 14. It does acknowledge that ***Rivas*** "expressly states that for tolling under RCW 4.16.190 to apply, 'the plaintiff's incompetency or disability must exist at the time the cause of action accrues.'" *Id.* It also acknowledges that ***Rivas*** "recognizes that the tolling provisions of RCW 4.16.190 continue to apply, even after the legislature adopted RCW 4.19.350." *Id.* Yet its reading of § 190 renders "accrual" nearly meaningless on the theory that, "[t]o apply the common law accrual standard to claims of medical negligence

by means of RCW 4.16.190 would defeat the clear intent of the legislature to abandon the use of common law accrual in cases governed by RCW 4.16.350." Slip Op. at 14.

Again, this is a non-sequitur that finds no support in the statute: if the Legislature meant to overrule the many cases applying the accrual doctrine, it would have done so expressly. ***Rivas***, 164 Wn.2d at 270 (citing ***Young v. Key Pharmaceuticals, Inc.***, 112 Wn.2d 216, 222, 770 P.2d 182 (1989)). As in ***Rivas*** and ***Young***, this Court should grant review and reverse.

CONCLUSION

For the reasons stated, this Court should grant review. Genuine issues of material fact precluded summary judgment, the Court should adopt RESTATEMENT § 6, and accrual means accrual.

RESPECTFULLY SUBMITTED this 1st day of November, 2013.

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CERTIFICATE OF SERVICE BY MAIL

I certify that I mailed, or caused to be mailed, a copy of the foregoing **PETITION FOR REVIEW** postage prepaid, via U.S. mail on the 15 day of November 2013, to the following counsel of record at the following addresses:

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

DAVID A. FALSBERG, Appellant, v. GLAXOSMITHKLINE, PLC or GLAXO SMITH KLINE, INC., a foreign corporation, also d/b/a GLAXOSMITHKLINE, LLC, GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP, GLAXOSMITHKLINE BIOLOGICALS, NORTH AMERICA, GLAXOSMITHKLINE CONSUMER HEALTHCARE, LLC and GLAXOSMITHKLINE SERVICES, INC., and JACK S. CONWAY, MD, Respondents.	)	No. 68264-4-I UNPUBLISHED OPINION FILED: September 9, 2013

VERELLEN, J. — David Falsberg asks this court to expand the existing Washington drug manufacturer warning standards to include diagnostic tips for any physician who may treat complications from the use of the drug. But the established "learned intermediary" doctrine properly focuses upon the prescribing physician, and the warnings given here were adequate.

Falsberg developed toxic epidermal necrolysis (TEN), the most severe form of Stevens-Johnson syndrome (SJS), after taking the GlaxoSmithKline drug Lamictal, brand name for the drug lamotrigine. The superior court granted summary

judgment dismissing Falsberg's claims against GlaxoSmithKline for inadequate warnings and against his physician for negligence, negligent misrepresentation, and lack of informed consent. But because GlaxoSmithKline's Lamictal labels adequately warn physicians of the risks of SJS and TEN and the relevant statutes of limitations bar Falsberg's claims against his physician, we affirm.

FACTS

On February 15, 2007, psychiatrist Dr. Jack Conway prescribed Lamictal for Falsberg. Lamictal is an anticonvulsant used in the treatment of epilepsy and bipolar disorder. GlaxoSmithKline warned on its product label that Lamictal can cause SJS and TEN. SJS and TEN are characterized by a rash combined with mucosal involvement, such as bloodshot eyes, sore throat, and other pains involving the erosion of mucous membranes. The conditions are relatively rare and share symptoms with more common diseases. GlaxoSmithKline was aware of cases in which Lamictal-caused SJS had been misdiagnosed.

Dr. Conway told Falsberg that in rare instances, a rash may develop from taking Lamictal, and that he should stop taking it right away if he saw a rash. Dr. Conway instructed him to incrementally increase his dosage from 25 milligrams per day to 150 milligrams per day. After the increase to 150 millligrams, Falsberg began suffering flu-like symptoms, eye, mouth and throat pain, and blisters around his mouth. On April 4, 2007, Dr. Conway learned of the symptoms and instructed Falsberg to decrease his dosage to 75 milligrams.[1]

[1] It appears that Falsberg was not aware of a rash on his back when he described his symptoms to Dr. Conway.

The next day, April 5, 2007, Falsberg was found by his wife slumped over a computer, with a high fever and a rash. She took him to a medical clinic. At the clinic, he had symptoms including a sore throat, cough, fever, eye redness, nasal drainage, and rash. He was initially misdiagnosed with an upper respiratory infection with conjunctivitis and rash, given eye drops, and discharged. His symptoms worsened. The following day, Falsberg's wife took him to a hospital emergency department, where medical personnel determined that Falsberg needed intensive care and transferred him to a different hospital. There, a dermatologist diagnosed him with SJS.

Falsberg was transferred to the burn unit at a third hospital, where he received treatment for TEN. On April 7, Falsberg was placed in a medically-induced coma and surgery was performed. On or about June 14, his doctors concluded that his conditions had been caused by an adverse reaction to Lamictal. He remained hospitalized until July 10, 2007, when he was moved to a rehabilitation unit. Flasberg required full-time assistance until his recovery at the end of August 2007.

Ultimately, Falsberg filed this lawsuit against GlaxoSmithKline and Dr. Conway. GlaxoSmithKline and Dr. Conway successfully moved for summary judgment dismissing Falsberg's claims.[2]

Falsberg appeals.

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[2] Before the trial court, Dr. Conway and Falsberg disputed whether Dr. Conway's motion, originally filed pursuant to CR 12(c), was more appropriate for determination under CR 56 standards. The trial court expressly held that "the [court] considered all of the pleadings submitted [and] essentially converted it to a CR 56 motion. The [court] grants the motion based on the statute of limitations." Clerk's Papers at 512.

DISCUSSION

"Summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law."[3] This court reviews a summary judgment de novo,[4] viewing the facts in the light most favorable to the nonmoving party.[5]

Adequacy of Warnings Under Existing Washington Law

Falsberg asserts that the trial court erred in dismissing his claims against GlaxoSmithKline because the Lamictal label inadequately warns of the risks associated with the drug's use. We disagree.

Recognizing that unavoidably unsafe products such as prescription medications are incapable of being made completely safe,[6] Washington courts have adopted the negligence standard for drug manufacture labeling under Restatement (Second) of Torts section 402A comment k (1965).[7] Under this standard, a

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[3] Cerrillo v. Esparza, 158 Wn.2d 194, 200, 142 P.3d 155 (2006).

[4] Fiore v. PPG Indus. Inc., 169 Wn. App. 325, 333, 279 P.3d 972, review denied, 175 Wn.2d 1027, 291 P.3d 254 (2012).

[5] Vallandigham v. Clover Park Sch. Dist. No. 400, 154 Wn.2d 16, 26, 109 P.3d 805 (2005).

[6] See Terhune v. A.H. Robins Co., 90 Wn.2d 9, 12, 577 P.2d 975 (1978); Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493, 509-11, 7 P.3d 795 (2000).

[7] "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous . . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

prescription medication manufacturer is not subject to strict product liability when the product is properly prepared and the manufacturer adequately warns of the risk of injury from the drug's use.[8] Similarly, Washington's product liability actions statute, chapter 7.72 RCW, defines the manufacturer's duty as "the duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances."[9]

In Estate of LaMontagne v. Bristol-Meyers Squibb, this court held that a warning for a prescription drug may be adequate as a matter of law if it contains "specific and detailed information about the risks of using the drug,"[10] and meets the following test:

> To determine whether a warning is adequate requires an analysis of the warnings as a whole and the language used in the package insert. The court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in taking the prescription drug.[11]

Washington has also adopted the learned intermediary doctrine in assessing whether a drug manufacturer meets its duty to give adequate warnings. Under this doctrine, a drug manufacturer satisfies its duty to warn of dangers involved in use of a product if it gives "'adequate warning to the physician who prescribes it.'"[12]

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[8] Terhune, 90 Wn.2d at 13-14.

[9] RCW 7.72.030(c). The "danger" about which the manufacturer must warn is the specific adverse event or risk associated with use of the medication. See, e.g., Estate of LaMontagne v. Bristol-Meyers Squibb, 127 Wn. App. 335, 111 P.3d 857 (2005) (warnings were adequate as a matter of law where the drug label specifically warned of the risk of the medical condition that caused plaintiff's injury).

[10] 127 Wn. App. 335, 344, 111 P.3d 857 (2005).

[11] Id.

[12] Id. at 345 (quoting Terhune, 90 Wn.2d at 13).

Here, the critical inquiry regarding Falsberg's claim against GlaxoSmithKline is whether the Lamictal label in effect in February 2007 adequately warned medical personnel of the danger of SJS and TEN under the circumstances. The relevant Lamictal warning label unequivocally warns of the risk of SJS/TEN:

> 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.[13]

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.[14]

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

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[13] Clerk's Papers at 676 (emphasis added).

[14] Clerk's Papers at 678.

> [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.[15]

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.[16]

In assessing the adequacy of this label under the learned intermediary doctrine, this court's decision in LaMontagne is instructive.[17] As in LaMontagne, here the label unequivocally warned prescribing physicians of the risks involved with the medication.[18] The Lamictal label warnings in effect in February 2007 expressly and repeatedly warned of the risks of SJS and TEN. The Lamictal label also warned to discontinue use if a rash develops unless the rash clearly is unrelated to use of the drug, and that it is difficult to tell the difference between a benign rash and a serious rash.

As emphasized at oral argument, Falsberg contends that the Lamictal warnings are false and misleading because it is not in fact difficult to differentiate between a benign and a serious rash. Falsberg argues that GlaxoSmithKline had a

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[15] Clerk's Papers at 679.

[16] Clerk's Papers at 685.

[17] LaMontagne, 127 Wn. App. at 352.

[18] Id. at 345.

duty to include an additional warning that "SJS/TEN is a rash plus mucosal involvement,"[19] and that a jury should weigh the conflicting expert testimony on the adequacy of the warnings. Falsberg contends that the label should offer diagnostic advice because of the known risk of misdiagnosis. But Falsberg does not present a compelling argument that the label actually contains any false information or misrepresentation. Neither the Restatement nor LaMontagne support the proposition that a label must go beyond the warnings given to include diagnostic tips, or otherwise instruct a physician on how to practice medicine. Additionally, Falsberg does not establish that the warning to discontinue use at the first sign of rash was misleading just because it was more conservative than his proposed warning.

We conclude that the Lamictal label was adequate as a matter of law. 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 LaMontagne, the Lamictal warnings were adequate.[20]

Whether this Case Provides a Basis to Change Washington's Standard

Falsberg argues that this court should abandon Washington's standard, i.e., requiring a label to adequately warn a prescribing physician of the risks associated with the drug, in favor of the "warn every health care provider" standard adopted by the Oregon Supreme Court in McEwen v. Ortho Pharmaceutical Corp.[21] The

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[19] Appellant's Br. at 8.

[20] LaMontagne, 127 Wn. App. at 350-51.

[21] 270 Or. 375, 528 P.2d 522 (1974).

McEwen court concluded that, under Oregon law, a manufacturer has the duty to warn the prescribing physician, the treating physician, and "all members of the medical profession who come into contact with the patient in a decision-making capacity."[22] The court concluded that the prescribing physician learned intermediary "reasoning applies with equal force to the treating physician."[23] Falsberg argues that this court should adopt McEwen as a better-reasoned modern rule.

But strong policy considerations support Washington's focus upon the prescribing physician in applying the learned intermediary doctrine. Our Supreme Court has emphasized that "in examining the nature of the relationship between a drug manufacturer, a prescribing physician and a patient," the prescribing physician plays a unique and important role:

> [I]t is the physician who compares different products, selects the particular drug for the ultimate consumer and uses it as a tool of his or her professional trade. Under the learned intermediary doctrine, a drug company fulfills its duty by giving warnings regarding prescription drugs to the physician rather than to the patient.[24]

In Terhune v. A.H. Robins Co., our Supreme Court highlighted that the prescribing physician intermediary provides unique protection to the consumer of prescription medications:

> [It is] safe to surmise that ordinarily a physician will not prescribe or utilize a product which he does not consider reasonably safe, and that he will take into account the amount of testing, or lack thereof, which has been done with respect to the product. But in any event, because

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[22] Id. at 529.

[23] Id.

[24] 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).

> it is he who finally controls the dispensing of the product, it is just that he should be fully advised of the characteristics and dangers of the products and that the manufacturer should not be held to account if it has done its duty in this regard.[25]

This important policy consideration underlies the exception from strict liability for medical products embodied in comment k of the Restatement (Second) of Torts section 402A, an exception based upon principles that "have their basis in the character of the medical profession and the relationship which exists between the manufacturer, the physician and the patient."[26]

We also disagree with Falsberg's argument that the facts of this case present a compelling setting for adopting McEwen or otherwise expanding Washington's existing standards for a drug manufacturer's duty to warn. Here, Dr. Conway was both the prescribing physician and the treating physician when symptoms first appeared. Dr. Conway was aware of the manufacturer's warnings and, when he prescribed the drug, he advised Falsberg to discontinue use if he developed any rash. As to the emergency room physicians such as Dr. Lee, the record before us is minimal, and it appears to be speculative whether a more simplified rash plus mucosal involvement warning would have been of any significance.

The underlying rationale of McEwen is that if a warning to the prescribing physician is good, then a warning to all health care providers everywhere is better. But that would significantly alter Washington's existing learned intermediary

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[25] 90 Wn.2d 9, 16-17, 577 P.2d 975 (1978).

[26] Terhune, 90 Wn.2d at 16; see also Ruiz-Guzman, 141 Wn.2d at 506-08 (relationship between the prescribing physician, patient, and drug manufacturer as well as the character of the medical profession justifies treating prescription drugs differently from other dangerous products such as pesticides in the product liability context).

doctrine, and the facts in this record do not squarely present a basis for such a change.

We affirm the trial court's dismissal of Falsberg's claims against GlaxoSmithKline pursuant to CR 56.

Statute of Limitations

Falsberg contends that the trial court erred by dismissing his claims against Dr. Conway based on the relevant statutes of limitations. We disagree.

Falsberg initially filed a lawsuit against Dr. Conway in 2008, but later voluntarily dismissed the suit. In April 2010, Falsberg filed this lawsuit against GlaxoSmithKline. On July 12, 2010, he amended the complaint to include claims against Dr. Conway for medical negligence, negligent misrepresentation, and lack of informed consent.

The trial court granted Dr. Conway's motion to dismiss based on the lapse of the applicable statutes of limitations.[27] The trial court concluded that the statute of limitations for the informed consent claim lapsed on February 15, 2010 and the statute for the negligence claims lapsed on June 25, 2010.[28]

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[27] Because the trial court considered the parties' evidentiary submissions in resolving Dr. Conway's motion to dismiss, it converted the proceeding to one for summary judgment under CR 56.

[28] February 15, 2010 was three years from the date on which Dr. Conway first prescribed Lamictal for Falsberg, the relevant date for his informed consent claim. Dr. Conway performed his last act relevant to the negligence claims, instructing Falsberg to reduce his Lamictal dosage, on April 4, 2010. On March 22, 2010, before the expiration of the three-year statute of limitations pertinent to those claims, Falsberg mailed Dr. Conway a notice of intent to sue pursuant to former RCW 7.70.100(1), which resulted in an automatic extension of the statute of limitations ninety days from the date of mailing plus five court days. Including the extension provided by former RCW 7.70.100(1), the statute of limitations for the negligence claims expired on June 25, 2010.

RCW 4.16.350, the statute of limitations generally applicable to claims of medical negligence, provides:

> Any civil action for damages for injury occurring as a result of health care which is provided after June 25, 1976, against:
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> . . . a physician . . . .
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> . . . .
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> . . . based upon alleged professional negligence shall be commenced within three years of the act or omission alleged to have caused the injury or condition, or one year of the time the patient or his or her representative discovered or reasonably should have discovered that the injury or condition was caused by said act or omission, whichever period expires later.

Under RCW 4.16.350, the physician's last negligent act triggers a three-year limitation period; otherwise, discovery of a latent injury triggers a one-year period.

The last potentially negligent act by Dr. Conway relevant to the negligence claims was his April 4, 2007 instruction that Falsberg reduce his dosage of Lamictal by one-half rather than to discontinue the medication altogether. That is the date of the act or omission triggering the three-year limitation period under RCW 4.16.350. Falsberg makes no showing that he was incapacitated on April 4 when he called Dr. Conway, discussed his conditions of dizziness and flu-like symptoms, and received Dr. Conway's final instructions. At the latest, Falsberg learned of Dr. Conway's alleged breach and his injury after he came out of the induced coma. This later "discovery" would have triggered the one-year statute of limitations under RCW 4.16.350. Falsberg did not meet this deadline either.

Falsberg contends that his failure to meet these deadlines does not bar his claims because he was incapacitated beginning several days before his hospitalization and continuing until the end of August 2007. He argues that the

limitations periods should be tolled for that period under the disability-tolling provision of RCW 4.16.190(1):

> Unless otherwise provided in this section, if a person entitled to bring an action mentioned in this chapter . . . *be at the time the cause of action accrued* . . . incompetent or disabled to such a degree that he or she cannot understand the nature of the proceedings, such incompetency or disability as determined according to chapter 11.88 RCW, . . . the time of such disability shall not be a part of the time limited for the commencement of action.[29]

To resolve whether RCW 4.16.190 tolling applies to Falsberg's claims, we look to the applicable statutes to determine the times at which his claims accrued. Our primary goal when interpreting statutes is to effectuate the legislature's intent.[30] Falsberg argues that the trial court erroneously applied RCW 4.16.190(1) by using the RCW 4.16.350(3) concepts rather than the common-law definition of "accrual."[31] Falsberg's argument is not persuasive.

In enacting RCW 4.16.350, the legislature adopted narrow and specific standards for medical malpractice claims and abandoned common law standards for accrual which had been historically developed to account for discovery of foreign objects that remained latent before causing injury. In Gunnier v. Yakima Heart Center, our Supreme Court held that RCW 4.16.350(3) eliminated the common law concept of accrual from statute of limitations analysis with respect to medical negligence claims, except insofar as the elements of accrual are contained in the concept of "discovery" in RCW 4.16.350(3), which triggers a special one-year

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[29] (Emphasis added.)

[30] Wright v. Jeckle, 158 Wn.2d 375, 379, 144 P.3d 301 (2006).

[31] Under the common law approach, a medical negligence plaintiff's cause of action accrued only upon discovery of the injury. See Ruth v. Dight, 75 Wn.2d 660, 667-68, 453 P.2d 631 (1969).

statute of limitations.[32] To apply the common law accrual standard to claims of medical negligence by means of RCW 4.16.190 would defeat the clear intent of the legislature to abandon the use of common law accrual in cases governed by RCW 4.16.350. We decline to do so.

Falsberg's reliance on Rivas v. Overlake Hospital Medical Center is misplaced.[33] Rivas expressly states that for tolling under RCW 4.16.190 to apply, "the plaintiff's incompetency or disability must exist at the time the cause of action accrues."[34] Because the Rivas court did not address the issue of accrual, Rivas does not compel the conclusion that the common law definition for accrual applies to tolling under RCW 4.16.190. Rivas merely recognizes that the tolling provisions of RCW 4.16.190 continue to apply, even after the legislature adopted RCW 4.19.350.

Finally, the three-year limitations period applicable to any "informed consent" claim under RCW 7.70.050 began to run at the latest on April 4, 2007, the last date Dr. Conway adjusted Falsberg's dosage of Lamictal before his hospitalization. This was more than three years before he sued Dr. Conway.

The trial court properly dismissed Falsberg's claims against Dr. Conway based on the lapse of the statutes of limitations.

CONCLUSION

The trial court properly dismissed Falsberg's claims. We decline to expand the existing drug label warning standards. Falsberg's claim against

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[32] 134 Wn.2d 854, 860-62, 953 P.2d 1162 (1998)

[33] 164 Wn.2d 261, 189 P.3d 753 (2008).

[34] Id. at 267.

GlaxoSmithKline based on the Lamictal label does not present a genuine issue of material fact because the label is adequate as a matter of law. His claims against Dr. Conway are barred by the applicable statutory limitation periods.

Affirmed.

WE CONCUR:

Spearman, A.C.J.

Cox, J.