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NO. 68264-4-I

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

DAVID A. FALSBERG,

Appellant,

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.

BRIEF OF APPELLANT

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INTRODUCTION

David Falsberg suffered the worst case of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) that his Harborview burn doctor had ever seen. SJS and TEN are characterized by a severe rash plus mucosal involvement (*e.g.,* eye pain, mouth and throat pain, blistering around the mouth).

GlaxoSmithKlein (GSK) manufactures Lamictal®, its brand name for the drug lamotrigine. Lamictal® is a leading cause of SJS and TEN. Dr. Jack Conway, David's psychiatrist, prescribed Lamictal® for David. After Dr. Conway increased the dosage, David began suffering flu-like symptoms, eye pain, mouth and throat pain, and blisters around his mouth. Dr. Conway missed the diagnosis, and merely lowered the dosage, causing David's injuries to be much more severe. Several other doctors missed the diagnosis too. Misdiagnosis of SJS and TEN is extremely common.

David alleges that GSK's warning label is inadequate. The trial court dismissed both Dr. Conway (on the statute of limitations) and GSK (finding the warning label adequate as a matter of law). David was wholly incapacitated when his claims accrued, and three highly-qualified experts opined that GSK's label is both inadequate and misleading. This Court should reverse and remand for trial.

ASSIGNMENTS OF ERROR

1. The trial court erred in granting summary judgment to Dr. Conway and in entering its Order Granting Defendant Conway's Motion for Judgment on the Pleadings Pursuant to CR 12(c), dated June 24, 2011. CP 510-13.

2. The trial court erred in finding that the statute of limitations "ran" on February 15, 2010 (for informed consent) and on June 25, 2010 (for negligence). CP 512.

3. The trial court erred in denying reconsideration and entering its order denying reconsideration on July 25, 2011. CP 570-74.

4. The trial court erred in granting summary judgment to GSK and in entering its Order Granting Defendant GSK LLC's Motion for Summary Judgment, dated January 11, 2012. CP 1078-80.

5. The trial court erred in concluding that the 2007 Lamcital® label was adequate as a matter of law. CP 1079.

6. The trial court erred in concluding that Falsberg was required to present evidence that a specific doctor was actually misled by the false and misleading 2007 Lamictal® labeling in order to establish proximate cause. CP 1079.

7. The trial court erred in failing to find numerous genuine issues of material fact precluding summary judgment.

ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

1. 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?

2. 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)?

3. 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?

4. 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?

5. 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?

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

STATEMENT OF THE CASE

A. Summary judgment review is *de novo*.

This Court reviews summary judgments *de novo*. ***Fiore v. PPG Indus. Inc.***, __ Wn. App. __, ¶12, __ P.3d __ (2012) (citing ***Cerrillo v. Esparza***, 158 Wn.2d 194, 199, 142 P.3d 155 (2006)). "'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.'" *Id.* (quoting ***Cerrillo***, 158 Wn.2d at 200). The facts are taken (and are set forth below) in the light most favorable to the non-moving party. *Id.*

B. Dr. Conway prescribed Lamictal® for David Falsberg, who developed Stevens-Johnson Syndrome and TEN – the worst case his surgeon at the Harborview Burn Unit had ever seen – and was severely incapacitated.

In 2007, David Falsberg was a patient of Dr. Jack S. Conway, a psychiatrist. CP 26, 81, 227. On February 15, 2007, Dr. Conway prescribed Lamictal® (25 mg.) for David.[1] CP 27, 81, 227. Lamictal® is an anticonvulsant used in the treatment of epilepsy and bipolar disorder. CP 5-6. On March 22, 2007, Dr. Conway increased David's dosage to 150 mg. CP 27, 81, 227.

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[1] Because they are both mentioned here, we use David and Nancy Falsberg's first names to avoid confusion.

After the increase, David began experiencing symptoms, including flu-like symptoms (fever, muscle and joint pain), slurred speech, decreased balance, eye pain, mouth and throat pain, and blisters around his mouth. CP 27-28, 227. He and/or his wife, Nancy Falsberg, tried to reach Dr. Conway. CP 227. After finally hearing the symptoms over the phone on April 4, 2007, Dr. Conway did not ask to see David at his office, but decreased the Lamictal® dosage to 75 mg. CP 28, 82, 227.

On April 5, 2007, Nancy found David slumped over their computer with a high fever and a rash on his neck, running down and covering his back. CP 28, 82, 227. She took him to Swedish Physicians Clinic in Ballard with a severe sore throat, severe coughing, high fever, eye redness, nasal drainage, and a severe rash. *Id.*; CP 919. David was misdiagnosed with an upper respiratory infection with conjunctivitis and rash. CP 28, 82, 919. He was given eye drops and discharged home. *Id.*

The next day he was severely worse. CP 227. Nancy immediately took him to Emergency at Swedish/Ballard, where they determined he needed ICU care and transferred him to Swedish/First Hill. *Id.* A dermatologist at Swedish finally diagnosed David with Stevens-Johnson Syndrome (SJS), and

transferred him to the Burn Unit at Harborview, where he was treated for the most severe form of SJS, Toxic Epidermal Necrolysis, or TEN. *Id.*; CP 920-21. It was the worst case his Harborview burn doctor had ever seen. CP 966, 967.

David had been unaware of what was happening to him for days before he was admitted, and long thereafter. CP 228. He was at Harborview from April 6 to July 10, 2007. *Id.*; CP 397. On April 7, he was taken to surgery for debriding and was put into a medically induced coma because of the severity of his burns. CP 227, 403. For most of his hospitalization, he was kept in a coma using a cocktail that included Methadone and Propofol. CP 228.

On or about June 14, 2007, David's doctors concluded that the severe TEN that he endured, and his resulting injuries and disability, were caused by an adverse reaction to Lamictal. CP 50.

In July 2007, David was moved to a rehab unit, where he was unable to see or speak. CP 228. He contracted MRSA and was knocked out by heavy antibiotics and other medications. *Id.* He also had a peg tube surgically inserted into his abdomen and stomach and was heavily sedated. *Id.*

David was so gravely incapacitated when he came home from Harborview that he was completely dependent on Nancy for

nutrition, administration of his complex medication regimen, physical mobility and safety, emotional comfort, and any kind of social interaction. *Id.* From several days prior to his hospitalization until the end of August, David was helpless, dependent, and wholly incapable of appreciating or understanding any legal proceedings or requirements, potential causes of action, or even that he had been wrongfully injured. *Id.*; CP 233.

C. SJS and TEN are characterized by rash combined with mucosal involvement, but experts agree that the warnings on the Lamictal® label are grossly inadequate.

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 the mucous membranes. CP 902, 950, 958, 966. Most doctors may see one or two cases in a lifetime. CP 954, 960, 969. Indeed, it is extremely common for doctors of all kinds to miss the diagnosis initially, as repeatedly happened here. CP 902, 950-52, 954, 966.

Lamictal® is among the principal causes of SJS and TEN. CP 902, 966. As a result, it is vitally important that the Lamictal® warning label be sufficient to warn any sort of physician who might prescribe it, including psychiatrists. CP 954. This information could then be conveyed to the patient so he could recognize the problem

and go to a burn unit, emergency room, or an evaluating physician whom he could ask about SJS/TEN. CP 954, 967, 968.

To give an adequate warning, the labeling should conspicuously state that SJS/TEN is a rash plus mucosal involvement, including a definition of mucosal involvement (*e.g.*, bloodshot eyes, sore throat, painful urination, and erosion of the mucosal surfaces). CP 953, 967. The label should instruct both prescribing physicians and physicians who are responsible for subsequent patient care how to differentiate between a benign rash and a serious life-threatening rash by explaining that if a patient has a rash plus mucosal involvement, they have SJS. CP 953, 967.

1. Dr. Khandelwal.

Several experts opined that the Lamictal® label is inadequate for numerous reasons. Dr. Anjay Khandelwal, a burn surgeon who currently serves as Director of the Arkansas Children's Hospital Burn Center, treated David at Harborview. CP 966. Based on his knowledge, training, and experience, Dr. Khandelwal opined that the warnings and instructions provided by GSK are inadequate because they do not inform physicians that a rash plus mucosal involvement indicates SJS/TEN. *Id.* The Lamictal® label does not provide necessary warnings or

instructions to properly inform physicians evaluating a patient exhibiting rash plus mucosal involvement that the patient has SJS or TEN. CP 967.

Indeed, the labeling is misleading, where it mentions the risk of SJS in the "black box warning,"[2] but the last paragraph contains false and misleading information, claiming it is not possible to distinguish between benign and life threatening rashes (*id.*):

> 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. David's treating physician and experts each agreed that this paragraph is misleading, both in suggesting that a physician cannot distinguish a benign from a life-threatening rash, and in failing to tell a prescribing physician how to do so, as GSK was required to do. CP 902, 903, 951, 954, 955, 966-67, 969.

Dr. Khandelwal also notes that while the label informs physicians that Lamictal® should be discontinued if a rash occurs, it

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[2] A black box warning is the highest level of warning possible. CP 903.

limits that warning by stating, "unless the rash is [clearly] not drug related." CP 676, 967. Yet "the label gives no information to guide those physicians as to what is or is not drug-related." *Id.* As discussed below, Doctors Lindberg and Dajani opined that GSK was negligent in failing to do so. CP 903, 952-53.

All of this is particularly concerning because, out of the numerous SJS/TEN patients Dr. Khandelwal has treated, 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.

2. Dr. Lindberg.

Dr. Gordon Lindberg, Medical Director of the Burn Unit at the University of Colorado Hospital, opined based on his knowledge, training, and experience that the warnings and instructions for Lamictal are inadequate, false, and misleading. CP 901-02. Physicians learn how to warn patients through the drug label. CP 903. A physician should know all salient facts about the drug from reading the label. CP 908. Like Dr. Khandelwal, Dr. Lindberg has treated numerous patients with SJS/TEN, and while virtually all of them were diagnosed with rash plus mucosal involvement, for

virtually all of them, the SJS/TEN diagnosis was initially missed. CP 902.

In addition to telling doctors simply that rash plus mucosal involvement indicates SJS/TEN – which the label fails to do – it should explain "mucosal involvement" as including bloodshot eyes, sore throat, painful urination, and other pains involving erosion of the mucosal surfaces. *Id.* While the Lamictal® product information warns that SJS and TEN are known side effects, it fails to inform physicians how to differentiate a benign rash from a serious rash such as SJS/TEN. *Id.* It thus fails to explain how to differentiate drug-related from non-drug-related rashes. CP 903-04.

Dr. Lindberg also agrees that the label contains false and misleading information in the "box warning," claiming it is not possible to reliably predict which rashes will prove to be serious or life threatening. *Id.* Indeed, Dr. Lindberg believes that it is unconscionable for GSK to state that it is impossible to differentiate between rashes, and then claim that physicians should know that the label is in error in this litigation. CP 908.

3. Dr. Dajani.

Esam Z. Dajani, Ph.D., specializes in clinical pharmacology, toxicology, pharmaceutical research and development, and

regulatory affairs. CP 950. He notes that the drug warning label is a primary source of information for prescribing physicians and for physicians who evaluate potential adverse drug reactions. *Id.* The standard of care requires physicians to read the label when prescribing medications and to be aware of the warnings, contraindications, and signs and symptoms of an adverse reaction. *Id.* The standard of care also requires physicians evaluating adverse drug reactions to be aware of these signs and symptoms and of their potentially life-threatening consequences. *Id.*

Dr. Dajani reviewed thousands of pages GSK produced, documenting adverse events from the time Lamictal® was approved for use until the time David was diagnosed with TEN. CP 950. Fully confirming Drs. Khandelwal's and Lindberg'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 physicians that if a patient has a rash plus mucosal involvement they have SJS or TEN. CP 951. It negligently fails to do so. CP 953.

Dr. Dajani agrees that the label negligently fails to instruct physicians how to distinguish benign from life-threatening rashes.

CP 951. Indeed, the label falsely states that it is impossible to predict which rashes will prove serious or life threatening. *Id.* The label is therefore inadequate, false, misleading, and negligent. *Id.*

D. GSK knew that its Lamictal® label was inadequate.

Dr. Dajani also opined that GSK knew the importance of including information in the label to instruct physicians that Lamictal® may cause SJS/TEN. CP 951. GSK also knew the importance of including signs and symptoms which differentiate a benign rash from a serious life-threatening rash like SJS/TEN. *Id.* GSK's knowledge is evident from an article published in the official journal of the American Academy of Neurology in 2005, titled "*Risk of Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis in New Users of Antiepileptics.*" CP 951; *see also*, *Neurology* article at CP 957-63. This article, published roughly two years before David's injury, recommends that physicians be given specific information so that they can teach their patients how to decide what is a serious rash versus a benign rash. CP 952-53.

Significantly, the authors of this article are all affiliated with GSK in some fashion, and the research was sponsored by GSK.[3]

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[3] These affiliations and GSK's sponsorship are noted in the very small print at the bottom of CP 958.

CP 952, 958. Yet GSK never made the change recommended by its own researchers based on its own research studies. CP 953. With the information recommended by the article, David would have been able to point out to his physicians that he was having a drug reaction to Lamictal® and they would have been able to put into context his rash and blood-shot eyes. CP 954, 987.

Dr. Lindberg agrees that by 2005, GSK knew of the need to change its label by adding information to teach prescribing physicians how to differentiate between a benign rash and a serious life-threatening rash. CP 902. The article also states that although SJS and TEN are rare in patients using these drugs, the case characteristics show that the highest risk is during the first two months of use. CP 903. Since most clinicians are likely to see only one or two occurrences in a lifetime, their ability to identify a relatively narrow time window or high risk would facilitate early detection. *Id.* The label fails to provide this information. CP 902. In fact, the label falsely states that it is not possible to distinguish benign from life-threatening rashes. *Id.* By at least 2005, GKS knew that it needed to change its false and misleading label, but did nothing before David suffered his severe injuries in 2007. *Id.*; CP 906.

E. Procedural History.

On July 10, 2008, David sued Dr. Conway. CP 109. He subsequently dismissed this suit without prejudice. *Id.* On April 7, 2010, David filed suit against GSK. CP 1. On July 12, 2010, David filed his amended complaint, adding Dr. Conway, including claims of medical negligence, negligent misrepresentation (by omission), and lack of informed consent. CP 25, 33-36.

On or about May 19, 2011, Dr. Conway sought judgment on the pleadings. CP 107, 115. After a continuance, David responded, including declarations from Nancy and David, and excerpts from David's medical records. CP 210, 212-463. On June 24, 2011, the trial court dismissed the claims against Dr. Conway under the statute of limitations (SOL), finding that the SOL "ran" on February 15, 2010 (for informed consent) and on June 25, 2010 (for negligence). CP 512. On July 22, 2011, the trial court entered an amended order adding a finding that David filed his complaint against Dr. Conway on July 12, 2010. CP 567.

On July 25, 2011, the trial court entered an order denying reconsideration. CP 570-74. It determined that, while "[t]here is no doubt that Mr. Falsberg suffered grievous harm" and "became legally incapacitated (due to a medically-induced coma) for more

than two weeks," David's disability-tolling theory was insufficient, where the inception of his disability did not coincide with the date of the last alleged negligent act or omission attributable to Dr. Conway, but rather two or three days later. *Id.* Concluding that David's claim "accrued" prior to his disability, the court ruled that "the three-year statute of limitations for his medical malpractice action ran roughly two weeks before he filed his lawsuit against Dr. Conway" and was not tolled at all on account of David's disability. *Id.*

On September 9, 2011, the trial court entered a stipulated order dismissing David's CPA claim. CP 581-85.

On December 9, 2011, GSK sought summary judgment. CP 589-613. David responded, including the three expert declarations discussed above, and his own declaration. CP 874-987. On January 12, 2012, the trial court granted summary judgment to GSK. CP 1078-1080.

ARGUMENT

A. The trial court misinterpreted the legal term "accrued" in the proviso of RCW 4.16.190(1), erroneously requiring that a legal disability coincide precisely with the doctor's last act or omission.

Dr Conway asserted that the last day he had any interaction with David was April 4, 2007. CP 465, 472, 478. Dr. Conway conflated "the time the cause of action accrued" under RCW 4.16.190(1) with the date of the "act or omission alleged to have caused the injury or condition" under RCW 4.16.350(3). CP 472.[4] Dr. Conway contested that David had any legal disability on April 4, 2007, but that is disputed. *Compare* CP 473 *with* CP 228. The trial court accepted Dr. Conway's argument and granted summary judgment. CP 512, 567.

As discussed below, "accrual" is a legal term of art, not legislatively defined, and does not occur until all the essential elements of liability – duty, breach, causation, and damages – exist and are manifested. *See, e.g.*, CP 525-28. David's cause of action for medical malpractice did not "accrue" on April 4, 2007, before he suffered the injuries and damages caused by Conway's alleged negligence. *Id.* Rather, David established (or at least raised

[4] "The inquiry must focus on Mr. Falsberg's condition on April 4, 2007, and whether there is any evidence that he was incompetent under RCW 4.16.190(1) on that date." CP 472 (emphasis omitted).

genuine issues of material fact) that he was a "disabled" person for purposes of Washington's disability-tolling statute, RCW 4.16.190(1):

> . . . 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 . . . 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***. [Emphases added.]

Under RCW 11.88.010(1)(a), "a person may be deemed incapacitated as to person when the superior court determines the individual has a significant risk of personal harm based upon a demonstrated inability to adequately provide for nutrition, health, housing, or physical safety." *See also* ***Rivas v. Overlake Hosp. Med. Ctr.***, 164 Wn.2d 261, 269-70, 189 P.3d 753 (2008) (disability is a question of fact). Because of his SJS/TEN and resulting disability, the three-year limitations period of RCW 4.16.350(3) was tolled for the entire "time of such disability" – lasting from April 6 through some time in August 2007 – making his medical malpractice action timely within the (correctly calculated) limitations period. CP 228. This Court should reverse and remand for trial.

1. This Court reviews statutes *de novo*, harmonizing them whenever possible.

Statutory interpretation is a question of law, reviewed *de novo*. ***Rivas***, 164 Wn.2d at 266. A court's "fundamental objective" when interpreting a statute "is 'to discern and implement the intent of the legislature.'" ***Flight Options, LLC v. Dep't of Revenue***, 172 Wn.2d 487, 500, 259 P.3d 234 (2011) (quoting ***State v. J.P.***, 149 Wn.2d 444, 450, 69 P.3d 318 (2003)). Legislative intent is implemented "by giving effect to the plain meaning of a statute," which "may be gleaned 'from all that the Legislature has said in the statute and related statutes which disclose legislative intent about the provision in question.'" *Id.* (quoting ***Dep't of Ecology v. Campbell & Gwinn, LLC***, 146 Wn.2d 1, 11, 43 P.3d 4 (2002)). Here, the Court "must consider that tolling provisions, by nature, exist to assure all persons subject to a particular statute of limitations enjoy the full benefit of the limitation period." ***Rivas***, 164 Wn.2d at 267 (citing, *e.g.*, ***Castro v. Stanwood Sch. Dist. No. 401***, 151 Wn.2d 221, 226, 86 P.3d 1166 (2004)).

Finally, when (as here) two statutes relate to the same subject matter, they must be construed together. ***Hallauer v. Spectrum Props., Inc.***, 143 Wn.2d 126, 146, 18 P.3d 540 (2001). "Context is particularly important when harmonizing two statutes

where one references the other." ***Rivas***, 164 Wn.2d at 267. And when the Legislature employs different terms in a statutory scheme, it intends different meanings for each term. *See* ***Koenig v. City of Des Moines***, 158 Wn.2d 173, 182, 142 P.3d 162 (2006). This Court should give David the benefit of the tolling statute.

2. David's disability existed when his cause of action "accrued."

The fundamental inquiry is whether David's claimed legal disability existed "at the time the cause of action accrued" under RCW 4.16.190(1). *See* ***Rivas***, 164 Wn.2d at 269. David correctly asked the trial court to recognize the legal distinction "between, on one hand, the 'accrual' of a cause of action for tolling purposes and, on the other hand, when a statute of limitations commences to run." CP 525. This Court should reverse and remand for trial.

The SOL for any "injury occurring as a result of health care" against a physician based upon alleged professional negligence is three years from the act or omission, or one year from discovery, whichever is longer:

> . . . 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 . . . .

RCW 4.16.350(3). Unlike in RCW 4.16.190(1), the term "accrued" does not appear in this provision. The fundamental inquiries under 4.16.350(3) concern only the date of the physician's "act or omission," and the date the injured party discovered both the fact of his injury or condition and its iatrogenic cause. But the trial court focused on the date of Conway's last "act or omission," to the exclusion of the date David's cause of action "accrued," depriving David of RCW 4.16.190(1)'s protections.

In ***Rivas***, the Court determined that whether the plaintiff was disabled when her medical malpractice cause of action accrued for purposes of RCW 4.16.190(1) is a question of fact. 164 Wn.2d at 269-70 (citing and following ***Young v. Key Pharm., Inc.***, 112 Wn.2d 216, 770 P.2d 182 (1989)). The ***Rivas*** Court confirmed its long-standing resolution of any "conflict" between RCW 4.16.350 and RCW 4.16.190, assuring that med-mal plaintiffs are entitled to the latter statute's disability-tolling provisions. *Id.*

The term "accrued" as used in RCW 4.16.190(1) is not legislatively defined. When a term used in a statute has a well-accepted ordinary meaning, a regular dictionary may be consulted to ascertain the term's definition. ***City of Spokane ex rel. Wastewater Mgmt. Dep't v. Dep't of Revenue***, 145 Wn.2d 445,

454, 38 P.3d 1010 (2002). But where, as here, a technical term is used in its technical field, the term's meaning is best ascertained using a "technical rather than a general purpose dictionary." *Id.*

BLACK'S LAW DICTIONARY 23 (9th ed. 2009), defines "accrue" using a "knew or had reason to know" example:

> **1.** To come into existence as an enforceable claim or right; to arise <the plaintiff's cause of action for silicosis did not accrue until the plaintiff knew or had reason to know of the disease>.

This legal definition is consistent with Washington case law, holding generally that a cause of action only accrues when the plaintiff has a right to seek relief. ***Pietz v. Indermuehle***, 89 Wn. App. 503, 511, 949 P.2d 449 (1998). "[T]he right to apply to a court for relief requires each element of the action be susceptible of proof." ***Haslund v. City of Seattle***, 86 Wn.2d 607, 619, 547 P.2d 1221 (1976). "[A]n essential element of a cause of action based upon negligence or 'wrongful' acts, as alleged in respondents' complaint, is actual loss or damage." *Id.*

Applying statutory interpretation rules outlined above, conflating a physician's "act or omission" with the "accrual" of a cause of action is plain error. In contrast to RCW 4.16.190(1)'s tolling provision – which applies to any action "mentioned in this

chapter" – RCW 4.16.350(3)'s "language clearly does not provide that the limitations period commences with accrual of a cause of action." ***Gunnier v. Yakima Heart Ctr., Inc.***, 134 Wn.2d 854, 860-61, 953 P.2d 1162 (1998). This means that an "act or omission" that triggers the SOL for medical malpractice is conceptually distinct from "accrual" under the disability-tolling statute.

In the present case, David's cause of action for medical malpractice did not "accrue" on April 4, 2007, before his injuries and losses were actualized days, weeks, and months later. David's cause of action did not and could not "accrue" until April 6, 2007, at the earliest, when the hospital determined that he had a life-threatening, emergency medical condition requiring hospitalization and specialized burn care for his horrific injuries. David was confined to a hospital from April 6 through July 10, 2007, under sedation, and in a medically induced coma, and then was wholly dependent on Nancy well into August 2007, resulting in a legal disability spanning many months. CP 228. Thus, his July 12, 2010 amended complaint adding Dr. Conway was timely, where his legal disability tolled the SOL from April 6 through some time in August 2007. The Court should reverse and remand.

3. Genuine issues of material fact precluded summary judgment on disability tolling.

David also argued that summary judgment was precluded by substantial factual disputes on whether his legal disability coincided with, or preexisted, the moment his cause of action against Dr. Conway "accrued." CP 218-19, 528-529. At the very least, genuine issues of material fact on when David's disability arose, and when his action accrued, prohibit summary judgment here. *See* ***Rivas***, 164 Wn.2d at 269-70 (disability and accrual are questions of fact). Summary judgment was improper. The Court should reverse and remand on this independently sufficient ground.

B. GSK had a duty to warn Dr. Conway and the other doctors who missed the diagnosis that rash plus mucosal involvement is SJS , where it knew or should have known of the extreme danger of frequently missed diagnoses.

Under the Washington Product Liability Act (WPLA), manufacturers generally have a duty to give adequate warnings about products that are not reasonably safe (RCW 7.72.030(1)):

> (1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was ... not reasonably safe because adequate warnings or instructions were not provided.

Under subsection (c) of this statute, manufacturers have a specific duty to exercise reasonable care to warn when, as here, the

manufacturer learned (or a reasonably prudent manufacturer should have learned) about a specific danger: that physicians were misdiagnosing SJS/TEN absent a clear instruction that rash plus mucosal involvement indicates SJS (RCW 7.72.030(1)(c)):

> (c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a 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. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

It is undisputed that GSK sponsored the study underlying the *Neurolgy* article disclosing this risk two years before David's injury. GSK thus knew or should have known that physicians were extremely likely to misdiagnose SJS/TEN absent proper warnings. No reasonably prudent manufacturer would fail to warn in this dangerous situation, and GSK failed to exercise reasonable care. Yet its label is false and misleading. Under the WPLA's plain language, GSK had a duty to warn doctors of the specific danger.

C. The learned intermediary doctrine does not absolve GSK of its duty to warn doctors.

In the trial court, GSK solely relied on four arguments under the learned intermediary doctrine. CP 601-11. None of these arguments has merit. This Court should reverse and remand.

1. David did not argue that GSK had to warn him.

It first argued that the doctrine barred David's suit, "[t]o the extent Plaintiff's case rests on allegations that GSK failed to warn Plaintiff directly or made misrepresentations directly." CP 601-03. David's case does not rest on such allegations. This argument is a red herring.

2. GSK's warnings are not "adequate as a matter of law."

GSK's second argument under the learned intermediary doctrine was that its warnings were adequate as a matter of law. CP 603-07. GSK overstated the law in this area, relying primarily on ***Terhune v. A. H. Robins Co.***, 90 Wn.2d 9, 577 P.2d 975 (1978) and ***Estate of LaMontagne v. Bristol-Meyers Squibb***, 127 Wn. App. 335, 111 P.3d 857 (2005). These cases do not support GSK.

Terhune involved the application of RESTATEMENT (SECOND) OF TORTS § 402A (1965), *comment k*, an exception to strict liability for unavoidably unsafe prescription products like the Dalkon Shield. 90 Wn.2d at 12-13. At issue in ***Terhune*** was an argument that the

manufacturer had to warn the patient directly, which the Court rejected under the learned intermediary doctrine. *Id.* at 12-14 (citing numerous cases, including ***McEwen v. Ortho Pharm. Corp.***, 270 Or. 375, 528 P.2d 522 (1974), discussed *infra*). As noted above, however, David is not arguing that GSK had to warn him. ***Terhune*** is not controlling here.

LaMontagne addresses a more apposite issue, whether the manufacturer's warnings regarding Glucophage® adequately warned the prescribing doctor of the risks of the specific injury the plaintiff suffered. 127 Wn. App. at 337. Citing ***Terhune***, this 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)." *Id.* at 343. The Court then noted that 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 the plaintiff's circumstances. *Id.* at 350-51. Therefore, the warnings were adequate as a matter of law. *Id.*

LaMontagne thus does not address the situation presented here: warnings that not only fail to disclose what the manufacturer knew or should have known to be essential information (rash plus mucosal involvement indicates SJS), but actually contained the false and misleading assertion that it is not possible to distinguish between benign and life-threatening rashes. CP 676. The label here does note the risk of SJS, but omits crucial information – and even contains misleading information – according to GSK's own research. Again, ***LaMontagne*** is not controlling here.

Terhune cites and relies upon ***McEwen***, *supra*. ***Terhune***, 90 Wn.2d at 13. There, plaintiff went partially blind after taking prescribed oral contraceptives. ***McEwen***, 528 P.2d at 526. The label warnings specifically identified this risk, but falsely discounted it, and (as here) only warned doctors to discontinue use if serious symptoms occurred – 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 offers an example of the detailed relevant and careful analyses necessary where, as here, a label is false and misleading. The court notes that there is no question that drug

manufacturers have a duty to warn doctors of any dangerous side effects of which it knows, or should know. *Id.* at 528.[5] This is a continuous duty, requiring manufacturers to keep abreast of scientific developments and supplement its warnings based on additional information discovered from use of the drug. *Id.*

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 has "a duty to warn the medical profession of untoward effects

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[5] Citing ***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).

which the manufacturer knows, or has reason to know, are inherent in the use of its drug." *Id.* at 530.[6]

McEwen goes on to address breach, closely examining the alleged warnings and other evidence to find that the manufacturer knew or should have known the risk. *Id.* at 532-33. The court also raises and dismisses the idea that FDA approval absolves the manufacturer of its duty to warn. *Id.* at 533-35 (again citing numerous cases). ***McEwen*** ultimately holds that a jury could reasonably find the warnings inadequate, if not misleading, again carefully examining the warnings. *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

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[6] Citing, *inter alia*, ***Sterling Drug***, 370 F.2d 82; ***Stromsodt***, 411 F.2d 1390; ***Basko v. Sterling Drug, Inc.***, 416 F.2d 417 (2d Cir. 1969); ***Love***, 226 Cal. App. 2d 378; ***Krug***, 416 S.W.2d 143; *cf.* ***Davis v. Wyeth Laboratories, Inc.***, 399 F.2d 121 (9th Cir. 1968); *see also* ***Wright v. Carter Products, Inc.***, 244 F.2d 53 (2nd Cir. 1957); ***Hungerholt v. Land O'Lakes Creameries, Inc.***, 209 F. Supp. 177 (D.Minn.1962), *aff'd*, 319 F.2d 352 (8th Cir. 1963); ***Gerkin v. Brown & Sehler Co.***, 177 Mich. 45, 143 N.W. 48 (1913).

7.72.030(1)(c). It is undisputed that GSK failed to do so for two years after the article appeared.

While Washington courts have not yet addressed the issue, GSK's duty should extend to all medical professionals who come into contact with the patient. ***McEwen***, 528 P.2d at 529. In addition to ***McEwen***, in the trial court (at CP 892-93) David cited the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY, § 6(d)(1) ("RTT § 6"), which restates the learned intermediary doctrine in accord with ***McEwen*** and numerous other cases:

> § 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:

> Failure to instruct or warn is the major basis of liability for manufacturers of prescription drugs and medical devices. When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device

> is best for specific patients. Sometimes a warning serves to inform health-care providers of unavoidable risks that inhere in the drug or medical device. By definition, such a warning would not aid the health-care provider in reducing the risk of injury to the patient by taking precautions in how the drug is administered or the medical device is used. However, warnings 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.

Washington has not adopted RTT § 6. But ***Terhune*** cited ***McEwen*** as authority, and so does RTT § 6 (also citing ***Holley v. Burroughs Wellcome Co.***, 330 S.E.2d 228, 235 (N.C. Ct. App. 1985) (duty to warn nurse anesthetist)). This Court should follow ***McEwen*** and RTT § 6, holding that GSK's duty to warn extends to all medical professionals who came into contact with David in a decision-making capacity.

This is particularly relevant here because David's experts opined that the repeatedly missed diagnosis caused David's injuries to be worse than they might have been. Dr. Khandelwal noted that taking Lamictal® with SJS/TEN will make the SJS/TEN worse. CP 968. Both Dr. Khandelwal and Dr. Lindberg opined that David had SJS on April 4, yet Dr. Conway told him to take a half

dose more, which he did on April 5. CP 906, 968. Taking Lamictal® after he had SJS made his condition worse, and David lost a substantial chance for a better outcome. *Id.* Had the various physicians who saw David been alerted that rash plus mucosal involvement is SJS, they would have identified the SJS and told him to stop taking the drug. CP 907, 968. Dr. Dajani agreed with this, opining that delays in diagnosing SJS/TEN increase both the risk of death and the severity of the injuries short of death. CP 952. The warnings are grossly inadequate and misleading. CP 955.

Turning to breach, ***McEwen*** closely examined the alleged warnings and other evidence to find that the manufacturer knew or should have known the risk. *Id.* at 532-33. Here, both the fact that the label does note the risk of SJS, and the *Neurology* article written by GSK's former researcher based on research GSK sponsored, plainly show that GSK knew or should have known the risk. Summary judgment was not appropriate on this issue.

Unlike in ***McEwen***, it does not appear that GSK is arguing that FDA approval absolves it of its duty to warn. Should it raise that claim, this Court should reject it for the same reasons that ***McEwen*** rejected it. 528 P.2d at 533-35.

Finally, as in ***McEwen***, this Court should hold that a jury could reasonably find GSK's warnings inadequate, even misleading, again examining the warnings. *Id.* at 535-38. While it identifies a risk of SJS/TEN, the "black box" warning culminates with the false assertion that one cannot distinguish serious from benign rashes. CP 676, 903, 955, 967. Various sections say that other symptoms like fever and swelling may be a concern, and patients should be warned to see a physician. CP 700, 704. But these warnings fail to suggest that the patient go to a burn center or emergency room, rather than to the prescribing physician, who might be a psychiatrist like Dr. Conway, without the necessary knowledge to treat his burns. *Id.*; CP 953, 954, 967, 968, 987. And nowhere does the warning label state the most basic and important fact: rash plus mucosal involvement means SJS. CP 902, 903, 904, 951, 953, 955, 966, 967, 987.

In sum, ***McEwen*** and RTT § 6 strongly support a determination that summary judgment was inappropriate here. The Court should reverse and remand for trial.

3. David's experts' opinions establish genuine issues of material fact.

GSK's third argument was that David's experts did not establish any genuine issues of material fact. CP 607-10. GSK

asserted that the experts were merely claiming that GSK had to give detailed instructions on how to diagnose SJS/TEN. CP 607-08. But the experts said no such thing. As repeatedly stated above, they said that (a) the label lacks the most basic, straightforward statement that rash plus mucosal involvement indicates SJS/TEN; (b) the label contains the misleading statement that it is not possible to distinguish benign from life-threatening rashes; (c) the label rather should explain how to make such a distinction (*e.g.*, rash plus mucosal involvement indicates a severe danger); and that (d) the label also fails to direct a patient suffering rash plus mucosal involvement to the proper physician. This is hardly requiring GSK to teach doctors how to diagnose a patient.

GSK also argued that psychiatrists already know what GSK failed to put on the label. CP 609-10. As noted above, Dr. Lindberg believes that it is unconscionable for GSK to state that it is impossible to differentiate between rashes on its label, and then claim that physicians already know that the label is in error in this lawsuit. CP 908. GSK's duty is to adequately warn – it cannot evade its duty by claiming that doctors should already know what it has failed to warn them about.

4. Proximate cause is for the jury, whether under a traditional "but for" analysis, or under a "loss of chance" theory.

Finally on the learned intermediary doctrine, GSK argued that David could not prove that its false and misleading label proximately caused his injuries, where David allegedly cannot prove that Dr. Conway would have acted differently had the label been accurate. CP 610-11. Generally, a plaintiff must show "that the breach of duty was a cause in fact of the injury" and "that as a matter of law[,] liability should attach." ***Harbeson v. Parke-Davis, Inc.***, 98 Wn.2d 460, 475-76, 656 P.2d 483 (1983); *see* ***Baughn v. Honda Motor Co.***, 107 Wn.2d 127, 142, 727 P.2d 655 (1986).

"'Cause in fact refers to the "but for" consequences of an act – the physical connection between an act and an injury.'" ***Ayers v. Johnson & Johnson Baby Prods. Co.***, 117 Wn.2d 747, 753, 818 P.2d 1337 (1991) (quoting ***Hartley v. State***, 103 Wn.2d 768, 778, 698 P.2d 77 (1985)). Legal causation involves a determination, in light of "'logic, common sense, justice, policy, and precedent,'" that liability should attach as a matter of law. *Id.* at 756 (quoting ***King v. City of Seattle***, 84 Wn.2d 239, 250, 525 P.2d 228 (1974)).

Causation is generally for the jury. ***Ang v. Martin***, 154 Wn.2d 477, 490, 114 P.3d 637 (2005) (citing ***Hartley***, 103 Wn.2d at

778). The experts' testimony is ample to permit a jury to find but-for causation here. David's experts opined that if the label were accurate, Dr. Conway would have known (and he would have warned David so that he could tell his treating physicians) that his symptoms on April 4 were indicative of SJS/TEN. CP 907, 954, 968. The physicians who missed the diagnosis (like so many others) would not have been misled by the label, but rather would have identified the symptoms on April 4, David would not have taken another dose on April 5, and David would have had a substantially improved chance of a better outcome. CP 907, 953, 968. Indeed, the frequency of missed diagnoses itself shows that the label is inadequate and misleading.

In the alternative, David also argued that the traditional "but for" causation analysis should not apply, where GSK's inadequate and misleading label caused a series of misdiagnoses that deprived him of a chance at a better outcome. CP 896, n.11 (citing ***Mohr v. Grantham***, 172 Wn.2d 844, 262 P.3d 490 (2011); ***Daugert v. Pappas***, 104 Wn.2d 254, 704 P.2d 600 (1985); ***Gausvik v. Abbey***, 126 Wn. App. 868, 107 P.3d 98 (2005)). In ***Mohr***, our Supreme Court held that the "loss of chance" doctrine goes beyond losses of a better outcome in a wrongful death action under ***Herskovits v.***

Group Health Coop. of Puget Sound, 99 Wn.2d 609, 664 P.2d 474 (1983), into cases in which the harm is a lost chance at a better outcome for a surviving victim. ***Mohr***, 172 Wn.2d at 846-47.

The plaintiff in ***Mohr*** alleged that medical negligence caused her permanent brain damage and disability. She presented expert testimony that absent the doctor's negligence, "she would have had a 50 to 60 percent chance of a better outcome [of] no disability or, at least, significantly less disability." ***Mohr***, 172 Wn.2d at 849. The trial court dismissed the lawsuit on summary judgment because the plaintiff did not show "'but for' causation and the hesitancy of the court to expand ***Herskovits*** to the facts of this case." ***Mohr***, 172 Wn.2d at 849-50.

The ***Mohr*** Court reversed, "formally adopt[ed] the rationale of the [***Herskovits***] plurality opinion that the injury is the lost chance," and held that a lost-chance claim is not limited to cases that result in death, but also applies to med-mal claims where the ultimate harm is short of death. ***Mohr***, 172 Wn.2d at 859.

Like this case, ***Mohr*** is a medical malpractice action. There is no reasonable basis on which to distinguish ***Mohr*** from this case, a malpractice action that includes a product-liability-based claim that a drug manufacturer negligently failed to warn the doctor of

essential information, negligently failed to revise its warnings in light of its own research showing a serious danger of misdiagnosis, and even negligently misled medical providers, depriving David of a chance at a better outcome.

As discussed above, and as in ***Mohr***, there are genuine issues of material fact as to whether GSK's failures to adequately warn and its misleading assertions resulted in a diminished chance for a better outcome for David: if the label were accurate, Dr. Conway would have known (and could have warned) him that the April 4 symptoms indicated SJS/TEN. CP 907, 952, 968. The physicians who missed the diagnosis would not have been misled by the label, but rather would have identified the symptoms on April 4, and would not have told David to take another dose on April 5, substantially improving David's chances of a better outcome. CP 907, 953, 968. David was not required to "prove" that Dr. Conway himself was misled or that he would have acted differently had the warnings been adequate.

CONCLUSION

For the reasons stated above, both summary judgments were inappropriate. This Court should reverse and remand for trial against both Dr. Conway and GSK.

RESPECTFULLY SUBMITTED this 2nd day of August, 2012.

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CERTIFICATE OF SERVICE BY MAIL

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RCW 4.16.350

Action for injuries resulting from health care or related services — Physicians, dentists, nurses, etc. — Hospitals, clinics, nursing homes, etc.

Any civil action for damages for injury occurring as a result of health care which is provided after June 25, 1976, against:

(1) A person licensed by this state to provide health care or related services, including, but not limited to, a physician, osteopathic physician, dentist, nurse, optometrist, podiatric physician and surgeon, chiropractor, physical therapist, psychologist, pharmacist, optician, physician's assistant, osteopathic physician's assistant, nurse practitioner, or physician's trained mobile intensive care paramedic, including, in the event such person is deceased, his or her estate or personal representative;

(2) An employee or agent of a person described in subsection (1) of this section, acting in the course and scope of his or her employment, including, in the event such employee or agent is deceased, his or her estate or personal representative; or

(3) An entity, whether or not incorporated, facility, or institution employing one or more persons described in subsection (1) of this section, including, but not limited to, a hospital, clinic, health maintenance organization, or nursing home; or an officer, director, employee, or agent thereof acting in the course and scope of his or her employment, including, in the event such officer, director, employee, or agent is deceased, his or her estate or personal representative; 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, except that in no event shall an action be commenced more than eight years after said act or omission: PROVIDED, That the time for commencement of an action is tolled upon proof of fraud, intentional concealment, or the presence of a foreign body not intended to have a therapeutic or diagnostic purpose or effect, until the date the patient or the patient's representative has actual knowledge of the act of fraud or concealment, or of the presence of the foreign body; the patient or the patient's representative has one year from the date of the actual knowledge in which to commence a civil action for damages.

For purposes of this section, notwithstanding RCW 4.16.190, the knowledge of a custodial parent or guardian shall be imputed to a person under the age of eighteen years, and such imputed knowledge shall operate to bar the claim of such minor to the same extent that the claim of an adult would be barred under this section. Any action not commenced in accordance with this section shall be barred.

For purposes of this section, with respect to care provided after June 25, 1976, and before August 1, 1986, the knowledge of a custodial parent or guardian shall be imputed as of April 29, 1987, to persons under the age of eighteen years.

This section does not apply to a civil action based on intentional conduct brought against those individuals or entities specified in this section by a person for recovery of damages for injury occurring as a result of childhood sexual abuse as defined in RCW 4.16.340(5).

[2011 c 336 § 88; 2006 c 8 § 302. Prior: 1998 c 147 § 1; 1988 c 144 § 2; 1987 c 212 § 1401; 1986 c 305 § 502; 1975-'76 2nd ex.s. c 56 § 1; 1971 c 80 § 1.]

RCW 4.16.190
Statute tolled by personal disability.

(1) Unless otherwise provided in this section, if a person entitled to bring an action mentioned in this chapter, except for a penalty or forfeiture, or against a sheriff or other officer, for an escape, be at the time the cause of action accrued either under the age of eighteen years, or 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, or imprisoned on a criminal charge prior to sentencing, the time of such disability shall not be a part of the time limited for the commencement of action.

(2) Subsection (1) of this section with respect to a person under the age of eighteen years does not apply to the time limited for the commencement of an action under RCW 4.16.350.

[2006 c 8 § 303; 1993 c 232 § 1; 1977 ex.s. c 80 § 2; 1971 ex.s. c 292 § 74; Code 1881 § 37; 1877 p 9 § 38; 1869 p 10 § 38; 1861 p 61 § 1; 1854 p 364 § 11; RRS § 169.]

RCW 11.88.010

Authority to appoint guardians — Definitions — Venue — Nomination by principal.

(1) The superior court of each county shall have power to appoint guardians for the persons and/or estates of incapacitated persons, and guardians for the estates of nonresidents of the state who have property in the county needing care and attention.

(a) For purposes of this chapter, a person may be deemed incapacitated as to person when the superior court determines the individual has a significant risk of personal harm based upon a demonstrated inability to adequately provide for nutrition, health, housing, or physical safety.

(b) For purposes of this chapter, a person may be deemed incapacitated as to the person's estate when the superior court determines the individual is at significant risk of financial harm based upon a demonstrated inability to adequately manage property or financial affairs.

(c) A determination of incapacity is a legal not a medical decision, based upon a demonstration of management insufficiencies over time in the area of person or estate. Age, eccentricity, poverty, or medical diagnosis alone shall not be sufficient to justify a finding of incapacity.

(d) A person may also be determined incapacitated if he or she is under the age of majority as defined in RCW 26.28.010.

(e) For purposes of giving informed consent for health care pursuant to RCW 7.70.050 and 7.70.065, an "incompetent" person is any person who is (i) incompetent by reason of mental illness, developmental disability, senility, habitual drunkenness, excessive use of drugs, or other mental incapacity, of either managing his or her property or caring for himself or herself, or both, or (ii) incapacitated as defined in (a), (b), or (d) of this subsection.

(f) For purposes of the terms "incompetent," "disabled," or "not legally competent," as those terms are used in the Revised Code of Washington to apply to persons incapacitated under this chapter, those terms shall be interpreted to mean "incapacitated" persons for purposes of this chapter.

(2) The superior court for each county shall have power to appoint limited guardians for the persons and estates, or either thereof, of incapacitated persons, who by reason of their incapacity have need for protection and assistance, but who are capable of managing some of their personal and financial affairs. After considering all evidence presented as a result of such investigation, the court shall impose, by order, only such specific limitations and restrictions on an incapacitated person to be placed under a limited guardianship as the court finds necessary for such person's protection and assistance. A person shall not be presumed to be incapacitated nor shall a person lose any legal rights or suffer any legal disabilities as the result of being placed under a limited guardianship, except as to those rights and disabilities specifically set forth in the court order establishing such a limited guardianship. In addition, the court order shall state the period of time for which it shall be applicable.

(3) Venue for petitions for guardianship or limited guardianship shall lie in the county wherein the alleged incapacitated person is domiciled, or if such person resides in a facility supported in whole or in part by local, state, or federal funding sources, in either the county where the facility is located, the county of domicile prior to residence in the supported facility, or the county where a parent or spouse or domestic partner of the alleged incapacitated person is domiciled.

If the alleged incapacitated person's residency has changed within one year of the filing of the petition, any interested person may move for a change of venue for any proceedings seeking the appointment of a guardian or a limited guardian under this chapter to the county of the alleged incapacitated person's last place of residence of one year or more. The motion shall be granted when it appears to the court that such venue would be in the best interests of the alleged incapacitated person and would promote more complete consideration of all relevant matters.

(4) Under RCW 11.94.010, a principal may nominate, by a durable power of attorney, the guardian or limited guardian of his or her estate or person for consideration by the court if guardianship proceedings for the principal's person or estate are thereafter commenced. The court shall make its appointment in accordance with the principal's most

recent nomination in a durable power of attorney except for good cause or disqualification.

(5) Imposition of a guardianship for an incapacitated person shall not result in the loss of the right to vote unless the court determines that the person is incompetent for purposes of rationally exercising the franchise in that the individual lacks the capacity to understand the nature and effect of voting such that she or he cannot make an individual choice. The court order establishing guardianship shall specify whether or not the individual retains voting rights. When a court determines that the person is incompetent for the purpose of rationally exercising the right to vote, the court shall notify the appropriate county auditor.

[2008 c 6 § 802; 2005 c 236 § 3; (2005 c 236 § 2 expired January 1, 2006); 2004 c 267 § 139; 1991 c 289 § 1; 1990 c 122 § 2; 1984 c 149 § 176; 1977 ex.s. c 309 § 2; 1975 1st ex.s. c 95 § 2; 1965 c 145 § 11.88.010. Prior: 1917 c 156 § 195; RRS § 1565; prior: Code 1881 § 1604; 1873 p 314 § 299; 1855 p 15 § 1.]

RCW 7.72.030
Liability of manufacturer.

(1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.

(a) A product is not reasonably safe as designed, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product: PROVIDED, That a firearm or ammunition shall not be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged.

(b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.

(c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a 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. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

(2) A product manufacturer is subject to strict liability to a claimant if the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction or not reasonably safe because it did not conform to the manufacturer's express warranty or to the implied warranties under Title 62A RCW.

(a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.

(b) A product does not conform to the express warranty of the manufacturer if it is made part of the basis of the bargain and relates to a material fact or facts concerning the product and the express warranty proved to be untrue.

(c) Whether or not a product conforms to an implied warranty created under Title 62A RCW shall be determined under that title.

(3) In determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

[1988 c 94 § 1; 1981 c 27 § 4.]