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

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**BRIEF OF RESPONDENT DIANA SHERMAN**

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## I. Introduction.

Appellants Pliva, Inc., Teva Pharmaceuticals, Inc., and Barr Laboratories, Inc. (the “Generic Defendants”) sought this interlocutory appeal hoping to avoid responsibility for the injuries that Plaintiff-Respondent Diana Sherman sustained as a result of prolonged exposure (continuous ingestion over six years) to the metoclopramide drug that they manufactured. They do so notwithstanding their knowledge that exposure beyond just twelve weeks carried with it a substantial and rising risk of the permanent disfiguring and disabling conditions of tardive dyskinesia and tardive akathisia from which Mrs. Sherman now suffers and their failure to communicate that information to the physician who instructed her to take it. The trial judge, who presided over this case for the five-year period preceding this appeal, concluded in August 2017 that genuine fact issues exist for trial concerning whether Generic Defendants could be held at least partially<sup>1</sup> responsible for Mrs. Sherman’s life-altering injuries, given that they knew of those risks throughout the time that she ingested the harmful drug and yet made no attempt to communicate them to those in

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<sup>1</sup> In its current posture, the trial would also encompass Mrs. Sherman’s claims against her prescribing physician, Dr. Bruce Silverman, and his medical practice, Gastroenterology Associates PLLC (“GEA”) (Dr. Silverman and GEA referred to collectively as the “Physician Defendants”). As explained *infra*, Notes 4 and 7, the jury would also be entitled to attribute liability to other defendants who have previously settled, including all of the manufacturers of the brand-name drug Reglan (whose product Mrs. Sherman never ingested) and two other manufacturers of the generic version metoclopramide.

the physician community, who were in the best position to use that information to protect patients like Mrs. Sherman from injury. The trial court therefore set this case for trial so that those fact issues could be tried to a jury with instructions to apportion fault among all of the potentially-responsible defendants.

Generic Defendants ask this Court to reverse the trial court's denial of their motion for summary judgment notwithstanding these factual disputes, contending that they should escape liability on three legal grounds, but each fails as a matter of law. First, the Generic Defendants contend that Mrs. Sherman cannot establish a causal connection between their communication failures and Mrs. Sherman's injuries. This contention rests entirely on the testimony of her prescribing physician (defendant Dr. Silverman) that he does not read drug package warning labels for the medicines he prescribes. Generic Defendants suggest this testimony compels judgment as a matter of law in their favor under a 50-year-old Washington Supreme Court case, *Douglas v. Bussabarger*, 73 Wn.2d 476, 478, 438 P.2d 929 (1968). This argument, however, suffers from two fatal flaws. First, and perhaps foremost, it ignores other record evidence which creates a genuine dispute of material fact regarding causation, *i.e.*, testimony from other members of the GEA partnership and staff which establishes that had the Generic Defendants communicated the

drug's approved warnings adequately, such as in the form of "Dear Doctor" letters or reprints of published scientific research, they would have shared that information with the entire partnership and changed their prescribing practices. Indeed, the record shows that once GEA became aware of the drug's dangers (which occurred only when Mrs. Sherman's trial counsel contacted them about her injuries prior to filing suit – notably, *not* as a result of any communication from any of the manufacturer-defendants), they in fact *did* change their policy, which now disfavors prescribing metoclopramide for any longer than 12 weeks due to risk of the very injuries that Mrs. Sherman sustained by ingesting it for over six years.

Second, the Generic Defendants' causation argument also fails because, even setting aside the factual disputes described above, the *Douglas* case is inapposite in any event. The *Douglas* court concluded that the doctor's testimony that he did not read the label on the injurious drug's package before administering it negated the causal connection between the lack of a warning label and the plaintiff's injuries. That case is therefore quite different, factually, from this one, in that it involved a doctor administering a drug (during surgery) from a labeled container, rather than prescribing it for filling at a pharmacy (from a container which should have been but was not labeled with new warnings that none of the

plaintiff's doctors had ever seen), and it centered only on the adequacy of the drug package's label, not, as here, the manufacturers' failure to communicate new, stronger warnings that the FDA mandated because the previous warnings were found to be inadequate. In the context of the distinguishable facts in this case, Generic Defendants' argument overstates the irrelevant 50-year-old holding in *Douglas*. The record contains evidence sufficient to support a jury's finding of a causal connection between the Generic Defendants' failure to communicate adequate warnings regarding the dangers of prolonged exposure to metoclopramide and plaintiff Sherman's injuries, and the trial court properly denied summary judgment on that basis.

The Generic Defendants' alternative arguments, premised on preemption and the existence of a legal duty, fare no better than their defective causation argument. As to preemption, the trial court correctly found viable Mrs. Sherman's claims that Generic Defendants violated Washington's product liability law when they failed to update their product labels or communicate updated warnings to the physician community. Attempting to avoid this undesirable result, Generic Defendants ask this Court to extend the United States Supreme Court's decision in *Pliva, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567 (2011), well beyond its original scope. Premised on the "sameness" requirement

of federal law, *i.e.* that a generic drug manufacturer cannot make unilateral changes to a label approved by the FDA for use on the brand-name version, *Mensing* held only that a state cannot require a generic manufacturer to provide different warning labels than federal law mandates of brand manufacturers, because compliance with both federal and state law would then be impossible. Generic Defendants' argument is premised on a much broader application of that principle, to include within the preemptive ambit of federal law any claim related to provision of information about the drug, even where such information is the same as that approved for use on the label. Their contention is not only unsupported by the law, but even contradicted by the recent decisions of at least four state supreme courts<sup>2</sup> and the United States Solicitor General on behalf of the FDA, all of which rejected arguments like Generic Defendants' here, and held that the *Mensing* preemption, which must be construed narrowly, did not reach claims not involving the "sameness" requirement because they are of an entirely different ilk.

Finally, the trial court properly concluded that Washington law imposes a duty on drug manufacturers to disseminate accurate information about their products. Generic Defendants ask this Court to hold otherwise,

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<sup>2</sup> Generic Defendants' petitions for a writ of certiorari to the United States Supreme Court following three of those four state supreme court decisions that rejected their arguments were all denied.

but their argument ignores established Washington law supporting Sherman's claims, *i.e.*, that under RCW 5.40.050, a breach of a duty imposed by statute may be considered as evidence of negligence. The trial judge's conclusion that a company manufacturing drugs for sale within the State of Washington owes a general duty to avoid negligence regarding its communication of warnings is not erroneous, and Generic Defendants offer no viable basis to overturn it.

As explained in more detail below, the Generic Defendants' arguments do not support reversing the trial court's decision, informed by presiding over the case for five years, that their liability for failure to communicate adequate warnings to physicians like Dr. Silverman and his partners must be submitted to a jury. Because genuine fact issues exist for trial, this Court should affirm the trial court's denial of summary judgment and allow this case to proceed to trial against all remaining defendants.

## **II. Statement of the Case.**

### **A. Mrs. Sherman's Ingestion of Metoclopramide for More than Six Years, and Her Prescribing Physician's Lack of Knowledge of the Drug Manufacturer's Increasingly Intense Warnings Regarding the Severity of Risk Associated With Use Exceeding Twelve Weeks.**

The central facts relevant to this appeal are relatively straightforward. Plaintiff-Respondent Diana Sherman ingested generic metoclopramide as prescribed by her doctor for a continuous period

exceeding six years, from September 2004 to December 2010. (CP 443-448, 481-89, 541.) Her physician, defendant Dr. Silverman, prescribed metoclopramide to treat digestive ailments that were causing stomach pain. (*Id.* at 183-84.)

Generic Defendants manufactured most of the metoclopramide that Mrs. Sherman ingested in accordance with her doctor's advice.

Throughout the time that Mrs. Sherman was taking metoclopramide, the manufacturers' drug packaging included warnings regarding risks associated with its use, which evolved in their strength and severity over that time. As of early 2004, the package insert contained no reference to any suggested cap on the duration of treatment and indicated only that "Therapy longer than 12 weeks has not been evaluated and cannot be recommended." (CP 716<sup>3</sup>)

In February 2004, defendant Schwarz Pharma,<sup>4</sup> who was then the manufacturer of the brand version of the drug, Reglan, received the federal

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<sup>3</sup> Generic Defendants submitted the 1988 Physician's Desk Reference as Exhibit 14 to their Memorandum in Support of Motion for Summary Judgment and identified that exhibit as the Reglan Drug Label (CP 708, 712-716.) The statement "Therapy longer than 12 weeks has not been evaluated and cannot be recommended," is found on CP 716 in the section entitled **Dosage and Administration** at the bottom of the information presented to physicians who wish to use Reglan (or generic metoclopramide) to treat patients **For the Relief of Symptomatic Gastroesophageal Reflux**. See also *In re Reglan Litigation*, 226 N.J. at 321-22 (discussing labeling history).

<sup>4</sup> As reflected in Mrs. Sherman's pharmacy records, she did not ingest any of the brand version of the drug, whether manufactured by defendant Schwarz Pharma or its predecessors in interest Defendants A.H. Robins Company, Inc. and Wyeth (whom plaintiff contends intentionally misled doctors with a ghost-authored and fraudulent

Food and Drug Administration (“FDA”)’s approval to amend the drug’s insert to state explicitly, in two locations in bold type, that “**Therapy should not exceed 12 weeks in duration.**” *In re Reglan Litigation*, 226 N.J. 315, 336, 142 A.3d 725, 738 (2016). However, at the time Mrs. Sherman’s physician first prescribed metoclopramide to her in September 2004, the Generic Defendants had not added these warnings to package inserts shipped with the drugs to pharmacies. *Id.* Consistent with normal practice, Mrs. Sherman did not receive the package insert when her pharmacy dispensed the first metoclopramide prescription that was filled. Instead, she did receive a patient information monograph that was prepared by the pharmacy but nowhere did that patient information monograph tell her that the drug should not be used beyond 12 weeks. (CP 443-448, 473-474.) The current form of the requirement is expressed as a

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medical-journal article), (CP 852-872), or the subsequent brand Reglan manufacturer Alaven, Inc., which added a black box warning to the label in 2009. (CP 481-489.) Nevertheless, the brand manufacturers originally named in this lawsuit have all now contributed substantial but confidential sums to settle with Mrs. Sherman. Plaintiff also reached confidential but substantial settlements with two other generic manufacturers who, like Defendants Teva and PLIVA, also failed to communicate the new warnings to plaintiff’s physicians. Pursuant to RCW 7.70.080, these contributions will be applied as offsets to reduce, but not eliminate, the financial responsibility of the remaining defendants. Because of the serious brain damage injuries and economic damages suffered by plaintiff, she and her counsel believe that she is entitled to a very substantial verdict to fully compensate for the injuries caused by the cumulative wrongdoing among all of the defendants, all of whom will appear on the verdict form. Prior litigation involving Reglan and generic metoclopramide in other jurisdictions has resulted in several multi-million-dollar jury verdicts and hundreds of millions of dollars of settlements. *See Reglan and Tardive Dyskinesia Lawsuits*, available at ,” <https://www.drugwatch.com/reglan/lawsuits/> (last visited Sept. 18, 2018.)

Medication Guide.

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide.page>

Indeed, although Defendant Teva eventually added this warning to the package insert information that it sent to pharmacies, Defendant Pliva never distributed package inserts with the revised warning. *In re Reglan Litigation*, 226 N.J. at 336; *see also Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 359 (Iowa 2014) (“Although required by federal regulations to mirror the brand defendant's label, PLIVA did not update its metoclopramide packaging to include the new warning approved in 2004. The record is silent as to why PLIVA failed to add that warning.”); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 580 (6th Cir. 2013) (“Apparently, PLIVA never updated its metoclopramide labeling to include the new [2004] warning, nor communicated the change to any physicians.”). And neither Generic Defendant ever communicated these revised warnings to physicians or the physician community, as by a Dear Healthcare Provider letter or otherwise. (CP 554-55); *In re Reglan Litigation*, 226 N.J. at 336. As a result of these failures, neither Mrs. Sherman, nor, as explained below, her prescribing doctor, ever knew at any time throughout the six-year period that she continuously ingested metoclopramide, taking 10 mg tablets two

to three times daily, that the manufacturer was required by the FDA to warn against use in excess of 12 weeks. (*Id.* at 446)

Acting on an FDA mandate, then-brand-manufacturer Alaven again upgraded the drug's warnings in 2009 by adding a prominently-displayed "Black Box warning," which explained that use of metoclopramide for more than 12 weeks is not recommended due to its known link to tardive dyskinesia, a potentially permanent neurologic condition.<sup>5</sup> (*Id.* at 476-79.)

Specifically, the Black Box label warns as follows:

**WARNING: TARDIVE DYSKINESIA**

Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. The risk of developing tardive dyskinesia increases with duration of treatment and total cumulative dose. Metoclopramide therapy should be discontinued in patients who develop signs or symptoms of tardive dyskinesia. There is no known treatment for tardive dyskinesia. In some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped. Treatment 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.

Generic Defendant Teva did not begin including this FDA-approved Black Box warning on inserts shipped with the metoclopramide they manufactured until March 2005, nine months after Dr. Silverman first prescribed metoclopramide to Mrs. Sherman, and while they published the

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<sup>5</sup> As in 2004, the FDA approved modifying the Reglan label to add this Black Box warning in 2009, in accordance with applicable federal law.

new warnings on their company websites, they never actually provided the new warning information directly to physicians. *Id.* Pliva never did update their label. *Id.*

Neither Dr. Silverman nor any of his partners had knowledge of any of these changes in the drug's label, or of the increasing severity of risk associated with prolonged exposure as pronounced on the FDA's approved label, throughout the time that he instructed Mrs. Sherman to take it. (CP 175, 533, 953.) Dr. Silverman specifically testified that he does not read prescription drug labels, which are placed on or within the containers of their medication which is distributed to pharmacies, and therefore may never actually pass across the prescribing physician's desk. (*Id.* at 533, 536.) In addition to not reading drug labels, Dr. Silverman testified further that he typically does not read information received in the mail from pharmaceutical companies, and that in any event he never received any information regarding metoclopramide from any of the manufacturer-defendants in this case. (*Id.* at 533-37.) As to the source of his knowledge regarding drug indications and risks, he testified that he instead relies upon his clinical experience and the experience of colleagues, associates and mentors. (*Id.*)

Dr. Silverman did not learn of the serious risk of tardive dyskinesia associated with prolonged use of metoclopramide from any colleague,

associate or mentor, however (presumably, because they never knew either). Instead, he learned of that risk in a letter he received from Mrs. Sherman's counsel prior to the filing of this case, in 2013. (CP 747.) Shortly after receiving that information, GEA adopted a new practice-wide policy which advises against prescribing metoclopramide for any period exceeding 12 weeks. (CP 824-27, 936-38.) In other words, as soon as they became aware of the content of the Black Box warning – *i.e.* that prolonged overexposure to the drug can cause the permanent nerve conditions tardive dyskinesia and akathisia – they immediately changed their practice to discourage prescribing it for use any longer than 12 weeks except in the rarest circumstances and to require written informed consent from the patient. (*Id.*)

The information finally sent by Mrs. Sherman's counsel came too late to benefit her. She had by then taken metoclopramide continuously for more than six years, and she already displayed symptoms of tardive dyskinesia. (CP 448.) Her symptoms include distorting, embarrassing, and ultimately disabling abnormal involuntary movements of her face, neck, limbs and torso, as well as anxiety and restlessness of such a severity that they have led to suicide in other patients. (CP 1-2, 58, 237-238, 768.) It is undisputed for purposes of this appeal that these

symptoms are attributable to her consumption of metoclopramide for a period greatly exceeding the recommended 12 weeks.

B. Procedural Posture.

Mrs. Sherman filed this lawsuit in the Grays Harbor County Superior Court, State of Washington, on October 31, 2013, seeking damages for the disfiguring and debilitating conditions that she suffers as a result of her prolonged toxic exposure to metoclopramide. (CP 1-56.) She filed an Amended Complaint on January 8, 2014. (CP 57-121.) Her Complaints identify as defendants the Generic Defendants who brought this appeal, as well as other manufacturers of the generic- and brand-versions of the drug who have now all resolved Sherman's claims against them by confidential settlement agreement. The Complaint also asserts claims against the pharmacy and pharmacists who dispensed the injurious metoclopramide to her,<sup>6</sup> and against Dr. Silverman and his medical practice GEA.

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<sup>6</sup> Mrs. Sherman claims that the pharmacists who dispensed metoclopramide for six years on Dr. Silverman's orders failed to inform her that he was prescribing metoclopramide far beyond the length of use approved by the FDA and that they failed to inform her of changes to the patient information monographs that accompanied each filling, which changes carried FDA-mandated stronger warnings. Her claims implicated patient-counseling requirements of Board of Pharmacy regulations adopted in 2001. *See*, CP247-249. The trial court granted the pharmacy defendants' motion for summary judgment, a ruling which Mrs. Sherman contests as erroneous due to its reliance on a Washington Supreme Court case, *McKee v. American Home Products, Corp.* 113 Wn.2d 701, 705, 782 P.2d 1045 (Wash. 1989), which has been superseded by the 2001 pharmacy board regulations. *See* WAC 246-869-220; 42 U.S.C. § 1396r-8. Once the Generic Defendants sought interlocutory review in this Court, Sherman also asked this Court to review the trial court's erroneous ruling on the pharmacy defendants' motion for

Early in the litigation, all of the Generic Defendants filed a motion for judgment on the pleadings, asking the trial court to dismiss the product liability and common-law negligence claims asserted against them based on essentially the same arguments they now present in this appeal – preemption, and absence of causation and legal duty. (*See* RP1 at 3.) The trial court denied their motion, finding that any concerns regarding the preemptive scope of federal law could be addressed on motions *in limine* prior to trial. (*Id.* at 71-75.) The parties therefore proceeded to discovery, at the conclusion of which each of the defendant groups (the Brand Defendants, the Generic Defendants, the Physician Defendants, and the Pharmacy Defendants) filed motions for summary judgment. The trial court denied in pertinent part the motions filed by all but the Pharmacy Defendants, once again concluding that the preemption doctrine did not reach nearly so broadly as the Generic Defendants suggested, and that Washington law readily supported both the existence of a legal duty on the part of a drug manufacturer to adequately inform prescribing physicians of

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summary judgment, so that all potential errors at the summary judgment stage could be resolved together. *See* Plaintiff-Respondent’s Alternative Motion for Discretionary Review, filed Jan. 8, 2018. This Court, however, denied that Alternative Motion as untimely.

Unless corrected, eliminating the pharmacists and the pharmacy as defendants at trial against the physician defendants and the Generic Manufacturers puts Mrs. Sherman at a great disadvantage because those defendants may be able to introduce revised patient information monographs which eventually told patients that use of metoclopramide beyond 12 weeks was dangerous, without her being able to tell the jury that her pharmacists were obligated to bring that information to her attention.

its dangers and a causal link between their failure to do so in this case and Mrs. Sherman's injuries. (*See* RP1 at 78-81.) Thereafter, the Brand Defendants and all but the two remaining Generic Defendants settled out of the case, and the court set a date for trial as to Plaintiff's claims against the Generic and Physician Defendants. This interlocutory appeal ensued when the Commissioner granted discretionary review sought by the remaining Generic Defendants.

C. The Backdrop of Metoclopramide-Injury Litigation.

It is also important to view the specific facts of this case in the broader context in which they arise. Mrs. Sherman is just one of thousands of people nationwide who have sustained injuries as a result of prolonged exposure to metoclopramide due to intentional or negligent misrepresentations disseminated by the A.H. Robins Company, Inc., which told doctors in a ghost-written fraudulent article that metoclopramide was safe in long-term use. (CP 86-90, 852-892) *Conte v. Wyeth*, 168 Cal. App.4th 89, 95 (2008). Manufacturers of the brand-version Reglan as well as of the generic-version metoclopramide, including all of the original manufacturer-defendants in this case, have reached settlements paying millions of dollars to plaintiffs alleging claims either very similar or identical to Plaintiff Sherman's claims in this case. *See* Pierson, Brendan, *Teva Settles 'vast majority' of lawsuits over generic*

*Reglan*, (Reuters Feb. 17, 2017), available at <https://www.reuters.com/article/health-teva/teva-settles-vast-majority-of-lawsuits-over-generic-reglan-idUSL1N1G20E5> (last visited Sept. 17, 2018); *see also* Teva Pharmaceutical Industries Limited Form 10-K for fiscal year ended Dec. 31, 2017, filed with United States Securities and Exchange Commission, at p. 55, *available at* <https://www.sec.gov/Archives/edgar/data/818686/000119312518039076/d529462d10k.htm> (last visited Sept. 17, 2018) (“Teva and/or its subsidiaries, including Watson Laboratories, Inc. (“Watson”) and Actavis Elizabeth LLC (“Actavis Elizabeth”), have been named as defendants in approximately 4,000 product liability lawsuits brought against them and other manufacturers by approximately 4,400 plaintiffs claiming injuries (including allegations of neurological disorders, such as tardive dyskinesia) from the long-term use of metoclopramide (the generic form of Reglan<sup>®</sup>).”).

### **III. Argument.**

#### **A. Standard of Review**

This court’s review encompasses two distinct questions: (1) whether the Commissioner’s grant of discretionary review under RAP 2.3(b)(1) was proper; and (2) if so, whether the trial court’s denial of summary judgment should be affirmed so that the case proceed to trial as

against all remaining defendants.<sup>7</sup> Plaintiff-Respondent Sherman asserts that, as a threshold matter, the answer to the first of those questions is “no,” thereby negating the need for any further consideration of the matters set forth in Generic Defendants’ brief. That is, because the trial court’s denial of summary judgment was not an “obvious error,” the Commissioner never should have granted this interlocutory review in the first place. Indeed, the Commissioner’s ruling itself recognizes that at least two of the three issues on which it granted review (preemption and duty) were *not obviously erroneous*. (See Ruling Granting Review at 11-17 (finding that denial of summary judgment as to preemption and existence of legal duty was not obviously erroneous).) Because RAP 2.3(b)(1) – the sole basis on which this review is even taking place – requires a finding of “obvious error,” review of at least the preemption and duty issues is improper.

Moreover, as explained below, the causation issue is not “obvious error” either. The sole premise of the Commissioner’s “obvious error” conclusion is the Washington Supreme Court’s decision in *Douglas v. Bussabarger*, but as explained *infra*, that case doesn’t even support the

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<sup>7</sup> As discussed above, *supra* Note 4, even though all of the brand and some of the generic defendants originally named in the Amended Complaint have settled, those defendants will still appear on the verdict form, along with the defendants actually present at trial, for purposes of allocation of damages under RCW 7.70.080.

conclusion Generic Defendants desire, much less render any contrary holding “obviously erroneous.” *Douglas* is both factually and legally inapposite, so the entire premise for this review is faulty, and the case should be remanded for trial.

If, however, this court sets accepts this interlocutory review notwithstanding the absence of any “obvious error” as required by RAP 2.3(b)(1), it still should affirm the trial court’s denial of summary judgment. An appellate court reviews a summary judgment ruling *de novo*, construing all evidence and all reasonable inferences from the evidence in the light most favorable to the non-moving party (here Mrs. Sherman). *Keck v. Collins*, 184 Wn.2d 358, 370 (2015); *Scrivener v. Clark College*, 181 Wn.2d 439, 444 (2014). The movant (here Generic Defendants) bears the burden of establishing the absence of any genuine dispute of material fact, and the standard is strict: “Any doubts as to the existence of a genuine issue of material fact [are] [*sic*] resolved against the moving party.” *Atherton Condo. Apartment-Owners Ass’n Bd. of Directors v. Blume Dev. Co.*, 115 Wn. 2d 506, 516, 799 P.2d 250, 257 (1990).

- B. A Jury Could Readily Find a Causal Connection Between the Generic Defendants’ Communication Failures Regarding the Dangers of their Drug Product and Sherman’s Prolonged Exposure to it for Over Twenty-Five Times the Recommended Duration.

The trial court properly denied summary judgment to Generic Defendants based on the presence of genuine issues of material fact concerning causation, given that (1) the Generic Defendants knew of FDA-mandated increases in the severity of metoclopramide warnings but did nothing to apprise the medical community of those changes, (2) Dr. Silverman never learned of those increased warnings at any point during the six-plus-years over which he prescribed metoclopramide to Mrs. Sherman, and (3) once he and his partners did learn of those risks, they immediately implemented an informed consent policy that discouraged prescribing metoclopramide in excess of 12 weeks except in extraordinary circumstances. Generic Defendants ignore this key evidence and instead focus solely on the undisputed fact that Dr. Silverman did not read the FDA-approved warning label (notwithstanding that label he did not read was never provided to him, to any of his colleagues, or to metoclopramide consumers, because neither Teva nor PLIVA adopted the revised FDA approved labels when Dr. Silverman first prescribed metoclopramide to Mrs. Sherman). They do so in an effort to bring this case within the narrow holding of the Washington Supreme Court in *Douglas v. Bussabarger*, 73 Wn.2d 476, 477, 438 P.2d 829 (1968), but that case involved the adequacy of the label on the drug's container, an issue not determinative in this

case, and so is inapposite. This Court should affirm the trial court's denial of summary judgment and remand this case for trial because, as described in more detail below, the record evidence readily supports an inference of causation between Generic Defendants' failure to communicate and Plaintiff Sherman's injuries.

**1. The Record Evidence Amply Supports the Requisite Causal Connection.**

The Generic Defendants' causation argument, which forms the foundation of this interlocutory appeal, focuses almost exclusively on one narrow component of the record regarding Dr. Silverman's ignorance about warnings that should have been (but were not) printed on metoclopramide package inserts. That is, Generic Defendants contend that because Dr. Silverman testified that he did not read the package inserts for Reglan or metoclopramide (or any other drug he prescribes), they are somehow relieved from liability, notwithstanding their failure to get the message to him in any other way. Their argument misses the point because Sherman's claims are *not about* what's on the label that Dr. Silverman proclaims he did not read. Instead, her claims are about Generic Defendants' failures to communicate to him, or to anyone in the physician community whose opinion he deems important, the multiple changes that were made to that label which substantially

increased the warnings associated with long-term use. Generic Defendants' flawed view of the record fails to take account of key testimony that supports the requisite causal connection and supports the trial court's denial of their motion for summary judgment.

In order to withstand a motion for summary judgment premised on causation, a tort plaintiff need only identify sufficient record evidence from which a jury could infer that a causal connection exists. *Attwood v. Albertson's Food Centers, Inc.*, 92 Wn. App. 326, 353, 966 P.2d 351 (1998) (citing *Douglas v. Freeman*, 117 Wn.2d 242, 252, 814 P.2d 1160 (1991)). "The plaintiff need not establish causation by direct and positive evidence, but only by a chain of circumstances from which the ultimate fact required is reasonably and naturally inferable." *Id.* (citing *Teig v. St. John's Hosp.*, 63 Wn.2d 369, 381, 387 P.2d 527 (1963)). Because causation is fact-intensive and often requires the drawing of inferences, it is well established under Washington law that "the question of proximate cause is for the jury, and it is only when the facts are undisputed and the inferences therefrom are plain and incapable of reasonable doubt or difference of opinion that it may be a question of law for the court." *Bernethy v. Walt Failor's, Inc.*, 97 Wn. 2d 929, 935, 653 P.2d 280, 283 (1982) (quoting *Mathers v. Stephens*, 22 Wn.2d 364, 370, 156 P.2d 227 (1945))

Most of the evidence on which Generic Defendants rely to negate causation is actually undisputed, but their view of the record is erroneously narrow. That is, no party disputes the Dr. Silverman did not read any package insert or container label associated with metoclopramide, at any time over the six-year period that he prescribed it to Mrs. Sherman. (CP 532-34.) He testified that he does not make a practice of reading *any* prescription drug label, with the exception of those drugs that are prescribed to him as the patient. (*Id.*) In addition, no party disputes that Dr. Silverman’s sole source of information about drugs he prescribes is his own “clinical training and experience and the experience of [his] colleagues and associates.” (*Id.* at 533.) The Generic Defendants point to this testimony and contend that it negates causation as a matter of law. This narrow view is flawed, though, because Dr. Silverman’s failure to read the package insert is irrelevant to Mrs. Sherman’s claim that Generic Defendants failed to communicate the drug’s approved warnings in *other* ways.

A review of the complete record at this interlocutory stage of proceedings supports at least an inference that Generic Defendants’ communication failures are causally connected to Sherman’s injuries. In addition to the testimony described above (and on which Generic Defendants rely), Dr. Silverman also testified that he never received

any information from the Generic Defendants (or any of the other manufacturers named as defendants in this case), notwithstanding that over the course of the six-year period that he prescribed it to Mrs. Sherman, the warning label changed two times to emphasize the significant risk of tardive dyskinesia associated with exposure exceeding 12 weeks, the second of which added a Black Box warning. (CP 533-535.) In other words, not only did Dr. Silverman not learn of the risks associated with use exceeding 12 weeks from the package insert or container label, but he also did not learn of it from any Generic Defendant or other manufacturer, or through pathways that he relied on, “colleagues and associates.”

Against this backdrop of evidence establishing the absence of any effective communication with Dr. Silverman regarding the drug’s risks lies significant additional record evidence establishing that if the drug manufacturers *had* communicated with him or his colleagues and peers, he *would* have changed his prescribing practices. On October 26, 2012, one full year prior to filing this lawsuit, Mrs. Sherman’s counsel Ralph D. Pittle sent a letter to Dr. Silverman requesting his assistance investigating potential claims against the Brand and Generic Defendants. (CP 633.) Mr. Pittle’s letter explained the causal link between tardive dyskinesia and long-term exposure to metoclopramide

and referenced the FDA's mandate of a black box warning in an effort to prevent long-term use. (*Id.*) This communication prompted further e-mail correspondence in late December 2012 between Mr. Pittle and Dr. Silverman's counsel Eric Norman. (*Id.* 630-31.) These letters uniformly communicated the goal of Mr. Pittle's inquiry – to speak with Dr. Silverman regarding his knowledge (or, lack thereof, as is actually the case) of the tardive dyskinesia risk associated with long-term metoclopramide use throughout the years that he prescribed it to Mrs. Sherman. (*Id.* at 630-33.)

Just over a month after the last such communication, Dr. Silverman's medical practice, defendant GEA, adopted a new policy requiring explicit patient counseling regarding the risks associated with metoclopramide ingestion for longer than 12 weeks and informed consent in connection with any metoclopramide prescription. (CP 825-827.) The policy imposed specific record-keeping requirements regarding such counseling and consent, and included issuing a letter to all existing patients who had been prescribed metoclopramide informing them of the risk and symptoms of tardive dyskinesia. (*Id.*) Dr. Ben Merrifield, one of Dr. Silverman's GEA partners, testified that he had no knowledge of the gravity of risk associated with prolonged metoclopramide use (he thought the risk of developing tardive

dyskinesia was as low as 1/500<sup>8</sup>), but that after receiving Mr. Pittle's letter, his practice adopted the new informed consent policy. (CP 940, 950) A managing nurse in the practice, Kelly Auvinen, corroborated this premise, by also testifying that she did not know of the drug's black box warning or associated risks prior to the time the policy was proposed and adopted. (CP 592.)

Based on this evidence, a jury could readily find a causal connection between the Generic Manufacturers' failures to communicate and Mrs. Sherman's ingestion of the drug for a period exceeding by nearly twenty-five times the recommended limit.<sup>9</sup> *Winter v. Novartis Pharmaceuticals Corp.*, 739 F.3d 405, 408-09 (2014) (“[A] change in prescribing patterns after receiving a warning is enough [evidence of causation] to create a submissible case.”). That Dr.

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<sup>8</sup> Studies conducted over the years in question showed that “as many as twenty-nine percent of those people who took the drug for several years developed tardive dyskinesia.” *In re Reglan Metoclopramide Litigation*, 81 A.3d 80, 84 (Pa. Super. 2013).

<sup>9</sup> Generic Defendants accuse the trial judge of engaging in “impermissible speculation and conjecture” upon concluding that the record contained sufficient evidence from which a reasonable jury could find a causal connection. Emphasizing the court's use of casual terminology (without reference to the fact that the trial judge issued his ruling on an informal telephone conference with counsel sandwiched between a jury trial and a vacation), Generic Defendants contend that because the trial judge framed his ruling in terms of what “you could argue” regarding the evidence, his ruling is inherently erroneous. This argument, however, fails to take account of the record evidence discussed above, and the case law supporting an inference of causation based on that evidence, as discussed below. Indeed, Generic Defendants' assertion that “no reasonable jury” could find causation based on the record evidence in this case is flatly contradicted by the case law discussed in this brief, including *Winter*, wherein not only did a jury find causation based on evidence very similar to that presented here, but the appellate court also upheld that finding as reasonable. *Winter*, 739 F.3d at 409.

Silverman does not read either container labels or package inserts for the drugs he prescribes, nor any materials he may receive in the mail from drug manufacturers – the facts on which Generic Defendants rely so heavily—will be strong evidence of Dr. Silverman’s negligence but are not determinative of the manufacturers’ allocable responsibility, because the evidence establishes that (1) his peers/colleagues *do* read Dear Doctor letters or otherwise pay attention to warnings issued by drug companies, and (2) Dr. Silverman listens to and acts on the advice of colleagues, associates, mentors and people in the academy whom he respects. (CP 533.)

The propriety of the trial court’s denial of summary judgment on these facts is bolstered by instructive authorities from other jurisdictions. For example, in *Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir. 1992), the court reversed the summary judgment on the manufacturer’s liability for injuries caused by ingestion of its drug because the prescribing doctor’s testimony failed to establish that he knew of all of the drug’s dangers at the time he prescribed it. *Garside*, 976 F.2d at 82. The court based its conclusion on a “line of cases” addressing a drug manufacturer’s request (as Generic Defendants make here) to be insulated from liability based on the physician’s knowledge of the drug’s risks. The court stated: “In all such cases, courts have

required that the physician's testimony show unequivocally that s/he knew at the relevant time *all* the information which would have been included in a proper warning.” *Garside*, 976 F.2d at 82 (collecting citations<sup>10</sup>); *see also* CP 820-821 (decision of Larimer County, Colorado District Court applying *Garside* in metoclopramide-injury case like this one, and holding that manufacturer was not insulated from liability because it had not “unequivocally established that [the physician] was aware of the information [p]laintiff assert[ed] should have been on the warning label at the time [the physician] prescribed Reglan to [her]”). In accordance with these authorities, this court should likewise deny summary judgment because the record here does not unequivocally establish that Dr. Silverman knew of adequate warnings – to the contrary, it establishes unequivocally that he and his partners did not.

**2. *Douglas v. Bussabarger* is Inapposite Here.**

The Washington Supreme Court’s decision in *Douglas v.*

*Bussabarger* does not affect, much less change, the result compelled by

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<sup>10</sup> Cases cited by *Garside* include: *Thomas v. HoffmanLaRoche, Inc.*, 949 F.2d 806, 811-814 (5th Cir.1992)(applying Mississippi law); *Plummer v. Lederle Lab.*, 819 F.2d 349, 358 (2d Cir. 1987)(applying California law); *Stanback v. Parke, Davis and Co.*, 657 F.2d 642, 645 (4th Cir. 1981)(applying Virginia law); *Windham v. Wyeth Lab., Inc.*, 786 F. Supp 607, 612 (S.D. Miss 1992) (applying Mississippi law).

the evidence described above. The Generic Defendants' heavy reliance on *Douglas v. Bussabarger* is misplaced, and their attempts to substantially broaden the holding of that case are without foundation. In *Douglas*, the plaintiff sustained injuries from an anesthetic drug administered by her surgeon during an operation. *Douglas v. Bussabarger*, 73 Wn. 476 (1968). A jury rendered defense verdicts on her claims against both the doctor (medical malpractice) and the drug's manufacturer (failure to warn). *Id.* at 477-78. The bulk of the court's appellate opinion focused on the claims against the doctor, and the court ultimately found sufficient errors to reverse the jury verdict in his favor and remand for a new trial. *Id.* at 491. As to the manufacturer, the court affirmed the verdict, offering only a few sentences of support. *Id.* at 477-78. Specifically, the court held that because the doctor testified that he did not read the label on the container of anesthetic that he administered to the plaintiff, the adequacy of the warnings printed on that container could not have caused the plaintiff's injuries. *Id.*

This case is distinguishable from *Douglas* in important ways. First and foremost, the claims in *Douglas* were completely different from Sherman's claims here. In *Douglas*, the plaintiff's sole claim against the manufacturer was that its container label failed to provide sufficient warnings about the drug's risks. *Id.* In its brief analysis of

this issue, the court emphasized the narrow scope of the plaintiff's claim: "The only claim raised by plaintiff is whether the company should have labeled the drug's container so as to warn of possible dangers of use of the drug." *Id.* at 477. In this case, Sherman's claims against the generic manufacturers do *not* center on (or even raise) the inadequacy of the drug's container label.<sup>11</sup> Instead, her claims focus on the Generic Defendants' failures, notwithstanding any labeling inadequacies, to disseminate accurate and updated information regarding the drug's risks. Whether the doctor read the label or not – the determinative fact in *Douglas* – is therefore irrelevant. *See Hibbs v. Abbott Labs.*, 62 Wn. App. 451, 457-58 (1991) (distinguishing *Douglas* on grounds it involved only a claim about the adequacy of the drug's container label, whereas the case at bar involved other claims not arising out of the label warnings); *see also Richards v. Upjohn Co.*, 95 N.M. 675, 680, 625 P.2d 1192 (1980) (distinguishing *Douglas* as not well reasoned, and holding that "[a] reasonable person need not conclude from the fact that a doctor was unaware of the drug

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<sup>11</sup> Plaintiff's claims against the brand-name defendants include claims that even as amended by brand-defendant Schwarz Pharma and Alaven, there is still misleading information in the Reglan label as a result of false and misleading information that the original brand manufacturer, A.H. Robins, delivered to the FDA. *See*, Declaration of James Freston, M.D., PhD. CP 857. However, recognizing that *Mensing* requires generic manufacturers to have labels that are the same as the brand label, plaintiff does not assert those claims against Generic Manufacturers.

company's warnings that, if the company had chosen to employ other more effective means to communicate the warnings, the doctor still would have remained unaware of the dangers").

Other courts have agreed that the doctor's failure to read the drug's label cannot alone negate the causal connection between a manufacturer's communication failures and a patient's drug-induced injuries. The United States Court of Appeals for the Eighth Circuit's decision in *Winter v. Novartis Pharmaceuticals Corp.*, 739 F.3d 405 (2014) is particularly instructive. In *Winter*, as here, the plaintiff was injured by a drug and sued the manufacturer based on its failure to provide sufficient information about the warnings to the healthcare provider who prescribed it. *Id.* at 408-09. Manufacturer Novartis defended, as Generic Defendants attempt here, on grounds the doctor's testimony that he did not read inserts before prescribing drugs severed any causal link between its duty to warn and plaintiff's injuries. *Id.* at 408. The court rejected that defense, finding sufficient evidence to support causation in the fact that once he eventually received a Dear Doctor letter containing adequate warnings, he changed his prescribing patterns. *Id.* at 408-09. The court criticized Novartis's focus on the doctor's failure to read the label as offering too narrow a view of the evidence because it "ignores other ways [the doctor] would receive

warnings.” *Id.* The court reasoned: “Novartis’s argument fails because a change in prescribing patterns after receiving a warning is enough to create a submissible case.” *Id.* (citing *Hanrahan v. Wyeth, Inc.*, No. 4:04CV01255ERW, 2012 WL 2395881, at \*10 (E.D. Mo. Jun. 25, 2012) and *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1168-70 (8th Cir. 2009) (stating that “failure to read a warning does not necessarily bar recovery”). Here, just as in *Winter*, there is evidence of a change in prescribing patterns after receiving a warning, which should be sufficient to create a submissible case.

*Douglas* is also distinguishable because the circumstances of the drug’s ingestion by the plaintiff were different. *Douglas* involved administration of a drug by a physician, rather than a doctor’s issuance of a prescription for filling elsewhere. Where a doctor actually administers a drug, his reading the label (or not) is far more relevant to the cause of the plaintiff’s injuries than where, as here, he simply issues a prescription. Where a physician issues a prescription, neither the drug container nor the package insert is available to him at that time, or any other time, unless he specifically seeks it out. In this situation, communications from the manufacturer, whether to that particular doctor or to others in the community who might then share it at continuing education conferences, in published peer-reviewed research,

or around the discussion table or water cooler, are the best and perhaps only way to communicate that information effectively.

In sum, Generic Defendants' (and the Commissioner's, in granting this interlocutory review) reliance on *Douglas* is misplaced. The facts and claims underlying the Washington Supreme Court's summary assertion regarding the impact of the doctor's failure to read the label of the drug he administered differ in critical ways from this case, which involves a different type of claim and different underlying evidence. As such, to reverse the trial court's denial of summary judgment as controlled by *Douglas* would substantially expand the scope of that decision without reason and in contravention of other persuasive law. The trial court properly rejected *Douglas* as irrelevant here, and this court should affirm that correct ruling.

**3. A Genuine Fact Issue Exists Regarding the Scope of Dr. Silverman's Knowledge Prior to Receiving Notice From Sherman's Counsel.**

The Generic Defendants' final attempt to evade liability on causation grounds rests upon the premise that Dr. Silverman knew all of the risks of prolonged exposure throughout the time he prescribed metoclopramide to Mrs. Sherman, but this premise finds no support in, and is even contradicted by, the record. Generic Defendants contend that Dr. Silverman was "fully aware" of the relevant risks when he

prescribed Reglan to Mrs. Sherman, but their only evidentiary support consists of two record citations, wherein Dr. Silverman indicated that he had “always talked about and would always watch for” movement disorders when prescribing metoclopramide, and that he typically prescribed it only as a “last resort.” CP 190, 202. This testimony is a far cry from establishing as a matter of law that he knew all of the drug’s risks throughout the entire time that he prescribed it. Nothing about this testimony even suggests, much less establishes, that he knew the manufacturer recommended, and the FDA approved, metoclopramide use for only up to twelve weeks. Nor does anything about this testimony establish or suggest that Dr. Silverman knew or understood the likelihood that a patient who ingests metoclopramide in excess of the recommended limit will suffer tardive dyskinesia, or that he had any inkling that the FDA mandated increased warnings including a Black Box in 2009. For surely, if Dr. Silverman had known those things, he would not have prescribed it to Mrs. Sherman for more than six years without ever mentioning those risks to her.

If anything, the record better supports determining as a matter of law that Dr. Silverman *lacked* knowledge of the drug risks, more so than that he possessed such knowledge. At minimum, genuine fact

issues exists for trial regarding the scope and extent of his knowledge, and the trial court's denial of summary judgment should be affirmed.

C. Generic Defendants Cannot Hide from Their State Tort Duties Behind an Impermissible Expansion of Narrow Federal Preemption Doctrine.

The preemption doctrine applicable in failure-to-warn cases against generic manufacturers encompasses only those state-law claims that would impose a duty with which compliance is impossible given directly conflicting, constitutionally supreme federal law. Pursuant to “*Mensing* preemption,” state tort laws cannot require a generic drug manufacturer to issue a different warning label from that approved by the FDA for use on the brand version of the drug. *Pliva, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); 21 U.S.C. § 335(j)(4)(G). In *Mensing*, preemption barred the plaintiffs’ state-tort-law claims that would have required the generic metoclopramide-manufacturer-defendants to place a strengthened warning on the label because the defendants could not meet the “sameness requirement” under the Food Drug and Cosmetics Act (“FDCA”) while simultaneously complying with a strengthened-warning requirement under state law. *Id.* The question under *Mensing* is narrow: does state law compel what is impossible under federal law? If not, then preemption does not apply. *See Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 363 (Iowa

2014), *cert. denied sub nom., PLIVA, Inc. v Huck*, 135 S. Ct. 1699 (2015) (referencing presumption against preemption).<sup>12</sup>

Despite its established limited origins and scope, Generic Defendants ask this Court to adopt a broad and expansive application of *Mensing* preemption doctrine and reverse the trial court’s determination (for the second time) that Mrs. Sherman’s claims fall beyond its reach. (*See* RP1 at 73-75 (2/13/15); *id.* at 79-80 (8/28/18).) Their contentions, however, contradict the law of *Mensing* and as applied by other courts. Indeed, recognizing the strength of authorities supporting the viability of Mrs. Sherman’s claims, this Court’s Commissioner concluded that the trial court did not obviously err in rejecting the preemption defense. (Comm’r Rul. at 13, 14, 16.) The trial court’s denial of summary judgment on Sherman’s failure-to-communicate and failure-to-update claims was not erroneous because federal preemption does not apply.

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<sup>12</sup> A predecessor case to *Mensing* provides instructive guidance about its limited scope. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the Supreme Court held that FDCA regulations applicable to brand manufacturers did not preempt a state-law tort action for inadequate warnings about the significant risks of administering Reglan.<sup>12</sup> *Levine*, 555 U.S. at 578. The Supreme Court explained that Congress did not intend the FDCA to preempt common-law tort suits because such suits serve “as a complementary form of drug regulation.” *Levine*, 555 U.S. at 578. More specifically, “[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.” *Id.* at 578-79. *Mensing* held that preemption applies only where the requirements of state and federal law directly conflict, so simultaneous compliance with both is impossible. *Mensing*, 564 U.S. at 614.

**1. Plaintiff's Claims Stemming From Generic Defendants' Failure to Update the Metoclopramide Label to Meet Federal Standards Cannot Be Preempted by Federal Law.**

Mrs. Sherman asserts that Generic Defendants breached their duty to warn her of their product's risks when they failed to update their warning label after the FDA approved strengthened warnings as to the brand version Reglan in 2004. (CP 96.) Generic Defendants' responsive affirmative defense expands *Mensing* preemption to encompass not just claims that the generic manufacturer failed to add new strengthened warnings *beyond* those approved for brand use, but also those claims premised (as here) on their failure to conform their label to the brand version's updated, FDA-approved warnings. Their argument is flawed, as *Mensing* preemption does not reach that far.

The parties agree on the key premises underlying Mrs. Sherman's failure-to-update claim:

1. FDCA regulations impose strict requirements for approval of drug labels, which the manufacturer of a new brand-name drug must meet. 21 U.S.C. § 335(a), (b)(1), (d); *see also Wyeth v. Levine*, 555 U.S. 555, 566-67 (2009).
2. After initial approval, a brand manufacturer must seek FDA approval of strengthened warnings, but need not await FDA approval to make the change. *Levine*, 55 U.S. at 567-67; 21 C.F.R. § 314.70(c)(6)(iii) (A), (C) (2006).
3. A simplified process applies to generic manufacturers. So long as they can establish equivalence, their product label is exempted from the lengthy approval process and instead subjected only to an ongoing "duty of sameness." 21 U.S.C.

§ 355(j)(2)(A)(v), 4(G); 21 C.F.R. §§ 314.94(a)(8), .127(a)(7); *see also Huck v. Wyeth*, 850 N.W.2d 353, 357 (Ia. 2014) (“[T]he [generic drug’s] labeling must be the same as the listed drug product’s labeling because the listed drug product is the basis for [generic drug] approval.”).

4. In 2004, the manufacturer of brand-name Reglan, Schwarz Pharma, obtained approval to strengthen the warning label to add in two locations in bold type that “**Therapy should not exceed 12 weeks in duration.**” (CP 450-51, 766.)
5. Neither Generic Defendant updated its label in 2004 to adopt the new warnings approved by the FDA. Although Teva later updated its label to add these warnings, Defendant PLIVA never did. *See Huck*, 850 N.W.2d at 359 (“Although required by federal regulations to mirror the brand defendant's label, PLIVA did not update its metoclopramide packaging to include the new warning approved in 2004. The record is silent as to why PLIVA failed to add that warning.”); *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578, 580 (6th Cir. 2013) (“Apparently, PLIVA never updated its metoclopramide labeling to include the new [2004] warning, nor communicated the change to any physicians.”).

Mrs. Sherman therefore attributes liability to Generic Defendants because they failed to add strengthened warnings approved by the FDA in 2004.

To apply *Mensing* preemption here, as Generic Defendants suggest, would contravene the very federal regulations that they contend preempt Sherman’s claims *Mensing* held only that preemption bars state-law claims which would impose a duty to strengthen a warning beyond what the FDA approved. *Mensing*, 564 at 617-18; *cf. Huck*, 850 N.W.2d at 364 (holding that claims premised on PLIVA’s failure to update its

labels to conform to the strengthened warnings approved by the FDA in 2004 “present a narrow path around *Mensing* preemption”).

*Mensing* preemption does not bar Sherman’s failure-to-update claim because she does not seek to impose a labeling requirement in conflict with federal law. Once the FDA approved strengthened warnings on the brand label, the “ongoing federal duty of ‘sameness’” required generic manufacturers to update their label to mirror it. *Mensing*, 564 U.S. at 618-19; *Huck*, 850 N.W.2d at 357; 21 U.S.C. § 331(a) (prohibiting sale of any misbranded drug); 21 C.F.R. § 314.94(a)(8)(iii) (requiring generic applicant to match label of brand drug); 21 C.F.R. § 314.150(b) (10) (providing FDA may withdraw drug approval if the generic’s label “is no longer consistent with that for [the brand-name]”). Generic Defendants failed to update their label, which subjects them to liability under Washington law.

Numerous other courts, including high-level appellate courts in at least three other states, have rejected the very preemption defense proffered by Generic Defendants here on the above-described reasoning. In *Huck*, the Iowa Supreme Court held that *Mensing* preemption did not reach the plaintiff’s failure-to-warn (update) claims based on PLIVA’s failure to adopt the 2004 upgraded warnings. *Huck*, 850 N.W.2d at 364. The Superior Court of Pennsylvania recently reached the same conclusion:

“[W]e agree that state negligence claims based upon the misbranding of drugs under the federal statute or failure to conform the generic label to the updated RLD label, a form of misbranding, are not foreclosed by *Mensing*.” *In re Reglan/Metoclopramide Litigation*, 81 A.3d 80, 95 (Pa. Super. 2013). The New Jersey Supreme Court followed suit, finding that “[n]o law prevented defendants from giving the same warnings that appeared on the labeling of the brand-name drug” so that compliance with both was not impossible. *In re Reglan Litigation*, 226 N.J. 315, 336, 142 A.3d 725, 738 (2016). That court rejected Generic Defendants’ preemption defense as “absurd”:

We reject the notion that a plaintiff can proceed with a state-law failure-to-warn claim against a brand-name drug manufacturer that used FDA-approved warnings, as was true in *Wyeth [v. Levine]*, but not against a generic manufacturer that provides warnings that do not even match the FDA-approved brand-name labeling. Congress could not have intended such an absurd result.

*Id.* at 341; *see also Teva Pharmaceuticals USA, Inc. v. Superior Court*, 217 Cal. App.4th 96, 106-07 (2013), *cert. denied* 135 S.Ct. 1152 (2015) (holding that conflict preemption did not bar failure-to-update claims based on manufacturers’ failure to conform label warnings for generic alendronate sodium to those approved by the FDA for brand Fosamax).<sup>13</sup>

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<sup>13</sup> Other federal and state courts have also concluded that failure-to-warn claims stemming from generic metoclopramide manufacturers’ failure to update their warning label to conform to the brand Reglan label are not preempted under *Mensing*. *Fulgenzi v.*

Generic Defendants cast aside this mounting weight of authority and in reliance on the U.S. Supreme Court’s decision in *Buckman v. Plaintiffs’ Legal Committee*, 531 U.S. 341, 352-53 (2001). That case is not applicable here. In *Buckman*, the Court held that the FDCA preempts state-law claims that “exist solely by virtue of” FDCA requirements. The plaintiffs’ fraud-on-the-FDA claims were preempted because they conflicted directly with the FDA’s power to police fraud against itself. *Buckman*, 531 U.S. at 347. The Court distinguished between fraud-on-the-FDA claims, redressed directly by federal law, and state-law claims that “run parallel” to federal requirements. *Id.* at 353. The former are preempted, but the latter are not. *Id.*

Sherman’s failure-to-update claim falls squarely into the latter category, in that it “runs parallel” to federal requirements rather than “exist[ing] solely by virtue of” them. The failure-to-update claim arises

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*PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013); *Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-CV-325 JAR, 2013 WL 3929059, at \*9 (E.D.Mo. July 29, 2013); *Phelps v. Wyeth, Inc.*, 938 F.Supp.2d 1055, 1061 (D.Or.2013); *Johnson v. Teva Pharm. USA, Inc.*, No. 2:10 CV 404, 2012 WL 1866839, at \*3 (W.D.La. May 21, 2012); *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846, at \*4 (M.D.La. Mar. 6, 2012); *Lyman v. Pfizer, Inc.*, No. 2:09-cv-262, 2012 WL 368675, at \*5-6 (D.Vt. Feb. 3, 2012); *Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2012 WL 79670, at \*5 (W.D.N.C. Jan. 11, 2012); *Del Valle v. PLIVA, Inc.*, No. B:11-113, 2011 WL 7168620, at \*5 (S.D.Tex. Dec. 21, 2011); *Fisher*, 817 F.Supp.2d at 805; *In re Reglan Litig.*, No. 289, 2012 WL 1613329 (N.J.Super.Ct. Law Div. May 4, 2012); *Hassett v. Dafoe*, 74 A.3d 202, 216 (Pa.Super.Ct.2013); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 679 (Mo.Ct.App.2014).

under the WPLA and common law of Washington. Generic Defendants breached their state-law duties by failing to provide adequate warnings on their drug labels, including by failing to conform those labels to strengthened warnings approved by the FDA in 2004. Thus, while federal law required the label update that Generic Defendants failed to make, Sherman’s claim is not premised upon that violation of federal law. Instead, it “runs parallel” to those federal requirements but is rooted in state tort law and is therefore not preempted. *See Buckman*, 531 U.S. at 353. Numerous courts agree, and likewise hold that *Buckman* is limited to the fraud-on-the-agency context. *See In re Reglan Litigation*, 226 N.J. at 339 (“The present case is different from *Buckman* because, here, the ‘critical element’ to plaintiffs’ claims is not defendants’ violation of the FDCA, but defendants’ failure to give adequate warnings about the prolonged use of metoclopramide.”); *Fulgenzi*, 711 F.3d at 586-87 (“Here, Fulgenzi’s suit is not even *premised* on a violation of federal law, but rather on an independent state duty. The alleged breach arises from the same act, but the legal basis is different. This is simply not grounds for preemption. The federal duty of sameness is not ‘a critical element’ in Fulgenzi’s case.”).<sup>14</sup>

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<sup>14</sup> Generic Defendants identify *Morris v. PLIVA, Inc.*, 771 F.3d 774, 777 (5th Cir. 2013) as the prime example of how *Buckman* might apply in this case. But, as the New Jersey Supreme Court recently stated, the Fifth Circuit “did not give any detailed analysis

**2. Federal Labeling Requirements Would Not Have Prohibited Generic Defendants From Communicating Information About Updated Warnings With the Medical Community.**

Nor does federal law preempt Mrs. Sherman's tort claims premised on Generic Defendants' failure to communicate the FDA-approved updated warnings in ways other than the drug label. The FDCA permits drug manufacturers to communicate with the medical community, including physicians, pharmacists, and patients, via methods beyond solely the drug container label and package insert. *See* Amicus Brief of the U.S. Solicitor General in No. 13-956, *Teva Pharmaceuticals USA, Inc. et al v Superior Court of California, Orange County, et al*, available at [https://www.justice.gov/sites/default/files/osg/briefs/2014/12/22/teva-cert4-govt\\_invite-osg\\_aay\\_v4b.pdf](https://www.justice.gov/sites/default/files/osg/briefs/2014/12/22/teva-cert4-govt_invite-osg_aay_v4b.pdf) (last visited Sept. 18, 2018). As exemplified by Dr. Silverman's testimony, some doctors never read the warning label on a medication they prescribe, which is filled elsewhere. "Dear Doctor" or "Dear Healthcare Provider" letters fill this void.

Dear Doctor letters of the sort described above are not just permitted but even encouraged by the FDCA and its implementing regulations, which do not distinguish between brand and generic

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or reasoning for that conclusion" and is therefore "not...persuasive." *In re Reglan Litigation*, 226 N.J. at 341. By contrast, the cases cited herein for the premise that *Buckman* is limited to fraud-on-the-agency situations do offer sound reasoning, which squares more directly with the Supreme Court's developed body of preemption law.

pharmaceutical manufacturers. 21 C.F.R. § 200.5. To comply with federal law, a Generic Defendant need only meet the “sameness requirement,” in that the letter cannot provide warnings that are different from those approved by the FDA.

Generic Defendants base their preemption argument here on a part of *Mensing* that references “Dear Doctor” letters, but they take the Court’s statements out of context. Generic Defendants contend that *Mensing* preempts not just claims that would require a generic manufacturer to use a different label, but also claims that would require generic manufacturers to transmit information to healthcare providers in other, non-container-label ways. *Mensing* does not sweep so broadly.

*Mensing* instructed only that “A Dear Doctor letter that contained *substantial new warnings*,” *i.e.* warnings that were stronger than those approved by the FDA for brand use, “would not be consistent with the drug’s approved labeling.” 564 U.S. at 615. Just as with the container label, then, claims which purport to require a generic manufacturer to send a letter containing substantially different warnings would be preempted. *Id.* The *Mensing* Court did not, however, extend this principle to the situation here. That is, nothing about *Mensing* suggests that a claim premised on a generic manufacturer’s failure to communicate *approved updated warnings* (as compared to new and different ones) is preempted.

The California Court of Appeal analyzed thoroughly the exact same preemption argument that Generic Defendants are offering here and rejected it soundly. *Teva Pharm. USA, Inc.*, 217 Ca. App. 4th at 112-14. The generic-manufacturer defendants in that case (including Teva, also defendant here) suggested that *Mensing* preemption should bar plaintiffs from proceeding on their claim that the generic manufacturers failed to communicate updated warnings regarding risks associated with generic alendronate sodium. *Id.* Just as here, the FDA had approved strengthened warnings for the brand version of the drug (Flosamate), but those warnings were never adequately communicated to prescribing physicians. The court rejected the preemption defense because *Mensing* did not support it. *Mensing*, the court explained, held only that “a generic drug manufacturer’s Dear Doctor letter ‘contain[ing] substantial new warning information would not be consistent with the drug’s approved labeling,’ and would therefore violate the duty of sameness. *Mensing* does not preempt a claim that a generic drug manufacturer failed to send a Dear Doctor letter containing the same information that is on the RLD’s approved label.” *Id.* at 114-15.

*Mensing* simply does not stand for the proposition for which Generic Defendants offer it—*i.e.*, that a generic manufacturer can send a Dear Doctor letter only if the brand manufacturer sends one. *Mensing*

preempts only claims that would require a generic manufacturer to issue a warning letter containing different warnings than those approved for the brand. The Superior Court of Pennsylvania and Supreme Court of Iowa both agree that failure-to-communicate claims like Sherman’s fall outside *Mensing*’s preemptive scope. *Huck*, 850 N.W.2d at 364 (“[I]t was not impossible for PLIVA to update its label and send informational letters consistent with the updated language, warning healthcare professionals and consumers that metoclopramide therapy should not exceed twelve weeks.”); *In re Reglan Metoclopramide Litigation*, 81 A.3d at 94-95 (finding failure to communicate claims not preempted); *see also Lyman v. Pfizer, Inc.*, 2012 WL 2970627, at \*10 (same).

D. Washington Law Imposes a Duty on Drug Manufacturers to Warn Consumers and the Medical Community of the Drug’s Dangers.

Generic Defendants’ final contention is that the trial court should have granted summary judgment because Washington law does not impose *any* duty on drug manufacturers to communicate updated warnings of their drug product’s known dangers. They attempt to support their no-duty contention with two arguments, but neither succeeds.

Their first contention rests on an overly narrow reading of the Washington Products Liability Act. Generic Defendants contend that because the statute references provision of warnings “with the product,” it

requires only that warnings be adhered to the product's container. But that is not what the statute says. The WPLA imposes a comprehensive duty to warn of risks known at the time of manufacture and discovered later:

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

(c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned ... about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

RCW § 7.72.030.

Contrary to the Generic Defendants' summary assertion otherwise, these provisions of the WPLA readily support attributing liability to drug manufacturers who provide inadequate warnings as Mrs. Sherman contends in this case.<sup>15</sup> Under paragraph (b), a manufacturer owes a duty to provide adequate warnings at the time that it places a product on the

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<sup>15</sup> Commissioner Bearse, in granting this interlocutory review, agreed that the WPLA supports imposition of a duty on Generic Defendants here. *See* Ruling Granting Review at 16 ("But arguably the product was not properly labeled if it did not include the updated labeling from 2004 or 2009." (citing RCW 7.72.030(1)(b) and (c))).

market. Mrs. Sherman’s failure-to-update claim directly implicates this duty, as she contends Generic Defendants knew about risks of metoclopramide and failed to provide information about those risks “with the product.” Generic Defendants did not include those warnings on the product label, or on the package insert, for much of the time that Mrs. Sherman ingested their metoclopramide products. *In re Reglan Litigation*, 142 A.3d 725, 226 N.J. 315, 322 (N.J. 2016). WPLA section 7.72.030 therefore applies because they did not warn of known risks “with the product.”

Paragraph (c) also imposes a relevant duty. It obligates manufacturers to disseminate new information about risks identified after the initial product sale. Wash. Rev. Code Ann. § 7.72.030(c). Generic Defendants knew the risk of tardive dyskinesia upon use in excess of 12 weeks (for the FDA required such warnings with the product beginning in 2004) but failed to disseminate that information either “with the product” or in any other way, by Dear Doctor letters or otherwise. Generic Defendants failed to “issu[e] warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances.” *Id.*

Generic Defendants ignore these provisions and contend summarily that the words “with the product” in paragraph (b) mean that

liability stems only from the inadequacy of warnings adhered to the product container. They identify no case law that even suggests, much less holds, that this interpretation is accurate. Instead, their only explanation is that because the WPLA's legislative history indicates a link to the Restatement, and Restatement § 402A requires provision of warnings on the container label, that the WPLA must have that same meaning. But the difference between the Restatement § 402A, which requires warnings on the product container, and the WPLA, which requires only that warnings be given "with the product," actually contradicts, rather than supports, the Generic Defendants' position on this issue. That is, if the Washington legislature was looking at the Restatement when it enacted the WPLA, but chose *not* to adopt the same "container" reference and instead required warnings "with the product," then the legislators apparently meant that the WPLA impose different, and more comprehensive, warning requirements.

In addition to ignoring the WPLA, Generic Defendants also disregard other provisions of the Code that impose a duty relevant to this case. Under RCW § 5.40.050, "[a] breach of a duty imposed by statute, ordinance, or administrative rule ... may be considered by the trier of fact as evidence of negligence." The record here contains evidence that Generic Defendants failed to comply with federal labeling requirements when, in 2004

and then later in 2009, the FDA approved strengthened warnings for brand Reglan, but Generic Defendants failed or refused to adopt or disseminate those warnings. In light of this evidence, Generic Defendants are subject to liability under RCW § 5.40.050, and Mrs. Sherman would be entitled to an instruction that the jury may consider Generic Defendants' non-compliance with federal law as evidence of their negligence. *See* WPI 60.03 ("The violation, if any, of a [statute]... is not necessarily negligence, but may be considered by you as evidence in determining negligence.").

The Generic Defendants' final attempt to avoid liability relies upon the learned intermediary doctrine as applied in *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978), but numerous significant factual distinctions render that case inapposite. In *Terhune*, a woman injured by a Dalkon Shield sued the manufacturer for failure to give adequate warnings. *Id.* at 13-14. Unlike this case, where the injurious product was dispensed to the plaintiff by a pharmacy acting in response to a physician's written prescription, there the injurious product was actually administered by the physician. *Id.* at 10. The manufacturer "instructed [the physician] on the proper procedure to use in making the insertion and ... advised of hazards connected with the use of these devices." *Id.* The manufacturer also provided the doctor with brochures describing the product's risks. *Id.* In light of those facts, the court held that the

manufacturer satisfied its duty to warn by making the product's dangers well known, in multiple media, to the physician who inserted it.

Here, Generic Defendants provided *none* of those warnings – via training, informational brochures, or otherwise – to Dr. Silverman or any other member of the medical community. Generic Defendants' failure to provide those warnings lies at the heart of Sherman's claims. Generic Defendants cannot hide behind the learned intermediary doctrine, which presupposes the provision of extensive warnings to the physician community, when Generic Defendants provided no such warnings. *Terhune* does not apply, and the trial court should be affirmed.

#### **IV. Conclusion.**

The trial court correctly denied summary judgment to the Generic Defendants because genuine issues of material fact exist for trial as to the liability of each of the remaining defendants in this case. Those fact issues necessitate determination by a jury, who can properly attribute fault among the responsible parties in accordance with Washington law. This Court should therefore affirm the trial court's order and remand this case for trial.

DATED this 19th day of September, 2018.

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