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	)	No. 68264-4-I UNPUBLISHED OPINION FILED: September 9, 2013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.

---

[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

---

[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]

---

[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":

---

[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

---

[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

---

[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

---

[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

---

[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]

---

[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:
>
> . . . 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.

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

---

[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

---

[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.