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COURT OF APPEALS, DIVISION II,  
OF THE STATE OF WASHINGTON

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DIANA SHERMAN, Plaintiff-Respondent,

v.

PLIVA, INC.; TEVA PHARMACEUTICALS USA, INC.; and BARR  
LABORATORIES, INC., Defendants-Appellants.

and

PFIZER, INC.; WYETH LLC (formerly known as WYETH, INC); WYETH  
HOLDINGS CORP.; WYETH PHARMACEUTICALS INC.; SCHWARZ  
PHARMA, INC.; UCB, INC; ALAVEN PHARMACEUTICAL LLC;  
QUALITEST PHARMACEUTICALS, INC.; GENERICS BIDCO I, LLC;  
RANBAXY PHARMACEUTICALS, INC.; BRUCE A. SILVERMAN,  
M.D.; GASTROENTEROLOGY ASSOCIATES, PLLC; GRACE KIM,  
R.Ph.; ROBERTA MATTHEWS, R.Ph.; RITE AID CORPORATION,  
Defendants.

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APPELLANTS' OPENING BRIEF

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## INTRODUCTION

In this products-liability lawsuit, Plaintiff Diana Sherman (“Ms. Sherman”) alleges that the manufacturers of the prescription drug Reglan (the generic version of which is known as metoclopramide) failed to adequately warn her about the drug’s purported risks. Her claim against Appellants (“Generic Defendants”<sup>1</sup>) is a single count under the Washington Products Liability Act (“WPLA”). But Ms. Sherman cannot satisfy her burden of proof on that claim because her prescribing physician, Dr. Bruce Silverman, was fully aware of the risks associated with metoclopramide and in any event did not even read Generic Defendants’ metoclopramide labels/warnings. Indeed, Dr. Silverman testified that he *never* reads drug warning labels or other communications from drug companies—he believes they are “meaningless” and filled with “gobbledygook.” CP1 at 175-76, 193, 205-06.<sup>2</sup>

Dr. Silverman’s unequivocal and unrebutted testimony that he never reads drug warning labels establishes that Ms. Sherman cannot prove that any alleged inadequacy in Generic Defendants’ warnings

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<sup>1</sup> The “Generic Defendants” are PLIVA, Inc., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. Plaintiff filed suit against additional generic drug manufacturers who are no longer in the case.

<sup>2</sup> CP1” and “CP2” refer to Volumes 1 and 2 of the Clerk’s Papers. “RP (02/13/17)” and “RP (08/28/17)” refer to the Report of Proceedings below.

“proximately caused” her injuries. RCW § 7.72.030(1). Washington law is clear: When a plaintiff’s doctor admits he “did not read the labeling” of a medical product, failure-to-warn claims against the product’s manufacturer fail *as a matter of law* because the plaintiff cannot establish proximate cause. *Douglas v. Bussabarger*, 73 Wn.2d 476, 478, 438 P.2d 829 (1968) (holding that a drug company’s alleged failure to warn “was not a proximate cause of plaintiff’s disability” because her doctor “did not read the labeling which was on the container”). The trial court, however, denied Generic Defendants’ motion for summary judgment, despite the undisputed evidence that Dr. Silverman did not “read anything” from drug companies. RP (08/28/17) at 80. In doing so, the trial court failed to even cite *Bussabarger*. As the Court Commissioner recognized in granting review, the trial court’s ruling “was obvious error in light of *Bussabarger*.” Commissioner Ruling at 7.

Ms. Sherman’s inability as a matter of law to establish proximate causation fully resolves this appeal and mandates reversal of the trial court’s order with direction to enter judgment for Generic Defendants. Although the Court may stop there, there are additional grounds that support judgment for Generic Defendants.

First, Ms. Sherman’s claim is preempted by federal law, under the U.S. Supreme Court’s decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567 (2011)—a case that involved *the same* drug (metoclopramide) and *the same* product warnings at issue here. In *Mensing*, the Court held that “federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus pre-empt,” “state tort-law claims based on ... drug manufacturers’ alleged failure to provide adequate warning labels for generic metoclopramide.” *Id.* at 608-09. Seeking to avoid *Mensing*, Ms. Sherman tries to recast her failure-to-warn claim by arguing, *inter alia*, that Generic Defendants may be held liable for allegedly failing “to communicate” about metoclopramide’s risks. Ms. Sherman’s position, however, is contrary to federal labeling regulations, was specifically rejected in *Mensing*, and conflicts with the overwhelming weight of case law since *Mensing*. Moreover, Ms. Sherman’s alternative argument—which she did not plead in her Complaint—that Generic Defendants allegedly failed to “update” their labels to reflect changes made to the Reglan labeling runs headlong into Congress’s prohibition on private rights of action under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 337(a), as explained by

the U.S. Supreme Court in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 352-53, 121 S. Ct. 1012 (2001).

Second, Ms. Sherman's failure-to-communicate theory has no basis in Washington law. Under the WPLA's plain text and common-law principles, product warnings are provided "with the product." RCW § 7.72.030(1)(b). There is no legal duty in Washington for a manufacturer to send *additional* warnings to doctors or to host seminars for the medical profession. In addition, Ms. Sherman's theory is inconsistent with the learned intermediary doctrine, which Washington courts long have applied in cases involving pharmaceutical products.

For any or all of those reasons, this Court should reverse the judgment of the trial court and remand with instructions to enter summary judgment for Generic Defendants.

### **ASSIGNMENT OF ERROR**

#### *The Error Below*

The Grays Harbor Superior Court erred in denying Generic Defendants' motion for summary judgment. RP (08/28/17) at 76-84.

#### *Issues Pertaining to Assignment of Error*

1. Ms. Sherman's physician testified that he did not read the Generic Defendants' metoclopramide labels before prescribing Reglan for Ms. Sherman and that he does not consider warnings from drug

manufacturers when making treatment decisions. The trial court erred by denying the motion for summary judgment despite the undisputed evidence that Generic Defendants' supposed failure to warn could not have caused Ms. Sherman's alleged injuries.

2. State-law tort claims that "turn on the adequacy of a [generic] drug's warnings are pre-empted by federal law." *Mutual Pharm. Co. v. Bartlett, Inc.*, 570 U.S. 472, 476, 133 S. Ct. 2466 (2013). The trial court erred by allowing Ms. Sherman to pursue a claim against Generic Defendants for allegedly failing to adequately warn doctors about risks associated with metoclopramide use.

3. The trial court erred by allowing Ms. Sherman to proceed on a "failure to communicate" theory even though the WPLA does not impose any duty for manufacturers to communicate a product's purported risks through means other than warnings provided with the product itself.

## STATEMENT OF THE CASE

### A. Factual Background

1. This action arises from Ms. Sherman's use of the prescription drug metoclopramide, some of which Generic Defendants manufactured. Metoclopramide is used to treat certain gastrointestinal conditions. CP2 at 506, 766. Both the brand-name metoclopramide drug (Reglan) and Generic Defendants' metoclopramide products are approved

by the United States Food and Drug Administration (“FDA”). CP1 at 129-30; CP2 at 689. Ms. Sherman used metoclopramide between 2004 and 2011 at the direction of her physician, Dr. Silverman, who is a gastroenterologist. CP1 at 58, 68. Ms. Sherman alleges that, as a result of “overexposure” to metoclopramide, she developed movement disorders called tardive dyskinesia and akathisia. *Id.* at 57-58.

Since 1985, the FDA-approved Reglan label has included warnings about the possible risks of tardive dyskinesia and akathisia. *See Mensing*, 564 U.S. at 609; CP2 at 715. The drug’s package insert also has stated that the risk of developing tardive dyskinesia is believed to increase with the duration of treatment and total cumulative dosage; that a patient can develop tardive dyskinesia even after “relatively brief treatment periods at low doses”; and that Reglan use for longer than 12 weeks “has not been evaluated and cannot be recommended.” *Id.* at 715-16. Nevertheless, Ms. Sherman alleges that, until 2009, the Reglan label contained “false statements and/or misleading half-truths.” CP1 at 80. Specifically, she alleges that the statement that drug-induced movement disorders occur in about 1 out of every 500 patients understated the drug’s risk based on the available scientific evidence (the “1-in-500” language). *Id.* at 80-81.

The manufacturers of Reglan revised the Reglan label in 2004 and 2009. In 2004, the brand-name drug manufacturer added statements to the “indications and usage” and “dosage and administration” sections of the label reiterating that Reglan therapy was indicated for short-term use (*i.e.*, not longer than 12 weeks in duration). CP2 at 766, 769. The revisions did not change the “Warnings, Precautions, or Contraindications” section of the label. CP1 at 83. In 2009, FDA required the brand-name drug manufacturer to add a “black box warning” to the Reglan label. CP1 at 84. That warning reorganized and reiterated the label’s existing admonitions that “[t]reatment with metoclopramide can cause tardive dyskinesia,” and that “[t]he risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose.” *Id.* The black box warning also stated that “[t]reatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing tardive dyskinesia.” *Id.* Neither the 2004 nor the 2009 labeling revisions changed the “1-in-500” language that Ms. Sherman has alleged is misleading. CP1 at 79-80.

2. When Ms. Sherman was referred to Dr. Silverman, she was “incapacitated” by digestive issues that were substantially “lowering [her] quality of life.” *Id.* at 180, 181, 184. Dr. Silverman diagnosed

Ms. Sherman with several digestive ailments, including bile reflux—a condition that irritated her stomach and, if left untreated, could cause corrosion, strictures, and esophageal cancer. *Id.* at 198. Dr. Silverman prescribed several different medications to Ms. Sherman over an extended period, but they “didn’t help her at all.” *Id.* at 196.

After initial treatment attempts failed, Dr. Silverman prescribed Reglan for Ms. Sherman. In doing so, he carefully weighed the drug’s “risks” and “benefits.” CP1 at 183-84, 202. In particular, Dr. Silverman was aware of the risk that metoclopramide use could lead to irreversible movement disorders. *Id.* at 186-87, 190. Despite the known risks, Dr. Silverman decided to prescribe Reglan for Ms. Sherman as a “last resort,” because the “suffering that she was enduring” made her “one of those rare patients that needed to go on that medication.” *Id.* at 202. And it worked: sustained metoclopramide treatment substantially improved Ms. Sherman’s symptoms, producing results that Dr. Silverman considered “remarkable.” *Id.* at 195-97. By contrast, when Ms. Sherman temporarily stopped taking the drug, her condition worsened and resulted in hospitalizations. *Id.* at 196. Dr. Silverman examined Ms. Sherman during each of her 18 office visits while she was taking metoclopramide, and he never observed any unusual movements. *Id.* at 188.

Significantly, Dr. Silverman testified that he does not rely on warning information from drug manufacturers when he makes treatment decisions. Indeed, he could not “recall ever reading a package insert” when prescribing a drug for a patient, and he considered drug labels “meaningless” because they are filled with “gobbledygook” and “legalese.” CP1 at 175-76, 193, 205-06. Dr. Silverman also does not review other communications from drug manufacturers, including so-called “Dear Doctor” letters. *Id.* at 177-78.<sup>3</sup> He testified that he did not “remember ever seeing one of those letters,” did not “have time to look at the mail coming in,” and did not rely on drug companies to “learn ... new information.” *Id.* at 177-78, 203-04, 212-13. Dr. Silverman was unequivocal on that point:

- Q. During the course of your gastroenterology practice, have you ever received communications from the FDA about particular drugs or about particular medical devices?
- A. I am not personally aware of direct communications to me. I get a stack of mail this high every day, and generally I don't have time to look at the mail coming in. That would not generally be how I would learn about some new information.
- Q. Okay. How about, have you ever received what are sometimes called Dear Doctor letters from drug manufacturers?
- A. I'm not aware of seeing those.

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<sup>3</sup> “Dear Doctor” letters are mass mailings sent directly from a drug manufacturer to physicians to inform physicians of important new information regarding a drug product. *See Mensing*, 564 U.S. at 615; 21 C.F.R. § 200.5.

Q. Okay.

A. But again, it would not—it may be in that stack of mail that I never open.

*Id.* at 177-78. Drug company representatives also could not convey new warning information to Dr. Silverman in person, because he and others at GEA “don’t allow them” into the office. *Id.* at 208.

Dr. Silverman further testified that he followed his usual practices when electing to prescribe metoclopramide for Ms. Sherman, meaning he did not rely on communications from drug companies. CP1 at 193-94, 204-06. Instead, he relied on his “clinical training and experience,” as well as “the experience of his colleagues[,] ... associates,” and “mentors.” *Id.* at 194; *see id.* at 204. He explained that, in the profession, it was well known that tardive dyskinesia was a risk associated with metoclopramide treatment that doctors “had to know [about] and watch for.” *Id.* at 192. In addition, Dr. Silverman testified emphatically that he did not read any package insert for Reglan or generic metoclopramide before prescribing the drug for Ms. Sherman (*id.* at 193-94):

Q. So is it correct that, prior to prescribing metoclopramide to Mrs. Sherman, you did not rely upon any package insert for Reglan or any package insert for any generic metoclopramide?

A. The short answer, that’s correct.

Q. Okay. And during the time that you were prescribing the medication to Mrs. Sherman, is it correct that you did not rely upon any package insert for Reglan or any package

insert for any generic metoclopramide when you made the decision to continue to prescribe it to her?

A. That's correct. I relied on my clinical training and experience and the experience of my colleagues and associates, and with mentors and people in the academic world who I respected.

Q. Okay. And would it then be correct that if the language in those package inserts, the Reglan package insert or a generic metoclopramide package insert, changed over the years while you were prescribing it to Mrs. Sherman, that didn't have any impact on your prescription decision because you weren't looking at those package inserts; is that correct?

A. That's correct.

3. In 2012, Ms. Sherman's counsel informed Dr. Silverman that Ms. Sherman planned to file a lawsuit to seek damages for the injuries she had allegedly suffered due to her metoclopramide use. CP1 at 209; CP2 at 630-31, 633. In response, and in order to mitigate any future liability risk for his practice, Gastroenterology Associates, PLLC ("GEA"), Dr. Silverman urged his partners to establish a new formal informed-consent policy for metoclopramide prescriptions. CP1 at 209; CP2 at 525-26. Under the 2013 policy that GEA adopted, patients must sign written consent forms that note the risk of developing tardive dyskinesia when using metoclopramide for longer than three months. CP2 at 560-62. Dr. Silverman testified that GEA adopted that policy to require written informed consent in response to Ms. Sherman's litigation threats. CP2 at 749-50. Three additional GEA employees confirmed that the new

policy was a direct response to Ms. Sherman's threatened suit. CP1 at 215 (Testimony of Dr. Ben Merrifield), 217 (Testimony of Kelly Auvinen), 220 (Testimony of Terri Stabnow). Ms. Sherman did not introduce evidence to dispute that testimony.

**B. Procedural History**

1. In 2013, Ms. Sherman filed suit in Grays Harbor Superior Court. CP1 at 1. Ms. Sherman's Complaint (as later amended) focused overwhelmingly on the alleged actions of the manufacturers of Reglan, whom she accused of distributing "consciously inaccurate" and "misleading" information about the risks of long-term Reglan use. *Id.* at 78-92, 98-115. Ms. Sherman also alleged that "[a]s a practice," doctors rely on information "disseminated to them, directly or indirectly, by the manufacturer of the brand name version of the drug, and not on information supplied by the manufacturers of the generic versions." *Id.* at 99. Ms. Sherman settled her claims against each brand-name drug manufacturer defendant.

Ms. Sherman also asserted claims against the Generic Defendants, Dr. Silverman and GEA, and a group of pharmacy defendants who dispensed metoclopramide to fill Ms. Sherman's Reglan prescriptions. CP1 at 61-63. As to the Generic Defendants, Ms. Sherman asserted a

single count under the WPLA, RCW § 7.72.030(1), for selling metoclopramide tablets that were allegedly unsafe “because adequate warnings and instructions were not provided with the product.” CP1 at 94-95. Ms. Sherman also faulted Generic Defendants for not informing the medical profession about the alleged risks of using metoclopramide by distributing scientific articles and “sponsoring” “educational programs,” or circulating Dear Doctor letters or other communications to describe the 2004 and 2009 updates to the Reglan label. *Id.* at 96-97.

2. Generic Defendants moved for judgment on the pleadings on the ground that Ms. Sherman’s claim is preempted by federal law, as explained in the U.S. Supreme Court’s *Mensing* decision. There, the Supreme Court recognized that it is “impossible” for generic drug manufacturers to fulfill state-law duties to strengthen product warnings while adhering to the federal duty to keep their labels “the same” as the labeling for the corresponding brand drug. 564 U.S. at 618. The Court accordingly held that the plaintiffs’ state law failure-to-warn claims were preempted. *Id.* at 620-21.

In opposing Generic Defendants' motion, Ms. Sherman conceded that, under federal law, Generic Defendants "could not change the label" for metoclopramide, RP (02/13/15) at 43, or provide "substantial new warning information" in Dear Doctor letters that conflicted with the FDA-approved labeling, CP1 at 399. But Ms. Sherman argued that Generic Defendants still could be liable under a "failure-to-communicate" theory, insisting, *inter alia*, that Generic Defendants were obliged to send Dear Doctor letters or similar communications to describe updates to the Reglan label in 2004 and 2009. *Id.* at 380. Generic Defendants explained in reply that Ms. Sherman's theory did not escape preemption because, under *Mensing* and FDA regulations, generic drug manufacturers cannot send letters emphasizing particular warnings if the brand-name manufacturer does not send them first.

The trial court denied Generic Defendants' motion. RP (02/13/15) at 73-75. The court recognized that it was "bound by the *Mensing* decision," but reasoned that the decision was not so "harsh" as to require dismissal. *Id.* Instead, the trial court suggested that it could address concerns about preemption through unspecified "motions in *limine* and [jury] instructions." *Id.* at 75.

3. After discovery, Generic Defendants moved for summary judgment. In addition to reasserting their preemption defense, Generic Defendants detailed the undisputed evidence foreclosing Ms. Sherman from establishing proximate causation under the Washington Supreme Court's *Bussabarger* decision. CP1 at 145-50. Generic Defendants also explained that Ms. Sherman's failure-to-communicate theory lacks support in Washington law because the WPLA does not impose any duty for manufacturers to send additional "communications" separate from those provided with the product. *Id.* at 143-45.

In opposition, Ms. Sherman introduced a new theory: She asserted that Generic Defendants had violated FDA regulations by failing to update their product labels for metoclopramide in 2004 and 2009 when the FDA approved changes to Reglan's label. *See* CP1 at 409-425. As Generic Defendants noted in reply, Ms. Sherman did not plead facts or introduce evidence to support that theory. CP2 at 688, 697. Generic Defendants also explained that Ms. Sherman's new "failure-to-update" theory was meritless in any event because (1) any such failure could not have proximately caused Ms. Sherman's alleged injuries given Dr. Silverman's testimony, (2) the claim is preempted by federal law, as only the FDA has authority to enforce the FDCA, *Buckman*, 531 U.S. at 349 n.4, 352-53,

and (3) there is no state-law duty to follow FDA labeling rules or to conform product labeling to that of another company's product. CP2 at 686-705.

The trial court denied Generic Defendants' motion in an oral ruling. RP (08/28/17) at 76-84. As to proximate cause, the court acknowledged that it had "struggled" with Dr. Silverman's testimony, but it stated that "despite Dr. Silverman's testimony," a jury might decide that he was not aware of "the latest warnings" for metoclopramide and would have "acted differently" if he had been informed. *Id.* at 78-80. The trial court further speculated that if Generic Defendants had distributed "more materials" about metoclopramide risks to Dr. Silverman's "mentors and his fellow doctors," the message might have trickled back to him. *Id.* at 80-81. In addition, despite the uniform testimony that GEA adopted its informed-consent policy in 2013 in response to Ms. Sherman's litigation threat, the trial court suggested the policy could be used to "impeach" Dr. Silverman's credibility and challenge his testimony that he had been aware of metoclopramide's risks when treating Ms. Sherman. *Id.* at 79.

The trial court also rejected Generic Defendants' alternative arguments for summary judgment. As to duty, the court stated, without elaboration or reference to the text of the WPLA, that a drug manufacturer

who profits from the sale of a drug “has a general duty to warn.” RP (08/28/17) at 79. As to preemption, the trial court relied on the reasoning from its earlier decision that, despite *Mensing*, Generic Defendants could have found a way to “hammer home a message” about metoclopramide’s risks if they had “really want[ed] to.” *Id.* at 80.

4. Generic Defendants moved for discretionary review under RAP 2.3(b)(1), asserting that the trial court had “committed an obvious error” by denying the motion for summary judgment. Commissioner Aurora R. Bearse granted the motion in a 17-page opinion.

Commissioner Bearse focused primarily on proximate causation. She concluded that the trial court’s decision was “obvious error in light of *Bussabarger*.” Commissioner Ruling at 8. That decision, she explained, follows the “majority” rule and holds that ““when a physician fails to read or rely on a drug manufacturer’s warnings, such failure constitutes the intervening, independent and sole proximate cause of the plaintiff’s injuries.”” *Id.* (quoting *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003)). As Commissioner Bearse explained, *Bussabarger* is controlling because “Dr. Silverman’s un rebutted testimony indicates that he never read warning labels or package inserts from drug manufacturers.” *Id.* at 9. She further noted that “Dr. Silverman said he

knew of the risk of developing tardive dyskinesia and prescribed the medication anyway.” *Id.* at 7-8 n.6.

Although Commissioner Bearse “premised” the grant of review “on the causation issue,” she also authorized Generic Defendants to pursue their federal preemption defense and to address the absence of a legal duty. Commissioner Ruling at 17. In doing so, Commissioner Bearse observed that federal law clearly preempted any claim that Generic Defendants should have provided different or stronger warnings than the brand manufacturer, whether on the product itself or through other communications. *Id.* at 12-13. And she noted that “the weight of authority” supports finding Ms. Sherman’s “failure to communicate” theory preempted in full. *Id.* at 14-15.

#### **STANDARD OF REVIEW**

This Court reviews summary judgment decisions de novo, and “perform[s] the same inquiry as the trial court.” *Elcon Constr., Inc. v. E. Wash. Univ.*, 174 Wn.2d 157, 164-65, 273 P.3d 965 (2012). Under Civil Rule 56(c), summary judgment is appropriate if there is “no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law.” “A material fact is one that affects the outcome of the litigation.” *Elcon Constr.*, 174 Wn.2d at 164-65 (quotation marks omitted).

To oppose summary judgment, a party “must be able to point to some facts which may ... refute the proof of the moving party in some material portion”—it may not “merely recite the incantation, ‘Credibility,’ and have a trial on the hope that a jury may disbelieve factually uncontested proof.” *Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619, 627, 818 P.2d 1056 (1991). Moreover, the nonmoving party “[can]not rely on mere allegations, denials, opinions, or conclusory statements,” *Int’l Ultimate, Inc. v. St. Paul Fire & Marine Ins. Co.*, 122 Wn. App. 736, 744, 87 P.3d 774 (2004), or “on speculation ... that unresolved factual issues remain,” *Doty-Fielding v. Town of S. Prairie*, 143 Wn. App. 559, 566, 178 P.3d 1054 (2008).

#### ARGUMENT

Ms. Sherman’s WPLA claim against Generic Defendants provides the “exclusive remedy for products liability claims” in Washington. *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409, 282 P.3d 1069 (2012). The WPLA provides that “[a] product manufacturer is subject to liability ... 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.” RCW § 7.72.030(1) (emphasis added).

The undisputed evidence entitles Generic Defendants to summary judgment. Any alleged inadequacy in Generic Defendants' warnings could not have caused Ms. Sherman's injuries because Dr. Silverman never read those warnings or any other communications from drug companies. Under controlling precedent, Dr. Silverman's un rebutted testimony fully resolves this appeal and requires reversal. *See Bussabarger*, 73 Wn.2d at 478.

Generic Defendants also are entitled to summary judgment because Ms. Sherman's failure-to-warn claim is preempted by federal law as established by the U.S. Supreme Court in *Mensing*. Ms. Sherman's attempt to avoid *Mensing* by recasting her claim as a "failure to communicate" or "failure to update" is unavailing, because those theories remain subject to federal preemption and have no basis in state law.

**I. The Undisputed Evidence Establishes That Ms. Sherman Cannot Prove Proximate Causation.**

To prevail against Generic Defendants, Ms. Sherman must show that their allegedly inadequate warning was the proximate cause of her injuries. *See* RCW § 7.72.030(1). "Proximate causation includes both cause in fact and legal causation." *Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 256, 978 P.2d 505 (1999). Cause in fact "refers to the 'but for' consequences of an act," whereas "[l]egal causation rests on

policy considerations as to how far the consequences of a defendant's acts should extend." *Baughn v. Honda Motor Co.*, 107 Wn.2d 127, 142, 146, 727 P.2d 655 (1986).

To establish factual causation, the link between an alleged product defect and the plaintiff's claimed injury must not be based on "speculation or conjecture," *Ruff v. Cnty. of King*, 125 Wn.2d 697, 707, 887 P.2d 886 (1995), or on a claim of what "might have" happened, *Hiner*, 138 Wn.2d at 258. Rather, the plaintiff must show that the supposed defect "more probably than not" caused her alleged injury. *Bruns v. PACCAR, Inc.*, 77 Wn. App. 201, 215, 890 P.2d 469 (1995). "If an event would have occurred regardless" of an alleged product defect, then that defect "is not the proximate cause of the plaintiff's injury." *Davis v. Globe Mach. Mfg. Co.*, 102 Wn.2d 68, 74, 684 P.2d 692 (1984); accord *Hiner*, 138 Wn.2d at 256-58.

When the relevant facts are undisputed and the permissible inferences are clear, proximate causation becomes a question of law. See *Ruff*, 125 Wn.2d at 703-04; *Moore v. Hagge*, 158 Wn. App. 137, 148, 241 P.3d 787 (2010). Here, Ms. Sherman cannot establish proximate causation as a matter of law because the undisputed facts show that her doctor (1) did not read the warning label for metoclopramide, (2) does not read

letters from drug companies or rely on their communications about drug products, and (3) already was aware of the risks associated with metoclopramide but decided those risks were outweighed by the benefits of treatment due to the severity of Ms. Sherman's condition.

**A. An Alleged Failure To Warn Cannot Be the Proximate Cause of Ms. Sherman's Injury Because her Doctor Prescribed Reglan Based on his own Clinical Experience and Without Reading the Warning Label.**

1. In failure-to-warn cases, a plaintiff cannot establish proximate causation without showing that she would have avoided injury if a more effective warning had been given. *See Anderson v. Weslo, Inc.*, 79 Wn. App. 829, 839, 906 P.2d 336 (1995); *Luttrell v. Novartis Pharm. Corp.*, 894 F. Supp. 2d 1324, 1344 (E.D. Wash. 2012). Outside the pharmaceutical context, a plaintiff who did not personally read a product's warning generally cannot make that showing—the strength of a warning is irrelevant if the warning was never read. *See, e.g., Hiner*, 138 Wn.2d at 257-58 (holding that the plaintiff could not establish proximate causation because she had not read her owner's manual and did not inspect the tires for instructions).

In pharmaceutical cases, Washington courts apply the “learned intermediary doctrine,” which shifts the focus from whether the plaintiff read and relied on the product warning to whether her doctor did so. *See*

*Luttrell*, 894 F. Supp. 2d at 1344. The doctrine is based on the premises that (1) a doctor has a “duty to inform himself of the qualities and characteristics of those products which he prescribes for ... his patients,” and (2) patients will “place primary reliance” on their doctor’s “judgment.” *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978).

When, as here, the learned intermediary doctrine applies, a drug manufacturer’s “duty to provide warnings to patients transfers to the doctor, who is in a better position to communicate them to the patient.” *Taylor v. Intuitive Surgical, Inc.*, 187 Wn.2d 743, 757, 389 P.3d 517 (2017). Thus, in jurisdictions like Washington that follow the doctrine, courts routinely hold “that when a physician fails to read or rely on a drug manufacturer’s warnings, such failure constitutes the ‘intervening, independent and sole proximate cause’ of the plaintiff’s injuries, *even where the drug manufacturer’s warnings were inadequate.*” *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003) (describing this as the “majority” rule and referencing *Bussabarger* in support).<sup>4</sup>

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<sup>4</sup> See also, e.g., *Rodriguez v. Stryker Corp.*, 680 F.3d 568, 575-77 (6th Cir. 2012) (holding causation could not be established where the plaintiff failed to introduce evidence that the proposed warning would have reached the physician or prevented the injury); *Pustejovsky v. PLIVA, Inc.*, 623 F.3d 271, 276-77 (5th Cir. 2010) (holding causation could not be established where the physician did not recall having read the package insert for metoclopramide); *Kilgore v. Boston Sci. Corp.*, No. 13-cv-09171, 2015

The Washington Supreme Court adopted that precise rule in *Bussabarger*, and it has now governed products-liability claims in this State for 50 years. There, the plaintiff sued a physician who performed an operation using an anesthetic and the drug company that manufactured it. The plaintiff argued that the manufacturer should have labeled the anesthetic's container to identify possible risks. But the Washington Supreme Court held that the plaintiff could not establish proximate causation *as a matter of law*, because her doctor testified that he had “relied on his own knowledge” in deciding to use the anesthetic and “did not read the labeling which was on the container.” 73 Wn.2d at 478.

*Bussabarger* dictates the outcome of this appeal. In fact, Dr. Silverman's testimony is even more clearly inconsistent with

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WL 5838513, at \*5 (S.D.W. Va. Oct. 5, 2015) (“Given [the physician's] explicit statement that he does not rely on the [drug instructions], ... the plaintiffs cannot establish proximate causation.”); *Kline v. Zimmer Holdings*, No. 13-513, 2015 WL 4077495, at \*25 (W.D. Pa. July 6, 2015) *aff'd*, 662 F. App'x 121 (3d Cir. 2016) (holding causation could not be established where the plaintiff's physician did not read the package insert because “even if the warning in this case were insufficient, it would not have made a difference”); *Whitener v. PLIVA, Inc.*, No. 10-cv-1552, 2014 WL 1276489, at \*6 (E.D. La. Mar. 27, 2014), *aff'd*, 606 F. App'x 762 (5th Cir. 2015) (granting summary judgment to generic manufacturers where the prescribing physician testified “that his decision to prescribe [metoclopramide to the plaintiff] was only based on his own experience”); *In re Trasyol Products Liab. Litig.*, No. 08-MD-01928, 2011 WL 2117257, at \*5 (S.D. Fla. May 23, 2011) (holding proximate causation could not be established because there was “no record evidence indicating that [the treating physician] read the warning that Plaintiff claims was inadequate, or that it played any role in [the] prescribing decision”); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 112, 85 Cal. Rptr. 3d 299 (2008) (“There can be no proximate cause where, as in this case, the prescribing physician did not read or rely upon the allegedly inadequate warnings promulgated by a defendant about a product.”).

proximate causation than the physician's testimony in *Bussabarger*. Dr. Silverman testified unequivocally and repeatedly that he did not review or rely on "any package insert for Reglan or any package insert for any generic metoclopramide." CP1 at 193-94. For that reason, he explained, the specific "language in those package inserts ... didn't have any impact on [his] decision" to prescribe the drug to Ms. Sherman. CP1 at 194. Indeed, Dr. Silverman believed FDA-approved warnings have little practical value. *Id.* at 193. Instead, as was true of the doctor in *Bussabarger*, Dr. Silverman relies on his own "clinical training and experience," and the experience of colleagues—not on warnings from drug companies. *Id.* at 194. Thus, under *Bussabarger*, any alleged inadequacy in Generic Defendants' product warning "was not a proximate cause of" Ms. Sherman's alleged injury. 73 Wn.2d at 478.

Notably, the *Bussabarger* Court held that the plaintiff could not establish proximate cause based solely on the fact that the plaintiff's doctor did not read "the labeling which was on the [product] container." *Id.* The Court did not speculate that the drug company might have captured the doctor's attention by sending a warning to him in some other way. But regardless, Dr. Silverman's testimony forecloses proof of proximate cause under Ms. Sherman's (legally baseless) "failure to

communicate” theory as well. Dr. Silverman testified unequivocally that he does not read Dear Doctor letters from drug companies, which he could not “remember ever seeing.” CP1 at 177-78. And he explained more generally that, as a matter of practice, he does not rely on information from drug companies to learn about a drug’s risks. *Id.* Ms. Sherman did not introduce any evidence to contradict that testimony.

2. Dr. Silverman’s un rebutted testimony also precludes a proximate causation finding for a second, related reason. Under Washington law, “a drug manufacturer’s failure to warn a prescribing physician cannot be the proximate cause of the patient’s injury if the physician was already aware of the risk involved in the use of the drug.” *Wash. State Physicians Ins. Exch. & Ass’n v. Fisons Corp.*, 122 Wn.2d 299, 315, 858 P.2d 1054 (1993) (citing 3 American Law of Products Liability § 32:61 (3d ed. 1993)). Numerous courts throughout the country have endorsed the same principle.<sup>5</sup>

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<sup>5</sup> See, e.g., *Baker v. App Pharm. LLP*, No. 09-cv-05725, 2012 WL 3598841, at \*10 (D.N.J. Aug. 21, 2012) (“Because [the prescribing physician] was aware of and understood the risks of [the drug], and did not choose to read [the drug’s] warning label or any additional information from Defendant, no reasonable jury could conclude that a different label would have altered [his] decision to administer [the drug].”); *In re Zyprexa Prod. Liab. Litig.*, No. 04-MD-1596, 2011 WL 182489, at \*3 (E.D.N.Y. Jan. 20, 2011) (granting summary judgment to the defendant where “the undisputed evidence ... show[ed] that the prescribing physicians were already aware of the risks ... at the time [the drug] was prescribed”); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170, 55 Tex. Sup. Ct. J. 774 (Tex. 2012) (“[W]hen the prescribing physician is aware of the product’s

Here, the undisputed evidence establishes that Dr. Silverman was fully aware of possible risks associated with long-term metoclopramide use when prescribing Reglan for Ms. Sherman. Dr. Silverman testified that he and other doctors in the field “always talked about and would always watch for” the development of movement disorders in patients “on metoclopramide.” CP1 at 190. Moreover, given his awareness of the drug’s risks, Dr. Silverman explained that he prescribed Reglan infrequently and only as “a last resort.” *Id.* at 202. In Ms. Sherman’s case, Dr. Silverman determined that she was “one of those rare patients that needed to go on the medication” given the severity and persistence of her digestive problems, as well as the failure of several previous treatment attempts. *Id.*; *see also id.* at 183-84, 196-97.

Ms. Sherman now disagrees with how Dr. Silverman weighed the risks and benefits of long-term metoclopramide use. And she is challenging his medical judgment in her medical malpractice case against Dr. Silverman and GEA. But no reasonable jury could hold Generic Defendants liable for allegedly failing to warn Dr. Silverman about risks that he already recognized and accounted for as part of his practice, particularly since he would not have read the warnings anyway.

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risks and decides to use it anyway, any inadequacy of the product’s warning, as a matter of law, is not the producing cause of the patient’s injuries.”).

**B. The Trial Court's Contrary Ruling on Proximate Causation Rests on Impermissible Speculation and Conjecture.**

As the Commissioner recognized, *Bussabarger* is “binding precedent” in Washington. Commissioner Ruling at 9. The trial court, however, failed to cite *Bussabarger* and made no attempt to reconcile that controlling Supreme Court authority with its decision to deny Generic Defendants’ motion for summary judgment. The rationales that the trial court offered instead do not withstand scrutiny.

1. The trial court acknowledged that it had “struggled” with Dr. Silverman’s testimony explaining that he did not “read anything” from drug companies. RP (08/28/17) at 80. But rather than accept that Dr. Silverman’s indifference to drug-company warnings made his treatment decisions the “intervening, independent and sole proximate cause” of Ms. Sherman’s alleged injuries, *Thom*, 353 F.3d at 856, the trial court engaged in speculation. Without identifying any basis in the WPLA for Ms. Sherman’s failure to-communicate theory, the trial court accepted the theory and surmised that if Generic Defendants had “hammer[ed] home a message” about metoclopramide’s risks to *other* doctors, “you could argue” that Dr. Silverman would have “gotten the message” and changed his practices. RP (08/28/17) at 80. The court based that hypothetical causal chain solely on Dr. Silverman’s testimony that when

making treatment decisions, he relies, in part, “on his fellow doctors and on mentors and on seminars.” *Id.*

The trial court’s “you could argue” reasoning, *id.*, is legally flawed. In opposing summary judgment, a plaintiff may not rest on mere argument about what theoretically could have happened; rather, she must “come forward *with evidence* to establish the existence of each essential element of [her] ... claim.” *Howell*, 117 Wn.2d at 625 (emphasis added). Ms. Sherman completely failed to do so, and the trial court’s decision impermissibly filled in the evidentiary gaps in her case with speculation.

Indeed, the trial court’s theory relies on several implausible leaps that lack any evidentiary support. In particular, the theory presupposes that although (1) Dr. Silverman and his colleagues were aware that metoclopramide use is sometimes associated with movement disorders, and (2) Dr. Silverman only used the drug as a “last resort,” CP1 at 202, and (3) the 2004 and 2009 updates to the Reglan label were available to Dr. Silverman’s colleagues, if (4) Generic Defendants had sent letters or other communications about the Reglan label updates, then certain unidentified colleagues and mentors of Dr. Silverman would have described those label changes to him, and (5) their descriptions somehow would have influenced his practice by providing him with information that

he already knew. No reasonable jury could base causation on that multi-layered chain of speculation and conjecture. *See Hiner*, 138 Wn.2d at 258 (rejecting as “mere speculation” the plaintiff’s suggestion that, although she had not reviewed the owner’s manual or looked for warnings on her tires, the tire’s installer “might have” read warnings if they had been on the tires).

Courts presented with similarly speculative causation theories have rightly rejected them, including in cases that involve warnings for metoclopramide. For example, in *Pustejovsky v. PLIVA, Inc.*, 623 F.3d 271 (5th Cir. 2010), the plaintiff tried to get around her doctor’s testimony that he “did not recall ever reading the [metoclopramide] package insert” by suggesting that a label change “might have come up in conversations with other physicians or been discussed at a continuing-education seminar.” *Id.* at 277. The Fifth Circuit held that those unsubstantiated assertions of “possible” scenarios failed to “demonstrate a genuine issue of material fact regarding causation.” *Id.* This Court too must reject a proximate causation theory that relies on guesswork and speculation.

2. The trial court also concluded that, although Dr. Silverman testified that he was aware of the risks associated with metoclopramide, a jury might “disbelieve[]” him. RP (08/28/17) at 79. In support, the Court

primarily focused on GEA's adoption in 2013 of an informed-consent policy for Reglan. *Id.* at 78. The trial court suggested that policy "may come in" as evidence "to impeach depending on how the testimony comes out at trial." *Id.* Although it is not entirely clear from the record, under the trial court's apparent theory, Ms. Sherman could use the 2013 policy as impeachment evidence because it supposedly shows that Dr. Silverman and GEA adopted new informed-consent procedures when they were made aware of the full scope of metoclopramide's risks. There are three basic problems with the trial court's reasoning.

First, the *only* evidence in the record demonstrates that GEA adopted the policy in response to Ms. Sherman's litigation threats. Specifically, Ms. Sherman's counsel sent Dr. Silverman a letter concerning a potential lawsuit against metoclopramide manufacturers, which led Dr. Silverman to believe that Ms. Sherman "intend[ed] to file a lawsuit ... naming [him] as well." CP2 at 747-48; *see also* CP2 at 630-31, 633. Indeed, Dr. Silverman concluded that "regardless of [GEA's] long-term experience with [metoclopramide], [GEA] needed to begin to reduce the risk" it faced from litigation by adopting new formal policies for prescribing the drug. CP1 at 209. Three other GEA employees confirmed that GEA adopted the 2013 policy in response to Ms. Sherman's threats of

litigation—not as the result of any new information about metoclopramide’s risks. CP1 at 215 (Testimony of Dr. Ben Merrifield), 217 (Testimony of Kelly Auvinen), 220 (Testimony of Terri Stabnow).

Second, the trial court erred by discounting Generic Defendants’ un rebutted evidence on the theory that the testimony of Dr. Silverman and others at GEA could be “disbelieved.” RP (08/28/17) at 79. A plaintiff cannot defeat summary judgment merely by asserting that a witness is not credible; she must introduce *evidence* to contradict the witness’s testimony. *See Howell*, 117 Wn.2d at 627. Thus, “[i]mpeachment of a witness ... is insufficient to raise an issue of material fact.” *Laguna v. Wash. State Dep’t of Transp.*, 146 Wn. App. 260, 267, 192 P.3d 374 (2008). The trial court departed from that well-established rule by speculating that the 2013 GEA policy could be used “to impeach” Dr. Silverman’s testimony and by allowing Ms. Sherman to overcome summary judgment on that basis.

Third, GEA’s policy provides absolutely no basis to question Dr. Silverman’s testimony that he never read package inserts or letters from drug companies. And it is pure speculation to suggest that if Generic Defendants had sent some unspecified communications to doctors separate from the package inserts, their message would have been viewed by

unidentified colleagues and mentors of Dr. Silverman, who, in turn, would have induced Dr. Silverman to change his approach in treating Ms. Sherman. The trial court's speculation falls far outside the "but for" proximate causation lens that controlling precedent requires.

Ms. Sherman's inability to establish proximate causation mandates summary judgment for Generic Defendants as a matter of law. Although there are other clear legal flaws with Ms. Sherman's WPLA claim, this Court may reverse the trial court's judgment based on that ground alone.

**II. Ms. Sherman's WPLA Claim Is Preempted By Federal Law.**

Ms. Sherman's claim against Generic Defendants also fails because it is preempted by federal law. Federal law strictly controls generic-drug labeling and specifically barred Generic Defendants from issuing the warnings that Ms. Sherman alleges state law required. Because it is "impossible" for generic drug manufacturers to comply with their federal obligations while also following a purported state-law duty to warn, the state-law duty must give way. *See* U.S. Const., Art. VI, cl. 2; *Mensing*, 564 U.S. at 612-13, 617.

**A. U.S. Supreme Court Precedent Establishes That Failure-To-Warn Claims Against Generic Drug Manufacturers Are Preempted Because They Cannot Unilaterally Change Their Product Warnings.**

Prescription drugs are subject to extensive federal oversight, but the U.S. Congress has adopted “meaningfully different” regulatory schemes for brand-name and generic drugs. *Mensing*, 564 U.S. at 626. Under the FDCA, manufacturers seeking to market a new drug using a new drug application (usually, the brand-name drug) must prove to the FDA that the drug is safe and effective for its intended use, and that the label proposed to accompany such drug is accurate and includes adequate instructions and warnings. *Id.* at 612 (citing 21 U.S.C. § 355(b)(1), (d)). Brand-name drug manufacturers are responsible for the accuracy of their own labeling. They must submit proposed drug labeling to the FDA for approval before marketing any new drug. 21 U.S.C. § 355(b)(1)(F). And after approval, they may use the FDA’s “changes-being-effected” process to strengthen a product warning without prior FDA approval. *Mensing*, 564 U.S. at 624; *see* 21 C.F.R. § 314.70(c)(6).

By contrast, generic drug manufacturers are subject to a different, abbreviated approval process. Generic drug applicants “piggy-back[]” on the application of a previously approved brand-name drug by showing their proposed product is “the same” as the brand-name drug in all

material respects. *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05, 132 S. Ct. 1670 (2012). Among other requirements, generic drugs must have the same FDA-approved labeling as the corresponding brand-name drug. 21 U.S.C. § 355(j)(2)(A)(v). That “federal duty of ‘sameness’” is ongoing: Even after a generic drug is approved, the manufacturer may not change the drug’s warning labeling unless the brand manufacturer does so first. *Mensing*, 564 U.S. at 613.

The U.S. Supreme Court has recognized that “the special, and different, regulation of generic drugs” sharply limits the viability of state-law tort claims challenging a generic product’s warnings. *Mensing*, 564 U.S. at 626. Specifically, the Court has held that although plaintiffs sometimes may pursue tort claims against brand manufacturers to challenge product warnings, *see Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009), failure-to-warn claims against generic drug manufacturers are preempted by federal law, because generic drug manufacturers cannot “independently change[]” their drug’s labels, *Mensing*, 564 U.S. at 617. As the Supreme Court explained in a subsequent decision applying *Mensing*, state-law claims that “turn on the adequacy of a [generic] drug’s warnings are pre-empted by federal law.” *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 476, 133 S. Ct. 2466 (2013); *see also Wagner v. Teva*

*Pharm. USA, Inc.*, 840 F.3d 355, 358-59 (7th Cir. 2016) (“[F]ederal law preempts” claims that “rely” on “the generic manufacturer’s failure to provide adequate information ... regardless of how [the claims] are styled.”).

Ms. Sherman’s Complaint is replete with allegations challenging the adequacy of the FDA-approved warnings for metoclopramide, as she charges the Reglan label contained false and/or misleading statements about the drug’s risks. *See, e.g.*, CR1 at 69-70, 80-81, 92, 94-98. But failure-to-warn claims against Generic Defendants premised on those allegations are clearly preempted under *Mensing*, as even Ms. Sherman conceded below. RP (02/13/15) at 43-44. Ms. Sherman nevertheless tries to evade federal preemption by re-characterizing her failure-to-warn claim as resting on “failure-to-communicate” or “failure-to-update” theories. As numerous courts have recognized, however, neither theory provides a valid basis to distinguish *Mensing*. *See* pp. 39, 41-42, *infra*.

**B. Ms. Sherman’s “Failure-To-Communicate” Theory Is Preempted.**

Ms. Sherman tries to side-step *Mensing* by arguing that her claim seeks to hold Generic Defendants liable for failing to communicate adequate product warnings using means separate from their package inserts for metoclopramide. But Ms. Sherman’s “failure-to-communicate”

theory is inconsistent with federal law on drug labeling and with the “duty of sameness” applied by the U.S. Supreme Court in *Mensing*.

Federal law strictly controls what information generic drug manufacturers may convey in their “labeling”—a category that “is so broadly defined” under federal law “that it encompasses nearly every form of communication with medical professionals.” *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 609 (N.D. Miss. 2013); *see* 21 U.S.C. § 321(m); 21 C.F.R. §§ 1.3, 202.1(l)(2). Under FDA regulations, any communications with doctors (such as in Dear Doctor letters) regarding a product’s “warnings, hazards, contraindications, side effects, and precautions” must be “the same in language and emphasis” as “the approved ... labeling” for the brand. 21 C.F.R. § 201.100(d)(1).

In *Mensing*, the Supreme Court applied those federal requirements to bar precisely the sort of end-run around preemption that Ms. Sherman is attempting here. The plaintiffs there argued that even if generic drug manufacturers could not unilaterally change their product labels to strengthen warnings, they “could have used ‘Dear Doctor’ letters to send additional warnings to prescribing physicians and other healthcare professionals.” 564 U.S. at 615. But the Supreme Court *rejected* that argument. The Court explained that “if generic drug manufacturers, but

not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading.’” *Id.*

Ms. Sherman has tried to distinguish *Mensing*, arguing that although Generic Defendants could not communicate warnings to doctors that differed in content from the brand-name drug label, they could have sent Dear Doctor letters discussing the 2004 and 2009 updates to the Reglan label. Federal law, however, does not let generic drug manufacturers send Dear Doctor Letters and similar warnings “unless their brand counterparts do so first.” *In re Darvocet, Darvon & Propoxphene Prods. Liability Litig.*, 756 F.3d 917, 932-33 (6th Cir. 2014).

It is undisputed that Reglan manufacturers did not send Dear Doctor letters following FDA-approved changes to the Reglan label. CP1 at 83-84, 91. Indeed, Ms. Sherman recognizes that her theory against Generic Defendants *depends* on her allegation that the brand-name drug manufacturers “did not give doctors adequate warning” about Reglan. CP1 at 392-93. According to Ms. Sherman, the brand-name drug manufacturers’ misstatements about Reglan created an obligation for Generic Defendants to correct the record. *Id.* But federal law and the “duty of sameness” forbid generic manufacturers from acting unilaterally

in that manner: “they are dependent on brand-names taking the lead.” *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013) (quotation marks omitted). For that reason, every federal court of appeals that has addressed the same failure-to-communicate theory has held that such a claim against generic drug manufacturers is preempted.<sup>6</sup> Numerous federal district and state courts have reached the same conclusion.<sup>7</sup>

The trial court’s contrary determination not only conflicts with the overwhelming weight of authority,<sup>8</sup> but also is irreconcilable with the Supreme Court’s reasoning in *Mensing* and with controlling federal regulations. A generic drug manufacturer cannot unilaterally send a Dear Doctor letter (or other similar warning) without violating FDA’s prohibition on warnings that depart in content or emphasis from the

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<sup>6</sup> See *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014); *Johnson v. Teva Pharm. USA*, 758 F.3d 605, 612 (5th Cir. 2014); *In re Darvocet*, 756 F.3d at 932-33; *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino*, 719 F.3d at 1249.

<sup>7</sup> See, e.g., *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 608-09 (N.D. Miss. 2013); *Garza v. Wyeth LLC*, No. 12-cv-198, 2013 WL 3293704, at \*3 (S.D. Tex. June 28, 2013); *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1348 n.11 (N.D. Ga. 2012); *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1125 (D. Or. 2012); *Harris v. Pharm. Assocs., Inc.*, No. 10-cv-3159, 2012 WL 6025954, at \*3 (E.D. La. Dec. 4, 2012); *Kellogg v. Wyeth*, No. 07-cv-82, 2012 WL 368658, at \*4-5 (D. Vt. Feb. 3, 2012); *Dietrich v. Actavis, Inc.*, 138 So. 3d 1163 (Fla. Dist. Ct. App. 2014) (Mem.).

<sup>8</sup> The trial court identified a “split” of authority on this preemption issue (RP (08/28/17) at 79-80), but the case law overwhelmingly favors the Generic Defendants’ position. In comparison to the numerous cases cited above, only a handful of courts have held that a “failure to communicate” theory like the one offered here can survive preemption under *Mensing*. See, e.g., *Teva Pharm. USA, Inc. v. Superior Court*, 217 Cal. App. 4th 96, 112, 158 Cal. Rptr. 3d 150 (2013); *In re Reglan/Metoclopramide Litig.*, 81 A.D.3d 80, 94-96 (Pa. Super. Ct. 2013).

brand's labeling. 21 C.F.R. § 201.100(d)(1). That follows because the act of sending such letters—which are reserved for important safety information—itsself communicates significant information about a warning's "emphasis." *Id.* And as the *Mensing* Court recognized, when generic drug manufacturers act unilaterally by sending Dear Doctor letters even though the brand drug manufacturer has not, it subverts the federal regulatory system because it "inaccurately impl[ies] a therapeutic difference between the brand and generic drugs." 564 U.S. at 615.

In short, Ms. Sherman's failure-to-communicate theory does not escape preemption under *Mensing*. And the trial court's assumption that Generic Defendants could have "hammer[ed] home a message" about metoclopramide's alleged risks (RP (08/28/17) at 80), even though the brand manufacturers did not, conflicts with federal law.

**C. Ms. Sherman's "Failure-To-Update" Theory Is Preempted.**

Ms. Sherman's new failure-to-update theory is equally flawed. As discussed above, the undisputed evidence clearly forecloses any possibility that an alleged failure by the Generic Defendants to update their labels could have been the proximate cause of Ms. Sherman's injuries because Dr. Silverman *never read those labels*. Notably, even the trial court did not suggest otherwise; instead, the court based its (erroneous

and speculative) proximate cause holding entirely on Ms. Sherman's failure-to-communicate theory. *See* pp. 16-17, *supra*.

In any event, Ms. Sherman's unpled failure-to-update theory is also preempted. A generic drug manufacturer's obligation to update its label to implement changes approved for the corresponding brand-name drug derives entirely from *federal* law, and specifically from the "duty of sameness" imposed by the FDCA and FDA regulations. *See Mensing*, 564 U.S. at 616; 21 U.S.C. § 355(j); 21 C.F.R. § 314.150(b)(10). But Congress vested the FDA with the *exclusive* authority to enforce the FDCA. *See* 21 U.S.C. § 337(a). Thus, in *Buckman*, the U.S. Supreme Court held that the FDCA preempts state-law claims premised on alleged violations of the FDCA or FDA regulations. 531 U.S. at 353. The Court explained that federal law precludes state-law claims that "exist solely by virtue of" FDCA requirements—*i.e.*, claims for which FDCA violations are "a critical element." *Id.*

Ms. Sherman's theory that Generic Defendants allegedly failed to update their labels following changes to the Reglan label "exist[s] solely by virtue of" FDA regulations. *Id.* Therefore, as other courts have held when faced with similar allegations, Ms. Sherman's claim against Generic

Defendants “sounds exclusively in federal (not state) law, and is preempted.” *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013).<sup>9</sup>

Resisting that conclusion, Ms. Sherman tries to adopt a narrow exception that developed in cases addressing express preemption clauses for “state-law causes of actions that parallel federal safety requirements.” *Buckman*, 531 U.S. at 352. *Buckman* makes clear, however, that “parallel” claims are viable *only* if they “rely[] on traditional state tort law which had predated the federal enactments.” *Id.* That rule is decisive here because, as Ms. Sherman conceded before the trial court, “[a] violation of the FDA requirement of putting the approved label on the bottle would not bring a cause of action under Washington state law.” RP (02/13/15) at 46. In other words, there is no duty under Washington law to “update” one drug label to conform to another drug label.

The purely federal basis underlying Ms. Sherman’s failure-to-update theory is made particularly obvious by the fact that she has alleged that the warning for Reglan remained inadequate even *after* the 2004 label

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<sup>9</sup> See also *Wagner v. Pfizer, Inc.*, No. 13-cv-497, 2014 WL 3447476, at \*4 (W.D. Wis. July 11, 2014); *Abicht v. PLIVA, Inc.*, Nos. 12-1278, 12-2172, 2013 WL 141724, at \*2-3 (D. Minn. Jan. 9, 2013); *Bell v. PLIVA, Inc.*, 845 F. Supp. 2d 967, 970 (E.D. Ark. 2012), *aff’d in part and rev’d in part on other grounds*, 716 F.3d 1087 (8th Cir. 2013); *Gross v. Pfizer, Inc.*, 825 F. Supp. 2d 654, 660 (D. Md. Nov. 22, 2011). To be sure, there is a split of authority on this issue. See, e.g., *In re Reglan Litig.*, 142 A.3d 725, 740-741, 226 N.J. 315 (2016). The decisions that have allowed “failure to update” claims to proceed cannot be squared with *Buckman*, because they let plaintiffs enforce inherently federal duties under the guise of state tort law.

update. CP1 at 79-80. It is “logically incoherent” for Ms. Sherman to suggest that Generic Defendants’ *state-law* duty to provide adequate warnings somehow compelled them to use the 2004 Reglan label, given Ms. Sherman’s repeated allegations “that no labels predating 2009 were adequate.” *Morris*, 713 F.3d at 777. Instead, Ms. Sherman’s theory is an impermissible attempt to enforce federal labeling rules.

**III. The WPLA Does Not Impose A Duty For Drug Manufacturers To Deliver Warnings Separately From Their Products.**

Finally, Generic Defendants are entitled to summary judgment because Ms. Sherman’s failure-to-communicate theory has no basis in state law. “Whether a manufacturer has a duty to warn is a question of law for the court.” *Esparza v. Skyreach Equip., Inc.*, 103 Wn. App. 916, 935, 15 P.3d 188 (2000). Under the WPLA, Generic Defendants are required to provide an adequate warning “with th[eir] product”—*i.e.*, on the package insert for metoclopramide. RCW § 7.72.030(1)(b). Ms. Sherman cannot overcome the basic problems with her failure-to-warn claim—including the fact that her doctor did not read the product label—by inventing a new state-law duty for manufacturers to deliver warnings separately from their products.

**A. The WPLA's Plain Text Forecloses Ms. Sherman's Failure-To-Communicate Theory.**

Ms. Sherman's single claim against Generic Defendants under the WPLA subjects manufacturers to liability if "[a] product is not reasonably safe because adequate warnings or instructions were not *provided with the product.*" RCW § 7.72.030(1)(b) (emphasis added). Thus, as summarized by the Washington Supreme Court, "the WPLA requires that warnings be provided with products." *Taylor*, 187 Wn.2d at 753. Nothing in RCW § 7.72.030(1)(b) requires manufacturers to provide *additional* warnings beyond those that accompany the product at the point of sale.

The limited nature of the WPLA's duty to warn is confirmed by its common-law backdrop. The WPLA incorporates certain background common-law tort principles, RCW § 7.72.020(1), including Section 402A of the Restatement (Second) of Torts concerning strict products liability. *See Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 505, 7 P.3d 795 (2000); *see also Taylor*, 187 Wn.2d at 754 ("The WPLA ... closely mirrors the Restatement (Second) of Torts § 402A."). Notably, in Section 402A, the comment that addresses product "[d]irections or warning[s]," specifies that "[i]n order to prevent [a] product from being unreasonably dangerous, the seller may be required to give directions or warning, *on the container*, as to its use." Restatement (Second) of Torts § 402A, *cmt. j.*

(emphasis added). A product “*bearing* such a warning ... is not ... unreasonably dangerous.” *Id.* Similarly, comment *k.*, which applies to prescription drugs and certain other beneficial but “unavoidably unsafe products,” *Ruiz-Guzman*, 141 Wn.2d at 505-09, stipulates that such products are not “*unreasonably* dangerous” if they are “properly prepared, and *accompanied by* proper directions and warning,” Restatement (Second) of Torts § 402A, *cmt. k.* (second emphasis added). Thus, as with the WPLA, there is no suggestion in Section 402A that manufacturers do more than ensure that warnings accompany their products.

Given that legal background, it is unsurprising that Ms. Sherman did not identify *any* basis in her pleadings for a “duty to communicate.” Instead, she paired (unsupported) allegations that “warnings and instructions were not provided *with the product*” with assertions that Generic Defendants “were not prohibited” by federal law from communicating the warnings in other ways, such as by sending Dear Doctor letters regarding what she described as “significant new warning information.” CP1 at 95-96 (emphasis added). Ms. Sherman is wrong that those communications “were not prohibited.” *See* Part II, *supra*. But regardless, she certainly has not identified a legal *duty* to send Dear Doctor letters—an action that could not have possibly made a difference

anyway, because Dr. Silverman never read communications from drug companies. CP1 at 177-78.

**B. Precedent Further Refutes Ms. Sherman's Failure-To-Communicate Theory.**

Ms. Sherman's failure-to-communicate theory also is inconsistent with case law addressing failure-to-warn claims for prescription drugs, including in particular Washington law applying the learned intermediary doctrine. In *Terhune*, the Washington Supreme Court explained that under the learned intermediary doctrine, a drug manufacturer satisfies its duty to warn a patient about a drug's risk so long as its "product is properly labeled *and carries the necessary instructions and warnings* to fully apprise the physician of the proper procedures for use and the dangers involved." 90 Wn.2d at 14 (emphasis added). Recently in *Taylor*, the Supreme Court reaffirmed that rule as applied to the duty to warn patients. *See* 187 Wn.2d at 755-56. Neither decision supports Ms. Sherman's argument that drug manufacturers lose the benefit of the learned intermediary rule if they do not provide separate notifications of the warnings "carrie[d]" by their products, *Terhune*, 90 Wn.2d at 14, through letters or other means intended to get doctors' attention.

In addition, numerous courts outside Washington have squarely rejected Ms. Sherman's theory. In *Guarino*, the Eleventh Circuit held that

the plaintiff's failure-to-communicate theory was not only preempted under *Mensing*, but also "fail[ed] on the merits." 719 F.3d at 1250. As the court explained, under the learned intermediary doctrine, "[p]harmaceutical manufacturers discharge their duty to warn ... by way of a package insert which accompanies [the product]." *Id.* (quotation marks omitted). Similarly, in *Metz v. Wyeth LLC*, 872 F. Supp. 2d 1335 (M.D. Fla. 2012), the court held that a failure-to-communicate theory was not viable because a warning that is "available ... in the package insert" fully satisfies a manufacturer's duty to warn, *id.* at 1344-45. And in *Brinkley v. Pfizer, Inc.*, No. 10-cv-0274, 2012 WL 1564945 (W.D. Mo. Apr. 12, 2012), the court rejected a failure-to-communicate theory against PLIVA, calling it an impermissible "backdoor" attempt to avoid *Mensing*. *Id.* at \*5. The court explained that "no state law require[ed] Pliva to communicate" with the medical community about the content of an FDA-approved label. *Id.*; see also *Kellogg v. Wyeth*, No. 07-cv-82, 2012 WL 12878737, at \*3 (D. Vt. Mar. 30, 2012) ("State tort law ... does not require a drug manufacturer to educate the healthcare profession.").

As those decisions show, Ms. Sherman's theory not only conflicts with the text of the WPLA, but it is also inconsistent with the logic of the

learned intermediary doctrine that Washington law long has endorsed. *See Terhune*, 90 Wn.2d at 14. This Court should accordingly reject it.

**CONCLUSION**

The Court should reverse the trial court's denial of Generic Defendants' motion for summary judgment and remand with instructions to enter judgment in Generic Defendants' favor.

RESPECTFULLY SUBMITTED this 13<sup>th</sup> day of July, 2018.

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