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No. 89529-5

SUPREME COURT OF THE STATE OF WASHINGTON

DAVID A. FALSBERG,

Appellant,

V.

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

Respondents.

ANSWER TO PETITION FOR REVIEW BY RESPONDENT JACK S. CONWAY, M.D.

Mary H. Spillane, WSBA #11981 Daniel W. Ferm, WSBA# 11466 WILLIAMS, KASTNER & GIBBS PLLC Attorneys for Respondent Jack S. Conway, M.D.

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I. IDENTITY OF RESPONDING PARTIES

Respondent Jack S. Conway, M.D., asks the Court to deny David Falsberg's petition for review of the Court of Appeals decision insofar as that decision pertains to Dr. Conway.

II. COURT OF APPEALS DECISION

As the decision pertains to Dr. Conway, the Court of Appeals, in an unpublished opinion issued on September 9, 2013 (with motions to publish denied on October 14, 2013), affirmed the trial court's dismissal of Mr. Falsberg's RCW ch. 7.70 medical negligence and "informed consent" claims on grounds that those claims were barred by the statute of limitations, RCW 4.16.350. *Falsberg v. GlaxoSmithKline*, No. 68264-4-1, 2013 Wash. App. LEXIS 2110 at *15-*21 (Wash. Ct. App., Sept. 9, 2013).

III. COUNTERSTATEMENT OF ISSUES PRESENTED FOR REVIEW AS AGAINST DR. CONWAY

- 1. Did the trial court and the Court of Appeals properly conclude that Falsberg's RCW ch. 7.70 claims against Dr. Conway were barred by the statute of limitations, RCW 4.16.350?
- 2. Did the trial court and the Court of Appeals properly conclude, as this court held in *Gunnier v. Yakima Heart Center*, 134 Wn.2d 854, 189 P.3d 753 (1998), that the legislature, in enacting RCW

A copy of the opinion from LEXIS is attached.

4.16.350 for medical malpractice claims, abandoned common law standards for accrual with respect to the three-year-from-act-or-omission limitations period, while retaining the elements of "discovery" accrual with respect to the one-year-from-discovery limitations period?

3. Did the trial court and the Court of Appeals properly conclude that Mr. Falsberg was competent at the time his claims against Dr. Conway accrued under RCW 4.16.350 such that RCW 4.16.190(1) tolling did not apply to remove the bar of the statute of limitations?

IV. COUNTERSTATEMENT OF THE CASE

Mr. Falsberg sued his former psychiatrist, Dr. Conway, and several GlaxoSmithKline ("GSK") entities for injuries he allegedly sustained due to an adverse reaction to the drug Lamictal, a GSK pharmaceutical product that Dr. Conway had prescribed. CP 25-57.

A. Factual Background.

On February 15, 2007, Dr. Conway had prescribed Lamictal to treat Mr. Falsberg for bipolar disorder. CP 27 (¶ 2.3), CP 34 (¶ 4.3(c)), CP 465, CP 519. Mr. Falsberg admits that Dr. Conway told him at the time that "in very rare instances there can be a rash" from taking it, that "very rarely people get very sick from it," and that he should "stop taking it right away" if he saw a rash. CP 489-91. Mr. Falsberg recalls Dr. Conway telling him "about the incrementalization," meaning that he would take

one pill (25 mg) per day in week one, two pills (50 mg) per day in week two, three pills (75 mg) per day in week three, and four pills (100 mg) per day in week four. CP 491. On March 22, 2007, Dr. Conway increased the dosage to 150 mg per day. CP 27 (¶ 2.4), CP 81 (¶ 2.4), CP 232 (¶ 5).

Mr. Falsberg claims that, when he got up on April 4, 2007, he "didn't feel great," and that later that morning he lost his balance and fell in his real estate broker's office after reviewing a 20-page real estate contract line by line with the broker. CP 504-06. He called Dr. Conway's office that afternoon:

- Q. Okay. So let's talk about the April 4th telephone call.
- A. All right.
- Q. Who called it, him?
- A. Me ... I called his office.
- Q. And when you called his office, did you get ahold of him right away or did he call you back?
- A. My recollection is that he called me back. He was good at that.
- Q. Okay. And then when he called you back, what did you tell him?
- A. I told him I had flu-like symptoms, I had blurred vision, I had dizziness. I had actually I believe I fell down I fell I know I fell down in my broker's office.
- Q. Okay.
- A. And he said hey, you been drinking all night, which I thought was funny but but that's what I recall.

CP 494-95. In retrospect, Mr. Falsberg believes he already had a rash, but did not see it because it was on his neck and back. CP 495; *see also* CP 1058 (¶ 8). After his April 4 phone call with Dr. Conway, Mr. Falsberg, as instructed, halved his dosage of Lamictal. CP 232 (¶ 8), 494.

On April 5, 2007, Mr. Falsberg's wife found him "slumped over the computer with a high fever and a rash on his neck, running down and covering his back" and took him to Swedish Physicians Clinic in Ballard, where Mr. Falsberg complained of sore throat, fever, eye redness, and nasal drainage, as well as the rash. CP 227, 232 (¶9). Mr. Falsberg was treated at Swedish and evidently discharged home because, according to his declaration testimony, the next morning, which would have been April 6, he was taken back to the Swedish/Ballard emergency room, transferred to the ICU at Swedish First Hill, and diagnosed with Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis ("SJS/TEN"). CP 232 (¶10). He was then transferred to the Harborview Medical Center burn unit, where he remained from April 7 until July 10, spending much of that time in a drug-induced coma. CP 232 (¶¶10-11).

² Mrs. Falsberg testified by declaration that those events occurred on April 6, CP 227 (¶ 9), but the amended complaint alleges that they occurred on April 5, CP 28 (¶ 2.8), CP 49 (¶ 14.8), and Dr. Conway's answer admits that the Swedish medical records (which are not of record) indicate they occurred on April 5. CP 82 (¶ 2.8).

B. Trial Court Proceedings.

Mr. Falsberg, through counsel, filed suit against Dr. Conway in July 2008, CP 109 (¶B), CP 117 (¶3), CP 153-63, but appeared *pro se* to obtain an order voluntarily nonsuiting that complaint without prejudice on October 2, 2008, CP 165.

In April 2010, he filed a "Complaint – Medical Negligence" against the GSK entities but not against Dr. Conway or any other licensed health care provider. CP 167-92. On July 12, 2010, he filed an amended complaint, CP 25-57, asserting claims against Dr. Conway, CP 27-36, for medical negligence, CP 33-35, negligent misrepresentation, CP 35, and "lack of informed consent," CP 35-36.

Dr. Conway answered the amended complaint, asserting as an affirmative defense the bar of the statute of limitations. CP 103. Dr. Conway subsequently moved for judgment on the pleadings based on the statute of limitations. CP 107-92. Mr. Falsberg responded, submitting a brief, CP 212-23, his declaration, CP 231-33, his wife's declaration, CP 226-30, and a copy of voluminous Harborview Medical Center records for Mr. Falsberg's April 7 to July 10, 2007 hospitalization, CP 234-463.

Mr. Falsberg asserted in his declaration that he had been in a druginduced coma or sedated, and "incapable of appreciating and understanding any legal proceedings or requirements..." from April 7 until well after his hospital discharge on July 10, 2007. CP 232-33 (¶¶11-12). His wife testified by declaration that her husband "[b]y April 3, 2007 ... was having symptoms of slurred speech, decreased balance, and he said he felt like he was getting the flu," and that "[d]uring a phone conversation the afternoon of April 4, 2007, Dr. Conway did not ask David to come in to see him [but rather told him] to decrease the Lamictal to (75 mg.)." CP 227 (¶¶7-8). Nancy Falsberg did not otherwise describe or characterize Mr. Falsberg's condition on April 4.

Mr. Falsberg claimed that there were two disputed issues of fact:

(1) when Dr. Conway's "last act" occurred for purposes of his *lack-of-informed-consent* claim; and (2) whether he "was an incapacitated person" entitled to disability tolling under RCW 4.16.190(1) as of an unspecified date and time. CP 214. He argued that he was hospitalized from April 6 through July 10, 2007, and that, under RCW 4.16.190(1), "the entire time period when Mr. Falsberg had been rendered an incapacitated person ... must be deducted from the computation of the three-year statute of limitations period." CP 218. He cited *Rivas v. Overlake Hosp. Med. Ctr.*, 164 Wn.2d 261, 189 P.3d 753 (2008), as support for his tolling-due-to-incapacitation argument. CP 217-18.

³ Mr. Falsberg also cited decisions concerning CR 12 and CR 56 motions, CP 216-17, and his claims as to the tolling effect of the RCW 7.70.100(1) Notice of Intent to Sue that he mailed to Dr. Conway on March 22, 2010, CP 221 (¶24). On appeal, Mr. Falsberg

In arguing that a factual dispute existed "as to when [the] 'last act' occurred for purposes of his lack-of-informed-consent claim," Mr. Falsberg contended that Dr. Conway had an obligation to inform him of the risks of and alternatives to continued use of Lamictal not only when he initially prescribed the drug on February 15, 2007, but also when he increased the dosage on March 22, and when he told Mr. Falsberg to halve the dosage on April 4. CP 220-21. Mr. Falsberg cited no authority for the proposition that a physician has a legal obligation to re-disclose risks and alternatives concerning the use of a drug with every dosage change.

Although not made explicit in his written submissions to the trial court, Mr. Falsberg's amended complaint, testimony and arguments implied that he had "symptoms" before April 4, 2007, of what he claims was the reaction to Lamictal that, by April 7, 2007, had become SJS/TEN. See CP 27-28 (¶¶2.5-2.6), 48 (¶14.5), 220 (¶21), 221 (¶23), 227 (¶¶6, 7), 232 (¶¶6, 7). At the hearing on Dr. Conway's motion, Mr. Falsberg's counsel asserted that Mr. Falsberg had begun having symptoms of an adverse reaction to Lamictal as early as March 22. 6/24/11 RP 12-13.

The trial court granted Dr. Conway's motion, CP 510-13, 565-69, treating it as one for summary judgment, 6/24/11 RP 24-25. The order

has made no arguments relating to his RCW 7.70.100(1) notice, or to CR 12 versus CR 56 motions.

was later amended, CP 565-69, to reflect the court's consideration of both of the replies Dr. Conway had filed, see CP 538-45, 546-48, 555. Mr. Falsberg's motion for reconsideration, CP 514-29, was denied. CP 570-74. After the court dismissed Mr. Falsberg's claims against GSK, CP 1078-80, Mr. Falsberg timely appealed, CP 1081-1106. The Court of Appeals, in an unpublished decision, affirmed the orders of dismissal, and denied subsequent motions to publish. Mr. Falsberg then timely filed a Petition for Review to this Court.

C. ARGUMENT WHY REVIEW SHOULD BE DENIED.

The medical malpractice statute of limitations, RCW 4.16.350 provides in pertinent part:

Any civil action for damages for injury occurring as a result of health care which is provided after June 25, 1976, against ... a physician ... 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 ... [Emphasis added.]

Thus, the medical statute of limitations sets forth two limitation periods – three years from the last act or omission alleged to have caused the injury or one year after discovery that the injury or condition was caused by the act or omission, with the latter-occurring period being the controlling one.

D. The Court of Appeals Applied Settled Law in Holding that RCW 4.16.350(3) Abandons Common Law "Accrual" For Purposes of the Three-Year Medical Malpractice Limitations Period.

As the Court of Appeals properly recognized, the reason the 1975-76 Legislature amended RCW 4.16.350(3) so that the last negligent act or omission triggers the three-year medical malpractice limitations period was – and, logically, can only have been – to *abandon* accrual-on-discovery triggering of the three-year limitations period:

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 statute of limitations. 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, 2013 Wash. App. LEXIS 2110 at *19-*20.

Discovery of injury – part of the common law accrual concept – still plays a role for statute of limitations purposes under RCW 4.16.350(3), but that role is only to trigger the *one*-year limitations period, within which Mr. Falsberg did not sue and has never claimed to have sued. Nor could he. On July 21, 2008, Mr. Falsberg first filed suit against Dr.

Conway (which he later voluntarily nonsuited) and, based on the allegations made in that July 2008 complaint, showed that he had "discovered" the essential elements of his claims against Dr. Conway by then. CP 153-60. Yet, he did not file this suit against Dr. Conway until July 12, 2010, well more than one year later.

The Court of Appeals here recognized what this Court recognized some fifteen years ago in *Gunnier v. Yakima Heart Ctr.*, 134 Wn.2d 854, 953 P.2d 1162 (1998):

The three-year period begins to run from "the act or omission alleged to have caused the injury or condition ..." RCW 4.16.350(3). This language clearly does not provide that the limitations period commences with accrual of a cause of action.

Further, history indicates that the Legislature intended to depart from common-law notions of accrual of a tort cause of action.

Gunnier, 134 Wn.2d at 859-60 (emphases added). Mr. Falsberg's petition argues not that the Legislature *cannot* do what it did in 1976, but rather that the Legislature must not have meant to do what the Court of Appeals and the *Gunnier* court have recognized that it "clearly" meant to do. Discretionary review is not warranted under any subdivision of RAP 13.4.

The *three*-year "from act or omission" medical malpractice limitations period (as opposed to the one-year "from discovery" limitations period) has, since 1976, begun to run without regard to "accrual," and thus

without regard to when the patient realized he has an injury, and instead begins to run from the date of the last allegedly negligent act or omission. Thus, it is nonsensical to argue, as Mr. Falsberg does, that the three-year limitations period nonetheless is tolled during a "time of ... disability" based on a statute (RCW 4.16.190(1)) that applies only if the patient was disabled "at the time the cause of action *accrued* [italics added]."

The trial court and the Court of Appeals were correct: the *three*-year statute of limitations began to run on Mr. Falsberg's medical malpractice claim against Dr. Conway on April 4, 2007. Mr. Falsberg's suit against Dr. Conway, which was filed on July 12, 2010, was filed more than a year after Mr. Falsberg discovered his cause of action (and he has never argued otherwise) and more than three years (plus 95 days, to include tolling under the notice of intent to sue provision of RCW 7.70.100(1))⁴ after the last allegedly negligent act by Dr. Conway which occurred on April 4, 2007. Thus, the courts below correctly determined that Mr. Falsberg sued too late.

E. The Court of Appeals Decision Is Not Inconsistent with *Rivas*.

Mr. Falsberg argues, Petition at 19, that the Court of Appeals decision is "inconsistent with" Rivas v. Overlake Hosp. Med. Ctr., 164

⁴ See Laws of 2007, ch. 119, §1. At least with respect to medical malpractice claims against non-public health care providers, the notice of intent to sue provision of RCW 7.70.100(1) was declared unconstitutional in Waples v. Yi, 169 Wn.2d 152, 234 P.3d 187 (2010).

Wn.2d 261, 189 P.3d 753 (2008). It is not, and could not be, because *Rivas* was not a statute of limitations or accrual decision; it addressed a different issue, *i.e.*, whether, to be "incompetent or disabled" for purposes of RCW 4.16.190, a person must have been incapacitated for a long enough period of time for a guardian to have been appointed pursuant to RCW ch. 11.88. This Court answered that question in the negative. While that negative answer may have implications for purposes of applying RCW 4.16.350(3)'s *one*-year limitations period, which is triggered by what amounts to accrual, but it has no implications for purposes of applying RCW 4.16.350(3)'s *three-year* limitations period. *Rivas* nowhere repudiates what the Court held and said in *Gunnier* about "accrual" having been abandoned for purposes of the *three-year* medical malpractice limitations period.

F. The Supreme Court Should Decline to Review the Trial Court's and Court of Appeals' Determinations that There Was No Question of Fact As to Whether Mr. Falsberg Was Disabled on April 4, 2007, Because the Petition Fails to Show that RAP 13.4(b) Criteria Are Met.

Mr. Falsberg's assertion, *Petition at 6*, that when he became disabled "is for the jury" is not accompanied by corresponding legal argument and (a) is not one he preserved in the trial court; (b) is demonstrably incorrect based on the evidence and applicable law of "dis-

ability"; and (c) is not one that warrants consideration on review because his petition does not demonstrate that RAP 13.4(b) criteria are met.

In his briefing to the Court of Appeals, Mr. Falsberg made a perfunctory, nine-line, argument, *App. Br. at 24*, that "substantial factual disputes" existed as to "whether his legal disability coincided with, or preexisted, the moment his cause of action against Dr. Conway 'accrued'." He cited "CP 218-19, 528-529" as support for that assertion. Those pages of the Clerk's Papers, however, consist of arguments made in his *briefing* to the trial court, not to any testimony or other *evidence*.

Second, Mr. Falsberg plainly was *not* disabled on April 4, 2007, in light of the evidence of record, *i.e.*, Mr. Falsberg's own testimony about what he did on April 4 and about his phone conversation with Dr. Conway that day. Although the Court of Appeals did not quote the testimony, Mr. Falsberg testified that, when he got up on April 4, 2007, he "didn't feel great," and later that morning he fell in his real estate broker's office after reviewing with the broker, line by line, a 20-page real estate contract. CP 504-06. That afternoon, he was still able to call Dr. Conway's office:

- Q. Okay. So let's talk about the April 4th telephone call.
- A. All right.
- Q. Who called it, him?
- A. Me ... I called his office.
- Q. And when you called his office, did you get ahold of him right away or did he call you back?

- A. My recollection is that he called me back. He was good at that.
- Q. Okay. And then when he called you back, what did you tell him?
- A. I told him I had flu-like symptoms, I had blurred vision, I had dizziness. I had actually I believe I fell down I fell I know I fell down in my broker's office.
- Q. Okay.
- A. And he said hey, you been drinking all night, which I thought was funny but but that's what I recall.

CP 494-95.⁵ After the April 4 phone conversation with Dr. Conway, Mr. Falsberg halved his dosage of Lamictal as instructed. CP 232 (¶ 8), 494. It was not until the next day, April 5, 2007, that Mr. Falsberg's wife found him "slumped over the computer with a high fever and a rash on his neck, running down and covering his back" and took him to the Swedish Physicians Clinic in Ballard,⁶ where he was not even hospitalized but rather was treated and released to home. CP 227, 232 (¶ 9).⁷

⁵ It is undisputed, as the Court of Appeals noted, Falsberg, 2013 Wash. App. LEXIS 2110 at *2, that Dr. Conway had told Mr. Falsberg in February 2007 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." CP 489-91. On April 4, Mr. Falsberg chose to describe his symptoms – not including a rash, which he either did not yet have or had on his back but had not noticed, CP 495 and 1058 (¶ 8) – by phone rather than see Dr. Conway or another health care provider to be examined.

⁶ Mrs. Falsberg testified by declaration that those events occurred on April 6, CP 227 (¶ 9), but the amended complaint alleges that they occurred on April 5, CP 28 (¶ 2.8), CP 49 (¶ 14.8), and Dr. Conway's answer admits that the Swedish medical records (which are not of record) indicate they occurred on April 5. CP 82 (¶ 2.8).

⁷ It was on April 6 that Mr. Falsberg was taken back to the Swedish/Ballard emergency room, transferred to the ICU at Swedish First Hill, diagnosed with Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis ("SJS/TEN"), and transferred to the Harborview Medical Center burn unit, where he remained from April 7 until July 10, spending much of that time in a drug-induced coma. CP 232 (¶¶10-11).

Mr. Falsberg acknowledged in his brief to the Court of Appeals, *App. Br. at 18*, that to be "incompetent or disabled" for purposes of RCW 4.16.190(1), a person must have "a significant risk of personal harm based upon a demonstrated inability to adequately provide for nutrition, health, housing, or physical safety [quoting RCW 11.88.020(1)(a)]." No reasonable jury could have found Mr. Falsberg disabled under that definition on April 4, when, within a few hours after having reviewed a 20-page contract line by line, he received from Dr. Conway the dosage-reducing instructions that he was able to follow, after which he remained able, even the next day, to sit down to work at a computer.

The trial court and the Court of Appeals correctly determined that Mr. Falsberg was not disabled on April 4, 2007, the last date when Dr. Conway provided allegedly negligent treatment. Under RCW 4.16.350(3), that was when the three-year limitations period began to run. April 4, 2007, was more than three years before Mr. Falsberg filed this suit against Dr. Conway on July 12, 2007, even after giving Mr. Falsberg the benefit of the 95-day extension afforded by the notice of intent provision of RCW 7.70.100(1), see Laws of 2007, ch. 119, §1. Thus, the Court of Appeals properly affirmed the trial court's summary judgment dismissal of Mr. Falsberg's medical malpractice claims against Dr. Conway on statute of

⁸ See footnote 4, supra.

limitations grounds. Mr. Falsberg does not demonstrate in his petition for review that any RAP 13.4(b) criteria for reviewing the "no dispute of fact" determinations are met.

V. <u>CONCLUSION</u>

For the foregoing reasons, the petition for review insofar as it pertains to Dr. Conway should be denied.

RESPECTFULLY SUBMITTED this 4th day of December, 2013.

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CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury under the laws of the State of Washington that on the 4th day of December, 2013, I caused a true and correct copy of the foregoing document, "Answer to Petition for Review by Respondent Jack S. Conway, M.D.," to be delivered in the manner indicated below to the following counsel of record:

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DATED this 4th day of December, 2013, at Seattle, Washington.

Carrie A. Custer, Legal Assistant



1 of 2 DOCUMENTS

DAVID A. FALSBERG, Appellant, v. GLAXOSMITHKLINE, PLC, ET AL., Respondents.

No. 68264-4-I

COURT OF APPEALS OF WASHINGTON, DIVISION ONE

2013 Wash. App. LEXIS 2110

September 9, 2013, Filed

NOTICE: RULES OF THE WASHINGTON COURT OF APPEALS MAY LIMIT CITATION TO UNPUBLISHED OPINIONS. PLEASE REFER TO THE WASHINGTON RULES OF COURT.

SUBSEQUENT HISTORY: Reported at Falsberg v. GlaxoSmithKline, PLC, 2013 Wash. App. LEXIS 2157 (Wash. Ct. App., Sept. 9, 2013)

PRIOR HISTORY: [*1]

Appeal from Superior Court King County. Docket No(s): 10-2-13102-7 SEA. Judgment or other matter being reviewed: (1) Order Granting Def Conway's Motion for Judgment on the Pleadings. (2) Second Amended Order Granting Def Conway's Motion for Judgment on the Pleadings. (3) Order on Motion for Reconsideration. (4) Order Granting Def GlaxoSmithLine Motion for Summary Judgment. Judge signing: The Honorable May I. Yu. Date entered: (1) 6/24/11. (2) 7/25/11. (3) 7/25/11. (4) 1/12/12.

DISPOSITION: Affirmed.

COUNSEL: Counsel for Appellant(s): Kenneth Wendell Masters, Masters Law Group PLLC, Bainbridge Island, WA; Lish Whitson, Kristy Lee Stell, Lish Whitson PLLC, Seattle, WA; James Leventhal, Benjamin I. Sachs, Leventhal, Brown & Puga, PC, Denver, CO.

Counsel for Respondent(s): John Coleman Graffe Jr., Alison H. Grennan, Johnson, Graffe, Keay, Moniz & Wick, LLP, Seattle, WA; Mary H. Spillane, Daniel W. Ferm, Williams Kastner & Gibbs, Seattle, WA; John Wentworth Phillips, Phillips Law Group PLLC, Seattle, WA.

JUDGES: AUTHOR: Verellen, J. WE CONCUR: Spearman, A.C.J., Cox, J.

OPINION BY: Verellen

OPINION

¶1 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.

¶2 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 [*2] 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

¶3 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.

- ¶4 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 [*3] to 150 milligrams, 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 It appears that Falsberg was not aware of a rash on his back when he described his symptoms to Dr. Conway.
- ¶5 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.
- ¶6 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 [*4] 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.
- ¶7 Ultimately, Falsberg filed this lawsuit against GlaxoSmithKline and Dr. Conway. GlaxoSmithKline and Dr. Conway successfully moved for summary judgment dismissing Falsberg's claims. ²
 - 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.

¶8 Falsberg appeals.

DISCUSSION

- ¶9 "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
 - 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, [*5] 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).

Adequacy of Warnings Under Existing Washington Law

- ¶10 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.
- ¶11 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 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
 - 6 See Terhune v. A.H. Robins Co., 90 Wn.2d 9, 12, 577 P.2d 975 (1978); [*6] 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).

- 8 Terhune, 90 Wn.2d at 13-14.
- 9 RCW 7.72.030(1)(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 [*7] law where the drug label specifically warned of the risk of the medical condition that caused plaintiffs injury).

¶12 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]

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

11 *Id.*

- ¶13 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
 - 12 Id. at 345 (quoting Terhune, 90 Wn.2d at 13).
- ¶14 Here, the critical inquiry regarding [*8] 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 RE-LIABLY 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 TREAT-MENT MAY NOT PREVENT A RASH FROM BECOMING LIFE THREAT-ENING OR PERMANENTLY DISA-BLING 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 [*9] 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":

[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]

- 13 Clerk's Papers at 676 (emphasis added).
- 14 Clerk's Papers at 678.
- 15 Clerk's Papers at 679.
- 16 Clerk's Papers at 685.

¶15 In [*10] 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.

- 17 LaMontagne, 127 Wn. App. at 352.
- 18 Id. at 345.

¶16 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 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 con-

tends that the label should offer diagnostic advice because of the known risk of misdiagnosis. But Falsberg does not present a compelling [*11] 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.

19 Appellant's Br. at 8.

¶17 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

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

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

¶18 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 [*12] Court in McEwen v. Ortho Pharmaceutical Corp. ²¹ The 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.

- 21 270 Or. 375, 528 P.2d 522 (1974).
- 22 Id. at 529.
- 23 Id.

¶19 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 [*13] drugs to the physician rather than to the patient. [24]

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).

¶20 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 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 [*14] which exists between the manufacturer, the physician and the patient." ²⁶

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),

¶21 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.

¶22 The underlying rationale of *McEwen* is that if a warning to the [*15] 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 doctrine, and the facts in this record do not squarely present a basis for such a change.

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

Statute of Limitations

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

¶25 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.

¶26 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

- 27 Because the trial court [*16] 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.

¶27 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:

... a physician

... based upon [*17] 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.

¶28 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 [*18] the one-year statute of limitations under RCW 4.16.350. Falsberg did not meet this deadline either.

¶29 Falsberg contends that his failure to meet these deadlines does not bar his claims because he was incapacitated beginning several days before his hospitaliza-

tion 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]

29 (Emphasis added.)

¶30 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 [*19] 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.

- 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).
- ¶31 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 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

[*20] to abandon the use of common law accrual in cases governed by *RCW 4.16.350*. We decline to do so.

¶32 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 plaintiffs 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 4.16.350.

- 33 164 Wn.2d 261, 189 P.3d 753 (2008).
- 34 Id. at 267.

¶33 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.

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

CONCLUSION

¶35 The trial court [*21] properly dismissed Falsberg's claims. We decline to expand the existing drug label warning standards. Falsberg's claim against 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.

¶36 Affirmed.

SPEARMAN, A.C.J., and COX, J., concur.

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Subject: Falsberg v. GlaxoSmithKline, et al. / Supreme Court No. 89529-5

Dear Clerk of Court,

Attached for filing in .pdf format is the Answer to Petition for Review by Respondent Jack W. Conway, M.D., in *Falsberg v. GlaxoSmithKline, et al.*, Supreme Court Cause No. 89529-5. The attorney filing this answer is Mary Spillane, WSBA No. 11981, (206) 628-6656, e-mail: mspillane@williamskastner.com.

Respectfully submitted,

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