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

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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INTRODUCTION

The undisputed facts of this case compel a grant of summary judgment to Generic Defendants. Plaintiff Diana Sherman alleges that Generic Defendants did not provide adequate warnings with their prescription drug product metoclopramide, the generic form of Reglan. But, as Ms. Sherman admits, her doctor never read Generic Defendants' metoclopramide package inserts. Indeed, Dr. Silverman testified that he does not review warning information from drug companies *at all*. That unrebutted testimony establishes, as a matter of law, that any alleged inadequacy in Generic Defendants' warnings is not the proximate cause of Ms. Sherman's alleged injuries. *See Douglas v. Bussabarger*, 73 Wn.2d 476, 478, 438 P.2d 829 (1968).

Seeking to avoid that straightforward outcome, Ms. Sherman abandons her allegations challenging the adequacy of the warnings accompanying Generic Defendants' products. *See Part II, infra*. Instead, she relies on a novel, but flawed, theory that faults Generic Defendants for not educating the medical profession at large about the purported risks associated with Reglan use. This "failure-to-communicate" theory has no basis in the Washington Products Liability Act and is irreconcilable with the learned intermediary doctrine. Moreover, the theory is premised

entirely on speculation. Her assertion that “Dear Doctor” letters or other communications from Generic Defendants would have reached Dr. Silverman and impacted his prescription decisions has no evidentiary support; indeed, Dr. Silverman’s testimony is directly to the contrary. CP1 at 175-78, 208. And adding to the strikes against the theory, courts have repeatedly held that claims based on it are preempted by federal law.

To gloss over those insurmountable problems with her case, Ms. Sherman turns to not-so-subtle emotional appeals to hold Generic Defendants “responsible” for her alleged injuries. *E.g.*, Sherman Br. 1, 2, 13, 15-16. Those appeals are not only legally irrelevant, but also they are misdirected: Ms. Sherman already has recovered “substantial ... sums” from the manufacturers of Reglan (whose alleged wrongdoing was the focus of her complaint), and she is set to go to trial against Dr. Silverman and his practice. *Id.* at 7-8 n.4, 15. The Court should reject her invitation to distort both the law and the record as it pertains to Generic Defendants and direct entry of summary judgment in their favor.

I. Ms. Sherman Misstates the Standard of Review and Repeatedly Mischaracterizes the Trial Record.

Ms. Sherman peppers her response brief with misstatements about controlling legal standards and significant mischaracterizations of the record. The examples noted highlight the indefensibility of

Ms. Sherman's claim against Generic Defendants.

At the outset, Ms. Sherman's suggestion (at 16-17) that the Court should revisit the Commissioner's decision to allow discretionary review is untimely. Any objection to the Commissioner's ruling was due within 30 days of the order. *See* RAP 17.7(a). Ms. Sherman did not object and cannot use her merits brief to belatedly challenge the Commissioner's order. *See State v. Glenn*, 115 Wn. App. 540, 554, 62 P.3d 921 (2003); *Hough v. Ballard*, 108 Wn. App. 272, 277 n.3, 31 P.3d 6, 15 (2001). Thus, the question presented is simply whether the trial court erred by denying Generic Defendants' motion for summary judgment. There is no reason to decide whether that error also was "obvious."

Ms. Sherman takes similar liberties with the record. Her brief improperly relies (at 7-8 n.4, 15-16) on websites describing legally irrelevant settlements in other cases. And she repeatedly cites materials that are not part of the summary judgment record because they were never "called to the attention of the trial court," RAP 9.12, including several pages of deposition testimony from Dr. Ben Merrifield. *Id.* at 12, 24-25 (citing CP Supp. at 940, 950).¹ She first submitted those materials as an

¹ The summary judgment record included only limited excerpts of Dr. Merrifield's testimony. *See* CP1 at 215, CP2 at 519-29, 739-44.

exhibit to a motion to bifurcate that she filed *after* this interlocutory appeal was already pending—and indeed, after the judge who ruled on the summary judgment motion had retired.

In addition to attempting to expand the record, Ms. Sherman makes several basic factual misstatements. For instance, she faults Teva for supposedly waiting “until March 2005” to include an “FDA-approved Black Box warning” on its package inserts, and she claims that PLIVA never made any such update. Sherman Br. 10-11. In fact, FDA did not approve a “black box warning” for Reglan *until 2009*. CP2 at 503, 517.²

Similarly, Ms. Sherman’s assertion (at 3, 12) that Dr. Silverman and his practice (GEA) first “learned of th[e] risk” associated with metoclopramide from “a letter [Dr. Silverman] received from Ms. Sherman’s counsel prior to the filing of this case” is directly contradicted by Dr. Silverman’s sworn testimony. Dr. Silverman explained that he “would always watch for movement disorders” at the time he prescribed Reglan to Ms. Sherman, which he did “as a last resort”

² Initially, Ms. Sherman correctly states that “the Black Box warning” was added to the Reglan label in 2009, but she contradicts that statement later in the same paragraph. Sherman Br. 10. She appears to conflate the 2009 label change with the 2004 label change. Notably, the 2004 label change did not add a “black box warning” or make *any* change to the label’s “Warnings, Precautions, or Contraindications” section. *See* Opening Br. 7. Further, PLIVA transferred its application to manufacture and sell generic metoclopramide in December 2008 (CP2 at 718), and there is no evidence that Teva did not incorporate the 2009 label change as soon as it was legally permissible.

because of the severity of her condition. CP1 at 190, 202. And far from suggesting that he “learned” of the drug’s risk from Ms. Sherman’s lawyer, Dr. Silverman lamented that her counsel’s letter to him “threatening legal action” forced his practice to give up “a clinically extremely useful tool,” which everyone at GEA “resent[ed] and regret[ted].” CP2 at 749; *see also* pp. 11-15, *infra*.

II. Ms. Sherman Has Abandoned Her Failure-to-Update Theory.

Ms. Sherman pursued two theories of liability in her summary judgment briefing: one premised on the Generic Defendants’ alleged “failure to update” their product labels for metoclopramide after FDA approved changes to Reglan’s label, and a second based on Generic Defendants’ alleged “failure to communicate” those label changes to the medical profession. Opening Br. 15-16. On appeal, Ms. Sherman has abandoned her failure-to-update theory. She leaves no doubt on her current position,³ stating emphatically that her “claims are *not about* what’s on the label” of Generic Defendants’ products. Sherman Br. 20; *see id.* at 29 (“Sherman’s claims against the generic manufacturers do *not* center on (or even raise) the inadequacy of the drug’s container label.”).

³ Ms. Sherman’s characterization of her claim is at odds with her pleading, which alleges that “adequate warnings and instructions were not provided with the [prescription drug] product[s]” manufactured by Generic Defendants. CP1 at 95.

Despite her vehemence, Ms. Sherman does an about face whenever her concession proves inconvenient. For example, in responding to Generic Defendants' preemption argument, Ms. Sherman focuses on case law addressing the same "failure-to-update claim" that she disavowed just pages earlier. Sherman Br. 34-41. Similarly, her contention that Generic Defendants breached a state-law duty under the WPLA relies unapologetically on the abandoned "failure-to-update" theory. *Id.* at 47, 48-49. Ms. Sherman cannot have it both ways. Her failure-to-update theory is not viable for multiple reasons, including Dr. Silverman's unrebutted testimony that he "did not read any package insert or container label associated with metoclopramide, at any time." Sherman Br. 22. She cannot tell the Court to disregard that theory, but then try to resurrect it in order to prop up her failure-to-communicate theory. Two legally defective theories do not add up to a viable claim.

III. The Summary Judgment Record and Controlling Precedent Preclude Ms. Sherman's Causation Theory.

A. *Douglas v. Bussabarger* Is Controlling.

Under *Bussabarger*, it has been the law for over 50 years that a plaintiff cannot sustain a failure-to-warn claim if the undisputed evidence shows that her doctor "did not read the labeling" provided by the drug company and instead "relied on his own knowledge." 73 Wn.2d at 478.

That well-established principle disposes of Ms. Sherman's claim against Generic Defendants. Dr. Silverman testified unequivocally that he relied on his own "clinical training and experience" when prescribing Reglan to Ms. Sherman, and that he does not read warnings from drug companies. Opening Br. 24-25.

Although Ms Sherman purports to distinguish *Bussabarger*, she repeatedly attacks the decision itself, which she brazenly calls "not well reasoned." Sherman Br. 1-2, 27-29. Those attacks are misplaced: As a decision of the Washington Supreme Court, *Bussabarger* binds this Court. Moreover, the majority of courts agree with *Bussabarger*, holding that "when a physician fails to read or rely on a drug manufacturer's warnings," the manufacturer's allegedly "inadequate warning" is not the proximate cause of the plaintiff's injuries. *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 856 (10th Cir. 2003). In the face of this case law, Ms. Sherman's reliance on an out-of-state decision that adopted the minority view (and expressly rejected Washington precedent) reveals the futility of her position. See Sherman Br. 29 (citing *Richards v. Upjohn Co.*, 95 N.M. 675, 680, 625 P.2d 1192 (1980)).

When Ms. Sherman actually engages with *Bussabarger*, she advances legally irrelevant distinctions. For instance, she contends (at 31)

that “the circumstances of the drug’s ingestion by the plaintiff were different” in that case because the doctor in *Bussabarger* administered the drug whereas here Dr. Silverman wrote a prescription. But an allegedly inadequate product warning is not the proximate cause of a plaintiff’s injuries in *either* scenario if her doctor did not read those warnings. Moreover, the learned intermediary doctrine refutes Ms. Sherman’s suggestion (at 31) that doctors cannot be expected to “seek[] ... out” warnings for products they prescribe. Under the doctrine, every doctor has a “duty to inform himself of the qualities and characteristics of those products which he *prescribes for* or administers to or uses on his patients.” *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978) (emphasis added); *see also McKee v. Am. Home Prods., Corp.*, 113 Wn.2d 701, 709, 782 P.2d 1045 (1989) (“a prescription drug manufacturer’s duty to warn ... runs only to the physician,” and the physician “owes the duty to the patient to monitor prescription drug usage”).

Ms. Sherman’s final attempt to explain away *Bussabarger* is also contrary to Washington law because it relies on a nonexistent “duty to communicate.” Sherman Br. 28-31. The WPLA does not impose any duty for drug manufacturers (or any other manufacturers) to deliver warnings separately from their products. *See* Opening Br. 43-47; pp. 18-

21, *infra*. Rather, Washington courts recognize that the foundation of prescription drug regulation in the United States is the warning that accompanies drug products, as federal law “requires manufacturers to accompany each package of prescription drugs with a package insert describing the drug and detailing its uses, contraindications, potential harmful effects, and directions to the physician for use.” *McKee*, 113 Wn.2d at 718 (citing 21 C.F.R. §§ 201.100(d), 201.56, 201.57). In any event, as discussed below, Ms. Sherman’s theory is built on multiple layers of speculation that cannot defeat summary judgment.⁴

B. Ms. Sherman’s Causation Theory Relies on Improper Speculation and Is Refuted by the Record.

In addition to its other flaws, Ms. Sherman’s failure-to-communicate theory is devoid of evidentiary support. Her assertion that letters or other communications from the Generic Defendants would have reached Dr. Silverman and prompted him to stop prescribing Reglan to Ms. Sherman relies on speculation and distortion of the record.

1. There is simply no evidence to suggest that Dr. Silverman ever would have reviewed a “Dear Doctor” letter or similar

⁴ The decision in *Hibbs v. Abbott Laboratories*, 62 Wn. App. 451, 814 P.2d 1186 (1991), is likewise irrelevant because the plaintiff there advanced a theory of liability that is not at issue here—*i.e.*, that the product was unreasonably dangerous *regardless* of whether the warnings were adequate. *Id.* at 457. Moreover, unlike in this case, the *Hibbs* Court noted that the plaintiff’s doctor “never said that he did not or would not have read the labeling” from the defendant’s product. *Id.*

communication from Generic Defendants regarding metoclopramide—much less that he would have changed Ms. Sherman’s prescription based on such a communication. As the trial court acknowledged but then immediately discounted, Dr. Silverman testified that he did not “read *anything*” that came from drug companies. RP (08/28/17) at 80 (emphasis added). Specifically, Dr. Silverman explained that his practice was to disregard letters from drug companies—they are placed in a “stack of mail” that he “never open[s]”—and to prevent drug company representatives from even entering his office. CP1 at 175-78, 208. This undisputed testimony completely undermines Ms. Sherman’s failure-to-communicate theory.

Undeterred, Ms. Sherman suggests that even though Dr. Silverman would not have read letters from Generic Defendants or listened to their representatives, Generic Defendants could have educated *other* doctors about the risks allegedly associated with metoclopramide who, in turn, might have passed the warnings on to Dr. Silverman. According to Ms. Sherman (at 26) Dr. Silverman’s “peers/colleagues *do* read Dear Doctor letters or otherwise pay attention to warnings issued by drug companies.” Notably, Ms. Sherman does not cite any evidence to support her claim. There is none. Nor does Ms. Sherman identify any particular

“peers/colleagues” who would have read hypothetical letters from Generic Defendants (but for some reason did not read the publicly available Reglan label itself) and would have discussed those letters with Dr. Silverman. Instead, she refers (at 20) to the vague possibility that Generic Defendants could have communicated about the Reglan warnings with unspecified individuals “in the physician community whose opinion [Dr. Silverman] deems important.”⁵ That is not an argument based on *evidence*. Rather, Ms. Sherman wants a chance to invite a jury to engage in conjecture. Controlling precedent makes clear that she may not do so. *See, e.g., Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 258, 978 P.2d 505 (1999). On summary judgment, Ms. Sherman had to make a factual “showing sufficient to establish an element essential to [her] case ... on which [she] will bear the burden of proof at trial.” *Briggs v. Nova Servs.*, 166 Wn.2d 794, 833, 213 P.3d 910 (2009). She failed to do so.

2. Lacking evidence to support her argument, Ms. Sherman fixates on a policy that Dr. Silverman’s practice first adopted in 2013 under the threat of litigation from Ms. Sherman’s own lawyer.

⁵ Indeed, Ms. Sherman implicitly admits that she has no evidence that those unidentified colleagues did not know the risks of metoclopramide. The best she can do is assert that they “*presumably*” were unaware of such risks, which she surmises is the reason they never discussed metoclopramide with Dr. Silverman. Sherman Br. 12 (emphasis added).

Sherman Br. 2-3, 12, 19, 23-25. According to Ms. Sherman, her attorney was the first person to apprise Dr. Silverman or anyone else at GEA about the risks associated with metoclopramide, and GEA then acted based on that information by adopting an informed-consent policy for Reglan. Ms. Sherman further surmises that GEA would have adopted a similar policy years earlier if Dr. Silverman had received similar warning information from Generic Defendants. The summary judgment record refutes her narrative.

The relevant evidence is clear and un rebutted: Dr. Silverman and three of his GEA colleagues *all* testified that GEA adopted its 2013 policy because Dr. Silverman was threatened with a lawsuit—*not* because Ms. Sherman’s lawyer provided new information about metoclopramide. *See* Opening Br. 31-32. In particular:

- Dr. Silverman testified that he understood that Ms. Sherman’s counsel was “intending to file a lawsuit ... naming [him]” and that GEA needed to change its policy “to reduce the risk of our company” given its “susceptibil[ity] to having lawsuits” “regardless of our long-term experience with [metoclopramide].” CP1 at 209, CP2 at 747-78. Dr. Silverman made clear that “[t]he only impact” his interaction with Ms. Sherman’s lawyer had on GEA’s “medical practice was that, as a result of his threatening legal action against us, our group then produced a—disclaimer letters and notifications.” CP2 at 749. He added that everyone at GEA “resents and regrets” the practice’s diminished ability to prescribe metoclopramide “because of threats of lawsuits.” *Id.*

- Dr. Ben Merrifield, a gastroenterologist at GEA, testified that the 2013 policy was adopted based on the recommendation of GEA’s “managers ... in the setting of what they said was a lawsuit against one of the partners,” *i.e.*, Dr. Silverman. CP1 at 215.
- Kelly Auvinen, a nurse and GEA’s Director of Operations, testified that the 2013 policy “came about because Dr. Silverman was potentially in a lawsuit regarding the risk of tardive dyskinesia and he was worried that whoever was suing him was going to somehow sue the other providers in the practice.” CP2 at 594-95.
- Terri Stabnow, a nurse at GEA, testified that “to the best of [her] knowledge,” the 2013 policy was created “because there was a potential lawsuit against Dr. Silverman for prescribing Reglan.” CP1 at 220.

Ms. Sherman has not identified any evidence to rebut that testimony. Nor did the trial court. Rather, the court suggested that a jury might “disbeliev[e]” the uniform testimony from four GEA employees on this issue. RP (08/28/17) at 79. But that improperly relieved Ms. Sherman of her burden to come forward with evidence. An unsupported challenge to the credibility of these four witnesses provides no basis to overcome summary judgment; Ms. Sherman cannot proceed to 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) (quotation marks omitted).

Ms. Sherman fails to address this uniform testimony from four GEA employees stating that GEA adopted the policy in response to

litigation threats. Instead, she cites snippets of testimony that she takes out of context, and which do not support her causation argument anyway. Ms. Sherman asserts (at 24) that Dr. Merrifield “testified that he had no knowledge of the gravity of risk associated with prolonged metoclopramide use.” That is just wrong. In fact, Dr. Merrifield (who first met Ms. Sherman during this lawsuit) testified that it “wouldn’t [have] change[d] anything” at GEA if they had received a letter describing the Reglan label updates. CP Supp. at 964.⁶ As Dr. Merrifield explained, the information contained in the Reglan 2009 black box warning was “consistent with what” the doctors at GEA “already knew.” *Id.* at 965.

Resisting that clear testimony, Ms. Sherman insists (at 24-25) that Dr. Merrifield must not have been aware of the true risks associated with Reglan because he testified that movement disorders were a rare side-effect from the drug that occurred in only about 1 in 500 patients. CP Supp. at 950-51. Ms. Sherman fails to mention, however, that during the entire time she was prescribed Reglan, the FDA-approved label contained the same “1 in 500” risk estimate that she now attacks—even after the 2004 and 2009 revisions. CP2 at 690-91 & n.4. The fact that

⁶ As noted, p. 3, n.1, Generic Defendants object to Ms. Sherman’s reliance on excerpts from Dr. Merrifield’s deposition that were not in the summary judgment record. But if the Court considers this evidence, it should review his full deposition testimony.

Ms. Sherman disputes that risk assessment (at 25 n.8, 29 n.11) is legally irrelevant because Generic Defendants were *prohibited* from sending communications that contradicted the Reglan labeling. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 615, 131 S. Ct. 2567 (2011).⁷

C. Ms. Sherman Relies on Inapposite Case Law.

Ms. Sherman conspicuously ignores the many decisions that echo the Washington Supreme Court's holding in *Bussabarger*. Opening Br. 23-24 & n.4, 30. For example, she does not even try to distinguish *Pustejovsky v. PLIVA, Inc.*, 623 F.3d 271 (5th Cir. 2010). Nor could she: The case involved the same drug and warnings at issue here, and the Fifth Circuit rejected as "speculat[ive]" the same basic causation theory pressed by Ms. Sherman—*i.e.*, that even though the plaintiff's doctor could not recall reading the generic manufacturer's package inserts, the warning might have "come up in conversations with other physicians." *Id.* at 277.

The cases that Ms. Sherman discusses instead are inapposite. She relies most heavily on *Winter v. Novartis Pharm. Corp.*, 739 F.3d 405 (8th Cir. 2014), which applied Missouri law to claims against a brand drug

⁷ Ms. Sherman also references the testimony of Kelly Auvinen, which Ms. Sherman claims "corroborated the premise" that GEA adopted its policy after learning new risk information from "Mr. Pittle's letter." Sherman Br. 25 (citing CP2 at 592). Again, that is just wrong. Ms. Auvinen, a nurse who "d[id]n't prescribe Reglan" (CP2 at 596), stated only that she "d[id]n't remember" whether she had been aware of the black box warning when she helped develop the informed consent policy (*id.* at 592). And as discussed, she testified that the policy "came about" because of Mr. Pittle's legal threats. *Id.* at 594-95.

manufacturer. *Winter* is easily distinguishable. The case involved an existing relationship between the defendant's sales representative and the doctor, and the court's analysis focused on testimony that (1) the plaintiff's treating physician obtained warnings from the brand manufacturer's "sales representatives," and (2) the brand manufacturer took affirmative steps to "prevent[]" warnings from reaching the plaintiff's doctor, including by "instruct[ing] its sales force not to mention the disease" allegedly caused by its product. *Id.* at 408-09. In short, the decision turned on the manufacturer's duty to speak completely and truthfully about a product's risks when touting that same product's benefits. That is not the situation here. To the contrary, Dr. Silverman testified that he did *not* rely on information from sales personnel; indeed, he did not even "allow them in [the] office." CP1 at 208.⁸ And there is absolutely no evidence to suggest that Generic Defendants tried to suppress information about metoclopramide.

In fact, there is no evidence that Generic Defendants ever employed sales representatives for metoclopramide. Rather, Ms. Sherman

⁸ The two decisions referenced for support in *Winter* also involved suits against brand manufacturers, and the court in *In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012), specifically relied on the possibility that the plaintiff's doctor might have learned about a warning disseminated by "sales representatives." *Id.* at 1169; *see also Hanrahan v. Wyeth, Inc.*, No. 04-cv-1255, 2012 WL 2395881, at *10 (E.D. Mo. Jun. 25, 2012).

concedes that, “[a]s a practice,” generic drug manufacturers do not have sales representatives who call on doctors about their drugs. CP1 at 99; *see also New York v. Actavis, PLC*, No. 14-cv-7015198, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014) (explaining that generic manufacturers “avoid marketing to physicians,” which is contrary to their business model). Ms. Sherman further admits that doctors do “not” typically rely “on information supplied by manufacturers of the generic versions” of a drug. *Id.* at 99, 103. Certainly Dr. Silverman did not rely on information from Generic Defendants—indeed, he did not even know which companies manufactured the metoclopramide that Ms. Sherman received. CP1 at 173. Notably, given those features of the generic drug market, the Eighth Circuit *declined* to extend *Winter*’s reasoning to a failure-to-warn case against manufacturers of generic metoclopramide. *See Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1138 (8th Cir. 2014).

The remaining cases referenced by Ms. Sherman (at 26-27 & n.10) do not support her attempt to establish causation in the face of Dr. Silverman’s testimony that he never read warnings from drug companies. Rather, those cases are, at best, relevant only to Generic Defendants’ *separate* argument that Dr. Silverman was familiar with the risks from metoclopramide independent of the product warnings. *See*,

e.g., *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 82 (1st Cir. 1992).⁹ Ms. Sherman’s argument on this issue lacks merit because she cannot identify any warnings in the Reglan label that Dr. Silverman did not understand. *See* Opening Br. 26-27. But completely separate from this issue, Generic Defendants are entitled to summary judgment because there is no evidence to suggest that Dr. Silverman would have read and relied on warnings from Generic Defendants. *See Pustejovsky*, 623 F.3d at 276-78 (affirming summary judgment *despite* evidence that the plaintiff’s doctor was not aware of the risks associated with metoclopramide because the plaintiff provided no “evidentiary support” for her speculation that updated warnings “might have reached” her doctor).

IV. Washington Law Does Not Impose a Duty for Generic Manufacturers “To Communicate” Warnings Separately From the Package Inserts Accompanying Their Products.

A. Ms. Sherman Does Not Identify any WPLA Provision That Supports Her Failure-To-Communicate Theory.

Generic Defendants also are entitled to summary judgment because Ms. Sherman’s failure-to-communicate theory has no foundation in the WPLA. Ms. Sherman’s multiple attempts to find a foothold in the text of

⁹ Notably, in the *majority* of the cases that Ms. Sherman references, the court held that causation could *not* be established. *See Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 817 (5th Cir. 1992); *Plummer v. Lederle Labs.*, 819 F.2d 349, 358-59 (2d Cir. 1987); *Stanback v. Park, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981); *Windham v. Wyeth Labs., Inc.*, 786 F. Supp. 607, 613 (S.D. Miss. 1992).

the WPLA for her theory all fail.

First, Ms. Sherman invokes (at 46-47) paragraph (b) of RCW § 7.72.030. As Ms. Sherman admits (*id.*), however, that provision is expressly limited to warnings provided “with the product.” RCW § 7.72.030(b). Thus, Ms. Sherman is only able to contend (at 47) that her failure-to-update claim implicates that provision—*not* that it provides any support for her separate failure-to-communicate theory. But Ms. Sherman stipulated that her claim is “*not about* what’s on the label” of Generic Defendants’ products. *See* p. 5, *supra*. Paragraph (b) thus provides no support for Ms. Sherman’s failure-to-communicate theory.

Second, Ms. Sherman invokes (at 47) paragraph (c) of RCW § 7.72.030. But the duty recognized in that provision only applies if a manufacturer first “learned about a danger connected with the product *after* it was manufactured.” RCW § 7.72.030(c) (emphasis added). Ms. Sherman never has alleged—much less introduced evidence to prove—that Generic Defendants learned about the risks associated with Reglan after manufacturing and distributing the metoclopramide that Ms. Sherman ingested. To the contrary, she has alleged those risks became well known as a result of studies dating back to the 1980s and 1990s. CP1 at 67. By its clear terms, paragraph (c) does not apply here.

Third, Ms. Sherman reaches outside the WPLA entirely to argue that she has a viable claim under RCW § 5.40.050—a provision that allows the trier of fact to treat the breach of duties “imposed by statute, ordinance, or administrative rule” as evidence of negligence. Sherman Br. 48-49. Ms. Sherman did not plead any negligence claim based on this provision (CP1 at 94), and she does not cite any precedent applying it in a products-liability case governed by the WPLA. Moreover, that sort of negligence-per-se theory is preempted by federal law. See p. 23, *infra*. Even aside from those problems, Ms. Sherman’s argument fails because it is disconnected from the failure-to-communicate theory that she is ostensibly defending. Federal law did not impose any duty on Generic Defendants to send “Dear Doctor” letters or other warnings separately from their products, and Ms. Sherman never argues otherwise.

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

Ms. Sherman’s attempt to explain away common-law precedent fares no better. Ms. Sherman concedes that Section 402A of the Second Restatement recognizes a duty to warn that *only* requires the “provision of warnings on the container label.” Sherman Br. 48. She nonetheless argues that the WPLA imposes “different, and more comprehensive warning requirements.” *Id.* Ms. Sherman offers no case law support for

her assertion, and it is contradicted by precedent recognizing that “the WPLA ... closely mirrors the Restatement (Second) of Torts § 402A.” *Taylor v. Intuitive Surgical, Inc.*, 187 Wn.2d 743, 754, 389 P.3d 517 (2017); *see also* RCW § 7.72.020(1). The minor textual difference on which Ms. Sherman relies—*i.e.*, that the Restatement refers to warnings “on the container” of a product, whereas the WPLA refers to warnings “with the product”—is far too slender a reed to support her argument.

Finally, Ms. Sherman fails to distinguish case law applying the learned intermediary doctrine, which establishes that a drug manufacturer satisfies its duty to warn if the manufacturer’s product “carries the necessary instructions and warnings.” *Terhune*, 90 Wn.2d at 14; *see* Opening Br. 46. Ms. Sherman reprises her contention that the doctrine should apply differently to prescription drug products that a doctor did not personally “administer[.]” and were instead “dispensed ... by a pharmacy.” Sherman Br. 49-50. *Terhune* refutes that argument, as the Washington Supreme Court explained that the learned intermediary doctrine applied to products “available only on prescription *or* through the services of a physician.” 90 Wn.2d at 14 (emphasis added).

V. **Ms. Sherman's Claim Is Preempted by Federal Law.**

Ms. Sherman's failure-to-warn claim also is preempted by federal law. Her arguments to the contrary elide case law that rejects her theory and fail to engage with controlling federal regulations.

Curiously, Ms. Sherman devotes much of her preemption argument to the failure-to-update theory that she repudiated. Sherman Br. 36-41. There is no reason for the Court to decide that preemption issue given Ms. Sherman's affirmation that she is not pursuing a claim based on the alleged "inadequacy of the drug's container label." *Id.* at 29.

In any event, Ms. Sherman cannot distinguish *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012 (2001), which held that state-law claims that turn on alleged violations of the FDCA or FDA regulations are preempted by federal law. *Id.* at 353. Ms. Sherman insists (at 40-41) that her claim merely "parallel[s]" federal requirements "but is rooted in state tort law." Her brief belies that characterization. Specifically, Ms. Sherman alleges (at 29 n.11) that the Reglan label *remains* inadequate because it "still" contains "misleading information," and she admits that Generic Defendants were legally required to use that warning. It thus makes no sense to assert that Generic Defendants violated a "parallel" state-law duty when they allegedly failed to adopt changes to match the "misleading" Reglan label. *Id.* State tort law does

not impose liability “for failure to attach an inadequate label”—indeed, the very idea is “logically incoherent.” *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013).

Instead, Ms. Sherman quite clearly is trying to hold Generic Defendants liable for allegedly violating *federal* labeling requirements, based on their purported failure to update their labels to match the Reglan label. She makes this point explicitly by arguing (at 48) that she can establish a claim under RCW § 5.40.050 based on Generic Defendants’ alleged “fail[ure] to comply with federal labeling requirements.” Ms. Sherman’s attempt to enforce federal law under the guise of state tort law is *exactly* what *Buckman* forbids.¹⁰

When Ms. Sherman finally turns to her failure-to-communicate theory (at 42-45), she ignores the overwhelming weight of authority holding that claims based on this theory are preempted.¹¹ Instead, she

¹⁰ See, e.g., *Metz v. Wyeth LLC*, 872 F. Supp. 2d 1335, 1343 n.9 (M.D. Fla. 2012) (“[A] private action alleging that Actavis breached a[] duty to Plaintiffs by failing to abide by FDA requirements must be dismissed.”); *Kapps v. Biosense Webster, Inc.*, 813 F. Supp. 2d 1128, 1151-52 (D. Minn. 2011) (“A negligence-per-se claim that is predicated on an alleged violation of the [Federal Food, Drug, and Cosmetic Act] ... is preempted.”); *Abicht v. PLIVA, Inc.*, Nos. 12-cv-1278, -2172, 2013 WL 141724, *3 (D. Minn. Jan. 9, 2013) (holding that a failure-to-update claim involving metoclopramide was preempted, and explaining that “[w]here federal law supplies the duty, a state claim to enforce that duty is, in substance if not in form, a cause of action under federal law”).

¹¹ See Opening Br. 39 & n.6 (citing *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 917, 932-33 (6th Cir. 2014); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir.

relies on a handful of state court decisions that adopted the minority view rejecting preemption, as well as an *amicus curiae* brief filed by the U.S. Solicitor General in 2013. *See id.* Those decisions (and the brief) rely on the premise that Generic Defendants could have sent Dear Doctor letters about updates to the Reglan label even though the Reglan manufacturer did not. That premise is inconsistent with both FDA regulations and the U.S. Supreme Court's *Mensing* decision.

Generic drug manufacturers may not communicate warnings that differ in language *or* “*emphasis*” from the warnings for the corresponding brand. 21 C.F.R. 201.100(d)(1) (*emphasis added*). Ms. Sherman’s argument (and the authority she relies on) focuses on the same “language” requirement, while overlooking the same “emphasis” rule. That omission is critical because the very act of sending a “Dear Doctor” to tout a new warning inherently conveys information about the warning’s “emphasis.” Opening Br. 40. For that reason, “if generic drug manufacturers, but not the brand-name manufacturer, sent such letters,” it “would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading.’” *Mensing*, 564 U.S. at 615.

2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013)); *see also* Opening Br. 39 n.7 (citing federal district court and state court decisions that reach the same conclusion).

Ms. Sherman's brief does not even *cite* this key regulation, much less grapple with its significance. As a result, her response to Generic Defendants' preemption argument is incomplete and flawed.

CONCLUSION

This 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 2nd day of November, 2018.

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